Adjunctive Devices for Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention
Comparative Effectiveness Review
Number 42

Adjunctive Devices for Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strengths and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family’s health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Structured Abstract

**Objectives.** This is a Comparative Effectiveness Review examining the benefits to harms of adjunctive devices to remove thrombi or protect against embolization in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI) of native vessels.

**Data sources.** MEDLINE®, Cochrane Database, and abstracts from major cardiology meetings were searched from 1996 through March 2011, as were www.clinicaltrials.gov and references from identified citations.

**Review methods.** Randomized controlled trials (RCTs), controlled observational studies enrolling ≥500 patients, and systematic reviews were eligible for inclusion. Data amenable to meta-analysis were pooled as relative risks (RRs) with accompanying 95-percent confidence intervals using a random-effects model.

**Results.** A total of 175 articles were included. Three direct comparative RCTs were identified comparing catheter aspiration with distal balloon protection devices or other catheter aspiration devices; they showed no significant differences for evaluated outcomes. The data comparing adjunctive devices with standard PCI (control) are predominantly in patients with ST-segment elevation myocardial infarction (STEMI).

In RCTs conducted in STEMI patients, catheter aspiration devices decreased the risk of a major adverse cardiovascular event (MACE) [RR 0.73 (0.61-0.88)] versus control. Catheter aspiration devices increased the achievement of ST-segment resolution [RR 1.51 (1.32-1.73)], myocardial blush grade of 3 (MBG-3) [RR 1.61 (1.41-1.84)], and thrombolysis in myocardial infarction (TIMI) 3 flow [RR 1.08 (1.04-1.12)], while reducing distal embolization [RR 0.56 (0.39-0.79)], no reflow [RR 0.52 (0.35-0.76)], and coronary dissection [RR 0.30 (0.12-0.75)] versus control. Other final health and intermediate outcomes were not significantly impacted by catheter aspiration devices versus control. In a majority of trials, the use of catheter aspiration devices increased procedural time upon qualitative assessment.

Distal filter embolic protection devices increased the risk of target revascularization [RR 1.61 (1.03-2.54)], although the use of mechanical thrombectomy or embolic protection devices did not significantly impact other final health outcomes or harms in RCTs. Qualitative assessment indicated that procedure time was increased versus control. Distal balloon or any embolic protection device increased the achievement of MBG-3 [RR 1.39 (1.15-1.69) and RR 1.20 (1.02-1.40), respectively] and TIMI-3 flow [RR 1.11 (1.03-1.19) and RR 1.06 (1.01-1.12), respectively] but did not significantly impact other intermediate outcomes versus control. Mechanical thrombectomy, distal filter, or proximal balloon embolic protection devices did not significantly impact any of the intermediate outcomes evaluated versus control. The associations between predetermined factors and outcomes in people receiving adjunctive devices were generally insufficient.
Conclusions. For most devices, there are few RCTs evaluating final health outcomes over a long period of followup, and furthermore the data outside of STEMI are scarce. Due to insufficient data, the safety of these devices is unclear.
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Executive Summary

Background

Coronary stents and adjunctive pharmacologic agents—including glycoprotein IIb/IIIa receptor inhibitors and thienopyridines—have improved the efficacy of percutaneous coronary intervention (PCI).\(^1,2\) However, dislodgement of atherothrombotic material from coronary lesions during PCI can result in distal embolization that leads to what is commonly referred to as the “no-reflow phenomenon.” This phenomenon, characterized by inadequate flow at the cardiac tissue level despite patent coronary vessels, is often defined as (1) a thrombolysis in myocardial infarction (TIMI) flow grade ≤2 despite vessel patency and the absence of dissection, spasm, or distal macroembolus, or (2) a myocardial blush grade (MBG) of 0 or 1. No reflow has been associated with larger infarcts, significant left ventricular systolic dysfunction, and an increased risk of a major adverse cardiovascular event (MACE) or death. Depending on the exact clinical definition used, the incidence of no reflow has been found to range from 12 to 39 percent of patients undergoing PCI.\(^1,2\)

Numerous adjunctive devices have been developed in an attempt to improve clinical outcomes by removing thrombi and to protect against distal embolization during PCI.\(^3\) These devices utilize different technologies and can be broadly classified as thrombus aspiration, mechanical thrombectomy, or embolic protection devices (i.e., distal balloon or filter embolic protection devices or proximal balloon embolic protection devices). Distal embolic protection devices are recommended for use in patients undergoing PCI of saphenous vein grafts due to their previously demonstrated ability to reduce MACE.\(^1,2\) Their use during acute coronary syndromes (ACSs)—particularly ST-segment elevation myocardial infarction (STEMI)—has been less well supported, mainly because of underpowered clinical trials that evaluated intermediate markers.\(^2\) More recently, larger randomized controlled trials (RCTs) of patients with STEMI have evaluated MACE as an endpoint and followed patients beyond hospital discharge (typically 3 to 12 months) but have given conflicting results.\(^4-7\) Thus, the comparative efficacy and safety of these devices are unclear and need to be systematically evaluated.

Objectives

Our objective was to perform a Comparative Effectiveness Review examining the benefits to harms associated with using adjunctive devices to remove thrombi or protect against distal embolization in patients with ACS who are undergoing PCI of native vessels. The Key Questions (KQs) examined in this report are:
KQ 1. In patients with ACS who are undergoing PCI of native vessels, what are the comparative effects of adjunctive devices from different classes (e.g., thrombus aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection) on intermediate outcomes (e.g., ST-segment resolution, MBG, TIMI-3 flow, ejection fraction, and distal embolization) and final health outcomes (mortality, MACE, health-related quality of life)?

KQ 2. In patients with ACS who are undergoing PCI of native vessels, how do the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

KQ 3. In patients with ACS who are undergoing PCI of native vessels, which patient characteristics (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of a thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, use of direct stenting) affect outcomes?

Analytic Framework
The analytic framework shown in Figure A is intended as an overview only. The links between the use of an intervention in a population and outcomes are described. The population includes all patients with ACS undergoing PCI of native vessels and is also assessed separately by sex, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, and use of direct stenting. The intervention is the use of an adjunctive thrombectomy or embolic protection device. The outcomes are separated into adverse events, intermediate outcomes, and final health outcomes. The adverse events of note include coronary dissection, perforation, and prolonged procedure time. The intermediate outcomes include ST-segment resolution, MBG, post-PCI TIMI-3 flow, ejection fraction, and distal embolization. The final health outcomes include mortality, MACE (including reinfarction, target revascularization, and stroke) and impact of therapy on health-related quality of life.
Methods

Input From Stakeholders

The University of Connecticut/Hartford Hospital Evidence-based Practice Center drafted a topic refinement document with proposed KQs after consultation with Key Informants. The Key Informants included six physicians: two provided methods expertise, two represented the payer’s perspective, one provided the local interventional cardiologist’s perspective, and the last provided both an interventional cardiologist and American College of Cardiology perspective. The Key Informants did not have financial or other declared conflicts. The public was invited to comment on the topic refinement document and KQs. After we reviewed the public commentary, we generated responses to public commentary, proposed revisions to the KQs, generated a preliminary protocol, and reviewed it with the Technical Expert Panel. The aforementioned Key Informants constituted the Technical Expert Panel. They provided feedback on the feasibility and importance of our approach and provided their unique insight. Again, no conflict of interest was identified. The draft Comparative Effectiveness Review report underwent peer and public review and was revised based on commentary.
Data Sources and Selection

We conducted a computerized literature search of the Cochrane Library and MEDLINE® databases for both RCTs and observational studies published from January 1996 through March 2010. The search was updated in March 2011 to incorporate new relevant literature. We did not apply any language restrictions. To locate unpublished studies and increase the sensitivity of our search, we reviewed references from identified studies and systematic reviews. We also searched abstracts from major cardiology meetings/organizations and ClinicalTrials.gov. Two independent reviewers assessed studies for inclusion in a parallel manner by using criteria defined a priori. RCTs or observational studies that enrolled 500 or more patients were eligible for inclusion if they (1) compared the use of adjunctive devices (thrombus aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection) to remove thrombi or protect against distal embolization before PCI versus a control (active or nonactive); (2) included only patients with ACS; (3) enrolled only patients with target lesion(s) in native vessels (studies in which less than 5 percent of patients with target vessel lesions in saphenous vein grafts were included); and (4) reported data on at least one prespecified patient morbidity, mortality, safety, or health-related quality-of-life outcome. Observational studies reporting multivariable adjusted results depicting the effect of prespecified patient characteristics on intermediate or terminal outcomes were included in the evaluation of KQ 3.

Data Extraction and Quality Assessment

Two reviewers used a standardized data extraction tool to independently extract study data. Validity assessment was performed using the recommendations in the Agency for Healthcare Research and Quality Methods Guide for Effectiveness and Comparative Effectiveness Reviews (www.effectivehealthcare.ahrq.gov). Studies were then given an overall quality score of good, fair, or poor.

Data Synthesis and Analysis

We qualitatively examined data from all identified studies. For each outcome, we conducted separate analyses of studies that compare each individual adjunctive device type with control and studies in which different adjunctive device types were directly compared to each other. We conducted separate analyses for studies that enrolled patients experiencing only STEMI, studies that enrolled patients experiencing non–ST-segment MI (NSTEMI) or unstable angina (UA), and studies that enrolled mixed ACS populations. We conducted meta-analyses when two or more RCTs that were adequate for data pooling were available for any outcome. Observational studies were not pooled with RCTs and were assessed in a qualitative fashion only. For dichotomous outcomes, weighted averages are reported as relative risks and risk differences with associated 95-percent confidence intervals. As heterogeneity between included studies was expected, a DerSimonian and Laird random-effects model was used when pooling data and calculating relative risks, risk differences, and 95-percent confidence intervals. Automatic “zero cell” correction was used for studies with no events for a particular outcome occurring in one group. Studies with no events occurring in both treatment and control groups were excluded from meta-analysis. When pooling continuous outcomes, weighted mean differences, along with 95-percent confidence intervals, were calculated by using a DerSimonian and Laird random-effects model. Statistical heterogeneity was addressed by using the I² statistic and the Cochrane Q-statistic. An
I² value of >50 percent was regarded as representative of important statistical heterogeneity. Egger’s weighted regression statistic was used to assess for the presence of publication bias. Statistics were performed by using StatsDirect statistical software, version 2.7.8 (StatsDirect Ltd., Cheshire, England). For all analyses, a p-value of <0.05 was considered statistically significant.

To assess the effect of heterogeneity on the conclusions of our meta-analysis, we conducted multiple subgroup and sensitivity analyses. These analyses were conducted to assess the methodological study quality (analyses limited to “good” studies only) and duration of followup on the efficacy of adjunctive devices. More specifically, for duration of followup, efficacy data representing the maximal extent of clinical followup after PCI and at different extents of clinical followup (in hospital, ≥30 days but <180 days, ≥180 days but <365 days, and ≥365 days) were pooled in separate analyses.

For KQ 3, patient demographics (age, sex, and ethnicity); baseline patient health status (smoking history, history of diabetes, ejection fraction, ischemia time, pre-PCI TIMI flow, presence of thrombus-containing lesion, and location of infarct-related artery); and concomitant treatment characteristics (rescue PCI, administration of glycoprotein IIb/IIIa inhibitors, and direct stenting) were assessed for their impact on the efficacy of adjunctive devices. Data from RCTs, observational studies, and individual patient data meta-analyses were utilized. For RCTs or controlled observational studies, data from subgroup analyses were abstracted, and when not reported, p-values for interaction between subgroups were calculated to aid in interpretation. Due to the limited amount of data reported for each patient demographic/health status in the literature as well as observed heterogeneity within time points and definitions of outcomes, meta-analyses were not conducted for this Key Question. Data from single-arm (all patients receiving an adjunctive device) observational study reports were included only if they conducted multivariate analysis to identify independent predictors of prespecified efficacy outcomes.

We used the Grading of Recommendations Assessment, Development and Evaluation system to assess the strength of evidence for each outcome of interest separately. This system uses four required domains—risk of bias, consistency, directness, and precision. Additional domains were not assessed because they were deemed irrelevant to this review. All assessments were made by two investigators, with disagreements resolved through discussion. When a large preponderance of data available for an outcome was of good quality, the strength of evidence was not inherently downgraded because of a small number of poorer quality trials or studies. The evidence pertaining to each Key Question was classified into four broad categories: high, moderate, low, or insufficient. The applicability of each study and the body of evidence per outcome were evaluated using the seven criteria for effectiveness studies: used a primary care population, used less stringent eligibility criteria, assessed final health outcomes, had adequate study duration with clinically relevant treatment modalities, assessed adverse events, had an adequate sample size, and used intention-to-treat analysis.

Results

Results of Literature Search

The literature search to identify articles that evaluated the impact of thrombectomy or embolic protection devices on final health or intermediate outcomes yielded 1,056 unique citations. After duplicates were removed, 978 articles remained. During the title and abstract
review, 571 articles were excluded, and during the full-text review, 244 articles were excluded. A total of 165 articles were found to match our inclusion criteria. Upon updating the literature search in March 2011, a total of 121 citations were retrieved, of which 10 were added to the 165 original citations, for a total of 175 included citations.

**KQ 1.** In patients with ACS who are undergoing PCI of native vessels, what are the comparative effects of adjunctive devices from different classes (e.g., thrombus aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection) on intermediate outcomes (e.g., ST-segment resolution, MBG, TIMI-3 flow, ejection fraction, and distal embolization) and final health outcomes (mortality, MACE, health-related quality of life)?

Fifty RCTs and seven controlled observational studies were included in this Key Question. Five final health outcomes (mortality, myocardial infarction, stroke, target revascularization, and MACE) and six intermediate outcomes (ST-segment resolution, MBG-3, TIMI-3 blood flow, ejection fraction, distal embolization, and no reflow) were assessed. A summary of the conclusions and strength of evidence for KQ 1 can be found in Table A. Those outcomes with insufficient strength of evidence rating are listed in Table C.

**STEMI Population**

Only two direct comparative randomized trials assessed for final health outcomes, and three direct comparative randomized trials assessed for intermediate health outcomes. All of the direct comparative randomized trials were constituted with patients who had STEMI; no information was available for mixed ACS or NSTEMI/UA populations. No controlled observational studies were available. For STEMI, no significant differences in final or intermediate health outcomes were found between different catheter aspiration devices when directly compared or between catheter aspiration devices and distal balloon embolic protection devices. Mechanical thrombectomy devices and other embolic protection devices were not evaluated in direct comparative trials.

In RCTs comparing PCI with a thrombectomy or embolic protection device versus standard PCI conducted in patients with STEMI, the use of catheter aspiration devices significantly decreased the risk of MACE but did not significantly impact other final health outcomes compared with control. Limiting the analysis to good-quality trials did not affect the results. The controlled observational studies found no significant impact of catheter aspiration device use on final health outcomes. In contrast, the use of mechanical thrombectomy devices, distal filter embolic protection devices, distal balloon embolic protection devices, proximal balloon embolic protection devices, or any one of the three embolic protection devices (embolic protection devices combined) did not significantly impact any of the final health outcomes in RCTs with one exception. Distal filter embolic protection devices significantly increased the risk of target revascularization. Limiting the analysis to good-quality trials did not alter these findings, and controlled observational studies yielded only nonsignificant differences between these device types and control for final health outcomes as well.

In RCTs comparing PCI with a thrombectomy or embolic protection device versus standard PCI conducted in patients with STEMI, use of catheter aspiration devices significantly increased
the achievement of ST-segment resolution, MBG-3, and TIMI-3 blood flow while significantly reducing the occurrence of distal embolization and no reflow. Limiting the results to good-quality trials yielded the same significant findings. In RCTs, ejection fraction was not significantly impacted by catheter aspiration therapy versus control. Two studies found no significant impact of catheter aspiration on TIMI-3 blood flow versus control. In contrast, the use of mechanical thrombectomy devices, distal filter embolic protection devices, or proximal balloon embolic protection devices did not significantly impact any of the intermediate outcomes evaluated in RCTs. Limiting the results to good-quality trials did not alter these findings. The use of distal balloon embolic protection devices or any of the three embolic protection devices (embolic protection devices combined) significantly increased the achievement of MBG-3 and TIMI-3 blood flow but did not impact other intermediate outcomes versus control in the other available RCTs. Limiting the results to good-quality trials did not alter these findings. In a sole controlled observational study, the use of mechanical thrombectomy devices was found to detrimentally reduce the achievement of TIMI-3 blood flow versus control, and no observational trials were available for embolic protection devices.

**Mixed ACS Population**

In patients with mixed ACS (STEMI or NSTEMI or UA), the dataset was much more limited than with trials and studies in the STEMI population. One RCT and one controlled observational study evaluated the impact of catheter aspiration devices on final health outcomes. The use of a catheter aspiration device did not significantly impact mortality in the RCT, but mortality was significantly reduced in the controlled observational study versus control. No other final health outcomes were evaluated in this trial and study. Mechanical thrombectomy devices, distal filter embolic protection devices, distal balloon embolic protection devices, proximal balloon embolic protection devices, or any one of the three embolic protection devices (embolic protection devices combined) did not significantly impact any of the final health outcomes that could be evaluated in controlled trials. One controlled observational study evaluated the impact of mechanical thrombectomy devices on final health outcomes, finding no significant impact of device therapy on mortality, myocardial infarction, target revascularization, or MACE. No controlled observational studies evaluated the impact of embolic protection devices on final health outcomes.

In patients with mixed ACS, the impact of device therapy on many intermediate outcomes was not assessed in RCTs or controlled observational studies. In RCTs conducted in patients with mixed ACS, catheter aspiration devices significantly increased the attainment of MBG-3 but did not significantly impact TIMI-3 blood flow. In RCTs, use of mechanical thrombectomy devices significantly increased the attainment of ST-segment resolution but did not significantly impact the attainment of TIMI-3 blood flow versus control. However, in a controlled observational study, the use of a mechanical thrombectomy device significantly reduced the attainment of TIMI-3 blood flow versus control. Use of distal filter embolic protection devices did not impact ejection fraction or TIMI-3 blood flow versus control in RCTs. Use of distal balloon embolic protection devices significantly increased the likelihood of
attaining ST-segment resolution\(^47\) and MBG-3,\(^43,47\) increased ejection fraction,\(^47\) and reduced the risk of no reflow\(^43\) versus control but did not impact attainment of TIMI-3 blood flow.\(^43,47\) The RCTs evaluating distal balloon embolic protection devices were not determined to be of good methodological quality. Proximal balloon embolic protection devices were not evaluated in the mixed ACS population. When the RCTs on embolic protection device versus control were combined, the attainment of TIMI-3 blood flow was not significantly impacted\(^43,44,47\) and the ejection fraction was increased in one trial\(^47\) but not in another, with other intermediate outcome results reflecting the individual device category results as reported above.

**NSTEMI or UA Population**

For patients with NSTEMI or UA, only two RCTs\(^49,50\) and no controlled observational studies were available that evaluated final health or intermediate health outcomes. Only distal filter embolic protection devices were compared in these RCTs, and they did not impact mortality, MACE, or TIMI-3 blood flow versus control, with insufficient data to evaluate no reflow. No other endpoints were evaluated.

**Table A. Conclusion and strength of evidence evaluations for final health and intermediate outcomes (KQ 1)**

<table>
<thead>
<tr>
<th>Population: Device Category, Outcome(^a)</th>
<th>Number of Studies, N (RCT, OBS)</th>
<th>Conclusion, RR/RD (95% CI) (^b)</th>
<th>Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI: Catheter aspiration devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>13 (10,3)</td>
<td>No effect; RR 0.69 (0.47 to 1.02)</td>
<td>Low</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12 (10,2)</td>
<td>No effect; RR 0.61 (0.36 to 1.04)</td>
<td>Low</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>11 (9,2)</td>
<td>No effect; RR 0.79 (0.61 to 1.02)</td>
<td>Low</td>
</tr>
<tr>
<td>MACE</td>
<td>13 (11,2)</td>
<td>Decreased risk (favors device); RR 0.73 (0.61 to 0.88), RD -0.03 (-0.10 to 0.001)</td>
<td>High</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>16 (15,1)</td>
<td>Increased risk (favors device); RR 1.51 (1.32 to 1.73), RD 0.22 (0.15 to 0.30)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>12 (11,1)</td>
<td>No effect(^c)</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>13 (13,0)</td>
<td>Increased risk (favors device); RR 1.61 (1.41 to 1.84), RD 0.22 (0.16 to 0.28)</td>
<td>Moderate</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>15 (13,2)</td>
<td>Increased risk (favors device); RR 1.08 (1.04 to 1.12), RD 0.06 (0.03 to 0.10)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>11 (10,1)</td>
<td>Decreased risk (favors device); RR 0.56 (0.39 to 0.79), RD -0.09 (-0.17 to -0.01)</td>
<td>High</td>
</tr>
<tr>
<td>No reflow</td>
<td>8 (8,0)</td>
<td>Decreased risk (favors device); RR 0.52 (0.35 to 0.76), RD -0.07 (-0.11 to -0.03)</td>
<td>High</td>
</tr>
<tr>
<td>STEMI: Mechanical thrombectomy devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>5 (5,0)</td>
<td>No effect; RR 1.16 (0.99 to 1.36)</td>
<td>Low</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>2 (2,0)</td>
<td>No effect(^c)</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>4 (4,0)</td>
<td>No effect; RR 1.07 (0.80 to 1.43)</td>
<td>Low</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>5 (4,1)</td>
<td>No effect; RR 0.98 (0.92 to 1.04)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>3 (3,0)</td>
<td>No effect; RR 0.44 (0.17 to 1.12)</td>
<td>Moderate</td>
</tr>
<tr>
<td>STEMI: Distal filter embolic protection devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target revascularization</td>
<td>2 (2,0)</td>
<td>Increased risk (favors control); RR 1.61 (1.03 to 2.54), RD 0.04 (-0.0006 to 0.08)</td>
<td>Low</td>
</tr>
</tbody>
</table>
Table A. Conclusion and strength of evidence evaluations for final health and intermediate outcomes (KQ 1) (continued)

<table>
<thead>
<tr>
<th>Population: device category, outcome</th>
<th>Number of studies, N (RCT, OBS)</th>
<th>Conclusion, RR/RD (95% CI)b</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>5 (5,0)</td>
<td>No effect; RR 1.34 (0.97 to 1.86)</td>
<td>Moderate</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>5 (5,0)</td>
<td>No effect; RR 1.05 (0.97 to 1.15)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>2 (2,0)</td>
<td>No effect⁴</td>
<td>Low</td>
</tr>
<tr>
<td>MBG-3</td>
<td>2 (2,0)</td>
<td>No effect; RR 0.97 (0.81 to 1.15)</td>
<td>Moderate</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>5 (5,0)</td>
<td>No effect; RR 1.00 (0.90 to 1.11)</td>
<td>Low</td>
</tr>
<tr>
<td>STEMI: Distal balloon embolic protection devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>4 (4,0)</td>
<td>No effect; RR 1.08 (0.91 to 1.29)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>6 (6,0)</td>
<td>No effect⁴</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>6 (6,0)</td>
<td>Increased risk (favors device); RR 1.39 (1.15 to 1.69), RD 0.15 (0.10 to 0.24)</td>
<td>High</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>8 (8,0)</td>
<td>Increased risk (favors device); RR 1.11 (1.03 to 1.19), RD 0.08 (0.02 to 0.14)</td>
<td>Low</td>
</tr>
<tr>
<td>STEMI: Combined embolic protection devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACE</td>
<td>12 (11,1)</td>
<td>No effect; RR 1.04 (0.84 to 1.29)</td>
<td>Moderate</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>10 (10,0)</td>
<td>No effect; RR 1.06 (1.00 to 1.13)</td>
<td>Low</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>9 (9,0)</td>
<td>No effect⁴</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>9 (9,0)</td>
<td>Increased risk (favors device); RR 1.20 (1.02 to 1.40), RD -0.004 (-0.02 to 0.01)</td>
<td>Moderate</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>14 (14,0)</td>
<td>Increased risk (favors device); RR 1.06 (1.01 to 1.12), RD 0.05 (0.01 to 0.10)</td>
<td>Low</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>6 (6,0)</td>
<td>No effect; RR 0.91 (0.64 to 1.30)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mixed ACS: Catheter aspiration devices</td>
<td>1 (1,0)</td>
<td>Increased risk (favors device); RR 4.45 (1.51 to 13.88), RD 0.30 (0.10 to 0.51)</td>
<td>Low</td>
</tr>
<tr>
<td>Mixed ACS: Mechanical thrombectomy devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1 (1,0)</td>
<td>Increased risk (favors device); RR 1.58 (1.05 to 2.57), RD 0.30 (0.03 to 0.54)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mixed ACS: Distal balloon embolic protection devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1 (1,0)</td>
<td>Increased risk (favors device); RR 1.58 (1.10 to 2.46), RD 0.29 (0.10 to 0.50)</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>2 (2,0)</td>
<td>Increased risk (favors device); RR 3.22 (1.03 to 10.10), RD 0.51 (0.18 to 0.84)</td>
<td>Moderate</td>
</tr>
<tr>
<td>No reflow</td>
<td>1 (1,0)</td>
<td>Decreased risk (favors device); RR 0.36 (0.20 to 0.59), RD -0.54 (-0.71 to -0.31)</td>
<td>High</td>
</tr>
<tr>
<td>Mixed ACS: Combined embolic protection devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1 (1,0)</td>
<td>Increased risk (favors device); RR 1.58 (1.10 to 2.46), RD 0.29 (0.10 to 0.50)</td>
<td>Moderate</td>
</tr>
<tr>
<td>MBG-3</td>
<td>2 (2,0)</td>
<td>Increased risk (favors device); RR 3.22 (1.03 to 10.10), RD 0.51 (0.18 to 0.84)</td>
<td>Moderate</td>
</tr>
<tr>
<td>No reflow</td>
<td>1 (1,0)</td>
<td>Decreased risk (favors device); RR 0.36 (0.20 to 0.59), RD -0.54 (-0.71 to -0.31)</td>
<td>High</td>
</tr>
</tbody>
</table>

a Outcomes reported are those with the longest duration of followup. Final health or intermediate outcomes graded as “insufficient” are not reported in this table but are listed in Table C.

b Pooled RR and RD are based on data from RCTs only; observational studies were used qualitatively.

c Based on qualitative evaluation of available data.
KQ 2. In patients with ACS who are undergoing PCI of native vessels, how do the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

Twenty-three RCTs and three controlled observational studies were included in this evaluation. Four adverse events (coronary dissection, coronary perforation, prolonged procedure time, and side branch occlusion) were assessed. Given the way procedure time was assessed in individual trials, the results could not be pooled for any of the device evaluations but were reviewed qualitatively. A summary of the conclusions and strength of evidence for KQ 2 can be found in Table B. Those outcomes with insufficient strength of evidence rating are listed in Table C.

**STEMI Population**

Only two direct comparative randomized trials evaluated for adverse events. Both of these direct comparative randomized trials were constituted with patients who had STEMI, and no information was available for mixed ACS or NSTEMI/UA populations. No controlled observational studies were available. For STEMI, no significant differences were found between different catheter aspiration devices for coronary dissection, no coronary perforations occurred in either group, and side branch occlusion was not assessed. For STEMI, no significant differences were found between catheter aspiration devices and distal balloon embolic protection devices for procedure time. Mechanical thrombectomy devices and other embolic protection devices were not evaluated in direct comparative trials.

In RCTs conducted in patients with STEMI, the use of catheter aspiration devices significantly decreased the risk of coronary dissection but did not significantly impact side branch occlusion versus control. In eight of nine RCTs assessing procedure time as well as in one controlled observational study, no significant change in time occurred versus control. The same results occurred when the dataset was limited to good-quality trials. The sole controlled observational study found no significant impact of catheter aspiration devices on the risk of coronary dissection versus control.

In RCTs conducted in patients with STEMI, the use of mechanical thrombectomy devices did not significantly impact coronary dissection, coronary perforation, or side branch occlusion, but in all three trials the procedure time was significantly increased versus control. Limiting the results to good-quality trials did not alter the conclusions. The sole controlled observational study found no significant impact of mechanical thrombectomy devices on the risk of coronary dissection versus control.

In RCTs conducted in patients with STEMI, the use of distal filter embolic protection devices did not significantly impact side branch occlusion versus control, and no coronary dissections or coronary perforations occurred in either group. However, the sole RCT evaluating procedure time found a significant increase in time with distal filter embolic protection devices versus control. Limiting the results to good-quality trials did not alter the conclusions, and no controlled observational studies were available.
In RCTs conducted in patients with STEMI, the use of distal balloon embolic protection devices did not significantly impact coronary perforation or side branch occlusion versus control, and no coronary dissections occurred in either group in the one trial reporting the outcome. Limiting the results to good-quality trials did not alter the conclusions, and no controlled observational studies were available.

The only available RCT conducted in patients with STEMI found that the use of proximal balloon embolic protection devices significantly increased procedure time versus control but did not assess for any other adverse event. Limiting the results to good-quality trials did not alter the conclusions, and no controlled observational studies were available.

In RCTs conducted in patients with STEMI, the use of embolic protection devices (distal or proximal, filter or balloon) did not significantly impact coronary dissection, coronary perforation, or side branch occlusion. In four of five trials, the procedure time was prolonged in patients receiving embolic protection devices versus control. Limiting the results to good-quality trials did not alter the conclusions, and no controlled observational studies were available.

### Mixed ACS, NSTEMI, or UA Populations

One RCT assessed the impact of distal balloon embolic protection device versus control on procedure time in mixed ACS. Procedure time was significantly prolonged in this evaluation. No other devices or adverse events were assessed in clinical trials or controlled observational studies.

#### Table B. Conclusion and strength of evidence evaluations for adverse events (KQ 2)

<table>
<thead>
<tr>
<th>Population: device category</th>
<th>Number of studies, N (RCT, OBS)</th>
<th>Conclusion, RR/RD (95% CI)</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI: Catheter aspiration devices</td>
<td>Coronary dissection 5 (4,1)</td>
<td>Decreases risk; RR 0.30 (0.12 to 0.75), RD -0.02 (-0.12 to 0.10)</td>
<td>High</td>
</tr>
<tr>
<td>Prolonged procedure time 9 (8,1)</td>
<td>No effect</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>STEMI: Mechanical thrombectomy devices</td>
<td>Prolonged procedure time 3 (3,0)</td>
<td>Prolongs time</td>
<td>High</td>
</tr>
<tr>
<td>STEMI: Distal balloon embolic protection devices</td>
<td>Coronary perforation 1 (1,0)</td>
<td>No effect; RR 5.11 (0.53 to infinity)</td>
<td>Low</td>
</tr>
<tr>
<td>Prolonged procedure time 3 (3,0)</td>
<td>Prolongs time</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Side branch occlusion 2 (2,0)</td>
<td>No effect; RR 0.93 (0.61 to 1.42)</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>STEMI: Proximal balloon embolic protection devices</td>
<td>Prolonged procedure time 1 (1,0)</td>
<td>Prolongs time</td>
<td>Moderate</td>
</tr>
<tr>
<td>STEMI: Combined embolic protection devices</td>
<td>Prolonged procedure time 5 (5,0)</td>
<td>Prolongs time</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mixed ACS: Distal balloon embolic protection devices</td>
<td>Prolonged procedure time 1 (1,0)</td>
<td>Prolongs time</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mixed ACS: Combined embolic protection devices</td>
<td>Prolonged procedure time 1 (1,0)</td>
<td>Prolongs time</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

*Outcomes reported are those with the longest duration of followup. Adverse events graded as “insufficient” are not reported in this table but are listed in Table C.

*Pooled RR and RD are based on data from RCTs only; observational studies were used qualitatively.

*Based on qualitative evaluation of available data.
Table C. Final, intermediate, and adverse outcomes with insufficient data

<table>
<thead>
<tr>
<th>Population: device category</th>
<th>Outcome with insufficient data</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEMI: Catheter aspiration devices versus distal balloon embolic protection devices</td>
<td>All outcomes</td>
</tr>
<tr>
<td>STEMI: Catheter aspiration devices versus catheter aspiration devices</td>
<td>All outcomes</td>
</tr>
<tr>
<td>STEMI: Catheter aspiration devices versus control</td>
<td>Stroke, HRQoL, perforation</td>
</tr>
<tr>
<td>STEMI: Mechanical thrombectomy devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, no reflow, coronary dissection, perforation</td>
</tr>
<tr>
<td>STEMI: Distal filter embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, HRQoL, distal embolization, no reflow, coronary dissection, perforation, prolonged procedure time</td>
</tr>
<tr>
<td>STEMI: Distal balloon embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, distal embolization, no reflow, coronary dissection, perforation</td>
</tr>
<tr>
<td>STEMI: Proximal embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ST-segment resolution, ejection fraction, MBG-3, TIMI-3, distal embolization, no reflow, coronary dissection, perforation</td>
</tr>
<tr>
<td>STEMI: Combined embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, HRQoL, no reflow, coronary dissection, perforation</td>
</tr>
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<td>Mixed ACS: Catheter aspiration devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ST-segment resolution, ejection fraction, TIMI-3, distal embolization, no reflow, coronary dissection, perforation, prolonged procedure time</td>
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<td>Mixed ACS: Mechanical thrombectomy devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ejection fraction, MBG-3, TIMI-3, distal embolization, no reflow, coronary dissection, perforation, prolonged procedure time</td>
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<tr>
<td>Mixed ACS: Distal filter embolic protection devices versus control</td>
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<tr>
<td>Mixed ACS: Distal balloon embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ejection fraction, TIMI-3, distal embolization, coronary dissection, perforation</td>
</tr>
<tr>
<td>Mixed ACS: Proximal balloon embolic protection devices versus control</td>
<td>All outcomes</td>
</tr>
<tr>
<td>Mixed ACS: Combined embolic protection devices versus control</td>
<td>Mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ejection fraction, TIMI-3, distal embolization, coronary dissection, perforation</td>
</tr>
<tr>
<td>UA/NSTEMI: Catheter aspiration devices versus control</td>
<td>All outcomes</td>
</tr>
<tr>
<td>UA/NSTEMI: Mechanical thrombectomy devices versus control</td>
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<tr>
<td>UA/NSTEMI: Distal filter embolic protection devices versus control</td>
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<td>UA/NSTEMI: Distal balloon embolic protection devices versus control</td>
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<td>UA/NSTEMI: Proximal embolic protection devices versus control</td>
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</tr>
<tr>
<td>UA/NSTEMI: Combined embolic protection devices versus control</td>
<td>All outcomes</td>
</tr>
</tbody>
</table>

Note: "All outcomes" includes all 15 final, intermediate, and adverse outcomes evaluated: mortality, myocardial infarction, stroke, target revascularization, MACE, HRQoL, ST-segment resolution, ejection fraction, MBG-3, TIMI-3, distal embolization, no reflow, coronary dissection, perforation, and prolonged procedure time.

ACS = acute coronary syndrome; HRQoL = health-related quality of life; MACE = major adverse cardiovascular event; MBG = myocardial blush grade; NSTEMI = non–ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction; TIMI = thrombolysis in myocardial infarction; UA = unstable angina.
KQ 3. In patients with ACS who are undergoing PCI of native vessels, which patient characteristics (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of a thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, use of direct stenting) affect outcomes?

Nine RCTs, an individual patient data meta-analysis, a pooled analysis, and five observational studies provided useful data for KQ 3. No RCTs evaluated the effect of ethnicity or ejection fraction on thrombectomy or embolic protection device efficacy. RCTs evaluating treatment effect stratified by subgroups found the following: (1) no statistically significant difference in outcomes with catheter aspiration, mechanical thrombectomy, or embolic protection device based on differences in sex, age, diabetes, smoking status, primary or rescue PCI, presence of thrombus-containing lesion, pre-PCI TIMI flow, or the use of direct stenting; (2) a trend (p-value for interaction <0.10 between subgroups) toward greater improvements in attaining complete ST-segment resolution with proximal balloon embolic protection in those receiving a glycoprotein IIb/IIIa inhibitor versus those without such therapy; and (3) a trend (p-value for interaction <0.10 between subgroups) toward greater improvements in attaining complete ST-segment resolution with proximal balloon embolic protection in those with an anterior infarct-related artery lesion versus lesions in other arteries.

There were conflicting data from RCTs regarding the effect of ischemic time on outcomes following the use of catheter aspiration devices. There was a trend (p-value for interaction <0.10 between subgroups) toward greater achievement of a higher MBG with catheter aspiration in those with ischemic times less than 180 minutes versus longer ischemic times. There was significantly greater improvement (p-value for interaction = 0.02 between subgroups) in the achievement of TIMI-3 flow with catheter aspiration and a trend (p-value for interaction <0.10 between subgroups) toward greater reductions in slow flow or no reflow in those with prolonged ischemic times (6 to 24 hours from symptom onset) versus those with shorter ischemic times.

An individual patient data meta-analysis (A pooled Analysis of Trials on ThrombEctomy in acute Myocardial infarction based on individual PatienT data; ATTEMPT) found that the use of aspiration or mechanical thrombectomy was associated with a survival benefit in the subgroup of patients treated with glycoprotein IIb/IIIa inhibitors but not in patients who did not receive them. No qualitative differences in mortality were seen when splitting the study population according to the presence or absence of diabetes, earlier or later time to reperfusion, type of vessel (left anterior descending, circumflex, right coronary artery) containing the culprit lesion, and lower or higher pre-PCI TIMI flow. The pooled analysis by De Vita and colleagues found that, in subgroups of short (≤3 hours) and intermediate (>3 hours to <6 hours) time to treatment (TTT), there was no significant difference between catheter aspiration and control on inhospital MACE, STSR, MBG 2-3, or TIMI-3. In the subgroup of long TTT (>6 hours and ≤12 hours), catheter aspiration devices significantly increased the rate of STSR and TIMI-3 blood flow compared with control but did not significantly impact other outcomes.

The Osaka Acute Coronary Insufficiency Study (OACIS) observational study found Killip class (a correlate to heart failure and ejection fraction) not to be a modifier of 30-day mortality with catheter aspiration device use. These are the only data available to evaluate the potential confounding effect of heart function on outcomes. The controlled observational study by
Sardella and colleagues found that use of catheter aspiration, age, and symptom to balloon time were significant predictors of cardiac death (no deaths were of noncardiac cause) at 2 years. Observational single-arm studies found catheter aspiration and/or embolic protection device efficacy to be negatively affected by increased age, prolonged ischemic time, female sex, presence of diabetes, and absence of baseline thrombus.

**Discussion**

Determining the balance of benefits to harms is difficult because many of the evaluations of final health outcomes and adverse events were underpowered, and the safety of devices overall is unclear due to insufficient amounts of data. We could not know for certain whether the nonsignificant increases or decreases were due to a real effect or to chance. The applicability of the body of evidence is highest for patients with STEMI undergoing primary PCI of the native vessels. Data are more highly applicable to male patients than female patients because of the enrollment of a consistently higher percentage of males across trials. The majority of data were derived from trials and studies conducted outside of the United States evaluating devices that are not currently available in the United States; therefore, their applicability was limited.

In the catheter aspiration trials, the risks of MACE and coronary dissection were significantly lower in the overall analysis and the good-quality trial analyses. The risks of mortality, myocardial infarction, stroke, target revascularization, and side branch occlusion were not significantly different from control. Eight of nine trials and one controlled observational study found a nonsignificant prolongation of the time needed to conduct the PCI procedure compared with control. Intermediate health outcomes showed significant reductions in distal embolization and no reflow, and significantly more patients experienced ST segment resolution, higher MBG, and near-normal (TIMI-3) blood flow though the target vessel compared with control. More research is needed to truly determine the balance of benefits to harms.

Mechanical thrombectomy device use did not result in any significant differences in the risk of mortality, stroke, MACE, coronary dissection, and coronary perforation in the overall analyses and analyses limited to good-quality trials. However, these devices significantly increased the time needed to conduct the PCI procedure in three trials. While the risks of myocardial infarction, target revascularization, mortality, and MACE were not significantly different from control, these findings may be misleading since many of the trials evaluating this procedure versus control had a short duration of followup. When we evaluated mortality and MACE in studies of 365 days or longer, we saw no significant difference in mortality risk, although a single trial found a significant reduction in MACE. Unlike the case with catheter aspiration devices, there were no significant beneficial effects on intermediate health outcomes with mechanical thrombectomy devices, and while most were in the right direction of effect, the chance of achieving near normal (TIMI-3) blood flow was not significantly different from control. More research is needed to truly determine the balance of benefits to harms with mechanical thrombectomy devices.

The use of embolic protection devices was based on a limited number of studies. One significant finding on final health outcomes (effect of distal filter on target revascularization) was seen in overall analyses or those limited to good-quality trials. It was difficult to assess the impact of these devices on final health outcomes and intermediate outcomes. In STEMI, distal balloon devices significantly increased the chance of achieving MBG-3 and near-normal (TIMI-3) blood flow but did not significantly impact the achievement of ST-segment resolution, prevention of no reflow, or the risk of distal embolization. Distal filter devices did not
significantly impact ST-segment resolution, distal embolization, no reflow, attainment of near-normal (TIMI-3) blood flow, or MBG. There was a paucity of trials available to evaluate adverse events with any of the embolic protection devices. The only significant finding was increased time to perform a PCI procedure compared with control for all three types of embolic protection devices individually and when evaluated all together. The balance of benefits to harms cannot be determined for these device classes.

Given the inadequate power in overall analyses and lack of data, we could not definitively determine the impact of therapy in subpopulations. No data were available to determine if the results differed based on ethnicity or ejection fraction. Given the available data, the concomitant use of a glycoprotein IIb/IIIa receptor antagonist and a device may be associated with a survival benefit.

**Future Research**

**Limitations of Current Research**

The use of thrombus removal and embolic protection devices holds promise in the adjunctive treatment of patients with ACS undergoing primary PCI. However, to truly discern the role of these devices in contemporary practice, a number of important research questions need to be answered.

While two direct comparative RCTs that evaluated final health outcomes were conducted, one comparing one catheter aspiration device with another and one comparing a catheter aspiration device with an embolic protection device, no significant differences were found and the trials were vastly underpowered to evaluate for final health and intermediate outcomes.

In our analysis, we found that for many endpoints, nonsignificant increases or decreases were seen compared with control, even when we evaluated compound endpoints, used the maximum duration of followup, and combined three different types of embolic protection devices together. All of these were strategies to enhance the power to detect differences between groups, but by and large, they did not provide adequate power. Ultimately, the impact of using these devices on long-term final health outcomes compared with control needs to be determined.

Applicability of the trials to American patients with ACS was in the low to moderate range for almost all outcomes because the trials were mostly conducted outside of the United States. It will be important to determine if the devices are equally effective in the hands of average interventional cardiologists in the United States. In addition, it is unclear how much experience the interventional cardiologists had in performing the procedures before enrolling patients in the clinical trials. It is unclear whether the use of the devices by average interventional cardiologists will result in a different balance of benefits to harms than with the more experienced, high-volume interventional cardiologists.

Given the inadequate power in overall analyses or lack of data, we cannot determine the impact of therapy in subpopulations (e.g., sex, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, use of direct stenting).

Based on these research gaps we propose the following avenues for future research.
Future Avenues for Research

Clinical Trials

- We believe that additional multicenter, randomized, placebo-controlled trials should be conducted to determine the impact of adjunctive clot removal or embolic protection devices on final health outcomes using a long-term followup.
  - Such trials should have adequate representation of interventional cardiologists from the United States and include both tertiary academic medical centers and large community-based hospitals.
  - Even if the trials are not large enough to determine efficacy in subgroups (e.g., sex, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, use of direct stenting), such data should be recorded and included in the results so future reviews of comparative effectiveness can pool these results and determine if the benefits or harms are uniformly distributed across the population or are centered within a certain subgroup.
  - Conducting these additional clinical trials would facilitate the performance of mixed-treatment meta-analyses or individual patient data meta-analyses to estimate the comparative effectiveness of different device classes.

- To truly determine comparative effectiveness, the devices found to have the best balance of benefits to harms compared with standard PCI should be directly compared in a multicenter, randomized, active controlled trial to determine the impact of adjunctive clot removal or embolic protection devices on final health outcomes using a long-term followup.
  - Such a trial should have adequate representation of interventional cardiologists from the United States and include both tertiary academic medical centers and large community-based hospitals.
  - Even if the trial is not large enough to determine efficacy in subgroups, such data should be included in the results.
  - Along with additional placebo-controlled trials, conducting direct comparative clinical trials would facilitate the performance of mixed-treatment meta-analyses or individual patient data meta-analyses to estimate the comparative effectiveness of device classes that are and are not being directly compared.

Observational Studies

- Future observational studies should determine if certain subpopulations may have accentuated or attenuated benefits or harms and whether benefits or harms differ between high-volume academic medical centers and lower volume community hospitals.
- Electronic medical records can be used as a source of data for future observational and effectiveness studies.


Glossary

**Acute coronary syndrome (ACS):** Any group of clinical symptoms compatible with acute myocardial ischemia. Acute coronary syndrome includes the spectrum of clinical conditions ranging from unstable angina to non–Q-wave myocardial infarction and Q-wave myocardial infarction.

**Catheter aspiration device:** Includes the Diver™, Diver™ CE, Export®, Pronto™, Rescue™, Thrombus®️tor, and TransVascular Aspiration Catheter®️ devices.

**Confidence intervals (CIs):** A range that is likely to include the given value. Usually presented as a percent. For example, a value with a 95-percent confidence interval implies that when a measurement is made 100 times, it will fall within the given range 95 percent of the time.

**DerSimonian and Laird Random-Effects Model:** A statistical method based on the assumption that the effects observed in different studies (in a meta-analysis) are truly different.

**Egger’s Weighted Regression Statistics:** A method of identifying and measuring publication bias.

**Embolic protection device:** Includes the following devices: FilterWire EX™, FilterWire EZ™, SpideRX™, AngioGuard™️, AngioGuard™️ XP, PercuSurge GuardWire®, PercuSurge GuardWire™️ Plus, and Proxis™️.

**I²:** Measure of the degree of variation due to statistical heterogeneity. Reported as a percent ranging from 0 to 100 percent.

**Mechanical thrombectomy device:** Includes the AngioJet® and X-Sizer® devices.

**Meta-analysis:** The process of extracting and pooling data from several studies investigating a similar topic to synthesize a final outcome.

**Myocardial blush grade (MBG):** An angiographic method of grading myocardial tissue perfusion ranging from grade 0 to grade 3. In grade 0, the dye fails to enter the microvasculature, with either minimal or no ground-glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit artery, indicating lack of tissue-level perfusion. In grade 1, the dye slowly enters but fails to exit the microvasculature. There is the ground-glass appearance (blush) or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature, and dye staining is present on the next injection (with approximately 30 seconds between injections). In grade 2, there is delayed entry and exit of dye from the microvasculature. There is the ground-glass appearance (blush) or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature, and dye staining is present on the next injection (with approximately 30 seconds between injections). In grade 3, there is normal entry and exit of dye from the microvasculature. There is a ground-glass appearance (blush) or opacification of the myocardium in the distribution of the culprit lesion that clears normally and is either gone or only mildly/moderately persistent at the end of the washout phase.
(i.e., dye is gone or is mildly/moderately persistent after three cardiac cycles of the washout phase and noticeably diminishes in intensity during the washout phase), similar to that in an uninvolved artery. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.

Non–ST-segment myocardial infarction (NSTEMI): An acute coronary syndrome characterized by myocardial ischemia without an elevation of the ST-segment on the electrocardiograph. Most patients who have non–ST-segment elevation will ultimately develop a non–Q-wave acute myocardial infarction.

Publication bias: The possibility that published studies may not represent all the studies that have been conducted and therefore create bias by being left out of a meta-analysis.

Q statistic: A test to assess the presence of statistical heterogeneity among several studies.

Relative risk (RR): The ratio of an event occurring in an exposed group to an event occurring in a nonexposed group in a given population. A ratio of one indicates no difference in the risk between the two groups.

Risk difference (RD): The absolute difference in the event rate between two comparison groups. A risk difference of zero indicates no difference between comparison groups.

Sensitivity analysis: A “what if” analysis that helps determine the robustness of a study. Helps determine the degree of importance of each variable for a given outcome.

Standard deviation (SD): A measure of the variability of a dataset. For a simple dataset with numbers, can be calculated using the following formula:
\[
\sigma = \sqrt{\frac{\sum(x-xm)^2}{N}}
\]
where
\[
\sigma \text{ is the standard deviation}
\]
\[
xm \text{ is the average}
\]
\[
\sum(x-xm) \text{ is the sum of } xm \text{ subtracted from each individual number } x
\]
\[
N \text{ is the total number of values}
\]
Note: Other formulas also exist.

Statistical heterogeneity: Variability in the observed effects among studies in a meta-analysis.

ST-segment myocardial infarction (STEMI): An acute coronary syndrome characterized by myocardial ischemia with elevation of the ST-segment on the electrocardiograph. Most patients who have ST-segment elevation will ultimately develop a Q-wave acute myocardial infarction.

Target revascularization: Any repeat percutaneous intervention or surgical bypass of the target lesion or segment of the target vessel.

Thrombolysis in myocardial infarction (TIMI) blood flow: Thrombolysis in myocardial infarction graded with a range from 0 to 3. A grade of 0 is defined as complete occlusion of the infarct-related artery. A grade of 1 is defined as some penetration of contrast material beyond the point of obstruction but without perfusion of the distal coronary bed. A grade of 2 is defined as
perfusion of the entire infarct vessel into the distal bed but with delayed flow compared with a normal artery. A grade of 3 is defined as full perfusion of the infarct vessel with normal flow.

**Unstable angina (UA):** An acute coronary syndrome characterized by chest pain that occurs unexpectedly and at rest. The most common cause of the chest pain is reduced blood flow to the myocardium caused by either atherosclerotic narrowing or constriction of the coronary arteries or partial blockage of the coronary arteries by a blood clot.
Introduction

Background

Coronary heart disease (CHD) is a leading cause of morbidity and mortality in the United States. According to the American Heart Association statistics, >650,000 deaths were attributed to CHD in 2003. Moreover, treatment costs for CHD represent the largest healthcare expenditure for a single disease in the United States.\(^1\)

Acute coronary syndromes (ACSs), which include the clinical entities of unstable angina (UA), nonST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI), account for more than 1.5 million hospital admissions annually in the United States alone. Approximately 1 million of these admissions are classified as UA/NSTEMI and approximately 500,000 are STEMI.\(^2\)

Percutaneous coronary intervention (PCI) has revolutionized the management of angina and myocardial infarction (MI), frequently negating the need for coronary bypass surgery and permitting a more rapid return to normal activities. The clinical use of PCI is reflected in the number of patients who undergo this procedure. In the United States alone, 664,000 procedures were performed in 652,000 patients in 2003, representing a 326 percent increase from the number of procedures performed in 1987.\(^1\)

Coronary stents and adjunctive pharmacologic agents—including glycoprotein IIb/IIIa receptor inhibitors and thienopyridines—have improved the effect of PCI establishing near normal antegrade blood flow in the vast majority of patients.\(^1,3-5\)

However, dislodgement of atherothrombotic material from coronary lesions during PCI can result in distal embolization that leads to what is commonly referred to as the “no-reflow phenomenon.” This phenomenon, characterized by inadequate flow at the cardiac tissue level despite patent coronary vessels is often defined as (1) a thrombolysis in myocardial infarction (TIMI) flow grade $\leq 2$ (Table 1) despite vessel patency and the absence of dissection, spasm or distal macroembolus, (2) a myocardial blush grade (MBG) of 0 or 1 (Table 2), or (3) a contrast perfusion defect observed upon myocardial contrast echocardiography. Depending on the exact clinical definition used, the incidence of no-reflow has been found to range from 12 to 39 percent,\(^1,3\) and may be associated with advanced age, presence of diabetes mellitus, left ventricular systolic dysfunction, longer ischemic times, poor initial TIMI flow grades, and anterior myocardial infarction.\(^6\)
Table 1. Thrombolysis in myocardial infarction (TIMI) Flow Grading System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Complete occlusion of the infarct-related artery</td>
</tr>
<tr>
<td>1</td>
<td>Some penetration of contrast material beyond the point of obstruction but without perfusion of the distal coronary bed</td>
</tr>
<tr>
<td>2</td>
<td>Perfusion of the entire infarct vessel into the distal bed but with delayed flow compared with a normal artery</td>
</tr>
<tr>
<td>3</td>
<td>Full perfusion of the infarct vessel with normal flow</td>
</tr>
</tbody>
</table>

Table 2. Myocardial blush grade

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Failure of dye to enter the microvasculature. Either minimal or no ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit artery indicating lack of tissue level perfusion.</td>
</tr>
<tr>
<td>1</td>
<td>Dye slowly enters but fails to exit the microvasculature. There is the ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature, and dye staining is present on the next injection (approximately 30 seconds between injections).</td>
</tr>
<tr>
<td>2</td>
<td>Delayed entry and exit of dye from the microvasculature. There is the ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit lesion that is strongly persistent at the end of the washout phase (i.e. dye is strongly persistent after 3 cardiac cycles of the washout phase and either does not or only minimally diminishes in intensity during washout).</td>
</tr>
<tr>
<td>3</td>
<td>Normal entry and exit of dye from the microvasculature. There is the ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit lesion that clears normally, and is either gone or only mildly/moderately persistent at the end of the washout phase (i.e. dye is gone or is mildly/moderately persistent after 3 cardiac cycles of the washout phase and noticeably diminishes in intensity during the washout phase), similar to that in an uninvolved artery. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.</td>
</tr>
</tbody>
</table>

A higher rate of adverse outcomes has been noted in patients with no-reflow, including larger infarcts, more significant left ventricular systolic dysfunction, and an increased risk of major adverse cardiovascular events (MACE) or death. Numerous adjunctive devices have been developed in an attempt to improve clinical outcomes by removing thrombi and to protect against distal embolization during PCI. These devices utilize different technologies and can be broadly classified as catheter aspiration, mechanical thrombectomy, or embolic protection devices (i.e., distal embolic balloon or filter protection devices or proximal embolic balloon protection devices) (Table 3). Distal embolic protection devices are recommended to be used in patients undergoing PCI of saphenous vein grafts due to previously demonstrated ability to reduce MACE. However, use of embolic protection devices in STEMI has been less well supported mainly because of underpowered clinical trials that evaluated intermediate markers. More recently, larger randomized controlled trials (RCTs) of patients with STEMI have evaluated MACE as an end point and followed patients beyond hospital discharge (typically 3 to 12 months) but have given conflicting results. Thus, the comparative effectiveness and safety of these devices is unclear and needs to be systematically evaluated.
Table 3. Thrombectomy and embolic protection devices used in the randomized controlled trials included in the quantitative synthesis

<table>
<thead>
<tr>
<th>Device Type (Mechanism)</th>
<th>Device Name</th>
<th>Manufacturer</th>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>Diver™</td>
<td>Invatec</td>
<td>Not/no longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>Diver™ CE</td>
<td>Invatec</td>
<td>Not/no longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>Export™</td>
<td>Medronic</td>
<td>Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and to sub-selectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion</td>
</tr>
<tr>
<td></td>
<td>Pronto™</td>
<td>Vascular solutions</td>
<td>Removal of emboli and thrombi from vessels in the arterial or deep venous system and to infuse diagnostic or therapeutic agents</td>
</tr>
<tr>
<td></td>
<td>Rescue™</td>
<td>Boston Scientific</td>
<td>Not/no longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>Thrombобuster®</td>
<td>Kaneka Medix</td>
<td>No FDA approved indication</td>
</tr>
<tr>
<td></td>
<td>TransVascular Aspiration Catheter® (TVAC)</td>
<td>Nipro</td>
<td>No FDA approved indication</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>AngioJet®</td>
<td>MEDRAD Interventional / Possis</td>
<td>Removal of thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 2 mm in diameter prior to balloon angioplasty or stent placement</td>
</tr>
<tr>
<td></td>
<td>X-Sizer®</td>
<td>ev3</td>
<td>Removal of thrombus in synthetic hemodialysis access grafts</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EX™</td>
<td>Boston Scientific</td>
<td>Use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.5 to 5.5 mm</td>
</tr>
<tr>
<td></td>
<td>FilterWire EZ™</td>
<td>Boston Scientific</td>
<td>Use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts and carotid arteries</td>
</tr>
<tr>
<td></td>
<td>SpideRX™</td>
<td>ev3</td>
<td>No longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>AngioGuard™</td>
<td>Cordis</td>
<td>No longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>AngioGuard™ XP</td>
<td>Cordis</td>
<td>Use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries</td>
</tr>
<tr>
<td></td>
<td>Filtrap</td>
<td>Nipro</td>
<td>No FDA approved indication</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire®</td>
<td>Medtronic</td>
<td>Not/no longer available for sale in US</td>
</tr>
<tr>
<td></td>
<td>PercuSurge GuardWire™ Plus</td>
<td>Medtronic</td>
<td>Use to contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection</td>
<td>Proxis™</td>
<td>St. Jude Medical</td>
<td>Use as a proximal embolic protection system to prevent distal release of and to aspirate embolic material (thrombus/debris) in saphenous vein coronary bypass graft(s) during percutaneous transluminal coronary angioplasty and/or stenting procedures and to control the flow of fluids in the coronary and peripheral vasculature</td>
</tr>
</tbody>
</table>
Objective

To perform a comparative effectiveness review examining the benefits to harms associated with using adjunctive devices to remove thrombi or protect against distal embolization in patients with ACS who are undergoing PCI of native vessels.

Key Questions

**Key Question 1.** In patients with ACS who are undergoing PCI of native vessels, what are the comparative effects of adjunctive devices from different classes (e.g., catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection) on intermediate outcomes (e.g., ST-segment resolution, MBG, TIMI-3 flow, ejection fraction and distal embolization) and final health outcomes (mortality, MACE, health-related quality-of-life)?

**Key Question 2.** In patients with ACS who are undergoing PCI of native vessels, how does the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

**Key Question 3.** In patients with ACS who are undergoing PCI of native vessels, which patient characteristics (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of a thrombus-containing lesion, infarct-related artery and prePCI TIMI flow, use of direct stenting) affect outcomes?

Analytic Framework

The analytic framework used is shown in Figure 1.
Figure 1. Analytic framework for adjunctive devices to remove thrombi and protect against distal embolization in patients with acute coronary syndromes who are undergoing percutaneous coronary intervention of native vessels

Patients with ACS undergoing PCI of native vessels and by gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa-inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and prePCI TIMI flow, use of direct stenting

Intermediate outcomes
- STSR
- MBG
- Post-PCI TIMI-3 Flow
- Ejection fraction
- Distal Embolization

Final health outcomes
- Mortality
- MACE (reinfarction, TR, stroke)
- Health-Related Quality-of-Life

Adjunctive use of thrombectomy or embolic protection devices

Abbreviations: ACS = acute coronary syndrome; KQ = key question; MACE = major adverse cardiovascular events; MBG = myocardial blush grade; PCI = percutaneous coronary intervention; STSR = ST-segment resolution; TIMI = thrombolysis in myocardial infarction; TR = target revascularization
Methods

Input From Stakeholders

The EPC drafted a topic refinement document with proposed key questions after consult with Key Informants. Our Key Informants included six physicians: two provided methods expertise, two represented the payer’s perspective, one provided the local interventional cardiologist’s perspective, and the last provided both an interventional cardiologist and American College of Cardiology perspective. Our Key Informants did not have financial or other declared conflicts. The public was invited to comment on the topic refinement document and key questions. After reviewing the public commentary, responses to public commentary, proposed revisions to the key questions, and a preliminary protocol was generated and reviewed with the Technical Expert Panel. The aforementioned Key Informants constituted our Technical Expert Panel and provided feedback on the feasibility and importance of our approach and provided their unique insight. Again, no conflict of interest was identified. The draft CER underwent peer review and public comments with revisions made based on commentary.

Searching for the Evidence: Literature Search Strategies for Identifying Relevant Studies to Answer the Key Questions

The following statement describing the population, intervention, comparator and outcomes (PICO) was used to design the literature search: Does the use of adjunctive devices in ACS patients (i.e. catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection, embolic protection devices combined) in combination with PCI of native vessels affect surrogate outcomes (e.g., ST-segment resolution, MBG, TIMI-3 flow, ejection fraction and distal embolization), health (mortality, MACE, health-related quality-of-life) or safety outcomes (coronary dissection, coronary perforation, prolonged procedure time) as compared to PCI alone? We conducted a computerized literature search of the Cochrane Library and Medline databases for both RCTs and observational studies that were published from January 1996 through March 2010. The search was restricted to 1996 and later to reflect contemporary practice. The complete search strategy is included in Appendix A. We did not apply any language restrictions. Additionally, in an attempt to locate unpublished studies and increase the sensitivity of our search, references from identified studies and systematic reviews were reviewed. Abstracts from major cardiology meetings (American Heart Association, American College of Cardiology, European Society of Cardiology, and the Transcatheter Cardiovascular Therapeutics (TCT) Conference of the Cardiovascular Research Foundation) and from the TCTMD (http://www.tctmd.com), the CardioSource Plus (http://www.cardiosource.com), and ClinicalTrials.gov (http://www.clinicaltrials.gov) web sites were searched and reviewed. The literature search was updated in March 2011 using the same search strategy. Scientific information packets for relevant devices were requested by the Scientific Resource Center.
Criteria for Inclusion and Exclusion of Studies in the Review

Two independent reviewers assessed studies for inclusion in a parallel manner by using criteria defined a priori. RCTs or controlled observational studies that enrolled a total of \( \geq 500 \) patients were eligible for inclusion if they (1) compared the use of adjunctive devices (i.e., catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection) to remove thrombi or protect against distal embolization versus a control (active or nonactive) before PCI, (2) included only patients with ACS, (3) enrolled only patients with a target lesion(s) in native vessels (studies with less than five percent of patients with target vessel lesions in saphenous vein grafts were included), and (4) reported data on at least one prespecified patient morbidity (ST-segment resolution, MBG, TIMI-3 blood flow, ejection fraction, distal embolization, MACE), mortality, safety (coronary dissection, coronary perforation, prolonged procedure time), or health-related quality-of-life outcome. Observational studies that enrolled \(< 500\) subjects total were excluded from Key Questions 1 and 2 because this range contains small initial experiences not representative of current practice and with numerous RCTs already in existence within this smaller sample size range, small studies were thought to be less helpful in defining the applicability of evidence in a tangible way. Observational studies that enrolled \(< 500\) subjects total were used to address Key Question 3 if they reported multivariable adjusted results depicting the effect of prespecified patient characteristics on intermediate or terminal outcomes. Systematic reviews with meta-analyses which met the inclusion criteria were manually reviewed for additional references.

Data Extraction and Data Management

Two reviewers used a standardized data extraction tool to independently extract study data. (Appendix B) Data extracted from each study included interventions, study design, inclusion and exclusion criteria, methodological quality criteria, study population, baseline patient characteristics, use of concurrent standard medical therapies, data needed to assess for applicability (as specified in Applicability of Evidence below), and prespecified benefits to harms (as specified in the Key Questions). Previous systematic reviews with meta-analysis addressing the same or similar topic and identified during our literature search are described in Appendix C for completeness.

Assessment of Methodological Quality of Individual Studies

Validity assessment was performed by two reviewers using the recommendations in the Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Each study was assessed for the following individual criteria: comparable study groups at baseline, detailed description of study outcomes, blinding of outcome assessors, intent-to-treat analysis, description of participant withdrawals (percent followup), and potential conflict of interest. Additionally, RCTs were assessed for randomization technique. Observational studies were assessed for sample size, participant selection method, exposure measurement method, potential design biases, and appropriate analyses to control for confounding. Studies were then given an overall quality score of good, fair, or poor (Table 4).
### Table 4. Summary ratings of quality of individual studies

<table>
<thead>
<tr>
<th>Quality Rating</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good (low risk of bias)</td>
<td>These studies have the least bias and results are considered valid. A study that adheres mostly to the commonly held concepts of high quality include the following: a formal randomized, controlled study; clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; less than 30 percent dropout; and clear reporting of dropouts.</td>
</tr>
<tr>
<td>Fair</td>
<td>These studies are susceptible to some bias, but it is not sufficient to invalidate results. They do not meet all the criteria required for a rating of good quality because they have some deficiencies, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.</td>
</tr>
<tr>
<td>Poor (high risk of bias)</td>
<td>These studies have significant flaws that imply biases of various types that may invalidate the results. They have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.</td>
</tr>
</tbody>
</table>

### Data Synthesis

We qualitatively examined data from all identified studies. For each outcome, we conducted separate analyses of studies that compare each individual adjunctive device type (e.g., catheter aspiration, mechanical thrombectomy, distal filter embolic protection, distal balloon embolic protection, proximal balloon embolic protection) with control and studies in which different adjunctive device types were compared to each other. We conducted separate analyses for studies that enrolled patients experiencing only STEMI, studies that enrolled patients experiencing NSTEMI or UA, and studies that enrolled patients with mixed ACS (STEMI or NSTEMI or UA). We conducted meta-analyses when two or more RCTs that were adequate for data pooling were available for any outcome. Observational studies were not pooled with RCTs and were assessed in a qualitative fashion only. For dichotomous outcomes, weighted averages are reported as relative risks (RR) and risk differences (RD) with associated 95 percent confidence intervals. As pooled RD may provide unstable estimates when control rates are heterogeneous, we report the control rate range to aid in interpretation. For intermediate outcomes depicting the extent of myocardial reperfusion (MBG, TIMI blood flow and ST-segment resolution), we defined attainment of optimal myocardial reperfusion as a MBG-3 or TIMI-3 blood flow (or a MBG or TIMI blood flow of at least two in studies not reporting the other endpoint) and complete ST-segment resolution as 70 percent resolution in peak ST-segments (or at least 50 percent resolution in studies not reporting the other endpoint). When possible we used results for ST-segment resolution reported at 60 minutes, although when unavailable, we utilized data reported immediately after the procedure or up to 90 minutes after. For studies with multiple time points, we used the time closest to 60 minutes.

For final health outcomes, we used the maximum duration of followup, defined as the longest time point from the procedure where the occurrence of a final health outcome is reported, as the base case analysis. As heterogeneity between included studies was expected, a DerSimonian and Laird random-effects model was used when pooling data and calculating RR, RD, and 95 percent confidence intervals. Automatic ‘zero cell’ correction was used for studies with no events for a particular outcome occurring in one group. Studies with no events occurring in both treatment and control groups were excluded from meta-analysis. When pooling continuous outcomes,
weighted mean differences along with 95 percent confidence intervals were calculated using a DerSimonian and Laird random-effects model.\textsuperscript{23}

Statistical heterogeneity was addressed by using both the Cochrane Q-statistic and the $I^2$ statistic. The $I^2$ statistic assesses the degree of inconsistency not due to chance across studies and ranges from 0-100 percent with the higher percentage representing a higher likelihood of the existence of heterogeneity. Whereas categorization of $I^2$ values may not be appropriate in all situations, an $I^2$ value of >50 percent has been regarded as representative of important statistical heterogeneity. Egger’s weighted regression statistic was used to assess for the presence of publication bias.\textsuperscript{24} Statistics were performed using StatsDirect statistical software, version 2.7.8 (StatsDirect Ltd., Cheshire, England). For all analyses, a p-value of <0.05 was considered statistically significant.

To assess the effect of heterogeneity (both clinical and methodological) on the conclusions of our meta-analysis, we conducted multiple subgroup and sensitivity analyses. These analyses were conducted to assess the methodological study quality (analyses limited to “good” studies only) and duration of followup on the efficacy of adjunctive devices. More specifically for duration of followup, data representing the maximal extent of clinical followup and at different extents of clinical followup (in-hospital, ≥ 30 days but <180 days, ≥ 180 days but < 365 days, and ≥ 365 days), were pooled in separate analyses.

For Key Question 3, patient demographics (age, sex, and ethnicity), baseline patient health status (smoking history, history of diabetes, ejection fraction, ischemia time, prePCI TIMI flow, presence of thrombus-containing lesion, and location infarct-related artery), and concomitant treatment characteristics (rescue PCI, administration of glycoprotein IIb/IIIa inhibitors, and direct stenting) were assessed for their impact on the efficacy of adjunctive devices. Data from RCTs, controlled observational studies and individual patient data meta-analyses were utilized. For RCTs or controlled observational studies, data from subgroup analyses were abstracted, and when not reported, p-values for interaction between subgroups were calculated to aid in interpretation (no adjustment for multiple hypothesis testing was performed).\textsuperscript{25} Due to the limited amount of data reported for each patient demographic/health status in the literature as well as observed heterogeneity within time points and definitions of outcomes, meta-analyses were not conducted for this key question. Data from single-arm (all patients receiving an adjunctive device) observational study reports were only included if they conducted multivariate analysis to identify independent predictor of prespecified outcomes.

**Grading the Evidence for Each Key Question**

We used the Grading of Recommendations Assessment, Development and Evaluation system to assess the strength of evidence for each outcome of interest separately. This system uses four required domains—risk of bias, consistency, directness, and precision. Additional domains were not assessed because they were deemed irrelevant to this review. All assessments were made by two investigators, with disagreements resolved through discussion. When a large preponderance of data available for an outcome was of good quality, the strength of evidence was not inherently downgraded because of a small number of poorer quality trials or studies. The evidence pertaining to each key question was classified into four broad categories: high, moderate, low grade or insufficient (Table 5). Below we describe in more detail the features that determined the strength of evidence for the different outcomes evaluated in this report.
Table 5. Definitions for grading the strength of evidence

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>There is high confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Low</td>
<td>Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Evidence either is unavailable or does not permit estimation of an effect.</td>
</tr>
</tbody>
</table>

**Risk of bias.** Risk of bias is the degree to which the included studies for any given outcome or comparison has a high likelihood of adequate protection against bias. This can be assessed through the evaluation of both design and study limitations. Whether the study was designed as an RCT or an observational study will be recorded. Studies were ranked as having no limitations, serious limitations, or very serious limitations.

**Consistency.** Consistency refers to the degree of similarity in the direction of the effect sizes from included studies within an evidence base. We assessed whether or not the effect sizes were on the same side of unity; whether the range of effect sizes was narrow, and the degree of statistical heterogeneity in evaluating consistency. We ranked this domain as no inconsistency, serious inconsistency, and very serious inconsistency. When only a single study was included, consistency was not judged.

**Directness.** Directness refers to whether the evidence links the compared interventions directly with health outcomes, and compares two or more interventions in head-to-head trials. Indirectness implies that more than one body of evidence is required to link interventions to the most important health outcomes. We ranked this domain as no indirectness, serious indirectness, and very serious indirectness.

**Precision.** Precision refers to the degree of certainty surrounding an effect estimate with respect to a given outcome. For example, when a meta-analysis is performed, we will evaluate the confidence interval around the summary effect size. A precise estimate is an estimate that would allow a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions (e.g. both clinically important superiority and inferiority), a circumstance that will preclude a conclusion.

**Applicability of Evidence**

To be designated an effectiveness study, it had to meet five of the following seven criteria: used a primary care population, used less-stringent eligibility criteria, assessed final health outcomes, had an adequate study duration with clinically relevant treatment modalities, assessed adverse events, had an adequate sample size, and used intention-to-treat analysis. Studies meeting fewer than five criteria were classified as efficacy studies and deemed to have less applicability. Table 6 identifies the factors that are important for determining applicability; those factors that were extracted into evidence tables for every study we evaluated. By using all of the applicable studies to answer a key question, the applicability of the body of evidence was then determined and reported separately and qualitatively for each outcome of interest.
Table 6. Applicability PICOTS and data to extract

<table>
<thead>
<tr>
<th>Feature</th>
<th>Condition that limits applicability</th>
<th>Features to be extracted into evidence table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Differences between patients in the study and the community</td>
<td>Eligibility criteria, demographics</td>
</tr>
<tr>
<td>Population</td>
<td>Events rates markedly different than in the community</td>
<td>Event rates in treatment and control groups</td>
</tr>
<tr>
<td>Intervention</td>
<td>Treatment not reflective of current practice</td>
<td>Type of device, device name</td>
</tr>
<tr>
<td>Comparator</td>
<td>Use of substandard alternative therapy</td>
<td>Type of comparator</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Intermediate end points, brief followup periods, improper definitions for outcomes, composite end points</td>
<td>Outcomes (benefits to harms) and how they were defined</td>
</tr>
<tr>
<td>Settings</td>
<td>Settings where standards of care differ markedly from setting of interest</td>
<td>Clinical setting and geographic setting</td>
</tr>
</tbody>
</table>
Results

Results of Literature Search

Upon conducting the original literature search to identify articles that evaluated the impact of thrombectomy or embolic protection devices on final health or intermediate outcomes, we retrieved 1056 unique citations. After duplicates were removed, 978 articles remained. During title and abstract review, 571 articles were excluded and during full text review 244 articles were excluded. Upon updating the literature search in March 2011, a total of 121 citations were retrieved. Of those, 10 citations were duplicates leaving 111 unique citations. Eighty-two and 19 citations were excluded at the abstract and full text level, respectively, leaving 10 citations which were added to the original literature base. All citations excluded at the full text level are listed in Appendix D along with the reason for exclusion. A total of 175 articles were found to match our inclusion criteria. A summary of search results is presented in Figure 2.
Abbreviations: ACS=acute coronary syndrome; n=number; NSTEMI=nonST segment elevation myocardial infarction; PCI=percutaneous coronary intervention; PRISMA=preferred reporting items for systematic reviews and meta-analyses; RCT=randomized controlled trial; STEMI=ST segment elevation myocardial infarction; UA=unstable angina
Key Question 1
In patients with ACS who are undergoing PCI of native vessels, what are the comparative effects of adjunctive devices from different classes (e.g., catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, distal filter embolic protection, proximal balloon embolic protection, embolic protection devices combined) on intermediate outcomes (e.g., ST-segment resolution, MBG-3, TIMI-3 blood flow, ejection fraction, distal embolization and no reflow) and terminal outcomes (mortality, myocardial infarction, stroke, target revascularization, MACE, and health-related quality-of-life)?

Key Points
Fifty RCTs and 7 controlled observational studies were included.

Direct Comparative Trials Assessing Final Health Outcomes in ACS
- Two direct comparative randomized trials were available that assessed final health outcomes in ACS.
  o One direct comparative randomized trial compared the use of catheter aspiration devices to distal balloon embolic protection devices in patients undergoing STEMI. In this controlled trial, no significant differences in mortality, myocardial infarction, stroke, target revascularization, or MACE were found at the longest duration of followup.
  o One direct comparative randomized trial compared the use of one catheter aspiration device to another catheter aspiration device in patients with STEMI. In this controlled trial, no significant differences in myocardial infarction, target revascularization, or MACE were found at the longest duration of followup with the other final health outcomes not being evaluated.

Direct Comparative Trials Assessing Intermediate Health Outcomes in ACS
- Three direct comparative randomized trials were available that assessed intermediate health outcomes in ACS.
  o Two direct comparative randomized trials compared the use of catheter aspiration devices to distal balloon embolic protection devices in patients undergoing STEMI. In these RCTs, no significant differences were found between groups for ST-segment resolution (one trial), ejection fraction (two trials), MBG-3 (one trial), TIMI-3 blood flow (one trial), or no reflow (one trial) with insufficient data for other intermediate endpoints.
  o One direct comparative randomized trial compared the use of one catheter aspiration device to another catheter aspiration device in patients with STEMI. In this controlled trial, no significant differences in ST segment resolution, MBG-3, or TIMI-3 blood flow occurred with insufficient data for other intermediate endpoints.
RCTs / Controlled Observational Studies in Patients with STEMI Assessing Final Health Outcomes

- Thirty-five RCTs and five controlled observational studies evaluated patients with STEMI undergoing PCI and compared a thrombectomy or embolic protection device versus control using the maximal duration of followup. Five final health outcomes [mortality, myocardial infarction, stroke, target revascularization and MACE] were evaluated.
  - In RCTs, the use of catheter aspiration devices significantly decreased the risk of MACE but did not significantly impact mortality, myocardial infarction, stroke, or target revascularization versus control using the maximal duration of followup.
    - When the clinical trials eligible for pooling were limited to higher quality trials, the risk for MACE was significantly reduced when catheter aspiration devices were used versus control but the other endpoints were nonsignificantly impacted.
    - When the clinical trials eligible for pooling were evaluated at different time periods, mortality was significantly reduced at 365 days and target revascularization and MACE were significantly reduced at 180 days, but no other significant effects were seen for these or other final health outcomes at other time periods.
    - Three controlled observational studies were generally supportive of findings from RCTs as no significant differences were found at 30 days and 365 days for all five final health outcomes, with exception of 30-day stroke where one of two studies found an increased risk with catheter aspiration use.
  - In RCTs, the use of mechanical thrombectomy devices did not significantly impact mortality, myocardial infarction, stroke, target revascularization or MACE versus control using the longest duration of followup.
    - When the clinical trials eligible for pooling were limiting to higher quality trials, no significant impact on mortality, myocardial infarction, stroke, target revascularization or MACE occurred versus control.
    - When the clinical trials eligible for pooling were evaluated at different time periods, target revascularization and MACE was significantly reduced at 180 days and 365 days (one trial), respectively, but no other significant effects were seen for these or other final health outcomes at other time periods.
    - A controlled observational study was supportive of the myocardial infarction, stroke, target revascularization, and MACE findings.
  - In RCTs, the use of distal filter, distal balloon, proximal balloon, or the use of any one of these embolic protection devices did not significantly impact mortality, myocardial infarction, stroke, or MACE versus control using the longest duration of followup. However the use of a distal filter device or any one of the embolic protection devices significantly increased the risk of target revascularization although this was not seen with distal balloon or proximal balloon devices.
    - Limiting the trials to higher quality trials did not result in any changes in the significance of findings for any final health outcome.
    - When clinical trials eligible for pooling were evaluated at different time periods, stroke was significantly reduced at 30 days (one trial) with the use of a distal balloon embolic protection device versus control and target revascularization and...
MACE were significantly increased at 365 days (1 trial) with the use of a distal filter embolic protection device versus control or any embolic protection device versus control. No other significant effects were seen for these or other final health outcomes at other time periods.

- In one controlled observational study the use of an embolic protection device did not significantly impact MACE versus control.

**RCTs / Controlled Observational Studies in Patients with STEMI Assessing Intermediate Health Outcomes**

- Thirty-seven RCTs and four controlled observational studies evaluated patients with STEMI undergoing PCI and compared a thrombectomy or embolic protection device versus control. Six intermediate health outcomes (ST-segment resolution, MBG-3, TIMI-3 blood flow, ejection fraction, distal embolization and no reflow) were evaluated.
  - In RCTs, the use of catheter aspiration devices significantly increased the occurrence of ST-segment resolution, achievement of a MBG-3 and TIMI-3 blood flow while significantly reducing the risk of distal embolization and the occurrence of no reflow versus control. In RCTs, ejection fraction was not significantly impacted by catheter aspiration use versus control in the majority of trials (9 of 11) while one controlled observational study found a decreased ejection fraction in the catheter aspiration group versus control.
  - When the clinical trials eligible for pooling were limited to higher quality trials, significant benefits were again seen for the aforementioned intermediate outcomes. No impact on ejection fraction was seen versus control.
  - A controlled observational study was supportive of the findings for distal embolization although the use of a catheter aspiration device did not significantly impact the risk of resolving ST-segment elevation or attaining TIMI-3 blood flow (two studies).
  - In RCTs, the use of mechanical thrombectomy devices did not significantly impact ST-segment resolution, MBG-3, TIMI-3 blood flow, distal embolization, or no reflow versus control. In RCTs, ejection fraction was not impacted by mechanical thrombectomy devices versus control.
  - When the clinical trials eligible for pooling were limiting to higher quality trials, no significant impact was seen on any of the aforementioned intermediate health outcomes versus control.
  - In a controlled observational study the use of a mechanical thrombectomy device was associated with a significantly reduced rate of TIMI-3 blood flow versus control.
  - In RCTs, the use of distal filter embolic protection devices did not significantly impact ST-segment resolution, ejection fraction, MBG-3, TIMI-3 blood flow, distal embolization, or no reflow versus control.
  - When the clinical trials eligible for pooling were limiting to higher quality trials, no significant impact was seen on any of the aforementioned intermediate health outcomes versus control.
  - In RCTs, the use of distal balloon embolic protection devices significantly increased the occurrence of a MBG-3 and TIMI-3 blood flow but did not significantly impact
ST-segment resolution, ejection fraction, distal embolization, or no reflow versus control.

- When the clinical trials eligible for pooling were limiting to higher quality trials, significant increases in the occurrence of achieving a MBG-3 and TIMI-3 blood flow were still seen but no significant impact was seen on any of the other aforementioned intermediate health outcomes versus control.
  - In RCTs, the use of proximal balloon embolic protection devices did not significantly impact ST-segment resolution, MBG-3, TIMI-3 blood flow, distal embolization or ejection fraction versus control with no data on the other intermediate health outcomes.
    - Only one trial was available for the aforementioned intermediate health outcomes versus control and it was determined to be of good methodological quality.
  - In RCTs, the use of embolic protection devices combined significantly increased the occurrence of a MBG-3 and TIMI-3 blood flow but did not significantly impact ST-segment resolution, ejection fraction, distal embolization, or no reflow versus control.
    - When the clinical trials eligible for pooling were limiting to higher quality trials, significant increases in the occurrence of achieving MBG-3 and TIMI-3 blood flow were still seen but no significant impact was seen on any of the other aforementioned intermediate health outcomes versus control.

**RCTs / Controlled Observational Studies in Mixed or Other ACS Populations Assessing Final Health Outcomes**

- Five RCTs and two controlled observational studies evaluated patients with mixed ACS (STEMI or NSTEMI or UA) undergoing PCI and compared a thrombectomy or embolic protection device versus control. Five final health outcomes [mortality, myocardial infarction, stroke, target revascularization and MACE] were evaluated.
  - In a RCT, the use of catheter aspiration devices did not significantly impact the risk of in-hospital mortality.
    - In a controlled observational study, the use of a catheter aspiration device significantly reduced the risk of 30-day mortality compared to control.
    - No trials or studies evaluated myocardial infarction, stroke, target revascularization, or MACE at any time period or mortality at additional time periods versus control.
  - In RCTs, the use of mechanical thrombectomy devices did not impact the risk of 30-day mortality (one trial), 30-day target revascularization (one trial), or 30-day MACE (one trial).
    - In an controlled observational study, the use of a mechanical thrombectomy device has no impact on the risk of 180-day mortality, myocardial infarction, target revascularization or MACE.
    - No trials or studies evaluated stroke or other aforementioned final health outcomes at other time points versus control.
  - In RCTs, the use of a distal filter embolic protection device did not impact the risk of 30-day mortality (one trial) or 180-day MACE (one trial) and there was insufficient data to analyze other final health outcomes. No additional trials or studies evaluated final health outcomes at additional time periods.
In RCTs, the use of distal balloon embolic protection devices did not impact the risk of mortality using the maximal duration of followup. Neither trial was determined to be of higher methodological quality.

- Evaluating the clinical trials at different time periods of followup did not result in any significant findings for mortality, although each analysis was based on a single trial.
- In a single trial, the risk of 180-day MACE was not impacted by the use of a distal balloon embolic protection device versus control.
- No trials or studies evaluated stroke, target revascularization or aforementioned final health outcomes at individual time points.

In RCTs, the use of an embolic protection device (distal or proximal; filter or balloon) did not impact the risk of mortality using the longest duration of followup.

- Limiting the pooled analysis to trials of higher methodological quality resulted in one trial and therefore pooling was not possible.
- Evaluating the trials at ≤ 30 days did not significantly impact mortality.
- No additional data for embolic protection devices combined was available in addition to what was reported in the individual embolic protection device categories.

- Two RCTs and no controlled observational studies evaluated patients with other ACSs (NSTEMI or UA) undergoing PCI and compared a thrombectomy or embolic protection device versus control. Five final health outcomes [mortality, myocardial infarction, stroke, target revascularization and MACE] were evaluated.
  - In RCTs, the use of a distal filter embolic protection device did not impact the risk of 30-day mortality (one trial), in-hospital (one trial) or 30-day MACE (one trial) versus control.
  - No trials or studies evaluated stroke and there was insufficient data to analyze myocardial infarction or target revascularization.
  - No other device categories were evaluated.

**RCTs / Controlled Observational Studies in Mixed or Other ACS populations Assessing Intermediate Health Outcomes**

- Six RCTs and one controlled observational study evaluated patients with mixed ACS (STEMI or NSTEMI or UA) undergoing PCI and compared a thrombectomy or embolic protection device versus control on intermediate health outcomes. Six intermediate health outcomes (ST-segment resolution, MBG-3, TIMI-3 blood flow, ejection fraction, distal embolization and no reflow) were evaluated.
  - In RCTs, the use of catheter aspiration devices did not significantly impact the risk of attaining TIMI-3 blood flow.
    - In a RCT, the use of a catheter aspiration device significantly increased the risk of attaining a MBG-3.
    - No trials or studies evaluated ST-segment elevation, ejection fraction, distal embolization or no reflow.
  - In RCTs, the use of mechanical thrombectomy devices significantly increased the risk of resolving ST-segment elevation (one trial) and had no impact on attaining TIMI-3 blood flow (one trial) versus control.
In an controlled observational study, the use of a mechanical thrombectomy device was associated with a significantly lower rate of TIMI-3 blood flow versus control.

No trials or studies evaluated ejection fraction, MBG-3, distal embolization or no reflow.

- In RCTs, the use of distal filter embolic protection devices did not impact ejection fraction (one trial) or TIMI-3 blood flow (one trial) versus control.
  - No trials or studies evaluated resolution of ST-segment elevation, MBG-3, distal embolization or no reflow.

- In RCTs, the use of a distal balloon embolic protection device significantly increased the risk of attaining a MBG-3 and did not impact the risk of attaining TIMI-3 blood flow. The trials included were not determined to be of higher methodological quality therefore sensitivity analysis was not possible.
  - In RCTs, the use of a distal balloon embolic protection device led to a significantly increased risk of resolving ST-segment elevation (one trial), significantly higher ejection fraction (one trial) and a significantly reduced risk of no reflow (one trial).
  - No trials or studies evaluated distal embolization.

- No studies or trials evaluated the use of proximal balloon embolic protection devices in patients with mixed ACS.

- In RCTs, the use of an embolic protection device did not impact the risk of attaining TIMI-3 blood flow.
  - In RCTs, the use of embolic protection devices increased ejection fraction in one trial and had no impact on ejection fraction in another trial.
  - For the resolution of ST-segment elevation, MBG-3, distal embolization, and no reflow no additional data the results are presented in the respective embolic protection device group and no additional data for embolic protection devices combined was available in addition to what was reported in the individual embolic protection device categories.

- Two RCTs and no controlled observational studies evaluated patients with other ACSs (NSTEMI or UA) undergoing PCI and compared a thrombectomy or embolic protection device versus control. Six intermediate health outcomes (ST-segment resolution, MBG-3, TIMI-3 blood flow, ejection fraction, distal embolization and no reflow) were evaluated.

  - In RCTs, the use of a distal filter embolic protection device did not impact the risk of attaining TIMI-3 blood flow (one trial) versus control.
    - In a RCT, the use of a distal filter embolic protection device did not impact the risk of distal embolization (one trial) versus control.
    - There was insufficient data to evaluate no reflow and no trials or studies evaluated resolution of ST-segment elevation, ejection fraction, MBG-3 or distal embolization.

- No other device categories were evaluated within this population.
Detailed Analysis

Study Design and Population Characteristics

Overall, 53 RCTs and 9 controlled observational studies have evaluated the impact of thrombectomy or embolic protection devices in ACS. Catheter aspiration, mechanical thrombectomy, distal filter embolic protection, distal balloon embolic protection and proximal balloon embolic protection devices have been evaluated for at least one endpoint but no studies evaluating proximal filter embolic protection devices met our inclusion and exclusion criteria.

One-hundred and twenty-seven publications of RCTs, which represent 43 unique trials (n=8185) met the inclusion criteria for the quantitative analysis. Of the 127 publications, 50 were full articles, 48 were abstracts, and 29 were slide presentations. Of the 43 unique trials, 37 were in patients with STEMI and six were in patients with mixed ACS. The trial characteristics, trial quality assessment, and baseline and procedural characteristics can be found in Appendix C and Appendix E.

Thirty-seven unique RCTs evaluated the impact of thrombectomy or embolic protection devices versus control on final, intermediate, or adverse health outcomes when used as an adjunct to PCI as compared to PCI alone in patients with STEMI. Of the 37 trials, 17 trials (n=3355) evaluated the impact of catheter aspiration devices, five trials (n=1374) evaluated the impact of mechanical thrombectomy devices, five trials (n=962) evaluated the impact of distal filter embolic protection devices, nine trials (n=1479) evaluated the impact of distal balloon embolic protection devices and one trial (n=284) evaluated the impact of proximal balloon embolic protection devices.

Amongst the 37 trials, the earliest trial was published in 2003 and the latest was published in 2010. The duration of followup of the trials ranged from in-hospital to 450 days. One trial reported a followup duration of 450 days, one of 240 days, one of 270 days, 13 trials reported a followup duration of 180 days, one trial reported a followup duration of 90 days, eight trials reported a followup duration of 30 days, and two trials reported a followup duration of 5-8 days. Fourteen trials received funding from industry, of which three reported additional funding from a university or clinical research grant. One trial reported a hospital as the funding source while 20 trials did not report a funding source and two trials were reported to be unfunded.

The mean age of patients enrolled in the 37 trials ranged from 55 to 69 years presenting within 6 to 48 hours of symptom onset. Twenty-one of the 34 trials included patients presenting within 12 hours of symptom onset. Males constituted at least half of the patients in the trials, ranging from 55.1 to 95 percent of the total population. The mean ischemic time reported in the 37 trials ranged from 120 to 510 minutes. The percent of patients presenting with TIMI 0/1 at baseline ranged from 54.8 to 100 percent. Of the 37 trials, 24 trials included patients with no prior fibrinolysis before the index PCI. Five trials included patients with prior fibrinolysis as well as primary PCI and eight trials did not report whether patients who received prior fibrinolysis were included or not.

Six unique trials evaluated the impact of thrombectomy or embolic protection devices versus control on final or intermediate health outcomes when used as an adjunct to PCI as compared to
PCI alone in patients with mixed ACS. Of these six trials, two evaluated catheter aspiration devices, one evaluated a distal filter embolic protection device, and three evaluated distal balloon embolic protection devices. The earliest trial was published in 2003 and the most recent trial was published in 2008. The duration of followup ranged from in-hospital to 730 days. Three trials reported followup duration of in-hospital, two trials reported followup duration of 180 days, and one trial reported followup duration of 730 days. One trial received funding from industry while the other 5 trials did not report a funding source.

The mean age of patients enrolled in the six trials ranged from 55.17 years to 65.9 years. The percentage of males ranged from 76.79 to 95 percent. Two trials reported mean ischemic time which ranged from 372 to 474 minutes. One trial reported the percent of patients with TIMI 0/1 blood flow at baseline which ranged from 57 to 64 percent. Two trials did not include patients who previously failed fibrinolytic therapy while the other four trials did not report this statistic.

Forty-eight publications met inclusion criteria for the qualitative synthesis. Of these publications, thirty-eight publications represented 20 unique studies (n=14771) and twenty-one publications represented eighteen unique systematic reviews with meta-analysis (n=80181). Of the 20 unique studies, 17 were full articles, nine were abstracts, and one was a slide presentation. Of the 20 unique studies, one study was a RCTs evaluating thrombectomy or embolic protection devices in patients with mixed ACS, nine studies were controlled observational studies, two studies were RCTs evaluating thrombectomy or embolic protection devices in patients with UA or NSTEMI, two studies were direct comparative RCTs, two studies were RCTs with selective inclusion/exclusion criteria in patients with STEMI, one study was a RCT with unique comparison in patients with STEMI, two studies were RCTs with unique comparison in patients with mixed ACS, and one study was a pooled analysis in STEMI patients. The characteristics of the studies, study quality assessment, and baseline and procedural characteristics can be found in Appendix C and Appendix E.

Amongst the 20 unique studies, the earliest study was published in 2002 and the latest was published in 2010. The duration of followup of the studies ranged from — in-hospital” to 365 days. The mean age of the patients in the 23 studies ranged from 49.3 to 68 years presenting within 3 hours to 12 hours of symptom onset. Males constituted at least half of the patients in the studies, ranging from 50 to 100 percent of the total population. Two studies used an active control as a comparator. One trial compared the use of the catheter aspiration device Thrombuster along with the use of mutant tissue plasminogen activator versus the use of the catheter aspiration device alone. The other trial compared the use of thrombectomy, distal protection and stenting versus thrombectomy and stenting alone. These two studies are therefore not discussed any further.

Of the 18 unique systematic reviews with meta-analysis (n=80181), 11 were full text articles and seven were abstracts. The earliest systematic review was published in 2006 and the latest was published in 2010. The number of studies included in each systematic review ranged from seven to 90 studies. The characteristics, quality assessment and results of these systematic reviews can be found in Appendix C. Although several recent systematic reviews have conducted meta-analyses, the majority are limited to patients with STEMI and do not evaluate adjunctive devices in other ACS, few included the analysis of adverse events which are further limited to procedure time and coronary perforation, and the most recent analyses did not evaluate embolic protection devices. Therefore, an updated analysis will more accurately reflect contemporary practice.
Specifically for key question 1, we present direct comparative data between agents first and subsequently present the comparisons of each type of device versus control for each endpoint.

Numerous endpoints of interest are evaluated at different time points and several trials report the endpoints at multiple time points. We present data for each endpoint at numerous time points as specified: maximum duration of followup (data using the longest reported time point evaluating that endpoint in the trial), ≤30 days (data using the shortest reported time point evaluating the endpoint in the trial up to and including 30 days), 365 days (data from a trial evaluating the endpoint for >365 days), 180 days (data from a trial evaluating the endpoint for 180 to 364 days), 30-days (data from a trial evaluating the endpoint for 30 to 179 days), and in-hospital (data from a trial evaluating the endpoint during the initial hospitalization).

Outcome Evaluation

A summary of the results for final health outcomes evaluated at the maximal duration of followup for each device category versus control can be found in Table 7 to Table 12 while the results for evaluations of intermediate outcomes in each device category versus control can be found in Table 13 to Table 26.

Mortality

Direct Comparative Trials

*bCatheter aspiration device versus distal balloon embolic protection device in patients with STEMI.* One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the GuardWire™ Plus distal balloon embolic protection device on mortality. In this trial, there was no difference in the risk of 30-day mortality [RR 1.00 (0.18, 5.54)].

Trials Versus Control

*bCatheter aspiration devices in patients with STEMI.* Eleven RCTs evaluated the impact of catheter aspiration devices versus control on mortality using the maximal duration of followup. One trial was excluded from the pooled analysis of relative risk because no events occurred in either group during the prespecified time period. In the 10 trials suitable for pooling, the use of catheter aspiration devices did not significantly impact the risk of mortality [RR 0.69 (0.47, 1.02)] (Figure 3). The weighted-mean followup for mortality using the maximal duration of followup was 7.92 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.64$).

When limiting the pooled analysis to only trials of good methodological quality the risk of mortality using the maximal duration of followup was in the catheter aspiration device group compared to control [RR 0.70 (0.47, 1.03)]. The weighted mean duration of followup for this analysis was 8.08 months. Statistical heterogeneity ($I^2=0$ percent) was not detected.

When the impact of catheter aspiration devices versus control was assessed in hospital [RR 0.81 (0.23, 2.86)], ≤30 days [RR 0.65 (0.39, 1.10)], 30-days [RR 0.61 (0.35, 1.07)], and 180-days [RR 0.89 (0.31, 2.51)] (Appendix Figures 1-4); no significant difference in the risk of mortality were seen in each analysis. In the 365-day analysis, there was a significant reduction in the risk of mortality with the use of catheter aspiration devices versus control in the two trials
with available data [RR 0.62 (0.39, 0.98)] (Appendix Figure 5). Using the risk difference for the analysis [RD -0.03 (-0.06, -0.002), (CER 0.08, 0.14)], 33 patients would need to be treated to prevent one death.

Three controlled observational studies evaluated the association between the use of catheter aspiration devices during PCI and 30-day mortality and 365-day mortality. In the first study, the Export® aspiration catheter was compared to control. There was no significant difference in 30-day or 365-day mortality between the groups (4.9 percent versus 4.6 percent, p=0.82, 5.8 percent versus 7.4 percent, p=0.70, respectively). The second two studies did not report the names of the devices used. In the first study, catheter aspiration was compared to control and the rate of 30-day hospitalization was not significantly different between the groups (5.1 percent versus 4.4 percent, p=0.749). Authors report that after regression analysis, the results remained nonsignificant, although details were not provided. In the second study, there was no difference in the 30-day mortality rate with use of a catheter aspiration device during PCI versus PCI without catheter aspiration (2.6 percent versus 2.4 percent, p=0.74).

**Figure 3. Impact of catheter aspiration devices versus control on mortality using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

![Relative risk meta-analysis plot](image)

Cochran Q: P=0.870

I²: 0 percent

Egger: P=0.638

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Catheter aspiration devices in other ACS populations.** One RCT evaluated the impact of the catheter aspiration device Rescue™ PT versus control on mortality in patients with acute
The risk of in-hospital mortality was not significantly different between the catheter aspiration device group and control [RR 1.00 (0.18, 5.60)].

One controlled observational study of patients with acute myocardial infarction evaluated the association between the use of catheter aspiration devices and 30-day mortality. The following catheter aspiration devices were included in this study: RESCUE™ catheter, Thrombuster® catheter, Transvascular Aspiration Catheter™ and Export® PercuSurge system. In univariate analysis, the use of a catheter aspiration device was associated with a significantly lower rate of 30-day mortality compared to PCI without catheter aspiration [HR 0.64 (0.45, 0.93)] although upon adjustment for baseline characteristics, there was no longer a significant benefit associated with catheter aspiration devices [HR 0.66 (0.36, 1.19)].

**Mechanical thrombectomy devices in patients with STEMI.** Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on mortality using the maximal duration of followup. One trial was excluded from the pooled analysis of relative risk because no deaths occurred within the prespecified time period in either group. In the four trials eligible for pooling, the use of a mechanical thrombectomy device did not significantly impact the risk of mortality [RR 1.19 (0.51, 2.76)] (Figure 4). The weighted-mean followup for mortality using the maximal duration of followup was 7.80 months. A higher level of statistical heterogeneity was detected ($I^2=54.9$ percent) and publication bias was not be detected (Egger’s $P=0.736$). All trials were determined to be of good methodological quality.

When the impact of mechanical thrombectomy devices versus control was assessed during hospitalization [RR 1.00 (0.24, 4.16)], ≤30 days [RR 1.25 (0.47, 3.32)], 30-days [same results as the ≤30 days analysis], 180-days [RR 1.35 (0.53, 3.44)] and 365-days [RR 0.50 (0.21, 1.17)], (Appendix Figures 6-7); no significant changes were seen although the in-hospital and 365-day analyses were each based on a single trial.

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and mortality. Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet® XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significant impact on the risk of in-hospital mortality compared to PCI without a mechanical thrombectomy device (2.9 percent versus 5.4 percent, $p=0.11$). After adjustment for baseline and angiographic characteristics, the use of a mechanical thrombectomy device did not significantly impact the odds of in-hospital mortality [OR 0.58 (0.26, 1.32)] compared to PCI without a mechanical thrombectomy device.
**Mechanical thrombectomy devices in other ACS populations.** One RCT evaluated the impact of mechanical thrombectomy devices versus control on mortality in patients with STEMI or UA.\(^\text{166}\) In this trial, the X-Sizer® device was compared to control. The use of a mechanical thrombectomy device did not significantly impact the risk of 30-day mortality [RR 2.00 (0.27, 14.89)] compared to control.

One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and mortality.\(^\text{153}\) The types of ACSs included in this study were not reported. Patients undergoing PCI with the mechanical thrombectomy device AngioJet® were compared to patients undergoing PCI without mechanical thrombectomy and mortality was evaluated at 270 days. The use of a mechanical thrombectomy device was associated with a significant impact on 180-day mortality compared to PCI without a mechanical thrombectomy device (5.0 percent versus 6.5 percent, \(p=0.53\)).

**Distal filter embolic protection devices in patients with STEMI.** Five RCTs evaluated the impact of distal filter embolic protection devices versus control on mortality using the maximal duration of followup.\(^\text{89,95,98,101,137}\) In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of mortality [RR 0.97 (0.54, 1.75)] (Figure 5). The weighted-mean followup for mortality using the maximal duration of followup was 10.84 months. Statistical heterogeneity and publication bias were not detected (\(I^2=0\) percent, Egger’s \(P=0.739\)).
Limiting the pooled analysis to only trials of good methodological quality, the risk of mortality using the maximal duration of followup remained nonsignificant [RR 0.97 (0.53, 1.79)]. The weighted mean duration of followup was 11.49 months. Statistical heterogeneity was not detected ($I^2=0$ percent).

When the impact of distal filter embolic protection devices versus control was assessed at ≤30 days [RR 1.02 (0.50, 2.08)], 30-days [same results as the ≤30 days analysis], 180-days [RR 1.25 (0.38, 4.16)] (Appendix Figure 8) and 365-days [RR 0.87 (0.43, 1.78)] no significant changes in the risk of mortality were seen in each analysis, although the 180-day analysis was based on a single trial.

No controlled observational trials were conducted that evaluated the impact of distal filter embolic protection devices on mortality.

**Figure 5. Impact of distal filter embolic protection devices versus control on mortality using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Ito, 2010**: 0.30 (0.00, 3.30)
- **Kelbaek, 2008**: 0.87 (0.43, 1.78)
- **Cura, 2007**: 1.25 (0.38, 4.16)
- **Guetta, 2007**: 4.81 (0.51, infinity)
- **Lefevre, 2004**: 0.88 (0.09, 8.17)
- **combined [random]**: 0.97 (0.54, 1.75)

Cochran Q: $P=0.760$

$I^2$: 0 percent

Egger: $P=0.739$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal filter embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal filter embolic protection devices versus control on mortality in other ACS populations using the maximal duration of followup. However, the trials were not suitable for pooling because one trial was conducted in patients with either STEMI or NSTEMI and the other trial was conducted in patients with either NSTEMI or UA. In the first trial, the impact of a distal filter embolic protection device (FilterWire EX™) on 30-day mortality versus control in patients with STEMI or NSTEMI was evaluated. The use of a distal filter embolic
protection device did not significantly impact the risk of 30-day mortality [RR 0.67 (0.14, 3.27)] compared to control. This trial was determined to be of good methodological quality. In the second trial, the impact of a distal filter embolic protection device (AngioGuard\textsuperscript{TM}) on 30-day mortality\textsuperscript{156} in patients with NSTEMI or UA was evaluated. The risk of 30-day mortality was not significantly different between the distal filter embolic protection device group and control [RR 1.00 (0.24, 2.45)]. This trial was determined to be of fair methodological quality.

No controlled observational studies of distal filter embolic protection devices assessed this outcome.

**Distal balloon embolic protection devices in patients with STEMI.** Four RCTs evaluated the impact of distal balloon embolic protection devices versus control on mortality using the maximal duration of followup.\textsuperscript{17,103,110,112,133} The use of a distal balloon embolic protection device did not significantly impact the risk of mortality using the maximal duration of followup [RR 0.82 (0.45, 1.51)] (Figure 6). The weighted-mean followup for mortality using the maximal duration of followup was 6 months. A lower level of statistical heterogeneity was found ($I^2=2.5$ percent) and publication bias was detected (Egger’s $P=0.023$). All trials were determined to be of good methodological quality.\textsuperscript{17,103,110,112,133}

When the impact of distal balloon embolic protection devices versus control was assessed at in-hospital [RR 0.69 (0.24, 2.03)], $\leq30$ days [RR 0.64 (0.30, 1.39)], 30-days [same results as the $\leq30$ day analysis], and 180-days [RR 0.86 (0.48, 1.57)] (Appendix Figures 9-10); no significant changes were seen in the risk of mortality in each analysis, although the in-hospital analysis is based on a single trial.

No controlled observational studies of distal balloon embolic protection devices assessed this outcome.
Figure 6. Impact of distal balloon embolic protection devices versus control on mortality using the maximal duration of followup versus control in patients with ST-segment elevation myocardial infarction

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal balloon embolic protection devices in other ACS populations. Two RCTs evaluated the impact of distal balloon embolic protection devices versus control on mortality in patients with acute myocardial infarction using the maximal duration of followup.\textsuperscript{125,131} The use of a distal balloon embolic protection device did not significantly impact the risk of mortality using the maximal duration of followup [RR 0.31 (0.10, 1.77)] (Figure 7). The weighted mean duration of followup was 10.99 months for this analysis. Neither trial was determined to be of good methodological quality.\textsuperscript{125,132}

When the impact of distal balloon embolic protection devices versus control was assessed during hospitalization [RR 0.33 (0.00, 2.79)]\textsuperscript{132} and at 365-days [RR 0.31 (0.05, 1.91)],\textsuperscript{125} no significant changes in risk were seen, although each analysis was based on a single trial.

One RCT evaluated the impact of distal balloon embolic protection devices versus abciximab therapy on 180-day mortality in patients with acute myocardial infarction.\textsuperscript{164} In this trial, the PercuSurge device was used. The risk of 180-day mortality could not be calculated because no events occurred in either group within the prespecified time period.

No controlled observational studies of distal balloon embolic protection devices assessed this outcome.
Figure 7. Impact of distal balloon embolic protection devices versus control on mortality using the maximal duration of followup in patients with mixed acute coronary syndromes

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on mortality. The use of a proximal balloon embolic protection device did not significantly impact the risk of 30-day mortality [RR 1.01 (0.18, 5.69)] or 180-day mortality [RR 0.51 (0.11, 2.33)] versus control.

Proximal balloon embolic protection devices in other ACS populations. No studies or trials were available that were evaluating the impact of proximal balloon embolic protection devices versus control on mortality in the population.

Embolic protection devices combined in patients with STEMI. Ten RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on the occurrence of mortality using the maximal duration of followup. In these trials, the use of embolic protection devices combined did not significantly impact the risk of mortality [RR 0.87 (0.58, 1.30)] (Figure 8). The weighted-mean followup for mortality using the maximal duration of followup was 8.11 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.254$).

When limiting the pooled analysis to only trials of good methodological quality, the risk of mortality using the maximal duration of followup remained nonsignificant in the embolic protection devices combined group compared to control [RR 0.87 (0.57, 1.31)]. The weighted mean followup for mortality using the maximal duration of followup was 8.31 months. No statistical heterogeneity was found ($I^2=0$ percent).
When the impact of embolic protection devices combined versus control was assessed at in-hospital [RR 0.69 (0.24, 2.03)], ≤30 days [RR 0.84 (0.50, 1.39)], 30-days [same results as the ≤30 day analysis], 180-days [RR 0.87 (0.52, 1.46)], and 365-days [RR 0.87 (0.43, 1.78)], (Appendix Figures 11-12); no significant changes in the risk of mortality were seen in each analysis, although the in-hospital and 365-day analyses were based on a single trial.

Figure 8. Impact of embolic protection devices combined versus control on mortality using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

- Ito, 2010: 0.30 (0.00, 3.30)
- Haeck, 2009: 0.51 (0.11, 2.33)
- Kelbaek, 2008: 0.87 (0.43, 1.78)
- Tahk, 2008: 0.19 (0.00, 1.81)
- Cura, 2007: 1.25 (0.38, 4.16)
- Guetta, 2007: 4.81 (0.51, infinity)
- Hahn, 2007: 0.12 (0.00, 0.91)
- Muramatsu, 2007: 0.97 (0.44, 2.14)
- Stone, 2005: 0.96 (0.38, 2.43)
- Lefevre, 2004: 0.88 (0.09, 8.17)
- Combined [random]: 0.87 (0.58, 1.30)

Cochran Q: P=0.798
P: 0 percent
Egger: P=0.254
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations.** Three RCTs evaluated the impact of embolic protection device (distal or proximal; filter or balloon) versus control in patients with mixed ACS on mortality using the maximal duration of followup. The use of an embolic protection device did not significantly impact the risk of mortality [RR 0.59 (0.18, 1.89)] versus control (Figure 9). The weighted mean duration of followup was 8.12 months for this analysis. Statistical heterogeneity was not detected ($I^2=0$ percent) but publication bias could not be evaluated. One trial was determined to be of good methodological quality, therefore a pooled analysis limited to trials of higher methodological quality was not possible.

When the impact of embolic protection devices combined versus control was evaluated at ≤30 days, no significant impact on the risk of mortality was found [RR 0.55 (0.12, 2.50)]. (Appendix Figure 13).
Figure 9. Impact of embolic protection devices combined versus control on mortality using the maximal duration of followup in patients with other acute coronary syndromes

Cochran Q: P=0.619
I²: 0 percent
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Myocardial Infarction

Direct Comparative Trials

Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on myocardial infarction using the maximum duration of followup which in this case was 365 days.\(^{158}\) Patients with either Q-wave or nonQ-wave myocardial infarctions were evaluated. In this trial, the use of Diver™-Invatec did not significantly impact the risk of 365-day Q-wave myocardial infarction [RR 2.88 (0.25 to infinity)] or the risk of 365-day nonQ-wave myocardial infarction [RR 0.32 (0.00, 3.63)] compared to Export®-Medtronic. This trial was determined to be of good methodological quality.

Catheter aspiration device versus catheter aspiration device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on 30-day myocardial infarction.\(^{160}\) In this trial, the use of Diver™ CE did not significantly impact the risk of 30-day myocardial infarction [RR 3.00 (0.26, infinity)] compared to Guardwire™ Plus.
Trials Versus Control

**Catheter aspiration devices in patients with STEMI.** Ten RCTs evaluated the impact of catheter aspiration devices versus control on the occurrence of myocardial infarction over the maximal duration of followup. In these trials, the use of catheter aspiration devices did not significantly impact the risk of myocardial infarction using the maximal duration of followup [RR 0.61 (0.36, 1.04)] (Figure 10). The weighted-mean followup for myocardial infarction in this analysis was 8.80 months. Statistical heterogeneity and publication bias were not detected (I^2=0 percent, Egger’s P=0.651).

When limiting the pooled analysis to only trials of good methodological quality, the risk of myocardial infarction using the maximal duration of followup remained nonsignificantly impacted in the catheter aspiration device group compared to control [RR 0.61 (0.36, 1.04)]. The weighted mean duration of followup was 8.80 months. Statistical heterogeneity (I^2=0 percent) was not detected.

When the impact of catheter aspiration device use versus control was assessed at in-hospital [RR 0.32 (0.03, 3.06)], <30 days [RR 0.55 (0.24, 1.25)], 30 days [RR 0.60 (0.25, 1.45)], 180 days [RR 0.70 (0.24, 1.99)], and 365 days [RR 0.51 (0.26, 1.00)] (Appendix Figures 14-18); no significant difference in the risk of myocardial infarction were seen versus control in each analysis.

Two controlled observational studies evaluated the association between the use of catheter aspiration devices during PCI and 30-day myocardial infarction and 365-day myocardial infarction. In the first study, the Export® aspiration catheter was compared to control. There was no significant difference in 30-day or 365-day myocardial infarction (1.2 percent versus 0.5 percent, p=0.59, 3.9 percent versus 1.4 percent, p=0.10, respectively). The second study did not report the catheter aspiration devices studied. The use of a catheter aspiration device was not associated with a significantly different rate of 30-day myocardial infarction compared to control (1.3 percent versus 1.9, p=0.44).
Figure 10. Impact of catheter aspiration devices versus control on myocardial infarction using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Cochran Q: P=0.915
I²: 0 percent
Egger: P=0.651
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Catheter aspiration devices in other ACS population. No trials or studies evaluated the impact of catheter aspiration devices versus control in this population.

Mechanical thrombectomy devices in patients with STEMI. Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on myocardial infarction using the maximal duration of followup.\(^{11,27,29,40,44}\) Two trials were excluded from the pooled analysis of relative risk because no myocardial infarctions occurred within the prespecified time period in either treatment group.\(^{27,40}\) In the three trials eligible for pooling, the use of a mechanical thrombectomy device did not significantly impact the risk of myocardial infarction [RR 0.71 (0.27, 1.85)]\(^{11,29,44}\) (Figure 11). The weighted-mean followup for myocardial infarction using the maximal duration of followup was 8.98 months. Statistical heterogeneity was not detected (I²=0 percent) and publication bias could not be evaluated. All of the trials in the pooled analysis were determined to be of good methodological quality.\(^{11,29,44}\)

When the impact of mechanical thrombectomy device use versus control was assessed at in-hospital [RR 1.00 (0.11, 9.41)], ≤30 days [RR 0.63 (0.21, 1.96)], 30 days [same results as the ≤30 days analysis], 180-days [RR 0.57 (0.17, 1.92)], 365-days [RR 0.66 (0.13, 3.29)] (Appendix Figures 19-20); no significant difference in the risk of myocardial infarction was seen in each analysis, although the 365-day analysis was based on a single trial.
One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and in-hospital myocardial infarction. Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet® XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significant difference in the rate of in-hospital myocardial infarction compared to PCI without a mechanical thrombectomy device (1.0 percent versus 2.5 percent, p=0.10).

**Figure 11. Impact of mechanical thrombectomy devices versus control on myocardial infarction using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

![Relative risk meta-analysis plot (random effects)](image)

Cochran Q: P=0.838  
I²: 0 percent  
Egger: Too few strata  
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Mechanical thrombectomy devices in other ACS populations.** One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and myocardial infarction. The types of ACSs included in this study were not reported. Patients undergoing PCI with the AngioJet® mechanical thrombectomy device were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significantly different rate of 180-day myocardial infarction compared to PCI without a mechanical thrombectomy device (4.0 percent versus 2.1 percent, p=0.14).
**Distal filter embolic protection devices in patients with STEMI.** Five RCTs evaluated the impact of distal filter embolic protection devices versus control on the occurrence of myocardial infarction using the maximal duration of followup versus control. One trial was excluded from the analysis because no events occurred in the groups compared. In these four remaining trials, the use of distal filter embolic protection devices did not significantly impact the risk of myocardial infarction using the maximal duration of followup [RR 0.72 (0.15, 3.34)] (Figure 12). The weighted-mean followup for myocardial infarction using the maximal duration of followup was 11.22 months. A lower level of statistical heterogeneity was detected ($I^2=39.8$ percent) but publication bias was not detected (Egger’s $P=0.128$).

Limiting the pooled analysis to only trials of good methodological quality the risk of myocardial infarction using the maximal duration of followup remained nonsignificant [RR 0.56 (0.06, 5.02)]. The weighted mean duration of followup was 11.93 months. A higher level of statistical heterogeneity was detected ($I^2=60$ percent).

When the impact of distal filter embolic protection devices use versus control was assessed at $\leq$30 days [RR 0.73 (0.12, 4.44), 30-days [same result as $\leq$30 days], 180-days [RR 0.09 (0.00, 0.74)], and 365-days [RR 2.35 (0.61, 9.00)] (Appendix Figure 21), no significant difference in the risk of myocardial infarction were observed, although the 180-day and 365-day results are each based on a single trial.

There were no available controlled observational studies evaluating this endpoint.

**Figure 12. Impact of distal filter embolic protection devices versus control on myocardial infarction using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Ito, 2010** 0.88 (0.09, 8.17)
- **Kelbaek, 2008** 2.35 (0.67, 8.28)
- **Cura, 2007** 0.09 (0.00, 0.74)
- **Guetta, 2007** 0.32 (0.00, 3.63)
- **Lefevre, 2004** 0.88 (0.09, 8.17)
- **combined [random]** 0.72 (0.15, 3.34)

Cochran Q: $P=0.173$

$P$: 39.8 percent

Egger: $P=0.128$
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal filter embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal filter embolic protection devices versus control in patients with other ACSs on myocardial infarction using the maximal duration of followup.\textsuperscript{126,156} These trials were not suitable for pooling because one trial evaluated patients with either STEMI or NSTEMI\textsuperscript{126} and the other trial evaluated patients with UA.\textsuperscript{156} Additionally, the risk of myocardial infarction could not be calculated in either case because no events occurred in either trial during the specified time period.

There were no available controlled observational studies evaluating this endpoint.

**Distal balloon embolic protection devices in patients with STEMI.** Five RCTs evaluated the impact of distal balloon embolic protection devices versus control on myocardial infarction using the maximal duration of followup.\textsuperscript{17,103,107,110,112,133} The use of a distal balloon embolic protection device did not significantly impact the risk of myocardial infarction [RR 0.67 (0.29, 1.57)] (Figure 13). The weighted-mean followup for myocardial infarction using the maximal duration of followup was 6 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.820$). All trials were determined to be of good methodological quality.\textsuperscript{17,103,107,110,112,133}

When the impact of distal balloon protection device use versus control was assessed at in-hospital [RR 0.32 (0.00, 3.71)], $\leq$30 days [RR 0.85 (0.32, 2.23)], 30 days [same results as the $\leq$30 days analysis], and 180 days [same results as maximal duration of followup analysis] (Appendix Figure 22-23); no significant differences in the risk of myocardial infarction were seen in each analysis, although the in-hospital analysis is based on a single trial.

There were no available controlled observational studies that evaluated this endpoint.
Distal balloon embolic protection devices in other ACS populations. One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on myocardial infarction in patients with acute myocardial infarction.\(^{164}\) The use of a distal balloon embolic protection device did not significantly impact the risk of 180-day myocardial infarction [RR 1.66 (0.34, 8.10)] compared to abciximab therapy.

There were no controlled observational studies that evaluated this endpoint.

Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis\(^{\text{TM}}\) versus control on myocardial infarction.\(^{18,141}\) The use of a proximal balloon embolic protection device did not significantly impact the risk of having a myocardial infarction over 30 days [RR 0.68 (0.14, 3.34)] or 180 days [RR 1.0.1 (0.24, 4.33)].

Proximal balloon embolic protection devices in other ACS populations. No trials or studies were available that evaluated the impact of proximal balloon embolic protection devices versus control on myocardial infarction in this population.
**Embolic protection devices combined in patients with STEMI.** Eleven RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on the occurrence of myocardial infarction using the maximal duration of followup. One trial was excluded from the pooled analysis because no events occurred in the groups compared. In the remaining ten trials, the use of embolic protection devices combined did not significantly impact the risk of myocardial infarction [RR 0.83 (0.45, 1.53)] (Figure 14). The weighted-mean followup for myocardial infarction using the maximal duration of followup was 8.08 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger's $P=0.372$).

When limiting the pooled analysis to only trials of good methodological quality, the risk of myocardial infarction using the maximal duration of followup remained nonsignificant in the embolic protection devices combined group compared to control [RR 0.83 (0.45, 1.55)]. The weighted-mean followup for myocardial infarction using the maximal duration of followup was 8.27 months. No statistical heterogeneity was found ($I^2=0$ percent).

When the impact of embolic protection devices combined versus control was assessed at in-hospital [RR 0.32 (0.00, 3.71)], ≤30 days [RR 0.83 (0.41, 1.69)], 30-days [same results as the ≤30 days analysis], 180-days [RR 0.65 (0.31, 1.33)], and 365-days [RR 2.35 (0.67, 8.28)] (Appendix Figures 24-25); no significant differences in the risk of myocardial infarction were seen in each analysis, although the in-hospital and 365-day analyses were based on a single trial each.

There were no available controlled observational studies that evaluated this endpoint.
Figure 14. Impact of embolic protection devices combined versus control on myocardial infarction using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Cochran Q: P=0.689
I²: 0 percent
Egger: P=0.372

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Embolic protection devices combined in other ACS populations. No trials or studies were available that evaluated the impact of any embolic protection device versus control on myocardial infarction in addition to the three trials reported above. Pooling was not suitable because each trial evaluated a different ACS.

Stroke

Direct Comparative Trials

Catheter aspiration devices versus distal balloon embolic protection devices in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on stroke. The risk of 30-day stroke could not be calculated because no events occurred in either group during the specified time period.
Trials Versus Control

*Catheter aspiration devices in patients with STEMI.* Five RCTs evaluated the impact of catheter aspiration devices versus control on stroke using the maximal duration of followup.\(^1^4,15,49,71,74,82,83\) One trial was excluded from the pooled analysis because no events occurred in either group during the prespecified time period.\(^74\) In the four trials eligible for pooling, the use of catheter aspiration devices did not significantly impact the risk of stroke [RR 3.18 (0.73, 13.88)] (Figure 15). The weighted-mean followup for stroke using the maximal duration of followup was 0.79 months. There was no statistical heterogeneity (\(I^2=0\) percent) but publication bias was detected (Egger’s \(P=0.001\)). All of the trials included in the pooled analysis were determined to be of good methodological quality.\(^1^4,15,49,71,74,82,83\)

The four trials which evaluated stroke using the maximal duration of followup are the same trials and data included in the analysis of \(\leq 30\) day stroke above\(^1^4,15,71,83\) because the maximal duration of followup for stroke in the four trials was \(\leq 30\) days. The use of a catheter aspiration device did not significantly impact the risk of in-hospital stroke [RR 4.94 (0.52, infinity)] versus control in a single trial and \(30\) days stroke occurrence in three others [RR 2.77 (0.51, 14.98)] (Appendix Figure 26). One trial evaluated the impact of catheter aspiration devices on 180-day stroke.\(^74\) In this trial, the use of the Pronto\(^\text{TM}\) extraction catheter was compared to control. No stroke events occurred in either treatment arm, therefore a relative risk and risk difference could not be evaluated.

Two controlled observational studies evaluated the association between the use of catheter aspiration devices during PCI and \(30\)-day stroke\(^1^4,15^2\) and \(365\)-day stroke.\(^1^4^4\) In the first study, the Export\(^\text{®}\) aspiration catheter was compared to control. There was no significant difference in \(30\)-day or \(365\)-day stroke (0 percent versus 0 percent, \(p=1.00\), 0 percent versus 0.06 percent, \(p=0.10\), respectively).\(^1^4^4\) In the second study, the name of the catheter aspiration device name was not reported.\(^1^5^2\) The use of a catheter aspiration device was associated with a significantly higher rate of \(30\)-day stroke compared to control (1.3 percent versus 0.4 percent, \(p=0.03\)).
**Figure 15. Impact of catheter aspiration devices versus control on stroke using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Sardella, 2009**: 4.94 (0.52, infinity)
- **Chevalier, 2008**: 5.37 (0.57, infinity)
- **Kaltoft, 2006**: 4.95 (0.52, infinity)
- **Silva-Orrego, 2006**: * (excluded)
- **Burzotta, 2005**: 1.00 (0.11, 9.42)
- **Combined [random]**: 3.18 (0.73, 13.88)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P=0.807
F: 0 percent
Egger: P=0.001

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Catheter aspiration devices in other ACS populations.** There were no trials or studies that evaluated catheter aspiration devices in other ACS populations.

**Mechanical thrombectomy in patients with STEMI.** Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on stroke using the maximal duration of followup. One trial was excluded from the pooled analysis of relative risk because no strokes occurred within the prespecified time period in either treatment group. In the four trials eligible for pooling, the use of a mechanical thrombectomy device did not significantly impact the risk of stroke [RR 2.42 (0.75, 7.78)] (Figure 16). The weighted-mean followup for this analysis was 5.79 months. Statistical heterogeneity and publication bias were not detected (I²=0 percent, Egger’s P=0.227). All of the pooled trials were determined to be of good methodological quality.

When the impact of mechanical thrombectomy versus control was assessed at ≤30 days [RR 1.89 (0.55, 6.48)], 30-days [same results as the ≤30 days analysis], 180-days [RR 2.05 (0.27, 15.78)], and 365-days [RR 1.99 (0.26, 15.14)] (Appendix Figures 27-28); no significant differences in the risk of stroke were seen in each analysis, although the 365-day analysis is based on a single trial.
One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and in-hospital stroke\(^{145}\). Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet\(^{\text{®}}\) XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significantly different rate of in-hospital stroke compared to PCI without a mechanical thrombectomy device (0.5 percent versus 0.4 percent, \(p=1.00\)).

**Figure 16. Impact of mechanical thrombectomy devices versus control on occurrence of stroke using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Migliorini, 2010**: 1.99 (0.26, 15.14)
- **Ali, 2006**: 2.00 (0.43, 9.28)
- **Lefèvre, 2005**: 5.05 (0.53, infinity)
- **Antoniucci, 2004**: 3.00 (0.26, infinity)
- **Napodano, 2003**: * (excluded)
- **combined [random]**: 2.42 (0.75, 7.78)

Cochran Q: \(P=0.956\)

I\(^2\): 0 percent

Egger: \(P=0.227\)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Mechanical thrombectomy devices in other ACS populations.** No trials or studies assessed the use of mechanical thrombectomy devices in other ACS populations.

**Distal filter embolic protection devices in patients with STEMI.** One RCT evaluated the impact of a distal filter embolic protection device versus control on the occurrence of stroke using the maximal duration of followup.\(^{89}\) In this trial, the use of a distal filter embolic protection device did not significantly impact the risk of long-term occurrence of stroke [RR 1.51 (95 percent CI=0.30 to 7.52)]. The duration of followup for stroke was 1 month. The trial was determined to be of good methodological quality.\(^{89}\)
**Distal filter embolic protection devices in other ACS populations.** One RCT evaluated the impact of the distal filter embolic protection device FilterWire versus control on stroke in patients with NSTEMI or STEMI. The risk of 30-day stroke could not be calculated because no events occurred in either group during the specified time period. No controlled observational studies assessed for this endpoint.

**Distal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of distal balloon embolic protection devices versus control on stroke using the maximal duration of followup. In this trial, the use of the GuardWire Plus was compared to control therapy. The use of a distal balloon embolic protection device did not significantly impact the risk of stroke at 180 days [RR 0.48 (0.10, 2.22)]. The impact of distal balloon embolic protection devices on stroke was also evaluated in this trial at 30 days. The use of a distal balloon embolic protection device significantly decreased the risk of ≤30-day stroke [RR 0.11 (0.00, 0.94)] and 30-day stroke [same results as the ≤30 day analysis] versus control. This trial was determined to be of good methodological quality. No controlled observational studies assessed for this endpoint.

**Distal balloon embolic protection devices in other ACS populations.** No trials or studies were available that evaluated the impact of distal balloon embolic protection devices versus control on stroke in this population.

**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of the proximal balloon embolic protection device Proxis versus control on stroke. The use of a proximal balloon embolic protection device did not significantly impact the risk of having a stroke over 30 days [RR 0.34 (0.01, 3.81)] or 180 days [RR 0.20 (0.00, 1.92)].

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies were available that evaluated the impact of proximal balloon embolic protection devices versus control on stroke in this population.

**Embolic protection devices combined in patients with STEMI.** Three RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on the occurrence of stroke using the maximal duration of followup. In these trials, the use of embolic protection devices combined did not significantly impact the risk of stroke [RR 0.68 (0.22, 2.11)] (Figure 17). The weighted mean followup for stroke using the maximal duration of followup was 3.74 months. Statistical heterogeneity was not detected (I²=0 percent) and publication bias could not be calculated due to the number of studies available. All of the trials were determined to be of good methodological quality.

When the impact of embolic protection devices combined was assessed at ≤30 days [RR 0.56 (0.11, 2.84)] and 180-days [RR 0.39 (0.09, 1.71)] (Appendix Figures 29-30); no significant difference in the risk of stroke were seen versus control.
Figure 17. Impact of embolic protection devices combined versus control on stroke using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Cochran Q: P=0.459
I²: 0 percent
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Embolic protection devices combined in other ACS populations. No trials or studies were available that evaluated the impact of any embolic protection device versus control on stroke in this population in addition to the one trial reported above, and therefore pooling was not possible.

Target Revascularization

Direct Comparative Trials

Catheter aspiration device versus catheter aspiration device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver<sup>TM</sup>-Invatec catheter aspiration device versus the Export<sup>®</sup>-Medtronic catheter aspiration device on 365-day target revascularization. In this trial, the use of Diver<sup>TM</sup>-Invatec did not significantly impact the risk of 365-day target revascularization [RR 1.44 (0.30, 7.00)] compared to Export<sup>®</sup>-Medtronic. In this trial, no events occurred in either group at 30-days.

Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI. One direct comparative trial evaluated the impact of the catheter aspiration device Diver<sup>TM</sup> CE versus the distal balloon embolic protection device Guardwire<sup>TM</sup> Plus on 30-day
target revascularization.\textsuperscript{160} In this trial, there was no difference in the risk of 30-day target revascularization [RR 1.00 (0.11, 9.45)].

**Trials Versus Control**

**Catheter aspiration devices in patients with STEMI.** Nine RCTs evaluated the impact of catheter aspiration devices versus control on target revascularization using the maximal duration of followup.\textsuperscript{12,14-16,19,49,62,64,68,74,82,83,138} In these trials, the use of catheter aspiration devices did not significantly impact the risk of target revascularization [RR 0.79 (0.61, 1.02)] (Figure 18). The weighted-mean followup for target revascularization using the maximal duration of followup was 9.48 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.548$).

When limiting the pooled analysis to only trials of good methodological quality,\textsuperscript{12,14,16,49,62,64,68,74,82,83,138} the risk of target revascularization using the maximal duration of followup remained nonsignificant with the use of a catheter aspiration device group compared to control [RR 0.79 (0.61, 1.02)]. The weighted mean duration of followup was 9.48 months. Statistical heterogeneity was not detected ($I^2=0$ percent).

When the impact of catheter aspiration devices versus control was assessed at 180 days [RR 0.61 (0.39, 0.94)] (Appendix Figure 31) a significant reduction in the risk of target revascularization versus control was seen. Using the risk difference for the analysis [RD –0.03 (-0.06, 0.002), (CER 0.01, 0.20)] 33 patients would need to be treated to prevent one target revascularization. However, at in-hospital [RR 1.35 (0.26, 6.94)], <30 days [RR 0.85 (0.53, 1.38)], 30 days [RR 0.82 (0.50, 1.35)] and 365 days [RR 0.87 (0.63, 1.19)] (Appendix Figures 32-35); no significant differences in the risk of target revascularization were seen versus control in each analysis.

Two controlled observational studies evaluated the association between the use of catheter aspiration devices during PCI and 30-day target revascularization\textsuperscript{144,152} and 365-day target revascularization.\textsuperscript{144} In the first study, the Export® aspiration catheter was compared to control. There was no significant difference in 30-day or 365-day target revascularization (2.4 percent versus 1.9 percent, $p=0.936$, 7.8 percent versus 7.1 percent, $p=0.923$, respectively).\textsuperscript{144} In the second study, the name of the catheter aspiration device name was not reported.\textsuperscript{152} The use of a catheter aspiration device was not associated with a significantly different rate of 30-day target revascularization compared to control (1.9 percent versus 2.5 percent, $p=0.46$).
Figure 18. Impact of catheter aspiration devices versus control on target revascularization using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Catheter aspiration devices in other ACS populations. No trials or studies assessed target revascularization in other ACS populations.

Mechanical thrombectomy in patients with STEMI. Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on target revascularization using the maximal duration of followup.\textsuperscript{11,27,29,40,44} Two trials were excluded from the pooled analysis of relative risk because no target revascularizations occurred within the prespecified time period in either treatment group.\textsuperscript{27,44} In the three trials eligible for pooling, the use of a mechanical thrombectomy device did not significantly impact the risk of target revascularization [RR 0.87 (0.36, 2.10)]\textsuperscript{11,29,40} (Figure 19). The weighted-mean followup for target revascularization using the maximal duration of followup was 6.22 months. A lower level of statistical heterogeneity was detected ($I^2$=39.2 percent) and publication bias could not be evaluated. All of the pooled trials were determined to be of good methodological quality.\textsuperscript{11,29,40}

When the impact of mechanical thrombectomy devices versus control was assessed at $\leq$30 days [RR 1.62 (0.21, 12.55)], 30 days [same results as the $\leq$30 days analysis], 180-days [RR 0.55 (0.33, 0.92)], and 365-days [RR 0.68 (0.41, 1.13)] (Appendix Figures 36-37); no significant differences in the risk of target revascularization were seen versus control in each analysis. The 365-day analysis is based on a single trial.
One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and in-hospital target revascularization.\textsuperscript{145}

Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet\textsuperscript{\textregistered} XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significant difference in the rate of in-hospital target revascularization compared to PCI without a mechanical thrombectomy device (2.7 percent versus 2.1 percent, \(p=0.57\)).

**Figure 19. Impact of mechanical thrombectomy devices versus control on target revascularization using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

**Mechanical thrombectomy devices in other ACS populations.** One RCT evaluated the impact of the X-Sizer\textsuperscript{\textregistered} mechanical thrombectomy device versus control on 30-day target revascularization in patients with STEMI or UA.\textsuperscript{166} The use of a mechanical thrombectomy device did not significantly impact the risk of 30-day target revascularization [RR 0.33 (0.00, 3.75)] compared to control.

One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and 180-day target revascularization.\textsuperscript{153} The types of ACSs included in this study were not reported. Patients undergoing PCI with the mechanical thrombectomy device AngioJet\textsuperscript{\textregistered} were compared to patients undergoing PCI without mechanical thrombectomy and target revascularization was evaluated at 270 days. The use of a mechanical thrombectomy
device was not associated with a significantly different rate of 180-day target revascularization compared to PCI without a mechanical thrombectomy device (5.5 percent versus 4.8 percent, \( p=0.72 \)).

**Distal filter embolic protection devices in patients with STEMI.** Three RCTs evaluated the impact of distal filter embolic protection devices versus control on target revascularization using the maximal duration of followup.\(^{89,94,95,137}\) One trial was excluded from the analysis because no events occurred in the groups compared.\(^{137}\) In the two remaining trials, the use of distal filter embolic protection devices significantly increased the risk of target revascularization using the maximal duration of followup [RR 1.61 (1.03, 2.54)] (Figure 20). The weighted-mean followup for target revascularization using the maximal duration of followup was 13.36 months. Using the risk difference [RD 0.04 (-0.0006, 0.08), (CER 0 to 0.09)], one case of target revascularization would occur with the use of a distal filter embolic protection device in 25 cases. All three trials were determined to be of good methodological quality.\(^{89,94,95,137}\)

Target revascularization at 365-days was significantly increased with the use of mechanical thrombectomy devices versus control [RR 1.78 (1.09, 2.93)] although this was based on a single trial. Using the risk difference [RD 0.01 (-0.005, 0.03), (CER 0.07] one case of target revascularization would occur with the use of a distal filter embolic protection device in 100 cases. Target revascularization at \( \leq 30 \) days [RR 3.02 (0.61, 14.84)], 30-days [RR 3.02 (0.70, 13.01)], and 180-days [RR 1.00 (0.35, 2.82)] was not significantly impacted although each analysis is based on a single trial.

No controlled observational studies were available that assessed for this endpoint.

**Figure 20. Impact of distal filter embolic protection devices versus control on target revascularization using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

![Relative risk meta-analysis plot (random effects)](image)

Cochran Q: \( P=0.341 \)

P: Too few strata

48
**Distal filter embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal filter embolic protection devices versus control on target revascularization in patients with other ACSs using the maximal duration of followup.\textsuperscript{126,156} These trials were not suitable for pooling because the first trial evaluated patients with either NSTEMI or STEMI\textsuperscript{126} and the second trial evaluated patients with UA.\textsuperscript{156} Both trials evaluated target revascularization at 30-days although the risk could not be calculated because no events occurred in either trial during the specified time period.\textsuperscript{126,156}

**Distal balloon embolic protection devices in patients with STEMI.** Five RCTs evaluated the impact of distal balloon embolic protection devices versus control on target revascularization using the maximal duration of followup.\textsuperscript{17,103,107,110,112,133} The use of a distal balloon embolic protection device did not significantly impact the risk of target revascularization [RR 0.93 (0.61, 1.42)] (Figure 21). The weighted-mean followup for target revascularization using the maximal duration of followup was 6 months. Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s P=0.369). All of the trials were determined to be of good methodological quality.\textsuperscript{17,103,107,110,112,133}

When the impact of distal balloon embolic protection devices versus control was assessed at in-hospital [RR 0.32 (0, 3.71)], ≤30 days [RR 1.38 (0.55, 3.50)], 30 days [same results as the ≤30 days analysis], and 180 days [RR 0.93 (0.61, 1.42)] (Appendix Figures 38-39); no significant differences in the risk of target revascularization were seen versus control in each analysis, although the in-hospital analysis is based on a single trial.

No controlled observational studies assessed for this outcome.
Figure 21. Impact of distal balloon embolic protection devices versus control on target revascularization using maximal duration of followup in patients with ST-segment elevation myocardial infarction

**Legend:** The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal balloon embolic protection devices in other ACS populations.** One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on target revascularization in patients with acute myocardial infarction. The use of a distal balloon embolic protection device did not significantly impact the risk of 180-day target revascularization [RR 1.11 (0.46, 2.67)] compared to abciximab therapy.

No controlled observational studies assessed for this outcome in this population.

**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on target revascularization. The use of a proximal balloon embolic protection device did not significantly impact the risk of target revascularization over 30 days [RR 0.51 (0.14, 1.81)] or 180 days [RR 0.71 (0.29, 1.75)].

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies were available that evaluated the impact of proximal balloon embolic protection devices versus control on target revascularization in the population.

Cochran Q: P=0.597
P²: 0 percent
Egger: P=0.369

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**Stone, 2005**

**Muramatsu, 2007**

**Matsuo, 2007**

**Hahn, 2007**

**Tahk, 2008**
**Embolic protection devices combined in patients with STEMI.** Nine RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on target revascularization using the maximal duration of followup. One trial was excluded from the analysis because no events occurred in the groups compared. In the eight remaining trials, the use of embolic protection devices combined did not significantly impact the risk of long-term occurrence of target revascularization [RR 1.11 (0.80, 1.52)] (Figure 22). The weighted mean followup for target revascularization using the maximal duration of followup was 8.60 months. A lower level of statistical heterogeneity was detected as was a trend towards publication bias (I²=10 percent, Egger’s P=0.066). All of the trials were determined to be of good methodological quality.

When the impact of embolic protection devices combined versus control was assessed at 365-days the risk of target revascularization was significantly increased with the use of embolic protection devices versus control [RR 1.78 (1.09, 2.93)] although this was based on a single trial. Using the risk difference [RD 0.05 (0.009, 0.10), (CER 0.07)] one case of target revascularization would occur for every 25 patients who undergo surgery with an embolic protection device. At in-hospital [RR 0.32 (0.00 to 3.71)], <30 days [RR 1.24 (0.62, 2.48)] 30 days [same results as the <30 days analysis] and 180 days [RR 0.90 (0.63, 1.30)], no significant differences in risk of target revascularization were seen versus control, although the in-hospital analysis is based on a single trial.

No controlled observational studies assessed for this endpoint.

**Figure 22. Impact of embolic protection devices combined versus control on target revascularization using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

![Relative risk meta-analysis plot (random effects)](image-url)
Embol protection devices combined in other ACS populations. No trials or studies were available that evaluated the impact of any embolic protection device versus control on target revascularization in addition to the 3 trials reported above. Pooling was not suitable because each trial evaluated a different ACS.

Combined MACE

MACE was reported as a composite outcome in trials and the definition used in each trial corresponding to the extracted data can be found in Appendix Tables 87-98. Overall, the definitions of MACE within each analysis were found to be similar and appropriate for meta-analysis.

Direct Comparative Trials

Catheter aspiration device versus catheter aspiration device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on 365-day MACE.\textsuperscript{158} In this trial, the use of Diver™-Invatec did not significantly impact the risk of 365-day MACE [RR 2.40 (0.57, 10.41)] compared to Export®-Medtronic. This same trial evaluated the impact of the Diver™-Invatec versus the Export®-Medtronic device on 30-day MACE.\textsuperscript{158} The use of Diver™-Invatec did not significantly impact the risk of 30-day MACE [RR 0.65 (0.13, 3.16)] compared to Export®-Medtronic.

Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on 30-day MACE.\textsuperscript{160} In this trial, the use of Diver™ CE did not significantly impact the risk of 30-day MACE [RR 1.33 (0.35, 5.16)] compared to Guardwire™ Plus.

Trials Versus Control

Catheter aspiration devices in patients with STEMI. Eleven RCTs evaluated the impact of catheter aspiration devices versus control on MACE of maximal duration of follow-up.\textsuperscript{12,14-16,19,49,54,62,64,68,69,71,83,85,138} In these trials, the use of a catheter aspiration device significantly reduced the occurrence of MACE using the maximal duration of follow-up [RR 0.73 (0.61, 0.88)] (Figure 23). The weighted-mean follow-up for MACE using the maximal duration of follow-up was 12.43 months. Statistical heterogeneity and publication bias were not detected (I^2=0 percent, Egger’s P=0.965). Given the risk difference [RD -0.03 (-0.01, 0.001), CER (0.02 to 0.35)], 33 people would need to be treated with a catheter aspiration device to prevent one MACE.

When limiting the pooled analysis to only trials of good methodological quality,\textsuperscript{12,14-16,19,49,54,62,68,69,71,83,138} the risk of MACE using the maximal duration of follow-up remained significantly reduced in the catheter aspiration device group compared to control [RR 0.73 (0.61, 0.88)]. The weighted mean duration of follow-up was 12.66 months. Statistical heterogeneity was not detected (I^2=0 percent). Given the risk difference [RD -0.03 (-0.07, 0.003), (CER 0.02 to
0.35)], 34 people would need to be treated with a catheter aspiration device to prevent one MACE.

When the impact of catheter aspiration devices versus control was assessed at in-hospital [RR 0.97 (0.36, 2.58)], ≤30 days [RR 0.80 (0.57, 1.12)], 30 days [RR 0.79 (0.56, 1.13)], and 365 days [RR 0.61 (0.26, 1.41)] (Appendix Figures 42-45); no significant differences in the risk of MACE were seen versus control in each analysis while a significant decrease in risk at 180 days [RR 0.66 (0.47, 0.94)] (Appendix Figure 46) was seen with the use of a catheter aspiration device versus control. Given the risk difference [RD -0.04 (-0.10, -0.003), (CER 0.06 to 0.27)], 25 people would need to be treated with a catheter aspiration device to prevent one MACE.

Two controlled observational studies evaluated the association between the use of catheter aspiration devices during PCI and 30-day MACE and 365-day MACE. In the first study, the Export® aspiration catheter was compared to control. The use of catheter aspiration was not associated with a significant difference in the rate of MACE at 30-days or 365-days versus control (8.5 percent versus 6.8 percent, p=0.47, 12.8 percent versus 14.1 percent, p=0.79, respectively). The catheter aspiration devices included in the second study was not reported. The use of a catheter aspiration device was not associated with a significant difference in the rate of 30-day MACE compared to control (5.5 percent versus 5.3 percent, p=0.81). The use of a catheter aspiration device was not associated with a significant difference in the rate of 30-day MACE [HR 0.96 (0.56, 1.52)] or 365-day MACE [HR 1.03 [0.68, 1.55]].

Figure 23. Impact of catheter aspiration devices versus control on MACE using maximal duration of follow-up in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Cochran Q: P=0.645
F: 0 percent
Egger: P=0.965
**Legend:** The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Catheter aspiration devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Mechanical thrombectomy in patients with STEMI.** Four RCTs evaluated the impact of mechanical thrombectomy devices versus control on MACEs using the maximal duration of followup.\(^11,27,29,40\) One trial was excluded from the pooled analysis of relative risk because there were no MACE at the prespecified time-point in either treatment groups.\(^27\) In the three trials eligible for pooling, the use of a mechanical thrombectomy device did not significantly impact the risk of MACE using the maximal duration of followup [RR 1.23 (0.50, 3.01)]\(^11,29,40\) (Figure 24). The weighted mean followup for MACE was 6.22 months. A higher level of statistical heterogeneity was found (I\(^2\)=79.9 percent) and publication bias could not be evaluated. The three pooled trials were all determined to be of good methodological quality.\(^11,29,40\)

When the impact of mechanical thrombectomy devices versus control was assessed at \(\leq30\) days [RR 1.28 (0.37, 4.38)], \(30\) days [same results as the \(\leq30\) days analysis] and \(180\)-days [RR 0.71 (0.41, 1.20)] (Appendix Figures 47-48), no significant difference in the risk of MACE were seen versus control. One trial evaluated the impact of mechanical thrombectomy devices on 365-day MACE versus control.\(^11\) In this trial, the use of the AngioJet\(^\text{®}\) rheolytic thrombectomy system was compared to control therapy and significantly decreased the risk of 365-day MACE [RR 0.66 (0.44, 0.97)] versus control. Given the risk difference for 365-day MACE [RD -0.10 (-0.15, -0.01), (CER 0.23)], 10 people would need to be treated with a catheter thrombectomy device in order to prevent one occurrence of MACE.

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and in-hospital MACE.\(^145\) Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet\(^\text{®}\) XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significant difference in the rate of in-hospital MACE compared to PCI without a mechanical thrombectomy device (7.5 percent versus 9.0 percent, \(p=0.47\) and remained nonsignificant after adjustment for baseline and angiographic characteristics [OR 0.83 (0.48, 1.42)].
Figure 24. Impact of mechanical thrombectomy devices versus control on MACE using the maximal duration of followup in patients with ST-segment elevation myocardial infarction

Cochran Q: P=0.007
I²: 79.9 percent
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Mechanical thrombectomy devices in other ACS populations. One RCT evaluated the impact of the mechanical thrombectomy device X-Sizer® versus control on 30-day MACE in patients with STEMI or UA. The risk of 30-day MACE was not significantly different between the mechanical thrombectomy device group and control [RR 1.00 (0.18, 5.43)].

One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and 180-day MACE. The types of ACSs included in this study were not reported. Patients undergoing PCI with the mechanical thrombectomy device AngioJet® were compared to patients undergoing PCI without mechanical thrombectomy and MACE was evaluated at 270 days. The use of a mechanical thrombectomy device was not associated with a significant difference in the rate of 180-day MACE compared to PCI without a mechanical thrombectomy device (14.0 percent versus 11.6 percent, p=0.35).

Distal filter embolic protection devices in patients with STEMI. Five RCTs evaluated the impact of distal filter embolic protection devices versus control on the occurrence of MACE using the maximal duration of followup. In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of MACE using the maximal duration of followup [RR 1.34 (0.97, 1.86)] (Figure 25). The weighted-mean followup for MACE was 10.84 months. Statistical heterogeneity and publication bias were not detected (I²=0 percent, Egger’s P=0.419).

When limiting the pooled analysis to only trials of good methodological quality the risk of MACE remained nonsignificant with distal filter embolic protection devices compared to
control [RR 1.36 (0.98, 1.89)]. The weighted mean duration of followup was 11.49 months. Statistical heterogeneity was not detected ($I^2=0$ percent).

When the impact of distal filter embolic protection devices versus control was assessed at 365-days, there was a significant increase in the risk of MACE [RR 1.48 (1.03, 2.15)] although this was based on a single trial. Using the risk difference [RD 0.06 (0.004, 0.12), (CER 0.13)], one case of MACE would occur with the use of a distal filter embolic protection device in 17 cases. MACE at $\leq 30$ days [RR 1.29 (0.77, 2.15)], 30 days [same results as the $\leq 30$ day analysis], and 180 days [RR 1.10 (0.68, 1.78)] (Appendix Figures 49-50) was not significantly different versus control in each analysis.

No controlled observational studies were available that assessed for this endpoint.

**Figure 25. Impact of distal filter embolic protection devices versus control on MACE using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

**Legend:** The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal filter embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal filter embolic protection devices versus control in patients with other ACSs on MACE using the maximal duration of followup. These trials were not suitable for pooling because the first trial evaluated patients with either NSTEMI or UA and the second trial evaluated patients with either STEMI or NSTEMI. In the trial evaluating patients with NSTEMI or UA, the FilterWire EZ$^\text{TM}$ device was compared to control. The use of a distal filter embolic protection device was not associated with a significant impact on the risk of MACE at in-hospital [RR 1.24 (0.50, 3.06)] and at 30-days [RR 1.08 (0.45, 2.59)] compared to...
In the trial evaluating patients with either STEMI or NSTEMI, the FilterWire EX device was compared to control. The use of a distal filter embolic protection device did not significantly impact the risk of 180-day MACE [RR 1.08 (0.53, 2.23)] compared to control.

**Distal balloon embolic protection devices in patients with STEMI.** Six RCTs evaluated the impact of distal balloon embolic protection devices versus control on MACE using the maximal duration of followup. One study was excluded from the pooled analysis of relative risk because there were no MACE at the prespecified time point in either treatment group. In the five studies eligible for pooling, the use of a distal embolic protection device did not significantly impact the risk of MACE [RR 0.87 (0.64, 1.19)] (Figure 26). The weighted-mean followup for MACE was 6 months. Statistical heterogeneity was not detected ($I^2=0$ percent) but publication bias was detected (Egger’s $P=0.032$). All of the trials were determined to be of good methodological quality.

When the impact of distal embolic protection devices was assessed at ≤30 days [RR 0.74 (0.44, 1.23)], 30 days [same results as the ≤30 day analysis], and 180 days [RR 0.87 (0.64, 1.19)] (Appendix Figures 51-52); no significant differences in the risk of MACE were seen versus control in each analysis.

No controlled observational studies assessed for this endpoint.

**Figure 26. Impact of distal balloon embolic protection devices versus control on MACE using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

![Relative risk meta-analysis plot (random effects)](chart)

Cochran Q: $P=0.685$

$P$: 0 percent

Egger: $P=0.032$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Distal balloon embolic protection devices in other ACS population. One RCT evaluated the impact of the distal balloon embolic protection device GuardWire® PercuSurge versus control on MACE in patients with acute myocardial infarction. The use of a distal filter embolic protection device did not significantly impact the risk of 180-day MACE [RR 0.33 (0.05, 1.87)] compared to control.

No controlled observational studies evaluated this endpoint in this population.

Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on MACE. The use of a proximal balloon embolic protection device did not significantly impact the risk of MACE over 30 days [RR 0.34 (0.01, 8.23)] or 180 days [RR 0.74 (0.36, 1.54)].

Proximal balloon embolic protection devices in other ACS populations. No trials or studies were available that evaluated the impact of proximal balloon embolic protection devices versus control on MACE in this population.

Embolic protection devices combined in patients with STEMI. Twelve RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on MACE using the maximal duration of followup. The trial by Zhou et al was excluded from the pooled analysis of relative risk because no events occurred within the prespecified time period in either control or treatment group. In the 11 trials suitable for pooling, the use of embolic protection devices combined did not significantly impact the risk of long-term occurrence of MACE [RR 1.04 (0.84, 1.29)] (Figure 27). The weighted mean followup for MACE using the maximal duration of followup was 7.97 months. Statistical heterogeneity and publication bias were not detected (I²=0 percent, Egger’s P=0.084). The analysis was then limited to only trials of good methodological quality although one trial was excluded from the analysis because no events occurred in either group during the prespecified time period. The ten trials of good methodological quality suitable for pooling, the risk of MACE remained nonsignificant in the combined embolic protection device group compared to control [RR 1.03 (0.82, 1.29)]. The weighted mean followup for MACE using the maximal duration of followup was 8.15 months. A lower level of statistical heterogeneity was detected (I²=4 percent).

When the impact of distal embolic protection devices versus control was assessed at 365-days, the risk of MACE was significantly increased with the use of embolic protection devices versus control [RR 1.48 (1.03, 2.14)] although this was based on a single trial. Using the risk difference [RD 0.06 (0.005, 0.12), (CER 0.13)] one case of MACE would occur for every 17 patients who undergo surgery with an embolic protection device. At ≤30 days [RR 0.92 (0.66, 1.30)], 30 days [same results as the ≤30 day analysis], and 180 days [RR 0.91 (0.71, 1.16)] (Appendix Figures 53-54), no significant differences in the risk of MACE were seen versus control in each analysis.

One controlled observational study evaluated the association between the use of a distal protection device and 365-day MACE in patients with STEMI. In this study, the device name was not reported nor was the distinction between distal balloon and distal filter. There was no significant difference in the adjusted rate of 365-day MACE when comparing the distal
protection group with those who did not receive distal protection during PCI [HR 0.85 (0.59, 3.48)].

**Figure 27. Impact of embolic protection devices combined versus control on MACE using the maximal duration of followup in patients with ST-segment elevation myocardial infarction**

![Graph showing impact of embolic protection devices on MACE](image)

**Legend:** The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations.** No trials or studies were available that evaluated the impact of any embolic protection device versus control on MACE in addition to the three trials reported above, and pooling was not suitable because each trial evaluated a different ACS.

**Table 7. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating catheter aspiration devices in patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>7.92</td>
<td>0.69 (0.47 to 1.02)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.80</td>
<td>0.61 (0.36 to 1.04)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.79</td>
<td>3.18 (0.73 to 13.88)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>9.48</td>
<td>0.79 (0.61 to 1.02)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>12.43</td>
<td>0.73 (0.61 to 0.88)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events
Table 8. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating mechanical thrombectomy devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>7.80</td>
<td>1.19 (0.51 to 2.76)</td>
<td>54.9</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.98</td>
<td>0.71 (0.27 to 1.85)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>5.79</td>
<td>2.42 (0.75 to 7.78)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6.22</td>
<td>0.87 (0.36 to 2.10)</td>
<td>39.2%</td>
</tr>
<tr>
<td>MACE</td>
<td>6.22</td>
<td>1.23 (0.50 to 3.01)</td>
<td>79.9%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 9. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating distal filter embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>10.84</td>
<td>0.97 (0.54 to 1.75)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>11.22</td>
<td>0.72 (0.15 to 3.34)</td>
<td>39.8%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>1.51 (0.30 to 7.52)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>13.36</td>
<td>1.61 (1.03 to 2.54)</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>10.84</td>
<td>1.34 (0.97 to 1.86)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 10. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6</td>
<td>0.82 (0.45 to 1.51)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>6</td>
<td>0.67 (0.29 to 1.57)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>0.48 (0.10 to 2.22)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6</td>
<td>0.93 (0.61 to 1.42)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>6</td>
<td>0.87 (0.64 to 1.19)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 11. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating proximal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6</td>
<td>0.51 (0.11 to 2.33)*</td>
<td>NA</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>6</td>
<td>1.01 (0.24 to 4.33)*</td>
<td>NA</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>0.20 (0 to 1.93)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6</td>
<td>0.71 (0.29 to 1.75)*</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>6</td>
<td>0.74 (0.36 to 1.54)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable
Table 12. Final health outcomes using the maximal duration of followup in randomized controlled trials evaluating embolic protection devices combined in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>8.11</td>
<td>0.87 (0.58 to 1.30)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.08</td>
<td>0.83 (0.45 to 1.53)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>3.74</td>
<td>0.68 (0.22 to 2.11)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>8.60</td>
<td>1.11 (0.80 to 1.52)</td>
<td>10%</td>
</tr>
<tr>
<td>MACE</td>
<td>7.97</td>
<td>1.04 (0.84 to 1.29)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Health-Related Quality of Life

Direct Comparative Trials

No direct comparative trials evaluated the impact of catheter aspiration, mechanical thrombectomy or embolic protection devices on this endpoint.

Trials Versus Control

Catheter aspiration devices. No trials or studies evaluated the impact of catheter aspiration devices on this endpoint.

Mechanical thrombectomy devices. No trials or studies evaluated the impact of catheter aspiration devices on this endpoint.

Distal Balloon Embolic Protection Devices. No trials or studies evaluated the impact of distal balloon embolic protection devices on this endpoint.

Proximal Balloon Embolic Protection Devices. No trials or studies evaluated the impact of proximal balloon embolic protection devices on this endpoint.

Embolic Protection Devices Combined. No trials or studies evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on this endpoint.

ST-Segment Resolution

ST-segment resolution was defined in different ways in different trials. We defined ST-segment resolution as ≥70 percent resolution at 60 minutes if reported, ≥50 percent resolution at 60 minutes if ≥70 percent resolution at 60 minutes data was not reported, or ≥70 percent resolution postPCI or at 90 minutes if 60 minute data was unavailable.

Direct Comparative Trials

Catheter aspiration device versus catheter aspiration device in STEMI. One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on ST-segment resolution. In this trial, ST-segment resolution was defined as resolution great than or equal to 70 percent at 90 minutes. The
use of Diver™-Invatec did not significantly impact the risk of resolving ST-segment elevation [RR 0.79 (0.61, 1.00)] compared to Export®-Medtronic.

Catheter aspiration device versus distal balloon protection device in ACS. One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on ST-segment resolution.¹⁶⁰ In this trial, ST-segment resolution was defined as greater than or equal to 70 percent up to 6 hours postprocedure (measured immediately after the procedure and at 90 minutes and 6 hours postprocedure). The use of Diver™ CE did not significantly impact the risk of resolving ST-segment elevation [RR 0.97 (0.72, 1.32)] compared to Guardwire™ Plus.

Trials Versus Control

Catheter aspiration devices in patients with STEMI. Fifteen RCTs evaluated the impact of catheter aspiration devices versus control on ST-segment resolution and were included in the pooled analysis.¹²,¹⁴-¹⁶,¹⁹,²⁰,⁶²,⁶⁹,⁷¹,⁷⁴,⁸³,⁸⁵-⁸⁷,⁸⁷,¹³⁸,¹⁷⁶ The use of a catheter aspiration device significantly increased the risk of resolving ST-segment elevation versus control [RR 1.51 (1.32, 1.73)] (Figure 28). A higher level of statistical heterogeneity was found (I²=64.2) as was the presence of publication bias (Egger’s P=0.041). Given the risk difference [RD 0.22 (0.15, 0.30), (CER 0.11 to 0.65)], five people would need to be treated with a catheter aspiration device to allow one person to experience ST-segment resolution.

When limiting the pooled analysis to only trials of good methodological quality¹²,¹⁴-¹⁶,⁶²,⁶⁹,⁷¹,⁷⁴,⁸³,¹³⁸,¹⁷⁶ the risk of resolving ST-segment elevation remained significantly increased in the catheter aspiration device group compared to control [RR 1.39 (1.21, 1.61)]. A higher level of statistical heterogeneity was detected (I²=60.4 percent). Given the risk difference [RD 0.18 (0.10, 0.26), (CER 0.27 to 0.65)], six people would need to be treated with a catheter aspiration device to allow one person to experience ST-segment resolution.

One RCT evaluated the impact of the catheter aspiration device Diver™ CE versus control on ST-segment resolution although was not included in the pooled analysis. In this trial patients were only included in if they attained TIMI-3 blood flow postprocedure, therefore it was not included in the pooled analysis of ST-segment resolution. The use of a catheter aspiration device did not significantly impact the risk of resolving ST-segment elevation [RR 0.93 (0.52, 1.62)] compared to control.

One controlled observational study evaluated the association between the use of catheter aspiration devices during PCI and resolution of ST-segment elevation.¹⁵² The catheter aspiration devices included in this study were not reported. The use of a catheter aspiration device was not associated with significant difference in the rate of resolution of ST-segment elevation (48.2 percent versus 50.3 percent, p=0.51).
Figure 28. Impact of catheter aspiration devices versus control on ST-segment resolution in patients with ST-segment elevation myocardial infarction

Cochran Q: P < 0.001
I²: 64.2 percent
Egger: P=0.041

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Catheter aspiration devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

Mechanical thrombectomy devices in patients with STEMI. Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on ST-segment resolution. The use of a mechanical thrombectomy device did not significantly impact the risk of resolving ST-segment elevation [RR 1.16 (0.99, 1.36)] (Figure 29). A higher level of statistical heterogeneity was found (I²=75.1 percent) but publication bias was not detected (Egger’s P=0.402). All of the trials in the pooled analysis were determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint.
Figure 29. Impact of mechanical thrombectomy devices versus control on ST-segment resolution in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Mechanical thrombectomy devices in other ACS populations. One RCT evaluated the impact of the mechanical thrombectomy device X-Sizer® versus control on ST-segment resolution in patients with STEMI or UA. ST-segment resolution was defined as resolution greater than 50 percent after the procedure. The use of a mechanical thrombectomy device significantly increased the risk of resolving ST-segment elevation [RR 1.58 (1.05, 2.57)] compared to control. Given the risk difference for ST-segment resolution [RD 0.30 (0.03, 0.54), (CER 0.52)], three people would need to be treated with a mechanical thrombectomy device in order to have one person experience ST-segment resolution. This trial was determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.

Distal filter embolic protection devices in patients with STEMI. Five RCTs evaluated the impact of distal filter embolic protection devices versus control on ST-segment resolution. In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of resolving ST-segment elevation [RR 1.05 (0.97, 1.15)] (Figure 30). Statistical heterogeneity and publication bias were not detected (I²=0 percent, Egger’s P=0.279). When limiting the pooled analysis to only trials of good methodological quality, the risk of resolving of ST-segment elevation remained nonsignificant [RR 1.05 (0.96, 1.15)]. Statistical heterogeneity was not detected (I²=0 percent).
No controlled observational studies assessed for this endpoint in this population.

**Figure 30. Impact of distal filter embolic protection devices versus control on ST-segment resolution in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Ito, 2010**: 2.01 (0.81, 5.42)
- **Kelbaek, 2008**: 1.05 (0.96, 1.16)
- **Cura, 2007**: 1.02 (0.78, 1.34)
- **Guetta, 2007**: 0.99 (0.74, 1.33)
- **Lefevre, 2004**: 1.24 (0.81, 1.98)
- **combined [random]**: 1.05 (0.97, 1.15)

Cochran Q: P=0.651
I²: 0 percent
Egger: P=0.279

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal filter embolic protection devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Distal balloon embolic protection devices in patients with STEMI.** Four RCTs evaluated the impact of distal balloon embolic protection devices versus control on ST-segment resolution.\(^{103,107,112,133}\) The use of a distal balloon embolic protection device did not significantly impact the risk of resolving ST-segment elevation [RR 1.08 (0.91, 1.29)] (Figure 31). A lower level of statistical heterogeneity was found (I\(^2\)=41.2 percent) but publication bias was not detected (Egger’s P=0.311). All of the trials were determined to be of good methodological quality.\(^{103,107,112,133}\)

No controlled observational studies assessed for this endpoint in this population.
Figure 31. Impact of distal balloon embolic protection devices versus control on ST-segment resolution in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Cochran Q: P=0.164
I²: 41.2 percent
Egger: P=0.311
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal balloon embolic protection devices in other ACS populations. One RCT evaluated the impact of the distal balloon embolic protection device Guardwire™ Plus versus control on early resolution of ST-segment elevation in patients with acute myocardial infarction. The use of a distal balloon embolic protection device significantly increased the risk of resolving ST-segment elevation compared to control [RR 1.58 (1.10, 2.46)]. Given the risk difference [RD 0.29 (0.10, 0.50), (CER 0.50)], three people would need to be treated with a distal balloon embolic protection device to have one patient experience an ST segment resolution. This trial was determined to be of poor methodological quality.

One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on ST-segment resolution in patients with acute myocardial infarction. ST-segment resolution was defined as ≥70 percent at 60 minutes. The use of a distal balloon embolic protection device did not significantly impact the risk of resolving ST-segment elevation [RR 1.28 (0.86, 1.92)] compared to abciximab therapy.

No controlled observational studies assessed for this endpoint in this population.

Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on ST-segment resolution. The use of a proximal balloon embolic protection device did not
significantly impact the risk of resolving ST-segment elevation [RR 1.11 (0.97, 1.28)]. The trial was determined to be of good methodological quality.  

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Embolic protection devices combine in patients with STEMI.** Ten RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on ST-segment resolution.  

In these trials, the use of embolic protection devices combined did not significantly impact the risk of resolving ST-segment elevation [RR 1.06 (1.00, 1.13)] (Figure 32). Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.117$).

When limiting the analysis to only trials of good methodological quality the risk of resolving ST-segment elevation remained nonsignificant in the combined embolic protection device group compared to control [RR 1.06 (1.00, 1.13)]. Statistical heterogeneity was not detected ($I^2=0$ percent).

**Figure 32. Impact of embolic protection devices combined versus control on ST-segment resolution in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>2.01 (0.81, 5.42)</td>
</tr>
<tr>
<td>Haeck, 2009</td>
<td>1.11 (0.97, 1.28)</td>
</tr>
<tr>
<td>Kelbaek, 2008</td>
<td>1.05 (0.96, 1.16)</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>1.02 (0.78, 1.34)</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>0.99 (0.74, 1.33)</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>1.87 (1.16, 3.34)</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>0.97 (0.72, 1.32)</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>1.07 (0.81, 1.41)</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>1.02 (0.89, 1.18)</td>
</tr>
<tr>
<td>Lefevre, 2004</td>
<td>1.24 (0.81, 1.98)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>1.06 (1.00, 1.13)</td>
</tr>
</tbody>
</table>

Cochran Q: $P=0.534$

F: 0 percent

Egger: $P=0.117$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combine in other ACS populations.** No trials or studies were available in addition to the two trials reported above that evaluated the impact of any embolic
protection device versus control on ST-segment resolution in this patient population. Pooling was not suitable because a different comparator was used in each trial.

**Ejection Fraction**

**Direct Comparative Trials**

*Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI.* One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on left-ventricular ejection fraction (Table 13). There was no significant difference in the mean left-ventricular ejection fraction between Diver™ CE and Guardwire™ Plus groups at baseline (45 percent ±11 versus 46 percent ±10, p=0.56) or at 30 days postprocedure (54 percent ±12 versus 54 percent ±11, p=0.60), respectively.

*Catheter aspiration device versus distal balloon embolic protection device versus control in patients with STEMI.* One direct comparative randomized trial evaluated the impact of catheter aspiration devices and distal balloon embolic protection devices on 6-month ejection fraction (Table 13). In this trial, patients were randomized to one of three groups, catheter aspiration with Rescue™ or Thrombuster® devices, distal balloon embolic protection with PercuSurge or GuardWire devices, or to control therapy. Patients were excluded from the trial if they had coronary no reflow or slow flow. Ejection fraction at 180-days did not differ significantly amongst the three groups (50 percent ±8 versus 54 percent ±11 versus 52 percent ±12, p=NS).

**Table 13. Ejection fraction of direct comparative randomized controlled trials in ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration Catheter Aspiration</td>
<td>Diver™ Invatec catheter Export® Medtronic</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Diver™ CE catheter GuardWire™ Plus</td>
<td>61</td>
<td>30d</td>
<td>54 (12)</td>
<td>54 (11)</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Rescue™ or Thrombuster® systems PercuSurge GuardWire® Control</td>
<td>25</td>
<td>180d</td>
<td>52 (12)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>24</td>
<td>180d</td>
<td>54 (11)</td>
<td></td>
</tr>
</tbody>
</table>

*Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; SD=standard deviation*

**Trials Versus Control**

*Catheter aspiration devices in patients with STEMI.* Eleven RCTs evaluated the impact of catheter aspiration devices versus control on ejection fraction but were not amenable for statistical pooling therefore results are reported qualitatively (Table 14). In the first trial the mean left ventricular ejection fraction at baseline did not differ between the two groups (p=0.60). When baseline mean LVEF values were compared to mean LVEF at 6 months, a greater improvement was noted in the catheter aspiration group compared to control (48 percent ±6 to 55 percent ±6 versus 48 percent ±7 to 49 percent ±8,
p<0.001), respectively. In the second trial there was no significant difference in the left ventricular ejection fraction at 7 days between the catheter aspiration group and control (48 percent ±12 versus 45 ±11, p=0.04). In the third trial a subset of patients with anterior myocardial infarction from the original trial were randomized to evaluate ejection fraction. No difference in the mean ejection fraction was found at 3-5 days postprocedure (46.3 percent ±8.6 versus 44.3 percent ±9.5, p=0.06) or at 3 months (49.0 percent ±9.3 versus 46.7 percent ±10.6, p=0.30) between the catheter aspiration and control groups, respectively. In the fourth trial, patients were only included in the trial if they achieved a TIMI-3 blood flow postprocedure. In this trial, the mean left ventricular ejection fraction was not significantly different at 7 days postprocedure between the catheter aspiration device group and control (50.1 percent ±8.4 versus 46.5 percent ±7.9, p=NS). In the fifth trial there was no significant difference in the left ventricular ejection fraction at 5-8 days between the catheter aspiration device group and control (46.7 percent ±11 versus 42.5 percent ±10, p=0.16). In the sixth trial there was no significant difference between the catheter aspiration group and control in mean left ventricular ejection fraction at baseline (51.3 ±11.9 versus 51.3 ±11.9, p=0.99) or at 6 months (57.1 ±12.5 versus 56.7 ±12.3, p=0.77). In the seventh trial there was no significant difference in the mean left ventricular ejection fraction at 28 days between the catheter aspiration device group and control (56 percent ±10 versus 57 percent ±10, p=0.51). In the eighth trial the mean ejection fraction was reported in a figure and with use of Engauge Digitizer Version 2.0 to read the figure the values for ejection fraction were obtained. There was no significant difference between the catheter aspiration group and control in mean left ventricular ejection fraction immediately postprocedure (37.29 percent ±9.97 versus 36.67 percent ±3.03, p=NS) and at 6 months (42.97 percent ±9.97 versus 41.28 percent ±3.37, p=NS). In the ninth trial there was no significant difference in the median left ventricular ejection fraction at 30 days between the catheter aspiration device group and control (51 percent (43-57) versus 53 percent (47-58), p=0.13). In a substudy of 50 participants from the trial by Burzotta et al. ejection fraction was reported in a figure. Engauge Digitizer, Version 2.0 was used to read the figure and obtain values for ejection fraction. Mean ejection fraction was significantly greater in the catheter aspiration group compared to control at 24 hours (50.36 percent ±8.76 versus 45.75 percent ±7.49, p<0.05), 1 week (53.34 percent ±10.99 versus 48.09 percent ±9.4, p<0.05), and 6 months (53.28 percent ±10.04 versus 47.72 percent ±8.28, p<0.05). Mean ejection fraction at 1 week and at 6 months was significantly greater than mean ejection fraction at 24 hours in the catheter aspiration group (p<0.05). In the eleventh trial the mean left ventricular ejection fraction did not differ significantly between the catheter aspiration group and control in-hospital (56.5 percent ±9.1 versus 52.8 ±12.8, p=NS) or at 3 months (60.3 percent ±9.2 versus 55.3 percent ±14.7, p=NS).

One controlled observational study evaluated the impact of catheter aspiration devices versus control on left ventricular ejection fraction. The use of a catheter aspiration device significantly decreased left ventricular ejection fraction versus control postPCI (49±11 versus 53±11, p<0.0005).

**Catheter aspiration devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver™ CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export™ Thrombectomy Catheter</td>
<td>55</td>
<td>180d</td>
<td>55 (6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>56</td>
<td>---</td>
<td>49 (8)</td>
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<tr>
<td>Lipiecki, 2009</td>
<td>Export™ Catheter</td>
<td>20</td>
<td>7d</td>
<td>48 (12)</td>
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<td></td>
<td>Control</td>
<td>24</td>
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<tr>
<td>Moura, 2009</td>
<td>TAC</td>
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<td></td>
<td>Control</td>
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<td>---</td>
</tr>
<tr>
<td>Sardella, 2009*</td>
<td>Export™ Medtronic (EM)</td>
<td>38</td>
<td>3-5d</td>
<td>46.3 (8.6)</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>37</td>
<td>---</td>
<td>44.3 (9.5)</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009*</td>
<td>Export™ Medtronic (EM)</td>
<td>36</td>
<td>90d</td>
<td>49.0 (9.3)</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>36</td>
<td>---</td>
<td>46.7 (10.6)</td>
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<td>Wita, 2009</td>
<td>Diver™ CE</td>
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<td>7d</td>
<td>50.1 (8.4)</td>
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<tr>
<td></td>
<td>Control</td>
<td>23</td>
<td>---</td>
<td>46.5 (7.9)</td>
<td>---</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export™ Aspiration Catheter</td>
<td>37</td>
<td>28d</td>
<td>56 (10)</td>
<td>0.51</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>37</td>
<td>---</td>
<td>57 (10)</td>
<td>---</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Export™ Aspiration Catheter</td>
<td>---</td>
<td>---</td>
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<td>Control</td>
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</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue™/Diver™</td>
<td>32</td>
<td>5-8d</td>
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<td>0.16</td>
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<tr>
<td></td>
<td>Control</td>
<td>31</td>
<td>---</td>
<td>42.5 (10.0)</td>
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</tr>
<tr>
<td>Ikani, 2008</td>
<td>TVAC®</td>
<td>103</td>
<td>180d</td>
<td>57.1 (12.5)</td>
<td>0.77</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>113</td>
<td>---</td>
<td>56.7 (12.3)</td>
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</tr>
<tr>
<td>Svilas, 2008</td>
<td>6F Export™ Aspiration Catheter</td>
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<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>DeLuca, 2006*</td>
<td>Diver™ CE</td>
<td>38</td>
<td>PostPCI</td>
<td>37.29 (9.97)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>38</td>
<td>---</td>
<td>36.67 (3.03)</td>
<td>---</td>
</tr>
<tr>
<td>DeLuca, 2006*</td>
<td>Diver™ CE</td>
<td>35</td>
<td>180d</td>
<td>42.97 (9.97)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>36</td>
<td>---</td>
<td>41.28 (3.37)</td>
<td>---</td>
</tr>
<tr>
<td>Kaltoft, 2006</td>
<td>Rescue™ Catheter</td>
<td>108</td>
<td>30d</td>
<td>51 (43-57)</td>
<td>0.13</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>107</td>
<td>---</td>
<td>53 (47-58)*</td>
<td>---</td>
</tr>
<tr>
<td>Lee, 2006</td>
<td>Export™ Aspiration Catheter</td>
<td>---</td>
<td>---</td>
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<tr>
<td></td>
<td>Control</td>
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<td>---</td>
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</tr>
<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto™ Extraction Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Burzotta, 2005*</td>
<td>Diver™ CE</td>
<td>25</td>
<td>1d</td>
<td>50.36 (8.76)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>25</td>
<td>---</td>
<td>45.75 (7.49)</td>
<td>---</td>
</tr>
<tr>
<td>Burzotta, 2005*</td>
<td>Diver™ CE</td>
<td>25</td>
<td>7d</td>
<td>53.34 (10.99)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>25</td>
<td>---</td>
<td>48.09 (9.4)</td>
<td>---</td>
</tr>
<tr>
<td>Burzotta, 2005*</td>
<td>Diver™ CE</td>
<td>25</td>
<td>180d</td>
<td>53.28 (10.04)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>25</td>
<td>---</td>
<td>47.72 (8.28)</td>
<td>---</td>
</tr>
<tr>
<td>Noel, 2005</td>
<td>Export™</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2004*</td>
<td>Rescue™</td>
<td>35</td>
<td>In-hospital</td>
<td>56.5 (9.1)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>32</td>
<td>---</td>
<td>52.8 (12.8)</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2004*</td>
<td>Rescue™</td>
<td>35</td>
<td>90d</td>
<td>60.3 (9.2)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>32</td>
<td>---</td>
<td>55.3 (14.7)</td>
<td>---</td>
</tr>
</tbody>
</table>

*Data from a single study; †Median (interquartile range)

Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention, SD=standard deviation; TAC=Thrombectomy Aspiration Catheter; TVAC®=Transvascular aspiration catheter
**Mechanical thrombectomy in patients with STEMI.** Two RCTs evaluated the impact of mechanical thrombectomy devices versus control on ejection fraction but were not amenable for statistical pooling therefore results are reported qualitatively (Table 15). In the first trial there was no significant difference in ejection fraction at 14 to 28 days postprocedure between the mechanical thrombectomy device group and control (51.3 percent ±11.53 versus 52.3 ±10.89, p=0.38). In the second trial the mean ejection fraction significantly improved in the mechanical thrombectomy device group (49.3 percent ±7.6 to 51.9 percent ±7.9, p=0.02) and in control (48.8 percent ±5.9 to 49.9 percent ±8.9, p=0.04) from baseline to 30 days. There was no significant difference in ejection fraction between the mechanical thrombectomy device group and control at baseline (p=0.50) or at 30 days (p=0.26). Ejection fraction was also measured at discharge and did not differ significantly between the mechanical thrombectomy device group and control (51.0 percent ±7.7 versus 48.7 percent ±10.9, p=0.29).

**Mechanical thrombectomy devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Table 15. Ejection fraction in randomized controlled trials evaluating mechanical thrombectomy devices in patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet® Rheolytic Thrombectomy</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>AngioJet® Catheter Control</td>
<td>197</td>
<td>14-28d</td>
<td>51.3 (11.53)</td>
<td>0.38</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer® Catheter Control</td>
<td>205</td>
<td>--</td>
<td>52.3 (10.89)</td>
<td>---</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet® Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Napodano,* 2003</td>
<td>X-Sizer® Catheter Control</td>
<td>46</td>
<td>In hospital</td>
<td>51.0 (7.7)</td>
<td>0.29</td>
</tr>
<tr>
<td>Napodano,* 2003</td>
<td>X-Sizer® Catheter Control</td>
<td>46</td>
<td>30d</td>
<td>48.7 (10.9)</td>
<td>---</td>
</tr>
</tbody>
</table>

*Data from a single study

Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; SD=standard deviation

**Distal filter embolic protection devices in patients with STEMI.** Two RCTs evaluated the impact of distal filter embolic protection devices versus control on ejection fraction but were not amenable for statistical pooling therefore results are reported qualitatively (Table 16). In the first trial there was no significant difference in ejection fraction measured at 48 to 72 hours postprocedure between the distal filter embolic protection device group and control (47.4 percent ±9.9 versus 45.3 percent ±7.3, p=0.29). In the second trial left ventricular ejection fraction measured after the procedure did not differ significantly between the distal filter embolic protection device group and control (47 percent versus 44 percent, p=0.56).

No controlled observational studies assessed for this endpoint in this population.
Table 16. Ejection fraction in randomized controlled trials evaluating distal filter embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap</td>
<td>Filtrap</td>
<td>19</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>17</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ™ or SpiderX™ protection device</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX™</td>
<td>SpideRX™</td>
<td>70</td>
<td>2-3d</td>
<td>47.4 (9.9)</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>70</td>
<td>---</td>
<td>45.3 (7.3)</td>
<td>---</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ™</td>
<td>Control</td>
<td>51</td>
<td>Post PCI</td>
<td>47 (---)</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>49</td>
<td>---</td>
<td>44 (---)</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuard™ XP</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention; SD=standard deviation

Distal filter embolic protection devices in other ACS populations. One RCT evaluated the impact of the distal filter embolic protection device FilterWire EX™ versus control on ejection fraction in patients with either NSTEMI or STEMI (Table 17). In this trial, ejection fraction values were reported in a figure, therefore Engauge Digitizer, Version 2.0 was used to read the figure and obtain values for ejection fraction. There was no significant difference in the ejection fraction measured at 3 days postprocedure between the distal filter embolic protection device group and control (47.57 percent ±10.94 versus 51.22 percent ±11.75, p= 0.26).

No controlled observational studies assessed for this endpoint in this population.

Table 17. Ejection fraction in randomized controlled trials evaluating thrombectomy or embolic protection devices in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire®</td>
<td>100</td>
<td>3d</td>
<td>47.57 (10.94)</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>100</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire™</td>
<td>34</td>
<td>Post PCI</td>
<td>51.2 (14.5)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>46.7 (12.2)</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver™ CE</td>
<td>34</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue™ PT</td>
<td>34</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire®</td>
<td>34</td>
<td>Post PCI</td>
<td>51.2 (14.5)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>46.7 (12.2)</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire®</td>
<td>34</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer®</td>
<td>34</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Control</td>
<td>30</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention; SD=standard deviation
**Distal balloon embolic protection devices in patients with STEMI.** Six RCTs evaluated the impact of distal balloon embolic protection devices versus control on ejection fraction but were not amenable for statistical pooling therefore results are reported qualitatively (Table 18).\(^{17,103,107,110,119,133,135}\) In the first trial, there was a significantly higher ejection fraction at 3 and 6 months postPCI in the distal balloon embolic protection device group versus control (51.6 ±3.6 versus 49.3±5.3 percent and 53.0±3.7 percent versus 50.8±5.2 percent, respectively, p<0.05 for both comparisons).\(^{135}\) Authors reported that the difference between the two groups at 1 month was not significantly different although values were not reported. In the second trial there was no significant difference in the mean ejection fraction at baseline (52.1 percent ±9.4 versus 49.0 percent ±11.2, p=0.10) or at 6 months (58.1 percent ±11.4 versus 54.6 percent ±10.3, p=0.24) between the distal balloon embolic protection device group and control.\(^{17}\) The change in left ventricular ejection fraction from baseline to 6 months did not differ significantly between the distal balloon embolic protection device group and control (6.18 percent ±9.46 versus 5.65 percent ±8.64, p=0.83), respectively.\(^{17}\) In the third trial there was no significant difference in left ventricular ejection fraction at 3 days postprocedure (50 percent ±9 versus 49 percent ±13, p=0.60) or at 6 months (48 percent ±16 versus 50 percent ±9, p=0.74) between the distal balloon embolic protection device group and control.\(^{103}\) In the fourth trial there was no significant difference in left ventricular ejection fraction after the procedure (46.1 percent ±9.5 versus 55.4 percent ±13.9, p=.99) or at 6 months (61.9 percent versus 62.7 percent, p=0.36) between the distal balloon embolic protection device group and control.\(^{107}\) In the fifth trial there was no significant difference in left ventricular ejection fraction postprocedure (54.0 percent versus 53.8 percent, p=0.90), at 1 month (55.3 percent versus 55.4 percent, p=NS) or at 6 months (57.1 percent versus 57.1 percent, p=NS) between the distal balloon embolic protection device group and control.\(^{110,133}\) In the sixth trial there was no significant difference in mean left ventricular ejection fraction at discharge (47 percent ±9 versus 48 percent ±8, p=0.89) between the distal balloon embolic protection device group and control.\(^{119}\)

No controlled observational studies assessed for this endpoint in this population.

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010*</td>
<td>PercuSurge Guardwire(^{TM}) Plus Control</td>
<td>46</td>
<td>90d</td>
<td>51.6 (3.6)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Duan, 2010*</td>
<td>PercuSurge Guardwire(^{TM}) Plus Control</td>
<td>50</td>
<td></td>
<td>49.3 (5.3)</td>
<td></td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire(^{TM}) Control</td>
<td>52</td>
<td>180d</td>
<td>50.8 (5.2)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Tähk, 2008</td>
<td>PercuSurge GuardWire(^{TM}) Control</td>
<td>48</td>
<td>180d</td>
<td>58.1 (11.4)</td>
<td></td>
</tr>
<tr>
<td>Hahn, 2007*</td>
<td>GuardWire(^{TM}) Control</td>
<td>19</td>
<td>3d</td>
<td>50 (9)</td>
<td>0.60</td>
</tr>
<tr>
<td>Hahn, 2007*</td>
<td>GuardWire(^{TM}) Control</td>
<td>20</td>
<td></td>
<td>49 (13)</td>
<td></td>
</tr>
<tr>
<td>Matsuo, 2007*</td>
<td>GuardWire(^{TM}) Distal Protection System Control</td>
<td>80</td>
<td>PostPCI</td>
<td>46.1 (9.5)</td>
<td>0.99</td>
</tr>
<tr>
<td>Matsuo, 2007*</td>
<td>GuardWire(^{TM}) Distal Protection System Control</td>
<td>74</td>
<td></td>
<td>55.4 (13.9)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 18. Ejection fraction in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction (continued)

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matsuo, 2007*</td>
<td>GuardWire® Distal Protection System Control</td>
<td>80</td>
<td>180d</td>
<td>61.9 (---)</td>
<td>0.36</td>
</tr>
<tr>
<td>Muramatsu, 2007*</td>
<td>GuardWire™ Plus System Control</td>
<td>173</td>
<td>PostPCI</td>
<td>54.0 (---)</td>
<td>0.90</td>
</tr>
<tr>
<td>Muramatsu, 2007*</td>
<td>GuardWire™ Plus System Control</td>
<td>133</td>
<td>30d</td>
<td>55.3 (---)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Muramatsu, 2007*</td>
<td>GuardWire™ Plus System Control</td>
<td>108</td>
<td>180d</td>
<td>57.1 (---)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Zhou, 2007*</td>
<td>PercuSurge GuardWire® Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire® Control</td>
<td>8</td>
<td>Hospital discharge (mean 22±4 d)</td>
<td>47 (9)</td>
<td>0.89</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire™ Plus Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Data from a single study

Abbreviations: d=days; EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention; SD=standard deviation

### Distal balloon embolic protection devices in other ACS populations

One RCT evaluated the impact of the distal balloon embolic protection device Guardwire™ Plus versus control on ejection fraction in patients with acute myocardial infarction (Table 17). The distal balloon embolic protection device group had a significantly higher post procedural mean left ventricular ejection fraction compared to control (51.2±14.5 percent versus 46.7±12.2 percent, p=0.02).

One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on ejection fraction in patients with acute myocardial infarction (Table 19). There was no significant difference in median left ventricular ejection fraction upon admission between the distal balloon embolic protection device group and the abciximab group [43 percent (39-45) versus 40 (38-44), p=NS], respectively. Left ventricular ejection fractions increased in both groups at 6 months (46 percent (45-49) versus 46 percent (44-50), p=NS), although the changes were not significantly different between groups.

No controlled observational studies assessed for this endpoint in this population.

### Table 19. Ejection fraction in randomized controlled studies with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge® Guardwire Abciximab</td>
<td>57</td>
<td>6m</td>
<td>46 (45-49)*</td>
<td>NS</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy+ Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: EF=ejection fraction; m=months; n=number of participants included in the analysis of ejection fraction; NS=not significant; SD=standard deviation
Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis\textsuperscript{TM} versus control on ejection fraction in patients with STEMI\textsuperscript{190} (Table 20). There was no significant difference in ejection fraction at 4 to 6 months postPCI in the Proxis\textsuperscript{TM} group versus control (50 percent ±11 versus 50 percent ±12, \(p=0.46\)).

### Table 20. Ejection fraction in randomized controlled trials evaluating proximal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis\textsuperscript{TM}</td>
<td>96</td>
<td>4-6m</td>
<td>50 (11)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>110</td>
<td></td>
<td>50 (12)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: EF=ejection fraction; m=months; n=number of participants included in the analysis of ejection fraction; SD=standard deviation

Proximal balloon embolic protection devices in patients with other ACS. No RCT or controlled observational studies evaluated the impact of proximal balloon embolic protection devices versus control on this outcome.

Embolic protection devices combined. No additional studies evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) aside from those reported in their respective device categories.

### Myocardial Blush Grade

#### Direct Comparative Trials

**Catheter aspiration device versus catheter aspiration device in patients with STEMI.** One direct comparative randomized trial evaluated the impact of the Diver\textsuperscript{TM}-Invatec catheter aspiration device versus the Export\textsuperscript{®}-Medtronic catheter aspiration device on MBG.\textsuperscript{158} The use of Diver\textsuperscript{TM}-Invatec did not significantly impact the risk of attaining a MBG-3 [RR 0.71 (0.42, 1.18)] compared to Export\textsuperscript{®}-Medtronic.

**Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI.** One direct comparative randomized trial evaluated the impact of the catheter aspiration device Diver\textsuperscript{TM} CE versus the distal balloon embolic protection device Guardwire\textsuperscript{TM} Plus on MBG.\textsuperscript{160} The use of Diver\textsuperscript{TM} CE did not significantly impact the risk of attaining a MBG of 2 [RR 0.97 (0.77, 1.23)] compared to Guardwire\textsuperscript{TM} Plus.

### Trials Versus Control

**Catheter aspiration devices in patients with STEMI.** Thirteen RCTs evaluated the impact of catheter aspiration devices versus control on MBG and were included in the pooled analysis.\textsuperscript{12-16,19,20,62,69,74,83,86,87,138,175,176} The use of a catheter aspiration device significantly increased the risk of attaining a MBG-3 [RR 1.61 (1.41, 1.84)] (Figure 33). A higher level of statistical heterogeneity was found (\(I^2=55.4\) percent) but publication bias was not detected (Egger’s \(P=0.117\)). Give the risk difference [RD 0.22 (0.16, 0.28), (CER 0.12 to 0.71)], five people would need to receive the catheter aspiration device to cause one person to experience a MBG-3.

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When limiting the pooled analysis to trials of only good methodological quality, the risk of attaining a MBG-3 remained significantly increased [RR 1.75 (1.44, 2.14)]. A higher level of statistical heterogeneity was detected ($I^2 = 69.2$) and a trend towards publication bias was detected (Egger’s $P=0.07$). Given the risk difference for attaining a MBG-3 [RD 0.25 (0.16, 0.33), (CER 0.13 to 0.71)], four people would need to receive the catheter aspiration device to cause one person to experience a MBG-3.

One RCT evaluated the impact of the catheter aspiration device Diver™ CE versus control on MBG although was not included in the pooled analysis. In this trial, patients were only included if they attained TIMI-3 blood flow postprocedure, therefore it was not included in the pooled analysis of MBG. The use of a catheter aspiration device did not significantly impact the risk of attaining a MBG-3 [RR 1.04 (0.62, 1.69)] compared to control.

No controlled observational studies assessed for this endpoint in this population.

Figure 33. Impact of catheter aspiration devices versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Cochran Q: $P=0.008$
$I^2$: 55.4 percent
Egger: $P=0.117$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Catheter aspiration devices in other ACS populations.** One RCT evaluated the impact of the catheter aspiration device Diver™-Invatec versus control on MBG in patients with acute myocardial infarction. The use of a catheter aspiration device significantly increased the risk of attaining a MBG-3 [RR 4.45 (1.51, 13.88)] compared to control. Given the risk difference for
MBG-3 [RD 0.30 (0.10, 0.51), (CER 0.09)], three people would need to be treated with a catheter aspiration device to cause one person to achieve a MBG-3. This trial was determined to be of poor methodological quality.

No controlled observational studies assessed for this endpoint in this population.

**Mechanical thrombectomy devices in patients with STEMI.** Four RCTs evaluated the impact of mechanical thrombectomy devices versus control on MBG. The use of a mechanical thrombectomy device did not significantly impact the risk of attaining a MBG-3 [RR 1.07 (0.80, 1.43)] (Figure 34). A higher level of statistical heterogeneity was found (I²=76.5 percent) but publication bias was not detected (Egger’s P=0.408). All trials were determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.

**Figure 34. Impact of mechanical thrombectomy devices versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction**

Cochran Q: P=0.005
P: 76.5 percent
Egger: P=0.408
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Mechanical thrombectomy devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

Distal filter embolic protection devices in patients with STEMI. Two RCTs evaluated the impact of distal filter embolic protection devices versus control on MBG.\(^{95,98}\) In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of attaining a MBG-3 [RR 0.97 (0.81, 1.15)] (Figure 35). Publication bias could not be evaluated. Both of the trials were determined to be of good methodological quality.\(^{95,98}\)

No controlled observational studies assessed for this endpoint in this population.

Figure 35. Impact of distal filter embolic protection devices versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Cochran Q: P=0.692
P: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal filter embolic protection devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

Distal balloon embolic protection devices in patients with STEMI. Six RCTs evaluated the impact of distal balloon embolic protection devices versus control on MBG.\(^{17,103,107,111,112,133}\) The use of a distal balloon embolic protection device significantly increased the risk of attaining MBG-3 [RR 1.39 (1.15, 1.69)] (Figure 36). A lower level of statistical heterogeneity was found (I\(^2\)=43.5 percent) but publication bias was not detected (Egger’s P=0.203). Given the risk
difference [RD 0.15 (0.10, 0.24), (CER 0.20 to 0.53)], seven people would need to be treated with a distal balloon embolic protection device to cause one person to experience a MBG-3. All of the trials were determined to be of good methodological quality.\textsuperscript{17,103,107,111,112,133}

No controlled observational studies assessed for this endpoint in this population.

**Figure 36. Impact of distal balloon embolic protection devices versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

![Meta-analysis plot](image)

Cochran Q: P=0.115
I\(^2\): 43.5 percent
Egger: P=0.203

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal balloon embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal balloon embolic protection devices versus control on MBG in patients with acute myocardial infarction.\textsuperscript{125,130} The use of a distal balloon embolic protection device significantly increased the risk of attaining a MBG-3 [RR 3.22 (1.03, 10.10)] compared to control (Figure 37). Given the risk difference [RD 0.51 (0.18, 0.84), (CER 0.14 to 0.37)], two people would need to be treated with a distal balloon embolic protection device in order to cause one to achieve a MBG-3. Neither trial was determined to be of good methodological quality.\textsuperscript{125,130}

One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on MBG in patients with acute myocardial infarction.\textsuperscript{164} The use of a distal balloon embolic protection device did not significantly impact the risk of attaining a MBG-3 [RR 0.94 (0.71, 1.25)] versus abciximab therapy.

No controlled observational studies assessed for this endpoint in this population.
Figure 37. Impact of distal balloon embolic protection devices versus control on myocardial blush grade of 3 in patients with mixed acute coronary syndrome

Cochran Q: P=0.020
P: Too few strata
Egger: P=To few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on MBG. The use of a proximal balloon embolic protection device did not significantly impact the risk of attaining MBG-3 [RR 0.98 (0.88, 1.10)]. Limiting the analysis to trials of good methodological quality did not change the results.

No controlled observational studies assessed for this endpoint in this population.

**Proximal balloon embolic protection devices in other ACS.** No trials or studies assessed for this endpoint in this population.

**Embolic protection devices combined in patients with STEMI.** Nine RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on MBG. In these trials, the use of embolic protection devices combined significantly increased the risk of attaining a MBG-3 [RR 1.20 (1.02, 1.40)] (Figure 38). A high level of statistical heterogeneity was detected (I²=68.2 percent) but publication bias was not detected (Egger’s P=0.055). Given the risk difference [RD 0.09 (0.02, 0.17), (CER 0.20 to 0.82)], eleven people would need to be treated with an embolic protection device to cause one person to achieve a MBG-3. All of the trials were determined to be of good methodological quality.
**Figure 38. Impact of embolic protection devices combined versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- Haeck, 2009: 0.98 (0.87, 1.10)
- Tahk, 2008: 1.82 (1.25, 2.75)
- Cura, 2007: 0.94 (0.75, 1.18)
- Guetta, 2007: 1.01 (0.76, 1.35)
- Hahn, 2007: 1.26 (0.48, 3.39)
- Matsuo, 2007: 1.33 (0.97, 1.85)
- Muramatsu, 2007: 1.24 (0.83, 1.86)
- Zhou, 2007: 1.96 (1.32, 2.99)
- Stone, 2005: 1.16 (0.98, 1.36)
- Combined [random]: 1.19 (1.02, 1.40)

Cochran Q: P=0.002
F: 68.2 percent
Egger: P=0.055

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

*Embolic protection devices combined in other ACS populations.* No trials or studies were available that evaluated the impact of an embolic protection device versus control on MBG-3 in this patient population in addition to the two trials pooled and reported in the distal balloon embolic protection device section above.

**TIMI-3 Blood Flow**

**Direct Comparative Trials**

*Catheter aspiration device versus catheter aspiration device in patients with STEMI.* One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on TIMI-3 blood flow. The use of Diver™-Invatec did not significantly impact the risk of attaining TIMI-3 blood flow [RR 0.89 (0.71, 1.10)] compared to Export®-Medtronic.

*Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI.* One direct comparative randomized trial evaluated the impact of the catheter aspiration device Diver™ CE versus the distal balloon embolic protection device Guardwire™ Plus on TIMI-3 blood flow. The use of Diver™ CE did not significantly impact the risk of attaining TIMI-3 blood flow [RR 0.98 (0.89, 1.08)] compared to Guardwire™ Plus.
Trials Versus Control

**Catheter aspiration devices in patients with STEMI.** Thirteen RCTs evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow. The use of a catheter aspiration device significantly increased the risk of attaining TIMI-3 blood flow [RR 1.08 (1.04, 1.12)] (Figure 39). A lower level of statistical heterogeneity was found ($I^2$ =11.5 percent) but no publication bias was detected (Egger’s $P=0.585$). Given the risk difference [RD 0.06 (0.03, 0.10), (CER 0.68 to 0.88)], 17 people would need to be treated with a catheter aspiration device to cause one person to achieve TIMI-3 blood flow.

Limiting the pooled analyses to trials of good methodological quality still resulted in a significantly increased risk of attaining TIMI-3 blood flow [RR 1.07 (1.04, 1.11)]. A lower level of statistical heterogeneity was found ($I^2$=0 percent). Given the risk difference [RD 0.06 (0.03, 0.10), (CER 0.68 to 0.88)], 17 people would need to be treated with a catheter aspiration device to cause one person to achieve TIMI-3 blood flow.

Two controlled observational studies evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow. In the first study, the use of a catheter aspiration device did not significantly impact the achievement of TIMI-3 blood flow versus control (89.1 percent versus 87.6 percent, $p=0.67$). In the second study, the use of a catheter aspiration device did not significantly impact the achievement of TIMI-3 blood flow versus control (88.3 percent versus 86.5 percent, $p=0.471$).

**Figure 39. Impact of catheter aspiration devices versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

Cochran Q: $P=0.329$

$P$: 11.5 percent
Catheter Aspiration Devices in other ACS populations. Two RCTs evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow in patients with acute myocardial infarction. The use of a catheter aspiration device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 1.15 (0.82, 1.62)] compared to control (Figure 40). Both trials were determined to be of poor methodological quality. No controlled observational studies assessed for this endpoint in this population.

Figure 40. Impact of catheter aspiration devices versus control on TIMI-3 blood flow in patients with mixed acute coronary syndrome

Relative risk meta-analysis plot (random effects)

Mechanical thrombectomy devices in patients with STEMI. Four RCTs evaluated the impact of mechanical thrombectomy devices versus control on TIMI-3 blood flow. The use of a mechanical thrombectomy device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 0.98 (0.92, 1.04)] (Figure 41). A high level of statistical heterogeneity was found ($I^2=67.5$ percent) but publication bias was not detected (Egger’s $P=0.464$). All of the trials were determined to be of good methodological quality.

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and TIMI-3 blood flow. Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet® XMI or XVG catheter, were compared to patients...
undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was associated with a significantly lower rate of TIMI-3 blood flow compared to PCI without a mechanical thrombectomy device (86 percent versus 90 percent, p=0.04).

**Figure 41. Impact of mechanical thrombectomy devices versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction**

![Diagram showing impact of mechanical thrombectomy devices versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction.]

Cochran Q: P=0.026  
P: 67.5 percent  
Egger: P=0.464

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Mechanical Thrombectomy Devices in other ACS populations.** One RCT evaluated the impact of the mechanical thrombectomy device X-Sizer® versus control on TIMI-3 blood flow in patients with STEMI or UA. The use of a mechanical thrombectomy device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 1.07 (0.86, 1.36)] compared to control. This trial was determined to be of good methodological quality.

One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and TIMI-3 blood flow. The types of ACSs included in this study were not reported. Patients undergoing PCI with the mechanical thrombectomy device AngioJet® were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was associated with a significantly lower rate of TIMI-3 blood flow compared to PCI without a mechanical thrombectomy device (85 percent versus 93 percent, p=0.003). However, there were significantly more patients with TIMI-3 blood flow in the mechanical thrombectomy device group at baseline compared to the group without mechanical thrombectomy (15 percent versus 27 percent, p=0.001).
Distal Filter Embolic Protection Devices in patients with STEMI. Five RCTs evaluated the impact of distal filter embolic protection devices versus control on TIMI-3 blood flow. In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of attaining TIMI-3 blood flow [RR 1.00 (0.90, 1.11)] (Figure 42). A higher level of statistical heterogeneity was detected ($I^2=69.6$ percent) although publication bias was not detected (Egger’s $P=0.252$).

When limiting the pooled analysis to only trials of good methodological quality, the risk of attaining TIMI-3 blood flow remained nonsignificant in the distal filter embolic protection device group versus control [RR 1.02 (0.90, 1.15)]. A higher level of statistical heterogeneity was detected ($I^2=70.2$ percent).

No controlled observational studies assessed for this endpoint in this population.

Figure 42. Impact of distal filter embolic protection devices versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

- Ito, 2010: 1.17 (0.85, 1.73)
- Kelbaek, 2008: 1.11 (1.05, 1.17)
- Cura, 2007: 0.92 (0.77, 1.07)
- Guetta, 2007: 0.94 (0.80, 1.08)
- Lefevre, 2004: 0.94 (0.78, 1.11)
- Combined [random]: 1.00 (0.90, 1.11)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal filter embolic protection devices in other ACS populations. Three RCTs evaluated the impact of distal filter embolic protection devices versus control in patients with other ACSs on TIMI-3 blood flow although were not suitable for pooling because each trial evaluated a different ACS. In the first trial, the FilterWire EZ™ device was compared to control in patients with NSTEMI. The use of a distal filter embolic protection device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 0.99 (0.90, 1.09)]. In the second trial the Angioguard™ device was compared to control in patients with UA. The risk of attaining...
TIMI-3 blood flow could not be calculated because all patients in both groups attained TIMI-3 blood flow after the procedure. In the third trial, the FilterWire EX™ was compared to control in patients with either NSTEMI or STEMI. The risk of attaining TIMI-3 blood flow was not different between the distal filter embolic protection device group and control [RR 1.00 (0.92, 1.09)]. Of the three trials, this one trial was determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.

**Distal balloon embolic protection devices in patients with STEMI.** Nine RCTs evaluated the impact of distal balloon embolic protection devices versus control on TIMI-3. One study was excluded from the pooled analysis of relative risk because all patients in both groups achieved TIMI-3 blood flow with the same number of participants in each group. In the eight trials eligible for pooling, the use of a distal balloon embolic protection device significantly increased the risk of attaining TIMI-3 blood flow [RR 1.11 (1.03, 1.19)] (Figure 43). A higher level of statistical heterogeneity was found (I²=60.4 percent) but publication bias was not detected (Egger’s P=0.094). Using the risk difference [RD 0.08 (0.02, 0.14), (CER 0.69 to 1.00)], for every 13 patients who undergo surgery with a distal balloon embolic protection device 1 will achieve TIMI-3 blood flow. When limiting the analysis to trials of good methodological quality, the achievement of TIMI-3 blood flow remained significantly increased in the distal balloon embolic protection device group versus control [RR 1.09 (1.01, 1.17)]. Using the risk difference [RD 0.07 (0.01 to 0.13), (CER 0.75 to 0.96)] for every 15 patients who undergo surgery with a distal balloon embolic protection device one will achieve TIMI-3 blood flow.

No controlled observational studies assessed for this endpoint in this population.

**Figure 43. Impact of distal balloon embolic protection devices versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

Cochran Q: P=0.014
P: 60.4 percent
**Distal balloon embolic protection devices in other ACS populations.** Two RCTs evaluated the impact of distal balloon embolic protection devices versus control on TIMI-3 blood flow in patients with acute myocardial infarction.\(^{125,130}\) The use of a distal balloon embolic protection device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 1.36 (0.65, 2.86)] compared to control (Figure 44). Neither trial was determined to be of good methodological quality.

One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge versus abciximab therapy on TIMI-3 blood flow in patients with acute myocardial infarction.\(^{164}\) The use of a distal balloon embolic protection device did not significantly impact the risk of attaining TIMI-3 blood flow [RR 1.01 (0.87, 1.15)] versus abciximab therapy.

No controlled observational studies assessed for this endpoint in this population.

**Figure 44. Impact of distal balloon embolic protection devices versus control on TIMI-3 blood flow in patients with mixed acute coronary syndrome**

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**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of the proximal balloon embolic protection device Proxis\(^\text{TM}\) versus control on TIMI-3 blood flow.\(^{18}\) The use of a proximal balloon embolic protection device did not significantly
impact the risk of attaining TIMI-3 blood flow [RR 1.06 (0.98, 1.16)]. This trial was determined to be of good methodological quality.\textsuperscript{18}

\textbf{Proximal balloon embolic protection devices in other ACS populations.} No trials or studies assessed for this endpoint in this population.

\textit{Embolic protection devices combined in patients with STEMI.} Fifteen RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on TIMI-3 blood flow.\textsuperscript{17,18,89,95,98,101,103,107,111,112,119,133,135-137} The trial by Okamura et al was excluded from the pooled analysis of relative risk because no events occurred within the prespecified time period in either control or treatment group. In the trials 14 suitable for pooling, the use of embolic protection devices combined significantly increased the risk of attaining TIMI-3 blood flow [RR 1.06 (1.01, 1.12)] (Figure 45). Using the risk difference [RD 0.05 (0.01, 0.10), (CER 0.69 to 0.96)] 1 patient would attain TIMI-3 blood flow after surgery for every 25 patients who undergo surgery with an embolic protection device. A high level of statistical heterogeneity was detected ($I^2=58.3$ percent) but publication bias was not detected (Egger’s $P=0.811$).

When the pooled analysis was limited to only trials of good methodological quality,\textsuperscript{17,18,89,95,98,103,107,111,112,133,135,137} the risk of attaining TIMI-3 blood flow remained significantly increased in the combined embolic protection device group compared to control [RR 1.06 (1.01, 1.12)]. A higher level of statistical heterogeneity was detected ($I^2=55.4$ percent).
**Figure 45. Impact of embolic protection devices combined versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

Cochran Q: P=0.003
I²: 58.3 percent
Egger: P=0.811

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations.** Three RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control in patients with mixed ACS (acute myocardial infarction, not otherwise specified) on attaining TIMI-3 blood flow. The use of an embolic protection device did not significantly impact the risk of attaining TIMI-3 blood flow versus control [RR 1.15 (0.93, 1.41)] (Figure 46). One trial was determined to be of higher methodological quality, therefore sensitivity analysis was not possible based on trial quality.
Figure 46. Impact of embolic protection devices combined versus control on TIMI-3 blood flow in patients with mixed acute coronary syndrome

Cochran Q: P=0.001
I²: 85.5 percent
Egger: P=Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal Embolization

Direct Comparative Trials

No direct comparative trials evaluated the impact of catheter aspiration, mechanical thrombectomy or embolic protection devices on this endpoint.

Trials Versus Control

Catheter aspiration devices in patients with STEMI. Ten RCTs evaluated the impact of catheter aspiration devices versus control on distal embolization. The use of a catheter aspiration device significantly decreased the risk of distal embolization [RR 0.56 (0.39, 0.79)] (Figure 47). A lower level of statistical heterogeneity was found (I²=43.4 percent) but no publication bias was detected (Egger’s P=0.161). Given the risk difference [RD -0.09 (-0.17, -0.01), (CER 0.03 to 0.66)], 12 people would need to be treated with a catheter aspiration device to prevent one person from experiencing distal embolization.

When limiting the pooled analysis to only trials of good methodological quality, the risk of distal embolization remained significantly decreased in the catheter aspiration device group compared to control [RR 0.48 (0.34, 0.66)]. A lower level of statistical heterogeneity was detected (I²=33.7 percent). Given the risk difference [RD -0.14 (-0.23, -0.04), (CER 0.06 to 0.66)], seven people would need to be treated with a catheter aspiration device to prevent one person from experiencing distal embolization.
One controlled observational study evaluated the association between the use of catheter aspiration devices during PCI and distal embolization. The catheter aspiration devices included in this study were not reported. The use of a catheter aspiration device was associated with a significantly higher rate of distal embolization (9.0 percent versus 3.2 percent, p<0.0001).

**Figure 47. Impact of catheter aspiration devices versus control on distal embolization in patients with ST-segment elevation myocardial infarction**

Catheter aspiration devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

Mechanical thrombectomy devices in patients with STEMI. Three RCTs evaluated the impact of mechanical thrombectomy devices versus control on distal embolization. The use of a mechanical thrombectomy device did not significantly impact the risk of distal embolization [RR 0.44 (0.17, 1.12)] (Figure 48). A lower level of statistical heterogeneity was found (I²=41.6 percent) and publication bias could not be evaluated. All of the trials were determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.
**Figure 48. Impact of mechanical thrombectomy devices versus control on distal embolization in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

Cochran: P=0.181  
I²: 41.6 percent  
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Mechanical thrombectomy devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Distal filter embolic protection devices in patients with STEMI.** One RCT evaluated the impact of a distal filter embolic protection device versus control on distal embolization.\(^95\) In this trial, the use of a distal filter embolic protection device did not significantly impact the risk of distal embolization [RR 0.63 (0.22, 1.73)]. This trial was determined to be of good quality.\(^95\) No controlled observational studies assessed for this endpoint in this population.

**Distal filter embolic protection devices in other ACS populations.** One RCT evaluated the impact of the distal filter embolic protection device FilterWire EX\(^{TM}\) versus control on distal embolization in patients with either NSTEMI or STEMI.\(^{126}\) The use of a distal filter embolic protection device did not significantly impact the risk of distal embolization [RR 0.38 (0.11, 1.26)] compared to control. This trial was determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.

**Distal balloon embolic protection devices in patients with STEMI.** Four RCTs evaluated the impact of distal balloon embolic protection devices versus control on distal embolization.\(^{103,107,112,133}\) The use of a distal balloon embolic protection device did not
significantly impact the risk of distal embolization [RR 1.10 (0.67, 1.81)] (Figure 49). A lower level of statistical heterogeneity was found ($I^2 = 5.8$ percent) and publication bias was not detected (Egger’s $P=0.176$). All of the trials were determined to be of good methodological quality$^{103,107,112,133}$ did not change the results.

No controlled observational studies assessed for this endpoint in this population.

**Figure 49. Impact of distal balloon embolic protection devices versus control on distal embolization in patients with ST-segment elevation myocardial infarction**

**Distal balloon embolic protection devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.

**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of the proximal balloon embolic protection device Proxis$^\text{TM}$ versus control on distal embolization.$^{18}$ The use of a proximal balloon embolic protection device did not significantly impact the risk of having distal embolization [RR 0.71 (0.37, 1.35)]. This single trial was determined to be of good quality.$^{18}$

No controlled observational studies assessed for this endpoint in this population.

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies assessed for this endpoint in this population.
**Embolic protection devices combined in patients with STEMI.** Six RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on distal embolization.\(^{18,95,103,107,112,133}\) In these trials, the use of embolic protection devices combined did not significantly impact the risk of distal embolization [RR 0.91 (0.64, 1.30)] (Figure 50). A low level of statistical heterogeneity was detected ($I^2=0.2$ percent) but publication bias was not detected (Egger’s $P=0.409$). All of the trials were determined to be of good methodological quality.

**Figure 50. Impact of embolic protection devices combined versus control on distal embolization in patients with ST-segment elevation myocardial infarction**

![Relative risk meta-analysis plot (random effects)](image)

- Haeck, 2009: $0.71 (0.38, 1.33)$
- Cura, 2007: $0.63 (0.22, 1.73)$
- Hahn, 2007: $0.70 (0.24, 1.99)$
- Matsuo, 2007: $1.16 (0.35, 3.86)$
- Muramatsu, 2007: $0.55 (0.18, 1.74)$
- Stone, 2005: $1.60 (0.85, 3.03)$
- Combined [random]: $0.91 (0.64, 1.30)$

Cochran Q: $P=0.415$

$F$: 0.2 percent

Egger: $P=0.409$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations.** No trials or studies were available that evaluated the impact of any embolic protection device versus control on distal embolization in addition to the one trial reported above, and therefore pooling was not possible.

**Direct Comparative Trials**

**Catheter aspiration device versus distal balloon protection device in STEMI.** One direct comparative randomized trial evaluated the impact of the Diver\textsuperscript{TM} CE catheter aspiration device
versus the Guardwire™ Plus distal balloon embolic protection device on no reflow. In this study, a composite of no reflow / slow reflow was reported. The use of Diver™ CE did not significantly impact the risk of no reflow / slow reflow [RR 1.25 (0.38, 4.14)] compared to Guardwire™ Plus.

**Trials Versus Control**

*Catheter aspiration devices in patients with STEMI.* Eight RCTs evaluated the impact of catheter aspiration devices versus control on no reflow. The use of a catheter aspiration device significantly decreased the risk of no reflow [RR 0.52 (0.35, 0.76)] (Figure 51). A low level of statistical heterogeneity was found (I²=15.7 percent) but no publication bias was detected (Egger’s P=0.278). Given the risk difference [RD -0.07 (-0.11, -0.03), (CER 0.05 to 0.27)], 15 people would need to be treated with a catheter aspiration device in order to prevent one no reflow event from occurring.

When limiting the pooled analysis to only trials of good methodological quality, the risk of having no reflow remained significantly decreased in the catheter aspiration device group compared to control [RR 0.45 (0.27, 0.75)]. A lower level of statistical heterogeneity was detected (I²=22.3 percent). Given the risk difference [RD -0.08 (-0.12, -0.05), (CER 0.10 to 0.19)], thirteen people would have to be treated with a catheter aspiration device to prevent one no reflow event from occurring.

No controlled observational studies assessed for this endpoint in this population.

*Figure 51. Impact of catheter aspiration devices versus control on no reflow in patients with ST-segment elevation myocardial infarction*

![Relative risk meta-analysis plot (random effects)](image-url)

- **Dudek, 2010:** 0.58 (0.28, 1.17)
- **Liistro, 2009:** 0.20 (0.05, 0.78)
- **Chevalier, 2008:** 0.33 (0.12, 0.93)
- **Ikari, 2008:** 0.64 (0.39, 1.05)
- **Lee, 2006:** 1.64 (0.45, 6.04)
- **Silva-Orrego, 2006:** 0.18 (0.05, 0.70)
- **Burzotta, 2005:** 0.68 (0.22, 2.11)
- **Noel, 2005:** 0.31 (0.08, 1.16)
- **combined [random]:** 0.52 (0.35, 0.76)

*Cochran Q: P=0.307
P: 15.7 percent
Egger: P=0.278*
**Legend:** The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

*Catheter aspiration devices in other ACS populations.* No trials or studies assessed for this endpoint in this population.

*Mechanical thrombectomy devices in patients with STEMI.* Three RCTs evaluated the impact of mechanical thrombectomy devices versus control on no reflow.\(^{29,40,44}\) The use of a mechanical thrombectomy device did not significantly impact the risk of no reflow \([RR 0.50 (0.17, 1.48)]\) (Figure 52). A lower level of statistical heterogeneity was found \(I^2 = 41.7\) percent. All of the trials were determined to be of good methodological quality.\(^{29,40,44}\)

No controlled observational studies assessed for this endpoint in this population.

**Figure 52. Impact of mechanical thrombectomy devices versus control on no reflow in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Ali, 2006**
  
  \(1.21 (0.40, 3.67)\)

- **Letèvre, 2005**
  
  \(0.31 (0.09, 1.00)\)

- **Napodano, 2003**
  
  \(0.20 (0.03, 1.23)\)

- **combined [random]**
  
  \(0.50 (0.17, 1.48)\)

Cochran Q: P=0.180

I²: 41.7 percent

Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

*Mechanical thrombectomy devices in other ACS populations.* No RCTs or controlled observational studies assessed for this endpoint in this population.

*Distal filter embolic protection devices in patients with STEMI.* Two RCTs evaluated the impact of distal filter embolic protection devices versus control on no reflow.\(^{95,101}\) In these trials, the use of distal filter embolic protection devices did not significantly impact the risk of having no reflow \([RR 0.59 (0.14, 2.51)]\) (Figure 53). Only one of these trials was determined to be of
good methodological quality. In that trial there was no difference in the risk of no reflow with the use of a distal filter embolic protection device versus control [RR 1.00 (0.18, 5.55)].

No controlled observational studies assessed for this endpoint in this population.

**Figure 53. Impact of distal filter embolic protection devices versus control on no reflow in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

![Relative risk meta-analysis plot](image)

Cochran Q: P=0.409
F: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal filter embolic protection devices in other ACS populations.** One RCT evaluated the impact of distal filter embolic protection devices on no reflow in patients with NSTEMI or UA. In this trial, the Angioguard™ device was compared to control. The risk of no reflow could not be calculated because no events occurred in either group.

No controlled observational studies assessed for this endpoint in this population.

**Distal balloon embolic protection devices in patients with STEMI.** Four RCTs evaluated the impact of distal balloon embolic protection devices versus control on no reflow. The use of a distal balloon embolic protection device did not significantly impact the risk of no reflow [RR 0.51 (0.19, 1.33)] (Figure 54). Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.880$). All of the trials were determined to be of good methodological quality.
Figure 54. Impact of distal balloon embolic protection devices versus control on no reflow in patients with ST-segment elevation myocardial infarction

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Distal balloon embolic protection devices in other ACS populations. One RCT evaluated the impact of the distal balloon embolic protection device PercuSurge GuardWire™ Plus Temporary Occlusion and Aspiration System versus control on no reflow in patients with acute myocardial infarction.\(^{125}\) The use of a distal balloon embolic protection device significantly decreased the risk of no reflow compared to control [RR 0.36 (0.20, 0.59)]. Given the risk difference for no reflow [RD -0.54 (-0.71, -0.31), CER 0.02 to 0.05]), two people would need to be treated with a distal balloon embolic protection device to prevent one person from experiencing no reflow. This trial was determined to be of good methodological quality.

No controlled observational studies assessed for this endpoint in this population.

Proximal balloon embolic protection devices in patients with STEMI. No trials or studies evaluated the impact of proximal balloon embolic protection devices on this endpoint.

Proximal balloon embolic protection devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

Embolic protection devices combined in patients with STEMI. Six RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on no reflow.\(^{95,101,103,107,112,133}\) In these trials, the use of embolic protection devices combined did not
significantly decreased the risk of having no reflow [RR 0.53 (0.24, 1.18)] (Figure 55). Statistical heterogeneity and publication bias were not detected ($I^2=0$ percent, Egger’s $P=0.969$). When limiting the analysis to only trials of good methodological quality$^{95,103,107,112,133}$ the risk of no reflow remain nonsignificant in the embolic protection devices combined group versus control [(RR 0.58 (0.25, 1.37)]]. No statistical heterogeneity was found ($I^2=0$ percent).

**Figure 55. Impact of embolic protection devices combined versus control on no reflow in patients with ST-segment elevation myocardial infarction**

Cochran Q: $P=0.603$

$I^2$: 0 percent

Egger: $P=0.969$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations**. No trials or studies were available that evaluated the impact of any embolic protection device versus control on no reflow in this population in addition to the two trials reported above. Pooling was not suitable because the trials evaluated different ACS.

**Table 21. Intermediate health outcomes in randomized controlled trials evaluating catheter aspiration devices in patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.61 (1.41 to 1.84)</td>
<td>55.4%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.08 (1.04 to 1.12)</td>
<td>11.5%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.56 (0.39 to 0.79)</td>
<td>43.4%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.52 (0.35 to 0.76)</td>
<td>15.7%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.51 (1.32 to 1.73)</td>
<td>64.2%</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>
Table 22. Intermediate health outcomes in randomized controlled trials evaluating mechanical thrombectomy devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.07 (0.80 to 1.43)</td>
<td>76.5%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>0.98 (0.92 to 1.04)</td>
<td>67.5%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.44 (0.17 to 1.12)</td>
<td>41.6%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.50 (0.17 to 1.48)</td>
<td>41.7%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.16 (0.99 to 1.36)</td>
<td>75.1%</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Table 23. Intermediate health outcomes in randomized controlled trials evaluating distal filter embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>0.97 (0.81 to 1.15)</td>
<td>NA</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.00 (0.90 to 1.11)</td>
<td>69.6%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.63 (0.22 to 1.82)*</td>
<td>NA</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.59 (0.14 to 2.51)</td>
<td>NA</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.05 (0.97 to 1.15)</td>
<td>0%</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Table 24. Intermediate health outcomes in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.39 (1.15 to 1.69)</td>
<td>43.5%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.11 (1.03 to 1.19)</td>
<td>60.4%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>1.10 (0.67 to 1.81)</td>
<td>5.8%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.51 (0.19 to 1.33)</td>
<td>0%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.08 (0.91 to 1.29)</td>
<td>41.2%</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Table 25. Intermediate health outcomes in randomized controlled trials evaluating proximal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>0.98 (0.88 to 1.10)*</td>
<td>NA</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.06 (0.98 to 1.15)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.71 (0.37 to 1.35)*</td>
<td>NA</td>
</tr>
<tr>
<td>No reflow</td>
<td>---†</td>
<td>---†</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.11 (0.97 to 1.28)*</td>
<td>NA</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Result is based on a single trial; † Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; HRQOL=health-related quality of life; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction
Table 26. Intermediate health outcomes in randomized controlled trials evaluating embolic protection devices combined in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.20 (1.02 to 1.40)</td>
<td>68.2%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.06 (1.01 to 1.12)</td>
<td>58.3%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.91 (0.64 to 1.30)</td>
<td>0.2%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.53 (0.24 to 1.18)</td>
<td>0%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.06 (1.00 to 1.13)</td>
<td>0%</td>
</tr>
<tr>
<td>HRQOL</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; HRQOL=health-related quality of life; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Discussion

While there were a number of controlled trials where patients undergoing PCI were treated with a thrombectomy or embolic protection device plus standard of care therapy or standard of care therapy alone, the duration of followup, the time points at which they evaluated events and the number of times they evaluated events also varied considerably between trials. For our base case analysis, we used the maximum duration of followup to allow the pooling of a greater number of individual studies. However, we also evaluated for the shortest duration of followup within a trial and at several durational ranges specified a priori. As such, we sought to determine if the effects seen during the maximal duration of followup was representative of the results derived using other time frames. Although several systematic reviews have conducted meta-analysis in the past, the majority are limited to patients with STEMI and did not evaluate adjunctive devices in other ACS and the most recent analyses did not evaluate embolic protection devices. Therefore, applicability of those results to contemporary practice is limited.

Final health outcomes in patients with STEMI. In patients with STEMI, the impact of catheter aspiration devices was directly compared to distal balloon embolic protection devices on final health outcomes in only one direct comparative RCT. In this trial, no significant differences in mortality, myocardial infarction, stroke, target revascularization, or MACE were found at the longest duration of followup. Given limited direct comparative trial data, the superiority of one device over another cannot be directly determined.

In patients with STEMI, the use of catheter aspiration devices significantly reduced the occurrence of MACE versus standard of care by 27 percent using the maximum duration of followup (12.43 months). To prevent one major adverse cardiovascular events, 33 patients would need to be treated with a catheter aspiration device. Using other time cut-offs, the directionality of effect for MACE was similar but statistical significance was only maintained at the 180-days evaluation (studies reporting MACE outcomes from in-hospital to 365 days after the procedure). When we assessed individual components of MACE (mortality, myocardial infarction, or target revascularization) using the maximal duration of followup, no significant reductions were found and limiting the pooled analyses to trials of good quality did not impact the significance of results. When other time periods were assessed, mortality was significantly reduced by 38 percent at the 365-days, target revascularization was significantly reduced by 38 percent at 180-days, and MACE was significantly reduced by 34 percent at 180-days. While there was a significant reduction in MACE with catheter aspiration devices versus control, there is a nonsignificant three-fold increase in the risk of developing stroke using the maximum duration
of followup (0.79 months). The direction of effect suggests an increased risk of stroke with catheter aspiration devices regardless of the time point chosen.

In patients with STEMI, the use of mechanical thrombectomy devices did not significantly impact the risk of mortality, myocardial infarction, stroke, target revascularization or MACE at the maximal duration of followup although a higher level of statistical heterogeneity was found in the mortality, target revascularization, and MACE analyses. Like with the catheter aspiration analyses at various time periods, a significant reduction in the risk of 365-day MACE and 180-day target revascularization was found with mechanical aspiration device use versus control. All of the trials included in the pooled analyses were determined to be of higher methodological quality therefore sensitivity analyses based on trial methodological quality did not reduce the observed heterogeneity or impact the overall results. When evaluating each final health outcome by individual time point; statistical heterogeneity could not longer be evaluated in most cases because too few studies were left to evaluate. Therefore it is difficult to say whether the inclusion of various time points in the pooled analysis of final health outcomes contributed to the higher level of statistical heterogeneity when evaluating mechanical thrombectomy devices.

Given this data, we could not make any determinations as to whether catheter aspiration or mechanical thrombectomy are superior strategies versus standard of care or whether one type of device is superior to another.

In patients with STEMI, the use of distal filter, distal balloon, proximal balloon or embolic protection devices combined (distal or proximal; filter or balloon) did not significantly impact the risk of mortality, myocardial infarction, stroke, or MACE at the maximal duration of followup versus control. The risk of target revascularization was significantly increased with the use of distal filter embolic protection devices or embolic protection devices combined versus control using the maximal duration of followup, although this was not seen with the other embolic protection device classes. Pooled analyses of final health outcomes at individual time points were limited within the distal filter and balloon embolic protection device categories because of the few number of trials reporting these outcomes and the rare occurrence of events in the trials which did report results. Therefore, the majority of individual time points could not be evaluated in these device categories or risk was based on a single trial. No significant findings were observed, with few exceptions. Distal filter embolic protection devices and any embolic protection device significantly increased the risk of target revascularization at 365 days (1 trial each) and of MACE at 365 days (1 trial each) versus control. A significant reduction in the risk of 30 day stroke was seen when distal balloon embolic protection devices were compared to control. Pooling of results for proximal balloon embolic protection devices was not possible since only one trial was available with reported outcomes. Final health outcomes were reported at 30 and 180 days were nonsignificant for all analyses. Within any embolic protection device category (distal or proximal; filter or balloon), limiting the pooled analyses to trials determined to be of higher methodological quality did not change the direction or significance of the results pertaining to any of the final health outcomes.

Given this data, we could not make any determinations as to whether one embolic protection device category is a superior strategy versus standard of care or whether one type of device is superior to another, or to catheter aspiration or mechanical thrombectomy devices.

**Final health outcomes in patients with other ACSs.** In patients with mixed ACS (STEMI, NSTEMI, or UA) trials were identified evaluating the impact of four device categories (catheter aspiration, mechanical thrombectomy, distal filter and distal balloon embolic protection devices)
on final health outcomes. Overall data was very limited and only trials evaluating distal balloon and embolic protection devices combined were amenable to pooling. Additionally, the range of time points at which final health outcomes were reported made comparison across device categories difficult. No significant differences were found between any of the device categories and control on all of the final health outcomes. Overall, making comparisons across device categories or within device categories comparing various time points for a single outcome is difficult given the limited number of trials and studies in patients with mixed ACS.

In patients with NSTEMI or UA a limited number of studies which evaluated thrombectomy or embolic protections devices were identified. Two RCTs which evaluated the impact distal filter embolic protection devices versus control on final health outcomes using the maximal duration of followup were identified although were not amenable to pooling. Of the five final health outcomes, MACE and mortality were reported with results which could be evaluated, although no significant difference between the distal filter embolic protection devices and control were found. No other studies or trials were found in this patient population for the other device categories.

**Intermediate health outcomes.** In patients with STEMI, the impact of catheter aspiration devices was directly compared to distal balloon embolic protection devices on intermediate health outcomes in a single direct comparative RCT. In this trial, none of the intermediate health outcomes reached statistical significance. No other trials or studies were found to directly compare device categories on their impact on final health outcomes.

In patients with STEMI, the use of a catheter aspiration device significantly improved intermediate health outcomes, including resolution of ST-segment elevation, achievement of MBG-3 and TIMI-3 blood flow, and reduction in distal embolization and no reflow. However, the use of a catheter aspiration device does not appear to significantly impact ejection fraction versus control. Although not amenable to pooling, the majority of trials which evaluated ejection fraction showed no significant differences (9 of the 11 trials) and these trials evaluated ejection fraction within a wide range of time points including immediately postPCI up to 6 months postPCI. The use of mechanical thrombectomy devices did not significantly impact any of the intermediate health outcomes. In a controlled observational study, the use of a mechanical thrombectomy device significantly decreased the rate of TIMI-3 blood flow versus control. Although not amenable to pooling, in the two trials which evaluated the impact of mechanical thrombectomy devices on ejection fraction versus control, no significant differences were seen. Overall, it appears that the use of catheter aspiration devices more favorably impacts intermediate health outcomes than the use of mechanical thrombectomy devices, although this is based on indirect comparisons.

Distal filter embolic protection devices, distal balloon embolic protection devices, and embolic protection devices combined did not have significant impact on most intermediate health outcomes versus control. A single trial evaluating the impact of proximal balloon embolic protection devices versus control was identified therefore pooling was not possible. The significant findings included the impact of distal balloon and embolic protection devices combined both significantly increasing the risk of achieving a MBG-3 and TIMI-3 blood flow. In the evaluation of ejection fraction, data was not amenable to pooling. The impact of distal balloon and distal filter embolic protection device on ejection fraction versus control was reported, although only one trial evaluating distal balloon embolic protection devices found a significantly higher ejection fraction versus control at 90 and 180 days.
In patients with mixed ACS (STEMI, NSTEMI, or UA) RCTs sparsely reported intermediate health outcomes comparing thrombectomy or embolic protection devices versus control and most data was not amenable to pooling. One RCT demonstrated a significant increase in the risk of resolving ST-segment resolution with the use of mechanical thrombectomy devices versus control. No other trials evaluated any device categories on ST-segment resolution. Mixed results were observed in the evaluation of the risk of attaining TIMI-3 blood flow. Pooled results evaluating the impact of catheter aspiration devices, distal balloon embolic protection devices, or embolic protection devices combined did not show a significant difference versus control. Both in the evaluation of catheter aspiration devices and distal balloon embolic protection devices, a significant increase in the risk of attaining MBG-3 was seen, although only the analysis of distal balloon embolic protection devices was based on a pooled analysis. A significant reduction in the risk of no reflow in the distal balloon embolic protection device versus control was noted. One trial reported the impact of distal filter embolic protection devices on ejection fraction at 3 days versus control, and no significant change was seen.

In patients with NSTEMI or UA, limited data was available regarding the impact of thrombectomy or embolic protection devices versus control on intermediate health outcomes. The use of distal filter embolic protection devices did not significantly impact the risk of attaining TIMI-3 blood flow. No other trials or studies evaluated other device categories or other intermediate health outcomes, therefore the impact of thrombectomy or embolic protection devices versus control on intermediate health outcomes in this population is difficult to evaluate.

**Key Question 2**
In patients with ACS who are undergoing PCI of native vessels, how does the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

**Key Points**
Twenty three RCTs and two controlled observational studies were included.

**Direct Comparative Trials in ACS Patients Assessing Adverse Outcomes**
- Two direct comparative randomized trials in patients with STEMI undergoing PCI evaluated adverse outcomes.
  - One direct comparative randomized trial compared a catheter aspiration device to another catheter aspiration device. In this trial, the use of one catheter aspiration device versus another did not significantly impact the risk of coronary dissection. No patients experienced coronary perforation in either group.
  - One direct comparative randomized trial compared a catheter aspiration device to a distal balloon embolic protection device. In this trial, the use of a catheter aspiration device did not impact procedure time compared to a distal balloon embolic protection device.
  - No direct comparative trials evaluated side branch occlusion.
RCTs / Controlled Observational Studies in Patients with STEMI Assessing Adverse Outcomes

- Twenty RCTs and three controlled observational studies evaluated patients with STEMI undergoing PCI and compared a thrombectomy or embolic protection device versus control. Four adverse events (coronary dissection, coronary perforation, prolonged procedure time, and side branch occlusion) were evaluated.
  - In RCTs eligible for pooling, the use of catheter aspiration devices versus control significantly reduced the risk of coronary dissection and did not significantly impact the risk of side branch occlusion. In the one trial in which coronary perforation was assessed, no events occurred in either group. Nine trials evaluated procedure time although were ineligible for pooling. In eight of the nine trials the use of catheter aspiration devices versus control did not significantly prolong procedure time. One controlled observational study found no significant difference in procedure time between catheter aspiration and control.
    - When limited to good quality trials, catheter aspiration device use still reduced the risk of coronary dissection with nonsignificant effects on the other aforementioned adverse events.
    - One controlled observational study found no significant impact of catheter aspiration devices on the risk of coronary dissection versus control.
  - In RCTs, the use of mechanical thrombectomy devices versus control did not significantly impact the risk of coronary dissection, coronary perforation, or side branch occlusion. Three trials evaluated the impact of mechanical thrombectomy devices versus control on procedure time although were ineligible for pooling. In all three trials the procedure time was significantly prolonged in the mechanical thrombectomy device group versus control.
    - When limited to good quality trials, significant increases in procedural time and nonsignificant effects on the risk of coronary dissection, coronary perforation, or side branch occlusion occurred.
    - One controlled observational study found no significant impact of mechanical thrombectomy devices on the risk of coronary perfusion versus control.
  - In RCTs, the use of distal filter embolic protection devices versus control did not significantly impact the risk of side branch occlusion. No coronary dissections and coronary perforations occurred in either group in the one trial reporting these outcomes. Use of a distal filter embolic protection device increased the procedure time versus control in the one trial evaluating this outcome.
    - Limiting to good quality trials yielded the same results.
    - No controlled observational studies were available.
  - In RCTs, the use of distal balloon embolic protection devices versus control did not significantly impact the risk of coronary perforation or side branch occlusion. One trial evaluated the impact of distal balloon embolic protection devices versus control on coronary dissection although no events occurred in either group. Three trials evaluated the impact of distal balloon embolic protection devices versus control on procedure time although were not amenable to pooling. In two of the three trials, procedure time was significantly prolonged with the use of a distal balloon embolic protection device versus control.
    - Limiting to good quality trials yielded the same results.
- No controlled observational studies were available.
  o In a RCT, the use of a proximal balloon embolic protection device versus control significantly prolonged procedure time. No other trials or studies evaluated the impact of proximal balloon embolic protection devices versus control on adverse events of interest.
  - Limiting to good quality trials yielded the same results.
  - No controlled observational studies were available.
- In RCTs eligible for pooling, the use of an embolic protection device (distal or proximal; filter or balloon) did not significantly impact the risk of side branch occlusion. In a single trial, the use of an embolic protection device did not significantly impact the risk of coronary perforation versus control. The risk of coronary dissection could not be calculated in the single trial which reported this outcome. Five RCTs evaluated the impact of an embolic protection device on procedure time although were ineligible for pooling. In four of the five trials procedure time was significantly prolonged with the use of an embolic protection device versus control.

**RCTs / Controlled Observational Studies in Mixed or Other ACS Populations Assessing Adverse Outcomes**

- One RCT evaluated patients with mixed ACS (STEMI, NSTEMI, or UA) undergoing PCI and comparing thrombectomy or embolic protection devices versus control on adverse events.
  o In a RCT, the use of a distal balloon embolic protection device versus control significantly prolonged the procedure time.
  o No other trials or studies evaluated other device categories or adverse events.
- No trials or studies evaluating patients with NSTEMI or UA undergoing PCI and comparing catheter aspiration, mechanical thrombectomy, or embolic protection devices versus control on adverse events were identified.

**Detailed Analysis**

**Study Design and Population Characteristics**

The study design and population characteristic have been previously described in key question one. Although several systematic reviews have conducted meta-analyses in the past, the majority are limited to patients with STEMI and did not evaluate adjunctive devices in other ACS, only two were identified to evaluate adverse events limited to procedure time and coronary perforation, and the most recent analyses did not evaluate embolic protection devices. Therefore, applicability of those results to contemporary practice is limited.

Specific to key question two, we present direct comparative data between agents first and subsequently present the comparisons of each type of device versus control for each endpoint.

**Outcome Evaluation**

A summary of the results for adverse events comparing each device category to control can be found in Table 27 to Table 32.
Coronary Dissection

Direct Comparative Trials

*Catheter aspiration device versus catheter aspiration device in patients with STEMI.* One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on coronary dissection. In this trial, the use of Diver™-Invatec did not significantly impact the risk of coronary dissection [RR 0.33 (0.00, 3.71)] compared to Export®-Medtronic. This trial was determined to be of good methodological quality.

Trials Versus Control

*Catheter aspiration devices in patients with STEMI.* Five RCTs evaluated the impact of catheter aspiration devices on coronary dissection versus control. The use of catheter aspiration devices significantly decreased the risk of coronary dissection [RR 0.30 (0.12, 0.75)] (Figure 56). No statistical heterogeneity or publication bias was found ($I^2=0$ percent, Egger’s $P=0.626$). All of the trials were determined to be of good methodological quality. Given the risk difference [RD -0.02 (-0.12, 0.10), (CER 0.0 to 0.1)], 50 people would need to be treated with a catheter aspiration device to prevent one person from experiencing a coronary dissection.

One controlled observational study evaluated the association between the use of catheter aspiration devices during PCI and coronary dissection versus control. The names of the catheter aspiration devices included in this study were not reported. The use of a catheter aspiration device during PCI was not associated with a significantly different rate of coronary dissection compared to PCI without the use of a catheter aspiration device (6.6 percent versus 5.3 percent, $p=0.32$).
Figure 56. Impact of catheter aspiration devices on coronary dissection versus control in patients with ST-segment elevation myocardial infarction

Catheter aspiration devices in other ACS populations. No trials or studies evaluated the impact of catheter aspiration devices on this outcome.

Mechanical thrombectomy devices in patients with STEMI. One RCT evaluated the impact of a mechanical thrombectomy device on coronary dissection versus control. The use of a mechanical thrombectomy device did not significantly impact the risk of coronary dissection [RR 1.51 (0.57, 4.01)]. This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

Mechanical thrombectomy devices in other ACS populations. No trials or studies evaluated the impact of mechanical thrombectomy devices on this outcome.

Distal filter embolic protection devices in patients with STEMI. One RCT evaluated the impact of distal filter embolic protection devices on coronary dissection versus control. The risk of coronary dissection could not be calculated because no events occurred in either control or treatment group. This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.
**Distal filter embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal filter embolic protection devices on this outcome.

**Distal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of distal balloon embolic protection devices on coronary dissection versus control. The risk of coronary dissection could not be calculated because no events occurred in either control or treatment group. This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

**Distal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in patients with STEMI.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Embolic protection devices combined in patients with STEMI.** Two RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on coronary dissection versus control. In these two trials, the risk could not be calculated because no events occurred in either control or treatment group. Both trials were determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

**Embolic protection devices combined in other ACS populations.** No trials or studies evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on this outcome.

**Coronary Perforation**

**Direct Comparative Trials**

**Catheter aspiration devices versus catheter aspiration device in patients with STEMI.** One direct comparative randomized trial evaluated the impact of the Diver™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on coronary perforation. The risk of coronary perforation could not be calculated because no events occurred in either group during this trial. This trial was determined to be of good methodological quality.

**Trials Versus Control**

**Catheter aspiration devices in patients with STEMI.** One RCT evaluated the impact of using a catheter aspiration device on coronary perforation versus control. The risk of coronary
perforation could not be calculated because no events occurred in either control or treatment group.

No controlled observational studies evaluated this endpoint in this population.

**Catheter aspiration devices in other ACS populations.** No trials or studies evaluated the impact of catheter aspiration devices on this outcome.

**Mechanical thrombectomy devices in patients with STEMI.** Two RCTs evaluated the impact of mechanical thrombectomy devices on coronary perforation versus control.\textsuperscript{11,40} The use of mechanical thrombectomy devices did not significantly impact the risk of coronary perforation [RR 1.04 (0.15, 7.04)] (Figure 57). Publication bias could not be evaluated since only two studies were available. Both trials were determined to be of good methodological quality.\textsuperscript{11,40}

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and coronary perforation versus control.\textsuperscript{145} Patients undergoing PCI with a mechanical thrombectomy device, either the AngioJet\textsuperscript{®} XMI or XVG catheter, were compared to patients undergoing PCI without mechanical thrombectomy. The use of a mechanical thrombectomy device was not associated with a significant difference in the rate of coronary perforation compared to PCI without a mechanical thrombectomy device (0.0 percent versus 0.2 percent, \(p>0.99\)).

**Figure 57. Impact of mechanical thrombectomy devices on coronary perforation versus control in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Migliorini, 2010**
  - Relative risk: 0.32 (0.00, 3.67)

- **Ali, 2006**
  - Relative risk: 2.01 (0.26, 15.27)

combined [random]
  - Relative risk: 1.04 (0.15, 7.04)

Cochran Q: \(P=0.366\)

F: Too few strata

Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
**Mechanical thrombectomy devices in other ACS populations.** No trials or studies evaluated the impact of mechanical thrombectomy devices on this outcome.

**Distal filter embolic protection devices in patients with STEMI.** One RCT evaluated the impact of a distal filter embolic protection device on coronary perforation versus control.\(^95\) The risk of coronary perforation could not be calculated because no events occurred in either control or treatment group.

No controlled observational studies evaluated this endpoint in this population.

**Distal filter embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal filter embolic protection devices on this outcome.

**Distal balloon embolic protection devices in patients with STEMI.** Two RCTs evaluated the impact of distal balloon embolic protection devices on coronary perforation versus control.\(^111,112\) In one trial no events occurred in either the control or treatment group.\(^111\) In the other trial the use of a distal balloon embolic protection device did not significantly impact the risk of coronary perforation [RR 5.11 (0.53, infinity)]. Publication bias could not be calculated. Both trials were determined to be of good methodological quality.\(^111,112\)

No controlled observational studies evaluated this endpoint in this population.

**Distal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in patients with STEMI.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Embolic protection devices combined in patients with STEMI.** Three RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on coronary perforation versus control.\(^95,111,112\) In two trials no events occurred in either control or treatment group.\(^95,111\) In another trial,\(^112\) the use of an embolic protection device did not significantly impact the risk of coronary perforation [RR 5.11 (0.53, infinity)]. All of the trials were determined to be of good methodological quality.\(^95,111,112\)

No controlled observational studies evaluated this endpoint in this population.

**Embolic protection devices combined in other ACS populations.** No trials or studies evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on this outcome.
Prolonged Procedure Time

Direct Comparative Trials

*Catheter aspiration device versus catheter aspiration device in patients with STEMI*. One direct comparative randomized trial evaluated the impact of the Diver™ CE catheter aspiration device versus the Guardwire™ Plus distal balloon embolic protection device on procedure time. In this trial, there was no significant difference in procedure time between the Diver™ CE and Guardwire™ Plus groups (60 min ±24 versus 65 min ±28, p=0.36). This trial was determined to be of good methodological quality.

Trials Versus Control

*Catheter aspiration devices in patients with STEMI*. Nine RCTs evaluated the impact of catheter aspiration devices on procedure time versus control but were not amenable to pooling. In the first trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (75.7±33.0 min versus 75.9±38.7 min, p=0.90). In the second trial, patients were only included in the trial if they achieved a TIMI-3 blood flow postprocedure. The mean procedure time was not significantly different between the catheter aspiration device group and control (39.5±10.1 min versus 32.3±18.6 min, p=0.14). In the third trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (36.7±18.0 min versus 34.5±21.5 min, p=0.08). In the fourth trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (87.0±32.4 min versus 93.6±78.6 min, p=0.16). In the fifth trial, the median procedural time was not significantly different between the catheter aspiration device group and control [28 min (14-42) versus 26 min (12-40), p=0.92]. In the sixth trial, procedure time (defined as lab to TIMI-3 blood flow time) was not significantly different between the catheter aspiration device group and control (49±18 min versus 53±23 min, p=0.54). In the seventh trial, the median procedural time was significantly prolonged in the catheter aspiration device group compared to control [39 minutes (29-48) versus 29 minutes (23-38), p=0.0001]. In the eighth trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (57±19 minutes versus 54±21 minutes, p=0.36). In the final trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (81±34 minutes versus 72±34 minutes, p=0.41). All included trials were determined to be of good methodological quality.

One controlled observational study evaluated the impact of catheter aspiration versus control on procedure time. In this study, the use of a catheter aspiration device was not associated with a prolonged procedure time versus control (41.2 minutes versus 36.5 minutes, p=0.12).

*Catheter aspiration devices in other ACS populations*. No trials or studies evaluated the impact of mechanical thrombectomy devices on this outcome.

*Mechanical thrombectomy devices in patients with STEMI*. Three RCTs evaluated the impact of mechanical thrombectomy devices on procedure time versus control although were not amenable to pooling. In the first trial, the median procedure time was significantly
prolonged in the mechanical thrombectomy device group compared to control [59.5 minutes (45-70) versus 46 minutes (35-60), p<0.001]. In the second trial, the mean procedure time was significantly prolonged in the mechanical thrombectomy device group compared to control (75.4±30.9 minutes versus 59.2±26.8 minutes), p<0.001. In the third trial, the mean procedure time was significantly prolonged in the mechanical thrombectomy device group compared to control (54±28 minutes versus 45±25 minutes, p=0.009). All three trials were determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

Mechanical thrombectomy devices in other ACS populations. No trials or studies evaluated the impact of mechanical thrombectomy devices on this outcome.

Distal filter embolic protection devices in patients with STEMI. One RCT evaluated the impact of distal filter embolic protection devices on procedure time versus control. In this trial, the SpideRX™ device was used. The median procedure time was significantly prolonged in the distal filter embolic protection device group compared to control [52 minutes (43-70) versus 43.5 minutes (30-54), p<0.001]. This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

Distal filter embolic protection devices in other ACS populations. One RCT evaluated the impact of distal filter embolic protection devices on procedure time. The mean procedure time was only reported for the device group (63 minutes ±17).

No controlled observational studies evaluated this endpoint in this population.

Distal balloon embolic protection devices in patients with STEMI. Three RCT evaluated the impact of distal balloon embolic protection devices on procedure time versus control although were not amenable to pooling. In the first trial, mean procedure time was significantly different between the distal balloon embolic protection device group and control (75.8±30 minutes versus 53±25 minutes, p<0.01). In the second trial, the mean procedure time was not significantly different between the distal balloon embolic protection device group and control (29.7±18.3 minutes versus 29.5±18.2 minutes, p=0.91). In the third trial the median procedure time was significantly prolonged in the distal balloon embolic protection device group compared to control [53 minutes (42-69) versus 39 minutes (29-51), p<0.001]. This trial was determined to be of good methodological quality.

One RCT evaluated the impact of distal balloon embolic protection devices on procedure time versus abciximab therapy. In this trial, the PercuSurge device was used. The median procedure time was not significantly different between the distal balloon embolic protection device group and the abciximab group [58 minutes (35-88) versus 43 minutes (25-87), p=NS]. This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

Distal balloon embolic protection devices in other ACS populations. One RCT evaluated the impact of distal balloon embolic protection devices on procedure time in patients with acute myocardial infarction. In this trial, the GuardWire® device was used. The mean procedure time was significantly prolonged in the distal balloon embolic protection device group compared to
control (25.01 minutes ±11.89 versus 31.98 minutes ±15.33, p=0.03). This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

**Proximal balloon embolic protection devices in patients with STEMI.** One RCT evaluated the impact of proximal balloon embolic protection devices on procedure time versus control.\(^{18}\) In this trial, the Proxis\(^{\text{TM}}\) device was used. The median procedure time was significantly prolonged in the proximal balloon embolic protection device group compared to control [45 minutes (36-58) versus 31 minutes (25-40), p<0.01].\(^{18}\) This trial was determined to be of good methodological quality.

No controlled observational studies evaluated this endpoint in this population.

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Embolic protection devices combined in patients with STEMI.** Five RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on prolonged procedure time versus control although were not amenable to pooling.\(^{18,95,107,112,133}\) The procedure time results have been reported in each of the respective embolic protection device categories above. No additional data was available. In four of the five trials, the procedure time was significantly prolonged in the embolic protection device group versus control.\(^{18,95,107,112}\)

**Embolic protection devices combined in other ACS populations.** One RCT evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on prolonged procedure time versus control\(^{125}\) whose results are reported under distal balloon embolic protection devices in other ACS populations. No additional data was available.

**Side Branch Occlusion**

**Direct Comparative Trials**

No direct comparative trials evaluated the impact of thrombectomy or embolic protection devices on this outcome.

**Trials Versus Control**

**Catheter aspiration devices in patients with STEMI.** Two RCTs evaluated the impact of catheter aspiration devices on side branch occlusion versus control.\(^{15,62}\) The use of catheter aspiration devices did not significantly impact the risk of side branch occlusion [RR 1.19 (0.40, 3.54)] (Figure 58). Publication bias could not be calculated since only two studies were available. Both of the trials were determined to be of good methodological quality.\(^{15,62}\)

No controlled observational studies evaluated this endpoint in this population.
Figure 58. Impact of catheter aspiration devices on side branch occlusion versus control in patients with ST-segment elevation myocardial infarction

Catheter aspiration devices in other ACS populations. No trials or studies evaluated the impact of catheter aspiration devices on this outcome.

Mechanical thrombectomy devices in patients with STEMI. One RCT evaluated the impact of a mechanical thrombectomy device on side branch occlusion versus control. In this trial, the use of a mechanical thrombectomy device did not impact the risk of side branch occlusion versus control [RR 1.00 (0.11, 9.41)]. This trial was determined to be of good methodological quality. No controlled observational studies evaluated this endpoint in this population.

Mechanical thrombectomy devices in other ACS populations. No studies evaluated the impact of mechanical thrombectomy devices on this outcome.

Distal filter embolic protection devices in patients with STEMI. One RCT evaluated the impact of a distal filter embolic protection device on side branch occlusion versus control. In this trial, the use of a distal filter embolic protection device did not significantly impact the risk of side branch occlusion versus control [RR 0.33 (0.00, 3.80)]. This trial was determined to be of good methodological quality.
**Distal filter embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal filter embolic protection devices on this outcome.

**Distal balloon embolic protection devices in patients with STEMI.** Two RCTs evaluated the impact of distal balloon embolic protection devices on side branch occlusion.\textsuperscript{107,112} The use of distal balloon embolic protection devices did not significantly impact the risk of side branch occlusion versus control [RR 0.93 (0.61, 1.42)] (Figure 59). Publication bias could not be calculated since only two studies were available. Both trials were determined to be of good methodological quality.\textsuperscript{107,112}

**Figure 59. Impact of distal balloon embolic protection devices on side branch occlusion versus control in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

![Relative risk meta-analysis plot](image)

Cochran Q: P=0.565
F: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Distal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of distal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in patients with STEMI.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.

**Proximal balloon embolic protection devices in other ACS populations.** No trials or studies evaluated the impact of proximal balloon embolic protection devices on this outcome.
**Embolic protection devices combined in patients with STEMI.** Three RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on side branch occlusion. In these trials, the use of embolic protection devices nonsignificantly decreased the risk of side branch occlusion [RR 0.91 (0.60, 1.39)] (Figure 60). Statistical heterogeneity was not detected ($I^2 = 0$ percent) and publication bias could not be determined due to the number of studies available. All of the trials were determined to be of good methodological quality.  

**Figure 60. Impact of embolic protection devices combined on side branch occlusion versus control in patients with ST-segment elevation myocardial infarction**

Relative risk meta-analysis plot (random effects)

- **Cura, 2007**
  - 0.33 (0.00, 3.80)

- **Matsuo, 2007**
  - 1.85 (0.25, 13.97)

- **Stone, 2005**
  - 0.91 (0.60, 1.39)

- **combined [random]**
  - 0.91 (0.60, 1.39)

Cochran Q: P=0.697  
P: 0 percent  
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

**Embolic protection devices combined in other ACS populations.** No trials or studies evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) on this outcome.

**Table 27. Adverse events in randomized controlled trials evaluating catheter aspiration devices in patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>0.30 (0.12 to 0.75)</td>
<td>0%</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>1.19 (0.40 to 3.54)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated the outcome and no events occurred  
Abbreviations: CI=confidence interval; NA=not applicable
Table 28. Adverse events in randomized controlled trials evaluating mechanical thrombectomy devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>1.51 (0.57 to 4.01)*</td>
<td>NA</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>1.04 (0.15 to 7.04)</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>1.00 (0.11 to 9.41)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Table 29. Adverse events in randomized controlled trials evaluating distal filter embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.33 (0.00 to 3.80)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred;
†Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Table 30. Adverse events in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>5.11 (0.53 to infinity)*</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.93 (0.61 to 1.42)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred;
†Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Table 31. Adverse events in randomized controlled trials evaluating proximal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>---*</td>
<td>---*</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome
Abbreviations: CI=confidence interval

Table 32. Adverse events in randomized controlled trials evaluating embolic protection devices combined in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Coronary perforation</td>
<td>5.11 (0.53 to infinity)*</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.91 (0.60 to 1.39)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because in the two trials that evaluated this outcome no events occurred; †Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Discussion

In patients with STEMI undergoing PCI and comparing a catheter aspiration, mechanical thrombectomy, or embolic protection device versus control, only a minority of trials reported on the occurrence of the four most important adverse events (coronary dissection, coronary perforation, prolonged procedure time, and side branch occlusion). This made it difficult to determine the balance of benefits to harms for these devices.
The use of catheter aspiration devices versus control significantly reduced the risk of coronary dissection and did not significantly impact the risk of side branch occlusion. One trial reported the outcome of coronary perforation although risk could not be calculated since no events occurred in either group. Overall, the use of catheter aspiration devices versus control did not significantly prolong procedure time in eight of nine trials and in one controlled observational study. When evaluated qualitatively, the procedure time were shortened in one trial, prolonged by 5 or less minutes in four trials and in one controlled observational study, and were more than 5 minutes prolonged in another four trials.

The use of mechanical thrombectomy devices versus control appears to be safe overall. In RCTs, the use of mechanical thrombectomy devices versus control did not significantly impact the risk of coronary dissection, coronary perforation, or side branch occlusion. However, mechanical thrombectomy devices appear to prolong the procedure time versus control. Three trials evaluated the impact of mechanical thrombectomy devices versus control on procedure time although were ineligible for pooling. In all three trials the procedure time was significantly prolonged in the mechanical thrombectomy device group versus control. The mean procedure time was prolonged by 9 to 16.2 minutes and one trial reported a median in which the procedure time was prolonged by 13.5 minutes.

Limited data was available to analyze the adverse events associated with the use of distal filter embolic protection devices versus control. In RCTs, the use of distal filter embolic protection devices versus control did not significantly impact the risk of side branch occlusion. The risk of coronary dissection and coronary perforation could not be calculated in the one trial in which it was reported. One trial evaluated procedure time which was significantly prolonged in the distal filter embolic protection device group versus control by a median of 8.5 minutes.

In RCTs, the use of distal balloon embolic protection devices versus control did not significantly impact the risk of coronary perforation or side branch occlusion. The risk of coronary dissection could not be calculated in the one trial which reported this outcome because no events occurred. Three trials evaluated the impact of distal balloon embolic protection devices versus control on procedure time although were not amenable to pooling. In two of the three trials, procedure time was significantly prolonged with the use of a distal balloon embolic protection device versus control. In these two trials, the procedure time was prolonged by a mean of 22.8 minutes and a median of 14 minutes.

The only adverse event which was reported in trials evaluating proximal balloon embolic protection devices versus control was procedure time. In one controlled trial, the procedure time was significantly prolonged in the proximal balloon embolic protection device group versus control by a median of 14 minutes.

When evaluating embolic protection devices combined (distal or proximal; filter or balloon), similar trends were observed as those evaluating the individual embolic protection device categories. The risk of coronary dissection could not be calculated because no events occurred in the trials which reported this outcome. Only one trial reported coronary perforation (distal balloon embolic protection device) therefore results did not change. The majority of trials evaluating embolic protection devices demonstrated a prolonged procedure time (four of five trials). The use of embolic protection devices combined did not significantly impact the risk of side branch occlusion, although a trend towards decreased risk was seen.

No trials or studies evaluating patients with NSTEMI or UA undergoing PCI and comparing thrombectomy or embolic protection devices versus control on adverse events were identified.
One trial evaluated patients with mixed ACS (STEMI, NSTEMI, or UA) undergoing PCI and comparing thrombectomy or embolic protection devices versus control on adverse events. In this trial, the use of a distal balloon embolic protection device versus control significantly prolonged the procedure time by a mean of 6.97 minutes.

Key Question 3
In ACS patients undergoing PCI of native vessels, which patient characteristics (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and prePCI TIMI flow, use of direct stenting) affect outcomes?

Key Points
A total of nine RCTs, an individual patient data meta-analysis, a pooled analysis, and five observational studies provided useful data for Key Question 3.

- RCTs evaluating treatment effect stratified by subgroups found the following:
  - No statistically significant difference in outcomes with catheter aspiration, mechanical thrombectomy or embolic protection devices efficacy based on differences in gender, age, diabetes, smoking status, primary or rescue PCI, presence of thrombus-containing lesion, prePCI TIMI flow, or the use of direct stenting.
  - A trend (P-value for interaction<0.10 between subgroups) towards greater improvements in attaining complete ST-segment resolution with proximal balloon embolic protection in those receiving a glycoprotein IIb/IIIa inhibitor versus those without such therapy.
  - A trend (P-value for interaction<0.10 between subgroups) towards greater improvements in attaining complete ST-segment resolution with proximal balloon embolic protection in those with an anterior infarct-related artery lesions versus lesions in other arteries.
  - Conflicting data was identified regarding the effect of ischemic time on outcomes following the use of catheter aspiration devices.
    - There was a trend (P-value for interaction<0.10 between subgroups) towards greater achievement of a higher MBG with catheter aspiration in those with ischemic times <180 minutes versus longer ischemic times.
    - There was significantly greater improvement (P-value for interaction=0.02) in the achievement of TIMI 3 flow with catheter aspiration and a trend (P-value for interaction <0.10 between subgroups) towards greater reductions in slow flow or no reflow in those with prolonged ischemic times (6 to 24 hours from symptom onset) versus those with shorter ischemic times.
  - It should be noted that results of subgroup analyses from RCTs may be prone to type 2 error and false findings resulting from multiple hypothesis testing.
No RCTs evaluated the effect of ethnicity or ejection fraction on thrombectomy or embolic protection device efficacy.

The individual patient data meta-analysis by Burzotta and colleagues\textsuperscript{171,172} found that the use of aspiration or mechanical thrombectomy was associated with a survival benefit in the subgroup of patients treated with glycoprotein IIb/IIIa inhibitors but not in those not receiving them.

- No qualitative differences in mortality were seen when splitting the study population according to the presence or absence of diabetes, earlier or later time to reperfusion, type of vessel (left anterior descending, circumflex, right coronary artery) containing the culprit lesion and lower or higher prePCI TIMI flow.

The pooled analysis by DeVita and colleagues\textsuperscript{143} found that in subgroups of short (≤3 hours) and intermediate (>3 hours to <6 hours) time to treatment (TTT) there was no significant difference between catheter aspiration and control on in-hospital MACE, STSR, MBG 2-3 or TIMI-3. In the subgroup of long TTT (>6 hours and ≤12 hours), catheter aspiration devices significantly increased the rate of STSR and TIMI-3 blood flow compared to control but did not significantly impact other outcomes.

The controlled observational study by Nakatani and colleagues\textsuperscript{149} found Killip class (a correlate to heart failure and ejection fraction) not to be a modifier of 30-day mortality with catheter aspiration device use. This constitutes the only data available to evaluate the potential confounding effect of heart function on outcomes.

The controlled observational study by Sardella and colleagues\textsuperscript{49} found that use of catheter aspiration, age, and symptom to balloon time were significant predictors of cardiac death (no deaths were of noncardiac cause) at 2 years.

Observational single arm studies found catheter aspiration and/or embolic protection device effectiveness to be negatively affected by increased age, prolonged ischemic time, female gender, presence of diabetes and absence of baseline thrombus.

**Detailed Analysis**

Study Design and Population Characteristics

A total of nine RCTs, an individual patient data meta-analysis, a pooled analysis and five observational studies were included in Key Question 3. All RCT data were in patients experiencing STEMI. STEMI was also an inclusion criterion for all trials in the individual patient data meta-analysis and the pooled analysis. Some of the observational studies included a mixed STEMI and NSTEMI population. Of the RCTs, 5, 2, 1, and 1 evaluated catheter aspiration, distal filter embolic protection, distal balloon embolic protection and proximal balloon embolic protection, respectively. None evaluated mechanical thrombectomy devices, although RCTs of these devices were included in the individual patient data meta-analysis. The pooled analysis evaluated catheter aspiration devices used in the three included RCTs. Outcomes evaluated in these trials included MBG, complete (>70 percent) ST-segment resolution, slow- and/or no-reflow, target vessel revascularization, MACE, TIMI blood flow and distal embolization.

**Outcomes Results**

Two trials provided subgroup results based on gender (Table 33).\textsuperscript{62,89} In the trial by Svilaas and colleagues, males were significantly less likely to experience a MBG of 0 or 1 if they received catheter aspiration than if they did not [RR 0.60 (0.44, 0.82)]. While females did not experience a significant reduction in achieving a MBG of 0 or 1 when the device was employed
[RR 0.74 (0.49, 1.11)], the reductions noted between the genders was not found to be statistically differ (P-value for interaction=0.43 between subgroups). In the trial by Kelbaeck and colleagues, males and females both had nonsignificant improvements in ST-segment resolution (≥70 percent at 90 minutes postPCI) when a filter distal embolic protection device was employed and the reductions were not found to differ statistically between genders (P-value for interaction=0.79 between subgroups).

Table 33. Results of subgroup analysis from randomized controlled trials evaluating the effect of gender on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (“X”R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008&lt;sup&gt;62&lt;/sup&gt; (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export&lt;sup&gt;69&lt;/sup&gt; Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Male Female</td>
<td>RR 0.60 (0.44 to 0.82) RR 0.74 (0.49 to 1.11)</td>
<td>0.43</td>
</tr>
<tr>
<td>Kelbaek, 2008&lt;sup&gt;89&lt;/sup&gt; (N=626)</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire-EZ&lt;sup&gt;TM&lt;/sup&gt; or SpiderX&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>STSR ≥ 70% 90 min postPCI</td>
<td>Male Female</td>
<td>RR 1.04 (0.93 to 1.16) RR 1.08 (0.84 to 1.40)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures. Abbreviations: CI=confidence interval; MBG=myocardial blush grade; min-minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

Three trials provided subgroup results stratified by age;<sup>62,83,89</sup> however, numerical data was obtainable for only one (Table 34).<sup>62</sup> The trial by Svilaas and colleagues demonstrated that both those over 65 years [RR 0.74 (0.55, 0.99)] and 65 years or younger [RR 0.58 (0.39, 0.88)] were less likely to experience a MBG of 0 or 1 if they used a catheter aspiration device, with no differences noted between groups (P-value for interaction=0.34 between subgroups). These findings are supported by results of the trial by Burzotta and colleagues, which also found that a catheter aspiration device was beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in both those greater than 60 and 60 years or younger (no numerical data reported).<sup>83</sup> The trial by Kelbaeck and colleagues suggested that age (<70 or ≥70) did not affect the efficacy of filter distal embolic protection (P-value for interaction between subgroups >0.10).<sup>89</sup>

Table 34. Results of subgroup analysis from randomized controlled trials evaluating the effect of age on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (“X”R 95%CI)</th>
<th>P-Values for Interaction Between Subgroups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008&lt;sup&gt;62&lt;/sup&gt; (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export&lt;sup&gt;69&lt;/sup&gt; Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Age &gt; 65 y/o Age ≤ 65 y/o</td>
<td>RR 0.74 (0.55 to 0.99) RR 0.58 (0.39 to 0.88)</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; y/o=years old

The impact of ethnicity was not evaluated as part of subgroup analyses and was only sporadically reported in the demographic tables of included trials. Thus we were unable to assess its affect on any outcome.
Two trials evaluated the impact of using filter distal embolic protection devices in patients with diabetes mellitus (Table 35). One trial provided subgroup results based on the presence or absence of diabetes mellitus while a second trial only provided the results in the diabetic subgroup. In the trial by Kelbaek and colleagues, there was a nonsignificant reduction in the risk of achieving ST-segment resolution (≥70 percent at 90 minutes postPCI) in diabetic patients [RR 0.81 (0.55 to 1.19)] but a nonsignificant increase in nondiabetic patients [RR 1.07 (0.97 to 1.17)], with a weak trend towards differences between the groups (P-value for interaction=0.17 between subgroups). In the trial by Cura and colleagues, those with diabetes had a nonsignificant reduction on the risk of achieving ST segment resolution (≥70 percent at 60 minutes postPCI) [RR 0.91 (0.65 to 1.29)]. In the total population of the trial by Cura and colleagues, the use of the device did not increase the proportion of patients achieving complete ST-segment resolution at 60 minutes (61 percent versus 60 percent; p=0.91) or any other time point. The device and endpoint were similar between trials so a pooled analysis of the diabetic subgroups of these two trials yielded a nonsignificant reduction in the risk of achieving ST-segment resolution [RR 0.86 (0.67 to 1.12)]. Due to the limited number of data points in this analysis statistical heterogeneity could not be assessed. Our literature search also identified a single individual patient data meta-analysis by Burzotta and colleagues. This meta-analysis pooled data from eleven RCTs of adjunctive thrombectomy devices (catheter aspiration or mechanical thrombectomy) (N=2686 patients) in patients with STEMI. Embolic protection device trials were not included in this meta-analysis. Kaplan–Meier analysis conducted in this meta-analysis showed that randomization to a thrombectomy device was associated with significantly lower risk of all-cause mortality (p=0.049), MACE (p=0.01) and the composite endpoint of death or myocardial infarction (p=0.01). Upon subgroup analysis undertaken in this meta-analysis, no qualitative difference in mortality was seen when splitting the study population according to the presence or absence of diabetes.

Table 35. Results of subgroup analysis from randomized controlled trials evaluating the effect of diabetes mellitus on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (“X”R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelbaek, 2008 (N=626)</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire- EZ TM or SpiderX TM</td>
<td>STSR ≥ 70% 90 min postPCI</td>
<td>Diabetes vs No Diabetes</td>
<td>RR 0.81 (0.55 to 1.19)</td>
<td>0.17</td>
</tr>
<tr>
<td>Cura, 2007 (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpiderRX TM</td>
<td>STSR ≥ 70% 60 min postPCI</td>
<td>Diabetes vs No Diabetes</td>
<td>RR 0.91 (0.65 to 1.29)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CI=confidence interval; min=minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

Three trials evaluated the impact of using embolic protection devices in patients with a history of smoking (Table 36). Two trials provided subgroup results based on the presence or absence of a history of current smoking while a third trial only provided the results in the current smoker subgroup. While the use of a proximal balloon embolic protection device in the trial by Haeck and colleagues significantly increased the risk of achieving ST-segment resolution...
(>70 percent postPCI) in smokers [RR 1.41 (1.11, 1.80)] but not nonsmokers [RR 1.32 (0.90, 1.95)], the results were similar between subgroups (P-value for interaction=0.78 between subgroups). In the trial by Stone and colleagues, the use of a balloon distal embolic protection device did not significantly impact the risk of achieving an ST-segment resolution (>70 percent at 30 minutes postPCI) in current smokers [RR 0.99 (0.81, 1.22)] or nonsmokers [RR 1.05 (0.87, 1.27)] with no difference seen between subgroups (P-value for interaction=0.68 between subgroups). In the trial by Cura and colleagues, smoking did not significantly impact the risk of achieving an ST-segment resolution (>70 percent 60 minutes postPCI) [RR 1.12, 0.93, 1.34)]. As noted above, in the total population of the trial by Cura and colleagues, the use of the device did not increase the proportion of patients achieving complete the ST-segment resolution at 60 minutes (61 percent versus 60 percent; p=0.91) or any other time point. When the current smoker subgroups of the trials were pooled, the risk of achieving an ST-segment resolution from embolic protection devices was nonsignificantly increased [RR 1.16 (0.95, 1.41)], but due to differences in the devices employed and the definitions of ST segment resolution, statistical heterogeneity was high (I²=63.3 percent).

### Table 36. Results of subgroup analysis from randomized controlled trials evaluating the effect of smoking on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cura, 2007*</td>
<td>Distal Filter</td>
<td>SpideRX™</td>
<td>STSR ≥ 70%</td>
<td>Current smoking</td>
<td>RR 1.12 (0.93 to 1.34)</td>
<td>NA</td>
</tr>
<tr>
<td>(N=140)</td>
<td>Embolic Protection</td>
<td></td>
<td>60 min postPCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stone, 2005*</td>
<td>Distal Balloon</td>
<td>GuardWire® Plus</td>
<td>STSR ≥ 70%</td>
<td>Current smoking</td>
<td>RR 0.99 (0.81 to 1.22)</td>
<td>0.68</td>
</tr>
<tr>
<td>(N=501)</td>
<td>Embolic Protection</td>
<td></td>
<td>30 min postPCI</td>
<td>No current smoking</td>
<td>RR 1.05 (0.87 to 1.27)</td>
<td></td>
</tr>
<tr>
<td>Haeck, 2009*</td>
<td>Proximal Balloon</td>
<td>Proxis™</td>
<td>PostPCI STSR ≥ 70%</td>
<td>Current smoking</td>
<td>RR 1.41 (1.11 to 1.80)</td>
<td>0.78</td>
</tr>
<tr>
<td>(N=284)</td>
<td>Embolic Protection</td>
<td></td>
<td></td>
<td>No current smoking</td>
<td>RR 1.32 (0.90 to 1.95)</td>
<td></td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CI=confidence interval; min=minutes; N=total number of participants enrolled; NA=not applicable; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

The impact of ejection fraction on outcomes was not evaluated in subgroup analysis, thus precluding evaluation. Only the trials by Burzotta and colleagues and Stone and colleagues provided subgroup results based on whether the device was used for primary angioplasty or for rescue angioplasty; however, the trial by Burzotta and colleagues did not provide any numerical data and thus was not included (Table 37). In this trial, a catheter aspiration device was not statistically significantly beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in either the subgroup of patients undergoing primary or rescue angioplasty (no numerical data reported). In subgroup analysis within the trial by Stone and colleagues, neither those receiving a balloon distal embolic protection device for primary [RR 1.05 (0.90, 1.22)] nor rescue angioplasty [0.91 (0.64, 1.29)] had significant impact on ST-segment resolution (>70 percent at 30 minutes postPCI) and no statistically significant difference was noted between subgroups (P-value for interaction=0.46 between subgroups).
Table 37. Results of subgroup analysis from randomized controlled trials evaluating the effect of failed thrombolysis on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stone, 2005 (N=501)</td>
<td>Distal Balloon</td>
<td>GuardWire Plus</td>
<td>STSR ≥ 70%</td>
<td>Primary angioplasty</td>
<td>RR 1.05 (0.90 to 1.22)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Embolic Protection</td>
<td>STSR ≥ 70%</td>
<td>30 min postPCI</td>
<td>Rescue angioplasty (after failed thrombolysis)</td>
<td>RR 0.91 (0.64 to 1.29)</td>
<td></td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures
Abbreviations: CI=confidence interval; min-minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

Only one trial evaluated the effect of concurrent GP IIb/IIIa inhibitor use on a catheter aspiration device’s efficacy. In this trial by Burzotta and colleagues, the use of a catheter aspiration device was not statistically significantly beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in either the subgroup who did or did not receive a GP IIb/IIIa inhibitor (no numerical data reported). In the aforementioned individual patient data meta-analysis, subgroup analysis according to administration of GP IIb/IIIa inhibitors showed that randomization to an adjunctive thrombectomy device was associated with a mortality benefit in the subgroup of patients treated with GP IIb/IIIa inhibitors [n=1787 patients; hazard ratio 0.61 (0.38 to 0.90); p=0.045], but not in those without GP IIb/IIIa inhibitors [n=899 patients; hazard ratio 0.93 (0.48 to 1.80); p=0.84]. In addition, two trials evaluated the affect of concurrent GP IIb/IIIa inhibitor use on an embolic protection device’s (distal filter and proximal balloon) ability to obtain complete ST-segment resolution (Table 38). In both the trial by Cura and colleagues and Haeck and colleagues, the subgroup of patients administered GP IIb/IIIa inhibitors achieved statistically significant increased rates of complete (>70 percent) ST-segment resolution [RR 1.36 (1.09 to 1.69) and RR 1.97 (1.17 to 3.32), respectively]. However in the trial by Haeck and colleagues, the subgroup not receiving a GP IIb/IIIa inhibitor did not realize a statistically significant improvement in complete ST-segment resolution [RR 1.20 (0.97 to 1.49)]. The P-value for interaction between GP IIb/IIIa inhibitor use and nonuse groups in this trial (proximal embolic balloon protection) was nearing statistical significance (p=0.08), suggesting concomitant GP IIb/IIIa inhibitor use may enhance the ability of embolic protection to achieve complete ST-segment resolution.

Table 38. Results of subgroup analysis from randomized controlled trials evaluating the effect of glycoprotein IIb/IIIa inhibitor use on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cura, 2007 (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpideRX T M</td>
<td>STSR ≥ 70%</td>
<td>GP2B3Ai use</td>
<td>RR 1.36 (1.09 to 1.69)</td>
<td>NA</td>
</tr>
<tr>
<td>Haeck, 2009 (N=284)</td>
<td>Proximal Balloon Embolic Protection</td>
<td>Proxis T M</td>
<td>PostPCI STSR ≥ 70%</td>
<td>GP2B3Ai use</td>
<td>RR 1.97 (1.17 to 3.32)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures
Abbreviations: CI=confidence interval; GP2B 3Ai=glycoprotein 2B 3A inhibitor; min-minutes; N=total number of participants enrolled; NA=not applicable; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution
A total of eight trials and one pooled analysis evaluated the effect of ischemia time on the efficacy of adjunctive devices to improve post-ST-segment myocardial infarction outcomes; however, only six of the eight trials provided numerical results (Table 39). In the trial by Svilaas and colleagues, regardless of total ischemia time (≥180 minutes or <180 minutes) patients were less likely to have a MBG of 0 or 1 postPCI when catheter aspiration was used [RR 0.73 (0.55 to 0.99) and RR 0.45 (0.28 to 0.74), respectively]. However, the P-value for interaction between subgroups trended towards statistical significance (p=0.09) suggesting catheter aspiration may be more effective in patients undergoing PCI within 180 minutes. The trial by Ikari and colleagues also supported the conclusion that catheter aspiration devices had beneficial effects on MBG in patients undergoing early- (<6 hours from symptom onset) and late- (6-24 hours) reperfusion [RRs of achieving a MBG-3 were 2.32 (1.50 to 3.58) and 2.34 (1.21 to 4.54), respectively; with no difference between subgroups (p-value for interaction =0.98 between subgroups). However, when looking at the slow/no-reflow or achievement of TIMI-3 blood flow endpoints in this trial, only patients undergoing late perfusion realized statistically significant benefits between longer and shorter ischemic times [RR 0.23 (0.07 to 0.72) and RR 1.45 (1.12 to 1.86)]. The P-value for interaction between subgroups of effect trended towards statistical significance for slow/no-reflow (p=0.07) and was statistically significant for the TIMI-3 blood flow endpoint (p=0.02). Neither results from the trial by Ikari and colleagues nor from an additional trial by Chao and colleagues demonstrated any ischemia time subgroup to statistically significantly benefit from catheter aspiration in respect to final health outcomes including target lesion or vessel revascularization, mortality, or combined major adverse cardiac events (all crossing the line of unity). Data from Chao did qualitatively appear to suggest decreasing efficacy of catheter aspiration on terminal endpoints as ischemic times increased; however, the effects between subgroups in each of these trials and endpoints were not found to be statistically significantly different (P-values for interaction all >0.25). On their own, the three trials evaluating embolic protection devices (one each of distal balloon, distal filter and proximal balloon) did not suggest embolic protection devices allowed patients to achieve complete ST-segment resolution to a greater or lesser extent in different ischemia time subgroups (P-value for interaction >0.22 for all between subgroups). Only those within the shorter ischemia time subgroup receiving proximal balloon embolic protection were found to have a statistically significantly increased chance of complete ST-segment resolution [RR 1.38 (1.06 to 1.80)]. When results from these three trials were pooled separately by shorter and longer ischemia subgroups, similar results were seen [pooled RR for shorter ischemia time 1.08 (0.85 to 1.38), \(I^2=63.8\) percent and pooled RR for longer ischemia time 1.09 (0.95 to 1.24), \(I^2=0\) percent]. The trial by Burzotta and colleagues found that a catheter aspiration device was beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in both those with ischemia times greater than 250 minutes and 250 minutes or less (no numerical data reported). The trial by Kelbaeck and colleagues suggested that ischemic time (stratified at 6 hours) did not affect the efficacy of distal filter embolic protection (P-value for interaction between subgroups >0.10). Upon subgroup analysis undertaken in the individual patient data meta-analysis, no qualitative difference in mortality was seen when splitting the study population according to shorter, intermediate or longer ischemia times. One pooled analysis by De Vita and colleagues pooled data from three RCT which compared catheter aspiration to standard procedure in patients with STEMI. Four outcomes were evaluated (in-hospital MACE, STSR ≥70 percent, TIMI-3 and MBG 2 or 3) based on three subgroups of time to treatment (TTT), defined as time from symptoms onset to catheter...
laboratory \(\leqslant 3\) hours (short TTT), \(>3\) hours to \(<6\) hours (intermediate TTT), and \(>6\) hours to \(\leqslant 12\) hours (long TTT)). Two hundred-ninety nine patients were analyzed overall with 128 in the short TTT subgroup, 135 in the intermediate TTT subgroup, and 36 in the long TTT subgroup. There was no significant difference between catheter aspiration and control in the outcomes evaluated in the short and intermediate TTT subgroups. In the long TTT subgroup, the catheter aspiration group was significantly more likely to achieve STSR (50 percent versus 20 percent, \(p=0.01\)) and TIMI-3 blood flow (88 percent versus 60 percent, \(p=0.01\)) versus control although none of the other outcomes were significant.

Table 39. Results of subgroup analysis from randomized controlled trials evaluating the effect of ischemic time on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device Type</th>
<th>Device Type</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (<em>X^R 95%CI)^</em></th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008** (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export® Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Total ischemic time (\geqslant 180) min</td>
<td>RR 0.73 (0.55 to 0.99)</td>
<td>RR 0.45 (0.28 to 0.74)</td>
<td>0.09</td>
</tr>
<tr>
<td>Chao, 2008** (N=74)</td>
<td>Catheter Aspiration</td>
<td>Export® Aspiration Catheter</td>
<td>ΔTIMI</td>
<td>Onset-to-lab interval of 0-240 min</td>
<td>MD 0.30 (-0.60 to 1.20)</td>
<td>MD 1.30 (0.46 to 2.14)</td>
<td>MD 0.10 (-1.05 to 1.25)</td>
</tr>
<tr>
<td>Chao, 2008** (N=74)</td>
<td>Catheter Aspiration</td>
<td>Export® Aspiration Catheter</td>
<td>ΔMBG</td>
<td>Onset-to-lab interval of 0-240 min</td>
<td>MD 1.30 (0.20 to 2.40)</td>
<td>MD 1.60 (0.84 to 2.36)</td>
<td>MD 0.60 (-0.71 to 1.91)</td>
</tr>
<tr>
<td>Chao, 2008** (N=74)</td>
<td>Catheter Aspiration</td>
<td>Export® Aspiration Catheter</td>
<td>6m MACE</td>
<td>Onset-to-lab interval of 0-240 min</td>
<td>RR 0.35 (0.08 to 1.56)</td>
<td>RR 0.27 (0.03 to 2.11)</td>
<td>RR 2.29 (0.26 to 20.13)</td>
</tr>
</tbody>
</table>
Table 39. Results of subgroup analysis from randomized controlled trials evaluating the effect of ischemic time on clinical outcome (continued)

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (“X” R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chao, 2008&lt;sup&gt;10&lt;/sup&gt; (N=74)</td>
<td>Catheter Aspiration</td>
<td>Export&lt;sup&gt;®&lt;/sup&gt; Aspiration Catheter</td>
<td>6m mortality</td>
<td>Onset-to-lab interval of 0-240 min</td>
<td>RR 0.83 (0.02 to 39.24)</td>
<td>RR 1.07 (0.02 to 50.43)</td>
</tr>
<tr>
<td>Chao, 2008&lt;sup&gt;10&lt;/sup&gt; (N=74)</td>
<td>Catheter Aspiration</td>
<td>Export&lt;sup&gt;®&lt;/sup&gt; Aspiration Catheter</td>
<td>6m TVR</td>
<td>Onset-to-lab interval of 0-240 min</td>
<td>RR 0.29 (0.03 to 2.54)</td>
<td>RR 1.08 (0.07 to 15.50)</td>
</tr>
<tr>
<td>Ikari, 2008&lt;sup&gt;16&lt;/sup&gt; (N=355)</td>
<td>Catheter Aspiration</td>
<td>Transvascular Aspiration Catheter&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Slow flow/No reflow</td>
<td>Early reperfusion (hospital arrival ≤ 6 h from symptom onset)</td>
<td>RR 0.80 (0.42 to 1.52)</td>
<td>RR 0.23 (0.07 to 0.72)</td>
</tr>
<tr>
<td>Ikari, 2008&lt;sup&gt;16&lt;/sup&gt; (N=355)</td>
<td>Catheter Aspiration</td>
<td>Transvascular Aspiration Catheter&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Final MBG=3</td>
<td>Early reperfusion (hospital arrival ≤ 6 h from symptom onset)</td>
<td>RR 2.32 (1.50 to 3.58)</td>
<td>RR 2.34 (1.21 to 4.54)</td>
</tr>
<tr>
<td>Ikari, 2008&lt;sup&gt;16&lt;/sup&gt; (N=355)</td>
<td>Catheter Aspiration</td>
<td>Transvascular Aspiration Catheter&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Final TIMI flow grade=3</td>
<td>Early reperfusion (hospital arrival ≤ 6 h from symptom onset)</td>
<td>RR 1.04 (0.94 to 1.15)</td>
<td>RR 1.45 (1.12 to 1.86)</td>
</tr>
<tr>
<td>Ikari, 2008&lt;sup&gt;16&lt;/sup&gt; (N=355)</td>
<td>Catheter Aspiration</td>
<td>Transvascular Aspiration Catheter&lt;sup&gt;®&lt;/sup&gt;</td>
<td>TLR (PCI or CABG)</td>
<td>Early reperfusion (hospital arrival ≤ 6 h from symptom onset)</td>
<td>RR 0.69 (0.36 to 1.31)</td>
<td>RR 0.31 (0.09 to 1.002)</td>
</tr>
<tr>
<td>Ikari, 2008&lt;sup&gt;16&lt;/sup&gt; (N=355)</td>
<td>Catheter Aspiration</td>
<td>Transvascular Aspiration Catheter&lt;sup&gt;®&lt;/sup&gt;</td>
<td>MACE</td>
<td>Early reperfusion (hospital arrival ≤ 6 h from symptom onset)</td>
<td>RR 0.74 (0.40 to 1.37)</td>
<td>RR 0.37 (0.13 to 1.05)</td>
</tr>
<tr>
<td>Sviolaas, 2008&lt;sup&gt;22&lt;/sup&gt; (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export&lt;sup&gt;®&lt;/sup&gt; Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Total ischemic time ≥ 180 min</td>
<td>RR 0.73 (0.55 to 0.99)</td>
<td>RR 0.45 (0.28 to 0.74)</td>
</tr>
<tr>
<td>Cura, 2007&lt;sup&gt;26&lt;/sup&gt; (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpideRX&lt;sup&gt;®&lt;/sup&gt;</td>
<td>STSR ≥ 70%</td>
<td>Median time to admission &lt; 150 min</td>
<td>RR 0.89 (0.69 to 1.16)</td>
<td>RR 1.12 (0.87 to 1.45)</td>
</tr>
<tr>
<td>Stone, 2005&lt;sup&gt;12&lt;/sup&gt; (N=501)</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire&lt;sup&gt;®&lt;/sup&gt; Plus</td>
<td>STSR ≥ 70%</td>
<td>Symptom onset to hospital arrival &lt; 1 h</td>
<td>RR 1.04 (0.82 to 1.32)</td>
<td>RR 1.03 (0.87 to 1.24)</td>
</tr>
</tbody>
</table>
Table 39. Results of subgroup analysis from randomized controlled trials evaluating the effect of ischemic time on clinical outcome (continued)

<table>
<thead>
<tr>
<th>Study Year</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (<em>X</em>R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck 2009 (N=284)</td>
<td>Proximal Balloon Embolic Protection</td>
<td>Proxis™ PostPCI STSR</td>
<td>Symptom onset to balloon time</td>
<td>RR 1.38 (1.06 to 1.80) RR 1.27 (0.90 to 1.78)</td>
<td>0.70</td>
<td></td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CABG=coronary artery bypass graft; CI=confidence interval; h=hours; m=months; MACE=major adverse cardiac events; MBG=myocardial blush grade; MD=mean difference; min=minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revascularization

Six trials evaluated the effect of visible thrombus at baseline on the efficacy of adjunctive devices (Table 40). The trial by Svilaas and colleagues evaluated the effect of catheter aspiration use on MBG in patients with and without visible thrombus. Regardless of the presence of visible thrombus at baseline, catheter aspiration use resulted in fewer patients having a MBG of 0 or 1 postprocedure [RR with visible thrombus 0.61 (0.43 to 0.87) and RR without visible thrombus 0.70 (0.50 to 0.98)]. A test for interaction between these subgroups showed no statistically significant difference in effect (p=0.58). The trial by Burzotta and colleagues found that a catheter aspiration device was beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in the subgroup of patients with a high thrombus burden (thrombus score of 4 to 6), but not those with a lower burden (thrombus score of 1 or 2) (no numerical data reported). The remaining four trials evaluated embolic protection devices use on obtainment of complete ST-segment resolution in patients with and without visible thrombus. In the trial by Kelbaeck and colleagues, those patients without visible thrombus at baseline were more likely to achieve complete ST-segment resolution when using a filter distal embolic protection device versus control [RR 1.17 (1.01 to 1.37); however, the same device did not appear to benefit patients with visible thrombus [RR 1.00 (0.89 to 1.12). The difference between these subgroups what not found to be statistically significant (P-value for interaction=0.11 between subgroups). The trial by Haeck and colleagues demonstrated contradictory results [RR with 1.31 (1.02 to 1.68) and RR without 1.39 (0.94 to 2.05) baseline thrombus, P-value for interaction=0.80 between subgroups]. In both the trial by Cura and colleagues and Stone and colleagues, the use of distal embolic protection (filter or balloon) was not found to be statistically significantly beneficial in either the visible thrombus or no thrombus subgroups. When embolic protection studies were pooled separately by baseline thrombus subgroup, neither the visible thrombus nor no visible thrombus subgroups demonstrated statistical significant effects on complete ST-segment resolution [RR with baseline visible thrombus 1.10 (0.95 to 1.27), I²=24.5 percent and RR without thrombus 1.12 (0.76 to 1.64), I²=not estimable).
Table 40. Results of subgroup analysis from randomized controlled trials evaluating the effect of visible thrombus on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (“X”R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008&lt;sup&gt;12&lt;/sup&gt; (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export&lt;sup&gt;®&lt;/sup&gt; Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Visible thrombus on angiography</td>
<td>RR 0.61 (0.43 to 0.87)</td>
<td>0.58</td>
</tr>
<tr>
<td>Kelbaek, 2008&lt;sup&gt;12&lt;/sup&gt; (N=626)</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire&lt;sup&gt;®&lt;/sup&gt;-EZ&lt;sup&gt;TM&lt;/sup&gt; or SpiderX&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>STSR ≥ 70% 90 min postPCI</td>
<td>Visible thrombus</td>
<td>RR 1.00 (0.89 to 1.12)</td>
<td>0.11</td>
</tr>
<tr>
<td>Cura, 2007&lt;sup&gt;9&lt;/sup&gt; (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpideRX&lt;sup&gt;®&lt;/sup&gt;</td>
<td>STSR ≥ 70% 60 min postPCI</td>
<td>Baseline thrombosis</td>
<td>RR 1.02 (0.78 to 1.35)</td>
<td>NA</td>
</tr>
<tr>
<td>Stone, 2005&lt;sup&gt;112&lt;/sup&gt; (N=501)</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire&lt;sup&gt;®&lt;/sup&gt; Plus</td>
<td>STSR ≥ 70% 30 min postPCI</td>
<td>Baseline thrombus</td>
<td>RR 1.04 (0.89 to 1.22)</td>
<td>0.56</td>
</tr>
<tr>
<td>Haeck, 2009&lt;sup&gt;18&lt;/sup&gt; (N=284)</td>
<td>Proximal Balloon Embolic Protection</td>
<td>Proxis&lt;sup&gt;®&lt;/sup&gt;</td>
<td>PostPCI STSR ≥ 70%</td>
<td>Baseline thrombus</td>
<td>RR 1.31 (1.02 to 1.68)</td>
<td>0.80</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures.

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; min=minutes; N= total number of participants enrolled; NA=not applicable; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution.

A total of six trials evaluated the effect of the infarct-related artery on the efficacy of adjunctive devices to improve postST-segment myocardial infarction outcome (Table 41).<sup>18,62,83,89,95,112</sup> In the trial by Svilas and colleagues, catheter aspiration was found to reduce the risk of postprocedure MBG of 0 or 1 in patients with the RCA as the infarct-related artery [RR 0.48 (0.29 to 0.81)] or other arteries [RR 0.71 (0.53 to 0.93)]. A test for interaction between these infarct-related artery subgroups showed no statistically significant difference in effect (p=0.19). The trial by Burzotta and colleagues found that a catheter aspiration device was not statistically significantly beneficial in obtaining both a MBG≥2 and complete ST-segment resolution in either those with a LAD or a RCA/CX as the infarct-related artery (no numerical data reported). Upon subgroup analysis undertaken in the individual patient data meta-analysis,<sup>171,172</sup> no qualitative difference in mortality was seen when splitting the study population according to the type of infarct-related artery (left anterior descending or circumflex artery or RCA). The remaining four trials evaluated embolic protection devices. In three of these four trials,<sup>89,95,112</sup> distal embolic protection devices (balloon or filter) failed to improve patients’ chance of attaining complete ST-segment resolution when evaluating patients by specific infarct-related artery subgroups. In addition, tests for interaction between infract-related artery subgroups showed no statistically significant difference in effect in these three trials (p>0.20 for all). However, in the trial by Haeck and colleagues, proximal balloon embolic protection was found to increase patients chances of achieving complete ST-segment resolution when the lesion was in an anterior artery [RR 2.41 (1.11 to 5.19)], but not in other arteries [RR 1.20 (0.99 to 1.46)].<sup>18</sup> A test for interaction between these infarct-related artery subgroups showed a trend towards a statistically significant difference in effect (p=0.09). Due to the heterogeneous nature by which trials divided subgroups, pooling was deemed inappropriate.
Table 41. Results of subgroup analysis from randomized controlled trials evaluating the effect of infarct-related artery on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008 (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export® Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>Infarct-related vessel: RCA, Infarct-related vessel: other</td>
<td>RR 0.48 (0.29 to 0.81) RR 0.71 (0.53 to 0.93)</td>
<td>0.19</td>
</tr>
<tr>
<td>Kelbaeck, 2008 (N=626)</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire-EZ® or SpiderX™</td>
<td>STSR ≥ 70% 90 min postPCI</td>
<td>LAD treated CX/RCA treated</td>
<td>RR 1.16 (0.96 to 1.40) RR 1.03 (0.94 to 1.14)</td>
<td>0.27</td>
</tr>
<tr>
<td>Cura, 2007 (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpideRX™</td>
<td>STSR ≥ 70% 60 min postPCI</td>
<td>Infarct-related vessel: LAD, Infarct-related vessel: NonLAD</td>
<td>RR 1.14 (0.78 to 1.68) RR 0.93 (0.81 to 1.08)</td>
<td>0.33</td>
</tr>
<tr>
<td>Stone, 2005 (N=501)</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire™ Plus</td>
<td>STSR ≥ 70% 30 min postPCI</td>
<td>LAD RCA or LCX</td>
<td>RR 0.83 (0.55 to 1.24) RR 1.09 (0.98 to 1.22)</td>
<td>0.20</td>
</tr>
<tr>
<td>Stone, 2005 (N=501)</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire™ Plus</td>
<td>STSR ≥ 70% 30 min postPCI</td>
<td>Proximal vessel (LAD, RCA, or LCX) Nonproximal vessel</td>
<td>RR 1.00 (0.80 to 1.25) RR 1.04 (0.86 to 1.24)</td>
<td>0.78</td>
</tr>
<tr>
<td>Haeck, 2009 (N=284)</td>
<td>Proximal Balloon Embolic Protection</td>
<td>Proxis™</td>
<td>PostPCI STSR ≥ 70%</td>
<td>Anterior artery No anterior artery</td>
<td>RR 2.41 (1.11 to 5.19) RR 1.20 (0.99 to 1.46)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures
Abbreviations: CI=confidence interval; CX=circumflex coronary artery; LAD=left anterior descending coronary artery; LCX=left circumflex; MBG=myocardial blush grade; min=minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RCA=right coronary artery; RR=relative risk; STSR=ST-segment resolution

In addition to the effect of infarct-related artery, trials have also evaluated whether proximal or nonproximal location of the lesion within an artery affects the efficacy of adjunctive devices to improve post-ST-segment myocardial infarction outcomes (Table 42). The trial by Svilaas and colleagues demonstrated that catheter aspiration devices work equally well in preventing a postprocedure MBG of 0 or 1 in proximal and nonproximal lesion subgroups [RR 0.60 (0.43 to 0.85) and RR 0.69 (0.49 to 0.97), respectively] (P-value for interaction between subgroups=0.57). While, in trial by Haeck and colleagues, only patients with proximally located lesions were shown to achieve a higher rate of complete ST-segment resolution with the use of proximal balloon embolic protection [RR 1.71 (1.14 to 2.55)]. Those in the nonproximal lesion subgroup did not realize statistically significant benefit [RR 1.18 (0.92 to 1.51)]. A test for interaction between these infract-related artery subgroups showed no statistically significant difference in effect (p=0.12). The trial by Kelbaeck and colleagues suggested that proximal or nonproximal lesion location did not affect the efficacy of filter distal embolic protection (P-value for interaction between subgroups >0.10) (numerical data not reported).
Table 42. Results of subgroup analysis from randomized controlled trials evaluating the effect of lesion location on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008^10 (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export^1</td>
<td>PostPCI MBG 0 or 1</td>
<td>Proximal lesion</td>
<td>RR 0.60 (0.43 to 0.85)</td>
<td>RR 0.69 (0.49 to 0.97)</td>
</tr>
<tr>
<td>Haeck, 2009^11 (N=284)</td>
<td>Proximal Balloon</td>
<td>Proxis™</td>
<td>PostPCI STSR ≥ 70%</td>
<td>Proximal lesion</td>
<td>RR 1.71 (1.14 to 2.55)</td>
<td>RR 1.18 (0.92 to 1.51)</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

Five trials evaluated the effect of baseline TIMI flow on the efficacy of adjunctive devices to improve postST-segment myocardial infarction outcomes; however, the trial by Burzotta and colleagues did not provide numerical data and is therefore not included in (Table 43). In the trial by Svilaas and colleagues, catheter aspiration was found to reduce the risk of postprocedural MBG of 0 or 1 in patients with a preprocedural TIMI blood flow of 0 or 1 [RR 0.72 (0.55 to 0.95)], but fell just shy of significance in those with a TIMI flow graded at 2 or 3 [RR 0.60 (0.36 to 1.10)] (P-value for interaction between subgroups=0.54). Similar results were found in the trial by Burzotta and colleagues, which found that a catheter aspiration device was beneficial (obtained both a MBG≥2 and complete ST-segment resolution) in those with a baseline TIMI flow of 0 or 1, but not those with a TIMI flow of 2 or 3 (no numerical data reported). Upon subgroup analysis undertaken in the individual patient data meta-analysis,^171,172 no qualitative difference in mortality was seen when splitting the study population according to preprocedural TIMI flow (0–1 or 2–3). Three trials evaluated distal embolic protection (two filter, one balloon). In each of these trials, no preprocedure TIMI subgroup was found to provide a statistically significant effect on complete ST-segment resolution.
Table 43. Results of subgroup analysis from randomized controlled trials evaluating the effect of baseline thrombolysis in myocardial infarction flow on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008 (N=1,071)</td>
<td>Catheter Aspiration</td>
<td>6-French Export® Aspiration Catheter</td>
<td>PostPCI MBG 0 or 1</td>
<td>PrePCI TIMI flow 0 or 1</td>
<td>RR 0.72 (0.55 to 0.95)</td>
<td>0.60 (0.36 to 1.01)</td>
</tr>
<tr>
<td>Kelbaek, 2008 (N=626)</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire-EZ™ or SpiderX™</td>
<td>STSR ≥ 70%</td>
<td>Baseline TIMI 0 to 1</td>
<td>RR 1.05 (0.93 to 1.18)</td>
<td>1.18</td>
</tr>
<tr>
<td>Cura, 2007 (N=140)</td>
<td>Distal Filter Embolic Protection</td>
<td>SpideRX™</td>
<td>STSR ≥ 70%</td>
<td>Baseline TIMI 0/1</td>
<td>RR 1.02 (0.79 to 1.33)</td>
<td>0.66</td>
</tr>
<tr>
<td>Stone, 2005 (N=501)</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire™ Plus</td>
<td>STSR ≥ 70%</td>
<td>Baseline TIMI 0 or 1</td>
<td>RR 1.03 (0.86 to 1.23)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; min=minutes; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction

Only one trial evaluated the effect of direct stenting on the efficacy of adjunctive devices to improve postST-segment myocardial infarction outcomes (Table 44). In both the direct stenting and no direct stenting patient subgroups, use of catheter aspiration in this trial had no effect on patients’ chances of attaining a postprocedure TIMI flow of 3, experiencing distal embolization or no reflow. The P-values for interaction between subgroups was not statistically significant for any of these endpoints (p>0.68). When evaluating the MBG-3 and the complete ST-segment resolution endpoints in this trial, patients not undergoing direct stenting received statistically significant benefit from catheter aspiration use [RR 2.07 (1.33 to 3.22) and RR 1.56 (1.00 to 2.45)], but patients undergoing direct stenting did not [RR 1.41 (0.96 to 2.07) and RR 1.41 (0.81 to 2.47), respectively]. However, the P-value for interaction between subgroups was not statistically significant for either endpoint (p≥0.20 for both).

Table 44. Results of subgroup analysis from randomized controlled trials evaluating the effect of direct stenting on clinical outcome

<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silva-Orrego, 2008 (N=148)</td>
<td>Catheter Aspiration</td>
<td>Pronto™ Extraction Catheter</td>
<td>PostPCI TIMI 3</td>
<td>Direct stenting No direct stenting</td>
<td>RR 1.18 (0.91 to 1.54)</td>
<td>RR 1.23 (0.93 to 1.61)</td>
</tr>
<tr>
<td>Silva-Orrego, 2008 (N=148)</td>
<td>Catheter Aspiration</td>
<td>Pronto™ Extraction Catheter</td>
<td>MBG 3</td>
<td>Direct stenting No direct stenting</td>
<td>RR 1.41 (0.96 to 2.07)</td>
<td>RR 2.07 (1.33 to 3.22)</td>
</tr>
<tr>
<td>Silva-Orrego, 2008 (N=148)</td>
<td>Catheter Aspiration</td>
<td>Pronto™ Extraction Catheter</td>
<td>Maximal STSR &gt; 70%</td>
<td>Direct stenting No direct stenting</td>
<td>RR 1.41 (0.81 to 2.47)</td>
<td>RR 1.56 (0.995 to 2.45)</td>
</tr>
</tbody>
</table>

133
<table>
<thead>
<tr>
<th>Study, Year (Total N)</th>
<th>Device Type</th>
<th>Device</th>
<th>Outcome</th>
<th>Characteristic</th>
<th>Effect Size (&quot;X&quot;R 95%CI)*</th>
<th>P-Values for Interaction Between Subgroups*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Silva-Orrego, 2008</strong> (N=148)</td>
<td>Catheter Aspiration</td>
<td>Pronto™ Extraction Catheter</td>
<td>DE</td>
<td>Direct stenting</td>
<td>RR 0.35 (0.02 to 5.35)</td>
<td>RR 0.38 (0.09 to 1.54)</td>
</tr>
<tr>
<td><strong>Silva-Orrego, 2008</strong> (N=148)</td>
<td>Catheter Aspiration</td>
<td>Pronto™ Extraction Catheter</td>
<td>No Reflow</td>
<td>Direct stenting</td>
<td>RR 0.12 (0.01 to 2.81)</td>
<td>RR 0.25 (0.03 to 1.80)</td>
</tr>
</tbody>
</table>

*Some values were calculated based upon available trial data or estimated from figures

Abbreviations: CI=confidence interval; DE=distal embolization; MBG=myocardial blush grade; N=total number of participants enrolled; PCI=percutaneous coronary intervention; RR=relative risk; STSR=ST-segment resolution

In addition to the results from the above-mentioned RCTs and individual patient data meta-analysis, five observational studies were identified that provide data addressing key question 3.

The largest of these observational studies was the prospective, multicenter Osaka Acute Coronary Insufficiency Study (OACIS). Researchers evaluated 3,913 patients who underwent PCI within 24 hours after symptom onset, of which, 990 patients (25.3 percent) were treated with catheter aspiration before PCI. Overall, OACIS found a trend towards 30-day mortality benefit with intracoronary thrombectomy [hazard ratio (HR) 0.658, p=0.17]. Intracoronary thrombectomy was an independent predictor of a lower 30-day mortality risk in patients aged ≥70 years (HR 0.239, p=0.007) and patients with diabetes mellitus (HR 0.275, p=0.039), but not in patients < 70 years of age or nondiabetics. P-value for interaction between subgroups was statistically significant for age (p=0.008), but not diabetes status (p=0.17). Furthermore, baseline TIMI flow, gender, smoking and Killip class (a correlate to heart failure and ejection fraction) were not found to be modifiers of 30-day mortality (P-value for interaction between subgroups >0.24). A second observational study was conducted by the researchers from the EXPIRA RCT which randomized patients who had a STEMI to catheter aspiration (n=88) versus standard PCI (n=87). A multivariate Cox proportional hazard regression model was used to identify independent predictors of cardiac death at 2 years. No deaths during the trial period were other than cardiac cause. Randomization to thrombus aspiration [HR 0.12 (0.006 to 0.251), p=0.006], age [HR 1.508 (1.055 to 2.156), p=0.024] and symptom to balloon time [HR 1.322 (1.078 to 1.622), p=0.007] were found to be significant predictors of cardiac death at 2 years. Diabetes, hypertension, and final MBG <2 were not found to significantly predict cardiac death.

The remaining three single-arm observational studies conducted multivariate analysis. Cohen and colleagues evaluated catheter aspiration with the Export® catheter in patients experiencing STEMI and undergoing primary PCI to identify covariates associated with successful thrombectomy (increase in TIMI flow grade of at least 1). Upon multivariate logistic regression analysis, researchers identified ischemic time <6 hours as the only independent predictor of successful thrombectomy (p=0.04). Kramer and colleagues evaluated the use of catheter aspiration (Rescue™ or Export®) or proximal balloon embolic protection (Proxis™) in 914 patients experiencing STEMI and undergoing primary PCI. They found that age >60 years [hazard ratio 1.83 (1.14 to 2.93)], female gender [hazard ratio 4.22 (2.29 to 7.76)] and the presence of diabetes mellitus [hazard ratio 1.73 (1.09 to 2.76)] were all independent predictors of increased mortality by four years, whereas, current smoking, total ischemic time and having the LAD as the infarct-related artery were not. Ochala and colleagues conducted a multivariate
analysis to determine independent predictors of achieving a postprocedure TIMI flow of 2 or 3 in the distal balloon embolic protection (PercuSurge) arm of a RCT of 120 ST-segment elevation patients undergoing primary PCI. In this analysis, the presence of baseline thrombus was found to independently predict increased odds of TIMI 2 or 3 flow in embolic protection device treated patients. LAD as the infarct-related artery, ischemic time greater than or equal to 6 hours and presence of diabetes mellitus were not found to be predictors of TIMI 2 or 3 flow attainment. 

Discussion

While a clinical trial or observational study may demonstrate an overall benefit for an intervention, this benefit may or may not occur to a similar extent across different types of constituents. As such, it is important to determine what, if any, data exists evaluating the impact of an intervention in these important subgroups. For Key Question 3, nine RCTs, an individual patient data meta-analysis,171,172 a pooled analysis, and five observational studies provided some insight. However, most of the evidence is in the form of subgroup analysis stratified by covariate within RCTs. These subgroup analyses were typically underpowered to demonstrate statistically significant differences within and between subgroups and we cannot be sure that the results attained were due to a lack of impact or lack of power. Clinical trials with larger sample sizes would be needed to draw more definitive conclusions from such analyses. Secondly, many of the included trials and studies conducted subgroup analyses on large numbers of covariates making conclusions susceptible to bias resulting from multiple hypothesis testing.

Finally, the clinical trials provide univariate evaluations and we do not know if the results are due the factor being investigated or due to a confounder that one subgroup has in a differing amount from another subgroup.

Randomized trials and an individual patient data meta-analysis of RCTs have not demonstrated statistically significant effect modification of aspiration, mechanical thrombectomy or embolic protection device efficacy by gender, diabetes, smoking status, primary or rescue PCI, presence of thrombus-containing lesion, prePCI TIMI flow, or the use of direct stenting. Furthermore, no RCTs evaluated the effect of ethnicity or ejection fraction on thrombectomy or embolic protection device efficacy. While randomized trials and the individual patient meta-analysis did not show an affect of age, diabetes, baseline thrombus and gender on aspiration or thrombectomy device efficacy, a limited number of observational studies did.

Individual randomized trials did not demonstrate a modifying effect of glycoprotein IIb/IIIa use on aspiration or mechanical thrombectomy device efficacy. However, the individual patient data meta-analysis found that randomization to aspiration or mechanical thrombectomy was associated with a survival benefit in the subgroup of patients treated with glycoprotein IIb/IIIa inhibitors, but not in those not receiving them. This may suggest a modifying effect of glycoprotein IIb/IIIa inhibitors with these devices. While embolic protection devices were not studied in the individual patient meta-analysis, a single randomized trial of proximal balloon protection demonstrated a similar modifying affect of glycoprotein IIb/IIIa inhibitor use; with greater efficacy in those receiving a glycoprotein IIb/IIIa inhibitor. Limited data exists evaluating the effect of glycoprotein IIb/IIIa inhibitor use on the efficacy of distal embolic protection devices.

It appears doubtful that ischemic time affects the efficacy of aspiration or mechanical thrombectomy devices or embolic protection devices. Data regarding the affect of ischemic time on efficacy of aspiration catheter efficacy (MBG and TIMI 3 flow) was conflicting in randomized trials; while, the OASIS observational study suggested prolonged ischemic time...
negatively affected the ability of thrombectomy or embolic protection devices to reduce mortality. A pooled analysis suggested prolonged time to treatment lead to greater efficacy (STSR and TIMI-3) of catheter aspiration devices. Neither beneficial nor harmful associations between ischemic time and aspiration or mechanical thrombectomy devices were observed in the individual patient data meta-analysis.

Individual randomized trials and the individual patient meta-analysis suggested no modification of aspiration or mechanical thrombectomy device efficacy based upon infarct-related artery. However, a single trial, found a trend towards statistically significant greater efficacy (complete ST-segment resolution) of proximal balloon embolic protection in those with an anterior infarct-related artery. No studies have evaluated whether distal embolic protection device efficacy is impacted by infarct-related artery location.

**Strength of Evidence and Applicability**

**Strength of Evidence**

A summary of the strength of evidence for Key questions 1 and 2 are in Table 45 and Table 46 while the full evaluation of the strength of evidence for each outcome is found in Appendix G.

A majority of the available evidence was in the STEMI population. In patients with STEMI, there was a high strength of evidence that catheter aspiration devices versus control decreased the risk of MACE, distal embolization and no reflow. The strength of evidence was moderate that catheter aspiration devices increased the attainment of ST-segment resolution, MBG-3, or TIMI-3 blood flow and had no effect on ejection fraction versus control. The strength of evidence was low that catheter aspiration devices had no effect on the risk of mortality, myocardial infarction, or target revascularization and insufficient for stroke, all versus control. Regarding adverse events, the strength of evidence for catheter aspiration devices versus control was high that the risk of coronary dissection was decreased and that there was no effect on prolongation of procedure time. The strength of evidence was insufficient that catheter aspiration devices had no effect versus control on coronary perforation.

The strength of evidence associated with all final health outcomes in the STEMI population undergoing PCI with a mechanical thrombectomy device was insufficient due to limited data available per outcome. No reflow was also graded with insufficient evidence. There was moderate strength of evidence that mechanical thrombectomy devices had no effect on the risk distal embolization, ejection fraction or attainment of TIMI-3 blood flow versus control. The strength of evidence was low that mechanical thrombectomy devices had no effect ST-segment resolution or attainment of a MBG-3. When analyzing different time points for the outcome of MACE, there was a significant reduction in the risk of MACE at 365 days [RR 0.66 (0.44, 0.97)] not seen in evaluations at earlier time periods, although this was based on a single randomized controlled trial. The strength of evidence for prolongation of procedure time was high for mechanical thrombectomy devices versus control, while the strength of evidence was insufficient for coronary dissection or perforation due to the limited amount of data.

For comparisons between distal filter embolic protection devices and control, no evaluation had a high strength of evidence. The strength of evidence was moderate that there was no effect on the risk of MACE, ST-segment resolution, or attainment of a MBG-3. The strength of evidence was low that there was increased risk of target revascularization and no effect on the attainment of TIMI-3 blood flow or ejection fraction. The strength of evidence was insufficient
for mortality, myocardial infarction, stroke, distal embolization and no reflow. For adverse outcomes, the strength of evidence was insufficient for all outcomes.

The strength of evidence was high that there was an increased risk of attaining a MBG-3 with the use of a distal balloon embolic protection device versus control. The strength of evidence was moderate that there was no effect on ST-segment resolution and ejection fraction and low that there was increased risk on attainment of TIMI-3 blood flow with the use of distal balloon embolic protection devices versus control. The strength of evidence was insufficient for mortality, myocardial infarction, target revascularization, MACE, distal embolization and no reflow due to the limited amount of data. Regarding adverse outcomes, strength of evidence was low that there was prolonged procedure time while insufficient for other adverse outcomes comparing distal balloon embolic protection devices versus control.

For all final health, intermediate and adverse outcomes the strength of evidence was insufficient for the comparison of proximal balloon embolic protection devices versus control with one exception. The strength of evidence was moderate that proximal balloon embolic protection devices prolong procedure time versus control.

For comparisons between embolic protection devices combined versus control, the strength of evidence was moderate that the attainment of a MBG-3 was increased with the use of an embolic protection device versus control and that there was no effect on the risk of MACE, distal embolization, or ejection fraction. The strength of evidence was low that there was increased risk of attaining TIMI-3 blood flow and that there was no effect on the risk of ST-segment resolution with the use of embolic protection devices combined versus control. All other outcomes were insufficient due to the limited amount of data available. In terms of adverse outcomes, the strength of evidence was moderate that the use of embolic protection devices combined prolong procedure time versus control while insufficient for all other adverse outcomes.

In the mixed ACS population strength of evidence was predominately insufficient or low for all device categories versus control. There was a high strength of evidence that distal balloon embolic protection devices decreased the risk of no reflow versus control, which was propagated into the embolic protection devices combined analysis. There was a moderate strength of evidence that mechanical devices and distal balloon embolic protection devices increased the attainment of ST-segment resolution and that distal balloon embolic protection devices increased the attainment of MBG-3 versus control and prolonged procedure time. Both distal balloon results were propagated into the embolic protection devices combined analyses. The strength of evidence was low that catheter aspiration devices increased the attainment of MBG-3 versus control. All other outcomes for all device categories were insufficient.

In the UA / NSTEMI population the strength of evidence was insufficient for all final health, intermediate, and adverse outcomes due to the limited amount of data available for each comparison and outcome.

**Applicability**

The applicability of evidence was high for four evaluations: the impact of distal balloon embolic protection devices on stroke versus control and the impact of mechanical thrombectomy devices on coronary dissection, perforation and prolonged procedure time versus control. Applicability of the trials was in the moderate to low range (52.6 percent and 43.3 percent of comparisons, respectively) for all other outcomes because the trials were mostly conducted outside of the United States. The applicability of individual trials, studies, and the body of
evidence per outcome assessed can be found in Appendix H along with the description of factors that impacted the applicability of the body of evidence.

Table 45. Summary of the strength of evidence for Key Question 1: In patients with acute coronary syndrome who are undergoing percutaneous coronary intervention of native vessels, does the use of an adjunctive device affect final or intermediate health outcomes compared to usual care?

<table>
<thead>
<tr>
<th>Population-Device Category</th>
<th>Number and Type of Studies N (RCT, OBS)</th>
<th>Conclusion</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEMI- Catheter Aspiration Devices</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>13 (10,3)</td>
<td>No effect</td>
<td>L</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12 (10,2)</td>
<td>No effect</td>
<td>L</td>
</tr>
<tr>
<td>Stroke</td>
<td>6 (4,2)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>11 (9,2)</td>
<td>No effect</td>
<td>L</td>
</tr>
<tr>
<td>MACE</td>
<td>13 (11,2)</td>
<td>Decreases risk</td>
<td>H</td>
</tr>
<tr>
<td>HRQOL</td>
<td>0</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>16 (15,1)</td>
<td>Increases risk</td>
<td>M</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>12 (11,1)</td>
<td>No effect</td>
<td>M</td>
</tr>
<tr>
<td>MBG-3</td>
<td>13 (13,0)</td>
<td>Increases risk</td>
<td>M</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>15 (13,2)</td>
<td>Increases risk</td>
<td>M</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>11 (10,1)</td>
<td>Decreases risk</td>
<td>H</td>
</tr>
<tr>
<td>No reflow</td>
<td>8 (8,0)</td>
<td>Decreases risk</td>
<td>H</td>
</tr>
<tr>
<td><strong>STEMI- Mechanical Thrombectomy Devices</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mortality</td>
<td>5 (4,1)</td>
<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Myocardial infarction</td>
<td>4 (3,1)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>Stroke</td>
<td>5 (4,1)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>4 (3,1)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>MACE</td>
<td>4 (3,1)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>HRQOL</td>
<td>0</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>5 (5,0)</td>
<td>No effect</td>
<td>L</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>2 (2,0)</td>
<td>No effect</td>
<td>M</td>
</tr>
<tr>
<td>MBG-3</td>
<td>4 (4,0)</td>
<td>No effect</td>
<td>L</td>
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<tr>
<td>TIMI-3</td>
<td>5 (4,1)</td>
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<td>M</td>
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<td>Distal embolization</td>
<td>3 (3,0)</td>
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<td>M</td>
</tr>
<tr>
<td>No reflow</td>
<td>3 (3,0)</td>
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<td><strong>STEMI- Distal Filter Embolic Protection Devices</strong></td>
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<td>Mortality</td>
<td>5 (5,0)</td>
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<td>Myocardial infarction</td>
<td>4 (4,0)</td>
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<td>I</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (1,0)</td>
<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Target revascularization</td>
<td>2 (2,0)</td>
<td>Increased risk</td>
<td>L</td>
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<tr>
<td>MACE</td>
<td>5 (5,0)</td>
<td>No effect</td>
<td>M</td>
</tr>
<tr>
<td>HRQOL</td>
<td>0</td>
<td>No/limited data</td>
<td>I</td>
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<tr>
<td>ST-segment resolution</td>
<td>5 (5,0)</td>
<td>No effect</td>
<td>M</td>
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<tr>
<td>Ejection fraction</td>
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<td>No effect</td>
<td>L</td>
</tr>
<tr>
<td>MBG-3</td>
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<td>No effect</td>
<td>M</td>
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<tr>
<td>TIMI-3</td>
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<td>L</td>
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<tr>
<td>Distal embolization</td>
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</tr>
<tr>
<td>No reflow</td>
<td>2 (2,0)</td>
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</tbody>
</table>
Table 45. Summary of the strength of evidence for Key Question 1: In patients with acute coronary syndrome who are undergoing percutaneous coronary intervention of native vessels, does the use of an adjunctive device affect final or intermediate health outcomes compared to usual care? (continued)

<table>
<thead>
<tr>
<th>Population-Device Category</th>
<th>Number and Type of Studies N (RCT, OBS)</th>
<th>Conclusion</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEMI- Distal Balloon Embolic Protection Devices</strong></td>
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<td>Myocardial infarction</td>
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<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Stroke</td>
<td>1 (1,0)</td>
<td>No/limited data</td>
<td>I</td>
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<td>Target revascularization</td>
<td>5 (5,0)</td>
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<td><strong>MACE</strong></td>
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<th>Population-Device Category</th>
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<th>Conclusion</th>
<th>SOE</th>
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<td>I</td>
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<td>Stroke</td>
<td>1 (1,0)</td>
<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Target revascularization</td>
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<td>No/limited data</td>
<td>I</td>
</tr>
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<td>MACE</td>
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<td>I</td>
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<tr>
<td>Ejection fraction</td>
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<td>I</td>
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<td>MBG-3</td>
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<td>No/limited data</td>
<td>I</td>
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<tr>
<td>TIMI-3</td>
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<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Distal embolization</td>
<td>1 (1,0)</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>No reflow</td>
<td>0</td>
<td>No/limited data</td>
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<td><strong>STEMI- Embolic Protection Devices Combined</strong></td>
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<td>No/limited data</td>
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<td>No/limited data</td>
<td>I</td>
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<tr>
<td>Stroke</td>
<td>3 (3,0)</td>
<td>No/limited data</td>
<td>I</td>
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<td>Target revascularization</td>
<td>8 (8,0)</td>
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<td>MACE</td>
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<td>M</td>
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<td>HRQOL</td>
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</tr>
<tr>
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<td>No effect</td>
<td>M</td>
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<tr>
<td>MBG-3</td>
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<td>Increases risk</td>
<td>M</td>
</tr>
<tr>
<td>TIMI-3</td>
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<tr>
<td>Distal embolization</td>
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<td>M</td>
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<tr>
<td>No reflow</td>
<td>6 (6,0)</td>
<td>No/limited data</td>
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<td><strong>UA/NSTEMI- Catheter Aspiration Devices</strong></td>
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<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>0</td>
<td>No/limited data</td>
<td>I</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>No/limited data</td>
<td>I</td>
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<td><strong>Target revascularization</strong></td>
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<td><strong>Ejection fraction</strong></td>
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<tr>
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**UA/NSTEMI- Distal Filter Embolic Protection Devices**

| **Mortality** | 1 (1,0) | No/limited data | I   |
| **Myocardial infarction** | 1 (1,0) | No/limited data | I   |
| **Stroke** | 0 | No/limited data | I   |
| **Target revascularization** | 1 (1,0) | No/limited data | I   |
| **MACE** | 1 (1,0) | No/limited data | I   |
| **HRQOL** | 0 | No/limited data | I   |
| **ST-segment resolution** | 0 | No/limited data | I   |
| **Ejection fraction** | 0 | No/limited data | I   |
| **MBG-3** | 0 | No/limited data | I   |
| **TIMI-3** | 1 (1,0) | No/limited data | I   |
| **Distal embolization** | 0 | No/limited data | I   |
| **No reflow** | 1 (1,0) | No/limited data | I   |

**UA/NSTEMI- Distal Balloon Embolic Protection Devices**

| **Mortality** | 0 | No/limited data | I   |
| **Myocardial infarction** | 0 | No/limited data | I   |
| **Stroke** | 0 | No/limited data | I   |
| **Target revascularization** | 0 | No/limited data | I   |
| **MACE** | 0 | No/limited data | I   |
| **HRQOL** | 0 | No/limited data | I   |
| **ST-segment resolution** | 0 | No/limited data | I   |
| **Ejection fraction** | 0 | No/limited data | I   |
| **MBG-3** | 0 | No/limited data | I   |
| **TIMI-3** | 0 | No/limited data | I   |
| **Distal embolization** | 0 | No/limited data | I   |
| **No reflow** | 0 | No/limited data | I   |

**UA/NSTEMI- Proximal Balloon Embolic Protection Devices**

| **Mortality** | 0 | No/limited data | I   |
| **Myocardial infarction** | 0 | No/limited data | I   |
| **Stroke** | 0 | No/limited data | I   |
| **Target revascularization** | 0 | No/limited data | I   |
| **MACE** | 0 | No/limited data | I   |
| **HRQOL** | 0 | No/limited data | I   |
| **ST-segment resolution** | 0 | No/limited data | I   |
| **Ejection fraction** | 0 | No/limited data | I   |
Table 45. Summary of the strength of evidence for Key Question 1: In patients with acute coronary syndrome who are undergoing percutaneous coronary intervention of native vessels, does the use of an adjunctive device affect final or intermediate health outcomes compared to usual care? (continued)

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Mixed ACS- Distal Balloon Embolic Protection Devices

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Mixed ACS- Proximal Balloon Embolic Protection Devices

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Mixed ACS- Embolic Protection Devices Combined

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(continued)

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<tr>
<td>No reflow</td>
<td>1 (1,0)</td>
<td>Decreases risk</td>
<td>H</td>
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</table>

Outcomes reported are those with the longest duration of follow-up

Abbreviation: ACS=acute coronary syndrome; AOE=applicability of evidence; H=high; HRQOL=health-related quality of life; I=insufficient; L=low; M=moderate; MACE=major adverse cardiovascular event; MBG=myocardial blush grade; NA=not applicable; NSTEMI=nonST-segment elevation myocardial infarction; OBS=observational; RCT=randomized controlled trial; SOE=strength of evidence; STEMI=ST-segment elevation myocardial infarction; TIMI=thrombolysis in myocardial infarction; UA=unstable angina

Table 46. Summary of the strength of evidence for Key Question 2: In patients with acute coronary syndrome who are undergoing percutaneous coronary intervention of native vessels, does the use of an adjunctive device affect adverse outcomes compared to usual care?

<table>
<thead>
<tr>
<th>Population-Device Category</th>
<th>Number and Type of Studies N (RCT, OBS)</th>
<th>Conclusion</th>
<th>SOE</th>
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</thead>
<tbody>
<tr>
<td>STEMI- Catheter Aspiration Devices</td>
<td></td>
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<tr>
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<tr>
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</table>
Table 46. Summary of the strength of evidence for Key Question 2: In patients with acute coronary syndrome who are undergoing percutaneous coronary intervention of native vessels, does the use of an adjunctive device affect adverse outcomes compared to usual care? (continued)

<table>
<thead>
<tr>
<th>Population-Device Category</th>
<th>Number and Type of Studies N (RCT, OBS)</th>
<th>Conclusion</th>
<th>SOE</th>
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<tr>
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Discussion

The determination of the balance of benefits to harms is difficult because many of the final health outcome and adverse event evaluations are underpowered. We cannot know for certain whether the nonsignificant increases or decreases are due to a real effect or to chance. The applicability of the body of evidence is highest for patients with STEMI undergoing primary PCI of the native vessels. Data is more highly applicable to male patients versus female patients, because of the enrollment of a consistently higher percentage of males across trials. The majority of data is derived from trials and studies conducted outside of the United States evaluating devices that are not currently available in the United States, therefore the applicability is limited. Overall, applicability is low in patients with other ACSs or in patients undergoing rescue PCI.

In the catheter aspiration trials, the risk of MACE and coronary dissection were significantly lower in the overall analysis and the good quality trial analyses. The risk of mortality, myocardial infarction, stroke, target revascularization and side branch occlusion were not significantly different versus control. Eight of nine trials and one controlled observational study found a nonsignificant prolongation of the time needed to conduct the PCI procedure versus control. Intermediate health outcomes showed significant reductions in distal embolization and no reflow and significantly more patients experienced ST segment resolution, higher MBG, and near normal (TIMI-3) blood flow though the target vessel versus control. As such, more research is needed to truly determine the balance of benefits to harms.

Mechanical thrombectomy device use did not result in any significant differences in the risk of mortality, stroke, MACE, coronary dissection, and coronary perforation in the overall analyses and analyses limited to good quality trials. However, these devices significantly increased the time needed to conduct the PCI procedure in three trials. While the risk of myocardial infarction, target revascularization, mortality and MACE were not significantly different versus control, these findings may be misleading since many of the trials evaluating this procedure versus control had a shorter duration of follow-up. When we evaluated mortality and MACE in studies of 365 days or longer, there was no significant difference in mortality risk although there was a significant reduction in MACE, based on the results of a single trial. Unlike with catheter aspiration devices, there are no significant beneficial effects on intermediate health outcomes and while most are in the right direction of effect, the chance of achieving near normal (TIMI-3) blood flow was not significantly different versus control. As such, more research is needed to truly determine the balance of benefits to harms with mechanical thrombectomy devices.

The use of embolic protection devices was based on a limited number of studies and one significant finding (distal filter on target revascularization) on final health outcomes was seen in overall analyses or those limited to good quality trials. It was difficult to assess the impact on final health outcomes and intermediate outcomes for these devices. In STEMI, distal balloon devices significantly increased the chance of achieving a MBG-3, near normal (TIMI-3) blood flow but did not significantly impact the achievement of ST-segment resolution, prevention of no reflow, or the risk of distal embolization. Distal filter devices did not significantly impact ST-segment resolution, distal embolization, no reflow, attainment of near normal (TIMI-3) blood flow, or MBG. There was a paucity of trials available to evaluate adverse events with any of the embolic protection devices. The only significant findings was an increased time to perform a PCI procedure for all three types of embolic protection devices individually and when evaluated all together versus control. As such, the balance of benefits to harms cannot be determined for these device classes.
Given the inadequate power in overall analyses or lack of data, we could not definitively determine the impact of therapy in subpopulations. No data was available to determine if the results differed based on ethnicity or ejection fraction. Given the available data, the concomitant use of a glycoprotein IIb/IIIa receptor antagonist and a device may be associated with a survival benefit.
Future Research

Limitations of Current Research

The use of thrombus removal and embolic protection devices hold promise in the adjunctive treatment of patients with ACS undergoing primary percutaneous coronary intervention. However, to truly discern the role of these devices in contemporary practice, a number of important research questions need to be answered.

While two direct comparative randomized trials had been conducted and evaluated for multiple endpoints, one comparing one catheter aspiration device to another and one comparing a catheter aspiration device to an embolic protection device, no significant differences were found and the trials were vastly underpowered to evaluate for final health outcomes and underpowered to evaluate for intermediate health outcomes as well.

In our analysis, we found that for many endpoints, nonsignificant increases or decreases were found versus control, even when we evaluated compound endpoints, used the maximum duration of followup, and combined three different types of embolic protection devices together. All of these were strategies to enhance power to detect differences between groups but by and large, did not provide adequate power. Ultimately, the impact of using these devices on long term final health outcomes versus control needs to be determined.

Applicability of the trials was in the low to moderate range for almost all outcomes because the trials were mostly conducted outside of the United States. It will be important to determine if the devices are equally effective in the hands of average interventional cardiologists in the United States. In addition, it is unclear how much experience the interventional cardiologists had in performing the procedures before enrolling in the clinical trials. It is unclear whether the use of the devices by average interventional cardiologists will result in a different balance of benefits to harms versus the more experienced, high volume interventional cardiologists.

Given the inadequate power in overall analyses or lack of data, we cannot determine the impact of therapy in subpopulations (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and prePCI TIMI flow, use of direct stenting).

Based on these research gaps we propose the following avenues for future research.

Future Avenues for Research

Clinical Trials

- We believe that additional multicenter, randomized, placebo-controlled trials should be conducted to determine the impact of adjunctive clot removal or embolic protection devices on final health outcomes using a long term followup.
  - Such trials should have adequate representation of interventional cardiologists from the United States and include both tertiary academic medical centers and large community based hospitals as well.
  - Even if the trials are not large enough to determine efficacy in subgroups (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of thrombus-containing lesion, infarct-related artery and prePCI TIMI flow, use of direct
stenting); such data should be recorded and included in the results so future comparative effectiveness reviews could pool these results and determine if the benefits or harms are uniformly distributed across the population or are centered within a certain subgroup.

- Conducting these additional clinical trials would facilitate the conduction of mixed treatment meta-analyses or individual patient data meta-analyses to estimate the comparative effectiveness of different device classes.

- To truly determine the comparative effectiveness, the devices found to have the best balance of benefits to harms compared with standard PCI should be directly compared in a multicenter, randomized, active controlled trial to determine the impact of adjunctive clot removal or embolic protection devices on final health outcomes using a long term followup.
  - Such a trial should have adequate representation of interventional cardiologists from the United States and include both tertiary academic medical centers and large community based hospitals as well.
  - Even if the trial is not large enough to determine efficacy in subgroups; such data should be included in the results.
  - Along with additional placebo controlled trials, conducting direct comparative clinical trials would facilitate the conduction of mixed treatment meta-analyses or individual patient data meta-analyses to estimate the comparative effectiveness of device classes that are and are not being directly compared.

**Observational Studies**

- Future observational studies should determine if certain subpopulations may have accentuated or attenuated benefits or harms and whether benefits or harms differ between high volume academic medical centers and lower volume community hospital.
- Electronic medical records can be used as a source of data for future observational and effectiveness studies.
References and Included Studies


32. Lefevre T. Preliminary results of a randomized trial using X-SIZER in acute myocardial infarction for negligible embolization and optimal ST-segment resolution (XAMINE ST). Am J Cardiol 2002;90:TCT266.


63. Svilaa T, van der Horst IC, Zijlstra F. Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS)--study design. Am Heart J 2006;151:597.e1,597.e7. PMID: 16504620
65. de Smet BJ. Thrombus aspiration during percutaneous coronary intervention in acute myocardial infarction study (TAPAS)--study design. Am Heart J 2006;151:597.e1,597.e7. PMID: 16504620


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<th>Definition</th>
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<tr>
<td>ACS</td>
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<td>ACT</td>
<td>Activated clotting time</td>
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</tr>
<tr>
<td>H</td>
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<tr>
<td>HCL</td>
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<td>IU</td>
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<td>LBBB</td>
<td>Left bundle branch block</td>
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<td>LCX</td>
<td>Left circumflex</td>
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<tr>
<td>LV</td>
<td>Left ventricle</td>
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<tr>
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<tr>
<td>M</td>
<td>Month</td>
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<tr>
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<td>Major adverse cardiovascular event</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>--------------</td>
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<tr>
<td>MACCE</td>
<td>Major adverse cerebrovascular and cardiovascular event</td>
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<tr>
<td>Mg/dL</td>
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<tr>
<td>MI</td>
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<tr>
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<td>Relative risk</td>
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<td>S</td>
<td>Seconds</td>
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<tr>
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<td>Serum creatinine</td>
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<tr>
<td>SVG</td>
<td>Saphenous vein graft</td>
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<td>TEP</td>
<td>Technical Expert Panel</td>
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<tr>
<td>TBG</td>
<td>TIMI blush grade</td>
</tr>
<tr>
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<td>Thrombolysis in myocardial infarction</td>
</tr>
<tr>
<td>TMPG</td>
<td>TIMI myocardial perfusion grade</td>
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<tr>
<td>TL</td>
<td>Thrombolysis</td>
</tr>
<tr>
<td>TLR</td>
<td>Target lesion revascularization</td>
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<tr>
<td>TS</td>
<td>Thrombus score</td>
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<tr>
<td>TVAC®</td>
<td>Transvascular aspiration catheter</td>
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<tr>
<td>TVR</td>
<td>Target vessel revascularization</td>
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<td>U</td>
<td>Units</td>
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<tr>
<td>Y</td>
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Appendix A: Exact Search Strategy

Search Strategy for MEDLINE, CENTRAL, CDSR (each in OVID starting in 1996), and Web of Science (limited to meeting abstracts only)

1. myocardial infarction.mp. or Myocardial Infarction/
2. acute myocardial infarction.mp.
3. AMI.mp.
4. MI.mp.
5. STEMI.mp.
6. ST-segment elevation.mp.
7. ACS.mp.
8. NSTEMI.mp.
9. acute coronary syndrome.mp. or Acute Coronary Syndrome/
10. ST-segment resolution.mp.
11. unstable angina.mp. or Angina, Unstable/
12. Q-wave.mp.
13. no-reflow.mp.
14. distal embolization.mp.
15. Angioplasty, Transluminal, Percutaneous Coronary/ or percutaneous coronary intervention.mp.
16. PCI.mp.
17. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. thrombectomy.mp. or Thrombectomy/
19. embolic protection.mp.
20. distal protection.mp.
21. proximal protection.mp.
22. thrombus aspiration.mp.
23. aspiration catheter.mp.
24. rescue catheter.mp.
25. diver CE.mp.
26. Export catheter.mp.
27. transvascular aspiration catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
28. TVAC.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
29. Pronto.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
30. x-sizer.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
31. angiojet.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
32. filterwire.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
33. spiderx.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
34. spiderfx.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
35. angioguard.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
36. proxis.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
37. interceptor plus.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
38. rinspirator.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
39. microvena trap.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
40. percusurge.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
41. triactiv.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
42. cardioshield.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
43. thrombobuster.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
44. rio catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
45. fetch catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
46. quickcat.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
47. rubicon catheter.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
48. parodi anti-embolisation.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
49. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48
50. 17 and 49
51. 50 not carotid.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
52. limit 51 to humans
## Appendix B: Data Extraction Form

### Study Identification

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<tr>
<th>First Author:</th>
<th>Year:</th>
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<table>
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<th>Language (if not English):</th>
<th>Single or Multi-center:</th>
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<table>
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<tr>
<td>Government/Foundation</td>
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<tr>
<td>Academia</td>
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<td>Other/Unknown</td>
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<tr>
<td>Full-text</td>
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<tr>
<td>Abstract</td>
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<td>Other (specify):</td>
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### Design Characteristics

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<tbody>
<tr>
<td>RCT</td>
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<tr>
<td>Observational</td>
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<table>
<thead>
<tr>
<th>Random Allocation Concealment?</th>
<th>Y</th>
<th>N</th>
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</thead>
<tbody>
<tr>
<td>Blinded Outcome Assessment?</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Intention to treat principle used?</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>
**Study Population**

### Inclusion Criteria:
- Native vessel
- Acute MI within ____ hrs
- Angiographically visible thrombus
- Chest pain associated with ACS >__min

### Exclusion Criteria:
- Saphenous vein grafts
- Contraindication to GP 2B3A Inhibitor
- Cardiogenic shock
- Left- BBB
- Ventricular pacing at baseline
- Previous MI in past____days
- Inability to obtain informed consent
- Previous Coronary Bypass surgery
- Killip class IV
- Ventricular Tachycardia

### Device name:
- Catheter Aspiration (Export, TVAC, Rescue, Pronto, Diver CE)
- Mechanical Thrombectomy (Angiojet, X-Sizer)
- Balloon Distal Embolic Protection (Guardwire)
- Filter Distal Embolic Protection (Filterwire, SpiderX, Angioguard)
- Proximal Embolic Balloon Protection
- Proximal Embolic Filter Protection

### Follow-Up Months (study) :

### Define primary outcome:

<table>
<thead>
<tr>
<th>Device Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
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B-2
### Baseline Characteristics

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<tr>
<td>N</td>
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<td>Dyslipidemia, n/N (%)</td>
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<tr>
<td>Age, years (mean± SD)</td>
<td></td>
<td>Hypertension n/N (%)</td>
<td></td>
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<tr>
<td>Males, n/N (%)</td>
<td></td>
<td>Baseline TIMI 0-1 Flow, n/N (%) or mean ± SD, specify</td>
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<tr>
<td>Anterior MI n/N (%)</td>
<td></td>
<td>DM n/N (%)</td>
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<td>Family history of CAD n/N (%)</td>
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<td>Smoker n/N (%)</td>
<td></td>
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<td>Prior Myocardial Infarction n/N (%)</td>
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<td>Failed TL n/N (%)</td>
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<td>Mean Ischemic Time, min (mean± SD or median±IQR, specify) Definition:</td>
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<td>Killip Class n/N (%) Definition:</td>
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<tr>
<td>Definition:</td>
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<td>Thrombus Score n/N (%) Definition:</td>
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<td>LCX Lesion</td>
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<td>Unstable Angina</td>
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<td>Multi-vessel Disease n/N (%)</td>
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<td>Visible lesion on angiography n/N (%)</td>
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<td>Definition:</td>
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<td>Definition:</td>
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<tr>
<td>Pre-cTFC (mean± SD)</td>
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<td></td>
<td>Pre-LVEF (mean± SD)</td>
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Concurrent Drugs Used

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<td>Ticlopidine</td>
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<td>Clopidogrel</td>
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<td>GP2B3A</td>
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Procedural Characteristics

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<tbody>
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</table>

| Stent n/N (%)                                         |              |               |
| Direct Stent n/N (%)                                  |              |               |
| Need of IABP n/N (%)                                  |              |               |
| Need of pacing n/N (%)                                |              |               |
| Emergency CABG n/N (%)                                |              |               |
| GP2B3A use n/N (%) Define use:                        |              |               |
| Lesion debris removed from filter n/N (%)             |              |               |
### Surrogate Outcomes

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<td>Post-PCI TIMI 3 n/N (%)</td>
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<tr>
<td>Post cTFC (mean % ±SD)</td>
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<td>LVEF (mean % ±SD)</td>
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<td>Distal embolization n/N (%)</td>
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<td>Infarct size (mean % ± SD)</td>
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<td>Slow Reflow n/N (%)</td>
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<td>CK-MB n/N (%) or mean ± SD</td>
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### Safety Outcomes

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<td>Prolonged Procedure n/N (%)</td>
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<td>Other (please specify):</td>
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### ST-Segment Resolution

#### Post Procedure/immediate

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<th>&lt;30%</th>
<th>30-70%</th>
<th>&gt;70%</th>
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<tbody>
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<table>
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<table>
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<tr>
<td>Control Group n/N (%)</td>
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Other measures of ST resolution:
### Final Health Outcomes

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<td>Other individual endpoints included in MACE or MACCE not listed below</td>
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<tr>
<td>Mortality n/N (%)</td>
<td>Definition</td>
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<tr>
<td>TVR n/N (%)</td>
<td></td>
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<tr>
<td>Reinfarction n/N (%)</td>
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<tr>
<td>Stroke n/N (%)</td>
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## Appendix C. Characteristics and Quality Assessment of Included Trials, Studies and Systematic Reviews With Meta-analyses

### Table 1. Characteristics and quality assessment of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Publication type: Full text and slide presentation</td>
<td><strong>Inclusion criteria:</strong> First STEMI referred for primary PCI; within 6 hours from chest pain onset, with ≥2mm ST-segment elevation in at least two contiguous leads and ≥3mm ST-segment elevation in at least one lead, with occluded IRA at baseline angiography and vessel reference diameter ≥2.5mm</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3, DE (post-procedure); STSR &gt; 70% (immediately post-procedure, 60 min) <strong>Final:</strong> MACE (reinfarction, death) (in-hospital); MACE (mortality, reinfarction, re-PCI or re-CABG), mortality, reinfarction, TVR (in-hospital, 180 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes 2. Were outcomes assessed using a valid methodology and criteria? Yes 3. Were outcome assessors blind to exposure/intervention status? Partially 4. Were incomplete outcome data adequately addressed? Yes 5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes 6. Was the overall loss to followup low (&lt; 30%)? Yes 7. Conflict of interest reported and insignificant? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good</td>
</tr>
<tr>
<td>PHIRATE</td>
<td><strong>Geographical location:</strong> Poland, Italy, Hungary</td>
<td><strong>Exclusion criteria:</strong> Prior MI, PCI, CABG; patients in cardiogenic shock; treated with fibrinolysis before admission to catheterization lab</td>
<td><strong>Safety:</strong> NR</td>
<td></td>
</tr>
<tr>
<td>Funding: Unfunded</td>
<td>Randomization: Sealed white envelopes with names of study groups were used, prepared beforehand, in blocks of 4 and 6 patients to achieve balanced allocation</td>
<td><strong>Intervention:</strong> Primary PCI with Diver CE thrombectomy system followed by direct stenting</td>
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<tr>
<td>Number of centers: 10</td>
<td><strong>Comparator:</strong> Standard balloon predilation followed by stenting</td>
<td><strong>Duration of followup (d):</strong> 180</td>
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<tr>
<td>Number of participants enrolled: 196</td>
<td>Followup: 100%</td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>Liistro, 2009</td>
<td><strong>Publication type:</strong> Full text, slide presentation</td>
<td><strong>Inclusion criteria:</strong> Symptoms associated with ACS &gt; 30 min, &lt; 12 h symptom onset, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads</td>
<td><strong>Intermediate:</strong> MBG ≥ 2, TIMI-3, DE, no reflow (post-procedure); EF (post-procedure and 180 d); STSR ≥ 70% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<tr>
<td></td>
<td><strong>Geographical location:</strong> Italy</td>
<td><strong>Exclusion criteria:</strong> Contraindication to GP2BAi, previous MI, inability to obtain informed consent, rescue PCI after failed lysis, absence of optimal ECHO apical view, existence of disease with life expectancy &lt; 6 m</td>
<td><strong>Final:</strong> MACE, TLR, reinfarction (180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
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<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td><strong>Intermediate:</strong></td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
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<td></td>
<td><strong>Number of centers:</strong> 1</td>
<td><strong>Intervention:</strong> PCI with thrombus aspiration by Export Aspiration Catheter</td>
<td><strong>Final:</strong></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
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<tr>
<td></td>
<td><strong>Randomization:</strong> Computer generated random assignment number 1:1 in blocks of 10</td>
<td><strong>Comparator:</strong> Standard PCI</td>
<td><strong>Final:</strong> MACE, TLR, reinfarction (180 d)</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
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<td><strong>Outcome assessment:</strong> Evaluated by 2 readers without the knowledge of clinical status, treatment modality, angiographic and echocardiographic data</td>
<td><strong>Duration of followup (d):</strong> 180</td>
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<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td></td>
<td><strong>Number of participants enrolled:</strong> 111</td>
<td><strong>Followup:</strong> 100%</td>
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<td>7. Conflict of interest reported and insignificant? No</td>
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<td>8. Were the methods used for randomization adequate? Yes</td>
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Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipiecki, 2009</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: Chest pain associated with ACS &gt; 30 min, TIMI 0/1 of proximal segment of LAD, LCX, or RCA, ST-segment elevation ≥ 2 mm in 2 or more ECG lead, PCI scheduled within 48 h of symptom onset, success of guidewire to cross culprit lesion, first STEMI</td>
<td>Intermediate: MBG-2, TIMI-3, DE (post-procedure); EF (7 d); STSR &gt; 70% (90 min, 24 h)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes 2. Were outcomes assessed using a valid methodology and criteria? Yes 3. Were outcome assessors blind to exposure/intervention status? Partial 4. Were incomplete outcome data adequately addressed? Yes 5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can't tell 6. Was the overall loss to followup low (&lt; 30%)? Can't tell 7. Conflict of interest reported and insignificant? Yes 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Fair</td>
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<tr>
<td></td>
<td>Geographical location: France</td>
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<tr>
<td></td>
<td>Funding: Regional Project of Clinical Research grant and Medtronic Company</td>
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<td></td>
<td>Number of centers: 1</td>
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<tr>
<td></td>
<td>Randomization: Randomized 1:1</td>
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<td></td>
<td>Outcome assessment: Coronary flow assessment offline by 2 experienced interventional cardiologist</td>
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<td></td>
<td>Number of participants enrolled: 44</td>
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<td></td>
<td>Duration of followup (d):</td>
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<td></td>
<td>Followup:</td>
<td>NR</td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>Moura, 2009</td>
<td><strong>Publication type:</strong></td>
<td>Inclusion criteria: Acute STEMI within 6 h</td>
<td>Intermediate: MBG ≥ 2 (post-procedure); STSR &gt; 70% (NR)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> Brazil</td>
<td>Exclusion criteria: NR</td>
<td>Final: MACE (mortality, new MI, stent thrombosis, TVR) (in-hospital, 30 d, 270 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td>Intervention: Thrombectomy aspiration catheter</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> NR</td>
<td>Comparator: Conventional PCI with stent</td>
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<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> NR</td>
<td>Duration of followup (d): 270</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell</td>
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<tr>
<td></td>
<td><strong>Outcome assessment:</strong> NR</td>
<td>Followup: NR</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 152</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
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<td>8. Were the methods used for randomization adequate? Can’t tell</td>
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Overall quality rating: Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Sardella, 2009 | EXPIRA | **Publication type:** Full text, slide presentation | **Intermediate:** MBG ≥ 2, TIMI ≥ 2, (post-procedure); EF (3-5 d post-procedure); STSR > 70% (90 min) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes  
2. Were outcomes assessed using a valid methodology and criteria? Yes  
3. Were outcome assessors blind to exposure/intervention status? Yes  
4. Were incomplete outcome data adequately addressed? Yes  
5. Was the differential loss to followup between the compared groups low (< 10%)? Yes  
6. Was the overall loss to followup low (< 30%)? Yes  
7. Conflict of interest reported and insignificant? No  
8. Were the methods used for randomization adequate? Can't tell  
Overall quality rating: Good |
<p>| <strong>Geographical location:</strong> NR | | <strong>Inclusion criteria:</strong> First STEMI, ≤ 9 h symptom onset, IRA ≥ 2.5 mm, TS ≥ 3, TIMI ≤ 1, &gt; 18 y |  | |
| <strong>Funding:</strong> NR | | <strong>Exclusion criteria:</strong> Previous PCI on IRA, MI or CABG, cardiogenic shock, 3-vessel or left main disease, severe valvular heart disease, thrombolysis, contraindication to GP2B3Ai |  | |
| <strong>Number of centers:</strong> 1 | | <strong>Intervention:</strong> Primary PCI with Export Medtronic |  | |
| <strong>Randomization:</strong> Random assignment 1:1 | | <strong>Comparator:</strong> Primary PCI |  | |
| <strong>Outcome assessment:</strong> Blinded operators using an off-line dedicated workstation | | <strong>Duration of followup (d):</strong> 720 |  | |
| <strong>Number of participants enrolled:</strong> 175 | | <strong>Followup:</strong> 100% |  | |</p>
<table>
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<tr>
<th>Study, Year</th>
<th>Publication type:</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
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<tbody>
<tr>
<td>Chao, 2008</td>
<td>Full text</td>
<td>Inclusion criteria: STEMI with chest pain &gt; 30 min and ST-segment elevation ≥ 0.1 mV in 2 or more ECG leads within 12 h of symptom onset, eligible for primary PCI</td>
<td>Intermediate: MBG, TIMI blood flow (post-procedure); EF (30 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td>Exclusion criteria: Previous CABG, Killip IV, ventricular tachycardia, significant left main disease, culprit vessel diameter &lt; 2mm, existing TIMI-3 flow without visible thrombus in IRA</td>
<td>Final: MACE (mortality, stroke, nonfatal reinfarction), mortality, TVR (180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
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<tr>
<td></td>
<td></td>
<td>Intervention: Primary PCI with Export aspiration catheter</td>
<td>Safety: Coronary dissection, procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
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<td>Comparator: Primary PCI</td>
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<td>4. Were incomplete outcome data adequately addressed? Yes</td>
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<td>Number of participants enrolled: 74</td>
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<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
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<td>Duration of followup (d): 180</td>
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<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td>Followup: 100%</td>
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<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
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<td>8. Were the methods used for randomization adequate? Can’t tell</td>
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<td>Overall quality rating: Good</td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Publication type: Full text, slide presentation</td>
<td><strong>Inclusion criteria:</strong> Acute MI within 12 h of symptom onset, TIMI 0/1 before placing wire, age ≥ 18 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads, vessel diameter ≥ 2.5 mm</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR &gt; 50% (60 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>EXPORT</td>
<td>Geographical location: Europe and India</td>
<td><strong>Exclusion criteria:</strong> Cardiogenic shock, pacemaker, fibrinolytic treatment, cardiac arrest, treatment with GP2B3Ai, medical condition with expected survival &lt; 1 y, participation in other investigations</td>
<td><strong>Final:</strong> MACCE (mortality, reinfarction, emergent bypass surgery, TLR or TVR, cerebrovascular accident), mortality, TVR, TLR, reinfarction, cerebrovascular accident (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: Medtronic Vascular</td>
<td><strong>Intervention:</strong> Primary PCI with Export aspiration catheter followed by stenting</td>
<td><strong>Safety:</strong> Procedure time, side branch occlusion</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 24</td>
<td><strong>Comparator:</strong> Conventional stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Computerized telephone system on a 1:1 basis</td>
<td><strong>Number of participants enrolled:</strong> 249</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Three independent interventional cardiologist reviewed MACE and serious adverse device events, ECG and angiographic results analyzed by an independent core laboratory</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td></td>
<td></td>
<td><strong>Followup:</strong> 100%</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
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<td>8. Were the methods used for randomization adequate? Yes</td>
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Overall quality rating: Good
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<tbody>
<tr>
<td>Ciszewski, 2008</td>
<td>Abstract</td>
<td>Poland</td>
<td>NR</td>
<td>1</td>
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<td>NR</td>
<td>135</td>
<td>TIMI &lt; 2, ≤ 12 h from symptom onset, first anterior or inferior STEMI, LAD or RCA lesion</td>
<td>NR</td>
<td>Thrombectomy with Rescue or Diver followed by stent implantation</td>
<td>Standard primary PCI with stenting</td>
<td>5-8</td>
<td>Intermediate: EF (5-8 d)</td>
<td>NR</td>
<td>Final: Mortality (3-7 d)</td>
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<td>3. Were outcome assessors blind to exposure/intervention status? Can't tell</td>
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<td>4. Were incomplete outcome data adequately addressed? Yes</td>
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<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
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<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td>7. Conflict of interest reported and insignificant? Can't tell</td>
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<td>8. Were the methods used for randomization adequate? Can't tell</td>
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<td>Overall quality rating: Fair</td>
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</tbody>
</table>

C-8
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Publication type</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ikari, 2008</td>
<td>Full text, slide presentation, abstract</td>
<td><strong>Inclusion criteria:</strong> AMI ≤ 24 h and &gt; 30 min from symptom onset, age ≥ 21 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or new LBBB</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3, EF (post-procedure, 180 d); DE, no reflow (post-procedure); STSR &gt; 70% (immediately post-procedure, 3-6 h)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>VAMPIRE</td>
<td></td>
<td><strong>Exclusion criteria:</strong> Cardiogenic shock, fibrinolytic treatment, previous CABG, chronic renal failure (Cr &gt; 2.0 mg/dL or HD), presence of primary thrombolysis prior to randomization, history of cardiac arrest, left main disease, target vessel &lt; 2.5 or &gt; 5 mm in diameter</td>
<td><strong>Final:</strong> MACE (mortality, recurrence of MI, TLR) (in-hospital, 240 d, 720 d), mortality, recurrence of MI, TLR, (in-hospital, 240 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Intervention:</strong> Primary PCI with TVAC</td>
<td><strong>Safety:</strong> Coronary dissection, perforation, procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Comparator:</strong> PCI without thrombectomy</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Number of participants enrolled:</strong> 355</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
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<td></td>
<td></td>
<td><strong>Duration of followup (d):</strong> 240</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td>7. Conflict of interest reported and insignificant? No</td>
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<td></td>
<td></td>
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<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svilaas, 2008</td>
<td><strong>Publication type:</strong> Full text, slide presentation</td>
<td><strong>Inclusion criteria:</strong> AMI ≤ 12 h and &gt; 30 min from symptom onset, ST-segment elevation ≥ 0.1 mV in 2 or more ECG leads</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3 (post-procedure); STSR &gt; 70% (30-60 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>TAPAS</td>
<td><strong>Geographical location:</strong> Netherlands</td>
<td><strong>Exclusion criteria:</strong> Fibrinolytic therapy, inability to obtain informed consent, known existence of disease with life expectancy &lt; 6 m</td>
<td><strong>Final:</strong> MACE (mortality, reinfarction, TVR), mortality, reinfarction, TVR (30 d, 365 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Medtronic, Thorax Center of university Medical Center</td>
<td><strong>Intervention:</strong> Primary PCI with thrombus aspiration by 6-French Export Aspiration Catheter</td>
<td><strong>Safety:</strong> Coronary dissection, procedure time, side branch occlusion</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 1</td>
<td><strong>Comparator:</strong> Conventional PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> Computerized voice-response system to select randomly permuted blocks of 3-6 stratified by the interventional cardiologist</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Coronary angiogram data analyzed at an independent core laboratory</td>
<td><strong>Followup:</strong> 91.59% in device group, 91.42% in control group</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 1071</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
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<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
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<td></td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Publication type:</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>DeLuca, 2006</td>
<td>Full text</td>
<td>Inclusion criteria: Anterior STEMI with chest pain &gt; 30 min and new persistent ST-segment elevation ≥ 0.1mV in 2 or more ECG leads, identified thrombus on IRA at coronary angiography, age ≥ 18 y</td>
<td>Intermediate: MBG-3, TIMI-3 (post-procedure); EF (post-procedure, 180 d); STSR &gt; 70% (90 min)</td>
<td>- Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exclusion criteria: Previous MI or CABG, 3 vessel CAD, severe valvular heart disease, TIMI-2 or 3 flow at initial angiography, unsuccessful PCI (no antegrade flow or &gt; 50% residual stenosis in the IRA)</td>
<td>Final: MACE (mortality, reinfarction, hospitalization for CHF), mortality, reinfarction (180 d)</td>
<td>- Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention: Primary PCI with Diver CE aspiration thrombectomy catheter</td>
<td>Safety: Coronary dissection</td>
<td>- Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparator: Conventional PCI</td>
<td></td>
<td>- Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration of followup (d): 180</td>
<td></td>
<td>- Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Followup: 92.11% in device group, 94.74% in control group</td>
<td></td>
<td>- Was the overall loss to followup low (&lt; 30%)? Yes</td>
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<td></td>
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<td></td>
<td>- Conflict of interest reported and insignificant? Yes</td>
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<tr>
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<td>- Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
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<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Kaltoft, 2006</td>
<td><strong>Publication type:</strong> Full text, slide presentation</td>
<td><strong>Inclusion criteria:</strong> Symptom onset &gt; 30 min and &lt; 12 h; ST-segment elevation ≥ 2 mm in 2 or more ECG leads, PCI indicated upon angiography, IRA suitable for thrombectomy</td>
<td><strong>Intermediate:</strong> TIMI-3, DE (post-procedure); EF (30 d); STSR &gt; 70% (immediately post-procedure, 90 min, 6 h)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> Denmark</td>
<td><strong>Exclusion criteria:</strong> LBBB, previous MI within 30 d, previous CABG, fibrinolytic treatment, inability to obtain informed consent, left main disease, need for mechanical ventilation, severe heart failure treated with IABP</td>
<td><strong>Final:</strong> MACE (mortality, reinfarction, disabling stroke), mortality, reinfarction, disabling stroke (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Partially by Boston Scientific</td>
<td><strong>Intervention:</strong> Primary PCI with Rescue catheter</td>
<td><strong>Safety:</strong> Procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 1</td>
<td><strong>Comparator:</strong> Standard PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> Telephone line-accessible computer based block randomization using varying block sizes (6/4/2) stratified by sex and diabetes compliant with international criteria for proper concealment</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Angiographic measurements made by 4 experienced observers blinded to randomization</td>
<td><strong>Followup:</strong> 73.15% in device group, 83.18% in control group</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 215</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
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<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
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Overall quality rating: Good
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<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
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<th>Outcomes of Interest (Timing)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Lee, 2006</td>
<td><strong>Publication type:</strong> Abstract</td>
<td><strong>Inclusion criteria:</strong> STEMI scheduled for primary PCI</td>
<td><strong>Intermediate:</strong> MBG-3, STSR, DE, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can't tell</td>
</tr>
<tr>
<td>TSUNAMI</td>
<td><strong>Geographical location:</strong> Korea</td>
<td><strong>Exclusion criteria:</strong> NR</td>
<td><strong>Final:</strong> NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td><strong>Intervention:</strong> Primary PCI with Export aspiration catheter</td>
<td><strong>Safety:</strong> NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> NR</td>
<td><strong>Comparator:</strong> Primary PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> NR</td>
<td><strong>Duration of followup (d):</strong> In-hospital</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> NR</td>
<td><strong>Followup:</strong> 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 133</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Silva-Orrego, 2006 | **Publication type:** Full text, abstract, slide presentation | **Inclusion criteria:** Continuous chest pain > 30 min and < 12 h, ST-segment elevation ≥ 0.1 mV (≥ 0.2 mV in case of anterior leads) in ≥ 3 ECG leads, technical feasibility for primary angioplasty independent of initial TIMI flow or angiographic evidence of intraluminal thrombus in culprit artery | **Intermediate:** MBG-3, TIMI-3, STSR, DE, no reflow (post-procedure) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes  
2. Were outcomes assessed using a valid methodology and criteria? Yes  
3. Were outcome assessors blind to exposure/intervention status? Yes  
4. Were incomplete outcome data adequately addressed? Yes  
5. Was the differential loss to followup between the compared groups low (< 10%)? Yes  
6. Was the overall loss to followup low (< 30%)? Yes  
7. Conflict of interest reported and insignificant? No  
8. Were the methods used for randomization adequate? Can't tell |
<p>| <strong>DEAR-MI</strong> | <strong>Geographical location:</strong> Italy | <strong>Exclusion criteria:</strong> Contraindication to GP2B3Ai, cardiogenic shock, LBBB, ventricular pacing, previous MI or CABG, fibrinolytic treatment | <strong>Final:</strong> Mortality, TVR, reinfarction, stroke (in-hospital, 180 d) | Overall quality rating: Good |
| <strong>Funding:</strong> Niguarda Hospital, Milan | <strong>Randomization:</strong> Randomly assigned on a 1:1 basis | <strong>Intervention:</strong> Primary PCI with Pronto extractor catheter | <strong>Safety:</strong> Coronary dissection, procedure time |  |
| <strong>Number of centers:</strong> 1 | <strong>Outcome assessment:</strong> Angiographic and ECG data analysis by 2 blinded observers | <strong>Comparator:</strong> Standard angioplasty with stenting | | |
| <strong>Number of participants enrolled:</strong> 148 | <strong>Duration of followup (d):</strong> 180 | <strong>Followup:</strong> 100% | | |</p>
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Burzotta, 2005 | **Publication type:** Full text | **Inclusion criteria:** Acute STEMI within 12 h, eligible for primary or rescue PCI | **Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure), EF(24 h); STSR > 70% (post-procedure) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes  
| REMEDIA | **Geographical location:** Italy | **Exclusion criteria:** No angiographic exclusion criteria were applied | **Final:** MACE (major adverse events), mortality, TLR, reinfarction, stroke (30 d);  
| | **Funding:** NR | **Intervention:** Primary or rescue PCI with Diver CE | **Safety:** Procedure time | 2. Were outcomes assessed using a valid methodology and criteria? Yes  
| | **Number of centers:** 1 | **Comparator:** Standard PCI |  
| | **Randomization:** 1:1 by computer generated random series of numbers | **Duration of followup (d):** 30 | 3. Were outcome assessors blind to exposure/intervention status? Yes  
| | **Outcome assessment:** ECG analyzed by blinded cardiologist, angiographic data analyzed offline by two expert interventional cardiologists | **Followup:** 100% | 4. Were incomplete outcome data adequately addressed? Yes  
| | | | 5. Was the differential loss to followup between the compared groups low (< 10%)? Yes  
| | **Number of participants enrolled:** 99 | | 6. Was the overall loss to followup low (< 30%)? Yes  
| | | | 7. Conflict of interest reported and insignificant? No  
| | | | 8. Were the methods used for randomization adequate? Yes  
<p>| | | | Overall quality rating: Good |</p>
<table>
<thead>
<tr>
<th>Study, Year</th>
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<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noel, 2005</td>
<td>Publication type: Abstract</td>
<td>Inclusion criteria: Acute STEMI within 12 h, initial TIMI flow &lt; 3 Exclusion criteria: NR Intervention: PCI with Export Comparator: PCI Duration of followup (d): 1 h Followup: In-hospital</td>
<td>Intermediate: TIMI &lt; 3, no reflow, (post-procedure); STSR &gt; 50%, STSR &gt; 70% (60 min) Final: MACE, mortality (NR) Safety: NR</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell 2. Were outcomes assessed using a valid methodology and criteria? Can’t tell 3. Were outcome assessors blind to exposure/intervention status? Can’t tell 4. Were incomplete outcome data adequately addressed? Can’t tell 5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell 6. Was the overall loss to followup low (&lt; 30%)? Can’t tell 7. Conflict of interest reported and insignificant? No 8. Were the methods used for randomization adequate? Can’t tell Overall quality rating: Poor</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Publication type</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>Dudek, 2004</td>
<td>Full text, abstract</td>
<td><strong>Inclusion criteria:</strong> AMI, TIMI 0/1 or 2/3 with large thrombus in IRA documented by angiogram, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads. <strong>Exclusion criteria:</strong> Cardiogenic shock, previous fibrinolytic treatment, previous GP2B3Ai, IRA reference diameter &lt; 2.5 mm. <strong>Intervention:</strong> Primary PCI with Rescue system. <strong>Comparator:</strong> Primary PCI. Duration of followup (d): 90.</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3 (post-procedure); EF (in-hospital, 90 d); STSR &gt; 70% (60 min). <strong>Final:</strong> NR. <strong>Safety:</strong> NR.</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes. 2. Were outcomes assessed using a valid methodology and criteria? Yes. 3. Were outcome assessors blind to exposure/intervention status? Partially. 4. Were incomplete outcome data adequately addressed? Yes. 5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell. 6. Was the overall loss to followup low (&lt; 30%)? Can’t tell. 7. Conflict of interest reported and insignificant? No. 8. Were the methods used for randomization adequate? Yes. Overall quality rating: Fair.</td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome.

Abbreviations: ACS=acute coronary syndrome; AMI=acute myocardial infarction; CABG=coronary artery bypass graft; CAD=coronary artery disease; CHF=congestive heart failure; CHF=congestive heart failure; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; ECHO=echocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; HD=hemodialysis; IABP=intra-aortic balloon pump; IRA=infarct related artery; LAD=left anterior descending artery; LBBB=left bundle branch block; LCX=left circumflex; m=months; MACCE=Major adverse cardiac and cerebrovascular events; MBG=myocardial blush grade; mg/dL=milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; MRI=magnetic resonance imaging; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; RCA=right coronary artery; SPECT=single-photon emission computerized tomography; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TS=thrombus score; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization; y=years.
<table>
<thead>
<tr>
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<th>Outcomes of Interest (Timing)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td><strong>Publication type:</strong> Full text, slide presentation</td>
<td><strong>Inclusion criteria:</strong> STEMI with chest pain &gt; 30 min and &lt; 12 h, ST-segment elevation &gt; 1 mm in 2 or more ECG leads or a new LBBB, TIMI thrombus grade 3-5 after infarct artery wiring, IRA &gt; 2.5 mm on visual assessment</td>
<td><strong>Intermediate:</strong> MBG-3,TIMI-3 post-procedure; STSR &gt; 50% (30 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> International</td>
<td><strong>Exclusion criteria:</strong> Fibrinolytic treatment for current AMI, history of stroke in the last 30 d or any history of haemorrhagic stroke, major surgery in last 6 wk, comorbidities with expected survival &lt; 1 y, participation in another study, TIMI thrombus grade &lt; 3, IRA diameter &lt; 2.5 mm, previous stenting of IRA, inability to identify IRA</td>
<td><strong>Final:</strong> MACCE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d, 180 d, 365 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Medrad Interventional/ Possis</td>
<td><strong>Safety:</strong> Perforation, procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
<td></td>
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<tr>
<td></td>
<td><strong>Number of centers:</strong> Multiple</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
<td></td>
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<tr>
<td></td>
<td><strong>Randomization:</strong> Computer generated sequence of number and assignments were provided by a centralized telephone system</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
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<tr>
<td></td>
<td><strong>Outcome assessment:</strong> STSR assessed by physicians blinded to treatment assignment at a central core laboratory, all angiographic markers of reperfusion and quantitative coronary angiography analysis performed at central core laboratory by physicians not involved in study, clinical events by independent committee blinded to treatment allocation</td>
<td><strong>Intervention:</strong> Rheolytic thrombectomy with AngioJet followed by direct stenting</td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
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<td></td>
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<td><strong>Comparator:</strong> Direct stenting</td>
<td>7. Conflict of interest reported and insignificant? No</td>
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<td><strong>Duration of followup (d):</strong> 365</td>
<td>8. Were the methods used for randomization adequate? Yes</td>
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<td></td>
<td></td>
<td><strong>Followup:</strong> 96.09% in device group, 97.90% in control group</td>
<td>Overall quality rating: Good</td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
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<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td>Ali, 2006</td>
<td>Publication type: Full text, slide presentation</td>
<td>Inclusion criteria: &lt; 12 h from symptom onset, age ≥ 18 y, anterior or large inferior myocardial infarction (new ST-segment elevation &gt; 1 mm in 2 or more ECG leads in V1 to V6 or II, III and aVF), reference coronary artery &gt; 2 mm in diameter</td>
<td>Intermediate: MBG-3, TIMI-3, DE, no reflow (post-procedure), EF (14-28 d); STSR &gt; 70% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>AIMI</td>
<td>Geographical location: USA, Canada</td>
<td>Exclusion criteria: Contraindication to GP2B3Ai, cardiogenic shock (SBP &lt; 80 mmHg requiring inotrope), inability to obtain informed consent, known prior EF &lt; 35%, major surgery within last 6 w, history of stroke within 30 d, history of haemorrhagic stroke</td>
<td>Final: MACCE (mortality, reinfarction, emergent CABG, TLR, stroke, stent thrombosis), reinfarction, stroke, TLR (30 d); mortality (30 d, 180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: Possis Medical, Millenium Incorporation</td>
<td>Outcome assessment: Independent adjudication committee for clinical events, infarct size and angiographic data, analyzed by core laboratory. ECG analyzed by reviewers blinded to the treatment assignment</td>
<td>Safety: Coronary dissection, perforation, procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: Multiple</td>
<td>Intervention: Conventional PCI with AngioJet catheter</td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Comparator: Conventional PCI</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 480</td>
<td>Duration of followup (d): 30</td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Followup: 82.08% in device group, 85.42% in control group</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Good</td>
<td></td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>Publication type: Full text, abstract, slide presentation</td>
<td>Inclusion criteria: AMI &lt; 12 h, chest pain &gt; 30 min, ST elevation ≥ 2 mm in 2 or more ECG leads, de novo lesion, single vessel treatment in a native vessel ≥ 2.5 mm in diameter, thrombus containing lesion, TIMI 0/1 in IRA, patients amenable to PCI</td>
<td>Intermediate: MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR &gt; 50% (60 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: France, Germany, Italy, Austria, UK, and Spain</td>
<td>Exclusion criteria: Saphenous vein graft, LBBB, fibrinolytic treatment, Killip ≥ III, previous PCI in IRA, rescue PCI, IRA with excessive proximal tortuosity or severe calcification, osital lesion, LVEF &lt; 30%, contraindication to emergency CABG, current participation in any other study</td>
<td>Final: MACCE (major adverse cardiac and cerebral events), mortality, TVR, reinfarction, stroke (30 d, 180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 14</td>
<td>Comparator: PCI with balloon angioplasty and/or stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly assigned on a 1:1 basis</td>
<td>Duration of followup (d): 180</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Coronary angiogram, MBG, and ECG analyzed by blinded independent core laboratory</td>
<td>Followup: 90% in device group, 94.06% in control group</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 201</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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</tr>
<tr>
<td>Antoniucci, 2004</td>
<td><strong>Publication type:</strong> Full text, abstract</td>
<td><strong>Inclusion criteria:</strong> Chest pain &gt; 30 min, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads</td>
<td><strong>Intermediate:</strong> STSR ≥ 50% (30 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> Italy</td>
<td><strong>Exclusion criteria:</strong> BBB or pacing at baseline, previous MI, fibrinolytic treatment, IRA &lt; 2.5 mm on visual angiography, inability to obtain informed consent</td>
<td><strong>Final:</strong> MACE, mortality, TVR, stroke (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td><strong>Intervention:</strong> PCI with AngioJet</td>
<td><strong>Safety:</strong> NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 1</td>
<td><strong>Comparator:</strong> Direct IRA stenting only</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> Computer generated sequence and assignment using a closed envelope system</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Independent analysis of ECG, scintigrams, and angiograms by investigators unaware of patients’ treatment assignments</td>
<td><strong>Followup:</strong> 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 100</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Napodano, 2003 | Publication type: Full text, slide presentation | Inclusion criteria: AMI within 12 h, chest pain > 30 min, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads, ST-segment depression in right pre-cordial leads, angiographic evidence of intramural thrombus in IRA, TIMI ≤ 2 and /or ≥ 70% diameter stenosis, TS ≥ 2, vessel accessible to X-Sizer | Intermediate: MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (at discharge); STSR ≥ 50% (60 min) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes  
2. Were outcomes assessed using a valid methodology and criteria? Yes  
3. Were outcome assessors blind to exposure/intervention status? Partially  
4. Were incomplete outcome data adequately addressed? Yes  
5. Was the differential loss to followup between the compared groups low (< 10%)? Yes  
6. Was the overall loss to followup low (< 30%)? Yes  
7. Conflict of interest reported and insignificant? No  
8. Were the methods used for randomization adequate? Can’t tell |
| MIRANO | Geographic location: Italy | Exclusion criteria: Contraindication to GP2B3Ai and antiplatelets, LBBB, ventricular pacing at baseline, pregnancy, left main stem lesions, IRA diameter < 2.5 mm | Final: Mortality, TVR, reinfarction, stroke (in-hospital, 30 d) | Overall quality rating: Good |
| | Funding: NR | Intervention: Thrombectomy with X-Sizer catheter system followed by stenting | Safety: Side branch occlusion | |
| | Number of centers: 1 | Comparator: Conventional stenting | | |
| | Randomization: Randomly assigned on 1:1 basis | Number of participants enrolled: 92 | | |
| | Outcome assessment: Angiographic data analyzed offline by 2 experienced operators blinded to clinical data | Duration of followup (d): 30 | | |
| | | Followup: 100% | | |

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome. Abbreviations: AMI=acute myocardial infarction; BBB=bundle branch block; CABG=coronary artery bypass graft; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MACCE=major adverse cardiac and cerebrovascular events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; mmHg=millimeters of mercury; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; SBP=systolic blood pressure; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TS=thrombus score; TVR=target vessel revascularization; w=weeks; y=years
Table 3. Characteristics and quality assessment of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: First anterior STEMI (chest pain &gt;30min and 0.1mV ST-segment elevation in 2 contiguous ECG leads) after successful PCI within 24h of symptom onset</td>
<td>Intermediate: TIMI-3 (post-procedure); STSR ≥70% (60 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: Cardiac shock, history of old MI, severe liver or renal dysfunction, history of allergic response to drugs, severe hypovolemia</td>
<td>Final: MACE (mortality, MI, TLR), mortality, MI, TLR (30d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: Unfunded</td>
<td>Intervention: PCI with distal filter protection (Filtrap)</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Comparator: Standard PCI</td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly assigned to either of the two groups</td>
<td>Duration of followup (d): 30 days</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Angiography images were analyzed offline by 2 experienced interventional cardiologists who were unaware of the index of microcirculatory resistance results</td>
<td>Followup: 100%</td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 36</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
<td></td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelbæk, 2008</td>
<td>Publication type: Full text, abstract, slide presentation</td>
<td>Inclusion criteria: Chest pain &gt; 30 min presenting within 12 h, age ≥18 y, total ST-segment elevation &gt; 4 mm in 2 or more ECG leads, high grade stenosis or occlusion of native coronary artery without excess tortuosity or calcification prohibiting advancement of filterwire to the distal vascular bed of the vessel</td>
<td>Intermediate: TIMI-3 (post-procedure) STSR &gt; 70% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>DEDICATIO N</td>
<td>Geographical location: Denmark</td>
<td>Exclusion criteria: Previous MI in target vessel area, culprit lesion in unprotected left main coronary arteries or saphenous vein grafts, GI bleed in the last month, childbearing potential or pregnancy, known renal failure, life expectancy &lt;1 y, linguistic problems</td>
<td>Final: MACE (mortality, TLR, reinfarction, stroke) (30 d, 240 d, 450 d); mortality, TLR, reinfarction, stroke (30 d); mortality, TLR, TVR, reinfarction (450d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 2</td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Centralized telephone randomization performed by computerized assignment stratified with regard to gender and presence of diabetes</td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt;10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Angiographic lesion characteristics were evaluated by independent core laboratory technicians unaware of treatment, commercial software was used to analyze ST-segment data, ECG were analyzed manually</td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt;30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 626</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
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<tr>
<td></td>
<td>Intervention: Primary PCI with FilterWire EZ or SpiderX</td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
<tr>
<td></td>
<td>Comparator: Primary PCI</td>
<td></td>
<td></td>
<td>Overall quality rating: Good</td>
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<tr>
<td></td>
<td>Duration of followup (d): 30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Followup: 96.79% in device group, 95.86% in control group</td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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</tr>
<tr>
<td>Cura, 2007</td>
<td><strong>Publication type:</strong></td>
<td>Inclusion criteria: Continuous chest pain ≥ 30 min and within 12 h of onset, ST-segment elevation ≥ 2 mm in 2 or more ECG leads consistent with AMI, age 21-80 y, referred for primary or rescue PCI, absence of conditions precluding evaluation of ST-segment changes on the admission ECG such as sustained idioventricular rhythm, Wolff-Parkinson-White syndrome, LBBB, ventricular pacemaker, or technically inadequate ECG</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3, EF, DE, no reflow (post-procedure); STSR &gt; 70% (60 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>PREMAIR</td>
<td><strong>Geographical location:</strong> Argentina, Chile, Israel</td>
<td><strong>Exclusion criteria:</strong> SVG, cardiogenic shock, previous CABG or PCI within 6 m, cardiac tamponade, aortic dissection, myocarditis, known renal failure (Cr &gt; 2 mg/dL), pregnancy, oral anticoagulation, allergy to nitrinol, stainless steel, aspirin, or thienopyridibe, TIMI-3 at baseline, culprit lesion &lt; 50% stenosis, vessel ≤ 2.5 mm, left main disease, bifurcation lesion, excessive proximal tortuosity, need for treatment of &gt; 1 vessel during index procedure</td>
<td><strong>Final:</strong> MACE (mortality, reinfarction, heart failure), mortality, TVR, reinfarction, (30 d,180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Partial funding from ev3</td>
<td><strong>Outcome assessment:</strong> ST-segment resolution, reperfusion, EF and angiographic data analyzed in a blinded manner by a core laboratory, clinical events adjudicated by a blinded committee</td>
<td><strong>Safety:</strong> Coronary dissection, perforation, procedure time, side branch occlusion</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 20</td>
<td><strong>Randomization:</strong> Randomized in a 1:1 ratio according to IRA and physician's intention to use GP2B3Ai</td>
<td><strong>Followup:</strong> 100%</td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 140</td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Can't tell</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can't tell</td>
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<td>Overall quality rating: Good</td>
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</table>

**Intervention:** PCI with SpiderX

**Comparator:** PCI

**Duration of followup (d):** 180

**Followup:** 100%
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
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<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Guetta, 2007 | **Publication type:** Full text, slide presentation | **Inclusion criteria:** < 24 h of chest pain with ≥ 1 episode of atypical pain lasting > 30 min, ST-segment elevation ≥ 1 mm in 2 ECG leads, age > 21 y, IRA 2.5 - 5.0 mm, coronary artery lesion suitable for PCI and filter device application, coronary artery occlusion or angiographic appearance of fresh thrombus | **Intermediate:** MBG-3, TIMI-3, EF (post procedure); STSR > 70% (60 min) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes  
2. Were outcomes assessed using a valid methodology and criteria? Yes  
3. Were outcome assessors blind to exposure/intervention status? Partially  
4. Were incomplete outcome data adequately addressed? Yes  
5. Was the differential loss to followup between the compared groups low (< 10%)? Yes  
6. Was the overall loss to followup low (< 30%)? Yes  
7. Conflict of interest reported and insignificant? Can’t tell  
8. Were the methods used for randomization adequate? Yes |
| **UPFLOW MI** | **Geographical location:** Israel | **Exclusion criteria:** Culprit lesion in a saphenous vein graft, contradiction to GP2B3Ai, aspirin, clopidogrel, or heparin, cardiogenic shock, inability to obtain informed consent, presumed distal vessel < 2.5 mm, relevant coronary left main involvement, vessel anatomy interfering with safe placement of filter device | **Final:** MACE (mortality, nonfatal MI, CHF), mortality, reinfarction (30 d) |  
**Safety:** NR |
| | **Funding:** Partial funding from Boston Scientific | **Intervention:** PCI with FilterWire EZ |  
**Comparator:** PCI |  
**Number of centers:** 5 | 
**Number of participants enrolled:** 100 | 
**Duration of followup (d):** 30 | 
**Followup:** 96.08% in device group, 97.96% in control group |  
**Overall quality rating:** Good |
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lefèvre, 2004</td>
<td>Publication type: Abstract, slide presentation</td>
<td>Inclusion criteria: AMI within 12 h with ST-segment elevation &gt; 2 mm in 2 or more ECG leads, clinical indication for primary PTCA, de novo or restenotic lesions in single native coronary vessel, vessel diameter ≥ 3 and &lt; 5.5 mm, target lesion stenosis &gt; 80%</td>
<td>Intermediate: TIMI-3, DE, no reflow (post-procedure); STSR &gt; 70% (NR)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>DIPLOMAT</td>
<td>Geographical location: France, Italy</td>
<td>Exclusion criteria: RBBB or LBBB, fibrinolytic treatment, Killip class IV, unprotected left main with &gt; 50% stenosis in case left coronary artery is treated, ostial target lesion, contraindication to aspirin, heparin, stainless steel or contrast media</td>
<td>Final: MACE (mortality + MI), mortality, AMI (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 5</td>
<td>Comparator: PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomized on a 1:1 basis</td>
<td>Duration of followup (d): 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: ECG and echocardiography analyzed at a central core laboratory</td>
<td>Followup: 93.75% in device group, 92.86% in control group</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 60</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; CHF=congestive heart failure; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GI=gastrointestinal; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; mg/dL= milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; PTCA= percutaneous transluminal coronary angioplasty; RBBB=right bundle branch block; STSR=ST-segment resolution; SVG=saphenous vein graft; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revascularization; y=years
Table 4. Characteristics and quality assessment of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>Publication type:</td>
<td>Inclusion criteria:</td>
<td>Intermediate:</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Full text</td>
<td>First anterior MI defined as chest pain lasting &gt;30 min but &lt;6h in conjunction with persistent ST-segment elevation in precordial leads; proximal lesion of LAD present and diameter of infarct lesion known or expected &gt;3mm without extensive tortuosity or lesion/vessel calcification, with 30mm or more of distal vessel</td>
<td>TIMI-3; EF (post-procedure)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location:</td>
<td></td>
<td>Final:</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>China</td>
<td></td>
<td>NR</td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding:</td>
<td></td>
<td>Safety:</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt;10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>NR</td>
<td></td>
<td>NR</td>
<td>6. Was the overall loss to followup low (&lt;30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers:</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Randomization:</td>
<td>Exclusion criteria:</td>
<td></td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td></td>
<td>Randomly assigned to either of the two groups</td>
<td>LVEF ≤25%; significant valve disease, pericardial disease; major surgery or active bleeding within last 6w; aspirin or heparin allergy; severe coexisting conditions that interfered with the ability of the patient to comply with the protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcome assessment:</td>
<td>Intervention:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Echocardiography was performed by observers who were blind to all clinical and angiographic data</td>
<td>PCI with distal balloon embolic protection (PercuSurge Guardwire Plus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>96</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Duration of followup (d):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>180 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Followup:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Pan, 2010</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: 65-81 years old admitted within 2-14h after symptom onset of acute STEMI (typical chest pain&gt;30min, ST-elevation ≥1mm in 2 contiguous leads and or &gt;2mm in precordial leads with visible thrombus) proven angiographically</td>
<td>Intermediate: TIMI-3 (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: China</td>
<td>Exclusion criteria: History of MI, prior PCI or CABG, cardiogenic shock, atrial fibrillation, cardiac arrest, hepatic or renal dysfunction, culprit lesion not suitable for PCI plus percutaneous thrombectomy</td>
<td>Final: NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Comparator: Standard PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly assigned to either of the two groups</td>
<td>Duration of followup (d): Post-procedure</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: NR</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 104</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Fair</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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</tr>
<tr>
<td>Tahk, 2008</td>
<td>Publication type: Full text, abstract</td>
<td>Inclusion criteria: First-time STEMI, chest pain &gt; 30 min, presentation within 12 h after symptom onset, ST-segment elevation &gt; 2 mV in 2 or more ECG leads, reference vessel diameter of target lesion 2.75 - 4.5 mm, diameter stenosis &gt; 70%, lesion length short enough to be covered by a single stent deployment</td>
<td>Intermediate: TMP-3; TIMI-3 (post-procedure); EF (post-procedure, 180 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Korea</td>
<td>Exclusion criteria: Saphenous vein or arterial graft lesion, contraindication to GP2B3Ai, cardiogenic shock, pregnancy, LVEF ≤ 25%, left main disease, bifurcation lesion, history of bleeding tendency or coagulopathy, allergy to radiocontrast dye, aspirin, clopidogrel or heparin, co-morbidity with expected survival &lt; 1 y</td>
<td>Final: MACE (mortality, reinfarction, ischemia-driven TVR), mortality, TVR, reinfarction (30 d,180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td>Funding:</td>
<td>Supported in part by Medtronic Inc.</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
<td></td>
</tr>
<tr>
<td>Number of centers: 7</td>
<td>Randomization: NR</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
<td></td>
</tr>
<tr>
<td>Outcome assessment: NR</td>
<td>Number of participants enrolled: 116</td>
<td>Intervention: Primary PCI with PercuSurge GuardWire system</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparator: Primary PCI</td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration of followup (d): 180</td>
<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Followup: 100%</td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
<td></td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hahn, 2007</td>
<td>Publication type:</td>
<td>Inclusion criteria: Chest pain &gt; 30 min but &lt; 12 h after symptom onset, ST-segment elevation &gt; 1 mm in 2 or more ECG leads or presumably new LBBB, IRA lesion eligible for primary PCI with stenting, distal vessel &gt; 2.5 mm in diameter and suitable for balloon occlusion and aspiration device</td>
<td>Intermediate: MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (3 d, 180 d); STSR &gt; 50% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No</td>
</tr>
<tr>
<td></td>
<td>Geographical location:</td>
<td>Exclusion criteria: Previous MI, hemodynamic instability, requirement for multivessel intervention during index PCI, contraindication to aspirin, clopidogrel or heparin</td>
<td>Final: MACE (mortality, MI, TLR), mortality, TLR, reinfarction (180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td>Intervention: Primary PCI with GuardWire</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Comparator: Primary PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Number of participants enrolled: 39</td>
<td>Duration of followup (d): 180</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Coronary angiograms analyzed by 2 blinded observers, MRI analyzed independently by 2 experienced radiologists blinded to the clinical information</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can't tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
</table>
| Matsuo, 2007 | Publication type: Full text | Inclusion criteria: STEMI within 24 h after onset with chest pain > 30 min, age ≥ 18 y, ST-segment elevation in 2 or more ECG leads, vascular diameter 3 cm distal to culprit lesion was 3 mm or more, no severe tortuosity or kinks | Intermediate: MBG-3, TIMI-3, DE, no reflow (post procedure); EF (post procedure, 180 d); STSR > 70% (30 min) | 1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes
2. Were outcomes assessed using a valid methodology and criteria? Yes
3. Were outcome assessors blind to exposure/intervention status? Can’t tell
4. Were incomplete outcome data adequately addressed? Yes
5. Was the differential loss to followup between the compared groups low (< 10%)? Yes
6. Was the overall loss to followup low (< 30%)? Yes
7. Conflict of interest reported and insignificant? Can’t tell
8. Were the methods used for randomization adequate? Yes

Geographical location: Japan

Funding: NR

Number of centers: 14

Randomization: Randomized using envelope method

Outcome assessment: NR

Number of participants enrolled: 154

Intervention: PCI with GuardWire Plus

Comparator: Conventional PCI

Duration of followup (d): 180

Followup: 100%

Safety: Procedure time, side branch occlusion

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Publication type:</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muramatsu, 2007</td>
<td>Full text</td>
<td><strong>Inclusion criteria:</strong> Native vessel, AMI within 12 h of chest pain onset, age ≥ 18 y, ST-segment elevation, patients considered treatable by stenting</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (post-procedure, 30 d, 180 d); STSR &gt; 70% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>ASPARAGUS</td>
<td>Geographical location: Japan</td>
<td><strong>Exclusion criteria:</strong> SVG, left main trunk disease, reference vessel diameter &lt; 2.5 mm, cardiopulmonary arrest</td>
<td><strong>Final:</strong> MACE (mortality, myocardial infarction or TVR) (30 d, 180 d); mortality, TVR, reinfarction (in-hospital, 30 d, 180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: Medtronic Japan Co. Ltd</td>
<td><strong>Intervention:</strong> Primary PCI with GuardWire Plus</td>
<td><strong>Safety:</strong> Procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 22</td>
<td><strong>Comparator:</strong> Primary PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomized according to envelope method</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Clinical and basic angiographic data collected and case report forms sent to and reviewed by reviewed by core laboratory</td>
<td><strong>Followup:</strong> 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 341</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhou, 2007</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: Continuous chest pain &gt; 30 min, &lt; 12 h from symptom onset, ST-segment elevation ≥ 0.1 mV in 2 or more contiguous ECG leads, culprit lesion with diameter stenosis ≥ 70% and TIMI flow grade ≤ 2</td>
<td>Intermediate: MBG-3, TIMI-3 (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: NR</td>
<td>Exclusion criteria: Thrombolytic treatment before PCI, GP2B3Ai before PCI, reference vessel diameter &lt; 3.0 mm, Killip IV or cardiogenic shock, left main coronary artery lesion</td>
<td>Final: MACE (in-hospital)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td>Intervention: Primary stenting with PercuSurge GuardWire</td>
<td>Safety: Coronary dissection, perforation</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: NR</td>
<td>Comparator: Primary stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomized using sealed envelopes</td>
<td>Duration of followup (d): In-hospital</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: TIMI flow grade and MBG evaluated by 2 experienced investigators who were blinded to all clinical data</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 112</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
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Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Okamura, 2005</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: Chest pain &gt; 30 min, and presentation ≤ 24 h after symptom onset, ST-segment elevation ≥ 2 mm in 2 or more ECG leads, TIMI 0,1 or 2 on initial angiogram, reference luminal diameter ≥ 3 mm in IRA</td>
<td>Intermediate: TIMI-3 (post-procedure); EF (discharge)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: Cardiogenic shock, previous CABG, atrial fibrillation</td>
<td>Final: NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Comparator: PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Duration of followup (d): In-hospital until discharge, 22 ± 4</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Data assessed using an offline personal computer</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 16</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can't tell</td>
</tr>
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</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Stone, 2005</td>
<td>EMERALD</td>
<td>Inclusion criteria: AMI &gt; 30 min but &lt; 6 h from symptom onset, age ≥ 18 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or presumably new LBBB, primary or rescue PCI, vessel diameter at the infarct lesion 2.5 - 5.0 mm without excess tortuosity or lesion/vessel calcification with 3 cm or more of distal vessel available</td>
<td>Intermediate: MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR &gt; 70% (30 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: USA, Canada, France, Italy, Germany, Switzerland, Japan</td>
<td>Exclusion criteria: Cardiogenic shock, CABG within 30 d, unprotected left main disease, renal insufficiency (Scr &gt; 2.5 mg/dL), hepatic dysfunction, multivessel intervention required during index PCI, cardiogenic shock, major surgery or active bleeding within 6 wk, allergy to aspirin, thienopyridine or heparin, neutropenia (&lt; 1000 neutrophils/mm³), thrombocytopenia (&lt; 100,000 platelets/mm³), non-cardiac condition with expected survival &lt; 1 y, current participation in another study</td>
<td>Final: MACE related to ischemic complications, mortality, TVR, reinfarction, stroke (30 d, 180 d); Safety: Perforation, procedure time, side branch occlusion</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: Medtronic</td>
<td></td>
<td></td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 38</td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Telephone randomization in random blocks of 4 or 6 patients stratified by intention to use GP2B3Ai and by primary versus rescue PCI</td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td></td>
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<td>Intervention: PCI GuardWire Plus</td>
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<td>Comparator: PCI</td>
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<td></td>
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<td>Duration of followup (d): 180</td>
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<tr>
<td></td>
<td></td>
<td>Followup: 93.06% in device group and 89.76% in control group</td>
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<tr>
<td></td>
<td></td>
<td>Number of participants enrolled: 501</td>
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</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome.

Abbreviations: AMI=acute myocardial infarction; CABG=coronary artery bypass graft; cm=centimeters; Cr=creatinine; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; IRA=infarct related artery; LBBB=left bundle branch block; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MBG=myocardial blush grade; mg/dL=milligrams/deciliter; MI=myocardial infarction; min=minutes; mm=millimeters; mV=millivolts; MRI=magnetic resonance imaging; NR=not reported; PCI=percutaneous coronary intervention; SCr=serum creatinine; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; wk=weeks; y=years
Table 5. Characteristics and quality assessment of randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Publication type: Full text, abstract, slide presentation</td>
<td>Inclusion criteria: Symptoms of MI &lt; 6 h after onset, persistent ST-segment elevation of ≥ 200 µV in 2 or more contiguous leads, TIMI 0/1 after first angiogram, coronary anatomy suitable for treatment with the Proxis system</td>
<td>Intermediate: MBG-3, TIMI-3, DE, (post-procedure); STSR ≥ 70% (60 min); ejection fraction (120-180d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>PREPARE Geographical location: Netherlands and Canada</td>
<td>Exclusion criteria: Age &lt; 18 y, contraindication to use of GP2B3Ai, co-existent condition with limited life expectancy, prior CABG or lytics, recurrent MI in the same myocardial area, ECG unsuitable for STSR evaluation (LBBB, ventricular pacemaker, atrial fibrillation), left main occlusion, left main stenosis &gt; 30%, heavy proximal calcification, small infarct related artery (&lt; 2.5 mm in diameter), proximal location of lesion with insufficient landing zone for Proxis system (generally &lt; 10-12 mm)</td>
<td>Final: MACE (death, spontaneous or procedural MI, stroke, percutaneous or surgical TVR), mortality, reinfarction, TVR, stroke (30d, 180d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: St. Jude Medical, University of Amsterdam</td>
<td>Intervention: Primary PCI with Proxis device</td>
<td>Safety: Procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 2</td>
<td>Comparator: Primary PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomized on a 1:1 basis</td>
<td>Duration of followup (d): 30</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: STSR analysis performed by a central core laboratory, coronary angiograms assessed by 2 experienced investigators blinded to all other data, clinical event data obtained from hospital records and telephone interviews</td>
<td>Followup: 89.36% in device group, 90.21% in control group</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 284</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can't tell</td>
</tr>
</tbody>
</table>

* Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Overall quality rating: Good
Table 6. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>A-F Trial</td>
<td>Publication type: Slide presentation</td>
<td>Inclusion criteria: NSTEMI ACS with high risk features during 24 h prior to angiography (elevated troponin, angina at rest, dynamic ST or T-wave changes, not ST-segment elevation MI), culprit lesion with 2 or more high risk angiographic features (intra-coronary filling deficit consistent with thrombus, lesion ulceration, eccentric shape, irregular or scalloped border, abrupt edges to lesion, lesion length &gt; 20 mm)</td>
<td>Intermediate: TIMI-3 (post-procedure)</td>
</tr>
<tr>
<td>A-F Trial</td>
<td>Geographical location: Canada, Australia, New Zealand</td>
<td>Funding: Boston Scientific</td>
<td></td>
<td>Final: MACE (mortality, recurrent MI, emergency CABG, repeat TVR) (in-hospital, 30 d)</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 14</td>
<td>Randomization: NR</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Unblinded design, core laboratories for ECG and angiographic data</td>
<td>Number of participants enrolled: 151</td>
<td>Exclusion criteria: NR</td>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Intervention: PCI with distal filter embolic protection using BSC FilterWire EZ</td>
<td>Comparator: Standard PCI</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Duration of followup (d): 30</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Fair
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Publication type</th>
<th>Geographical location</th>
<th>Funding</th>
<th>Number of centers</th>
<th>Randomization</th>
<th>Outcome assessment</th>
<th>Number of participants enrolled</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Duration of followup (d)</th>
<th>Followup</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2003</td>
<td>Full text, abstract</td>
<td>Poland</td>
<td>Paper sponsored by Komitet Badan Naukowych (Scientific Research Committee)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>31</td>
<td>Consent to participate, unstable angina, patient qualified to single vessel coronary angioplasty with the use of stent in the vessel &gt; 3 mm in diameter, no contraindications to GP2B3Ai</td>
<td>Recent STEMI, LVEF&lt; 30%, complete closing of the vessel, cancer, impaired liver and kidney function, increased transferases (&gt; 3 times the max normal values), muscle diseases, CK-MB level above normal at baseline, age &gt; 75 y, alcohol abuse, hypersensitivity to used medication, continuation of treatment to cyclosporine and other immunosuppressant drugs, pregnancy and breast feeding</td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
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<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
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<td></td>
<td></td>
<td></td>
<td>PCI with distal filter embolic protection using Angioguard</td>
<td>Angioplasty supported by pharmacotherapy</td>
<td>30</td>
<td>100%</td>
<td>TIMI-3, no reflow (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: ACS=Acute coronary syndrome; CABG=coronary artery bypass graft; CK-MB=creatine kinase MB-isoenzyme; d=days; ECG=electrocardiogram; GP2B3Ai=glycoprotein IIb IIIa inhibitor; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MI=myocardial infarction; mm=millimeters; NR=not reported; NSTEMI=non-ST-segment elevation myocardial infarction; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=Thrombolysis myocardial infarction; TVR=target vessel revascularization; y=years
Table 7. Characteristics and quality assessment of randomized controlled trials evaluating thrombectomy or distal protection devices versus control in the mixed acute coronary syndrome population

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Publication type: Full text, abstract</td>
<td>Geographical location: India</td>
<td>Inclusion criteria: AMI patients with angiographically detected thrombotic lesions who were to undergo primary/rescue PCI within 24 h of onset of chest pain</td>
<td>Intermediate: TMP-3, TIMI-3, DE, no reflow (post-procedure)</td>
</tr>
<tr>
<td>RAPID</td>
<td></td>
<td>Funding: NR</td>
<td>Exclusion criteria: NR</td>
<td>Final: Mortality (730 d)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of centers: 1</td>
<td>Intervention: PCI with distal balloon embolic protection using PercuSurge GuardWire Plus Temporary Occlusion and Aspiration System</td>
<td>Safety: Procedure time</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly divided into 2 groups depending on whether PercuSurge was used or not</td>
<td></td>
<td>Comparator: PCI</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Coronary angiograms reviewed by 2 independent cardiologists unaware of the patients’ medical histories and details</td>
<td>Duration of followup (d): 720</td>
<td></td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 67</td>
<td>Followup: 100%</td>
<td></td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can't tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Fair
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glick, 2005</td>
<td><strong>Publication type:</strong> Full text, abstract</td>
<td><strong>Inclusion criteria:</strong> Both at least 1 episode of typical angina pain &gt; 30 min within the preceding 48 h and coronary artery lesion deemed suitable for stent placement and application of filter wire plus at least one of the following: ST-segment elevation ≥ 1 mm in 2 or more ECG leads, elevation of creatinine kinase ≥ 3 times the upper limit with concomitant rise of MB isoenzyme, coronary artery occlusion with angiographic appearance of fresh thrombus</td>
<td><strong>Intermediate:</strong> MBG &gt; 1, TIMI-3, DE (post-procedure); EF (3 d, 180 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>PROMISE</td>
<td><strong>Geographical location:</strong> Germany</td>
<td><strong>Exclusion criteria:</strong> Presumed distal vessel diameter &lt; 3 mm, relevant coronary left main involvement, vessel anatomy interfering with safe placement of filterwire, culprit lesion in saphenous vein graft, contraindication to abxicimab, aspirin, clopidogrel, or heparin, mechanical ventilation or inotropic support, inability to give informed consent</td>
<td><strong>Final:</strong> MACE (180 d); mortality, reinfarction (30 d, 180 d); TVR, stroke (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Boston Scientific</td>
<td><strong>Intervention:</strong> PCI with distal filter embolic protection using FilterWire EX</td>
<td><strong>Safety:</strong> NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 1</td>
<td><strong>Comparator:</strong> PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> Randomization sequence set in blocks of 20 by statistician, unknown to the investigators and medical staff</td>
<td><strong>Outcome assessment:</strong> MRI images examined by 2 experienced observers who were unaware of the patients' group assignment, angiographic images analyzed offline by independent core laboratory</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 200</td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Sardella, 2005</td>
<td>Publication type: Abstract</td>
<td><strong>Inclusion criteria:</strong> Anterior MI undergoing primary PCI of de novo coronary lesions with angiographic presence of intracoronary thrombus</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3 (post procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Geographical location: NR</td>
<td></td>
<td><strong>Final:</strong> NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td><strong>Exclusion criteria:</strong> NR</td>
<td><strong>Safety:</strong> NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of centers: NR</td>
<td><strong>Intervention:</strong> PCI with catheter aspiration using Diver-Invatec plus stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td><strong>Comparator:</strong> Conventional coronary stenting</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: NR</td>
<td><strong>Duration of followup (d):</strong> 180</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 62</td>
<td><strong>Followup:</strong> NR</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

**Overall quality rating:** Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kunii, 2004</td>
<td>Publication type: Abstract</td>
<td>Inclusion criteria: &lt; 24 h of symptom onset, lesion diameter &gt; 2.5 mm, no severe calcification at or proximal to the lesion, no proximal tortuosity preventing Rescue use or stent delivery, no cardiogenic shock, no left main disease</td>
<td>Intermediate: TIMI-3 (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell</td>
</tr>
<tr>
<td>NONSTOP</td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: NR</td>
<td>Final: Mortality (in-hospital)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td>Intervention: PCI with catheter aspiration using Rescue PT catheter</td>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of centers: NR</td>
<td>Comparator: Primary stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Duration of followup (d): In-hospital</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: NR</td>
<td>Followup: NR</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 258</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
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<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nanasato, 2004</td>
<td>Publication type: Abstract</td>
<td>Inclusion criteria: AMI within 12 h of onset</td>
<td>Intermediate: MBG-3, TIMI-3, EF, (post procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: NR</td>
<td>Final: NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of centers: NR</td>
<td>Comparator: Conventional PCI</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Duration of followup (d): In-hospital</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: NR</td>
<td>Followup: NR</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 64</td>
<td>Safety: NR</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Poor</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Publication type:</td>
<td>Geographical location:</td>
<td>Funding:</td>
<td>Number of centers:</td>
</tr>
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<td>-------------------</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Abstract</td>
<td>Japan</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

- **Population, Interventions and Follow-up**

  - **Inclusion criteria:** First anteroseptal MI undergoing coronary intervention and stenting within 12 h from onset of MI and who had coronary blood flow measurements immediately after the procedure.

- **Intervention:** PCI with balloon distal embolic protection using Guard Wire PercuSurge system.

- **Comparator:** PCI.

- **Duration of followup (d):** 180.

- **Followup:** 100% for MACE and mortality.

<table>
<thead>
<tr>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate: NR</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td>Final: MACE (180 d); mortality (in-hospital)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td>Safety: NR</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Can’t tell</td>
</tr>
<tr>
<td>4. Were incomplete outcome data adequately addressed? Can’t tell</td>
<td></td>
</tr>
<tr>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
</tr>
<tr>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
</tr>
<tr>
<td>7. Conflict of interest reported and insignificant? Can’t tell</td>
<td></td>
</tr>
<tr>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
<td></td>
</tr>
</tbody>
</table>

**Overall quality rating:** Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beran, 2002</td>
<td>Publication type:</td>
<td>Inclusion criteria:</td>
<td>Intermediate:</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? <strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td>Full text, abstract</td>
<td>STEMI with chest pain &gt; 30 min and ST-segment elevation &gt; 1 mm 2 or more ECG leads, patients with UA were allowed if presented with recurrent chest pain at rest associated with ST-segment or T-wave changes, native vessel occlusion or intraluminal filling defect</td>
<td>TIMI-3, STSR &gt; 50% (post-procedure)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? <strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exclusion criteria:</td>
<td>Final:</td>
<td>3. Were outcome assessors blind to exposure/intervention status? <strong>Partially</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NR</td>
<td>MACE, mortality, TVR (30 d)</td>
<td>4. Were incomplete outcome data adequately addressed? <strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention:</td>
<td>Safety:</td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? <strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mechanical thrombectomy with X-Sizer followed by stenting or PTCA</td>
<td>NR</td>
<td>6. Was the overall loss to followup low (&lt; 30%)? <strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparator:</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? <strong>No</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PTCA or stenting</td>
<td></td>
<td>8. Were the methods used for randomization adequate? <strong>Can’t tell</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Duration of followup (d):</td>
<td></td>
<td>Overall quality rating: <strong>Good</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; d=days; DE=distal embolization; ECG=electrocardiogram; EF=ejection fraction; GP2B3Ai=glycoprotein IIb IIIa inhibitor; h=hours; LVEF=left ventricular ejection fraction; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; MRI=magnetic resonance imaging; NR=not reported; PCI=percutaneous coronary intervention; PTCA=percutaneous transluminal coronary angioplasty; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; UA=unstable angina
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Publication type: Full text, abstract</td>
<td>Inclusion criteria: STEMI (chest pain &gt; 30 min and new ST-segment elevation ≥ 2 mm in 2 or more contiguous ECG leads) within 12 h of symptom onset, de novo coronary lesion, occluded single native vessel ≥ 2.5 mm in diameter, angiographically identifiable thrombus (filling defect within the coronary lumen surrounded by contrast medium observed in multiple projections, without calcium within the filling defect or persistence of contrast medium within the coronary lumen), TIMI flow grade 0-1 and age &gt; 18 y</td>
<td>Intermediate: MGB-3, TIMI-3 (post-procedure); STSR &gt; 70% (90 min)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Italy</td>
<td></td>
<td>Final: MACE (cardiac death, Q and non-Q-wave MI, TVR), TVR, reinfarction (30 d, 365 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td></td>
<td>Safety: Coronary dissection, perforation</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomly assigned in a 1:1 basis</td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Coronary angiograms analyzed offline by 2 expert interventional cardiologists in a blinded manner</td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt;30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 103</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Trial Characteristics</td>
<td>Population, Interventions and Followup*</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<td>-------------</td>
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</tr>
<tr>
<td>Yan, 2007</td>
<td>Publication type:</td>
<td>Inclusion criteria: Symptoms &gt; 30 min but &lt; 12 h, ST segment elevation ≥ 2 mV in 2 or more contiguous inferior ECG leads and total occlusion of the left coronary artery</td>
<td>Intermediate: MBG &gt; 2, TIMI-3, no reflow/slow flow (post-procedure); STSR &gt; 70% (90 min); EF (30 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Final: MACE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Safety: Procedure time</td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td>Geographical location:</td>
<td>Exclusion criteria: LBBB, previous MI within last 30 d, fibrinolytic treatment, previous CABG, left main stenosis, need for mechanical ventilation, severe heart failure treated with IABP and tortuous IRA unsuitable for thrombectomy</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention: PCI with catheter aspiration using Diver CE</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparator: PCI with distal balloon embolic protection using Guardwire Plus</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly assigned on a 1:1 basis according to a computer generated random series of number</td>
<td></td>
<td>Overall quality rating: Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Coronary angiograms reviewed offline by 2 experienced observers who were blinded to randomization</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Number of participants enrolled: 122</td>
<td>Duration of followup (d): 30</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Followup: 100%</td>
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</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: CABG=coronary artery bypass graft; d=days; ECG=electrocardiogram; EF=ejection fraction; h=hours; IABP= intra-aortic balloon pump; IRA=infarct related artery; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization; y=years
Table 9. Characteristics and quality assessment of randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: Age &gt; 18 y, chest pain &gt; 20 min in conjunction with persistent ST-segment elevation in the precordial leads, LAD closure (TIMI-0), restored blood flow after PCI (TIMI-3) within 12 h from MI onset</td>
<td>Intermediate: MBG 2-3 (post-procedure); EF (7 d, 30 d)</td>
<td>Overall quality rating: Good</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Poland</td>
<td>Exclusion criteria: Cardiogenic shock, history of previous MI, hypertrophic cardiomyopathy, significant valvular disease, lack of IRA identification, residual stenosis after PCI &gt; 50%, electrical instability, ICD or pacemaker, or females of child bearing potential</td>
<td>Final: NR</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td>Safety: Procedure time</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td></td>
<td>3. Were outcome assessors blind to exposure/intervention status? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomized on a 1:1 basis</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Quantitative analysis of all images by 1 investigator blinded to the type of procedure, using a quantitative analysis tool</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 42</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intervention: Catheter aspiration using Diver CE flowed by stenting</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comparator: Stenting</td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duration of followup (d): 30</td>
<td></td>
<td>Overall quality rating: Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Followup: 100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study, Year</td>
<td>Publication type</td>
<td>Geographical location</td>
<td>Funding</td>
<td>Number of centers</td>
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<td>------------------</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Full text</td>
<td>Japan</td>
<td>NR</td>
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</table>

Overall quality rating: Fair

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome
Abbreviations: d=days; ECG=electrocardiogram; ECHO=echocardiogram; EF=ejection fraction; h=hours; ICD=implantable cardioverter-defibrillator; IRA=infarct related artery; LAD=left anterior descending artery; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; SPECT=single-photon emission computerized tomography; TIMI=thrombolysis in myocardial infarction; y=years
Table 10. Characteristics and quality assessment of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: First onset STEMI, no contraindication to mutant plasminogen activator</td>
<td>Intermediate: TMP-3, TIMI-3 (post-procedure); EF (1-3 d, 180 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: Age &gt; 75 y, presence of active bleeding (intracranium, GI or urinary tract), intracranial lesion (tumor, aneurysm, AV malformation), intracranial/spinal surgery or injury within 2 m, persistent BP &gt; 180 mmHg systolic or &gt; 100 mmHg diastolic, post cardiopulmonary resuscitation</td>
<td>Final: Mortality, TVR reinfarction, stroke (180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: Randomly assigned using the envelope method</td>
<td>Intervention: PCI with catheter aspiration using Thrombuster and mutant tissue plasminogen activator</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: TMP grade assessed by single observer who was blinded to the treatment assignment and clinical outcome</td>
<td>Comparator: PCI with catheter aspiration using Thrombuster</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 44</td>
<td>Duration of followup (d): 180</td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td>Followup: 100%</td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Yes</td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; AV=arteriovenous; BP=blood pressure; CK-MB=creatine kinase MB-isoenzyme; d=days; EF=ejection fraction; GI=gastrointestinal; h=hours; IRA=infarct related artery; m=months; MBG=myocardial blush grade; MI=myocardial infarction; mm=millimeters; mmHg=millimeters of mercury; mV=millivolts; NR=not reported; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=thrombolysis in myocardial infarction; TMP=TIMI myocardial perfusion; TVR=target vessel revascularization; y=years
Table 11. Characteristics and quality assessment of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td><strong>Publication type:</strong> Full text</td>
<td><strong>Inclusion criteria:</strong> AMI &lt; 12 h referred for primary PCI, ≥ 2 or 3 signs/symptoms of AMI (typical clinical symptom, new ST-segment elevation in at least 2 adjacent leads ≥ 0.2 mV in V₁-V₂ and 0.1mV in other leads, elevation of troponin / CK-MB levels above MI cut-off values), critical stenosis or total occlusion of IRA and reference diameter of IRA distally to occlusion between 3.0 - 4.5 mm</td>
<td><strong>Intermediate:</strong> MBG-3, TIMI-3 (post-procedure); EF (180 d)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> Poland</td>
<td><strong>Exclusion criteria:</strong> Lack of patients’ informed consent, critical stenosis of left main artery, complex occlusive lesion (&gt; 20 mm length or in the segment bent at 90° or incorporating ostium of a large side branch &gt; 2 mm in diameter), cardiogenic shock, respiratory distress requiring intubation, previous PCI in the culprit artery, previous surgical myocardial revascularization, contraindication to abxiximab, aspirin, clopidogrel or heparin, critical lesions in other segments of coronary arteries requiring revascularization within 6 m., valvular disease requiring surgical intervention</td>
<td><strong>Final:</strong> Mortality (death/cardiovascular death), TVR, reinfarction (180 d)</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> KBN Grant</td>
<td><strong>Safety:</strong> Procedure time</td>
<td></td>
<td>3. Were outcome assessors blind to exposure/intervention status? Partially</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> NR</td>
<td></td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Randomization:</strong> NR</td>
<td></td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Angiographic data analysis by independent investigator</td>
<td></td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 120</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

Overall quality rating: Good
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Trial Characteristics</th>
<th>Population, Interventions and Followup*</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kanaya, 2003</td>
<td>Publication type: Abstract</td>
<td>Inclusion criteria: AMI within 12 h of symptom onset</td>
<td>Intermediate: TIMI-3 (post-procedure)</td>
<td>1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: NR</td>
<td>Final: NR</td>
<td>2. Were outcomes assessed using a valid methodology and criteria? Can’t tell</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Comparator: Thrombectomy and stenting</td>
<td></td>
<td>4. Were incomplete outcome data adequately addressed? Yes</td>
</tr>
<tr>
<td></td>
<td>Randomization: NR</td>
<td>Duration of followup (d): In-hospital</td>
<td></td>
<td>5. Was the differential loss to followup between the compared groups low (&lt; 10%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: NR</td>
<td>Followup: 100%</td>
<td></td>
<td>6. Was the overall loss to followup low (&lt; 30%)? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 60</td>
<td></td>
<td></td>
<td>7. Conflict of interest reported and insignificant? No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8. Were the methods used for randomization adequate? Can’t tell</td>
</tr>
</tbody>
</table>

*Duration of followup is reported as the original study’s longest reported followup and followup is reported for the study’s pre-specified primary outcome

Abbreviations: AMI=acute myocardial infarction; d=days; h=hours; NR=not reported; TIMI=thrombolysis in myocardial infarction

Overall quality rating: Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Study Characteristics</th>
<th>Population, Intervention, and Followup</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Publication type: Full text</td>
<td><strong>Inclusion criteria:</strong> Patients undergoing primary or rescue PCI for STEMI (chest pain or equivalent symptoms at rest &gt;30 min, with ST-segment elevation in ≥2 contiguous leads); presenting &gt;12h included only if persistent chest pain was present at the time of initial evaluation; patients with ST-segment depressing ≥1mm in precordial leads suggesting posterior MI and new or presumed LBBB were included if coronary occlusion was confirmed on angiography</td>
<td><strong>Intermediate:</strong> TIMI 3 (post-procedure)</td>
<td>1. Unbiased selection of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: Canada</td>
<td><strong>Exclusion criteria:</strong> NR</td>
<td><strong>Final:</strong> Mortality, reinfarction, stroke, revascularization, MACE (365 d)</td>
<td>2. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Study design: Retrospective study</td>
<td><strong>Intervention:</strong> PCI with Export Aspiration Catheter</td>
<td><strong>Safety:</strong> Procedure time (post-procedure)</td>
<td>3. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td><strong>Comparator:</strong> PCI without prior thrombectomy</td>
<td></td>
<td>4. Adequate description of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td><strong>Duration of followup (d):</strong> 357 days in intervention and 363 days in control groups</td>
<td></td>
<td>5. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Angiograms reviewed by two trained investigators</td>
<td><strong>Covariates/potential confounders adjusted for:</strong> Killip class, final TIMI flow, age≥60 years, presence of three vessel disease, anterior infarction and ischemia time&gt;4hours for the survival analysis</td>
<td></td>
<td>6. Validated method for ascertaining clinical outcomes? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 535</td>
<td></td>
<td></td>
<td>7. Outcome assessment blinded to exposure? Partially</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>8. Adequate followup period? Yes?</td>
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<td>9. Completeness of followup? Yes?</td>
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<td>10. Analysis controls for confounding? Yes</td>
</tr>
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<td>11. Analytic methods appropriate? Yes</td>
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<td>Overall quality rating: Good</td>
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<td>Study, Year</td>
<td>Study Characteristics</td>
<td>Population, Intervention, and Followup</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<tr>
<td></td>
<td>Abstract</td>
<td></td>
<td></td>
<td>2. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td>Geographical location: South Korea</td>
<td>Exclusion criteria: NR</td>
<td>Final: Mortality (in-hospital)</td>
<td></td>
<td>3. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td>Study design: Propensity-matched cohort</td>
<td>Safety: NR</td>
<td></td>
<td>4. Adequate description of the cohort? No</td>
</tr>
<tr>
<td>Funding: NR</td>
<td>Comparator: PCI without thrombus aspiration</td>
<td></td>
<td></td>
<td>5. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td>Number of centers: NR</td>
<td>Duration of followup (d): 30 days</td>
<td></td>
<td></td>
<td>6. Validated method for ascertaining clinical outcomes? Can’t tell</td>
</tr>
<tr>
<td>Outcome assessment: NR</td>
<td>Covariates/potential confounders adjusted for: NR</td>
<td></td>
<td></td>
<td>7. Outcome assessment blinded to exposure? Can’t tell</td>
</tr>
<tr>
<td>Number of participants enrolled: 858</td>
<td></td>
<td></td>
<td></td>
<td>8. Adequate followup period? No</td>
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Overall quality rating: Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Study Characteristics</th>
<th>Population, Intervention, and Followup</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ko, 2009</td>
<td><strong>Publication type:</strong> Abstract</td>
<td><strong>Inclusion criteria:</strong> Acute STEMI, PCI within 3 h of symptom onset</td>
<td><strong>Intermediate:</strong> NR</td>
<td>12. Unbiased selection of the cohort? Partially</td>
</tr>
<tr>
<td>KAMIR</td>
<td><strong>Geographical location:</strong> Korea</td>
<td><strong>Exclusion criteria:</strong> NR</td>
<td><strong>Final:</strong> MACE (365 d)</td>
<td>13. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Study design:</strong> Registry</td>
<td><strong>Intervention:</strong> PCI with distal protection device (device name NR)</td>
<td><strong>Safety:</strong> NR</td>
<td>14. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td><strong>Comparator:</strong> PCI without distal protection device</td>
<td></td>
<td>15. Adequate description of the cohort? No</td>
</tr>
<tr>
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<td><strong>Number of centers:</strong> NR</td>
<td></td>
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<td>16. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> NR</td>
<td><strong>Duration of followup (d):</strong> 365</td>
<td></td>
<td>17. Validated method for ascertaining clinical outcomes? Can't tell</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 1050</td>
<td><strong>Covariates/potential confounders adjusted for:</strong> NR, subgroup analyses based on LV dysfunction and use of GP2B3Ai</td>
<td></td>
<td>18. Outcome assessment blinded to exposure? Can't tell</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19. Adequate followup period? Yes</td>
</tr>
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<td></td>
<td>20. Completeness of followup? Yes</td>
</tr>
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<td></td>
<td>21. Analysis controls for confounding? Yes</td>
</tr>
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<td>22. Analytic methods appropriate? Yes</td>
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**Overall quality rating:** Poor
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Study Characteristics</th>
<th>Population, Intervention, and Followup</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nilsen, 2009</td>
<td><strong>Publication type:</strong> Abstract</td>
<td><strong>Inclusion criteria:</strong> See table 2 of original study ²</td>
<td><strong>Intermediate:</strong> DE¹, (post-procedure); STSR &gt; 70%¹ (60 min)</td>
<td>1. Unbiased selection of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> NR</td>
<td><strong>Exclusion criteria:</strong> See table 2 of original study ²</td>
<td></td>
<td>2. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Study design:</strong> Retrospective cohort</td>
<td><strong>Intervention:</strong> PCI with catheter aspiration (Device name NR)</td>
<td><strong>Final:</strong> MACE (mortality, reinfarction, ischemic TVR, stroke), mortality, reinfarction, ischemic TVR, stroke (30 d)</td>
<td>3. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> NR</td>
<td><strong>Comparator:</strong> PCI without catheter aspiration</td>
<td></td>
<td>4. Adequate description of the cohort? No</td>
</tr>
<tr>
<td></td>
<td><strong>Number of centers:</strong> 123</td>
<td><strong>Duration of followup (d):</strong> 30</td>
<td></td>
<td>5. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Core lab analysis¹</td>
<td><strong>Covariates/potential confounders adjusted for:</strong> NR</td>
<td></td>
<td>6. Validated method for ascertaining clinical outcomes? Can't tell</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 3298, 3233¹</td>
<td></td>
<td></td>
<td>7. Outcome assessment blinded to exposure? Yes</td>
</tr>
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<td>8. Adequate followup period? Yes</td>
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<td>9. Completeness of followup? Yes</td>
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<td>10. Analysis controls for confounding? Yes</td>
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<td>11. Analytic methods appropriate? Yes</td>
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Overall quality rating: Fair
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Study Characteristics</th>
<th>Population, Intervention, and Followup</th>
<th>Outcomes of Interest (Timing)</th>
<th>Quality Assessment / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nakatani, 2007</td>
<td>OACIS</td>
<td>Inclusion criteria: Undergoing PCI, AMI/symptoms within 24 h</td>
<td>Intermediate: NR</td>
<td>Unbiased selection of the cohort? Yes</td>
</tr>
<tr>
<td>Geographical location: Japan</td>
<td>Exclusion criteria: Admittance &gt; 24 h (or time unknown) after onset of AMI, treated conservatively, with thrombolytic therapy, emergent CABG, or with distal protection</td>
<td>Final: Mortality (cardiac and non-cardiac) (30 d)</td>
<td>Selection minimizes baseline differences in prognostic factors? Yes</td>
<td></td>
</tr>
<tr>
<td>Study design: Prospective registry</td>
<td>Intervention: PCI with catheter aspiration (RESCUE catheter, Thrombuster catheter, TVAC catheter, Export PercuSurge System)</td>
<td>Safety: NR</td>
<td>Sample size calculated? No</td>
<td></td>
</tr>
<tr>
<td>Funding: Government (Japanese Ministry of Education, Culture, Sports, Sciences, and Technology); Foundation (Japan Arteriosclerosis Prevention Fund)</td>
<td>Comparator: PCI without catheter aspiration</td>
<td></td>
<td>Adequate description of the cohort? Yes</td>
<td></td>
</tr>
<tr>
<td>Number of centers: 25</td>
<td>Outcome assessment: NR</td>
<td>Duration of followup (d): 30</td>
<td>Validated method to ascertain exposure? Yes</td>
<td></td>
</tr>
<tr>
<td>Outcome assessment: NR</td>
<td>Number of participants enrolled: 3913</td>
<td>Covariates/potential confounders adjusted for: Mortality adjusted for hospital volume, age, male gender, diabetes mellitus, hypertension, hyperlipidemia, smoking, body mass index ≥ 25 kg/m², a history of myocardial infarction, preangina, Killip class ≥ II, ST-segment elevation myocardial infarction, onset to admission &lt; 12 h, angiographic findings (including multivessel disease, collateral circulation, and initial TIMI grade flow), use of stenting</td>
<td>Validated method for ascertaining clinical outcomes? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Outcome assessment blinded to exposure? Can't tell</td>
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</tr>
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<td></td>
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<td></td>
<td>Adequate followup period? Yes</td>
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<td></td>
<td>Completeness of followup? Yes</td>
<td></td>
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<td></td>
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<td></td>
<td>Analysis controls for confounding? Yes</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Analytic methods appropriate? Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overall quality rating: Fair</td>
<td></td>
</tr>
<tr>
<td>Study, Year</td>
<td>Study Characteristics</td>
<td>Population, Intervention, and Followup</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Publication type: Full text</td>
<td>Inclusion criteria: Undergoing primary or rescue PCI, symptoms consistent with AMI lasting &lt; 24 h, ST-segment elevation ≥ 1 mm in two contiguous leads</td>
<td>Intermediate: TIMI-3 (post-procedure)</td>
<td>1. Unbiased selection of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td>Geographical location: NR</td>
<td>Exclusion criteria: SVG culprit, stent thrombosis</td>
<td>Final: MACE (mortality, reinfarction, TVR, stroke), mortality, TVR, stroke, reinfarction (in-hospital)</td>
<td>2. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td>Study design: Retrospective cohort</td>
<td>Intervention: PCI with mechanical thrombectomy (AngioJet XMI or XVG catheter)</td>
<td>Safety: Coronary artery perforation</td>
<td>3. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td>Funding: NR</td>
<td>Comparator: PCI without mechanical thrombectomy</td>
<td></td>
<td>4. Adequate description of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of centers: 1</td>
<td>Duration of followup (d): In-hospital</td>
<td></td>
<td>5. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td></td>
<td>Outcome assessment: Examined according to whether patient received mechanical thrombectomy or not</td>
<td>Covariates/potential confounders adjusted for: MACE and mortality adjusted for baseline clinical and angiographic characteristics</td>
<td></td>
<td>6. Validated method for ascertaining clinical outcomes? Yes</td>
</tr>
<tr>
<td></td>
<td>Number of participants enrolled: 1260</td>
<td></td>
<td></td>
<td>7. Outcome assessment blinded to exposure? Yes</td>
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<td>8. Adequate followup period? Yes</td>
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<td></td>
<td></td>
<td></td>
<td>9. Completeness of followup? Yes</td>
</tr>
<tr>
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<td></td>
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<td>10. Analysis controls for confounding? Yes</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>11. Analytic methods appropriate? Yes</td>
</tr>
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<td></td>
<td></td>
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<td>Overall quality rating: Fair</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Study Characteristics</td>
<td>Population, Intervention, and Followup</td>
<td>Outcomes of Interest (Timing)</td>
<td>Quality Assessment / Comments</td>
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<td>-------------</td>
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</tr>
<tr>
<td>Simonton, 2006</td>
<td><strong>Publication type:</strong> Full text</td>
<td><strong>Inclusion criteria:</strong> Undergoing PCI, TIMI thrombus grade ≥ 3, 9 m followup available, no use of distal protection device</td>
<td><strong>Intermediate:</strong> TIMI-3 (post-procedure)</td>
<td>1. Unbiased selection of the cohort? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Geographical location:</strong> United States</td>
<td><strong>Exclusion criteria:</strong> Inability to provide informed consent</td>
<td><strong>Final:</strong> MACE (mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event), mortality, TVR, MI (270 d)</td>
<td>2. Selection minimizes baseline differences in prognostic factors? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Study design:</strong> Prospective registry</td>
<td><strong>Intervention:</strong> PCI with mechanical thrombectomy (AngioJet)</td>
<td><strong>Safety:</strong> NR</td>
<td>3. Sample size calculated? No</td>
</tr>
<tr>
<td></td>
<td><strong>Funding:</strong> Unknown</td>
<td><strong>Comparator:</strong> PCI without mechanical thrombectomy or distal protection</td>
<td></td>
<td>4. Adequate description of the cohort? No</td>
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<tr>
<td></td>
<td><strong>Number of centers:</strong> 9</td>
<td><strong>Duration of followup (d):</strong> 270</td>
<td></td>
<td>5. Validated method to ascertain exposure? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Outcome assessment:</strong> Patient contact by phone for clinical outcome assessment, physician adjudicated MACE events, routine data audits</td>
<td><strong>Covariates/potential confounders adjusted for:</strong> Unadjusted</td>
<td></td>
<td>6. Validated method for ascertaining clinical outcomes? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Number of participants enrolled:</strong> 1368</td>
<td></td>
<td></td>
<td>7. Outcome assessment blinded to exposure? Can't tell</td>
</tr>
</tbody>
</table>

**Abbreviations:** AMI=acute myocardial infarction; CABG=coronary artery bypass graft; d=days; DE=distal embolization; h=hours; GP2B3Ai=glycoprotein IIb IIIa inhibitor; Kg/m²=kilogram-meter squared; LV=left ventricular; m=months; MACE=major adverse cardiac events; MI=myocardial infarction; min=minutes, mm=millimeter; NR=not reported; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft; TVAC=transvascular aspiration catheter; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Review Characteristics</th>
<th>Population, Intervention, Comparator, Outcomes of Interest (Timing)</th>
<th>Outcomes [&quot;X&quot;R (95%CI)]</th>
<th>Quality Scoring/Comments</th>
<th>AMSTAR assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mongeon, 2010</td>
<td><strong>Number of studies (participants):</strong> Overall analysis: 21 (4299) Aspiration-only analysis: 16 (3365)</td>
<td><strong>Population:</strong> Primary and rescue PCI in STEMI only</td>
<td>Overall analysis Intermediate: TIMI-3: OR 1.38 (0.97 to 2.01) TMPG-3: OR 2.50 (1.48 to 4.41) No reflow: OR 0.39 (0.18 to 0.69) DE: OR 0.46 (0.28 to 0.70) STSR ≥ 50%: OR 2.22 (1.60 to 3.23)</td>
<td><strong>AMSTAR assessment:</strong> 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Can’t answer 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? No 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? No 11. Was the conflict of interest stated? No</td>
<td>Total 'Yes' responses (out of 11): 6</td>
</tr>
</tbody>
</table>

**Study design(s) included:** RCTs only (full text and abstracts)

**Literature search:** Undefined electronic databases; reference review; international meeting program review; updated thru October 2009

**Languages:** English, French

**Statistical methods:** Bayesian random-effects model

**Population:** Primary and rescue PCI in STEMI only

**Intervention:** PCI with catheter aspiration or mechanical thrombectomy

**Comparator:** PCI without thrombectomy

**Outcomes (Timing):** Mortality, MACE (mortality, MI or stroke) (30 d); TIMI-3, TMPG 3, no reflow, DE, and STSR ≥ 50% (post-procedure); procedure time, STBT

**Overall analysis**

**Intermediate:**
- TIMI-3: OR 1.38 (0.97 to 2.01)
- TMPG-3: OR 2.50 (1.48 to 4.41)
- No reflow: OR 0.39 (0.18 to 0.69)
- DE: OR 0.46 (0.28 to 0.70)
- STSR ≥ 50%: OR 2.22 (1.60 to 3.23)

<table>
<thead>
<tr>
<th>AMSTAR assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was an 'a priori' design provided? Yes</td>
</tr>
<tr>
<td>2. Was there duplicate study selection and data extraction? Yes</td>
</tr>
<tr>
<td>3. Was a comprehensive literature search performed? Can’t answer</td>
</tr>
<tr>
<td>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes</td>
</tr>
<tr>
<td>5. Was a list of studies (included and excluded) provided? No</td>
</tr>
<tr>
<td>6. Were the characteristics of the included studies provided? Yes</td>
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<td>7. Was the scientific quality of the included studies assessed and documented? Yes</td>
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<td>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes</td>
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<td>9. Were the methods used to combine the findings of studies appropriate? Yes</td>
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<td>10. Was the likelihood of publication bias assessed? No</td>
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<td>11. Was the conflict of interest stated? No</td>
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<td>Total 'Yes' responses (out of 11): 6</td>
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<td>Study, Year</td>
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<tr>
<td>Tamhane, 2010</td>
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**AMSTAR assessment:**
1. Was an 'a priori' design provided? **Yes**
2. Was there duplicate study selection and data extraction? **Yes**
3. Was a comprehensive literature search performed? **Yes**
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? **Yes**
5. Was a list of studies (included and excluded) provided? **Yes**
6. Were the characteristics of the included studies provided? **Yes**
7. Was the scientific quality of the included studies assessed and documented? **Yes**
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? **Yes**
9. Were the methods used to combine the findings of studies appropriate? **Yes**
10. Was the likelihood of publication bias assessed? **Yes**
11. Was the conflict of interest stated? **Yes**

**Total 'Yes' responses (out of 11): 11**
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<th>Study, Year</th>
<th>Review Characteristics</th>
<th>Population, Intervention, Comparator, Outcomes of Interest (Timing)</th>
<th>Outcomes [“X”R (95%CI)]</th>
<th>Quality Scoring/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burzotta, 2009</td>
<td>Number of studies (participants): Overall analysis:11 (2686)</td>
<td>Population: STEMI only</td>
<td>Final: TLR/TVR: OR 0.87 (0.67 to 1.12)</td>
<td>AMSTAR assessment: 1. Was an 'a priori' design provided? Yes</td>
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<tr>
<td>and De Vita, 2009</td>
<td>Study design(s) included: RCTs only (full-text, abstracts, and expert slide presentations)</td>
<td>Intervention: PCI with catheter aspiration or mechanical thrombectomy</td>
<td>MI: OR 0.72 (0.47 to 1.10) Mortality: OR 0.71 (0.49 to 1.00) Mortality + MI: OR 0.70 (0.52 to 0.93) MACE: OR 0.80 (0.65 to 0.98)</td>
<td>2. Was there duplicate study selection and data extraction? No</td>
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<td></td>
<td>Languages: No restrictions</td>
<td>Outcomes (Timing): TLR/TVR, MI, mortality, MACE (all-cause mortality, TLR/TVR, MI) and mortality + MI (longest available clinical outcome)</td>
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<td>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes</td>
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<td></td>
<td>Statistical methods: Individual patient-data meta-analysis. Peto fixed effects method for patient-level analysis (according to event counts reported at the longest available followup) as well as a random effect method with generic inverse variance weighting (according to risk estimates obtained with Cox proportional hazard analysis). Peto fixed effects method results reported.</td>
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<td>5. Was a list of studies (included and excluded) provided? No</td>
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<td>6. Were the characteristics of the included studies provided? Yes</td>
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<td>7. Was the scientific quality of the included studies assessed and documented? Yes</td>
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<td>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes</td>
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<td>9. Were the methods used to combine the findings of studies appropriate? Yes</td>
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<td>10. Was the likelihood of publication bias assessed? Yes</td>
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<td>11. Was the conflict of interest stated? Yes</td>
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<td>Total 'Yes' responses (out of 11): 9</td>
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<tr>
<td>Study, Year</td>
<td>Review Characteristics</td>
<td>Population, Intervention, Comparator, Outcomes of Interest (Timing)</td>
<td>Outcomes [&quot;X&quot;R (95%CI)]</td>
<td>Quality Scoring/Comments</td>
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<tr>
<td>Inaba, 2009</td>
<td><strong>Number of studies (participants):</strong>&lt;br&gt;Overall analysis: 25 (5919)&lt;br&gt;Aspiration-only analysis: 10 (2656)&lt;br&gt;Mechanical-only analysis: 5 (934)&lt;br&gt;Embolic Protection-only analysis: 10 (2329)</td>
<td><strong>Population:</strong>&lt;br&gt;AMI only</td>
<td><strong>Overall Analysis</strong>&lt;br&gt;Intermediate:&lt;br&gt;MBG &lt; 3: RR 0.75 (0.66 to 0.84)&lt;br&gt;STSR &lt; 70%: RR 0.77 (0.68 to 0.87)&lt;br&gt;Final:&lt;br&gt;Mortality: RR 0.78 (0.57 to 1.05)</td>
<td><strong>AMSTAR assessment:</strong>&lt;br&gt;1. Was an ‘a priori’ design provided? Yes&lt;br&gt;2. Was there duplicate study selection and data extraction? Yes&lt;br&gt;3. Was a comprehensive literature search performed? Yes&lt;br&gt;4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes&lt;br&gt;5. Was a list of studies (included and excluded) provided? No&lt;br&gt;6. Were the characteristics of the included studies provided? Yes&lt;br&gt;7. Was the scientific quality of the included studies assessed and documented? Yes&lt;br&gt;8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes&lt;br&gt;9. Were the methods used to combine the findings of studies appropriate? Yes&lt;br&gt;10. Was the likelihood of publication bias assessed? Yes&lt;br&gt;11. Was the conflict of interest stated? Yes&lt;br&gt;<strong>Total ‘Yes’ responses (out of 11):</strong> 10</td>
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<td><strong>Study design(s) included:</strong>&lt;br&gt;RCTs only (full-text, oral presentations, and expert slide presentations)</td>
<td><strong>Intervention:</strong>&lt;br&gt;PCI with catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, or distal filter embolic protection</td>
<td><strong>Aspiration-only analysis</strong>&lt;br&gt;Intermediate:&lt;br&gt;MBG &lt; 3: RR 0.56 (0.36 to 0.87)&lt;br&gt;STSR &lt; 70%: RR 0.69 (0.58 to 0.83)&lt;br&gt;Final:&lt;br&gt;Mortality: RR 0.56 (0.36 to 0.87)</td>
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<td><strong>Comparator:</strong>&lt;br&gt;PCI without thrombectomy</td>
<td><strong>Mechanical-only analysis</strong>&lt;br&gt;Intermediate:&lt;br&gt;MBG &lt; 3: RR 1.98 (0.92 to 4.27)&lt;br&gt;STSR &lt; 70%: RR 0.61 (0.37 to 1.02)&lt;br&gt;Final:&lt;br&gt;Mortality: RR 1.98 (0.92 to 4.27)</td>
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<td><strong>Literature search:</strong>&lt;br&gt;Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process &amp; other Non-Indexed Citations, Cochrane Central Register of Randomized controlled trial, and Cochrane Database of Systematic Reviews through March 2009. Relevant reviews and conference proceedings from major international cardiology meetings including AHA, ACC, and ESC. Oral presentations and expert slide presentations from TCT (<a href="http://www.tctmd.com">http://www.tctmd.com</a>), EuroPCR (<a href="http://www.europcr.com">www.europcr.com</a>), ACC (<a href="http://www.acc.org">www.acc.org</a>), AHA (<a href="http://www.americaheart.org">http://www.americaheart.org</a>), and ESC (<a href="http://www.escardio.org">www.escardio.org</a>) from January 2006 and December 2008. Search limited to human studies and filter for RCT applied.</td>
<td><strong>Outcomes (Timing):</strong>&lt;br&gt;MBG &lt; 3, STSR &lt; 70% (&lt; 50% &lt; 70% not available) (post-procedure); mortality (NR)</td>
<td><strong>Embolic Protection-only analysis</strong>&lt;br&gt;Intermediate:&lt;br&gt;MBG &lt; 3: RR 0.79 (0.48 to 1.31)&lt;br&gt;STSR &lt; 70%: RR 0.94 (0.84 to 1.04)&lt;br&gt;Final:&lt;br&gt;Mortality: RR 0.79 (0.48 to 1.31)</td>
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<td></td>
<td><strong>Languages:</strong>&lt;br&gt;No restrictions</td>
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<td><strong>Statistical methods:</strong>&lt;br&gt;Dersimonian and Laird random effects model with RR and 95% CI for dichotomous variables and WMD and 95% CI for continuous variables</td>
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<tr>
<td>Study, Year</td>
<td>Number of studies (participants):</td>
<td>Population, Intervention, Comparator, Outcomes of Interest (Timing)</td>
<td>Outcomes [&quot;X&quot;R (95%CI)]</td>
<td>Quality Scoring/Comments</td>
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<tr>
<td>Amin, 2009</td>
<td><strong>Overall analysis: 23 (5728)</strong></td>
<td><strong>Population:</strong> STEMI only</td>
<td>Overall Analysis Intermediate: TIMI &lt; 3: OR 0.68 (0.58 to 0.79)</td>
<td><strong>AMSTAR assessment:</strong></td>
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<td>Thrombectomy-only analysis‡: 16 (3848)</td>
<td><strong>Intervention:</strong> PCI with thrombectomy (catheter aspiration, or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection)</td>
<td>MBG &lt; 3: OR 0.66 (0.58 to 0.75)</td>
<td>1. Was an 'a prior' design provided? No</td>
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<td>Distal Protection-only analysis‡: 7 (1880)</td>
<td><strong>Comparator:</strong> PCI without thrombectomy</td>
<td>Failed STSR: OR 0.65 (0.58 to 0.73)</td>
<td>2. Was there duplicate study selection and data extraction? No</td>
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<td>Study design(s) included:</td>
<td>RCTs (full-text, abstracts, and expert talks and slides)</td>
<td><strong>Outcomes (Timing):</strong> MBG &lt; 3, TIMI &lt; 3 (post-procedure); failed STSR (&lt; 50% or &lt; 70%)</td>
<td><strong>Thrombectomy-only Analysis‡ Intermediate:</strong> TIMI &lt; 3: OR 0.66 (0.55 to 0.80)</td>
<td>3. Was a comprehensive literature search performed? Yes</td>
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<td><strong>Literature search:</strong> RCTs from pervious meta-analyses. Searched MEDLINE database and expert talks, slides, and abstracts that were not included in earlier meta-analyses</td>
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<td>MBG &lt; 3: OR 0.61 (0.52 to 0.71)</td>
<td>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes</td>
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<td></td>
<td><strong>Languages:</strong> NR</td>
<td></td>
<td>Failed STSR: OR 0.57 (0.50 to 0.65)</td>
<td>5. Was a list of studies (included and excluded) provided? Yes</td>
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<td></td>
<td><strong>Statistical methods:</strong> DerSimonian and Laird random effects models</td>
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<td><strong>Distal Protection-only Analysis‡ Intermediate:</strong> TIMI &lt; 3: OR 0.71 (0.53 to 0.93)</td>
<td>6. Were the characteristics of the included studies provided? Yes</td>
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<td>MBG &lt; 3: OR 0.83 (0.65 to 1.05)</td>
<td>7. Was the scientific quality of the included studies assessed and documented? Yes</td>
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<td>Failed STSR: OR 0.88 (0.72 to 1.08)</td>
<td>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes</td>
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<td>9. Were the methods used to combine the findings of studies appropriate? Yes</td>
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<td>10. Was the likelihood of publication bias assessed? No</td>
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<td>11. Was the conflict of interest stated? No</td>
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Total 'Yes' responses (out of 11): 7
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<th>Study, Year</th>
<th>Review Characteristics</th>
<th>Population, Intervention, Comparator, Outcomes of Interest (Timing)</th>
<th>Outcomes [&quot;X&quot;R (95%CI)]</th>
<th>Quality Scoring/Comments</th>
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<tbody>
<tr>
<td>Bavry, 2008</td>
<td><strong>Number of studies (participants):</strong> Overall analysis: 30 (6415) Aspiration-only analysis: 13 (3026) Mechanical-only analysis: 5 (934) Embolic Protection-only analysis: 12 (2442)</td>
<td><strong>Population:</strong> AMI within 12 hours <strong>Intervention:</strong> PCI with catheter aspiration, mechanical thrombectomy, or embolic protection device <strong>Comparator:</strong> PCI without thrombectomy</td>
<td><strong>Overall Analysis</strong> Intermediate: TBG-3: RR 1.38 (1.20 to 1.58) Complete STSR: RR 1.27 (1.15 to 1.41) <strong>Final:</strong> Mortality (WMF 5 m): RR 0.87 (0.67 to 1.13) MI: RR 0.71 (0.48 to 1.05) TVR: RR 0.92 (0.75 to 1.13) Stroke: RR 1.92 (0.96 to 3.83) MACE: RR 0.88 (0.74 to 1.04)</td>
<td><strong>AMSTAR assessment:</strong> 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? No 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest stated? Yes</td>
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<td></td>
<td><strong>Study design(s) included:</strong> RCTs only (full-text, abstracts, and oral/expert slide presentations)</td>
<td><strong>Outcomes (Timing):</strong> Mortality, MI, TVR, stroke, MACE (mortality, MI, TVR) (maximal extent of clinical followup); mortality (hospital discharge to 30 d); TBG-3, complete STSR (60 min)</td>
<td><strong>Aspiration-only analysis</strong> Intermediate: TBG-3: RR 1.69 (1.26 to 2.28) Complete STSR: RR 1.41 (1.21 to 1.64) <strong>Final:</strong> Mortality (WMF 6.2 m): RR 0.63 (0.43 to 0.93) Mortality (WMF 6.2 m): RR 0.65 (0.40 to 1.06) MI (WMF 6.2 m): RR 0.65 (0.37 to 1.12) TVR (WMF 6.2 m): RR 0.83 (0.64 to 1.08) Stroke (WMF 6.2 m): RR 3.43 (0.85 to 14) MACE (WMF 6.2 m): RR 0.76 (0.62 to 0.95)</td>
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<td><strong>Literature search:</strong> Cochrane and Medline databases from January 1996 to June 2008; Manual search of supplements from the Journal of the American College of Cardiology, Circulation, European Heart Journal, and American Journal of Cardiology; Review of prior meta-analyses; Search of <a href="http://clinicaltrials.gov">http://clinicaltrials.gov</a> and <a href="http://www.tctmd.com">www.tctmd.com</a>.</td>
<td><strong>Mechanical-only analysis</strong> Intermediate: TBG-3: RR 1.16 (0.71 to 1.90) Complete STSR: RR 1.25 (0.99 to 1.58)</td>
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<td><strong>Languages:</strong> No restrictions</td>
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Total 'Yes' responses (out of 11): 10
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<td></td>
<td><strong>Statistical methods:</strong></td>
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<td>Final:</td>
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<td></td>
<td>Mantel-Haenszel fixed effects model used to construct summary risk ratios (RR) and risk differences, a DerSimonian Laird random effects model used for random effects summary estimates. Outcomes were reported using fixed-effects model unless there was significant heterogeneity, where random-effects model was used</td>
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<td>Mortality (WMF 4.6 m): RR 1.93 (1.00 to 3.72)</td>
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<td>Mortality (WMF 1.0 m): RR 2.01 (0.95 to 4.23)</td>
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<td>MI (WMF 2.1 m): RR 0.67 (0.19 to 2.33)</td>
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<td>TVR (WMF 2.1 m): RR 1.14 (0.43 to 3.01)</td>
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<td>Stroke (WMF 2.1 m): RR 2.67 (0.71 to 10.0)</td>
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<td>MACE (WMF 2.1 m): RR 1.64 (0.60 to 4.44)</td>
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<td></td>
<td><strong>Embolic Protection-only analysis</strong></td>
<td>Intermediate:</td>
<td>Final:</td>
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<td>TBG-3: RR 1.18 (1.02 to 1.38)</td>
<td>Mortality (WMF 3.7m): RR 0.92 (0.60 to 1.40)</td>
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<td>Complete STSR: RR 1.07 (0.98 to 1.16)</td>
<td>Mortality (WMF 0.8m): RR 0.79 (0.49 to 1.29)</td>
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<td>MI (WMF 3.7m): RR 0.82 (0.44 to 1.51)</td>
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<td>TVR (WMF 3.7): RR 1.04 (0.74 to 1.47)</td>
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<td>Stroke (WMF): RR 0.99 (0.34 to 2.92)</td>
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<td>MACE (WMF 3.7m): RR 0.95 (0.69 to 1.30)</td>
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<td>Study, Year</td>
<td>Review Characteristics</td>
<td>Population, Intervention, Comparator, Outcomes of Interest (Timing)</td>
<td>Outcomes [&quot;X&quot;R (95%CI)]</td>
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<tr>
<td>Burzotta, 2008</td>
<td>Number of studies (participants): Overall analysis: 18 (3180) Thrombectomy-only analysis†: 12 (1934) Distal Protection-only analysis†: 6 (1246)</td>
<td>Population: STEMI only</td>
<td>Overall Analysis Intermediate: TIMI &lt; 3: OR 0.76 (0.51 to 1.12) MBG &lt; 3: OR 0.53 (0.37 to 0.76) DE: OR 0.54 (0.37 to 0.81) Absence of STSR &gt; 70%: OR 0.60 (0.45 to 0.78)</td>
<td>AMSTAR assessment: 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest stated? No</td>
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<td>Study design(s) included: RCTs (full-texts, abstracts, and expert slides presentations)</td>
<td>Intervention: PCI with thrombectomy (catheter aspiration, or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection)</td>
<td>Final: Mortality or MI: OR 0.85 (0.54 to 1.33) MACCE: OR 1.01 (0.63 to 1.60)</td>
<td>Total 'Yes' responses (out of 11): 10</td>
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<td>Literature search: MEDLINE database search according to a modified Robinson and Dickersin strategy. TCT (<a href="http://www.tctmd.com">http://www.tctmd.com</a>), EuroPCR (<a href="http://www.europcr.com">www.europcr.com</a>), ACC (<a href="http://www.acc.org">www.acc.org</a>), AHA (<a href="http://www.americaheart.org">http://www.americaheart.org</a>), and ESC (<a href="http://www.escardio.org">www.escardio.org</a>) websites searched</td>
<td>Comparator: PCI without thrombectomy</td>
<td>Thrombectomy-only Analysis† Intermediate: TIMI &lt; 3: OR 0.68 (0.42 to 1.09) MBG &lt; 3: OR 0.42 (0.23 to 0.75) DE: OR 0.51 (0.28 to 0.92) Absence of STSR &gt; 70%: OR 0.46 (0.32 to 0.66)</td>
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<td>Languages: No restrictions</td>
<td>Outcomes (Timing): Mortality or MI, MACCE (mortality, MI, TVR, stroke) (up to 30 d); DE, Absence of STSR &gt; 70% (within 90 min); TIMI &lt; 3, MBG &lt; 3 (post-procedure)</td>
<td>Final: Mortality or MI: OR 1.07 (0.50 to 2.32) MACCE: OR 1.09 (0.60 to 1.96)</td>
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<td>Statistical methods: Both Mantel-Haenszel fixed effects and Der Simonian and Laird random effects models were used however, as significant heterogeneity was present, the data are presented according to the random effects model.</td>
<td>Distal Protection-only Analysis† Intermediate: TIMI &lt; 3: OR 0.95 (0.43 to 2.12) MBG &lt; 3: OR 0.72 (0.55 to 0.96) DE: OR 0.55 (0.28 to 1.08) Absence of STSR &gt; 70%: OR 1.01 (0.79 to 1.29)</td>
<td>Final: Mortality or MI: OR 0.68 (0.39 to 1.19) MACCE: OR 0.81 (0.40 to 1.65)</td>
<td></td>
</tr>
<tr>
<td>Study, Year</td>
<td>Review Characteristics</td>
<td>Population, Intervention, Comparator, Outcomes of Interest (Timing)</td>
<td>Outcomes [&quot;X&quot;R (95%CI)]</td>
<td>Quality Scoring/Comments</td>
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<tr>
<td>De Luca, 2008</td>
<td><strong>Number of studies (participants):</strong> Overall analysis: 9 (2417)</td>
<td><strong>Population:</strong> STEMI only</td>
<td><strong>Intermediate:</strong> TIMI-3: OR 1.59 (1.26 to 2.0) TMPG-3: OR 2.44 (2.04 to 2.92) DE: OR 0.30 (0.20 to 0.44)</td>
<td><strong>AMSTAR assessment:</strong> 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest stated? Yes</td>
</tr>
<tr>
<td></td>
<td><strong>Study design(s) included:</strong> RCTs only (full-text, abstracts, and oral/expert slide presentations)</td>
<td><strong>Intervention:</strong> PCI with catheter aspiration</td>
<td><strong>Final:</strong> Mortality: OR 0.58 (0.34 to 0.98)</td>
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<tr>
<td></td>
<td><strong>Literature search:</strong> Electronic databases (MEDLINE, CENTRAL, EMBASE, and The Cochrane Central Register of Randomized controlled trial from January 1990 to May 2008. Scientific session abstracts (from January 1990 to May 2008) and oral presentation and/or expert slide presentations (from January 2002 to May 2008) on TCT, AHA, ESC, ACC, and EuroPCR websites. Reference list of relevant studies scanned</td>
<td><strong>Comparator:</strong> PCI without thrombectomy</td>
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<td></td>
<td><strong>Languages:</strong> No restrictions</td>
<td><strong>Outcomes (Timing):</strong> Mortality (30 d); TIMI-3, MBG-3, DE (post-procedure)</td>
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<tr>
<td></td>
<td><strong>Statistical methods:</strong> DerSimonian and Laird random effects model</td>
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</table>

Total 'Yes' responses (out of 11): 11
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Review Characteristics</th>
<th>Population, Intervention, Comparator, Outcomes of Interest (Timing)</th>
<th>Outcomes [*&quot;X&quot;R (95%CI)]</th>
<th>Quality Scoring/Comments</th>
</tr>
</thead>
</table>
| Grines, 2008 | **Number of studies (participants):** Overall analysis: 90 (25094) | Population: STEMI with chest pain more than 30 min and less than 24 hours treated with primary or rescue PCI | Intermediate: TIMI-3: OR 1.12 (0.70 to 2.27) | **AMSTAR assessment:**  
|             | **Study design(s) included:** RCTs and non-RCTs | Intervention: PCI with mechanical thrombectomy (Angiojet) | Final: Mortality : OR 0.98 (0.53 to 1.50) MACE: OR 1.25 (0.54 to 2.40) | **Was an 'a priori' design provided?** Yes  
|             | **Literature search:** Published (U.S. National Library of Medicine Database) and FDA sources for AngioJet experience and on published sources only for the PCI reference experience from January 1, 1999, to March 1, 2007. | Comparator: PCI without thrombectomy | | **Was there duplicate study selection and data extraction?** Yes  
|             | **Languages:** English | Outcomes (Timing): Mortality, MACE (mortality, recurrent MI, stroke, TVR) (short-term ≤ 42 d); TIMI-3 (post-procedure) | | **Was a comprehensive literature search performed?** Yes  
|             | **Statistical methods:** Bayesian random-effects model. Bayesian hierarchical model used to compare short-term mortality estimates from RCTs and non-RCTs and to provide a pooled meta-analytic estimate across study designs | | | **Was the status of publication (i.e. grey literature) used as an inclusion criterion?** Yes  
|             | | | | **Was a list of studies (included and excluded) provided?** No  
|             | | | | **Were the characteristics of the included studies provided?** Yes  
|             | | | | **Was the scientific quality of the included studies assessed and documented?** No  
|             | | | | **Was the scientific quality of the included studies used appropriately in formulating conclusions?** Yes  
|             | | | | **Were the methods used to combine the findings of studies appropriate?** Yes  
|             | | | | **Was the likelihood of publication bias assessed?** Yes  
|             | | | | **Was the conflict of interest stated?** Yes  
<p>|             | | | | <strong>Total 'Yes' responses (out of 11): 9</strong> |</p>
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Review Characteristics</th>
<th>Population, Intervention, Comparator, Outcomes of Interest (Timing)</th>
<th>Outcomes ['X'R (95%CI)]</th>
<th>Quality Scoring/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Luca, 2007</td>
<td>Number of studies (participants): Overall analysis: 21 (3721) Thrombectomy-only analysis: 13 (2219) Distal Protection-only analysis: 8 (1502) Study design(s) included: RCTs (full-text, abstracts, oral presentations, and expert slide presentations) Literature search: electronic databases (MEDLINE and CENTRAL) from January 1990 to October 2006 and the scientific session abstracts in Circulation, Journal of American College of Cardiology, European Heart Journal, and American Journal of Cardiology from January 1990 to October 2006. Oral presentations and or expert slide presentation (searched on the TCT (<a href="http://www.tctmd.com">www.tctmd.com</a>), EuroPCR (<a href="http://www.europcr.com">www.europcr.com</a>), ACC (<a href="http://www.acc.org">www.acc.org</a>), AHA (<a href="http://www.aha.org">www.aha.org</a>), and ESC (<a href="http://www.escardio.org">www.escardio.org</a>) websites) from January 2002 to October 2005. Languages: No restrictions Statistical methods: DerSimonian and Laird random-effects models</td>
<td>Population: AMI Intervention: PCI with thrombectomy (catheter aspiration or mechanical thrombectomy) or embolic protection device (distal balloon or distal filter embolic protection) Comparator: PCI without thrombectomy Outcomes (Timing): Mortality (30 d); TIMI-3, MBG-3, DE (post-procedure); coronary perforation (NR) Overall Analysis Intermediate: TIMI-3: OR 1.34 (1.02 to 1.76) MBG-3: OR 2.21 (1.48 to 3.32) DE: OR 0.58 (0.39 to 0.87) Final: Mortality: OR 0.97 (0.64 to 1.46) Safety: Coronary perforation: OR 3.05 (0.48 to 19.40) Thrombectomy-only Analysis: TIMI-3: OR 1.43 (0.99 to 2.06) MBG-3: OR 2.64 (1.35 to 5.16) DE: OR 0.52 (0.32 to 0.85) Final: Mortality: OR 1.32 (0.76 to 2.31) Safety: Coronary perforation: OR 2.1 (0.18 to 22.30) Distal Protection-only Analysis: TIMI-3: OR 1.22 (0.79 to 1.86) MBG-3: OR 1.73 (1.09 to 2.75) DE: OR 0.7 (0.35 to 1.39) Final: Mortality: OR 0.66 (0.35 to 1.23) Safety: Coronary perforation: OR 5.15 (0.25 to 107.9)</td>
<td>AMSTAR assessment: 1. Was an 'a priori' design provided? No 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest stated? Yes Total 'Yes' responses (out of 11): 10</td>
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<tr>
<td>Study, Year</td>
<td>Review Characteristics</td>
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<td>Outcomes [&quot;X&quot;R (95%CI)]</td>
<td>Quality Scoring/Comments</td>
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<tr>
<td>Kunadian, 2007</td>
<td><strong>Number of studies (participants):</strong> Overall analysis: 14 (2630)</td>
<td><strong>Population:</strong> AMI only</td>
<td><strong>Overall Analysis</strong> Final: Mortality or reinfarction: OR 0.82 (0.55 to 1.24)</td>
<td><strong>AMSTAR assessment:</strong> 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? No 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? No 11. Was the conflict of interest stated? No</td>
</tr>
<tr>
<td><strong>Study design(s) included:</strong> RCTs (full-texts and abstracts)</td>
<td><strong>Intervention:</strong> PCI with thrombectomy (catheter aspiration or mechanical thrombectomy) or embolic protection (distal balloon or distal filter embolic protection) device</td>
<td><strong>Thrombectomy-only Analysis</strong> Final: Mortality or reinfarction: OR 0.98 (0.53 to 1.83)</td>
<td><strong>Total 'Yes' responses (out of 11):</strong> 6</td>
<td></td>
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<tr>
<td><strong>Literature search:</strong> PubMed, OVID, the Cochrane databases, references of articles, and abstracts of conference proceedings from September 2000 to October 2005. Hand-searched relevant journals and used the Science Citation Index to cross reference any articles that met the inclusion criteria. Searched <a href="http://www.tctmd.com">www.tctmd.com</a> and <a href="http://www.theheart.org">www.theheart.org</a> websites</td>
<td><strong>Comparator:</strong> PCI without thrombectomy</td>
<td><strong>Mortality:</strong> OR 0.92 (0.56 to 1.51)</td>
<td></td>
<td><strong>Languages:</strong> NR</td>
</tr>
<tr>
<td><strong>Statistical methods:</strong> Both Mantel-Haenzel fixed effects model and the DerSimonian and Laird random effects model were used, however results are reported from the random effects model.</td>
<td><strong>Outcomes (Timing):</strong> Mortality or reinfarction, mortality, reinfarction, MACE (nonfatal reinfarction, stroke, repeat TVR) (30 d)</td>
<td><strong>Reinfarction:</strong> OR 0.78 (0.40 to 1.52)</td>
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<td><strong>MACE:</strong> OR 1.00 (0.71 to 1.42)</td>
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<td><strong>Thrombectomy-only Analysis</strong> Final: Mortality or reinfarction: OR 0.68 (0.37 to 1.23)</td>
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<td></td>
<td></td>
<td>Mortality: OR 0.70 (0.34 to 1.44)</td>
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<td>Reinfarction: OR 0.67 (0.24 to 1.85)</td>
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<td></td>
<td></td>
<td>MACE: OR 0.75 (0.44 to 1.28)</td>
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<td><strong>Distal Protection-only Analysis</strong> Final: Mortality or reinfarction: OR 0.68 (0.37 to 1.23)</td>
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<tr>
<td></td>
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<td>Mortality: OR 0.70 (0.34 to 1.44)</td>
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<tr>
<td></td>
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<td>Reinfarction: OR 0.67 (0.24 to 1.85)</td>
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<tr>
<td></td>
<td></td>
<td>MACE: OR 0.75 (0.44 to 1.28)</td>
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</table>

*Names of devices along with category are in Table 1 of original text. More information in reference ID # 9; †Names of devices along with category are in Table 1 of original text; ‡Names of devices along with category are in Table 1 of original text; §Names of devices along with category are in Table 1 of original text; ||Names of devices along with category are on pages 489-490 of original text.
Abbreviations: ACC=American College of Cardiology; AHA=American Heart Association; AMI=acute myocardial infarction; CI=confidence interval; d=days; DE=distal embolization; ESC=European Society of Cardiology; FDA=Food and Drug Administration; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; min=minutes; m=months; NR=not reported; OR=odds ratio; PCI=percutaneous coronary intervention; PT=procedure time; RCT=randomized control trial; RR=relative risk; STBT=symptom onset to balloon time; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; TBG=Timi blush grade; TCT=Transcatheter Cardiovascular Therapeutics; TIMI=thrombolysis in myocardial infarction; TMPG=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revascularization; U.S.=United States; WMF=weighted mean followup; WMD=weighted mean difference

Table 14. Characteristics and quality assessment of systematic reviews with meta-analyses published in abstract form

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Total Studies (Participants)</th>
<th>Inclusion Criteria</th>
<th>Outcomes (Timing)</th>
<th>Overall Outcomes [&quot;X&quot;R (95%CI)]</th>
<th>Outcomes of Device Subtypes [&quot;X&quot;R (95%CI)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Masotti 2008 and Salazar, 2008</td>
<td>7 (1456)</td>
<td>STEMI; RCT evaluating thrombectomy, distal protection and aspiration devices</td>
<td>Mortality, reinfarction, mortality + reinfarction (6 m)</td>
<td>Mortality: OR 0.75 (0.41 to 1.36) Reinfarction: OR 0.5 (0.23 to 1.1) Mortality + reinfarction: OR 0.62 (0.38 to 1.01)</td>
<td>Thrombectomy + aspiration Mortality: OR 0.69 (0.2 to 2.34) Reinfarction: OR 0.71 (0.14 to 3.68) Mortality+reinfarction: OR 0.66 (0.23 to 1.9)</td>
</tr>
<tr>
<td>Masotti 2008</td>
<td>8 (2527)</td>
<td>RCT using embolic protection devices in patients with STEMI</td>
<td>Mortality (6 m)</td>
<td>Mortality: OR 0.60 (0.40 to 0.89)</td>
<td>Aspiration Mortality: OR 0.49 (0.29 to 0.82)</td>
</tr>
<tr>
<td>Mongeón 2008</td>
<td>16 (2944)</td>
<td>STEMI; RCT comparing primary PCI with and without thrombectomy</td>
<td>No reflow, STSR &gt; 50%, TMPG-3, TIMI-3, DE (post-procedure)</td>
<td>No-reflow: OR 0.35 (0.10 to 0.95) STSR &gt; 50%: OR 2.24 (1.40 to 3.82) TMPG-3: OR 2.45 (1.11 to 5.81) TIMI-3: OR 1.32 (0.84 to 2.28) DE: OR 0.58 (0.19 to 1.45)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Total Studies (Participants)</th>
<th>Inclusion Criteria</th>
<th>Outcomes (Timing)</th>
<th>Overall Outcomes [“X”R (95%CI)]</th>
<th>Outcomes of Device Subtypes [“X”R (95%CI)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Masotti 2007</td>
<td>10 (2275)</td>
<td>RCT using thrombectomy or distal protection devices in conjunction with PCI</td>
<td>Mortality, reinfarction, mortality + reinfarction (1m)</td>
<td>Mortality: OR 0.77 (0.5 to 1.20) Reinfarction: OR 0.66 (0.30 to 1.46) Mortality + reinfarction: OR 0.73 (0.49 to 1.09)</td>
<td>Thrombectomy Mortality: OR 0.69 (0.39 – 1.22) Reinfarction: OR 0.59 (0.18 – 1.94) Mortality + reinfarction: OR 0.66 (0.39 – 1.11) Distal protection Mortality: OR 0.91 (0.43 – 1.90) Reinfarction: OR 0.72 (0.25 – 2.12) Mortality + reinfarction: OR 0.84 (0.46 – 1.56)</td>
</tr>
<tr>
<td>Brahmbhatt 2006</td>
<td>11 (NR)</td>
<td>Thrombectomy in the setting of STEMI, RCT in full text or abstracts from TCT, AHA, ACC</td>
<td>MACE (30d): MBG≥2, MBG-3, TIMI-3, STSR &gt; 50% (post-procedure)</td>
<td>MBG-3: OR 2.73 (2.07 to 3.6) MBG ≥ 2: OR 1.87 (1.21 to 1.89) TIMI-3: 1.56 (1.07 to 2.28) STSR &gt; 50%: 3.5 (2.17 to 5.65) MACE: 0.94 (0.6 to 1.47)</td>
<td>N/A</td>
</tr>
<tr>
<td>Salazar 2006 and Salazar 2006</td>
<td>9 (2060)</td>
<td>RCT using thrombectomy or distal protection devices in conjunction with PCI</td>
<td>Mortality, reinfarction, mortality + reinfarction (1 m)</td>
<td>Mortality: OR 0.78 (0.5 to 1.23) Reinfarction: OR 0.70 (0.31 to 1.59) Mortality + reinfarction: OR 0.76 (0.51 to 1.13)</td>
<td>Thrombectomy Mortality: OR 0.7 (0.4 to 1.27) Reinfarction: OR 0.67 (0.19 to 2.37) Mortality + reinfarction: OR 0.7 (0.41 to 1.19) Distal protection Mortality: OR 0.9 (0.44 to 1.91) Reinfarction: OR 0.73 (0.25 to 2.12) Mortality + reinfarction: OR 0.85 (0.46 to 1.06)</td>
</tr>
<tr>
<td>Qayyum 2006</td>
<td>7 (2447)</td>
<td>Trials that examined effects on mortality or recurrent AMI of distal protection devices within 30 days of SVG without AMI and PCI for native vessel AMI</td>
<td>Mortality(30 d)</td>
<td>Mortality: OR 0.69 (0.39 to 1.22)</td>
<td>N/A</td>
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</table>

Abbreviations: ACC=American College of Cardiology; AHA=American heart Association; AMI=acute myocardial infarction; d=days; m=months; MACE=major adverse cardiac events; MBG=myocardial blush grade; N/A: not applicable; OR=odds ratio; PCI=percutaneous coronary intervention; RCT=randomized controlled trial; STEMI=ST-segment elevation myocardial infarction; STSR=ST-segment resolution; SVG=saphenous vein graft; TCT=Transcatheter Cardiovascular Therapeutics; TIMI=thrombolysis in myocardial infarction; TMPG=TIMI myocardial perfusion grade
## Appendix D: Excluded Studies From Full-text Review

<table>
<thead>
<tr>
<th>Reference</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adlbrecht C, Bonderman D, Plas C, et al. Thrombus bound endothelin and</td>
<td>Uncontrolled study</td>
</tr>
<tr>
<td>leukocytes extracted by thrombectomy in acute myocardial infarction correlate with ST-segment resolution [abstract]. <em>Circulation</em> 2006;114:458</td>
<td></td>
</tr>
<tr>
<td>Ai H, Wang CM, Zhu XL, et al. [Effect of aspiration of coronary thrombus upon prognosis of patients in primary percutaneous coronary intervention]. *Chung-Hua i Hsueh Tsa Chih [Chinese Medical Journal]*2010;90:728-9</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Ali A, LaLond T, Schreiber T, et al. Reduction in no-flow, slow flow, and distal embolization with Angiojet thrombectomy-facilitated catheter-based reperfusion therapy for acute myocardial infarction [abstract]. <em>Am J Cardiol</em> 2002;90:TCT268</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Ali A, Rehan A, Rahbar M, et al. Rheolytic thrombectomy in acute myocardial infarction results in a higher degree of ST-segment resolution [abstract]. <em>Am J Cardiol</em> 2002;90:TCT39</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Ali A, Schreiber TL. The role of percutaneous thrombectomy in the contemporary treatment of acute myocardial infarction. <em>J Invasive Cardiol</em> 2004;16:546-8</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
<tr>
<td>Alidjan F. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R)-device [abstract]. <em>Circulation</em> 2006;114:739</td>
<td>Uncontrolled study</td>
</tr>
<tr>
<td>Amabile N, Cochet A, Lorgis L, et al. Impact of thrombectomy devices for reperfusion of STEMI in the real world: insights from cardiac magnetic resonance imaging [abstract]. <em>Circulation</em> 2009;120:S337</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>An Y, Kaji S, Yamamuro A, et al. Thrombus aspiration during primary percutaneous coronary intervention improves myocardial viability and infarct transmurality: a magnetic resonance imaging study [abstract]. <em>J Am Coll Cardiol</em> 2009;53:A282</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. <em>J Invasive Cardiol</em> 2006;18:32C-34C</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
<tr>
<td>Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. <em>J Invasive Cardiol</em> 2006;18:32C-34C</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
<tr>
<td>Bartorelli AL. Acute thrombosis of a coronary artery aneurysm: toughing it out with the poor man's thrombectomy catheter technique. <em>Catheter Cardiovasc Interv</em> 2006;68:403-5</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
<tr>
<td>Bass TA. Mechanical thrombectomy to the RESCUE. <em>Catheter Cardiovasc Interv</em> 2002;55:244</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
<tr>
<td>Belardi J. Beyond the limit on percutaneous intervention of saphenous vein graft. <em>Catheter Cardiovasc Interv</em> 2005;64:387-8</td>
<td>A narrative review, editorial or letter to the editor</td>
</tr>
</tbody>
</table>

Berger-Kucza A, Lelek M, Wita K, et al. Thrombus aspiration for microvascular Not an RCT or an
<table>
<thead>
<tr>
<th>Reference</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>protection in patients with acute MI undergoing early primary PCI [abstract]. <em>Circulation</em> 2008;118:E311</td>
<td>observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Bertrand OF, Larose E, Costerousse O, et al. Effects of Aspiration Thrombectomy on Necrosis Size and Ejection Fraction After Transradial Percutaneous Coronary Intervention in Acute ST-Elevation Myocardial Infarction [abstract]. <em>Can J Cardiol</em> 2010; 26:106D</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Biasucci LM, de Maria GL, de Vito L, et al. Microparticles are increased in thrombectomy-aspirated blood of ST-elevation myocardial infarction patients and correlate with fibrinogen and thrombus burden [abstract]. <em>J Thromb Haemost</em> 2010;8:57</td>
<td>Uncontrolled study</td>
</tr>
<tr>
<td>Bilge AK, Nisanci Y, Yilmaz E, et al. Effects of percutaneous coronary thrombectomy with the X-sizer catheter on epicardial flow and microvascular function in acute coronary syndrome. <em>Clin Appl Thromb Hemost</em> 2005;11:461-6</td>
<td>Not an RCT or an observational study enrolling more than 500 patients</td>
</tr>
<tr>
<td>Blackman DJ, Channon KM. Prevention of embolisation during percutaneous vein graft intervention using a Filter Wire distal protection device. <em>Heart</em> 2003;89:376</td>
<td>A narrative review, editorial or letter to the editor</td>
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<td>A narrative review, editorial or letter to the editor</td>
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<td>Park CH, Salem M, Jauhar R, et al. Effect of distal protection or thrombectomy on corrected thrombolysis in myocardial infarction frame counts in stenting for acute myocardial infarction [abstract]. <em>J Am Coll Cardiol</em> 2003;41:356A-357A</td>
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<td>Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI</td>
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<td>Reho I, Gruner C, Roffi M. Coronary thrombectomy by retrieval of an open embolus-protection filter device. <em>Heart</em> 2008;94:274</td>
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<td>Remondino A, Seiler C, Rakht R, et al. Distal embolisation protection during</td>
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<td>percutaneous coronary intervention in acute myocardial infarction protects coronary collateral flow [abstract]. Eur Heart J 2003;24:713</td>
<td>observational study enrolling more than 500</td>
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<td>Seth A. Another &quot;nail in the coffin&quot; for protection devices in acute MI? Catheter Cardiovasc Interv 2008;71:E3-4</td>
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<td>Not an RCT or an observational study enrolling more than 500</td>
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<td>Shiba M, Nakamura M, Wada M. The distal protection during primary PCI is associated with delayed recovery of myocardial perfusion in AMI patients [abstract]. Am J Cardiol 2005;95:28A-29A</td>
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<td>Sun Jiaan. No Heel Phenomenon in Primary PCI of AMI: Effect of Super-Selective Injection of Nitroprusside Combined with ZEEK Thrombus Aspiration. <em>Circulation</em> 2010;122:P1304</td>
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<td>Thrombectomy catheter during primary stenting in acute myocardial infarction patients with high-grade thrombus [abstract]. Am J Cardiol 2005;96:76H</td>
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<td>Testa L, Bedogni F, Biondi Zoccai GG. Letter by Testa et al regarding article, &quot;presence of older thrombus is an independent predictor of long-term mortality in patients with ST-elevation myocardial infarction treated with thrombus aspiration during primary percutaneous coronary intervention&quot;. Circulation 2009;120:e3</td>
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<td>von Korn H, Yu JT, Ohlow M, et al. The export aspiration system in patients with acute coronary syndrome and visible thrombus demonstrates no remarkable benefit [abstract]. J Am Coll Cardiol 2006;47:38B</td>
<td>Not an RCT or an observational study enrolling more than 500</td>
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<td>Yip HK, Wu CJ, Chang HW, et al. Effect of the PercuSurge GuardWire device on the integrity of microvasculature and clinical outcomes during primary transradial coronary intervention in acute myocardial infarction. Am J Cardiol 2003;92:1331-5</td>
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### Appendix E: Baseline and Procedural Characteristics of Included Trials and Studies

Table 15. Baseline characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

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<th>Study, Year</th>
<th>Group Description</th>
<th>N</th>
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<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HT N (%)</th>
<th>HC L (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
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<td>61.2 (11.3)</td>
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<td>31</td>
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</table>

*Symptom onset to balloon, ischemic time, symptom to randomization, symptom onset to hospital, symptom onset to laboratory, symptom onset to angiography, symptom onset to admission, symptom onset to procedure; †Mean for the total study population; ‡Median (interquartile range); §% of visible thrombi out of all thrombi; TIMI < 3 Abbreviations: DM = diabetes mellitus; FHx = family history; HCL = hypercholesterolemia; HTN = hypertension; IRA = infarct-related artery; LAD = left anterior descending artery; MI = myocardial infarction; N = number of participants in the group; SD = standard deviation; TAC = thrombectomy aspiration catheter; TIMI = thrombolysis in myocardial infarction; TL = thrombolysis; TVAC = transvascular aspiration catheter
Table 16. Procedural characteristics of randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
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<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE Control</td>
<td>100</td>
<td>---</td>
<td>99/100 (99)</td>
<td>75/100 (75)</td>
<td>62/100 (62)</td>
<td>Aspirin 325mg and clopidogrel 600mg pre-PCI</td>
<td>Heparin 70 U/kg pre-PCI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>96</td>
<td>---</td>
<td>93/96 (96.8)</td>
<td>5/96 (5.2)</td>
<td>60/96 (63)</td>
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<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
<td>55</td>
<td>75.7 (30.0)</td>
<td>55/55 (100)</td>
<td>55/55 (100)</td>
<td>5/96 (5.2)</td>
<td>Aspirin 500 mg and clopidogrel 600 mg load pre-PCI</td>
<td>Heparin 70 IU/kg pre-PCI</td>
</tr>
<tr>
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<td>Control</td>
<td>56</td>
<td>75.9 (38.7)</td>
<td>56/56 (100)</td>
<td>5/56 (9)</td>
<td>56/56 (100)</td>
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<td>Lipecki, 2009</td>
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<td>19/20 (95)</td>
<td>10/20 (55)</td>
<td>5/20 (25)</td>
<td>Aspirin and clopidogrel 300 mg load pre-PCI</td>
<td>Heparin pre-PCI</td>
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<td>24</td>
<td>---</td>
<td>22/24 (92)</td>
<td>6/24 (33)</td>
<td>15/24 (62)</td>
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<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>76</td>
<td>---</td>
<td>45/76 (59)</td>
<td>62/76 (82)</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>76</td>
<td>---</td>
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</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM) Control</td>
<td>87</td>
<td>88/88 (100)</td>
<td>67/88 (76.2)</td>
<td>88/88 (100)</td>
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<td>Aspirin 300 mg and clopidogrel 300 mg pre-PCI</td>
<td>Heparin 7.5 UI pre-PCI</td>
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<td>Control</td>
<td>88</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>Aspirin and clopidogrel (for 12 m) post-PCI</td>
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<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>37</td>
<td>49 (18)†</td>
<td>35/37 (95)</td>
<td>19/37 (51)</td>
<td>7/37 (19)</td>
<td>Aspirin 300 mg and clopidogrel 300 mg load pre-PCI</td>
<td>Heparin 70-100 IU/kg IV (ACT &gt;200 s) pre-PCI and for at least 24 hours</td>
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<tr>
<td></td>
<td>Control</td>
<td>37</td>
<td>53 (23)†</td>
<td>34/37 (92)</td>
<td>4/37 (11)</td>
<td>12/37 (32)</td>
<td>Aspirin 100 mg/d indefinitely and clopidogrel 75 mg/d for 3 m post-PCI</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>120</td>
<td>36.7 (18.0)</td>
<td>120/120 (100)</td>
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<td>---</td>
<td>Aspirin and clopidogrel used at investigator’s discretion</td>
<td>Heparin used at investigator’s discretion</td>
</tr>
<tr>
<td></td>
<td>Control</td>
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<td>34.5 (21.5)</td>
<td>129/129 (100)</td>
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<td>65/65 (100)</td>
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<td>Aspirin pre-PCI</td>
<td>Heparin (ACT≥300 s) pre-PCI</td>
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<td>Ikari, 2008</td>
<td>TVAC Control</td>
<td>178</td>
<td>87.0 (32.4)</td>
<td>167/178 (94.1)</td>
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<td>Ticlopidine (cilostizol if intolerant to ticlopidine) and aspirin pre-PCI</td>
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<tr>
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<td>180</td>
<td>93.6 (78.6)</td>
<td>160/171 (93.4)</td>
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† Denotes significant difference.
<table>
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<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
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<tr>
<td>Svilaas, 2008</td>
<td>6F Export Aspiration Catheter Control</td>
<td>535</td>
<td>28 (14-42)*</td>
<td>442/279 (92.3)</td>
<td>295/535 (55.1)</td>
<td>469/502 (93.4)</td>
<td>Aspirin 500 mg bolus and clopidogrel 600mg pre-PCI and standard aspirin and clopidogrel therapy post-PCI</td>
<td>Heparin 5000 IU pre-PCI plus additional doses based on ACT</td>
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<td>536</td>
<td>26 (12-40)*</td>
<td>438/476 (92.0)</td>
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<tr>
<td>DeLuca, 2006</td>
<td>Diver CE Control</td>
<td>38</td>
<td>---</td>
<td>38/38 (100)</td>
<td>35/38 (92.1)</td>
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<td>Aspirin 300 mg pre-PCI and 100 mg/d post-PCI and ticlopidine 250 mg BID for at least 4 weeks or clopidogrel 300 mg followed by 75 mg/d for at least 4 weeks</td>
<td>Heparin 8000 IU IV pre-PCI continued for 48 hours post-PCI</td>
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<td>38</td>
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<td>38/38 (100)</td>
<td>2/38 (5.3)</td>
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<td>108</td>
<td>39 (29-48)*</td>
<td>103/108 (95)</td>
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<td>104/108 (96)</td>
<td>Aspirin 300 mg and clopidogrel 300 mg pre-PCI</td>
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<td>29 (23-38)*</td>
<td>104/107 (97)</td>
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<td>100/107 (93)</td>
<td>Aspirin 75 mg/d and clopidogrel 75 mg/d for 12 m post-PCI</td>
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<td>52/74 (70)</td>
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<td>Heparin 60 U/kg pre-PCI</td>
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<td>Burzotta, 2005</td>
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<td>81 (43)</td>
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<td>33/50 (66.0)</td>
<td>34/50 (68.0)</td>
<td>Aspirin and clopidogrel (300 mg load followed by 75 mg/d) for at least 4 weeks</td>
<td>Heparin (ACT 250-300 s)</td>
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<td>72 (34)</td>
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<td>12/49 (24.4)</td>
<td>31/49 (63.3)</td>
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<td>Rescue System Control</td>
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<td>---</td>
<td>Aspirin 75 mg/d, clopidogrel (initially 300 mg, followed by 75 mg/d) or ticlopidine (500 mg/d) for 1 m</td>
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*Median (interquartile range); †Lab to TIMI-3
Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; TAC=thrombectomy aspiration catheter; TVAC=transvascular aspiration catheter; U=units
Table 17. Baseline characteristics of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HT (%)</th>
<th>HC (%)</th>
<th>Smoker (%)</th>
<th>FHx (%)</th>
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<td>Migliorini 2010</td>
<td>AngioJet Rheolytic Thrombectomy</td>
<td>25</td>
<td>63.0 (12.3)</td>
<td>76</td>
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<td>83.9</td>
<td>135 (86-227)†</td>
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<td>AngioJet Catheter</td>
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<td>60 (51.0-69.0)†</td>
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<td>59.9 (49.0-70.0)†</td>
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</tr>
<tr>
<td>Antoniucici 2004</td>
<td>AngioJet Control</td>
<td>50</td>
<td>63 (13)</td>
<td>82</td>
<td>76</td>
<td>234 (120)</td>
<td>---</td>
<td>34</td>
<td>0</td>
<td>34</td>
<td>---</td>
<td>18</td>
<td>36</td>
<td>46</td>
<td>38</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>50</td>
<td>66 (12)</td>
<td>78</td>
<td>80</td>
<td>264 (168)</td>
<td>---</td>
<td>46</td>
<td>0</td>
<td>46</td>
<td>---</td>
<td>16</td>
<td>38</td>
<td>48</td>
<td>28</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Napodano2003</td>
<td>X-Sizer Catheter</td>
<td>46</td>
<td>61.3 (10.8)</td>
<td>82.6</td>
<td>73.9</td>
<td>202.9 (204.9)</td>
<td>17.4</td>
<td>39.1</td>
<td>---</td>
<td>100</td>
<td>13.0</td>
<td>60.9</td>
<td>50.0</td>
<td>45.6</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>46</td>
<td>63.6 (11.7)</td>
<td>71.7</td>
<td>84.7</td>
<td>165.7 (134.7)</td>
<td>6.5</td>
<td>43.5</td>
<td>---</td>
<td>100</td>
<td>13.0</td>
<td>65.2</td>
<td>52.1</td>
<td>34.8</td>
<td>---</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Symptom onset to emergency room, symptom onset to angiogram, time to treatment, symptom onset to hospital; Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis
Table 18. Procedural characteristics of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy Control</td>
<td>256</td>
<td>59.5 (44.7-70)*</td>
<td>256/256 (100)</td>
<td>256/256 (100)</td>
<td>249/256 (97)</td>
<td>Aspirin 325 mg po or 500 mg IV and clopidogrel 600 mg load pre-PCI or 100 to 325 mg/d indefinitely and clopidogrel 75 mg/d for 6 m post-PCI</td>
<td>Heparin 70 U/kg bolus with additional doses (ACT 200-250 s)</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>AngioJet Catheter Control</td>
<td>240</td>
<td>75.4 (30.9)</td>
<td>224/240 (93.7)</td>
<td>228/240 (95.0)</td>
<td>---</td>
<td>Aspirin 325 mg and clopidogrel 300 mg load then 75 mg/d for at least 4 weeks (ticlopidine 500mg load then 250 BID if intolerant to clopidogrel)</td>
<td>Heparin during PCI (ACT &gt;250 s)</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>100</td>
<td>54 (28)</td>
<td>100/100 (100)</td>
<td>60/100 (60)</td>
<td>55/100 (55)</td>
<td>Aspirin pre-PCI</td>
<td>Heparin 70 U/kg (ACT &gt;250 s)</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>50</td>
<td>---</td>
<td>49/50 (98)</td>
<td>49/50 (98)</td>
<td>---</td>
<td>Aspirin 325 mg/d indefinitely and ticlopidine (500 mg/d for 1 m) or clopidogrel (75 mg/d for 1 m)</td>
<td>Heparin 70 U/kg bolus and additional doses (ACT 200-300 s)</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>46</td>
<td>---</td>
<td>43/46 (93.5)</td>
<td>28/46 (60.8)</td>
<td>20/46 (43.4)</td>
<td>Aspirin 250-500 mg IV pre-PCI during PCI and 100-375 mg/d indefinitely post-PCI Ticlopidine 250 mg twice/d pre-PCI/during PCI and post-PCI Clopidogrel 75 mg/d pre-PCI/during PCI and post-PCI for 1 m</td>
<td>Heparin 70 U/kg IV pre-PCI during PCI and 7-12 IU/kg/hour for 48 hours (ACT &gt;250 s)</td>
</tr>
</tbody>
</table>

*Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; po=by mouth; s=seconds; SD=standard deviation; U=units
<table>
<thead>
<tr>
<th>Study Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI 0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoker (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control 19</td>
<td>62.7 (12)</td>
<td>79</td>
<td>89</td>
<td>275 (223)</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>--</td>
<td>--</td>
<td>47</td>
<td>58</td>
<td>74</td>
<td>68</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control 312</td>
<td>62 (12.3)</td>
<td>74.4</td>
<td>67</td>
<td>200 (26-1350)</td>
<td>6.4</td>
<td>---</td>
<td>0</td>
<td>44</td>
<td>68</td>
<td>9.0</td>
<td>32.1</td>
<td>18.6</td>
<td>56.7</td>
<td>36.5</td>
<td></td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX Control 70</td>
<td>60.2 (9.9)</td>
<td>86</td>
<td>85</td>
<td>150 (80-270)</td>
<td>21</td>
<td>---</td>
<td>3</td>
<td>53</td>
<td>90</td>
<td>19</td>
<td>56</td>
<td>---</td>
<td>33</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control 49</td>
<td>60 (12)</td>
<td>82</td>
<td>78</td>
<td>180 (90-420)</td>
<td>12</td>
<td>---</td>
<td>---</td>
<td>51</td>
<td>---</td>
<td>22</td>
<td>44</td>
<td>48</td>
<td>43</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardX Control 32</td>
<td>61 (15)</td>
<td>81</td>
<td>71.88</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>41</td>
<td>100</td>
<td>19</td>
<td>50</td>
<td>62</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>

*Symptom onset to hospital, symptom onset to angiography, symptom onset to emergency room; †Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis
Table 20. Procedural characteristics of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>19</td>
<td>---</td>
<td>19/19 (100)</td>
<td>---</td>
<td>---</td>
<td>Aspirin 200mg and ticopidine 200mg or clopidogrel 300mg pre-PCI</td>
<td>Heparin 8000 U IV pre-PCI</td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>312</td>
<td>---</td>
<td>307/312 (98)</td>
<td>301/312 (97)</td>
<td>Aspirin 300-500 mg and clopidogrel 300-600 mg pre-PCI Clopidogrel continued for 1 year and aspirin continued indefinitely</td>
<td>Heparin 10,000 IU pre-PCI</td>
<td></td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX Control</td>
<td>70</td>
<td>52 (43-70)*</td>
<td>69/70 (99)</td>
<td>18/70 (26)</td>
<td>Aspirin 325 mg and clopidogrel 300-600 mg load pre- or immediately after PCI Clopidogrel recommended for 12 m and aspirin indefinitely post-PCI</td>
<td>---</td>
<td>Heparin IV during PCI (ACT&gt;250 s)</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>51</td>
<td>---</td>
<td>38/51 (74)</td>
<td>---</td>
<td>Aspirin 500 mg IV or 200 mg orally and clopidogrel 300 mg load pre-PCI</td>
<td>---</td>
<td>Heparin 70 U/kg pre-PCI</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>32</td>
<td>---</td>
<td>32/32 (100)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=international units; IV=intravenous; kg=kilogram; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; TAC=thrombectomy aspiration catheter; TVAC=transvascular aspiration catheter; U=units

Table 21. Baseline characteristics of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus Control</td>
<td>46</td>
<td>55 (7)</td>
<td>86.96</td>
<td>80.4</td>
<td>289 (58)</td>
<td>---</td>
<td>100</td>
<td>0</td>
<td>100</td>
<td>---</td>
<td>6.5</td>
<td>17.4</td>
<td>15.2</td>
<td>63.0</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire Control</td>
<td>52</td>
<td>67 (6.1)‡</td>
<td>61.54‡</td>
<td>73.1</td>
<td>157 (47)</td>
<td>0</td>
<td>40.4‡</td>
<td>35.8‡</td>
<td>55.8</td>
<td>---</td>
<td>32.7</td>
<td>55.8</td>
<td>---</td>
<td>42.3</td>
<td>---</td>
</tr>
</tbody>
</table>

‡Median (interquartile range)
Table 22. Procedural characteristics of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge</td>
<td>60</td>
<td>55.9 (13.9)</td>
<td>85/67</td>
<td>339.3 (189.2)</td>
<td>0/53</td>
<td>0/53</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>GuardWire Control</td>
<td>56</td>
<td>58.8 (14.5)</td>
<td>71/76</td>
<td>327.8 (209.5)</td>
<td>0/56</td>
<td>0/56</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>19</td>
<td>55 (45-62)</td>
<td>79/95</td>
<td>212 (160-325)</td>
<td>---</td>
<td>58/0</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>20</td>
<td>56 (45-65)</td>
<td>95/75</td>
<td>248 (185-480)</td>
<td>---</td>
<td>55/0</td>
<td>---</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System</td>
<td>80</td>
<td>65 (12)</td>
<td>86/78</td>
<td>312 (252)</td>
<td>5/---</td>
<td>---</td>
<td>57/---</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>GuardWire Plus</td>
<td>173</td>
<td>63.5 (12.3)</td>
<td>78.6/69</td>
<td>252 (168)</td>
<td>1.7/---</td>
<td>---</td>
<td>0/50</td>
</tr>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge</td>
<td>52</td>
<td>55 (14)</td>
<td>62/100</td>
<td>310 (145)</td>
<td>---/---</td>
<td>0/54</td>
<td>---/---</td>
</tr>
<tr>
<td></td>
<td>GuardWire Control</td>
<td>60</td>
<td>57 (15)</td>
<td>67/100</td>
<td>315 (176)</td>
<td>---/---</td>
<td>0/48</td>
<td>---/---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge</td>
<td>8</td>
<td>59 (13)</td>
<td>75/75</td>
<td>450 (348)</td>
<td>---/---</td>
<td>25/---</td>
<td>25/38</td>
</tr>
<tr>
<td></td>
<td>GuardWire Control</td>
<td>8</td>
<td>59 (8)</td>
<td>88/33</td>
<td>510 (492)</td>
<td>---/---</td>
<td>75/---</td>
<td>25/63</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus</td>
<td>252</td>
<td>58.5 [51.1-69.3]</td>
<td>76.2/64.0</td>
<td>233 (178-296)</td>
<td>9.5/---</td>
<td>18.3/40.2</td>
<td>72.7/7.5</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>249</td>
<td>59.8 [52.1-69.3]</td>
<td>80.7/67.8</td>
<td>211 (158-273)</td>
<td>12.4/---</td>
<td>18.9/38.5</td>
<td>72.1/17.3</td>
</tr>
</tbody>
</table>

*Symptom onset to stenting, symptom onset to balloon, symptom onset to hospital arrival, symptom onset to reperfusion, elapsed time before reperfusion; † Median (interquartile range); ‡ total study population
Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

---
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire Control</td>
<td>60</td>
<td>60/60 (100)</td>
<td>0/60 (0)</td>
<td>---</td>
<td>Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI</td>
<td>Heparin IV during PCI (ACT 300 s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>56</td>
<td>56/56 (100)</td>
<td>1/56 (1.8)</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire Control</td>
<td>19</td>
<td>19/19 (100)</td>
<td>---</td>
<td>1/19 (5.3)</td>
<td>Appropriate antiplatelet therapy</td>
<td>Heparin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20</td>
<td>29/20 (100)</td>
<td>---</td>
<td>1/20 (5.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System Control</td>
<td>80</td>
<td>75.8 (30)</td>
<td>---</td>
<td>9/80 (11)</td>
<td>Aspirin 100 mg and ticlopidine 200 mg pre-PCI</td>
<td>Heparin 5000 U (ACT &gt;250 s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>74</td>
<td>53 (25)</td>
<td>---</td>
<td>5/74 (7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>GuardWire Plus System Control</td>
<td>173</td>
<td>29.7 (18.3)*</td>
<td>173/173 (100)</td>
<td>---</td>
<td>Aspirin 81-100 mg/d and ticlopidine 200 mg/d for at least 2 weeks</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>168</td>
<td>29.5 (18.2)*</td>
<td>168/168 (100)</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire Control</td>
<td>52</td>
<td>52/52 (100)</td>
<td>---</td>
<td>0/52 (0)</td>
<td>Aspirin 300 mg and clopidogrel 300 mg pre-PCI then aspirin 100 mg/d and clopidogrel 75 mg/d post-PCI</td>
<td>Heparin IV during PCI (ACT ≥300 s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>60</td>
<td>60/60 (100)</td>
<td>---</td>
<td>0/60 (0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire Control</td>
<td>8</td>
<td>8/8 (100)</td>
<td>---</td>
<td>---</td>
<td>Aspirin 243 mg at least 30 min pre-PCI</td>
<td>Heparin 100 U/kg IV</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8</td>
<td>8/8 (100)</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus Control</td>
<td>252</td>
<td>53 (42-69)*</td>
<td>244/252 (96.8)</td>
<td>210/252 (83.3)</td>
<td>Aspirin 324 mg and clopidogrel 300 mg pre-PCI</td>
<td>Heparin IV 70 U/kg bolus (ACT &gt;300 s pre-PCI or 200-300 s if GP2B3Ai used)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>249</td>
<td>39 (29-51)*</td>
<td>241/249 (96.8)</td>
<td>208/249 (83.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Operation time; †Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; kg=kilogram; mg=milligram; min=minutes; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units
Table 23. Baseline characteristics of randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)$^*$</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>141</td>
<td>62 (11)</td>
<td>80</td>
<td>98.58</td>
<td>170 (132-234)</td>
<td>6</td>
<td>---</td>
<td>0</td>
<td>29</td>
<td>76</td>
<td>12</td>
<td>31</td>
<td>21</td>
<td>50</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>143</td>
<td>59 (11)</td>
<td>80</td>
<td>96.50</td>
<td>153 (126-212)</td>
<td>9</td>
<td>---</td>
<td>0</td>
<td>29</td>
<td>66</td>
<td>6</td>
<td>23</td>
<td>13</td>
<td>65</td>
<td>38</td>
</tr>
</tbody>
</table>

*Symptom onset to balloon; $^*$Median (interquartile range)

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 24. Procedural characteristics of randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study Year</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>141</td>
<td>45 (36-58)*</td>
<td>---</td>
<td>15/141 (11)</td>
<td>61/141 (43)</td>
<td>Aspirin 300 mg pre-PCI and at least 80 mg/d post-PCI and clopidogrel 600 mg load pre-PCI followed by 75 mg/d post-PCI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>143</td>
<td>31 (25-40)*</td>
<td>---</td>
<td>27/143 (19)</td>
<td>50/143 (35)</td>
<td>Heparin 70 U/kg pre-PCI</td>
<td></td>
</tr>
</tbody>
</table>

*Median (interquartile range)

Abbreviations: d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; SD=standard deviation; U=units
Table 25. Baseline characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndrome

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoker (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>30</td>
<td>55.17 (12)</td>
<td>90 ---</td>
<td>---</td>
<td>53</td>
<td>100</td>
<td>20</td>
<td>3</td>
<td>17</td>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gick 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>100</td>
<td>62.9 (11.3)</td>
<td>86</td>
<td>65</td>
<td>372 (210-726)</td>
<td>12</td>
<td>---</td>
<td>45</td>
<td>---</td>
<td>21</td>
<td>65</td>
<td>---</td>
<td>35</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Sardella 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>28</td>
<td>65.3 (11.2)</td>
<td>77.42</td>
<td>---</td>
<td>408 (138)†</td>
<td>---</td>
<td>100</td>
<td>0</td>
<td>---</td>
<td>100</td>
<td>---</td>
<td>78</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>129</td>
<td>64 (11.8)</td>
<td>79.84</td>
<td>---</td>
<td>---</td>
<td>0</td>
<td>34.1</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>55</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Nanasato 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>34</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Matsushita 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>24</td>
<td>63 (13)</td>
<td>83.33</td>
<td>---</td>
<td>0</td>
<td>100</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>30</td>
<td>55.9 (9.9)</td>
<td>73</td>
<td>80.00</td>
<td>291 (177)</td>
<td>10</td>
<td>35</td>
<td>23</td>
<td>30</td>
<td>---</td>
<td>17</td>
<td>53</td>
<td>60</td>
<td>57</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>31</td>
<td>53.9 (10.0)</td>
<td>77</td>
<td>74.19</td>
<td>279 (185)</td>
<td>10</td>
<td>35</td>
<td>10</td>
<td>32</td>
<td>---</td>
<td>13</td>
<td>36</td>
<td>58</td>
<td>55</td>
<td>---</td>
</tr>
</tbody>
</table>

*Symptom onset to balloon, symptom onset to percutaneous coronary intervention; †Median (interquartile range); ‡Mean for the total study population

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis
Table 26. Procedural characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndrome

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>30</td>
<td>25.01 (11.89)</td>
<td>---</td>
<td>10/30 (33)</td>
<td>13/30 (43)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>37</td>
<td>31.98 (15.33)</td>
<td>---</td>
<td>3/37 (8)</td>
<td>26/37 (70)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>100</td>
<td>---</td>
<td>28/28 (100)</td>
<td>28/28 (100)</td>
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<td></td>
<td></td>
<td></td>
<td>100</td>
<td>---</td>
<td>34/34 (100)</td>
<td>34/34 (100)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aspirin 500 mg IV and clopidogrel 600 mg load pre-PCI</td>
<td>Heparin 100 U/kg pre-PCI</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>28</td>
<td>---</td>
<td>28/28 (100)</td>
<td>28/28 (100)</td>
<td>---</td>
<td>---</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>34</td>
<td>---</td>
<td>34/34 (100)</td>
<td>34/34 (100)</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>129</td>
<td>---</td>
<td>129/129 (100)</td>
<td>129/129 (100)</td>
<td>---</td>
<td>---</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>129</td>
<td>---</td>
<td>129/129 (100)</td>
<td>129/129 (100)</td>
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<td></td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>34</td>
<td>---</td>
<td>---</td>
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<td>---</td>
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<td>---</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>32</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>56</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>30</td>
<td>---</td>
<td>14/30 (46.67)</td>
<td>22/30 (73)</td>
<td>STEMI or UA: Aspirin pre-PCI and 100 mg post-PCI and clopidogrel 600 mg immediately after stenting and then 75 mg/d for 30 d</td>
<td>STEMI: Heparin (ACT &gt;300 s) pre-PCI and during intervention</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>31</td>
<td>---</td>
<td>21/31 (68)</td>
<td>2/31 (6.45)</td>
<td>UA: low-molecular weight heparin pre-PCI and during intervention (ACT &gt;300 s)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Median (interquartile range)

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; STEMI=ST-segment elevation myocardial infarction; U=units; UA=unstable angina
Table 27. Baseline characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI 0/1 (%)</th>
<th>Mean ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoker (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster 2008</td>
<td>Distal Filter</td>
<td>Embolic Protection</td>
<td>FilterWire EZ</td>
<td>77</td>
<td>58 (11)</td>
<td>83</td>
<td>--</td>
<td>30 (4)</td>
<td>39</td>
<td>---</td>
<td>16</td>
<td>39</td>
<td>69</td>
<td>71</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>74</td>
<td>60 (13)</td>
<td>--</td>
<td>26 (4)</td>
<td>32</td>
<td>---</td>
<td>26</td>
<td>46</td>
<td>62</td>
<td>66</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dudek 2003</td>
<td>Distal Filter</td>
<td>Embolic Protection</td>
<td>AngioGuard</td>
<td>15</td>
<td>59.4 (66.6)</td>
<td>66.6</td>
<td>---</td>
<td></td>
<td>60</td>
<td>---</td>
<td>0</td>
<td>40</td>
<td>26.0</td>
<td>---</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16</td>
<td>49.3 (8.4)</td>
<td>62.5</td>
<td></td>
<td>50</td>
<td>---</td>
<td>0</td>
<td>62.5</td>
<td>31.0</td>
<td>---</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 28. Procedural characteristics of randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster 2008</td>
<td>Distal Filter</td>
<td>Embolic Protection</td>
<td>FilterWire EZ</td>
<td>77</td>
<td>--</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aspirin</td>
<td>Heparin 60 U/kg (ACT 200-300 s)</td>
</tr>
<tr>
<td>Dudek 2003</td>
<td>Distal Filter</td>
<td>Embolic Protection</td>
<td>AngioGuard</td>
<td>15</td>
<td>63 (17)</td>
<td>15/15 (100)</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; kg=kilogram; mg=milligram; n=number; N=number of participants in the group; s=seconds; SD=standard deviation; U=units
### Table 29. Baseline characteristics of direct comparative randomized controlled trials in ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>TIMI Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter Export</td>
<td>52</td>
<td>64.6 (12.5)</td>
<td>78.8</td>
<td>100</td>
<td>414 (60)</td>
<td>0</td>
<td>---</td>
<td>0</td>
<td>46.1</td>
<td>100</td>
<td>26.9</td>
<td>63.4</td>
<td>---</td>
<td>42.3</td>
<td>23.0</td>
</tr>
<tr>
<td></td>
<td>Catheter Aspiration</td>
<td>Export Medtronic</td>
<td>51</td>
<td>66.7 (14.1)</td>
<td>78.4</td>
<td>100</td>
<td>408 (54)</td>
<td>0</td>
<td>---</td>
<td>0</td>
<td>41.2</td>
<td>100</td>
<td>23.5</td>
<td>66.6</td>
<td>---</td>
<td>49.0</td>
<td>29.4</td>
</tr>
<tr>
<td>Yan 2007</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>61</td>
<td>60 (14)</td>
<td>82</td>
<td>100</td>
<td>350 (185)</td>
<td>---</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>---</td>
<td>31</td>
<td>62</td>
<td>54</td>
<td>62</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>61</td>
<td>60 (13)</td>
<td>84</td>
<td>100</td>
<td>345 (180)</td>
<td>---</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>---</td>
<td>28</td>
<td>57</td>
<td>56</td>
<td>61</td>
<td>23</td>
</tr>
</tbody>
</table>

*Symptom onset to balloon, Symptom onset to angiogram

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

### Table 30. Procedural characteristics of direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter Export Medtronic</td>
<td>52</td>
<td>---</td>
<td>52/52 (100)</td>
<td>32/52 (65.3)</td>
<td>52/52 (100)</td>
<td>Aspirin 300 mg and clopidogrel 300 mg load pre-PCI and aspirin 100 mg/d and clopidogrel 75 mg/d (for 6 m) post-PCI</td>
<td>Heparin (ACT &gt;250 s) and continued for 48 hours post-PCI</td>
</tr>
<tr>
<td>Yan 2007</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>61</td>
<td>60 (24)</td>
<td>39/61 (64)</td>
<td>7/61 (11)</td>
<td>Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI</td>
<td>Heparin 8000-10000 U IV during PCI and low-molecular weight heparin for 1 week if needed post-PCI</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIb IIIa inhibitor; IV=intravenous; m=months; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units
Table 31. Baseline characteristics of randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)*</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter</td>
<td>Diver CE</td>
<td>Control</td>
<td>19</td>
<td>56.6 (10.9)</td>
<td>79</td>
<td>100</td>
<td>268 (197)</td>
<td>0</td>
<td>100</td>
<td>---</td>
<td>100</td>
<td>---</td>
<td>5.3</td>
<td>42.0</td>
<td>10.5</td>
<td>68.4</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Aspiration</td>
<td>Control</td>
<td></td>
<td>23</td>
<td>58.1 (10.8)</td>
<td>70.9</td>
<td>100</td>
<td>323 (183)</td>
<td>0</td>
<td>100</td>
<td>---</td>
<td>100</td>
<td>0</td>
<td>16.7</td>
<td>1.0</td>
<td>8.3</td>
<td>83.3</td>
<td>7.0</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter</td>
<td>Rescue or Thrombuster systems</td>
<td>Control</td>
<td>25</td>
<td>68 (9)</td>
<td>100</td>
<td>---</td>
<td>---</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>---</td>
<td>45</td>
<td>45.0</td>
<td>55.0</td>
<td>50.0</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Aspiration</td>
<td>Distal Balloon GuardWire</td>
<td>Control</td>
<td>28</td>
<td>66 (13)</td>
<td>100</td>
<td>---</td>
<td>---</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>---</td>
<td>40</td>
<td>50.0</td>
<td>65.0</td>
<td>65.0</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Time to reperfusion

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis
### Table 32. Procedural characteristics of randomized controlled trials with selective inclusion / exclusion criteria in patient with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter</td>
<td>Aspiration</td>
<td>Diver CE Control</td>
<td>19/23 (100)</td>
<td>19/23 (100)</td>
<td>19/23 (100)</td>
<td>Aspirin and clopidogrel load pre-PCI</td>
<td>Heparin (ACT &gt;200 s)</td>
<td></td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter</td>
<td>Aspiration</td>
<td>Rescue or Thrombuster systems</td>
<td>25/24 (100)</td>
<td>24/24 (100)</td>
<td>28/28 (100)</td>
<td>Aspirin 162 mg and ticlopidine 200 mg pre-PCI and post-PCI</td>
<td>Heparin 10,000 U intra-arterial pre-PCI and 20,000 U/d IV post-PCI</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ACT=activated clotting time; d=days; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IV=intravenous; mg=milligram; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

### Table 33. Baseline characteristics of controlled observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)*</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoker (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>165</td>
<td>60 (11)</td>
<td>76</td>
<td>88</td>
<td>---</td>
<td>14</td>
<td>37</td>
<td>9.1</td>
<td>---</td>
<td>9</td>
<td>43</td>
<td>36</td>
<td>41</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Thrombus Aspiration</td>
<td>Control</td>
<td>429</td>
<td>62 (13)</td>
<td>77.6</td>
<td>---</td>
<td>---</td>
<td>15</td>
<td>45</td>
<td>19.7</td>
<td>---</td>
<td>9</td>
<td>44</td>
<td>42</td>
<td>44</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection Device</td>
<td>Control</td>
<td>1050† 58(12)§</td>
<td>72.5</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Control</td>
<td>2917</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>0</td>
<td>25.6</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Control</td>
<td>990</td>
<td>63.3 (11.7)</td>
<td>79.8</td>
<td>6.4</td>
<td>252 (288)</td>
<td>13.9</td>
<td>---</td>
<td>0</td>
<td>40.0</td>
<td>---</td>
<td>31.3</td>
<td>53.0</td>
<td>47.2</td>
<td>66.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2923</td>
<td>64.9 (11.4)</td>
<td>76.7</td>
<td>14.6</td>
<td>282 (330)</td>
<td>13.6</td>
<td>---</td>
<td>0</td>
<td>47.0</td>
<td>---</td>
<td>34.2</td>
<td>53.8</td>
<td>43.5</td>
<td>66.5</td>
<td></td>
</tr>
<tr>
<td>Study, Year</td>
<td>Device Category</td>
<td>Group</td>
<td>N</td>
<td>Mean Age (SD)</td>
<td>Male (%)</td>
<td>TIMI 0/1 (%)</td>
<td>Mean Ischemic Time in Minutes (SD)*</td>
<td>Prior MI (%)</td>
<td>Anterior MI (%)</td>
<td>Failed TL (%)</td>
<td>IRA LAD (%)</td>
<td>Visible Lesion (%)</td>
<td>DM (%)</td>
<td>HTN (%)</td>
<td>HCL (%)</td>
<td>Smoker (%)</td>
<td>FHx (%)</td>
</tr>
<tr>
<td>-------------</td>
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<td>--------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Chinnaiyan, Mechanical Thrombectomy 2006</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>239</td>
<td>62 (13)</td>
<td>60 --- ---</td>
<td>13</td>
<td>30.1</td>
<td>16</td>
<td>30.5</td>
<td>---</td>
<td>15</td>
<td>49</td>
<td>56</td>
<td>47</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simonton, Mechanical Thrombectomy 2006</td>
<td>AngioJet Control</td>
<td>200</td>
<td>---</td>
<td>50 --- ---</td>
<td>11</td>
<td>49.8</td>
<td>15</td>
<td>50.2</td>
<td>---</td>
<td>16</td>
<td>53</td>
<td>53</td>
<td>38</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Symptom onset to admission; †Total study population; ‡Mean for the total study population; §Multiple devices including Rescue catheter, Thrombuster catheter, Transvascular aspiration catheter and Export

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 34. Procedural characteristics of controlled observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3AII Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter Aspiration</td>
<td>Export Control</td>
<td>165</td>
<td>41.2*</td>
<td>---</td>
<td>---</td>
<td>88</td>
<td>79</td>
<td>---</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Thrombus Aspiration</td>
<td>Thrombus Aspiration Control</td>
<td>429</td>
<td>36.5</td>
<td>---</td>
<td>---</td>
<td>38.5</td>
<td>38.5</td>
<td>63.9% and 63.4% received clopidogrel loading dose of 600mg</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
<td>381</td>
<td>---</td>
<td>---</td>
<td>155/381 (40.7)</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices* Control</td>
<td>990</td>
<td>---</td>
<td>784/990 (79.2)</td>
<td>1789/2923 (61.2)</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Device Category</td>
<td>Group</td>
<td>N</td>
<td>Mean Procedure Time in Minutes (SD)</td>
<td>Stenting n/N (%)</td>
<td>Direct Stenting n/N (%)</td>
<td>Procedural GP2B3Ai Use n/N (%)</td>
<td>Anti-platelet Drugs Used</td>
<td>Anti-thrombotic Drugs Used</td>
</tr>
<tr>
<td>------------</td>
<td>----------------</td>
<td>-------</td>
<td>-----</td>
<td>----------------------------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>-----------------------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>239</td>
<td>---</td>
<td>215/239 (90)</td>
<td>---</td>
<td>132/239 (55)</td>
<td>---</td>
<td>Heparin (ACT&gt;250 s)</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>1021</td>
<td>---</td>
<td>878/1021 (86)</td>
<td>---</td>
<td>639/1021 (63)</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Multiple devices including Rescue catheter, Thrombuster catheter, Transvascular aspiration catheter and Export

Abbreviations: ACT=activated clotting time; GP2B3Ai=glycoprotein IIbIIIa inhibitor; n=number; N=number of participants in the group; s=seconds; SD=standard deviation

Table 35. Baseline characteristics of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)*</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoker (%)</th>
<th>FH (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA</td>
<td>23</td>
<td>58 (10)</td>
<td>82.61</td>
<td>34.78</td>
<td>186 (186)</td>
<td>0</td>
<td>---</td>
<td>---</td>
<td>43</td>
<td>---</td>
<td>61</td>
<td>48</td>
<td>65</td>
<td>74</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombuster</td>
<td>21</td>
<td>62 (8)</td>
<td>80.95</td>
<td>90.48</td>
<td>126 (78)</td>
<td>0</td>
<td>---</td>
<td>---</td>
<td>48</td>
<td>---</td>
<td>19</td>
<td>52</td>
<td>90</td>
<td>81</td>
<td>---</td>
</tr>
</tbody>
</table>

*Symptom onset to arrival

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; MtPA=mutant plasminogen activator; N=number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis

Table 36. Procedural characteristics of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
</table>

E-19
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Male (%)</th>
<th>TIMI-0/1 (%)</th>
<th>Mean Ischemic Time in Minutes (SD)</th>
<th>Prior MI (%)</th>
<th>Anterior MI (%)</th>
<th>Failed TL (%)</th>
<th>IRA LAD (%)</th>
<th>Visible Lesion (%)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>HCL (%)</th>
<th>Smoke (%)</th>
<th>FHx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire</td>
<td>Abscimab</td>
<td>57</td>
<td>57.75 (6.78)</td>
<td>52.6</td>
<td>3</td>
<td>84.2</td>
<td>360 (240-540)†</td>
<td>22.81</td>
<td>43.86</td>
<td>0</td>
<td>---</td>
<td>57.89</td>
<td>26.3</td>
<td>63.16</td>
<td>49.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>63</td>
<td>58.71 (7.41)</td>
<td>71.4</td>
<td>3</td>
<td>77.8</td>
<td>360 (300-720)†</td>
<td>20.63</td>
<td>41.27</td>
<td>0</td>
<td>---</td>
<td>71.43</td>
<td>---</td>
<td>61.90</td>
<td>---</td>
</tr>
</tbody>
</table>

**Table 37. Baseline characteristics of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome**

Abbreviations: DM=diabetes mellitus; FHx=family history; HCL=hypercholesterolemia; HTN=hypertension; IRA=infarct-related artery; LAD=left anterior descending artery; MI=myocardial infarction; N=total number of participants in the group; SD=standard deviation; TIMI=thrombolysis in myocardial infarction; TL=thrombolysis
Table 38. Procedural characteristics of randomized controlled trials with unique comparison in patients with mixed acute coronary syndrome

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>N</th>
<th>Mean Procedure Time in Minutes (SD)</th>
<th>Stenting n/N (%)</th>
<th>Direct Stenting n/N (%)</th>
<th>Procedural GP2B3Ai Use n/N (%)</th>
<th>Anti-platelet Drugs Used</th>
<th>Anti-thrombotic Drugs Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>57</td>
<td>58 (35-88)*</td>
<td>57/57 (100)</td>
<td>40/57 (57)</td>
<td>---</td>
<td>Aspirin 300 mg and clopidogrel 300 mg pre-PCI</td>
<td>Device group: heparin 100 IU/kg (ACT &gt;300 s) Abciximab group: heparin 70 IU/kg (ACT &gt;250 s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>63</td>
<td>43 (25-87)*</td>
<td>63/63 (100)</td>
<td>41/63 (65.7)</td>
<td>63/63 (100)</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal protection device</td>
<td>Thrombectomy + stenting + distal protection device</td>
<td>30</td>
<td>---</td>
<td>30/30 (100)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>30</td>
<td>---</td>
<td>30/30 (100)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: GP2B3Ai=glycoprotein IIbIIIa inhibitor; n=number; N=number of participants in the group; SD=standard deviation
## Appendix F: Additional Evidence Tables and Reference List

### Table 39. Mortality in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
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<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE</td>
<td>Death</td>
<td>3/100</td>
<td>---</td>
<td>4/100</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>3/96</td>
<td>---</td>
<td>3/96</td>
<td>---</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter</td>
<td>Cardiac death</td>
<td>---</td>
<td>---</td>
<td>1/55</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>---</td>
<td>0/56</td>
<td>---</td>
</tr>
<tr>
<td>Lipecki, 2009</td>
<td>Export Catheter</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM)</td>
<td>Death 720-day: cardiac death</td>
<td>0/88</td>
<td>0/88</td>
<td>0/88</td>
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</tr>
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<td></td>
<td>Control</td>
<td></td>
<td>1/87</td>
<td>1/87</td>
<td>1/87†</td>
<td>6/87†</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter</td>
<td>Death</td>
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<td>---</td>
<td>1/37</td>
<td>---</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>---</td>
<td>---</td>
<td>0/34</td>
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</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter</td>
<td>Cardiac+ non-cardiac death</td>
<td>---</td>
<td>4/120</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>5/129</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver</td>
<td>Death</td>
<td>5/135†</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Ikari, 2008</td>
<td>TVAC</td>
<td>Death</td>
<td>1/178</td>
<td>---</td>
<td>2/170‡</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>1/171</td>
<td>---</td>
<td>1/158‡</td>
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<tr>
<td>Svilas, 2008</td>
<td>6F Export Aspiration Catheter</td>
<td>Death</td>
<td>---</td>
<td>11/529</td>
<td>---</td>
<td>25/535**</td>
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<td></td>
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<td></td>
<td>---</td>
<td>21/531</td>
<td>---</td>
<td>41/536**</td>
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<tr>
<td>DeLuca, 2006</td>
<td>Diver CE</td>
<td>Death</td>
<td>---</td>
<td>---</td>
<td>0/35</td>
<td>2/20*</td>
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<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>---</td>
<td>2/38</td>
<td>4/28*</td>
</tr>
<tr>
<td>Kaltoft, 2006</td>
<td>Rescue Catheter</td>
<td>Death</td>
<td>---</td>
<td>0/108</td>
<td>---</td>
<td>---</td>
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<tr>
<td></td>
<td>Control</td>
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<td>---</td>
<td>1/107</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lee, 2006</td>
<td>Export Aspiration Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter</td>
<td>Death</td>
<td>0/74</td>
<td>---</td>
<td>0/74</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>0/74</td>
<td>---</td>
<td>0/70</td>
<td>---</td>
</tr>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE</td>
<td>Death 1/48§</td>
<td>3/48</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>2/48§</td>
<td>3/48</td>
<td>---</td>
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</tbody>
</table>
### Table 40. Mortality in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noel, 2005</td>
<td>Export</td>
<td>Death</td>
<td>1/48†</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>2/48</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System</td>
<td>Death</td>
<td>0/24</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>1/26</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*270-day data; †3-7 days post PCI in both the groups together; ‡240-day data; §In the catheterization lab; ¶Post-PCI; ‖Time period not specified; ‡30-day data; **365-day data
Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

*365-day data
Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group
Table 41. Mortality in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>Death</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1/17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kelbaek, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>Death</td>
<td>---</td>
<td>8/312</td>
<td>---</td>
<td>13/312*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8/314</td>
<td></td>
<td>15/314*</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX Control</td>
<td>Death</td>
<td>---</td>
<td>4/70</td>
<td>5/70</td>
<td>---</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>4/70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>Death</td>
<td>---</td>
<td>2/51</td>
<td>---</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>0/49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>Death</td>
<td>---</td>
<td>1/32</td>
<td>---</td>
<td>---</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1/28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*450 day data
Abbreviations: n=number; N=number of participants in the group

Table 42. Mortality in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>PercuSurge Guardwire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire Control</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire Control</td>
<td>Death</td>
<td>---</td>
<td>0/54</td>
<td>0/54</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2/52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire Control</td>
<td>Death</td>
<td>---</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>---</td>
<td>1/20</td>
<td>---</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System Control</td>
<td>Cardiac death</td>
<td>---</td>
<td>1/80</td>
<td>1/80</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>2/74</td>
<td>3/74</td>
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<td>7/168</td>
<td>7/168</td>
<td>11/168</td>
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</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire Control</td>
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<td>---</td>
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<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire Control</td>
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F-3
<table>
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<th>Study, Year</th>
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<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
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</thead>
<tbody>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus</td>
<td>Death</td>
<td>---</td>
<td>5/246</td>
<td>8/243</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>7/244</td>
<td>8/233</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 43. Mortality in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>Death</td>
<td>---</td>
<td>2/141</td>
<td>2/141</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>2/143</td>
<td>4/143</td>
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</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 44. Mortality in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>Death</td>
<td>1/30</td>
<td>---</td>
<td>---</td>
<td>1/30*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4/37*</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>Death</td>
<td>---</td>
<td>2/100</td>
<td>3/100</td>
<td>3/100</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>Death</td>
<td>2/129</td>
<td>2/129</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>Death</td>
<td>0/24</td>
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<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>Death</td>
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<td>2/33</td>
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</table>

*730-day data

Abbreviations: n=number; N=number of participants in the group
### Table 45. Mortality in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
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</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EZ</td>
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<tr>
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<td></td>
<td>Control</td>
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</tr>
<tr>
<td>Dudek, 2003</td>
<td>Distal Filter Embolic Protection</td>
<td>AngioGuard</td>
<td>---</td>
<td>---</td>
<td>0/15</td>
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</tr>
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<td></td>
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<td>Control</td>
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<td>---</td>
<td>0/16</td>
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</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 46. Mortality in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter</td>
<td>Cardiac death</td>
<td>---</td>
<td>2/52</td>
<td>---</td>
<td>2/50*</td>
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<tr>
<td></td>
<td></td>
<td>Export Medtronic</td>
<td></td>
<td>---</td>
<td>3/51</td>
<td>---</td>
<td>0/48*</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter</td>
<td>Death</td>
<td>---</td>
<td>2/61</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Plus</td>
<td></td>
<td>---</td>
<td>2/61</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*365-day data

Abbreviations: n=number; N=number of participants in the group

### Table 47. Mortality in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>Thrombuster systems</td>
<td></td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PercuSurge GuardWire</td>
<td></td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
Table 48. Mortality in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA Thrombuster</td>
<td>Death</td>
<td>---</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

Table 49. Mortality in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>Death</td>
<td>---</td>
<td>---</td>
<td>0/57</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device Thrombectomy+ Stenting</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>0/63</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 50. Mortality in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim, 2010</td>
<td>Catheter Aspiration</td>
<td>Thrombus Aspiration Control</td>
<td>Death</td>
<td>22/429 19/429</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009*</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>Death</td>
<td>---</td>
<td>10/381 70/2917</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009*</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>Cardiac death</td>
<td>---</td>
<td>10/381 64/2917</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices† Control</td>
<td>Death</td>
<td>---</td>
<td>37/990</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

---
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Mortality definition</th>
<th>In-hospital mortality n/N</th>
<th>30-day mortality n/N</th>
<th>180-day mortality n/N</th>
<th>365-day mortality n/N</th>
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</thead>
<tbody>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>Death</td>
<td>7/239</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>Death</td>
<td>---</td>
<td>---</td>
<td>10/200†</td>
<td>76/1168‡</td>
</tr>
</tbody>
</table>

*Data from a single study; † Rescue Catheter, Thrombuster Catheter, Transvascular Aspiration Catheter, Export Catheter; ‡270-day data; Abbreviations: n=number; N=number of participants in the group

Table 51. Myocardial infarction in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE Control</td>
<td>0/100</td>
<td>---</td>
<td>1/100</td>
<td>---</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
<td>---</td>
<td>---</td>
<td>3/55</td>
<td>---</td>
</tr>
<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM) Control</td>
<td>0/88</td>
<td>0/88</td>
<td>0/88</td>
<td>0/88*</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>---</td>
<td>2/120</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>TVAC Control</td>
<td>0/178</td>
<td>0/170†</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Svilas, 2008</td>
<td>6F Export Aspiration Catheter Control</td>
<td>---</td>
<td>4/529</td>
<td>---</td>
<td>12/535‡</td>
</tr>
<tr>
<td>DeLuca, 2006</td>
<td>Diver CE Control</td>
<td>---</td>
<td>1/35</td>
<td>---</td>
<td>23/536‡</td>
</tr>
<tr>
<td>Kaltol, 2006</td>
<td>Rescue Catheter Control</td>
<td>---</td>
<td>0/108</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Group</td>
<td>In-hospital myocardial infarction n/N</td>
<td>30-day myocardial infarction n/N</td>
<td>180-day myocardial infarction n/N</td>
<td>365-day myocardial infarction n/N</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------</td>
<td>----------------------------------------</td>
<td>----------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Lee, 2006</td>
<td>Export Aspiration Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter</td>
<td>0/74</td>
<td>---</td>
<td>0/74</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>074</td>
<td>---</td>
<td>2/74</td>
<td>---</td>
</tr>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE</td>
<td>---</td>
<td>2/48</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>2/48</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Noel, 2005</td>
<td>Export</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*730-day data; †240-day data; ‡365-day data;
Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 52. Myocardial infarction in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy</td>
<td>---</td>
<td>2/256</td>
<td>2/251</td>
<td>2/22*</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>3/245</td>
<td>3/242</td>
<td>3/220*</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>AngioJet Catheter</td>
<td>---</td>
<td>0/240</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/240</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter</td>
<td>---</td>
<td>1/100</td>
<td>2/100</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>3/101</td>
<td>4/101</td>
<td>---</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet</td>
<td>---</td>
<td>0/50</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/50</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter</td>
<td>0/46</td>
<td>2/46</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0/46</td>
<td>2/46</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*365-day data
Abbreviations: n=number; N=number of participants in the group
Table 53. Myocardial infarction in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/17</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kelbaek, 2008</td>
<td>FilterWire-EZ or SpiderX protection device</td>
<td>---</td>
<td>5/312</td>
<td>---</td>
<td>7/312*</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>1/314</td>
<td>---</td>
<td>3/314*</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX</td>
<td>---</td>
<td>0/70</td>
<td>0/70</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>5/70</td>
<td>5/70</td>
<td>---</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ</td>
<td>---</td>
<td>0/51</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>1/49</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP</td>
<td>---</td>
<td>1/32</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>1/28</td>
<td>---</td>
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</tr>
</tbody>
</table>

*450 day data

Abbreviations: n=number; N=number of participants in the group

Table 54. Myocardial infarction in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>1/54</td>
<td>1/54</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/52</td>
<td>1/52</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>---</td>
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<td>0/19</td>
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<tr>
<td></td>
<td>Control</td>
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<td>---</td>
<td>1/20</td>
<td>---</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System</td>
<td>---</td>
<td>1/80</td>
<td>1/80</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>System Control</td>
<td>---</td>
<td>---</td>
<td>0/74</td>
<td>0/74</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>GuardWire Plus System</td>
<td>0/173</td>
<td>0/173</td>
<td>0/173</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>1/168</td>
<td>1/168</td>
<td>1/168</td>
<td>---</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire</td>
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<tr>
<td></td>
<td>Control</td>
<td>---</td>
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</tr>
</tbody>
</table>
### Table 55. Myocardial infarction in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus</td>
<td>---</td>
<td>5/246</td>
<td>6/243</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>7/244</td>
<td>9/233</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 56. Myocardial infarction in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>1/30</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
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<td>3/57</td>
<td>---</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>---</td>
<td>0/100</td>
<td>0/100</td>
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</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>---</td>
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</table>

Abbreviations: n=number; N=number of participants in the group
Table 57. Myocardial infarction in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EZ</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2003</td>
<td>Distal Filter Embolic Protection</td>
<td>AngioGuard</td>
<td>---</td>
<td>0/15</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/16</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 58. Myocardial infarction in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter</td>
<td>---</td>
<td>0/52</td>
<td>---</td>
<td>1/50*</td>
</tr>
<tr>
<td></td>
<td>Catheter Aspiration</td>
<td>Export Medtronic</td>
<td>---</td>
<td>0/51</td>
<td>---</td>
<td>1/48*</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter</td>
<td>---</td>
<td>1/61</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Plus</td>
<td>---</td>
<td>0/61</td>
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<td>---</td>
</tr>
</tbody>
</table>

*730-day data
Abbreviations: n=number; N=number of participants in the group

Table 59. Myocardial infarction in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction n/N</th>
<th>30-day myocardial infarction n/N</th>
<th>180-day myocardial infarction n/N</th>
<th>365-day myocardial infarction n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or Thrombuster systems</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
Table 60. Myocardial infarction in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction</th>
<th>30-day myocardial infarction</th>
<th>180-day myocardial infarction</th>
<th>365-day myocardial infarction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA</td>
<td>---</td>
<td>---</td>
<td>1/19</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombuster</td>
<td>---</td>
<td>---</td>
<td>0/14</td>
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</tr>
</tbody>
</table>

Abbreviations: MtPA= mutant plasminogen activator; n=number; N=number of participants in the group

Table 61. Myocardial infarction in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction</th>
<th>30-day myocardial infarction</th>
<th>180-day myocardial infarction</th>
<th>365-day myocardial infarction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>---</td>
<td>---</td>
<td>3/57</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>---</td>
<td>---</td>
<td>2/63</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device Thrombectomy+ Stenting</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 62. Myocardial infarction in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital myocardial infarction</th>
<th>30-day myocardial infarction</th>
<th>180-day myocardial infarction</th>
<th>365-day myocardial infarction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration Export Control</td>
<td>---</td>
<td>2/164</td>
<td>---</td>
<td>6/154</td>
<td>---</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter aspiration Thrombus Aspiration Control</td>
<td>---</td>
<td>2/370</td>
<td>---</td>
<td>5/353</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection Distal Protection Device Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration Aspiration Catheter Control</td>
<td>---</td>
<td>5/381</td>
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</tbody>
</table>
Table 63. Stroke in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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</thead>
<tbody>
<tr>
<td>Dudek, 2008</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter</td>
<td>---</td>
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<tr>
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<td>Control</td>
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</tr>
<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter</td>
<td>---</td>
<td>---</td>
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<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM)</td>
<td>2/88</td>
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<tr>
<td></td>
<td>Control</td>
<td>0/87</td>
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<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter</td>
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<tr>
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<td>Control</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter</td>
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<td>2/120</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/129</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver</td>
<td>---</td>
<td>---</td>
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<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Ikari, 2008</td>
<td>TVAC</td>
<td>---</td>
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<tr>
<td></td>
<td>Control</td>
<td>---</td>
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</tr>
<tr>
<td>Svilaas, 2008</td>
<td>6F Export Aspiration Catheter</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>DeLuca, 2006</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kaltoft, 2006</td>
<td>Rescue Catheter</td>
<td>---</td>
<td>2/108</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/107</td>
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</tr>
<tr>
<td>Lee, 2006</td>
<td>Export Aspiration Catheter</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
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<td>---</td>
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<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter</td>
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<td>0/74</td>
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<tr>
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<td>Control</td>
<td>---</td>
<td>---</td>
<td>0/70</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE Control</td>
<td>---</td>
<td>1/48</td>
<td>---</td>
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</tr>
<tr>
<td>Noel, 2005</td>
<td>Export Control</td>
<td>---</td>
<td>1/48</td>
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</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System Control</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 64. Stroke in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy Control</td>
<td>---</td>
<td>0/256</td>
<td>1/251</td>
<td>2/221*</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>---</td>
<td>2/240</td>
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</tr>
<tr>
<td>Antonucci, 2004</td>
<td>AngioJet Control</td>
<td>---</td>
<td>1/101</td>
<td>0/101</td>
<td>---</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>0/46</td>
<td>0/46</td>
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<td>---</td>
</tr>
</tbody>
</table>

*365-day data
Abbreviations: n=number; N=number of participants in the group

Table 65. Stroke in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
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</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>---</td>
<td>3/312</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX Control</td>
<td>---</td>
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</tbody>
</table>

F-14
### Table 66. Stroke in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
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</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire Control</td>
<td>---</td>
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<tr>
<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System Control</td>
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<td>Muramatsu, 2007</td>
<td>GuardWire Plus System Control</td>
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<td>Zhou, 2007</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
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<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
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<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus Control</td>
<td>---</td>
<td>0/246</td>
<td>2/243</td>
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</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 67. Stroke in randomized controlled trials evaluating proximal balloon embolic protection versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>---</td>
<td>0/141</td>
<td>0/141</td>
<td>---</td>
</tr>
<tr>
<td>Haeck, 2009</td>
<td>Control</td>
<td>---</td>
<td>1/143</td>
<td>2/143</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
Table 68. Stroke in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>---</td>
<td>0/100</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>0/100</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>---</td>
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<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 69. Stroke in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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<tbody>
<tr>
<td>Webster, 2008</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EZ Control</td>
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<td>Dudek, 2003</td>
<td>Distal Filter Embolic Protection</td>
<td>AngioGuard Control</td>
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</table>

Abbreviations: n=number; N=number of participants in the group
### Table 70. Stroke in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Catheter Aspiration</td>
<td>Export Medtronic</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter</td>
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<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Plus</td>
<td>---</td>
<td>0/61</td>
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</table>

Abbreviations: n=number; N=number of participants in the group

### Table 71. Stroke in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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</thead>
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<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<td>Ozaki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or Thrombuster systems</td>
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<tr>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Control</td>
<td>---</td>
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<td>---</td>
<td>---</td>
<td>---</td>
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</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 72. Stroke in studies with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA</td>
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<td>---</td>
<td>0/19</td>
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<tr>
<td>Thrombuser</td>
<td>Thrombuster</td>
<td>---</td>
<td>---</td>
<td>0/14</td>
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</tbody>
</table>

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group
### Table 73. Stroke in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
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<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device</td>
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</table>

Abbreviations: n=number; N=number of participants in the group

### Table 74. Stroke in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>In-hospital stroke n/N</th>
<th>30-day stroke n/N</th>
<th>180-day stroke n/N</th>
<th>365-day stroke n/N</th>
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</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>---</td>
<td>0/164</td>
<td>---</td>
<td>0/154</td>
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<tr>
<td>Kim, 2010</td>
<td>Catheter Aspiration</td>
<td>Thrombus Aspiration Control</td>
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<td>0/370</td>
<td>---</td>
<td>2/353</td>
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<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>---</td>
<td>5/381</td>
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<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices* Control</td>
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<td>12/2917</td>
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<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>1/239</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>5/1021</td>
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</tbody>
</table>

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
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<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE</td>
<td>In-hospital: Re-PCI (TVR, TLR, non-infarct involved vessel or CABG) 180d: TLR</td>
<td>2/100</td>
<td>---</td>
<td>0/100</td>
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<td>Control</td>
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<td>1/96</td>
<td>---</td>
<td>1/96</td>
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<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
<td>TLR</td>
<td>---</td>
<td>---</td>
<td>4/55</td>
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<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>4/56</td>
<td>---</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>---</td>
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<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM)</td>
<td>TVR</td>
<td>---</td>
<td>0/88</td>
<td>5/87*</td>
<td>4/88†</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>TVR</td>
<td>---</td>
<td>0/87</td>
<td>0/88*</td>
<td>5/87†</td>
</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>TLR+TVR</td>
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<td>2/120</td>
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<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver Control</td>
<td>---</td>
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<tr>
<td>Ikari, 2008</td>
<td>TVAC Control</td>
<td>TLR</td>
<td>0/178</td>
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<td>20/170†</td>
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<td>Svilaas, 2008</td>
<td>6F Export Aspiration Catheter Control</td>
<td>TVR</td>
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<td>60/535³</td>
</tr>
<tr>
<td>DeLuca, 2006</td>
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<tr>
<td>Kaltoft, 2006</td>
<td>Rescue Catheter Control</td>
<td>---</td>
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<tr>
<td>Lee, 2006</td>
<td>Export Aspiration Catheter Control</td>
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<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter Control</td>
<td>TVR</td>
<td>1/74</td>
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<td>1/74</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>0/74</td>
<td>---</td>
<td>2/70</td>
<td>---</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Group</td>
<td>Target revascularization definition</td>
<td>In-hospital target revascularization n/N</td>
<td>30-day target revascularization n/N</td>
<td>180-day target revascularization n/N</td>
<td>365-day target revascularization n/N</td>
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</tr>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE Control</td>
<td>TLR</td>
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<tr>
<td>Noel, 2005</td>
<td>Export Control</td>
<td>---</td>
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<td>Dudek, 2004</td>
<td>Rescue System Control</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

*270-day data; †730-day data; ‡240-day data; §365-day data;  
Abbreviations: CABG=coronary artery bypass graft; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TIMI=thrombolysis in myocardial infarction; TLR=target lesion revascularization; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization

Table 76. Target revascularization in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
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<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thromboectmy Control</td>
<td>TVR</td>
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<td>2/256</td>
<td>18/251</td>
<td>22/221*</td>
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<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>TVR</td>
<td>---</td>
<td>2/100</td>
<td>3/100</td>
<td>---</td>
</tr>
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<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>TVR</td>
<td>---</td>
<td>0/101</td>
<td>5/101</td>
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<td>Napodano, 2003</td>
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<td>TVR</td>
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<td>0/46</td>
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</table>

*365-day data
Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization
Table 77. Target revascularization in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
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<td>Filtrap</td>
<td>TLR</td>
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<td>Control</td>
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<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device</td>
<td>TLR</td>
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<td>6/312</td>
<td>---</td>
<td>39/312*</td>
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<td>Control</td>
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<td>2/314</td>
<td>---</td>
<td>22/314*</td>
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<td>Cura, 2007</td>
<td>SpideRX</td>
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<td>6/70</td>
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<td>Guetta, 2007</td>
<td>FilterWire EZ</td>
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<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP</td>
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</tr>
</tbody>
</table>

*450 day data

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization

Table 78. Target revascularization in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
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<tbody>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire</td>
<td>TVR</td>
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<td>1/54</td>
<td>3/54</td>
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<tr>
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<td>Control</td>
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<td>---</td>
<td>1/52</td>
<td>2/52</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>TLR</td>
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<td>2/20</td>
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<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System</td>
<td>TVR</td>
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<td>5/80</td>
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<td>Control</td>
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<tr>
<td>Muramatsu, 2007</td>
<td>GuardWire Plus System</td>
<td>TLR</td>
<td>0/173</td>
<td>0/173</td>
<td>17/173</td>
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<td>1/168</td>
<td>16/168</td>
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<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire</td>
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</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire</td>
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<td>Control</td>
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</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus</td>
<td>TVR</td>
<td>9/246</td>
<td>15/243</td>
<td>13/233</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>6/244</td>
<td>---</td>
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<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

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Table 79. Target revascularization in randomized controlled trials evaluating proximal balloon embolic protection device versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009*</td>
<td>Proxis</td>
<td>Urgent percutaneous TVR</td>
<td>2/141</td>
<td>6/141</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>4/143</td>
<td>7/143</td>
<td>---</td>
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<tr>
<td>Haeck, 2009*</td>
<td>Proxis</td>
<td>Urgent percutaneous TLR</td>
<td>2/141</td>
<td>5/141</td>
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</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>3/143</td>
<td>5/143</td>
<td>---</td>
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</tr>
<tr>
<td>Haeck, 2009*</td>
<td>Proxis</td>
<td>Surgical TVR</td>
<td>1/141</td>
<td>1/141</td>
<td>---</td>
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<td></td>
<td>Control</td>
<td></td>
<td>2/143</td>
<td>3/143</td>
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<td>---</td>
</tr>
</tbody>
</table>
*Data from the same study

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 80. Target revascularization in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire</td>
<td>TVR</td>
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<td>---</td>
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<tr>
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<td>Control</td>
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<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire</td>
<td>Revascularization</td>
<td>0/100</td>
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<td>Control</td>
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<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
<td>---</td>
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<td></td>
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<td>Control</td>
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<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT</td>
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<td>Control</td>
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<td>---</td>
<td>---</td>
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<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire</td>
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<td>Control</td>
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<td>---</td>
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</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire</td>
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<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer</td>
<td>---</td>
<td>0/33</td>
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<tr>
<td></td>
<td></td>
<td>Control</td>
<td></td>
<td>1/33</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>
*Within 3 days of index procedure

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TVR=target vessel revascularization
Table 81. Target revascularization in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>Distal Filter</td>
<td>FilterWire EZ</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Embolic Protection</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2003</td>
<td>Distal Filter</td>
<td>AngioGuard</td>
<td>Revascularization</td>
<td>0/15</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td></td>
<td>Embolic Protection</td>
<td>Control</td>
<td>---</td>
<td>0/16</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 82. Target revascularization in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter Export Medtronic</td>
<td>TVR</td>
<td>---</td>
<td>0/52</td>
<td>---</td>
<td>3/50*</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>TVR</td>
<td>---</td>
<td>1/61</td>
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<td>---</td>
</tr>
</tbody>
</table>

*365-day data
Abbreviations: n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 83. Target revascularization in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
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<td>---</td>
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</tbody>
</table>

F-23
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Rescue or Thrombuster systems PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 84. Target revascularization in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration PA</td>
<td>Thrombuster+Mt PA Thrombuster</td>
<td>Re-intervention of IRA</td>
<td>---</td>
<td>---</td>
<td>4/19</td>
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</tr>
</tbody>
</table>

Abbreviations: IRA=infarct related artery; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention

Table 85. Target revascularization in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Abciximab</td>
<td>Re-PCI</td>
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<td>---</td>
<td>8/57</td>
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</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
Table 86. Target revascularization in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Target revascularization definition</th>
<th>In-hospital target revascularization n/N</th>
<th>30-day target revascularization n/N</th>
<th>180-day target revascularization n/N</th>
<th>365-day target revascularization n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>Any unplanned PCI performed for recurrent symptoms</td>
<td>4/164</td>
<td>7/370</td>
<td>---</td>
<td>12/154</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter Aspiration</td>
<td>Thrombus Aspiration Control</td>
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<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection Device</td>
<td>Distal Protection Device Control</td>
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</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>TVR</td>
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<td>7/381</td>
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<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices* Control</td>
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<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>TVR</td>
<td>5/239</td>
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</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>TVR</td>
<td>28/1021</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuser Catheter, Transvascular Aspiration Catheter, Export Catheter; †270-day data
Abbreviations: n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 87. Major adverse cardiac events in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE Control</td>
<td>Mortality, reinfarction, rePCI</td>
<td>5/100</td>
<td>5/96</td>
<td>5/100†</td>
<td>6/96†</td>
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<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
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<td>8/55</td>
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<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter Control</td>
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<td>---</td>
<td>7/56</td>
<td>---</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Group</td>
<td>MACE definition</td>
<td>In-hospital MACE</td>
<td>30-day MACE</td>
<td>180-day MACE</td>
<td>365-day MACE</td>
</tr>
<tr>
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<td>-------------</td>
<td>-------------</td>
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<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>Cardiac mortality, nonfatal reinfarction and TVR</td>
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<td>---</td>
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</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM) Control</td>
<td>---</td>
<td>---</td>
<td>0/88</td>
<td>4/88†</td>
<td>4/88*</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
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<td>7/120</td>
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<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
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<td>---</td>
<td>5/37</td>
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<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver Control</td>
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<td>10/37</td>
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<td>Ikari, 2008</td>
<td>TVAC Control</td>
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<td>22/170‖</td>
<td>62/175#</td>
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<tr>
<td>Svilas, 2008</td>
<td>6F Export Aspiration Catheter Control</td>
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<td>DeLuca, 2006</td>
<td>Diver CE Control</td>
<td>---</td>
<td>50/531</td>
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<td>109/536*</td>
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<tr>
<td>Kaltorf, 2006</td>
<td>Rescue Catheter Control</td>
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<td>3/35</td>
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<td>Lee, 2006</td>
<td>Export Aspiration Catheter Control</td>
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<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter Control</td>
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<tr>
<td>Burzotta, 2005</td>
<td>Diver CE Control</td>
<td>---</td>
<td>5/48</td>
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</tr>
<tr>
<td>Noel, 2005</td>
<td>Export Control</td>
<td>---</td>
<td>1/24††</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System Control</td>
<td>---</td>
<td>2/26††</td>
<td>---</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Reinfarction and mortality; †Cardiac Mortality, non fatal reinfarction, TVR and stroke; ‡70-Day data; ††730-day data; †240-day data; †*1095-day data; †#365-day data; †‡ no time period specified

Abbreviations: CHF=congestive heart failure; CVA=cerebrovascular accident; n=number; MACE=major adverse cardiac events; MI=myocardial infarction; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TLR=target lesion revascularization; TVAC=Transvascular aspiration catheter; TVR=target vessel revascularization
Table 88. Major adverse cardiac events in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy Control</td>
<td>Mortality, MI, TVR, stroke</td>
<td>---</td>
<td>8/256</td>
<td>28/251</td>
<td>33/22*</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>AngioJet Catheter Control</td>
<td>Mortality, new Q wave MI , emergent CABG, TLR, stroke, stent thrombosis</td>
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<td>16/240</td>
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</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>Major adverse cardiac and cerebral events</td>
<td>---</td>
<td>9/100</td>
<td>13/100</td>
<td>---</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>---</td>
<td>0/50</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>---</td>
<td>0/50</td>
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<td>---</td>
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</tbody>
</table>

*365-day data

Abbreviations: CABG=coronary artery bypass graft; n=number; MACE=major adverse cardiac events; MI=myocardial infarction; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 89. Major adverse cardiac events in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>Mortality, MI , TLR</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kelbaek, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>Mortality, TLR, reinfarction, stroke</td>
<td>---</td>
<td>17/312</td>
<td>22/312*</td>
<td>59/312†</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpiderRx Control</td>
<td>Mortality, reinfarction, HF</td>
<td>---</td>
<td>10/70</td>
<td>10/70</td>
<td>11/70</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>Mortality, non fatal MI, CHF</td>
<td>---</td>
<td>3/51</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>Mortality and MI</td>
<td>---</td>
<td>2/32</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*240-day data
† 450 day data

Abbreviations: CHF=congestive heart failure; HF=heart failure; MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TLR=target lesion revascularization
### Table 90. Major adverse cardiac events in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
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</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Duan, 2010</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire Control</td>
<td>Mortality, reinfarction and ischemia driven TVR</td>
<td>---</td>
<td>2/54</td>
<td>4/54</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>Mortality, MI and TLR</td>
<td>---</td>
<td>2/52</td>
<td>5/52</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>0/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsu, 2007</td>
<td>GuardWire Distal Protection System Control</td>
<td>Mortality, non lethal MI, heart failure, ischemia-driven revascularization</td>
<td>---</td>
<td>3/80</td>
<td>10/80</td>
<td>---</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>0/52</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>Control</td>
<td>0/60</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Stone, 2005*</td>
<td>GuardWire Plus Control</td>
<td>MACE related to ischemic complications</td>
<td>---</td>
<td>14/246</td>
<td>24/243</td>
<td>---</td>
</tr>
<tr>
<td>Stone, 2005*</td>
<td>GuardWire Plus Control</td>
<td>MACE related to LV dysfunction</td>
<td>---</td>
<td>36/246</td>
<td>40/243</td>
<td>---</td>
</tr>
</tbody>
</table>

*Data from a single study

Abbreviations: LV=left ventricular; MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

### Table 91. Major adverse cardiac events in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>Mortality, spontaneous or procedural MI, stroke, percutaneous or surgical TVR</td>
<td>---</td>
<td>6/141</td>
<td>11/141</td>
<td>---</td>
</tr>
<tr>
<td>Haeck, 2009</td>
<td>Control</td>
<td>---</td>
<td>10/143</td>
<td>15/143</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization
### Table 92. Major adverse cardiac events in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>---</td>
<td>---</td>
<td>13/100</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>1/24</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>---</td>
<td>---</td>
<td>2/33</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

### Table 93. Major adverse cardiac events in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EZ Control</td>
<td>Mortality, recurrent MI, emergent CAGB, repeat TVR 9/77 7/74</td>
<td>9/77 8/74</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2003</td>
<td>Distal Filter Embolic Protection</td>
<td>AngioGuard Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: CAGB=coronary artery bypass graft; MACE=Major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization
Table 94. Major adverse cardiac events in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec Catheter</td>
<td>Cardiac mortality, Q and non Q wave MI, TVR</td>
<td>---</td>
<td>2/52</td>
<td>---</td>
<td>5/50*</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Export Medtronic Diver CE catheter</td>
<td>Mortality, MI, TVR, stroke</td>
<td>---</td>
<td>3/51</td>
<td>---</td>
<td>2/48*</td>
</tr>
</tbody>
</table>

*365-day data

Abbreviation: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization

Table 95. Major adverse cardiac events in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or Thrombuster systems PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 96. Major adverse cardiac events in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA Thrombuster</td>
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<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MACE=major adverse cardiac events; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group
### Table 97. Major adverse cardiac events in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>---</td>
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</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Thrombectomy + Stenting + Distal Protection Device Thrombectomy + Stenting</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

### Table 98. Major adverse cardiac events in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>MACE definition</th>
<th>In-hospital MACE n/N</th>
<th>30-day MACE n/N</th>
<th>180-day MACE n/N</th>
<th>365-day MACE n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>Death, re-infarction, revascularization, stroke</td>
<td>14/164</td>
<td>25/370</td>
<td>---</td>
<td>21/154</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter Aspiration</td>
<td>Thrombus Aspiration Control</td>
<td>---</td>
<td>---</td>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>Mortality, re-infarction, TVR for ischemia, stroke</td>
<td>21/381</td>
<td>155/2917</td>
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</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices* Control</td>
<td>---</td>
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</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>Mortality, re-infarction, TVR, stroke</td>
<td>18/239</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>Mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event</td>
<td>---</td>
<td>---</td>
<td>28/200†</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter; †270-day data

Abbreviations: MACE=major adverse cardiac events; MI=myocardial infarction; n=number; N=number of participants in the group; TVR=target vessel revascularization
Table 99. ST-segment resolution in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE Control</td>
<td>50/100 39/96 70%</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
<td>39/55 22/56 70%</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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</tr>
<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter Control</td>
<td>11/19 11/24 70%</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td></td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>67/76 33/76 70%</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
</tbody>
</table>

F-32
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM) Control</td>
<td>70/88 34/87</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>---</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>88/120 84/129</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver Control</td>
<td>---</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Group</td>
<td>Composite STSR Definition* (n/N)</td>
<td>Immediately after PCI (n/N)</td>
<td>60 minutes after PCI</td>
<td>90 minutes after PCI</td>
<td>Other Times after PCI</td>
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<td>----------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>TVAC Control</td>
<td>37/115 28/105</td>
<td>70% &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>39/115 39/115</td>
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<td>6F Export Aspiration Catheter Control</td>
<td>275/486 219/496</td>
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<td>DeLuca, 2006</td>
<td>Diver CE Control</td>
<td>31/38 21/38</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Kaltott, 2006</td>
<td>Rescue Catheter Control</td>
<td>37/93 34/89</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Lee, 2006</td>
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<td>40/67 24/66</td>
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<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter Control</td>
<td>50/74 37/74</td>
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<td>10/74 27/74 37/74</td>
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<td>Burzotta, 2005</td>
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<td>Noel, 2005</td>
<td>Export Control</td>
<td>12/24 3/26</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>3/26 16/26</td>
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<tr>
<td>Study, Year</td>
<td>Group</td>
<td>Composite STSR Definition* (n/N)</td>
<td>Immediately after PCI</td>
<td>60 minutes after PCI</td>
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<tr>
<td>Dudek, 2004</td>
<td>Rescue System Control</td>
<td>27/40</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>6/40 6/40 27/40</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>Others</td>
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<td>8/32</td>
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<td>8/32 16/32 8/32</td>
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*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †24 hours after PCI; ‡Post procedure, time period not specified; §>50% Resolution; ||3-6 hours after PCI; ¶30-60 minutes after PCI; #6 hours after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter
Table 10. ST-segment resolution in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STS Definition* (n/N)</th>
<th>Immediately after PCI</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>189/240†‡</td>
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<tr>
<td>Ali, 2006</td>
<td>AngioJet Catheter Control</td>
<td>105/176 111/164</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>18/164§ 35/164§ 130/164§ 130/164§†</td>
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<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>61/90 50/95</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>45/50 36/50</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>38/46 24/46</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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*Composite STS: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †30 minutes after PCI; ‡>50% Resolution; §90 minutes (allowed up to 180 minutes) after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
<table>
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<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
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<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>9/19</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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<td>Control</td>
<td>4/17</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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<tr>
<td>Kelbaek, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>230/302</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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<td>Control</td>
<td>218/301</td>
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<td>Cura, 2007</td>
<td>SpiderRX Control</td>
<td>43/70</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>33/51</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>20/30</td>
<td>&lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others &lt;30% 30-70% &gt;70% Others</td>
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*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if >70% is unavailable, >50% at 60 minutes; †100% Resolution; ‡Post procedure, time period not specified; §>50% Resolution
Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
Table 102. ST-segment resolution in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI (n/N)</th>
<th>90 minutes after PCI (n/N)</th>
<th>Other Times after PCI (n/N)</th>
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<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus Control</td>
<td>...</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Pan, 2010</td>
<td>PercuSurge Guardwire Control</td>
<td>61/90</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Tahk, 2008</td>
<td>PercuSurge Guardwire Control</td>
<td>50/95</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Hahn, 2007</td>
<td>GuardWire Control</td>
<td>16/19 9/20</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Matsuo, 2007</td>
<td>GuardWire Distal Protection System Control</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Muramatsu, 2007</td>
<td>GuardWire Plus System Control</td>
<td>66/173 60/168</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Zhou, 2007</td>
<td>PercuSurge Guardwire Control</td>
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<td>Okamura, 2005</td>
<td>PercuSurge Guardwire Control</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
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<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus Control</td>
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<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable; >50% at 60 minutes; 180 minutes after PCI;
†‡50% Resolution; §30 minutes after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
Table 103. ST-segment resolution in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patient with ST-segment elevation myocardial infarction

<table>
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<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
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<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
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<tr>
<td>Haeck, 2009</td>
<td>Proxi Control</td>
<td>101/129 &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
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<td>Control</td>
<td></td>
<td>93/129</td>
<td>85/129</td>
<td>91/131</td>
<td>93/129</td>
<td>97/131</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †30 minutes after PCI; ‡≥70% at 120 minutes after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 104. ST-segment resolution in randomized controlled trials evaluating thrombectomy or distal protection devices versus control in mixed acute coronary syndromes population

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>--- &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>27/34†</td>
<td>27/34†</td>
<td>27/34†</td>
<td>27/34†</td>
<td>27/34†</td>
<td>27/34†</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>--- &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>--- &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>--- &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>15/30‡</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>--- &lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †30 minutes after PCI; ‡≥70% at 120 minutes after PCI

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
### Table 105. ST-segment resolution in randomized controlled trials evaluating thrombectomy or distal protection devices versus control in unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>&lt;30% 30-70% &gt;70% Others 19/23 12/23</td>
<td>&lt;30% 30-70% &gt;70% Others 19/23 12/23</td>
<td>&lt;30% 30-70% &gt;70% Others 19/23 12/23</td>
<td>&lt;30% 30-70% &gt;70% Others 19/23 12/23</td>
<td>&lt;30% 30-70% &gt;70% Others 19/23 12/23</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; *Early ST-segment resolution; †>50% Resolution

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

### Table 106. ST-segment resolution in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration Catheter</td>
<td>Diver Invatec catheter Export Medtronic</td>
<td>34/52 42/51</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others 34/52 42/51</td>
<td>&lt;30% 30-70% &gt;70% Others 34/52 42/51</td>
<td>&lt;30% 30-70% &gt;70% Others 34/52 42/51</td>
</tr>
</tbody>
</table>

*Composites STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration Distal Balloon Embolic Protection</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>35/61</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>36/61</td>
<td>35/61</td>
<td>36/61†</td>
<td>35/61†</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35/61†</td>
<td>36/61†</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; † Measured immediately, 90 minutes and 6 hours

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 107. ST-segment resolution in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>10/19</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13/19</td>
<td>10/19†</td>
<td>13/23†</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10/19†</td>
<td>13/23†</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Ozaki, 2006 | Catheter Aspiration Distal Balloon Embolic Protection | Rescue or Thrombuster systems PercuSurge GuardWire Control | ---                           | <30% 30-70% >70% Others    | <30% 30-70% >70% Others | <30% 30-70% >70% Others | <30% 30-70% >70% Others |
|             |                 |       |                                 | ---                         | ---                  | ---                  | ---                  |
|             |                 |       |                                 | ---                         | ---                  |                     |                     |

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; †>50% Resolution

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

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Table 108. ST-segment resolution in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA Thrombuster</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
</tr>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>29/57</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>12/57 16/57 29/57</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy +Stenting +Distal Protection Device Thrombectomy+Stenting</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: MtPA=Mutant Plasminogen Activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution

Table 109. ST-segment resolution in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI (n/N)</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>29/57</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>12/57 16/57 29/57</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy +Stenting +Distal Protection Device Thrombectomy+Stenting</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
Table 110. ST-segment resolution in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Composite STSR Definition* (n/N)</th>
<th>Immediately after PCI</th>
<th>60 minutes after PCI</th>
<th>90 minutes after PCI</th>
<th>Other Times after PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter aspiration</td>
<td>Thrombus aspiration Control</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter aspiration</td>
<td>Aspiration Catheter Control</td>
<td>153/318</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>153/318</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter aspiration</td>
<td>Multiple devices</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>---</td>
<td>&lt;30% 30-70% &gt;70% Others</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Composite STSR: >70% at 60 minutes, if this is unavailable, >70% at 90 minutes or 30 minutes after PCI, if 70% is unavailable, >50% at 60 minutes; † Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; STSR=ST-segment resolution
### Table 111. Ejection fraction of randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006*</td>
<td>Catheter Aspiration</td>
<td>Thrombuser+MtPA</td>
<td>17</td>
<td>1-3d</td>
<td>53 (12)</td>
<td>0.31</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombuser</td>
<td>16</td>
<td></td>
<td>48 (12)</td>
<td></td>
</tr>
<tr>
<td>Yamamoto, 2006*</td>
<td>Catheter Aspiration</td>
<td>Thrombuser+MtPA</td>
<td>18</td>
<td>180d</td>
<td>59 (8)</td>
<td>0.57</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombuser</td>
<td>12</td>
<td></td>
<td>56 (10)</td>
<td></td>
</tr>
</tbody>
</table>

*Data from a single study; MtPA=mutant plasminogen activator

Abbreviations: d=days; EF=ejection fraction; MtPA=mutant plasminogen activator; n=number of participants included in the analysis of ejection fraction; SD=standard deviation

### Table 112. Ejection fraction in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>n</th>
<th>Time EF Measured</th>
<th>Mean EF (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter aspiration</td>
<td>Thrombus aspiration</td>
<td>429</td>
<td>Post-PCI</td>
<td>49 (11)</td>
<td>0.0005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>429</td>
<td></td>
<td>53 (11)</td>
<td></td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices*</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical thrombectomy</td>
<td>AngioJet XMI or XVG</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuser Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: EF=ejection fraction; n=number of participants included in the analysis of ejection fraction; PCI=percutaneous coronary intervention; SD=standard deviation
### Table 113. Intermediate health outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE Control</td>
<td>67/88</td>
<td>86/98</td>
<td>---</td>
<td>10/98</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter Control</td>
<td>51/55*</td>
<td>53/55</td>
<td>4/55</td>
<td>2/55</td>
</tr>
<tr>
<td>Lipiecki, 2009</td>
<td>Export Catheter Control</td>
<td>40/56*</td>
<td>46/56</td>
<td>14/56</td>
<td>10/56</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC Control</td>
<td>68/75*</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM) Control</td>
<td>62/88</td>
<td>88/88</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter Control</td>
<td>43/120</td>
<td>98/120</td>
<td>11/120</td>
<td>4/120</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>TVAC Control</td>
<td>82/178</td>
<td>156/178</td>
<td>28/178</td>
<td>22/178†</td>
</tr>
<tr>
<td>Svilasas, 2006</td>
<td>6F Export Aspiration Catheter Control</td>
<td>224/490</td>
<td>431/501</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>DeLuca, 2006</td>
<td>Diver CE Control</td>
<td>14/38</td>
<td>30/38</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kaltoft, 2006</td>
<td>Rescue Catheter Control</td>
<td>---</td>
<td>93/104</td>
<td>9/104</td>
<td>---</td>
</tr>
<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter Control</td>
<td>65/74</td>
<td>66/74</td>
<td>4/74</td>
<td>2/74</td>
</tr>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE Control</td>
<td>21/50</td>
<td>41/50</td>
<td>4/50</td>
<td>4/48</td>
</tr>
<tr>
<td>Noel, 2005</td>
<td>Export Control</td>
<td>---</td>
<td>23/24</td>
<td>---</td>
<td>2/24‡</td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System Control</td>
<td>22/40</td>
<td>30/35</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*MBG≥2; TIMI<3; †Slow flow/no reflow/distal embolization

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TAC=Thrombectomy Aspiration Catheter; TIMI=thrombolysis in myocardial infarction; TVAC=Transvascular aspiration catheter
### Table 114. Intermediate health outcomes in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy Control</td>
<td>155/215</td>
<td>203/252</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>29/92</td>
<td>93/97</td>
<td>2/97</td>
<td>3/97</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>33/46</td>
<td>43/46</td>
<td>2/46</td>
<td>1/46</td>
</tr>
</tbody>
</table>

**Abbreviations:** MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

### Table 115. Intermediate health outcomes in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>---</td>
<td>17/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>---</td>
<td>295/312</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpiderRX Control</td>
<td>---</td>
<td>29/32</td>
<td>---</td>
<td>1/32*</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>---</td>
<td>27/28</td>
<td>---</td>
<td>3/28*</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>33/49</td>
<td>43/49</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Slow flow/no reflow/distal embolization

**Abbreviations:** MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction
Table 116. Intermediate health outcomes in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus</td>
<td>---</td>
<td>44/46</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>39/50</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire</td>
<td>---</td>
<td>46/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>36/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire</td>
<td>39/60</td>
<td>58/60</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>20/56</td>
<td>43/56</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>6/19</td>
<td>18/19</td>
<td>4/19</td>
<td>1/19</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>5/20</td>
<td>19/20</td>
<td>6/20</td>
<td>1/20</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>32/74</td>
<td>56/74</td>
<td>4/74</td>
<td>2/74</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>32/158</td>
<td>131/168</td>
<td>7/168</td>
<td>6/168</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire</td>
<td>34/52</td>
<td>50/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>20/60</td>
<td>48/60</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>8/8</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>8/8</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire Plus</td>
<td>138/226</td>
<td>219/239</td>
<td>22/237</td>
<td>1/238</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>120/227</td>
<td>215/241</td>
<td>14/242</td>
<td>6/242</td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 117. Intermediate health outcomes in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>113/141</td>
<td>131/141</td>
<td>14/141</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>117/143</td>
<td>125/143</td>
<td>20/143</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

F-47
Table 118. Intermediate health outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire</td>
<td>24/30</td>
<td>26/30</td>
<td>0/30</td>
<td>9/30</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire</td>
<td>64/100*</td>
<td>93/100</td>
<td>3/100</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
<td>11/28</td>
<td>24/28</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT</td>
<td>---</td>
<td>121/129</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire</td>
<td>24/34</td>
<td>34/34</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer</td>
<td>---</td>
<td>27/30</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*MBG>1

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 119. Intermediate health outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2006</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire EZ</td>
<td>---</td>
<td>72/77</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2003</td>
<td>Distal Filter Embolic Protection</td>
<td>AngioGuard</td>
<td>---</td>
<td>15/15</td>
<td>3/15</td>
<td>0/15</td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction
Table 120. Intermediate health outcomes in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter Export Medtronic</td>
<td>16/52</td>
<td>38/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter GuardWire Plus</td>
<td>22/51</td>
<td>42/51</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>
| *Slow flow/no reflow/distal embolization

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 121. Intermediate health outcomes in randomized controlled trials with selective inclusion/exclusion criteria in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>12/19</td>
<td>19/19</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>14/23</td>
<td>23/23</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ozeki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or Thrombuster systems</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 122. Intermediate health outcomes in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA Thrombuser</td>
<td>13/23</td>
<td>22/23</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction
### Table 123. Intermediate health outcomes in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>34/55</td>
<td>51/57</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device</td>
<td>---</td>
<td>26/30</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

### Table 124. Intermediate health outcomes in observational studies

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Post-PCI MBG-3 (n/N)</th>
<th>Post-PCI TIMI-3 (n/N)</th>
<th>Distal Embolization (n/N)</th>
<th>No reflow (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter aspiration</td>
<td>Export Control</td>
<td>---</td>
<td>147/165</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter aspiration</td>
<td>Thrombus aspiration Control</td>
<td>---</td>
<td>379/429</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device Control</td>
<td>---</td>
<td>371/429</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter Control</td>
<td>---</td>
<td>---</td>
<td>29/318 93/2915</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices* Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter Control</td>
<td>---</td>
<td>205/239</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet Control</td>
<td>---</td>
<td>170/200</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>Export Thrombectomy Catheter</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Lipietzki, 2009</td>
<td>Export Catheter</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Moura, 2009</td>
<td>TAC</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>Export Medtronic (EM)</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Export Aspiration Catheter</td>
<td>0/37</td>
<td>---</td>
<td>1/120</td>
<td>2/120</td>
</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Export Aspiration Catheter</td>
<td>---</td>
<td>---</td>
<td>0/129</td>
<td>2/129</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Rescue/Diver</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>TVAC</td>
<td>4/178</td>
<td>0/178</td>
<td>---</td>
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<tr>
<td>Svilaas, 2008</td>
<td>6F Export Aspiration Catheter</td>
<td>0/502</td>
<td>---</td>
<td>---</td>
<td>5/502</td>
</tr>
<tr>
<td>DeLuca, 2006</td>
<td>Diver CE</td>
<td>1/38</td>
<td>---</td>
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<tr>
<td>Kaltoft, 2006</td>
<td>Rescue Catheter</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Lee, 2006</td>
<td>Export Aspiration Catheter</td>
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<tr>
<td>Silva-Orrego, 2006</td>
<td>Pronto Extraction Catheter</td>
<td>0/74</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>Burzotta, 2005</td>
<td>Diver CE</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Noel, 2005</td>
<td>Export</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Rescue System</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

**Abbreviations:** n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter
### Table 126. Adverse outcomes in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>AngioJet Rheolytic Thrombectomy Control</td>
<td>---</td>
<td>0/256</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>X-Sizer Catheter Control</td>
<td>---</td>
<td>0/100</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>AngioJet Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>X-Sizer Catheter Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>1/46</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 127. Adverse outcomes in randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Filtrap Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>FilterWire-EZ or SpiderX protection device Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>SpideRX Control</td>
<td>0/70</td>
<td>0/70</td>
<td>0/70</td>
<td>0/70</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>FilterWire EZ Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>AngioGuardXP Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
Table 128. Adverse outcomes in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>PercuSurge Guardwire Plus</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>PercuSurge Guardwire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>GuardWire</td>
<td>---</td>
<td>---</td>
<td>2/80</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>1/74</td>
<td>---</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>GuardWire Plus</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>PercuSurge GuardWire</td>
<td>0/52</td>
<td>0/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0/60</td>
<td>0/60</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>PercuSurge GuardWire</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>GuardWire</td>
<td>---</td>
<td>---</td>
<td>34/238</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0/234</td>
<td>6/242</td>
<td>38/242</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 129. Adverse outcomes in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Proxis</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

Table 130. Adverse outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
</table>

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### Table 131. Adverse outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>0/30</td>
<td>---</td>
</tr>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Gick, 2005</td>
<td>Distal Filter Embolic Protection</td>
<td>FilterWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2005</td>
<td>Catheter Aspiration</td>
<td>Diver CE Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kunii, 2004</td>
<td>Catheter Aspiration</td>
<td>Rescue PT Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nanasato, 2004</td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Matsushita, 2003</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beran, 2002</td>
<td>Mechanical Thrombectomy</td>
<td>X-sizer Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 132. Adverse outcomes in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Diver Invatec catheter Export Medtronic</td>
<td>0/52</td>
<td>0/52</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Sardella, 2008</td>
<td>Catheter Aspiration</td>
<td>Export Medtronic</td>
<td>1/51</td>
<td>0/51</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yan, 2007</td>
<td>Catheter Aspiration</td>
<td>Diver CE catheter</td>
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<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>GuardWire Plus</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 133. Adverse outcomes in randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wita, 2009</td>
<td>Catheter Aspiration</td>
<td>Diver CE</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td></td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Catheter Aspiration</td>
<td>Rescue or Thrombuster systems</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge GuardWire Control</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: n=number; N=number of participants in the group

### Table 134. Adverse outcomes in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yamamoto, 2006</td>
<td>Catheter Aspiration</td>
<td>Thrombuster+MtPA Thrombuster</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

Abbreviations: MtPA=mutant plasminogen activator; n=number; N=number of participants in the group

### Table 135. Adverse outcomes in randomized controlled trials with unique comparison in patients with mixed acute coronary syndromes

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ochala, 2007</td>
<td>Distal Balloon Embolic Protection</td>
<td>PercuSurge Guardwire Abciximab</td>
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<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

F-55
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Device Category</th>
<th>Group</th>
<th>Coronary dissection (n/N)</th>
<th>Perforation (n/N)</th>
<th>Vessel spasm (n/N)</th>
<th>Side branch closure (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kanaya, 2003</td>
<td>Thrombectomy + Distal Protection Device</td>
<td>Thrombectomy + Stenting + Distal Protection Device</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Beaudoin, 2010</td>
<td>Catheter Aspiration</td>
<td>Export</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Catheter aspiration</td>
<td>Thrombus aspiration</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Distal Embolic Protection</td>
<td>Distal Protection Device</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Catheter Aspiration</td>
<td>Aspiration Catheter</td>
<td>21/318 154/2915</td>
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<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Nakatani, 2007</td>
<td>Catheter Aspiration</td>
<td>Multiple devices*</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>Chinnaiyan, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet XMI or XVG Catheter</td>
<td>--- 0/239</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Simonton, 2006</td>
<td>Mechanical Thrombectomy</td>
<td>AngioJet</td>
<td>--- 2/1021</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

*Rescue Catheter, Trombuser Catheter, Transvascular Aspiration Catheter, Export Catheter

Table 136. Adverse outcomes in observational studies

Table 137. Impact of catheter aspiration devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>8.08</td>
<td>0.70 (0.47 to 1.03)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.80</td>
<td>0.61 (0.36 to 1.04)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.79</td>
<td>3.18 (0.73 to 13.88)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>9.48</td>
<td>0.79 (0.61 to 1.02)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>12.66</td>
<td>0.73 (0.61 to 0.88)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events
### Table 138. Impact of mechanical thrombectomy devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>7.80</td>
<td>1.19 (0.51 to 2.76)</td>
<td>54.9</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.98</td>
<td>0.71 (0.27 to 1.85)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>5.79</td>
<td>2.42 (0.75 to 7.78)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6.22</td>
<td>0.87 (0.36 to 2.10)</td>
<td>39.2%</td>
</tr>
<tr>
<td>MACE</td>
<td>6.22</td>
<td>1.23 (0.50 to 3.01)</td>
<td>79.9%</td>
</tr>
</tbody>
</table>

**Abbreviations:** CI=confidence interval; MACE=major adverse cardiac events

### Table 139. Impact of distal filter embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>11.49</td>
<td>0.97 (0.53 to 1.79)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>11.93</td>
<td>0.56 (0.06 to 5.02)</td>
<td>60%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>1.51 (0.30 to 7.52)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>13.36</td>
<td>1.61 (1.03 to 2.54)</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>11.49</td>
<td>1.36 (0.98 to 1.89)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Results based on a single trial

**Abbreviations:** CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

### Table 140. Impact of distal balloon embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6</td>
<td>0.82 (0.45 to 1.51)</td>
<td>2.5%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>6</td>
<td>0.67 (0.29 to 1.57)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>0.48 (0.10 to 2.22)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6</td>
<td>0.93 (0.61 to 1.42)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>6</td>
<td>0.87 (0.64 to 1.19)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result based on a single trial

**Abbreviations:** CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable
Table 141. Impact of proximal balloon embolic protection devices versus control on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>6</td>
<td>0.51 (0.11 to 2.33)*</td>
<td>NA</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>6</td>
<td>1.01 (0.24 to 4.33)*</td>
<td>NA</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>0.20 (0 to 1.93)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>6</td>
<td>0.71 (0.29 to 1.75)*</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>6</td>
<td>0.74 (0.36 to 1.54)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Results based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 142. Impact of embolic protection devices combined on final health outcomes using the maximal duration of followup in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>8.31</td>
<td>0.87 (0.57 to 1.31)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>8.27</td>
<td>0.83 (0.45 to 1.55)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>3.74</td>
<td>0.68 (0.22 to 2.11)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>8.60</td>
<td>1.11 (0.80 to 1.52)</td>
<td>10%</td>
</tr>
<tr>
<td>MACE</td>
<td>8.15</td>
<td>1.03 (0.82 to 1.29)</td>
<td>4%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 143. Impact of catheter aspiration devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0.79</td>
<td>0.65 (0.39 to 1.10)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0.77</td>
<td>0.55 (0.24 to 1.25)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.79</td>
<td>3.18 (0.73 to 13.88)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>0.70</td>
<td>0.85 (0.53 to 1.38)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>0.79</td>
<td>0.80 (0.57 to 1.12)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events
**Table 144. Impact of mechanical thrombectomy devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>1.25 (0.47 to 3.32)</td>
<td>48.7%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>0.63 (0.21 to 1.96)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>1.89 (0.55 to 6.48)</td>
<td>0%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>1.62 (0.21 to 12.55)</td>
<td>62%</td>
</tr>
<tr>
<td>MACE</td>
<td>1</td>
<td>1.28 (0.37 to 4.38)</td>
<td>80.4%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

**Table 145. Impact of distal filter embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>1.02 (0.50 to 2.08)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>0.73 (0.12 to 4.44)</td>
<td>44.3%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>1.51 (0.30 to 7.52)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>3.02 (0.61 to 14.84)</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>1</td>
<td>1.29 (0.77 to 2.15)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Results based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

**Table 146. Impact of distal balloon embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction**

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>0.64 (0.30 to 1.39)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>0.85 (0.32 to 2.23)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>0.11 (0 to 0.94)*</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>1.38 (0.55 to 3.50)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>1</td>
<td>0.74 (0.44 to 1.23)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Results based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable
Table 147. Impact of proximal balloon embolic protection devices versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>1.01 (0.14 to 7.10)</td>
<td>NA</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>0.68 (0.11 to 3.99)</td>
<td>NA</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>0.34 (0.01 to 8.23)</td>
<td>NA</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>0.51 (0.13 to 1.99)</td>
<td>NA</td>
</tr>
<tr>
<td>MACE</td>
<td>1</td>
<td>0.61 (0.23 to 1.63)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Results based on a single trial
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

Table 148. Impact of embolic protection devices combined versus control on final health outcomes at ≤ 30 days in randomized controlled trials evaluating patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Final Health Outcome</th>
<th>Weighted Mean Followup (months)</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>0.84 (0.50 to 1.39)</td>
<td>0%</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>0.83 (0.41 to 1.69)</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>0.56 (0.11 to 2.84)</td>
<td>22.1%</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>1.24 (0.62 to 2.48)</td>
<td>0%</td>
</tr>
<tr>
<td>MACE</td>
<td>1</td>
<td>0.92 (0.66 to 1.30)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events

Table 149. In-hospital mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.81 (0.23 to 2.86)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.00 (0.24 to 4.16)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.69 (0.24 to 2.03)*</td>
<td>NA</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.69 (0.24 to 2.03)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial; * Risk could not be calculated because no trials evaluated this outcome
Abbreviations: CI=confidence interval; NA=not applicable

F-60
### Table 150. 30-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.61 (0.35 to 1.07)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.25 (0.47 to 3.32)</td>
<td>48.7%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.02 (0.50 to 2.08)</td>
<td>0%</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.64 (0.30 to 1.39)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Device</td>
<td>1.01 (0.18 to 5.69)*</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.84 (0.50 to 1.39)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

### Table 151. 180-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.89 (0.31 to 2.51)</td>
<td>2.8%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.35 (0.53 to 3.44)</td>
<td>58.4%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.25 (0.38 to 4.16)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.86 (0.48 to 1.57)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.51 (0.11 to 2.33)</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.87 (0.52 to 1.46)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

### Table 152. 365-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.62 (0.39 to 0.98)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.50 (0.21 to 1.17)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>0.87 (0.43 to 1.78)†</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.87 (0.43 to 1.78)†</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome
† based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable
### Table 153. In-hospital myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.32 (0.03 to 3.06)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.00 (0.11 to 9.41)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---†</td>
<td>---†</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.32 (0.00 to 3.71)*</td>
<td>NA</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---†</td>
<td>---†</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.32 (0.00 to 3.71)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial; †Risk could not be calculated because no trials evaluated this outcome.

Abbreviations: CI=confidence interval; NA=not applicable.

### Table 154. 30-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.60 (0.25 to 1.45)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.63 (0.21 to 1.96)</td>
<td>0%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>0.73 (0.12 to 4.44)</td>
<td>44.3%</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.85 (0.32 to 2.23)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.68 (0.14 to 3.34)*</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.83 (0.41 to 1.69)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial.

Abbreviations: CI=confidence interval; NA=not applicable.
Table 155. 180-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.70 (0.24 to 1.99)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.57 (0.17 to 1.92)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>0.09 (0 to 0.74)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.67 (0.29 to 1.57)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Device</td>
<td>1.01 (0.24, 4.33)</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.65 (0.31 to 1.33)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 156. 365-day myocardial infarction in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.51 (0.26 to 1.00)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.66 (0.13 to 3.29)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>2.35 (0.61 to 8.90)†</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>2.35 (0.61 to 8.90)†</td>
<td>NA</td>
</tr>
</tbody>
</table>

* Risk could not be calculated because no trials evaluated this outcome
† Based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

Table 157. In-hospital stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>4.94 (0.52 to infinity)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>---*</td>
<td>---*</td>
</tr>
</tbody>
</table>

* Risk could not be calculated because one trial evaluated this outcome and no events occurred; † Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable
### Table 158. 30-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>2.77 (0.51 to 14.98)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.89 (0.55 to 6.48)</td>
<td>0%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.51 (0.30 to 7.52)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.11 (0 to 0.94)*</td>
<td>NA</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.34 (0 to 3.87)*</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.56 (0.11 to 2.84)</td>
<td>22.1%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

### Table 159. 180-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>2.05 (0.27 to 15.78)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.48 (0.10 to 2.22)*</td>
<td>NA</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.20 (0.00 to 1.93)</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.39 (0.09 to 1.71)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

### Table 160. 365-day stroke in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>1.99 (0.26 to 15.14)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>---*</td>
<td>---*</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; NA=not applicable
### Table 161. In-hospital target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>1.35 (0.26 to 6.94)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---†</td>
<td>---†</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.32 (0.00 to 3.71)†</td>
<td>NA</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---†</td>
<td>---†</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.32 (0.00 to 3.71)‡</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Risk could not be calculated because no trials evaluated this outcome; ‡Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

### Table 162. 30-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>0.82 (0.50 to 1.35)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>1.62 (0.21 to 12.55)</td>
<td>62%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>3.02 (0.70 to 13.01)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>1.38 (0.55 to 3.50)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.51 (0.14 to 1.81)*</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>1.24 (0.62 to 2.48)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

### Table 163. 180-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>0.62 (0.40 to 0.96)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>0.55 (0.33 to 0.92)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.00 (0.35 to 2.82)†</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.93 (0.61 to 1.42)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.71 (0.29 to 1.75)</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.90 (0.63 to 1.30)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable
### Table 164. 365-day target revascularization in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration Devices</td>
<td>0.87 (0.63 to 1.19)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy Devices</td>
<td>0.68 (0.41 to 1.13)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.78 (1.09 to 2.93)$^\dagger$</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>1.78 (1.09 to 2.93)$^\dagger$</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome
$^\dagger$ Based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable

### Table 165. In-hospital MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.97 (0.36 to 2.58)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>---*</td>
<td>---*</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome; $^\dagger$ Risk could not be calculated because one trial evaluated this outcome and no events occurred

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable

### Table 166. 30-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.79 (0.56 to 1.13)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>1.28 (0.37 to 4.38)</td>
<td>80.4%</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.29 (0.77 to 2.15)</td>
<td>0%</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.74 (0.44 to 1.23)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.61 (0.23 to 1.57)$^*$</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.92 (0.66 to 1.30)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable
### Table 167. 180-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.66 (0.47 to 0.94)</td>
<td>0%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.71 (0.41 to 1.20)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.10 (0.68 to 1.78)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>0.87 (0.64 to 1.19)</td>
<td>0%</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>0.74 (0.36 to 1.54)</td>
<td>NA</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>0.91 (0.71 to 1.16)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable.

### Table 168. 365-day MACE in randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Aspiration</td>
<td>0.61 (0.26 to 1.41)</td>
<td>NA</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>0.66 (0.44 to 0.97)</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Filter Embolic Protection Devices</td>
<td>1.48 (1.03 to 2.15)†</td>
<td>NA</td>
</tr>
<tr>
<td>Distal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Proximal Balloon Embolic Protection Devices</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Embolic Protection Devices Combined</td>
<td>1.48 (1.03 to 2.15)†</td>
<td>NA</td>
</tr>
</tbody>
</table>

* Risk could not be calculated because no trials evaluated this outcome.
† Based on a single trial.
Abbreviations: CI=confidence interval; MACE=major adverse cardiac events; NA=not applicable.

### Table 169. Impact of catheter aspiration devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>$I^2$ for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.75 (1.44 to 2.14)</td>
<td>69.2%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.07 (1.04 to 1.11)</td>
<td>0%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.48 (0.34 to 0.66)</td>
<td>33.7%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.45 (0.27 to 0.75)</td>
<td>22.3%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.39 (1.21 to 1.61)</td>
<td>60.4%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction.
Table 170. Impact of mechanical thrombectomy devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.07 (0.80 to 1.43)</td>
<td>76.5%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>0.98 (0.92 to 1.04)</td>
<td>67.5%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.44 (0.17 to 1.12)</td>
<td>41.6%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.50 (0.17 to 1.48)</td>
<td>41.7%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.16 (0.99 to 1.36)</td>
<td>75.1%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 171. Impact of distal filter embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>0.97 (0.81 to 1.15)</td>
<td>NA</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.02 (0.90 to 1.15)</td>
<td>70.2%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.63 (0.22 to 1.82)</td>
<td>NA</td>
</tr>
<tr>
<td>No reflow</td>
<td>1.00 (0.18 to 5.55)*</td>
<td>NA</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.05 (0.96 to 1.14)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; NA=not applicable; TIMI=thrombolysis in myocardial infarction

Table 172. Impact of distal balloon embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.39 (1.15 to 1.69)</td>
<td>43.5%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.09 (1.01 to 1.17)</td>
<td>59.7%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>1.10 (0.67 to 1.81)</td>
<td>5.8%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.51 (0.19 to 1.33)</td>
<td>0%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.08 (0.91 to 1.29)</td>
<td>41.2%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction
Table 173. Impact of proximal balloon embolic protection devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>( I^2 ) for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>0.98 (0.88 to 1.10)*</td>
<td>NA</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.06 (0.98 to 1.16)*</td>
<td>NA</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.71 (0.38 to 1.33)*</td>
<td>NA</td>
</tr>
<tr>
<td>No reflow</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.11 (0.97 to 1.28)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial; \(^{\dagger}\) Risk could not be calculated because no trials evaluated this outcome

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; NA=not applicable; TIMI=thrombolysis in myocardial infarction

Table 174. Impact of embolic protection devices combined versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Intermediate health outcomes</th>
<th>Relative Risk (95% CI)</th>
<th>( I^2 ) for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG-3</td>
<td>1.20 (1.02 to 1.40)</td>
<td>68.2%</td>
</tr>
<tr>
<td>TIMI-3</td>
<td>1.06 (1.01 to 1.12)</td>
<td>55.4%</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0.91 (0.64 to 1.30)</td>
<td>0.2%</td>
</tr>
<tr>
<td>No reflow</td>
<td>0.58 (0.25 to 1.37)</td>
<td>0%</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1.06 (1.00 to 1.13)</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviations: CI=confidence interval; MBG=myocardial blush grade; TIMI=thrombolysis in myocardial infarction

Table 175. Impact of catheter aspiration devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>( I^2 ) for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>0.30 (0.12 to 0.75)</td>
<td>0%</td>
</tr>
<tr>
<td>Perforation</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>1.19 (0.40 to 3.54)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial; \(^{\dagger}\) Risk could not be calculated because one trial evaluated the outcome and no events occurred

Abbreviations: CI=confidence interval; NA=not applicable

Table 176. Impact of mechanical thrombectomy devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>( I^2 ) for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>1.51 (0.57 to 4.01)*</td>
<td>NA</td>
</tr>
<tr>
<td>Perforation</td>
<td>1.04 (0.15 to 7.04)</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>1.00 (0.11 to 9.41)*</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Result is based on a single trial

Abbreviations: CI=confidence interval; NA=not applicable
Table 177. Impact of distal filter embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Perforation</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.33 (0.00 to 3.80)†</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Table 178. Impact of distal balloon embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Perforation</td>
<td>5.11 (0.53 to infinity)†</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.93 (0.61 to 1.42)</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because one trial evaluated this outcome and no events occurred; †Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable

Table 179. Impact of proximal balloon embolic protection devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Perforation</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>---*</td>
<td>---*</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because no trials evaluated this outcome
Abbreviations: CI=confidence interval

Table 180. Impact of embolic protection devices combined versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Relative Risk (95% CI)</th>
<th>I² for Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
<td>---*</td>
<td>---*</td>
</tr>
<tr>
<td>Perforation</td>
<td>5.11 (0.53 to infinity)†</td>
<td>NA</td>
</tr>
<tr>
<td>Side-branch occlusion</td>
<td>0.91 (0.60 to 1.39)</td>
<td>0%</td>
</tr>
</tbody>
</table>

*Risk could not be calculated because in the two trials that evaluated this outcome no events occurred; †Result is based on a single trial
Abbreviations: CI=confidence interval; NA=not applicable
References for Evidence Tables


Lefevre T, Ludwig J, Garcia E, et al. Randomized study to evaluate the effect on ST-segment resolution using the X-Sizer XT catheter system in acute myocardial infarction patients (X-AMINE ST study). Am J Cardiol 2004;94:154E-5E.


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### Appendix G: Strength of Evidence for Outcomes

**Table 181. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus distal balloon embolic protection devices in ST-segment elevation myocardial infarction patients under key question 1**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>NA</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>2</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial blush grade 3</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Thrombolysis in myocardial infarction-3</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>No reflow</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
</tbody>
</table>

Abbreviation: NA=not applicable; RCT=randomized controlled trials
Table 182. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus catheter aspiration devices in ST-segment elevation myocardial infarction patients under key question 1

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial blush grade 3</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Thrombolysis in myocardial infarction -3</td>
<td>1</td>
<td>RCT</td>
<td>No serious limitation</td>
<td>NA</td>
<td>No serious indirectness</td>
<td>No imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>No reflow</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
</tbody>
</table>

Abbreviation: RCT=randomized controlled trials
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>13</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>12</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Stroke</td>
<td>6</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>11</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>13</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>High</td>
<td>Important</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>0</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>16</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>12</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial blush grade 3</td>
<td>13</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Thrombolysis in myocardial infarction -3</td>
<td>15</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>11</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>High</td>
<td>Important</td>
</tr>
<tr>
<td>No reflow</td>
<td>8</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>High</td>
<td>Important</td>
</tr>
</tbody>
</table>

Abbreviation: RCT=randomized controlled trials
**Table 184. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in ST-segment elevation myocardial infarction patients under key question 1**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>5</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Stroke</td>
<td>5</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Target revascularization</td>
<td>4</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>4</td>
<td>RCTs and Observational study</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Health-related quality of life</td>
<td>0</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>ST-segment resolution</td>
<td>5</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>Very serious imprecision</td>
<td>None</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>2</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial blush grade 3</td>
<td>4</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Low</td>
<td>Important</td>
</tr>
<tr>
<td>Thrombolysis in myocardial infarction-3</td>
<td>5</td>
<td>RCTs and Observational study</td>
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<td>Serious inconsistency</td>
<td>No serious indirectness</td>
<td>No serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>Distal embolization</td>
<td>3</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Moderate</td>
<td>Important</td>
</tr>
<tr>
<td>No reflow</td>
<td>3</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
</tbody>
</table>

Abbreviation: RCT=randomized controlled trials
Table 185. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>5</td>
<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
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<td>RCTs</td>
<td>No serious limitation</td>
<td>No serious inconsistency</td>
<td>No serious indirectness</td>
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<td>None</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Stroke</td>
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<td>RCT</td>
<td>No serious limitation</td>
<td>Not graded</td>
<td>No serious indirectness</td>
<td>Serious imprecision</td>
<td>None</td>
<td>Insufficient</td>
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Abbreviation: RCT=randomized controlled trials
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Abbreviation: RCT=randomized controlled trials
Table 187. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

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<tr>
<th>Outcome</th>
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<th>Indirectness</th>
<th>Imprecision</th>
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<td>Serious imprecision</td>
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</table>

Abbreviation: RCT=randomized controlled trials
Table 188. Strength of evidence for intermediate and final health outcomes for embolic protection devices combined versus control in ST-segment elevation myocardial infarction patients under key question 1

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<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
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<th>Importance</th>
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*Abbreviation: RCT=randomized controlled trials*
Table 189. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in patients with mixed acute coronary syndromes under key question 1

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<tr>
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<th>Indirectness</th>
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Abbreviation: RCT=randomized controlled trials

Table 190. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in patients with mixed acute coronary syndromes under key question 1

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<th>Indirectness</th>
<th>Imprecision</th>
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Abbreviation: RCT=randomized controlled trials

Table 191. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1
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<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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Abbreviation: RCT=randomized controlled trials

Table 192. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1
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<th>Indirectness</th>
<th>Imprecision</th>
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Abbreviation: RCT=randomized controlled trials

Table 193. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

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<th>Indirectness</th>
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Table 194. Strength of evidence for intermediate and final health outcomes for combined embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 1

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### Quality Assessment

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<td>No serious imprecision</td>
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Abbreviation: RCT=randomized controlled trials

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Table 195. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

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### Table 196. Strength of evidence for intermediate and final health outcomes for mechanical thrombectomy devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

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<th>Imprecision</th>
<th>Other Considerations</th>
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### Table 197. Strength of evidence for intermediate and final health outcomes for distal filter embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

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<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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**Abbreviation:** RCT=randomized controlled trials

**Table 198. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1**

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<thead>
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**Table 199. Strength of evidence for intermediate and final health outcomes for proximal balloon embolic protection devices versus control in unstable angina/non-ST-elevation myocardial infarction patients under key question 1**

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Table 200. Strength of evidence for intermediate and final health outcomes for combined embolic protection devices versus control in unstable angina/non-ST-segment elevation myocardial infarction patients under key question 1

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Abbreviation: RCT=randomized controlled trials

Table 201. Strength of evidence for adverse outcomes for catheter aspiration devices versus distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction under key question 2

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<td>Importance</td>
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Abbreviation: RCT=randomized controlled trials

Table 202. Strength of evidence for adverse outcomes for catheter aspiration devices versus catheter aspiration devices in patients with ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
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<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
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<th>Indirectness</th>
<th>Imprecision</th>
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<td>Important</td>
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Abbreviation: RCT=randomized controlled trials

Table 203. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
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<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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Abbreviation: RCT=randomized controlled trials
Table 204. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
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<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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<th>Importance</th>
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Abbreviation: RCT=randomized controlled trials

Table 205. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

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<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
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<th>Indirectness</th>
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<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
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<td>RCT</td>
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Abbreviation: RCT=randomized controlled trials

Table 206. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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Abbreviation: RCT=randomized controlled trials
Table 207. Strength of evidence for adverse outcomes for proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction under key question 2

<table>
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<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
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<th>Other Considerations</th>
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<td>No serious indirectness</td>
<td>Serious imprecision</td>
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<td>Important</td>
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Abbreviation: RCT=randomized controlled trials

Table 208. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with ST-segment elevation myocardial infarction under key question 2

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<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
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</table>

Abbreviation: RCT=randomized controlled trials

Table 209. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with mixed acute coronary syndromes under key question 2

<table>
<thead>
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<th>Outcome</th>
<th>Number of Studies</th>
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<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
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G-21
### Table 210. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with mixed acute coronary syndromes under key question 2

<table>
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<th>Indirectness</th>
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### Table 211. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

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<th>Imprecision</th>
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### Table 212. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

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<th>Importance</th>
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<td>Important</td>
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<td>RCT</td>
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<td>Serious imprecision</td>
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<td>Important</td>
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Abbreviation: RCT=randomized controlled trials
Table 213. Strength of evidence for adverse outcomes for proximal balloon embolic protection devices versus control in patients with mixed acute coronary syndromes under key question 2

<table>
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<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
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</table>

Table 214. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with mixed acute coronary syndromes under key question 2

<table>
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<th>Design</th>
<th>Limitations</th>
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<th>Quality</th>
<th>Importance</th>
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<td>Important</td>
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</table>

Abbreviation: RCT=randomized controlled trials

Table 215. Strength of evidence for adverse outcomes for catheter aspiration devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
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<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
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<td>Important</td>
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</table>
Table 216. Strength of evidence for adverse outcomes for mechanical thrombectomy devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
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<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
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<td>Important</td>
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</table>

Table 217. Strength of evidence for adverse outcomes for distal filter embolic protection devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
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<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
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</thead>
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<tr>
<td>Coronary dissection</td>
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<td>Insufficient</td>
<td>Important</td>
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</tr>
<tr>
<td>Perforation</td>
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<td>-</td>
<td>Insufficient</td>
<td>Important</td>
<td></td>
</tr>
<tr>
<td>Prolonged procedure time</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>Insufficient</td>
<td>Important</td>
<td></td>
</tr>
</tbody>
</table>

Table 218. Strength of evidence for adverse outcomes for distal balloon embolic protection devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
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<tbody>
<tr>
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<td>Insufficient</td>
<td>Important</td>
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</tr>
<tr>
<td>Perforation</td>
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<td>-</td>
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<td>Insufficient</td>
<td>Important</td>
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</tr>
<tr>
<td>Prolonged procedure time</td>
<td>0</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
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</table>

Table 219. Strength of evidence for adverse outcomes for proximal balloon embolic protection devices versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
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<tbody>
<tr>
<td>Coronary dissection</td>
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</tr>
</tbody>
</table>

G-24
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation</td>
<td>0</td>
<td>-</td>
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<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Prolonged procedure time</td>
<td>0</td>
<td>-</td>
<td>-</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
</tbody>
</table>

Table 220. Strength of evidence for adverse outcomes for embolic protection devices combined versus control in patients with unstable angina/non-ST-segment elevation myocardial infarction under key question 2

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies</th>
<th>Design</th>
<th>Limitations</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other Considerations</th>
<th>Quality</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary dissection</td>
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<td>-</td>
<td>-</td>
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<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Perforation</td>
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<td>-</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
<tr>
<td>Prolonged procedure time</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Insufficient</td>
<td>Important</td>
</tr>
</tbody>
</table>
### Appendix H: Applicability of Individual Studies and of the Body of Evidence

#### Table 221. Evaluation of applicability for individual randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dudek, 2010</strong></td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>Younger population (58 y) High male to female ratio (79-81%) Only patients undergoing primary PCI Short duration of followup (180 d) Diver CE device no longer available Adverse outcomes not reported Small sample size (N= 196) Use of ITT analysis not reported Conducted in Europe</td>
</tr>
<tr>
<td><strong>Liistro, 2009</strong></td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Assessed adverse outcomes Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>High male to female ratio (77-78%) Only patients undergoing primary PCI Short duration of followup (180 d) Small sample size (N =111) Conducted in Europe</td>
</tr>
<tr>
<td><strong>Lipiecki, 2009</strong></td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Enrolled primary care population</td>
<td>Population, Outcomes, Setting</td>
<td>Younger population (59 y) Final health outcomes not reported Short duration of followup (7 d) Adverse outcomes not reported Small sample size (N =44) Use of ITT analysis not reported Conducted in Europe</td>
</tr>
<tr>
<td><strong>Moura, 2009</strong></td>
<td>Study Designation: Efficacy study Composite Score: 2 of 7</td>
<td>Less stringent eligibility criteria Assessed final health outcomes</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>Baseline characteristics not reported Only patients undergoing primary PCI IRA not reported Use of antiplatelets and antithrombotic not reported Short duration of followup (270 d) Device name not reported Adverse outcomes not reported Small sample size (N =152) Use of ITT analysis not reported Conducted in South America</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Effectiveness Study Designation and Composite Score</td>
<td>Effectiveness Study Criteria Met</td>
<td>Applicability Limitation Category</td>
<td>Specific Factors Limiting Applicability</td>
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</tr>
<tr>
<td>Sardella, 2009</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Adequate study duration with clinically relevant treatments</td>
<td>Population, Outcomes, Setting</td>
<td>Only patients undergoing primary PCI Adverse outcomes not reported Small sample size (N =175) Use of ITT analysis not reported</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Assessed adverse outcome</td>
<td>Population, Setting</td>
<td>High male to female ratio (83.78 - 86.49%) Only patients undergoing primary PCI Short duration of followup (180 d) Small sample size (N =74) Use of ITT analysis not reported Conducted in Asia</td>
</tr>
<tr>
<td>Chevalier, 2008</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>• High male to female ratio (80-81%) • Only patients undergoing primary PCI • Short duration of followup (30 d) • Conducted in Europe and India</td>
</tr>
<tr>
<td>Ciszewski, 2008</td>
<td>Study Designation: Efficacy study Composite Score: 2 of 7</td>
<td>1. Assessed final health outcomes 2. Used intention to treat analysis</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>• Only patients undergoing primary PCI • IRA not reported • Use of antiplatelets and antithrombotic not reported • Short duration of followup (8 d) • Rescue and Diver devices no longer available • Adverse outcomes not reported • Small sample size (N =135) • Conducted in Europe</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis</td>
<td>Population, Intervention, Setting</td>
<td>• High male to female ratio (77.7-80.6%) • Only patients undergoing primary PCI • Short duration of followup (240 - 720 d) • TVAC device is not FDA approved • Conducted in Asia</td>
</tr>
<tr>
<td>Svilaas, 2008</td>
<td>Study Designation: Effectiveness study Composite Score: 6 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Adequate study duration with clinically relevant treatments 4. Assessed adverse outcome 5. Adequate sample size 6. Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>• High male to female ratio (67.9-73.1%) • Only patients undergoing primary PCI • Conducted in Europe</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Effectiveness Study Designation and Composite Score</td>
<td>Effectiveness Study Criteria Met</td>
<td>Applicability Limitation Category</td>
<td>Specific Factors Limiting Applicability</td>
</tr>
<tr>
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</tr>
</tbody>
</table>
| DeLuca, 2006 | Study Designation: Efficacy study Composite Score: 2 of 7 | 1. Assessed final health outcomes 2. Assessed adverse outcome | Population, Intervention, Setting | ● High male to female ratio (55.3- 71%)  
● Only patients undergoing primary PCI  
● Majority of IRAs were LAD (97.4- 100%)  
● Short duration of followup (180 d)  
● Diver CE device no longer available  
● Small sample size (N =76)  
● Use of ITT analysis not reported  
● Conducted in Europe |
● Only patients undergoing primary PCI  
● Short duration of followup (30 d)  
● Rescue device no longer available  
● Conducted in Europe |
| Lee, 2006 | Study Designation: Efficacy study Composite Score: 2 of 7 | 1. Enrolled primary care population 2. Less stringent eligibility criteria | Population, Outcomes, Setting | ● Only patients undergoing primary PCI  
● Use of antiplatelets and antithrombotic not reported  
● Final health outcomes not reported  
● Short duration of followup (in-hospital)  
● Adverse outcomes not reported  
● Small sample size (N =133)  
● Use of ITT analysis not reported  
● Conducted in Asia |
| Silva-Orrego, 2006 | Study Designation: Efficacy study Composite Score: 4 of 7 | 1. Less stringent eligibility criteria 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Used intention to treat analysis | Population, Setting | ● Younger population (57.3- 58.0 y)  
● High male to female ratio (76- 84%)  
● Only patients undergoing primary PCI  
● Short duration of followup (180 d)  
● Small sample size (N =148)  
● Conducted in Europe |
| Burzotta, 2005 | Study Designation: Efficacy study Composite Score: 4 of 7 | 1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Used intention to treat analysis | Population, Intervention, Setting | ● High male to female ratio (77.6-90%)  
● Short duration of followup (30 d)  
● Diver CE device no longer available  
● Small sample size (N =99)  
● Conducted in Europe |
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noel, 2005</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>1. Assessed final health outcomes Population, Outcomes, Setting</td>
<td></td>
<td>• Baseline characteristics not reported • Percentage of primary PCI versus rescue PCI not reported • IRA not reported • Use of antiplatelets and antithrombotic not reported • Short duration of followup (1 hr) • Adverse outcomes not reported • Small sample size (N = 50) • Use of ITT analysis not reported • Conducted in Europe</td>
</tr>
<tr>
<td>Dudek, 2004</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>1. Less stringent eligibility criteria Population, Intervention, Outcomes, Setting</td>
<td></td>
<td>• Younger population (56.7 - 59.1 y) • High male to female ratio (69-80%) • Only patients undergoing primary PCI • IRA not reported • Suboptimal use of anti-thrombotics • Final health outcomes not reported • Short duration of followup (90 d) • Rescue device no longer available • Small sample size (N = 72) • Use of ITT analysis not reported • Conducted in Europe</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; FDA=Food and Drug Administration; IRA=infarct related artery; ITT=intent to treat; LAD=left anterior descending artery; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Adequate study duration with clinically relevant treatments Assessed adverse outcome Adequate sample size</td>
<td>Population</td>
<td>High male to female ratio (76-81%) Only patients undergoing primary PCI Use of ITT analysis not reported</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Adequate sample size Used intention to treat analysis</td>
<td>Population</td>
<td>High male to female ratio (74.2-75.8%) Short duration of followup (30-180 d)</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>Assessed final health outcomes Assessed adverse outcome Adequate sample size Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>High male to female ratio (73-76%) Only patients undergoing primary PCI Suboptimal use of antiplatelets Short duration of followup (180 d) Conducted in Europe</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>Enrolled primary care population Less stringent eligibility criteria Assessed final health outcomes Used intention to treat analysis</td>
<td>Outcome, Setting</td>
<td>High male to female ratio (78-82%) Only patients undergoing primary PCI Short duration of followup (30 d) Adverse outcomes not reported Small sample size (N =100) Conducted in Europe</td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Assessed final health outcomes Assessed adverse outcomes Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>High male to female ratio (71.7-82.6%) Percentage of primary PCI versus rescue PCI not reported IRA not reported Short duration of followup (30 d) Small sample size (N =92) Conducted in Europe</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years
Table 223. Evaluation of applicability for individual randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ito, 2010</td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>Enrolled primary care population Less stringent inclusion criteria Assessed final health outcomes Used intention to treat analysis</td>
<td>Intervention, Outcomes, Setting</td>
<td>High male to female ratio (76-79%) Filtrap not available in the US Short duration of FU (30d) Adverse outcomes not reported Small sample size (N=26) Conducted in Asia</td>
</tr>
<tr>
<td>Kelbæk, 2008</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Adequate study duration with clinically relevant treatments Adequate sample size Used intention to treat analysis</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>High male to female ratio (72-74.4%) Only patients undergoing primary PCI SpiderX device no longer available Adverse outcomes not reported Conducted in Europe</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis</td>
<td>Population, Intervention, Setting</td>
<td>High male to female ratio (77-86%) Low percentage of rescue PCI (3.4%) Short duration of followup (180 d) SpiderX device no longer available Small sample size (N =140) Conducted in South America and Asia</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 2 of 7</td>
<td>Assessed final health outcomes Used intention to treat analysis</td>
<td>Population, Outcomes, Setting</td>
<td>Younger population (57-60 y) High male to female ratio (82%) Percentage of primary PCI versus rescue PCI not reported Short duration of followup (30 d) Adverse outcomes not reported Small sample size (N =100) Conducted in Asia</td>
</tr>
<tr>
<td>Lefèvre, 2004</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Outcomes, Setting</td>
<td>High male to female ratio (81- 83%) Percentage of primary PCI versus rescue PCI not reported Use of antiplatelets and antithrombotic not reported Short duration of followup (30 d) Adverse outcomes not reported Small sample size (N =60) Use of ITT analysis not reported Conducted in Europe</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years
Table 224. Evaluation of applicability for individual randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duan, 2010</td>
<td>Study Designation: Efficacy study Composite Score: 2 of 7</td>
<td>Adequate study duration with clinically relevant treatments Used intention to treat analysis</td>
<td>Population, Outcomes, Setting</td>
<td>Younger age group (55-56) High male to female ratio (82-87%) Only patients undergoing primary PCI 100% in one vessel (Left anterior descending) Final health outcomes not reported Adverse outcomes not reported Small sample size (n=96) Conducted in Asia</td>
</tr>
<tr>
<td>Pan, 2010</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Enrolled primary care population Adequate study duration with clinically relevant treatments Used intention to treat analysis</td>
<td>Outcomes, Intervention, Setting</td>
<td>Final health outcomes not reported Adverse outcomes not reported Small sample size (n=104) Guardwire not available in the US Conducted in Asia</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>Younger population (55.9-58.8 y) High male to female ratio (71-85 %) Only patients undergoing primary PCI Short duration of followup (180 d) PercuSurge GuardWire device no longer available Adverse outcomes not reported Small sample size (N =116) ITT not used Conducted in Asia</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>Younger population (55-56 y) High male to female ratio (79-95%) Only patients undergoing primary PCI Short duration of followup (180 d) GuardWire device no longer available Adverse outcomes not reported Small sample size (N =39) Use of ITT analysis not reported Conducted in Asia</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Effectiveness Study Designation and Composite Score</td>
<td>Effectiveness Study Criteria Met Category</td>
<td>Applicability Limitation Category</td>
<td>Specific Factors Limiting Applicability</td>
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<tr>
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</tr>
<tr>
<td>Matsuo, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome</td>
<td>Population, Intervention, Setting</td>
<td>• High male to female ratio (76-86%) • Percentage of primary PCI versus rescue PCI not reported • Short duration of followup (180 d) • GuardWire device no longer available • Small sample size (N =154) • Use of ITT analysis not reported • Conducted in Asia</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 4 of 7</td>
<td>1. Assessed final health outcomes 2. Assessed adverse outcome 3. Adequate sample size 4. Used intention to treat analysis</td>
<td>Population, Setting</td>
<td>• High male to female ratio (72.9-78.6%) • Only patients undergoing primary PCI • Use of antithrombotic not reported • Short duration of followup (30 d) • Conducted in Asia</td>
</tr>
<tr>
<td>Zhou, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>• Younger population (55-57 y) • Only patients undergoing primary PCI • Short duration of followup (in-hospital) • PercuSurge GuardWire device no longer available • Small sample size (N =112) • Use of ITT analysis not reported • Geographic location not reported</td>
</tr>
<tr>
<td>Okamura, 2005</td>
<td>Study Designation: Efficacy study Composite Score: 0 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>• Younger population (59y) • High male to female ratio (75-88%) • Percentage of primary PCI versus rescue PCI not reported • Final health outcomes not reported • Short duration of followup (22 d) • PercuSurge GuardWire device no longer available • Adverse outcomes not reported • ITT not used • Conducted in Japan</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>Study Designation: Effectiveness study Composite Score: 5 of 7</td>
<td>1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis</td>
<td>Population</td>
<td>• Younger population (58.5-59.8 y) • High male to female ratio (76.2-80.7%) • Short duration of followup (180 d)</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years
Table 225. Evaluation of applicability for individual randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>Study Designation: Efficacy study</td>
<td>Assessed final health outcomes</td>
<td>Population, Setting</td>
<td>Younger population (59-62 y)</td>
</tr>
<tr>
<td></td>
<td>Composite Score: 4 of 7</td>
<td>Assessed adverse outcome</td>
<td></td>
<td>High male to female ratio (80%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adequate sample size</td>
<td></td>
<td>Only patients undergoing primary PCI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Used intention to treat analysis</td>
<td></td>
<td>Short duration of followup (30 d)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Conducted in Europe and North America</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; PCI=percutaneous coronary intervention; y=years

Table 226. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes population

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parikh, 2008</td>
<td>Study Designation: Efficacy study</td>
<td>Assessed final health outcomes</td>
<td>Population, Intervention, Setting</td>
<td>Younger population (55.17-56.16 y)</td>
</tr>
<tr>
<td></td>
<td>Composite Score: 3 of 7</td>
<td>Assessed adverse outcome</td>
<td></td>
<td>High male to female ratio (90-95%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adequate study duration with clinically relevant treatments</td>
<td></td>
<td>Percentage of primary PCI versus rescue PCI not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of antiplatelets and antithrombotic not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>GuardWire device no longer available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Small sample size (N =67)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of ITT analysis not used</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Conducted in Asia</td>
</tr>
</tbody>
</table>

Gick, 2005    Study Designation: Efficacy study                  | Enrolled primary care population | Population, Intervention, Outcomes, Setting | High male to female ratio (80-86%)     |
<p>| Composite Score: 4 of 7 | Assessed final health outcomes |                                  |                                  | Percentage of primary PCI versus rescue PCI not reported |
| | Adequate sample size |                                  |                                  | Short duration of followup (30 - 180 d) |
| | Used intention to treat analysis |                                  |                                  | FilterWire device no longer available |
| |                                 |                                  |                                  | Adverse outcomes not reported        |
| |                                 |                                  |                                  | Conducted in Europe                  |</p>
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
</table>
| Sardella, 2005 | Study Designation: Efficacy study  
Composite Score: 0 of 7 | Population, Intervention, Outcomes, Setting | • High male to female ratio (77.42%)  
• Only patients undergoing primary PCI  
• Use of antiplatelets and antithrombotic not reported  
• Final health outcomes not reported  
• Short duration of followup (post-PCI)  
• Diver device no longer available  
• Adverse outcomes not reported  
• Small sample size (N = 62)  
• Use of ITT analysis not reported  
• Geographical location not reported | |
| Kunii, 2004 | Study Designation: Efficacy study  
Composite Score: 2 of 7 | Population, Intervention, Outcomes, Setting | • High male to female ratio (76-86 %)  
• Only patients undergoing primary PCI  
• Use of antiplatelets and antithrombotic not reported  
• Short duration of followup (in-hospital)  
• Rescue device no longer available  
• Adverse outcomes not reported  
• Use of ITT analysis not reported  
• Conducted in Asia | |
| Nanasato, 2004 | Study Designation: Efficacy study  
Composite Score: 0 of 7 | Population, Outcomes, Setting | • Baseline characteristics not reported  
• Final health outcomes not reported  
• Short duration of followup (post PCI)  
• Adverse outcomes not reported  
• Small sample size (N = 64)  
• Use of ITT analysis not reported  
• Conducted in Asia | |
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
</table>
| Matsushita, 2003 | Study Designation: Efficacy study  
Composite Score: 1 of 7 | 1. Assessed final health outcomes | Population, Intervention, Outcomes, Setting | • High male to female ratio (76.79-83.33)  
• Percentage of primary PCI versus rescue PCI not reported  
• IRA not reported  
• Use of antiplatelets and antithrombotic not reported  
• Short duration of followup (in-hospital to 180 d)  
• PercuSurge GuardWire not available  
• Adverse outcomes not reported  
• Small sample size (N =80)  
• Use of ITT analysis not reported  
• Conducted in Asia |
| Beran, 2002 | Study Designation: Efficacy study  
Composite Score: 3 of 7 | 1. Enrolled primary care population  
2. Assessed final health outcomes  
3. Used intention to treat analysis | Population, Outcomes, Setting | • Younger population (53.9-55.9 y)  
• High male to female ratio (73-77%)  
• Short duration of followup (30 d)  
• Adverse outcomes not reported  
• Small sample size (N =61)  
• Conducted in Europe |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years
Table 227. Evaluation of applicability for individual randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with unstable angina or non-ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webster, 2008</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Outcomes, Setting</td>
<td>Younger population (58-60 y) High male to female ratio (83-89%) Percentage of primary PCI versus rescue PCI not reported Use of antiplatelets and antithrombotic not reported Short duration of followup (30 d) Adverse outcomes not reported Small sample size (N =151) Use of ITT analysis not reported Conducted in Australia and North America</td>
</tr>
<tr>
<td>Dudek, 2003</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed final health outcomes</td>
<td>Population, Outcomes, Setting</td>
<td>Younger population (49.3-59.4 y) Percentage of primary PCI versus rescue PCI not reported IRA not reported Short duration of followup (30 d) AngioGuard not available Adverse outcomes not reported Small sample size (N =31) Use of ITT analysis not reported Conducted in Europe</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; y=years

Table 228. Evaluation of applicability for individual direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sardella, 2008</td>
<td>Study Designation: Effectiveness study Composite Score: 4 of 7</td>
<td>Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis</td>
<td>Population, Intervention, Setting</td>
<td>High male to female ratio (78.4-78.8%) Only patients undergoing primary PCI Diver not available Small sample size (N =103) Conducted in Europe</td>
</tr>
</tbody>
</table>

H-12
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yan, 2007</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis</td>
<td>Population, Intervention, Setting</td>
<td>High male to female ratio (82-84%) Only patients undergoing primary PCI Majority of IRAs were RCA (100%) Short duration of followup (30 d) Diver CE device no longer available Small sample size (N =122) Conducted in Asia</td>
</tr>
<tr>
<td>Wita, 2009</td>
<td>Study Designation: Efficacy study Composite Score: 1 of 7</td>
<td>Assessed adverse outcome</td>
<td>Population, Intervention, Outcome, Setting</td>
<td>Younger population (56.6–58.1 y) High male to female ratio (70.9-79%) Percentage of primary PCI versus rescue PCI not reported Majority of IRAs were LAD (100%) Final health outcomes not reported Short duration of followup (post-PCI - 30 d) Diver CE device no longer available Small sample size (N =42) Use of ITT analysis not reported Conducted in Europe</td>
</tr>
<tr>
<td>Ozaki, 2006</td>
<td>Study Designation: Efficacy study Composite Score: 0 of 7</td>
<td></td>
<td>Population, Intervention, Outcome, Setting</td>
<td>Only male patients (100%) Only patients undergoing primary PCI IRA not reported Final health outcomes not reported Short duration of followup (180 d) Rescue, Thrombuster, PercuSurge GuardWire devices no longer available Adverse outcomes not reported Small sample size (N =77) Use of ITT analysis not reported Conducted in Asia</td>
</tr>
</tbody>
</table>

Abbreviations: d=days; IRA=infarct related artery; N=total number of patients enrolled in the study; PCI=percutaneous coronary intervention; RCA=right coronary artery
<table>
<thead>
<tr>
<th>Study, Year</th>
<th>Effectiveness Study Designation and Composite Score</th>
<th>Effectiveness Study Criteria Met</th>
<th>Applicability Limitation Category</th>
<th>Specific Factors Limiting Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beaudoin, 2010</td>
<td>Study Designation: Effectiveness study Composite Score: 6 of 7</td>
<td>Enrolled primary care population Less stringent inclusion criteria Assessed final health outcomes Adequate study duration with clinically relevant treatments Assessed adverse health outcome Adequate sample size</td>
<td>Population</td>
<td>High male to female ratio (70-76%) IRA not reported Conducted in Canada ITT analysis not used</td>
</tr>
<tr>
<td>Kim, 2010</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Less stringent inclusion criteria Assessed final health outcomes Adequate sample size</td>
<td>Intervention, Outcomes, Setting</td>
<td>High male to female ratio (72.7-77.6%) Short duration of FU (30d) Aspiration catheter device name not reported Adverse outcomes not reported ITT analysis not used Conducted in Asia</td>
</tr>
<tr>
<td>Ko, 2009</td>
<td>Study Designation: Efficacy study Composite Score: 2 of 7</td>
<td>Assessed final health outcomes Adequate sample size</td>
<td>Population, Intervention, Outcomes, Setting</td>
<td>Younger population (58 y) High male to female ratio (72.5%) Percentage of primary PCI versus rescue PCI not reported IRA not reported Use of antiplatelets and antithrombotic not reported Distal protection device name not reported Adverse outcomes not reported ITT analysis not used Conducted in Asia</td>
</tr>
<tr>
<td>Nilsen, 2009</td>
<td>Study Designation: Efficacy study Composite Score: 3 of 7</td>
<td>Assessed final health outcomes Assessed adverse outcome Adequate sample size</td>
<td>Population, Intervention, Setting</td>
<td>Baseline characteristics not reported Only patients undergoing primary PCI IRA not reported Use of antiplatelets and antithrombotic not reported Short duration of followup (30 d) Aspiration catheter device name not reported ITT analysis not used Geographic location not reported</td>
</tr>
<tr>
<td>Study, Year</td>
<td>Effectiveness Study Designation and Composite Score</td>
<td>Effectiveness Study Criteria Met</td>
<td>Applicability Limitation Category</td>
<td>Specific Factors Limiting Applicability</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------</td>
<td>---------------------------------</td>
<td>----------------------------------</td>
<td>----------------------------------------</td>
</tr>
</tbody>
</table>
| Nakatani, 2007 | Study Designation: Efficacy study  
Composite Score: 2 of 7 | Assessed final health outcomes, Adequate sample size | Population, Interventions, Outcomes, Setting | High male to female ratio (76.7-79.8%)  
Only patients undergoing primary PCI  
Use of antiplatelets and antithrombotic not reported  
Short duration of followup (30 d)  
Rescue, Thrombuster, TVAC devices no longer available  
Adverse outcomes not reported  
ITT analysis not used  
Conducted in Asia |
| Chinnaiyan, 2006 | Study Designation: Efficacy study  
Composite Score: 4 of 7 | Enrolled primary care population, Assessed final health outcomes, Assessed adverse outcome, Adequate sample size | Population, Setting | Use of antiplatelets not reported  
Short duration of followup (in-hospital)  
ITT analysis not used  
Geographic location not reported |
| Simonton, 2006 | Study Designation: Efficacy study  
Composite Score: 2 of 7 | Assessed final health outcomes, Adequate sample size | Population, Outcomes | Baseline characteristics not reported  
Percentage of primary PCI versus rescue PCI not reported  
IRA not reported  
Use of antiplatelets and antithrombotic not reported  
Short duration of followup (270 d)  
Adverse outcomes not reported  
ITT analysis not used |

Abbreviations: d=days; IRA=infarct related artery; ITT=intent to treat; TVAC=transvascular aspiration catheter; PCI=percutaneous coronary intervention; y=year
<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus catheter aspiration</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of mortality. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of mortality. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of mortality. Overall applicability of the data is limited because a large majority of studies were conducted outside of the US and did not allow for adequate study duration to assess mortality. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients with other ACS or those undergoing rescue PCI.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of mortality. Overall applicability of data is limited because the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of mortality. Overall applicability of data is limited because all studies were conducted outside of the US, more than half of the data is derived from studies which evaluated a device that is not currently available in the US, and the majority of studies did not allow for adequate duration of followup to assess mortality. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of mortality. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI or in patients with other ACS.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of mortality. Applicability of the data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess mortality. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
</tbody>
</table>
Comparison | Strength of Applicability | Conclusion with Description of Applicability
--- | --- | ---
Embolic protection devices combined versus control | Moderate | Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of mortality. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess mortality. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.

**Table 232. Strength of applicability for the body of evidence evaluating myocardial infarction in patients with acute coronary syndromes**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus catheter aspiration</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of myocardial infarction. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of myocardial infarction. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of myocardial infarction. Overall applicability is limited because the majority of studies were conducted outside of the US and did not allow for adequate study duration to assess myocardial infarction. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of myocardial infarction. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of myocardial infarction. Overall data is limited because all studies were conducted outside of the US and the majority of studies did not allow for adequate duration of followup to assess myocardial infarction. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
### Table 233. Strength of applicability for the body of evidence evaluating stroke in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of myocardial infarction. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of myocardial infarction. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess myocardial infarction. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of myocardial infarction. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess myocardial infarction. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of stroke. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess stroke. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of stroke. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess stroke. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
Table 234. Strength of applicability for the body of evidence evaluating target revascularization in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus catheter aspiration</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of target revascularization. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of target revascularization. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of target revascularization. Overall applicability is limited because the majority of studies were conducted outside of the US and did not allow for adequate study duration to assess target revascularization. While the data is highly applicable to male patients with STEMI undergoing primary PCI, applicability of data is moderate in female patients, and low in patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of target revascularization. Overall, the majority of studies were conducted outside of the US and the majority of studies did not allow for adequate duration of followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared to control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of target revascularization. Overall, all studies were conducted outside of the US and the majority of studies did not allow for adequate duration of followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of target revascularization. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Comparison</td>
<td>Strength of Applicability</td>
<td>Conclusion with Description of Applicability</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of target revascularization. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess target revascularization. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of target revascularization. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess target revascularization. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 235. Strength of applicability for the body of evidence evaluating major adverse cardiac events in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of major adverse cardiovascular events. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared to control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of major adverse cardiovascular events. The overall applicability is limited because a majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess major adverse cardiovascular events. The applicability of the data is high in male patients with STEMI undergoing primary PCI and moderate in female patients. Applicability is low in patients undergoing rescue PCI and is not applicable in patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of major adverse cardiovascular events. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is low in patients with other ACS. Applicability is moderate in female patients and in patients undergoing rescue PCI.</td>
</tr>
</tbody>
</table>
### Table 236. Strength of applicability for the body of evidence evaluating resolution of ST-segment elevation in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Overall data is limited because all studies were conducted outside of the US, the majority of studies did not allow for adequate duration of followup to assess major adverse cardiovascular events, and the majority of the data is derived from studies which evaluated a device that is not currently available in the US. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US and most studies did not allow for adequate study duration to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI or in patients with other ACS.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Data is limited because the representative study was conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
<table>
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<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of resolving ST-segment elevation. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in resolving ST-segment elevation. The overall applicability is limited because the majority of studies were conducted outside of the US. Data is highly applicable in male patients with STEMI undergoing primary PCI and is moderately applicable to female patients. Data has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of the data is limited because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI while applicability is moderate in female patients and patients undergoing rescue PCI. Data is not applicable to other patients with other ACS.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of the data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is no longer available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable in female patients. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Overall applicability of data is limited because less than half of the data is derived from studies conducted within the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients undergoing rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of resolving ST-segment elevation. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of major adverse cardiovascular events. Applicability of the data is limited because a majority of the studies were conducted outside of the US and did not allow for adequate followup to assess major adverse cardiovascular events. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
</tbody>
</table>
Table 237. Strength of applicability for the body of evidence evaluating ejection fraction in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration devices</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in ejection fraction. Overall applicability is limited because the majority of data is derived from studies which evaluated devices that are not currently available in the US and most studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable in patients with other ACS.</td>
</tr>
<tr>
<td>versus control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter aspiration versus</td>
<td>Low</td>
<td>Compared with catheter aspiration devices, patients undergoing native vessel PCI with distal balloon embolic protection devices do not have a difference in ejection fraction. Overall data is limited because the data is derived from studies which were conducted in Asia and evaluated devices that are not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>distal balloon embolic protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical thrombectomy devices</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in ejection fraction. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI regardless if primary or rescue PCI and moderately applicable in female patients. Data is not applicable in patients with other ACS.</td>
</tr>
<tr>
<td>versus control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal filter embolic protection</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in ejection fraction. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is moderately applicable to patients with ACS undergoing primary PCI.</td>
</tr>
<tr>
<td>devices versus control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal balloon embolic protection</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in ejection fraction. Overall applicability is limited because all studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS. Data is not applicable to patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>devices versus control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embolic protection devices</td>
<td>Low</td>
<td>Compared with control, patient who undergo native vessel PCI with an embolic protection device do not have a difference in ejection fraction. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>combined versus control</td>
<td></td>
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</tbody>
</table>
### Table 238. Strength of applicability for the body of evidence evaluating myocardial blush grade of 3 in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus catheter aspiration</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of attaining a MBG-3. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of attaining a MBG-3. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in attaining a MBG-3. Overall applicability is limited because the majority of studies were conducted outside of the US. Data is highly applicable in male patients with STEMI undergoing primary PCI and is moderately applicable to female patients. Data has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of attaining a MBG-3. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of attaining a MBG-3. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is moderately applicable to patients with ACS undergoing primary PCI.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device have an increased risk in attaining a MBG-3. Overall applicability is limited because a majority of studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of attaining a MBG-3. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
</tbody>
</table>
Comparison & Description of Applicability

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of attaining a MBG-3. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus catheter aspiration</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of attaining TIMI-3 blood flow. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Catheter aspiration versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared to the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a difference in the risk of attaining TIMI-3 blood flow. Overall data is limited because the Diver CE device is not currently available in the US. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have an increased risk in attaining a TIMI-3 blood flow. The overall applicability is limited because a majority of data is derived from studies conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients with other ACS and in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of attaining a TIMI-3 blood flow. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients and patient undergoing rescue PCI. Data has low applicability in patients with other ACS.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of attaining a TIMI-3 blood flow. Overall data is limited because all studies were conducted outside of the US and more than half of the data is derived from studies which evaluated a device that is not currently available in the US. The data is highly applicable to male patients with STEMI and moderately applicable to patients with other ACS and female patients.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; MBG= Myocardial blush grade; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
Comparison | Strength of Applicability | Conclusion with Description of Applicability
--- | --- | ---
Distal balloon embolic protection devices versus control | Low | Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk in attaining TIMI-3 blood flow. Overall applicability is limited because a majority of studies were conducted outside of the US and close to half of the data is derived from studies which evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI.

Proximal balloon embolic protection devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of attaining TIMI-3 blood flow. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.

Embolic protection devices combined versus control | Low | Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of attaining TIMI-3 blood flow. Applicability of the data is limited because a majority of the studies were conducted outside of the US and evaluated devices not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. Data has low applicability in patients with other ACS or undergoing rescue PCI.

Catheter aspiration device versus control | Low | Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of distal embolization. Overall applicability is limited because a majority of data is derived from studies which evaluated devices that are not currently available in the US and most studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.

Mechanical thrombectomy devices versus control | Moderate | Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of distal embolization. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; TIMI=Thrombolysis in myocardial infarction; US=United States; Y=years
## Table 241. Strength of applicability for the body of evidence evaluating no reflow in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of distal embolization. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is applicable to patients with ACS undergoing primary PCI.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of distal embolization. Overall applicability is limited because a majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of distal embolization. Data is limited because the representative study was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of distal embolization. Applicability of the data is limited because a majority of the studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years
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<th>Comparison</th>
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<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of no reflow. Overall the data has limited applicability because the majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI and moderately applicable in female patients. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of no reflow. Overall data is limited because all studies were conducted outside of the US and the majority of data is derived from studies which evaluated a device that is not currently available in the US. Data is applicable to patients with ACS undergoing primary PCI.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of no reflow. Overall applicability is limited because a majority of studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and has low applicability to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with an embolic protection device do not have a difference in the risk of no reflow. Applicability of the data is limited because a majority of the studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI and moderately applicable to female patients. The data has low applicability in patients with other ACS or undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=Years

Table 242. Strength of applicability for the body of evidence evaluating coronary dissection in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration device versus catheter aspiration device</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Export, patients who undergo native vessel PCI with the catheter aspiration device Diver do not have a difference in the risk of coronary dissection. Applicability is limited because the trial was conducted in Italy and the Diver device is not available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is not applicable to patients with other ACS or undergoing rescue PCI.</td>
</tr>
<tr>
<td>Catheter aspiration devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of coronary dissection. Applicability is limited because all studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients and is not applicable to patients with other ACS or those undergoing rescue PCI.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>High</td>
<td>Compared with control, patients who undergo native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of coronary dissection. Data is highly applicable to patients with STEMI undergoing primary or rescue PCI. Data is not applicable to patients with other ACS.</td>
</tr>
</tbody>
</table>
Table 243. Strength of applicability for the body of evidence evaluating coronary perforation in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>High</td>
<td>Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of coronary perforation. Data is highly applicable to patients with STEMI undergoing primary or rescue PCI although is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of coronary perforation. Applicability is limited because the trial evaluated a device which is not currently available in the US. Data is highly applicable in patients with STEMI undergoing primary PCI. Data is not applicable to patients undergoing rescue PCI or those with other ACS.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Low</td>
<td>Compared with control, patients undergoing native vessel PCI with an embolic protection device do not have a difference in the risk of coronary perforation. Applicability is limited because the trial evaluated a device which is not currently available in the US. Data is highly applicable in patients with STEMI undergoing primary PCI. Data is not applicable to patients undergoing rescue PCI or those with other ACS.</td>
</tr>
</tbody>
</table>

Table 244. Strength of applicability for the body of evidence evaluating prolonged procedure time in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration device versus distal balloon embolic protection device</td>
<td>Low</td>
<td>Compared with the catheter aspiration device Diver CE, patients undergoing native vessel PCI with the distal balloon embolic protection device Guardwire Plus do not have a prolonged procedure time. Overall data is limited because the Diver CE device is not currently available in the US and the study was of short duration. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.</td>
</tr>
<tr>
<td>Catheter aspiration versus control</td>
<td>Moderate</td>
<td>Compared with control, patients undergoing native vessel PCI with a catheter aspiration device do not have a prolonged procedure time. Applicability is limited because all studies were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients, has low applicability in patients undergoing rescue PCI, and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>High</td>
<td>Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device have a prolonged procedure time. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients or those undergoing rescue PCI, and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Comparison</td>
<td>Strength of Applicability</td>
<td>Conclusion with Description of Applicability</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device have a prolonged procedure time. Applicability is limited because this study was conducted in South American and Asia and evaluated a device that is not currently available in the US. Data is highly applicable to male patients with STEMI undergoing primary PCI. The data is moderately applicable to female patients, has low applicability to patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device have a prolonged procedure time. Overall data is limited because half is derived from trials conducted in Asia and India. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to female patients or those with other ACS and has low applicability in patients undergoing rescue PCI.</td>
</tr>
<tr>
<td>Proximal balloon embolic protection device versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with a proximal balloon embolic protection device do not have a difference in the risk of prolonged procedure time. Data is limited because the representative trial was conducted outside of the US. Data is highly applicable to male patients of a younger mean age (less than 60Y) with STEMI undergoing primary PCI.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Low</td>
<td>Compared with control, patients who undergo native vessel PCI with an embolic protection device have a prolonged procedure time. Applicability is limited because most of the trials were conducted outside of the US. Data is highly applicable to male patients with STEMI undergoing primary PCI with moderate applicability to female patients. Data has low applicability to patients with other ACS or those undergoing rescue PCI.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 245. Strength of applicability for the body of evidence evaluating side branch occlusion in patients with acute coronary syndromes

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Strength of Applicability</th>
<th>Conclusion with Description of Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter aspiration versus control</td>
<td>Moderate</td>
<td>Compared with control, patients undergoing native vessel PCI with a catheter aspiration device do not have a difference in the risk of side branch occlusion. Overall applicability is limited because data is derived from Europe and India. Data is highly applicable to male patients with STEMI undergoing primary PCI with moderate applicability to female patients. Data is not applicable to patients undergoing rescue PCI or patients with other ACS.</td>
</tr>
<tr>
<td>Mechanical thrombectomy devices versus control</td>
<td>Low</td>
<td>Compared with control, patients undergoing native vessel PCI with a mechanical thrombectomy device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients in Europe with STEMI and moderately applicable to female patients. Data is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Distal filter embolic protection devices versus control</td>
<td>Low</td>
<td>Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients in South America and Asia with STEMI undergoing primary PCI, with moderate applicability in female patients. The device evaluated in this trial is not currently available in the US. Data has low applicability in patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Comparison</td>
<td>Strength of Applicability</td>
<td>Conclusion with Description of Applicability</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Distal balloon embolic protection devices versus control</td>
<td>Moderate</td>
<td>Compared with control, patients undergoing native vessel PCI with a distal balloon embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients with STEMI undergoing either primary or rescue PCI. Data is moderately applicable to female patients and is not applicable to patients with other ACS.</td>
</tr>
<tr>
<td>Embolic protection devices combined versus control</td>
<td>Moderate</td>
<td>Compared with control, patients undergoing native vessel PCI with an embolic protection device do not have a difference in the risk of side branch occlusion. Data is highly applicable to male patients with STEMI undergoing primary PCI. Data is moderately applicable to patients undergoing rescue PCI and is not applicable to patients with other ACS.</td>
</tr>
</tbody>
</table>

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States
Appendix I: Forest Plots for Results of Final Health Outcomes Analyzed at Individual Time Points

Figure 1. Impact of catheter aspiration devices versus control on in-hospital mortality.

Relative risk meta-analysis plot (random effects)

- **Silva-Orrego, 2006** (*excluded*)
- **Ikari, 2008**
  - Relative risk: 0.96 (0.10, 9.16)
- **Sardella, 2009**
  - Relative risk: 0.33 (0.00, 3.76)
- **Dudek, 2010**
  - Relative risk: 0.96 (0.23, 4.08)
- **Combined (random)**
  - Relative risk: 0.81 (0.23, 2.86)

Cochran Q: \( P = 0.832 \)

Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 2. Impact of catheter aspiration devices versus control on ≤30 day mortality.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.961
I²: 0%
Egger: P = 0.689

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 3. Impact of catheter aspiration devices versus control on 30-day mortality.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.892
I²: 0%
Egger: P = 0.976

Sardella, 2009
0.33 (0.00, 3.76)

Chevalier, 2008
0.86 (0.25, 2.89)

Svilaas, 2008
0.53 (0.26, 1.06)

Kaltott, 2006
0.33 (0.00, 3.78)

Burzotta, 2005
1.00 (0.24, 4.16)

combined [random]
0.61 (0.35, 1.07)
Figure 4. Impact of catheter aspiration devices versus control on 180-day mortality.

Relative risk meta-analysis plot (random effects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silva-Orrego, 2006</td>
<td>* (excluded)</td>
</tr>
<tr>
<td>De Luca, 2006</td>
<td>0.22 (0.00, 2.01)</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>1.86 (0.25, 14.12)</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>2.76 (0.24, infinity)</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>0.11 (0.00, 0.93)</td>
</tr>
<tr>
<td>Dudek, 2010</td>
<td>1.28 (0.33, 5.01)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>0.89 (0.31, 2.51)</td>
</tr>
</tbody>
</table>

Cochran Q: P = 0.391
I²: 2.8%
Egger: P = 0.487

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 5. Impact of catheter aspiration devices versus control on 365-day mortality.

Relative risk meta-analysis plot (random effects)

Svilaas, 2008 0.61 (0.38, 0.98)
De Luca, 2006 0.70 (0.16, 2.95)
combined [random] 0.62 (0.39, 0.98)

Cochran Q: P = 0.873
I²: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 6. Impact of mechanical thrombectomy devices versus control on ≤ 30-day mortality.

Relative risk meta-analysis plot (random effects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliorini, 2010</td>
<td>0.55</td>
<td>(0.17, 1.73)</td>
</tr>
<tr>
<td>Ali, 2006</td>
<td>5.50</td>
<td>(1.39, 21.99)</td>
</tr>
<tr>
<td>Lefèvre, 2005</td>
<td>1.01</td>
<td>(0.28, 3.60)</td>
</tr>
<tr>
<td>Antoniucci, 2004</td>
<td>* (excluded)</td>
<td></td>
</tr>
<tr>
<td>Napodano, 2003</td>
<td>1.00</td>
<td>(0.24, 4.16)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>1.25</td>
<td>(0.47, 3.32)</td>
</tr>
</tbody>
</table>

Cochran Q: P = 0.120
I²: 48.7%
Egger: P = 0.329

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 7. Impact of mechanical thrombectomy devices versus control on 180-day mortality.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 8. Impact of distal filter embolic protection devices versus control on ≤30 day mortality.

Relative risk meta-analysis plot (random effects)

- Lefevre, 2004: 0.88 (0.09, 8.17)
- Kelbaek, 2008: 1.01 (0.40, 2.56)
- Cura, 2007: 1.00 (0.28, 3.53)
- Guetta, 2007: 4.81 (0.51, infinity)
- Ito, 2010: 0.30 (0.00, 3.30)

Combined (random): 1.02 (0.50, 2.08)

Cochran Q: P = 0.805
P: 0%
Egger: P = 0.925

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 9. Impact of distal balloon embolic protection devices versus control on ≤30-day mortality.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.716
P: 0%
Egger: Too few strata

Tahk, 2008 0.19 (0.00, 1.81)
Muramatsu, 2007 0.69 (0.24, 2.03)
Stone, 2005 0.71 (0.24, 2.09)
combined [random] 0.64 (0.30, 1.39)
Figure 10. Impact of distal balloon embolic protection devices versus control on 180-day mortality.

Relative risk meta-analysis plot (random effects)

- Tahk, 2008: 0.19 (0.00, 1.81)
- Hahn, 2007: 0.35 (0.00, 3.88)
- Muramatsu, 2007: 0.95 (0.43, 2.08)
- Stone, 2005: 0.96 (0.38, 2.43)
- Combined [random]: 0.86 (0.48, 1.57)

Cochran Q: P = 0.709
P: 0%
Egger: P = 0.044

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
**Figure 11. Impact of embolic protection devices versus control combined on ≤30 day mortality.**

**Relative risk meta-analysis plot (random effects)**

- **Ito, 2010** \(0.30 (0.00, 3.30)\)
- **Haeck, 2009** \(1.01 (0.18, 5.69)\)
- **Keibaek, 2008** \(1.01 (0.40, 2.56)\)
- **Tahk, 2008** \(0.19 (0.00, 1.81)\)
- **Cura, 2007** \(1.00 (0.28, 3.53)\)
- **Guetta, 2007** \(4.81 (0.51, \text{infinity})\)
- **Muramatsu, 2007** \(0.69 (0.24, 2.03)\)
- **Stone, 2005** \(0.71 (0.24, 2.09)\)
- **Lefevre, 2004** \(0.88 (0.09, 8.17)\)
- **combined [random]** \(0.84 (0.50, 1.39)\)

**Cochran Q:** P = 0.931

**P:** 0%

**Egger:** P = 0.794

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 12. Impact of embolic protection devices combined versus control on 180-day mortality.

Relative risk meta-analysis plot (random effects)

- Haeck, 2009: 0.51 (0.11, 2.33)
- Tahk, 2008: 0.19 (0.00, 1.81)
- Cura, 2007: 1.25 (0.38, 4.16)
- Hahn, 2007: 0.35 (0.00, 3.88)
- Muramatsu, 2007: 0.95 (0.43, 2.08)
- Stone, 2005: 0.96 (0.38, 2.43)
- Combined [random]: 0.87 (0.52, 1.46)

Cochran Q: P = 0.836
P: 0%
Egger: P = 0.031

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 13. Impact of embolic protection devices combined versus control on ≤30 day mortality in patients with mixed acute coronary syndromes.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.677
Egger: P = Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 14. Impact of catheter aspiration devices versus control on in-hospital myocardial infarction.

Cochran Q: P = 1.000
I²: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 15. Impact of catheter aspiration devices versus control on ≤30 day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- Dudek, 2010: 0.32 (0.18, 5.50)
- Sardella, 2009: * (excluded)
- Chevalier, 2008: 2.15 (0.28, 16.30)
- Ikari, 2008: 0.32 (0.00, 3.67)
- Sivilaas, 2008: 0.40 (0.13, 1.20)
- Kaltoft, 2006: 0.33 (0.00, 3.78)
- Silva-Orrego, 2006: * (excluded)
- Burzotta, 2005: 1.00 (0.18, 5.50)
- combined [random]: 0.55 (0.24, 1.25)

Cochran Q: P = 0.816
I²: 0%
Egger: P = 0.809

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 16. Impact of catheter aspiration devices versus control on 30-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- **Sardella, 2009** *(excluded)*
- **Chevalier, 2008**: 2.15 (0.28, 16.30)
- **Svilaas, 2008**: 0.40 (0.13, 1.20)
- **Kaltoft, 2006**: 0.33 (0.00, 3.78)
- **Burzotta, 2005**: 1.00 (0.18, 5.50)
- **Combined [random]**: 0.60 (0.25, 1.45)

Cochran Q: P = 0.578
P: 0%
Egger: P = 0.499

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 17. Impact of catheter aspiration devices versus control on 180-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- *Silva-Orrego, 2006* 0.32 (0.00, 3.60)
- *De Luca, 2006* 3.25 (0.29, infinity)
- *Ikari, 2008* 0.31 (0.00, 3.55)
- *Sardella, 2009* 0.31 (0.00, 3.55)
- *Liistro, 2009* 1.02 (0.24, 4.26)
- *Dudek, 2010* 0.32 (0.05, 2.19)

Combined [random] 0.70 (0.24, 1.99)

Cochran Q: P = 0.721
F: 0%
Egger: P = 0.708

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 18. Impact of catheter aspiration devices versus control on 365-day myocardial infarction.

Cochran Q: P = 0.782
I²: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 19. Impact of mechanical thrombectomy devices versus control on ≤ 30-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- Migliorini, 2010: 0.64 (0.13, 3.17)
- Ali, 2006: * (excluded)
- Lefèvre, 2005: 0.34 (0.05, 2.31)
- Antonucci, 2004: * (excluded)
- Napodano, 2003: 1.00 (0.18, 5.50)
- Combined [random]: 0.63 (0.21, 1.96)

Cochran Q: P = 0.769
I²: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 20. Impact of mechanical thrombectomy devices versus control on 180-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.847
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 21. Impact of distal filter embolic protection devices versus control on ≤30-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- Lefevre, 2004: 0.88 (0.09, 8.17)
- Guetta, 2007: 0.32 (0.00, 3.63)
- Cura, 2007: 0.09 (0.00, 0.74)
- Kelbaek, 2008: 5.03 (0.79, 32.40)
- Combined [random]: 0.73 (0.12, 4.44)

* (excluded)

Cochran Q: P = 0.146
P: 44.3 percent
Egger: 0.128

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 22. Impact of distal balloon embolic protection devices versus control on ≤30-day myocardial infarction.

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.670
P: 0%
Egger: P = 0.517

Relative risk meta-analysis plot (random effects)

- Tahk, 2008: 2.89 (0.25, infinity)
- Matsuo, 2007: 2.78 (0.24, infinity)
- Muramatsu, 2007: 0.32 (0.00, 3.71)
- Stone, 2005: 0.71 (0.24, 2.09)
- Combined [random]: 0.85 (0.32, 2.23)
Figure 23. Impact of distal balloon embolic protection devices versus control on 180-day myocardial infarction.

Relative risk meta-analysis plot (random effects)

- Tahk, 2008: 0.96 (0.10, 9.09)
- Hahn, 2007: 0.35 (0.00, 3.88)
- Matsuo, 2007: 2.78 (0.24, infinity)
- Muramatsu, 2007: 0.32 (0.00, 3.71)
- Stone, 2005: 0.64 (0.24, 1.70)
- Combined (random): 0.67 (0.29, 1.57)

Cochran Q: P = 0.877
Egger: P = 0.820

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 24. Impact of embolic protection devices combined versus control on ≤30 day myocardial infarction.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.542
P: 0%
Egger: P = 0.982

Lefevre, 2004
0.88 (0.09, 8.17)

Stone, 2005
0.71 (0.24, 2.09)

Muramatsu, 2007
0.32 (0.00, 3.71)

Haeck, 2009
0.68 (0.14, 3.34)

Kelbaek, 2008
5.03 (0.79, 32.40)

Tahk, 2008
2.89 (0.25, infinity)

Cura, 2007
0.09 (0.00, 0.74)

Guetta, 2007
0.32 (0.00, 3.63)

Matsuo, 2007
2.78 (0.24, infinity)

Ito, 2010
*(excluded)

combined [random]
0.83 (0.41, 1.69)
Figure 25. Impact of embolic protection devices combined versus control on 180-day myocardial infarction.

Cochran Q: $P = 0.756$

Egger: $P = 0.880$

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 26. Impact of catheter aspiration devices versus control on 30-day stroke.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.647
P: 0%
Egger: Too few strata

Burzotta, 2005 1.00 (0.11, 9.42)
Kaltoft, 2006 4.95 (0.52, infinity)
Chevalier, 2008 5.37 (0.57, infinity)
combined [random] 2.77 (0.51, 14.98)
Figure 27. Impact of mechanical thrombectomy devices versus control on ≤ 30-day stroke.

Relative risk meta-analysis plot (random effects)

- Migliorini, 2010: 0.32 (0.00, 3.67)
- Ali, 2006: 2.00 (0.43, 9.28)
- Lefèvre, 2005: 5.05 (0.53, infinity)
- Antoniucci, 2004: 3.00 (0.26, infinity)
- Napodano, 2003: * (excluded)
- Combined [random]: 1.89 (0.55, 6.48)

Cochran Q: P = 0.641
I²: 0%
Egger: P = 0.870

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 28. Impact of mechanical thrombectomy devices versus control on 180-day stroke.

Relative risk meta-analysis plot (random effects)

- **Migliorini, 2010**: 0.96 (0.10, 9.21)
- **Lefèvre, 2005**: 5.05 (0.53, infinity)
- **Combined [random]**: 2.05 (0.27, 15.78)

Cochran Q: P = 0.424
F: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 29. Impact of embolic protection devices combined versus control on ≤30 day stroke.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.277
I²: 22.1%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 30. Impact of embolic protection devices combined versus control on 180 day stroke.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.624
I²: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Stone, 2005 0.48 (0.10, 2.22)
Haeck, 2009 0.20 (0.00, 1.93)
combined [random] 0.39 (0.09, 1.71)
Figure 31. Impact of catheter aspiration devices versus control on 180-day target revascularization.

Relative risk meta-analysis plot (random effects)

- **Dudek, 2010**: 0.32 (0.00, 3.66)
- **Liistro, 2009**: 1.02 (0.29, 3.56)
- **Sardella, 2009**: 0.09 (0.00, 0.74)
- **Chao, 2008**: 0.75 (0.20, 2.82)
- **Ikari, 2008**: 0.60 (0.36, 1.00)
- **Silva-Orrego, 2006**: 0.47 (0.06, 3.54)

**combined [random]**: 0.61 (0.39, 0.94)

Cochran Q: P = 0.759
P: 0%
Egger: P = 0.444

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 32. Impact of catheter aspiration devices versus control on ≤ 30 day target revascularization.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.832
I²: 0%
Egger: P = 0.254

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Burzotta, 2005 1.00 (0.11, 9.42)
Silva-Orrego, 2006 3.00 (0.26, infinity)
Svilaas, 2008 0.78 (0.46, 1.30)
Ikari, 2008 0.32 (0.00, 3.67)
Chevalier, 2008 2.15 (0.28, 16.30)
Sardella, 2009 1.92 (0.26, 14.53)
Dudek, 2010 0.85 (0.53, 1.38)

combined [random] 1.00 (0.11, 9.42)

Cochran Q: P = 0.832
I²: 0%
Egger: P = 0.254

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 33. Impact of catheter aspiration devices versus control on 30-day target revascularization.

Relative risk meta-analysis plot (random effects)

- Burzotta, 2005: 1.00 (0.11, 9.42)
- Sardella, 2009: * (excluded)
- Chevalier, 2008: 2.15 (0.28, 16.30)
- Svilaas, 2008: 0.78 (0.46, 1.30)
- Combined [random]: 0.82 (0.50, 1.35)

Cochran Q: P = 0.709
P: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 34. Impact of catheter aspiration devices versus control on 365-day target revascularization.

Relative risk meta-analysis plot (random effects)

Sarda, 2009

Svilaas, 2008

combined [random]

Cochran Q: P = 0.886
P: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 35. Impact of catheter aspiration devices versus control on in-hospital target revascularization.

Relative risk meta-analysis plot (random effects)

- **Dudek, 2010**
  - Relative risk: 1.92 (0.26, 14.53)

- **Ikari, 2008**
  - Relative risk: 0.32 (0.00, 3.67)

- **Silva-Omeg, 2006**
  - Relative risk: 3.00 (0.26, infinity)

- **Combined (random)**
  - Relative risk: 1.35 (0.26, 6.94)

Cochran Q: P = 0.575

I²: 0%

Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 36. Impact of mechanical thrombectomy devices versus control on ≤ 30-day target revascularization.

Relative risk meta-analysis plot (random effects)

- Migliorini, 2010: 0.32 (0.07, 1.37)
- Ali, 2006: 5.00 (0.78, 32.16)
- Lellèvre, 2005: 5.05 (0.53, infinity)
- Antoniucci, 2004: *
- Napodano, 2003: *
- Combined [random]: 1.62 (0.21, 12.55)

Cochran Q: P = 0.072
I²: 62%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 37. Impact of mechanical thrombectomy devices versus control on 180-day target revascularization.

Relative risk meta-analysis plot (random effects)

Migliorini, 2010
0.54 (0.31, 0.93)

Lefèvre, 2005
0.61 (0.16, 2.24)

combined [random]
0.55 (0.33, 0.92)

Cochran Q: P = 0.885
P: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 38. Impact of distal balloon embolic protection devices versus control on ≤30-day target revascularization.

Relative risk meta-analysis plot (random effects)

Tahk, 2008
2.89 (0.25, infinity)

Muramatsu, 2007
0.32 (0.00, 3.71)

Stone, 2005
1.49 (0.56, 3.96)

combined [random]
1.38 (0.55, 3.50)

Cochran Q: P = 0.600
I²: 0%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 39. Impact of distal balloon embolic protection devices versus control on 180-day target revascularization.

Cochran Q: P = 0.600
I²: 0%
Egger: 0.369

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Relative risk meta-analysis plot (random effects)

Tahk, 2008
Hahn, 2007
Matsuo, 2007
Muramatsu, 2007
Stone, 2005
combined [random]

1.44 (0.30, 7.04)
0.21 (0.00, 1.89)
0.51 (0.19, 1.39)
1.03 (0.55, 1.95)
1.11 (0.55, 2.24)
0.93 (0.61, 1.42)

Cochran Q: P = 0.600
I²: 0%
Egger: 0.369
Figure 40. Impact of embolic protection devices combined versus control on 180-day target revascularization.

Relative risk meta-analysis plot (random effects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haeck, 2009</td>
<td>0.71 (0.29, 1.75)</td>
</tr>
<tr>
<td>Tahk, 2008</td>
<td>1.44 (0.30, 7.04)</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>1.00 (0.35, 2.82)</td>
</tr>
<tr>
<td>Hahn, 2007</td>
<td>0.21 (0.00, 1.89)</td>
</tr>
<tr>
<td>Matsuo, 2007</td>
<td>0.51 (0.19, 1.39)</td>
</tr>
<tr>
<td>Muramatsu, 2007</td>
<td>1.03 (0.55, 1.95)</td>
</tr>
<tr>
<td>Stone, 2005</td>
<td>1.11 (0.55, 2.24)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>0.90 (0.63, 1.30)</td>
</tr>
</tbody>
</table>

Cochran Q: P = 0.799
P: 0%
Egger: P = 0.268

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 41. Impact of embolic protection devices combined versus control on ≤30 day target revascularization.

Cochran Q: P = 0.417
I²: 0%
Egger: P = 0.900

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Relative risk meta-analysis plot (random effects)

- To, 2010
- Haack, 2009
- Kielbaek, 2008
- Tahk, 2008
- Muramatsu, 2007
- Stone, 2005
- Combined [random]

Cochran Q: P = 0.417
P: 0%
Egger: P = 0.900

* (excluded)

Relative risk (95% confidence interval)
Figure 42. Impact of catheter aspiration devices versus control on in-hospital MACE.

Relative risk meta-analysis plot (random effects)

Ikari, 2008

0.48 (0.06, 3.64)

Sardella, 2009

1.98 (0.26, 14.95)

Dudek, 2010

0.96 (0.31, 3.02)

combined [random]

0.97 (0.36, 2.58)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.713
F: 0%
Egger: Too few strata
Figure 43. Impact of catheter aspiration devices versus control on ≤ 30 day MACE.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.948
I²: 0%
Egger: P = 0.739

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 44. Impact of catheter aspiration devices versus control on 30-day MACE.

Relative risk meta-analysis plot (random effects)

- **Sardella, 2009**: 0.33 (0.00, 3.76)
- **Chevalier, 2008**: 1.25 (0.45, 3.47)
- **Svilaas, 2008**: 0.72 (0.48, 1.09)
- **Kaltott, 2006**: 0.99 (0.18, 5.54)
- **Burzotta, 2005**: 1.00 (0.33, 3.05)
- **combined [random]**: 0.79 (0.56, 1.13)

Cochran Q: P = 0.844
P: 0%
Egger: P = 0.61

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 45. Impact of catheter aspiration devices versus control on 365-day MACE.

Relative risk meta-analysis plot (random effects)

Sardella, 2009

Svilaas, 2008

combined [random]

Cochran Q: 0.111
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 46. Impact of catheter aspiration devices versus control on 180-day MACE.

Relative risk meta-analysis plot (random effects)

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudek, 2010</td>
<td>0.80 (0.27, 2.40)</td>
</tr>
<tr>
<td>Liistro, 2009</td>
<td>1.16 (0.47, 2.91)</td>
</tr>
<tr>
<td>Sardella, 2009</td>
<td>0.44 (0.15, 1.29)</td>
</tr>
<tr>
<td>Chao, 2008</td>
<td>0.50 (0.19, 1.26)</td>
</tr>
<tr>
<td>Ikari, 2008</td>
<td>0.62 (0.38, 1.01)</td>
</tr>
<tr>
<td>De Luca, 2006</td>
<td>0.81 (0.21, 3.05)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>0.66 (0.47, 0.94)</td>
</tr>
</tbody>
</table>

Cochran Q: P = 0.785
P: 0%
Egger: P = 0.733

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 47. Impact of mechanical thrombectomy devices versus control on ≤ 30-day MACE.

Relative risk meta-analysis plot (random effects)

- **Migliorini, 2010**: 0.45 (0.20, 1.00)
- **Ali, 2006**: 4.00 (1.43, 11.29)
- **Lefèvre, 2005**: 1.30 (0.52, 3.25)
- **Antoniucci, 2004**: * (excluded)
- **combined [random]**: 1.28 (0.37, 4.38)

Cochran Q: P = 0.006
P: 80.4%
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 48. Impact of mechanical thrombectomy devices versus control on 180-day MACE.

Relative risk meta-analysis plot (random effects)

Migliorini, 2010
0.57 (0.37, 0.88)

Lefèvre, 2005
1.01 (0.50, 2.04)

combined [random]
0.71 (0.41, 1.20)

Cochran Q: P = 0.187
P: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 49. Impact of distal filter embolic protection devices versus control on ≤30 day MACE.

Relative risk meta-analysis plot (random effects)

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.664
I²: 0%
Egger: P = 0.449

<table>
<thead>
<tr>
<th>Study</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lefevre, 2004</td>
<td>0.30 (0.00, 3.30)</td>
</tr>
<tr>
<td>Kelbaek, 2008</td>
<td>1.71 (0.81, 3.62)</td>
</tr>
<tr>
<td>Cura, 2007</td>
<td>1.00 (0.45, 2.21)</td>
</tr>
<tr>
<td>Guetta, 2007</td>
<td>2.88 (0.43, 19.79)</td>
</tr>
<tr>
<td>Ito, 2010</td>
<td>0.30 (0.00, 3.30)</td>
</tr>
<tr>
<td>Combined [random]</td>
<td>1.29 (0.77, 2.15)</td>
</tr>
</tbody>
</table>
Figure 50. Impact of distal filter embolic protection devices versus control on 180-day MACE events.

Relative risk meta-analysis plot (random effects)

Cura, 2007 0.91 (0.42, 1.96)
Kelbaek, 2008 1.23 (0.68, 2.23)
combined [random] 1.10 (0.68, 1.78)

Cochran Q: P = 0.550
I²: Too few strata
Egger: Too few strata

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 51. Impact of distal balloon embolic protection devices versus control on ≤30-day MACE.

Cochran Q: P = 0.919
I²: 0%
Egger: P = 0.758

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: P = 0.919
I²: 0%
Egger: P = 0.758

Relative risk meta-analysis plot (random effects)

Stone, 2005
0.77 (0.40, 1.50)

Zhou, 2007
* (excluded)

Muramatsu, 2007
0.54 (0.19, 1.50)

Tahk, 2008
0.96 (0.17, 5.32)

combined [random]
0.74 (0.44, 1.23)
Figure 52. Impact of distal balloon embolic protection devices combined versus control on 180-day MACE.

Cochran Q: P = 0.685
I²: 0%
Egger: P = 0.032

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

0.89 (0.53, 1.49) Stone, 2005
0.97 (0.60, 1.56) Muramatsu, 2007
0.77 (0.36, 1.65) Matsuo, 2007
0.12 (0.00, 0.91) Hahn, 2007
0.77 (0.23, 2.52) Tahk, 2008

Combined (random) 0.87 (0.64, 1.19)

Cochran Q: P = 0.685
P: 0%
Egger: P = 0.032

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.
Figure 53. Impact of embolic protection devices combined versus control on ≤30 day MACE

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Cochran Q: $P = 0.744$

$\chi^2$: 0%

Egger: $P = 0.821$

Relative risk meta-analysis plot (random effects)

- Lefevre, 2004: 0.88 (0.16, 4.74)
- Stone, 2005: 0.77 (0.40, 1.50)
- Zhou, 2007: * (excluded)
- Muramatsu, 2007: 0.54 (0.19, 1.50)
- Kelbaek, 2008: 1.71 (0.81, 3.62)
- Takah, 2008: 0.96 (0.17, 5.32)
- Cura, 2007: 1.00 (0.45, 2.21)
- Guetta, 2007: 2.88 (0.43, 19.79)
- Matsuo, 2007: 0.93 (0.22, 3.91)
- Haeck, 2009: 0.61 (0.23, 1.57)
- Ito, 2010: 0.30 (0.00, 3.30)
- Ito, 2010: 0.92 (0.66, 1.30)
- Matsuo, 2007: 0.93 (0.22, 3.91)
- Muramatsu, 2007: 0.54 (0.19, 1.50)
- Zhou, 2007: * (excluded)
- Stone, 2005: 0.77 (0.40, 1.50)
- Lefevre, 2004: 0.88 (0.16, 4.74)
- Haeck, 2009: 0.61 (0.23, 1.57)
- Ito, 2010: 0.30 (0.00, 3.30)
- Ito, 2010: 0.92 (0.66, 1.30)
Figure 54. Impact of embolic protection devices combined versus control on 180-day MACE.

Relative risk meta-analysis plot (random effects)

Cochran Q: P = 0.828
Egger: P = 0.029

Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

- Haeck, 2009: 0.74 (0.36, 1.54)
- Kelbaek, 2008: 1.23 (0.68, 2.23)
- Tahk, 2008: 0.77 (0.23, 2.52)
- Cura, 2007: 0.91 (0.42, 1.96)
- Hahn, 2007: 0.12 (0.00, 0.91)
- Matsuo, 2007: 0.77 (0.36, 1.65)
- Muramatsu, 2007: 0.97 (0.60, 1.56)
- Stone, 2005: 0.89 (0.53, 1.49)
- Combined [random]: 0.91 (0.71, 1.16)

Cochran Q: P = 0.828
F: 0%
Egger: P = 0.029

Appendix J: Glossary

**Acute Coronary Syndrome:** Any group of clinical symptoms compatible with acute myocardial ischemia. Acute coronary syndrome includes the spectrum of clinical conditions ranging from unstable angina to non-Q-wave myocardial infarction and Q-wave myocardial infarction.

**Catheter Aspiration Device:** Including the Diver, Diver CE, Export, Pronto, Rescue, Thrombuster, and TransVascular Aspiration Catheter devices.

**Confidence Intervals (CIs):** A range that is likely to include the given value. Usually presented as a percent (%). For example, a value with 95% confidence interval implies that when a measurement is made 100 times, it will fall within the given range 95% of the time.

**Correlation Coefficient:** A value (which usually ranges from zero to one) that indicates the degree of relationship between two variables. For example, a correlation coefficient of one would indicate a strong relationship.

**DerSimonian and Laird Random-Effects Model:** A statistical method based on the assumption that the effects observed in different studies (in a meta-analysis) are truly different.

**Embolic Protection Device:** Included the following devices: FilterWire EX, FilterWire EZ, SpideRX, AngioGuard, AngioGuard XP, PercuSurge GuardWire, PercuSurge GuardWire Plus, Proxis

**Egger’s Weighted Regression Statistics:** A method of identifying and measuring publication bias.

**I²:** Measure of degree of variation due to statistical heterogeneity. Usually reported as a percent ranging from 0 to 100.

**Mechanical Thrombectomy Device:** Including the AngioJet and X-Sizer devices.

**Meta-Analysis:** The process of extracting and pooling data from several studies investigating a similar topic to synthesize a final outcome.

**Myocardial Blush Grade:** An angiographic method of grading myocardial tissue perfusion ranging from grade 0 to grade 3. In grade 0, the dye fails to enter the microvasculature with either minimal or no ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit artery indicating lack of tissue level perfusion. In grade 1, the dye slowly enters but fails to exit the microvasculature. There is the ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature and dye staining is present on the next injection (approximately 30 seconds between injections). In grade 2, there is delayed entry and exit of dye from the microvasculature. There is the ground glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit lesion that is strongly persistent at the end of the washout phase (i.e. dye is strongly persistent after 3 cardiac cycles of the washout phase and either does not or only minimally diminishes in intensity during washout). In grade 3, there is
normal entry and exit of dye from the microvasculature. There is a ground glass appearance ("blush") or opacification of the myocardium in the distribution of the culprit lesion that clears normally, and is either gone or only mildly/moderately persistent at the end of the washout phase (i.e. dye is gone or is mildly/moderately persistent after 3 cardiac cycles of the washout phase and noticeably diminishes in intensity during the washout phase), similar to that in an uninvolved artery. Blush that is of only mild intensity throughout the washout phase but fades minimally is also classified as grade 3.

**Non-ST Segment Myocardial Infarction:** An acute coronary syndrome characterized by myocardial ischemia without an elevation of the ST-segment on the electrocardiograph. Most patients who have non-ST-segment elevation will ultimately develop a non Q-wave acute myocardial infarction.

**Publication Bias:** The possibility that published studies may not represent all the studies that have been conducted, and therefore, create bias by being left out of a meta-analysis.

**Q Statistic:** A test to assess the presence of statistical heterogeneity among several studies.

**Relative Risks (RRs):** The ratio of an event occurring in an exposed group to an event occurring in a non-exposed group in a given population. A ratio of one indicates no difference in the risk between the two groups.

**Risk difference:** The absolute difference in the event rate between two comparison groups. A risk difference of zero indicates no difference between comparison groups.

**Sensitivity Analyses:** A ‘what if’ analysis that helps determine the robustness of a study. Helps determine the degree of importance of each variable for a given outcome.

**Standard Deviations (SDs):** A measure of the variability of a data set. For a simple data set with numbers, can be calculated using the following formula:

\[
\sigma = \left( \frac{\sum(x-x_m)^2}{N} \right)^{0.5}
\]

- \(\sigma\) is standard deviation
- \(x_m\) is the average
- \(\sum(x-x_m)\) is the sum of \(x_m\) subtracted from each individual number \(x\)
- \(N\) is the total number of values

Note: Other formulas also exist.

**Statistical Heterogeneity:** Variability in the observed effects among studies in a meta-analysis.

**ST-Segment Myocardial infarction:** An acute coronary syndrome characterized by myocardial ischemia with elevation of the ST-segment on the electrocardiograph. Most patients who have ST-segment elevation will ultimately develop a Q-wave acute myocardial infarction.

**Target Revascularization:** Any repeat percutaneous intervention or surgical bypass of the target lesion or segment of the target vessel.
**TIMI-3 Blood Flow**: Thrombolysis in myocardial infarction graded with a range from 0 to 3. A grade of 0 is defined as complete occlusion of the infarct related artery. A grade of 1 is defined as some penetration of contrast material beyond the point of obstruction but without perfusion of the distal coronary bed. A grade of 2 is defined as perfusion of the entire infarct vessel into the distal bed but with delayed flow compared with a normal artery. A grade of 3 is defined as full perfusion of the infarct vessel with normal flow.

**Unstable Angina**: An acute coronary syndrome characterized by chest pain which occurs unexpectedly and at rest. The most common cause of the chest pain is due to reduced blood flow to the myocardium caused by either atherosclerotic narrowing or constriction of the coronary arteries or partial blockage of the coronary arteries by a blood clot.