Effective Health Care Program

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

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)?

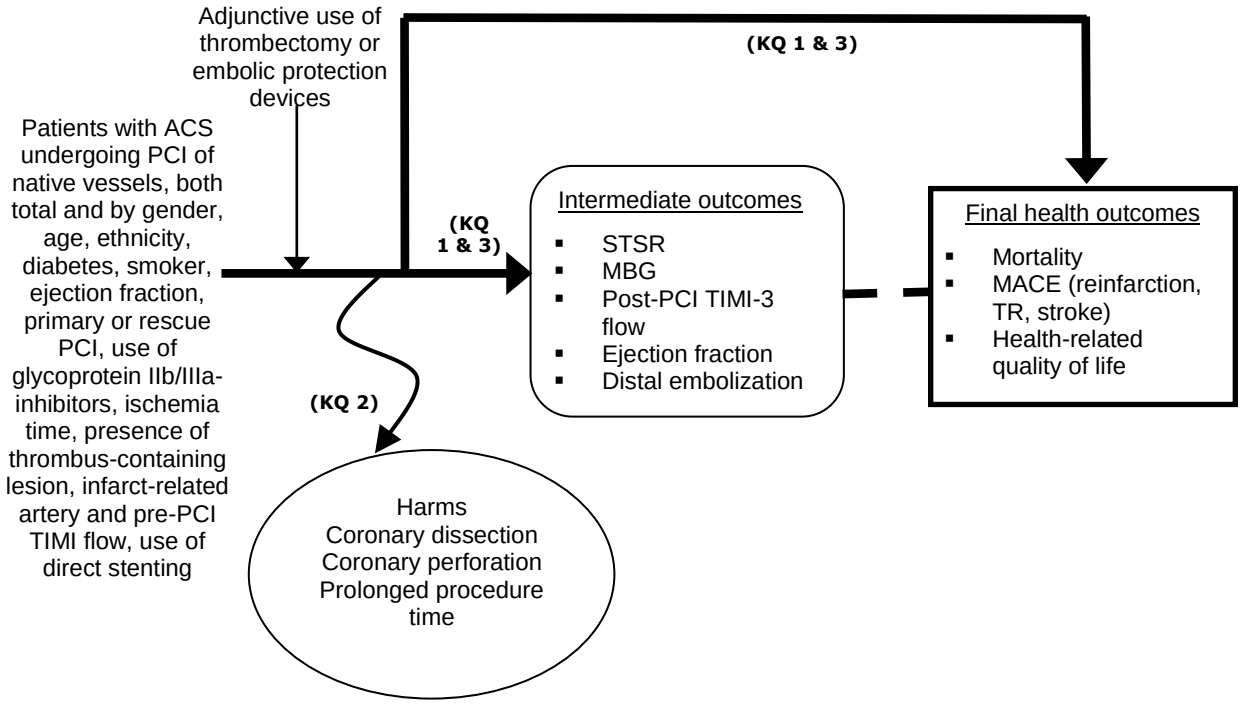
KQ 2. In patients with ACS who are undergoing PCI of native vessels, how do the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

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.

Figure A. Analytic framework for adjunctive devices to remove thrombi and protect against distal embolization in patients with ACS who are undergoing PCI of native vessels



Note: ACS = acute coronary syndrome; KQ = Key Question; MACE = major adverse cardiovascular event; 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 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.[8] 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.[8] Statistical heterogeneity was addressed by using the I^2 statistic and the Cochrane Q-statistic. An

I^2 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.[9] 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.[10] (No adjustment for multiple hypothesis testing was performed.) 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.[11]

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[4,6,7,12-58] and seven controlled observational studies[59-65] 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,[51,52] and three direct comparative randomized trials assessed for intermediate health outcomes.[51,52,54] 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[5,16,19,20,22-27,29,30,66-68] but did not significantly impact other final health outcomes[5,16,19,20,22-30,66,69,70] compared with control. Limiting the analysis to good-quality trials[5,16,19,20,22-29,66,68,69] did not affect the results. The controlled observational studies found no significant impact of catheter aspiration device use on final health outcomes.[62,64,65] 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[4,6,7,12-15,33-38,40,42,56-58,71-74] with one exception. Distal filter embolic protection devices significantly increased the risk of target revascularization.[6,56,73] Limiting the analysis to good-quality trials[4,6,7,12-15,33,34,36-38,40,42,71,72] did not alter these findings, and controlled observational studies[59,61] 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,[16-20,22-24,26-32,66,75,76] MBG-3,[16-20,22-24,26,28,29,31,32,66,76,77] and TIMI-3 blood flow[16,17,19,20,22-24,26-30,32,66,76,77] while significantly reducing the occurrence of distal embolization[16,17,19,20,22,23,27-29,31,66,76] and no reflow.[16,20,22,23,28-31,66,78] Limiting the results to good-quality trials[16,19,20,23,24,26-29,66,76,77,79] yielded the same significant findings. In RCTs, ejection fraction was not significantly impacted by catheter aspiration therapy versus control.[16,17,19,21,23,25-27,29,32,53] One controlled observational study was supportive of the distal embolization finding but did not find a significant impact on ST-segment resolution,[62] while a second study found a significant reduction in ejection fraction with catheter aspiration use versus control.[65] Two studies found no significant impact of catheter aspiration on TIMI-3 blood flow versus control.[64,65] 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.[4,6,7,12-15,33-42,56,73] Limiting the results to good-quality trials did not alter these findings.[4,6,7,12-15,33,34,36-42,56,73] 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[7,33,34,36-40,74,80] and TIMI-3 blood flow[6,7,13,33,34,36-41,56-58,74,80] but did not impact other intermediate outcomes versus control in the other available RCTs.[6,33,34,36-38,40,56,74,80] Limiting the results to good-quality trials did not alter these findings.[4,6,7,12-15,33-42] 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,[61] 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[46] and one controlled observational study[60] 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.[43,44,47,55] 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.[61] 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[45] but did not significantly impact TIMI-3 blood flow.[45,46] 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.[55] However, in a controlled observational study, the use of a mechanical thrombectomy device significantly reduced the attainment of TIMI-3 blood flow versus control.[63] Use of distal filter embolic protection devices did not impact ejection fraction or TIMI-3 blood flow versus control in RCTs.[44] 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)

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

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

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

[a] Outcomes reported are those with the longest duration of followup. Final health or intermediate outcomes graded as ~~in~~sufficient" 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.

Note: ACS = acute coronary syndrome; CI = confidence interval; MACE = major cardiovascular adverse event; MBG = myocardial blush grade; OBS = observational study; RCT = randomized controlled trial; RD = risk difference; RR = relative risk; STEMI = ST-segment elevation myocardial infarction; TIMI = thrombolysis in myocardial infarction.

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[4,13-16,20,23-29,33,37-40,42,43,51-53] and three controlled observational studies[61,62,64] 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.[51,52] 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.[51] For STEMI, no significant differences were found between catheter aspiration devices and distal balloon embolic protection devices for procedure time.[52] 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[23-26,28] but did not significantly impact side branch occlusion versus control.[20,24] In eight of nine RCTs assessing procedure time as well as in one controlled observational study, no significant change in time occurred versus control.[16,20,23-25,28,29,53,64] The same results occurred when the dataset was limited to good-quality trials.[16,20,23-25,28,29] The sole controlled observational study[62] 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,[4] coronary perforation,[4,15] or side branch occlusion,[14] but in all three trials the procedure time was significantly increased versus control.[4,13,15] Limiting the results to good-quality trials did not alter the conclusions. The sole controlled observational study[62] 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.[33] However, the sole RCT evaluating procedure time found a significant increase in time with distal filter embolic protection devices versus control.[33] 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[39,40] or side branch occlusion[37,40] versus control, and no coronary dissections occurred in either group in the one trial reporting the outcome.[37,40] Limiting the results to good-quality trials[37,39,40] 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.[42] 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,[33,39] coronary perforation,[33,39,40] or side branch occlusion.[33,37,40] In four of five trials, the procedure time was prolonged in patients receiving embolic protection devices versus control.[33,37,40,42] Limiting the results to good-quality trials[33,37,40,42] 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.[43] 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)

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

[a]Outcomes reported are those with the longest duration of followup. Adverse events graded as ~~in~~sufficient" 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.

Note: ACS = acute coronary syndrome; CI = confidence interval; OBS = observational study; RCT= randomized controlled trial; RD = risk difference; RR = relative risk; STEMI = ST-segment elevation myocardial infarction.

Table C. Final, intermediate, and adverse outcomes with insufficient data

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

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,[6,23-25,28,29,33,40,42] an individual patient data meta-analysis,[81,82] a pooled analysis,[83] and five observational studies[60,70,84-86] 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;[6,24,28,33,40,42] (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;[42] 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.[42]

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.[23-25] 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.[23]

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.[81,82] 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[83] 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.[60] 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[70] 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.[84,85,87]

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.

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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™, 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 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™.

I^2: 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 (~~–b~~lush") 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 is strongly persistent at the end of the washout phase (i.e., dye is strongly persistent after three 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 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:
$\sigma = ((\sum(x\text{-}xm))2/N)0.5$, where
σ is the standard deviation
xm is the average
$\sum(x\text{-}xm)$ is the sum of xm 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 (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 ≤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[7]

Grade 0	Complete occlusion of the infarct-related artery
Grade 1	Some penetration of contrast material beyond the point of obstruction but without perfusion of the distal coronary bed
Grade 2	Perfusion of the entire infarct vessel into the distal bed but with delayed flow compared with a normal artery
Grade 3	Full perfusion of the infarct vessel with normal flow

Table 2. Myocardial blush grade[8]

Grade 0	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.
Grade 1	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).
Grade 2	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).
Grade 3	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.

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.[9] 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).[10]

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.[1,3] However, use of embolic protection devices in STEMI has been less well supported mainly because of underpowered clinical trials that evaluated intermediate markers.[3] 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.[11-21] 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

Device Type (Mechanism)	Device Name	Manufacturer	FDA Approved Indication(s)
Catheter Aspiration	Diver™	Invatec	Not/no longer available for sale in US
	Diver™ CE	Invatec	Not/no longer available for sale in US
	Export®	Medtronic	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
	Pronto™	Vascular solutions	Removal of emboli and thrombi from vessels in the arterial or deep venous system and to infuse diagnostic or therapeutic agents
	Rescue™	Boston Scientific	Not/no longer available for sale in US
	Thrombobuster®	Kaneka Medix	No FDA approved indication
	TransVascular Aspiration Catheter® (TVAC)	Nipro	No FDA approved indication
Mechanical Thrombectomy	AngioJet®	MEDRAD Interventional / Possis	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
	X-Sizer®	ev3	Removal of thrombus in synthetic hemodialysis access grafts
Distal Filter Embolic Protection	FilterWire EX™	Boston Scientific	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
	FilterWire EZ™	Boston Scientific	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
	SpideRX™	ev3	No longer available for sale in US
	AngioGuard™	Cordis	No longer available for sale in US
	AngioGuard™ XP	Cordis	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
	Filtrap	Nipro	No FDA approved indication
Distal Balloon Embolic Protection	PercuSurge GuardWire®	Medtronic	Not/no longer available for sale in US
	PercuSurge GuardWire™ Plus	Medtronic	Use to contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures
Proximal Balloon Embolic Protection	Proxis™	St. Jude Medical	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

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)?

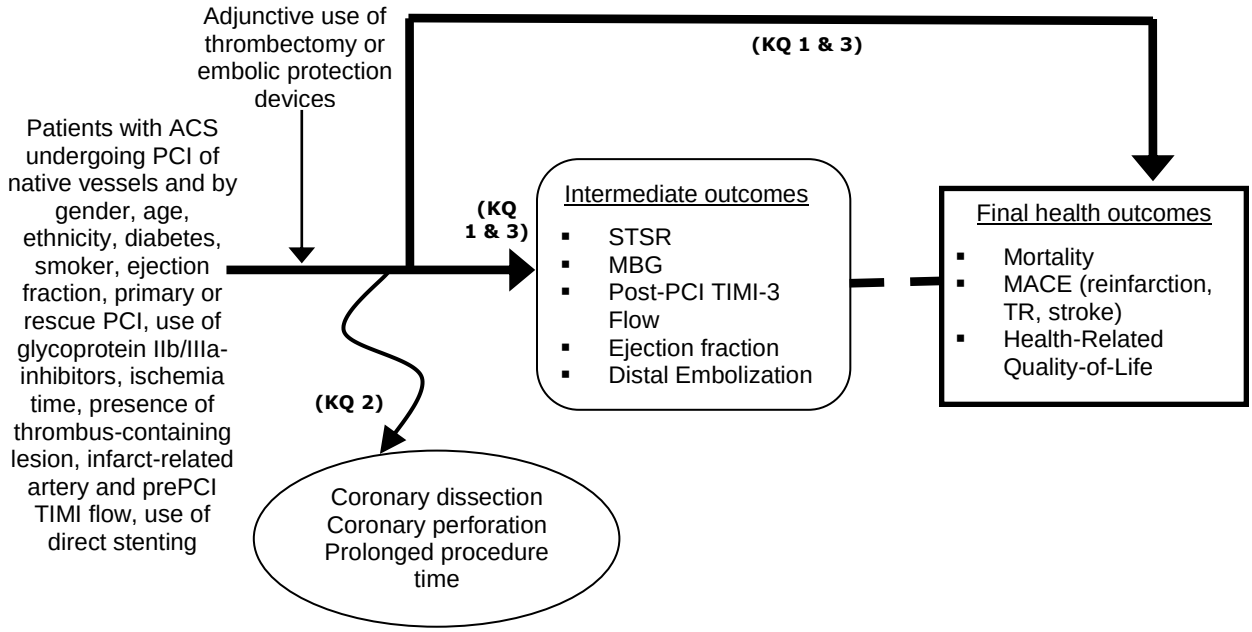
Key Question 2. In patients with ACS who are undergoing PCI of native vessels, how does the rate and type of adverse events (e.g., coronary dissection, coronary perforation, prolonged procedure time) differ between device types when compared to PCI alone?

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



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 ≥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.[22] 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

Quality Rating	Definition
Good (low risk of bias)	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.
Fair	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.
Poor (high risk of bias)	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.

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.[23] 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.[23]

Statistical heterogeneity was addressed by using the 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.[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).[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

Grade	Definition
High	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.
Moderate	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.
Low	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.
Insufficient	Evidence either is unavailable or does not permit estimation of an effect.

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.[26] 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

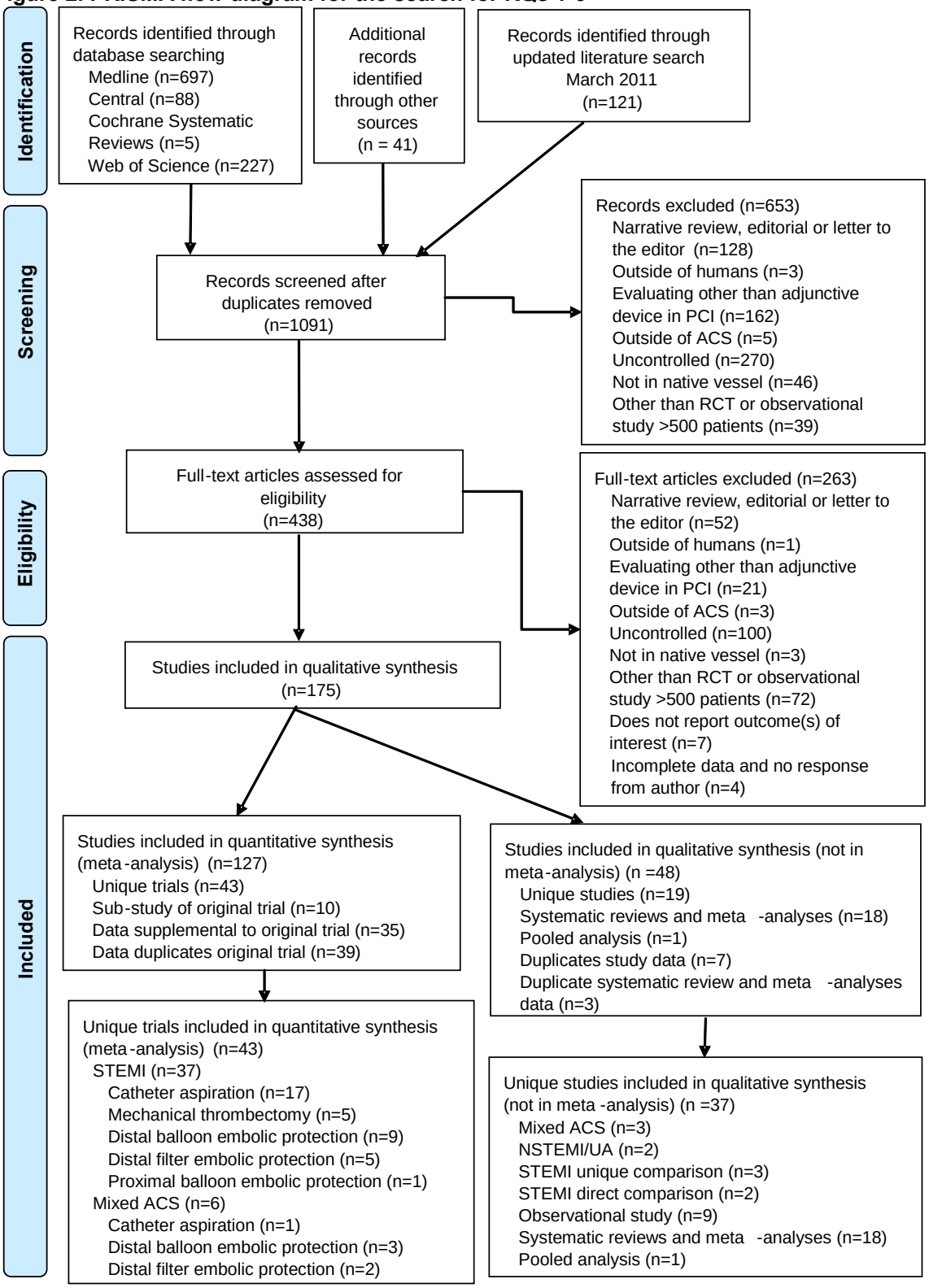
Feature	Condition that limits applicability	Features to be extracted into evidence table
Population	Differences between patients in the study and the community	Eligibility criteria, demographics
Population	Events rates markedly different than in the community	Event rates in treatment and control groups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

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.

Figure 2. PRISMA flow diagram for the search for KQs 1-3



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.
  - 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.
  - 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.
  - 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.
  - 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 [11-21,27-141] for the quantitative analysis. Of the 127 publications, 50 were full articles[11-18,27,29,40,44,62-64,66,68,69,71,72,74,75,83,84,88-90,95,98,103,107,111,112,114,115,119,123,125,133-141] 48 were abstracts,[20,21,28,30-33,52-60,70,76-79,85-87,91,93,96,99-102,104,105,108,109,116,117,120,122,124,127-132,134] and 29 were slide presentations.[15,19,34-37,39,41-43,45-50,61,67,73,80-82,92,93,97,110,118,121] 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[12-16,19-21,62,68,69,71,74,83,85-87,138] (n=3355) evaluated the impact of catheter aspiration devices, five trials[11,27,29,40,44] (n=1374) evaluated the impact of mechanical thrombectomy devices, five trials[89,95,98,101,137] (n=962) evaluated the impact of distal filter embolic protection devices, nine trials[17,103,107,111,112,119,133,135,136] (n=1479) evaluated the impact of distal balloon embolic protection devices and one trial [18] (n=284) evaluated the impact of proximal balloon embolic protection devices.

Amongst the 37 trials, the earliest trial was published in 2003[44] and the latest was published in 2010.[11,135-138] The duration of followup of the trials ranged from ~~in~~-hospital"[85,86,111,119,136] to 450 days.[139] 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.[125-128,130,131] Of these six trials, two evaluated catheter aspiration devices,[127,128] one evaluated a distal filter embolic protection device,[126] and three evaluated distal balloon embolic protection devices.[125,130,132] The earliest trial was published in 2003[132] and the most recent trial was published in 2008.[125] The duration of followup ranged from in-hopsital[128] to 730 days .[125] 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 fibrinoltyic therapy while the other four trials did not report this statistic.

Forty-eight publications met inclusion criteria for the qualitative synthesis.[142-189] Of these publications, thirty-eight publications represented 20 unique studies (n=14771) [142-168] and twenty-one publications represented eighteen unique systematic reviews with meta-analysis (n=80181). [169-189] Of the 20 unique studies, 17 were full articles,[143-146,148,149,153,154,156,158,160-166] nine were abstracts,[142,147,150-152,157,159,167,168] and one was a slide presentation.[155] Of the 20 unique studies, one study was a RCTs evaluating thrombectomy or embolic protection devices in patients with mixed ACS,[166] nine studies were controlled observational studies,[142,144-147,149,152-154] two studies were RCTs evaluating thrombectomy or embolic protection devices in patients with UA or NSTEMI,[155,156] two studies were direct comparative RCTs,[158,160] two studies were RCTs with selective inclusion/exclusion criteria in patients with STEMI,[162,163] one study was a RCT with unique comparison in patients with STEMI,[165] two studies were RCTs with unique comparison in patients with mixed ACS,[164,168] and one study was a pooled analysis in STEMI patients.[143] 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 group 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.[165] The other trial compared the use of thrombectomy, distal protection and stenting versus thrombectomy and stenting alone.[168] 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[169-171,176-179,189] and seven were abstracts.[180-187] 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

Catheter aspiration device versus distal balloon embolic protection device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver^{TM} CE catheter aspiration device versus the GuardWire^{TM} Plus distal balloon embolic protection device on mortality.[160] In this trial, there was no difference in the risk of 30-day mortality [RR 1.00 (0.18, 5.54)].

Trials Versus Control

Catheter 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.[14-16,19,49,62,64,68,69,71,74,82,83,85,138] One trial was excluded from the pooled analysis of relative risk because no events occurred in either group during the prespecified time period.[74] 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).

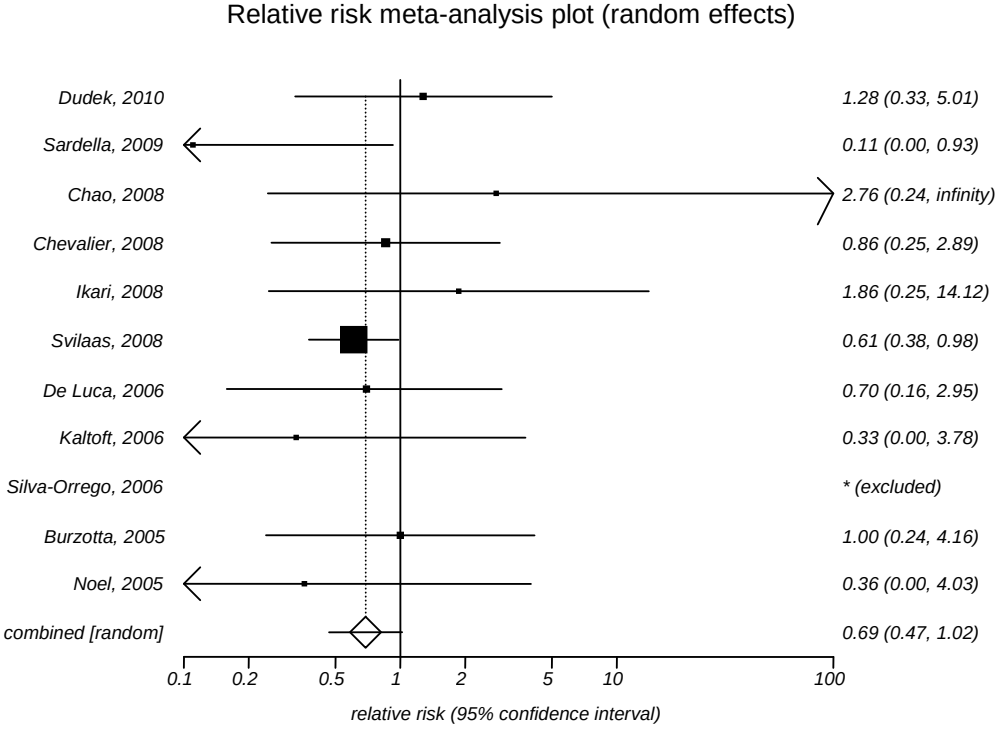
When limiting the pooled analysis to only trials of good methodological quality[14-16,19,49,62,64,68,69,71,74,82,83,138] the risk of mortality using the maximal duration of followup was in the catheter aspiration device group compared to control [RR 0.70 (0.47, 1.03)]. The weighted mean duration of followup 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[142,144,152] and 365-day mortality.[144] In the first study, the Export® aspiration catheter was compared to control.[144] 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).[144] 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.[142] 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).[152]

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



Cochran Q: P=0.870
I^2: 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

myocardial infarction.[128] 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)].

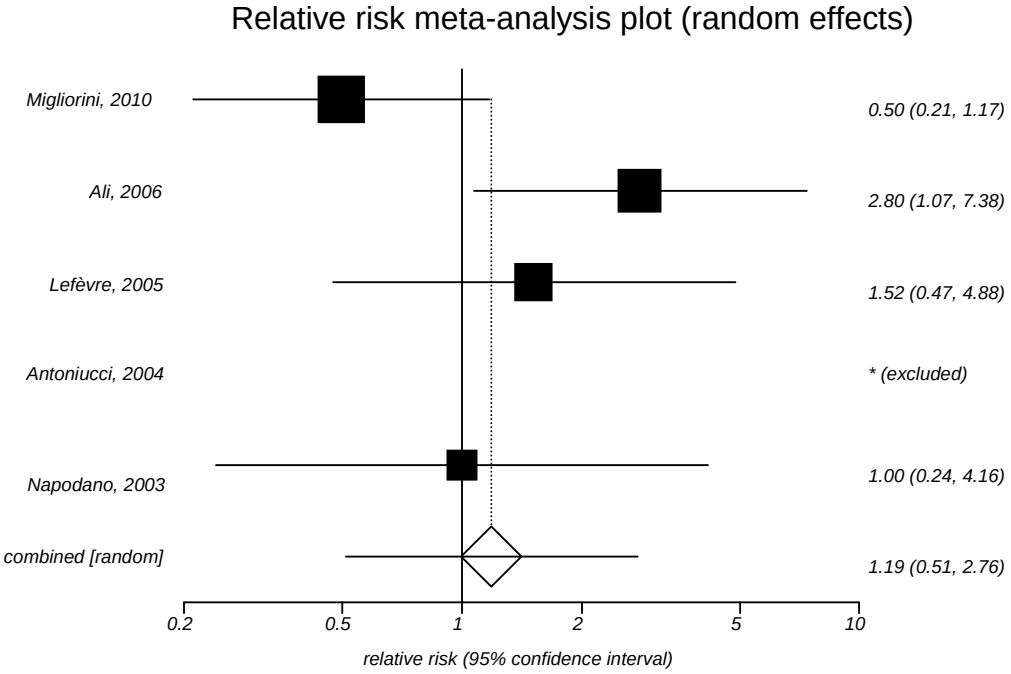
One controlled observational study of patients with acute myocardial infarction evaluated the association between the use of catheter aspiration devices and 30-day mortality.[149] The following catheter aspiration devices were included in this study: RESCUE™ catheter, Thrombuster® catheter, Transvascular 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.[11,27,29,40,44] One trial was excluded from the pooled analysis of relative risk because no deaths occurred within the prespecified time period in either group.[27] 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)][11,29,40,44] (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.[11,27,29,40,44]

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.[145] 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.

Figure 4. Impact of mechanical thrombectomy devices versus control on mortality using the maximal duration of followup in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.084
I^2: 54.9 percent
Egger: P=0.736
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 mechanical thrombectomy devices versus control on mortality in patients with STEMI or UA.[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.[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).

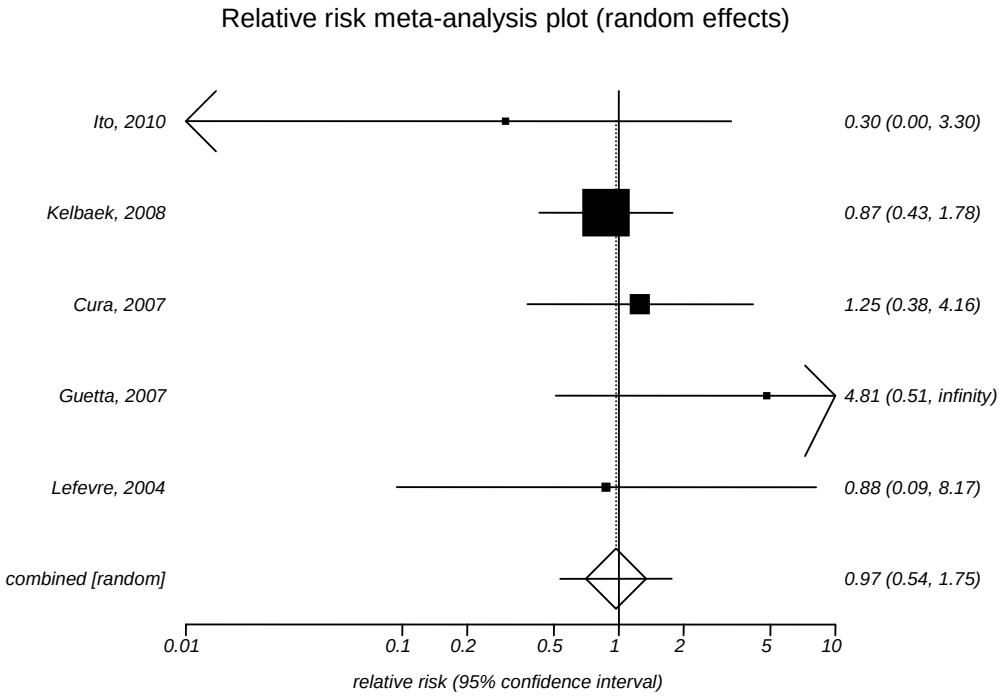
Distal filter embolic protection devices in patients with STEMI. Five RCTs evaluated the impact of distal filter embolic protection devices versus control on mortality using the maximal duration of followup.[89,95,98,101,137] In these trials, the use of distal filter embolic protection devices did not 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,[89,95,98,137] 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



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[126] and the other trial was conducted in patients with either NSTEMI or UA.[156] In the first trial, the impact of a distal filter embolic protection device (FilterWire EX™) on 30-day mortality versus control[126] 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™) on 30-day mortality[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.

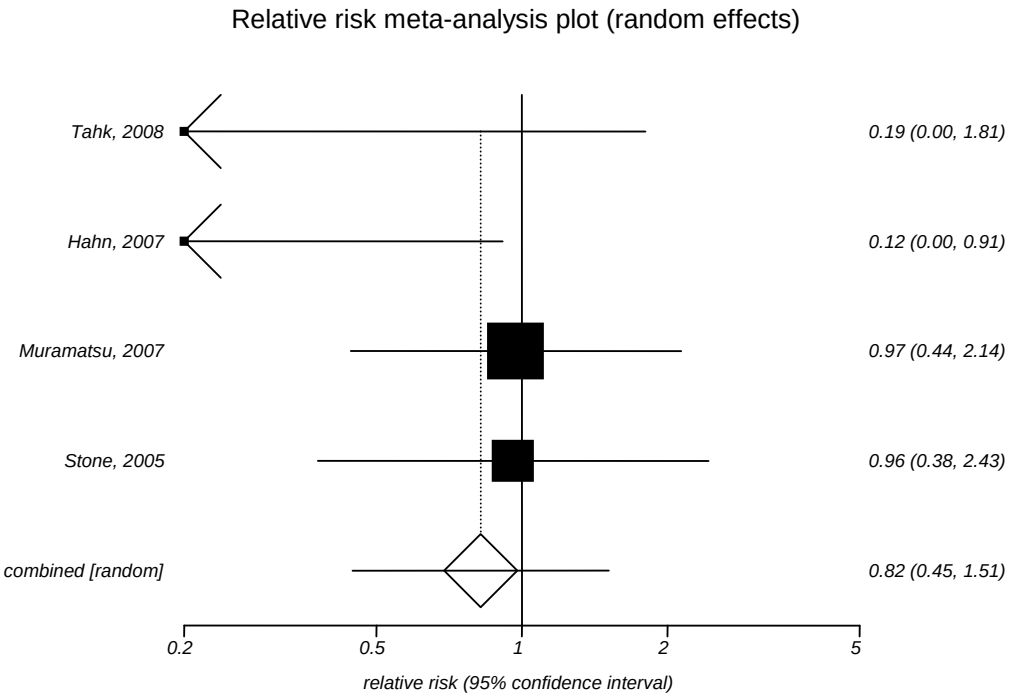
No controlled observational studies of distal filter embolic protection devices assessed this outcome.

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.[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.[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)], ≤30 days [RR 0.64 (0.30, 1.39)], 30-days [same results as the ≤30 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



Cochran Q: P=0.380
I^2: 2.5 percent
Egger: P=0.023
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.

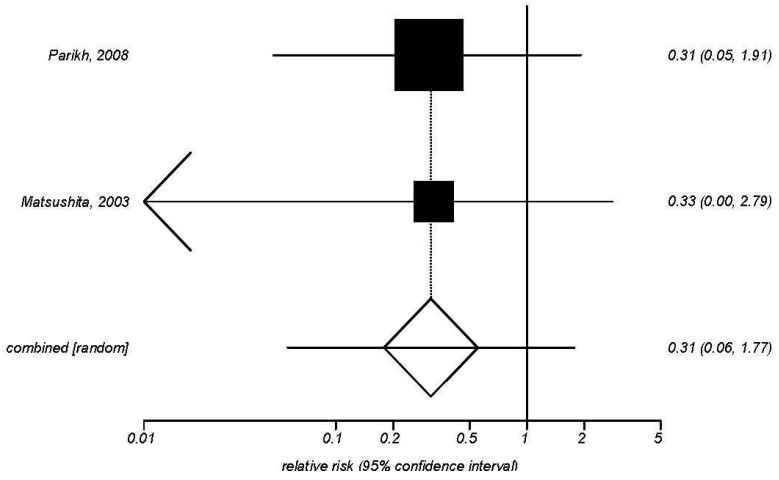
Distal balloon embolic protection devices in other ACS populations. Two RCTs evaluated the impact of distal balloon embolic protection devices versus control on mortality in patients with acute myocardial infarction using the maximal duration of followup.[125,131] The use of a distal balloon embolic 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.[125,132]

When the impact of distal balloon embolic protection devices versus control was assessed during hospitalization [RR 0.33 (0.00, 2.79)][132] and at 365-days [RR 0.31 (0.05, 1.91)],[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.[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



Cochran Q: P=0.976
I^2: Too few strata
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.

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.[18,141] 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.

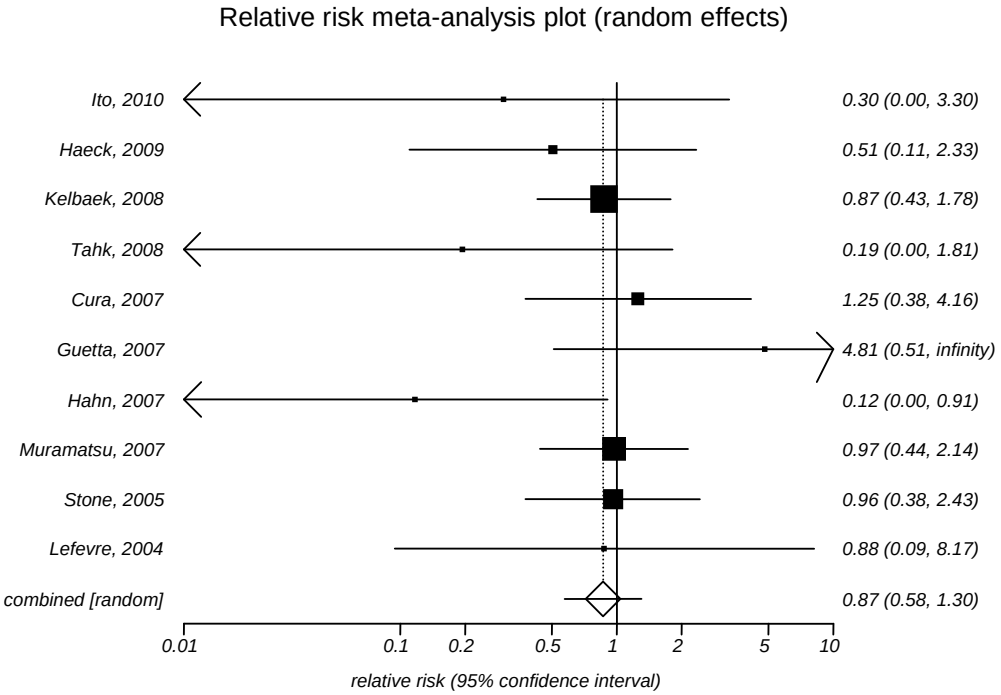
Proximal balloon embolic protection devices in other ACS populations. No studies or trials were available that were evaluating the impact of proximal balloon embolic protection devices versus control on mortality in the population.

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.[17,18,89,95,98,101,103,112,133,137] 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,[17,18,89,95,98,103,112,133,137] 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

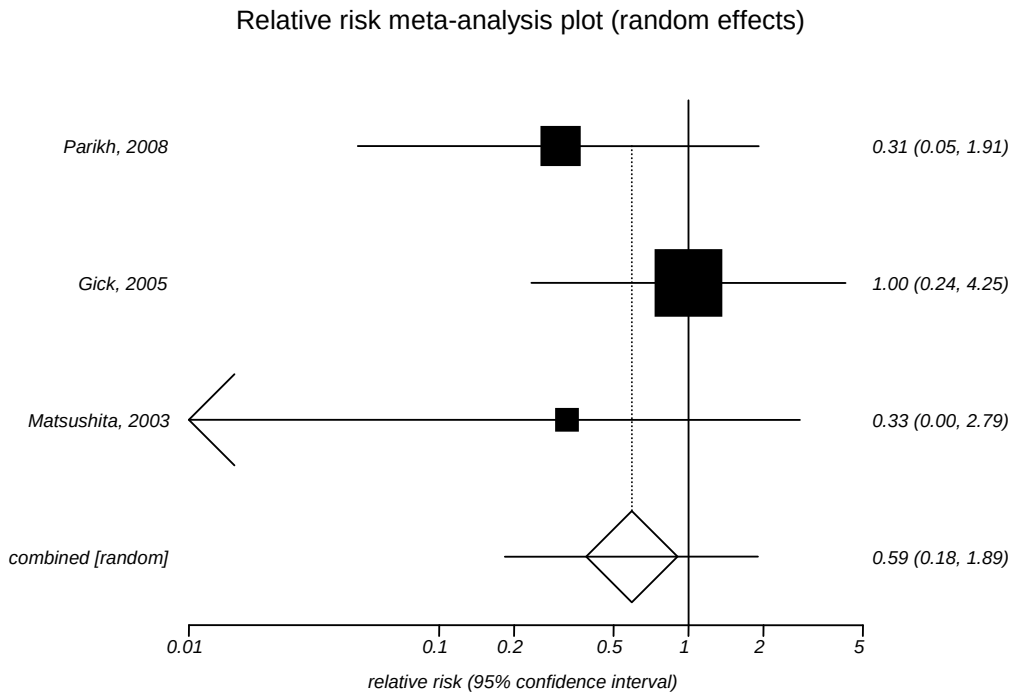


Cochran Q: P=0.798
I^2: 0 percent
Egger: P=0.254
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.[125,126,132] 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,[134] 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 ≤30days, 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
I^2: 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

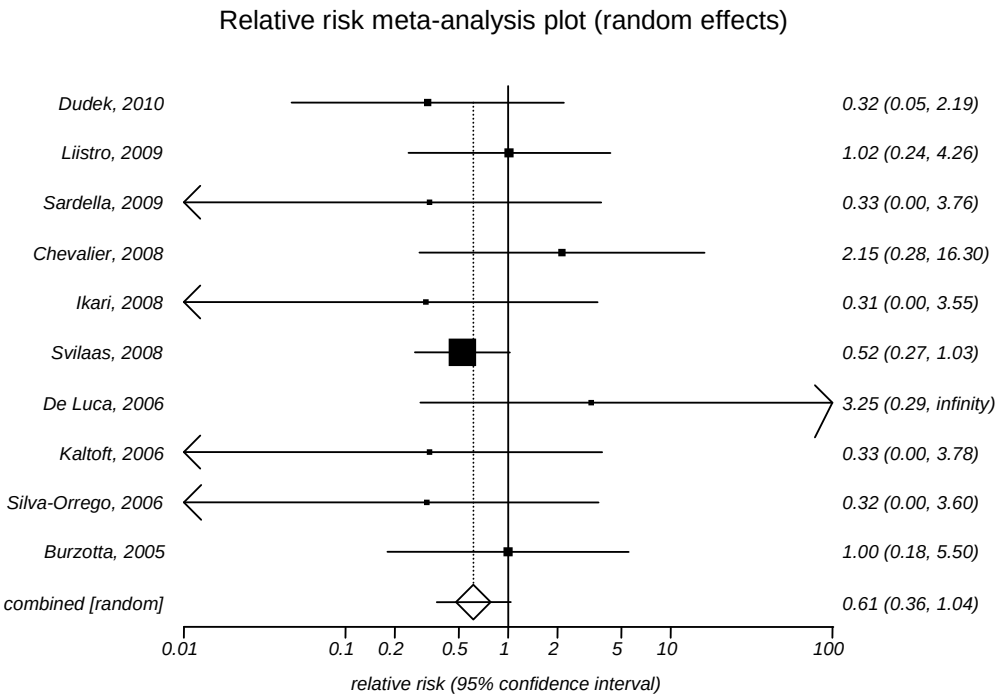
Catheter aspiration devices in patients with STEMI. Ten RCTs evaluated the impact of catheter aspiration devices versus control on the occurrence of myocardial infarction over the maximal duration of followup.[12,14-16,19,49,62,64,69,71,74,82,83,138] In these trials, the use of catheter aspiration devices 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[12,14-16,19,49,62,64,69,71,74,82,83,138] 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[144,152] and 365-day myocardial infaction.[144] 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).[144] The second study did not report the catheter aspiration devices studied.[152] 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
I^2: 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.

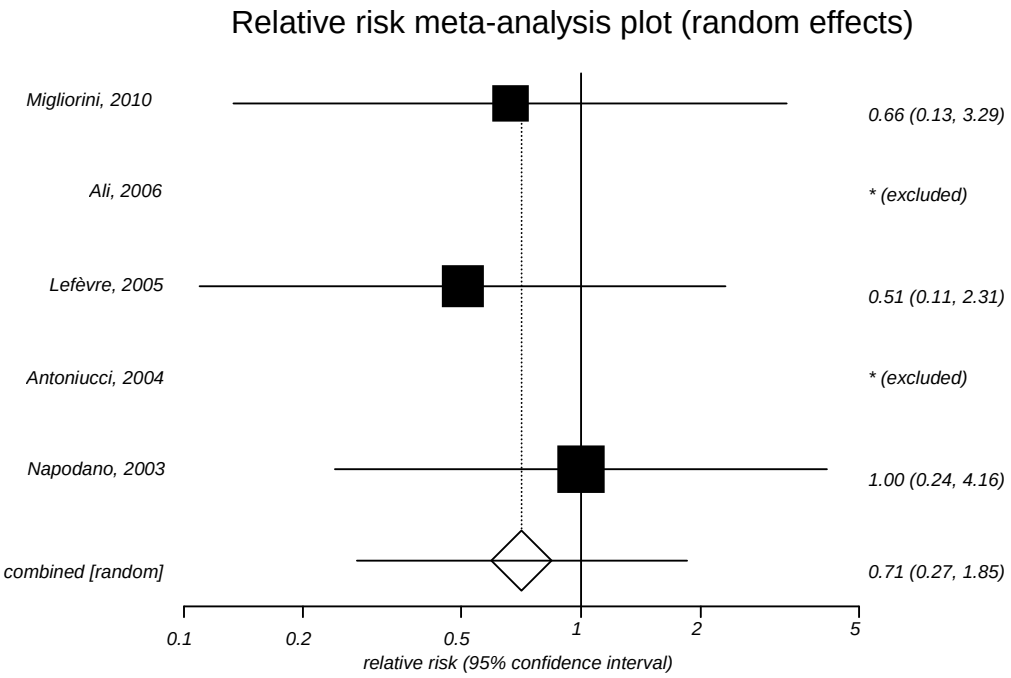
Catheter aspiration devices in other ACS population. No trials or studies evaluated the impact of catheter aspiration devices versus control in this population.

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 (I^2=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.[145] 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



Cochran Q: P=0.838
I^2: 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.[153] 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).

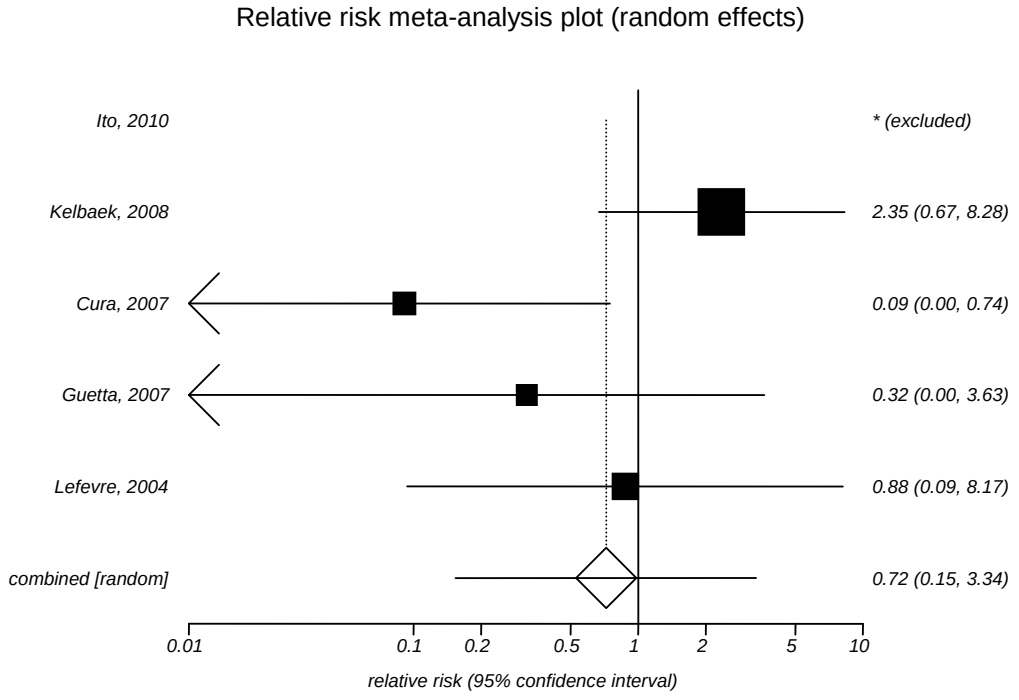
Distal filter embolic protection devices in patients with STEMI. Five RCTs evaluated the impact of distal filter embolic protection devices versus control on the occurrence of myocardial infarction using the maximal duration of followup versus control.[89,95,98,101,137] One trial was excluded from the analysis because no events occurred in the groups compared.[137] 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[89,95,98,137] 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 ≤30 days [RR 0.73 (0.12, 4.44), 30-days [same result as ≤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



Cochran Q: P=0.173
I²: 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.[126,156] These trials were not suitable for pooling because one trial evaluated patients with either STEMI or NSTEMI[126] and the other trial evaluated patients with UA.[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.

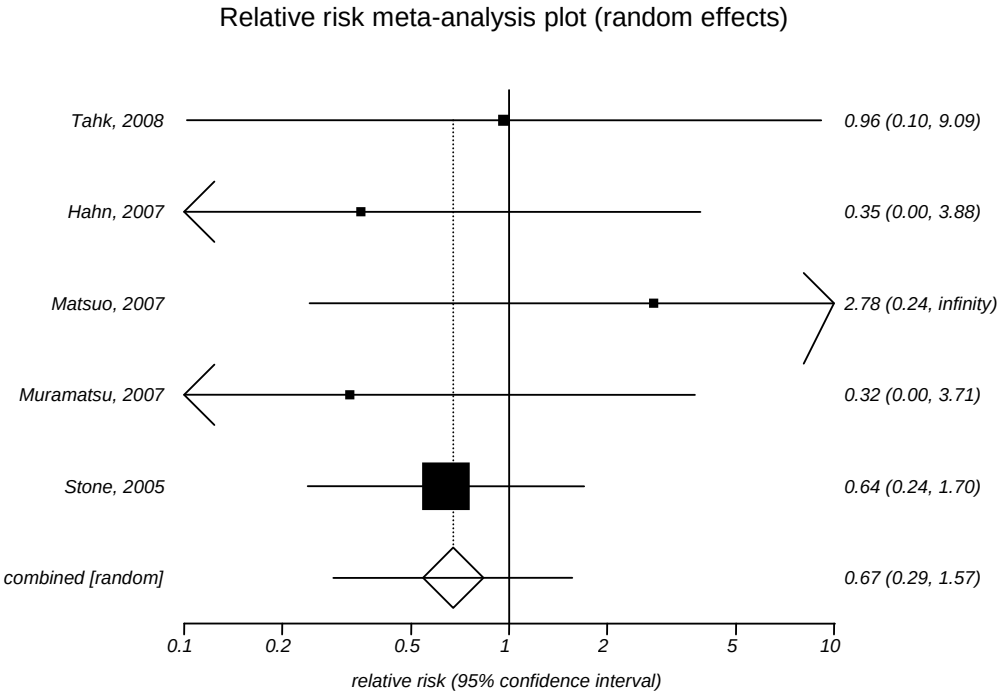
There were no available controlled observational studies evaluating this endpoint.

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.[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.[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)], ≤30 days [RR 0.85 (0.32, 2.23)], 30 days [same results as the ≤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.

Figure 13. Impact of distal balloon embolic protection devices versus control on myocardial infarction using the maximal duration of followup in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.877
I^2: 0 percent
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.

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™ 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.

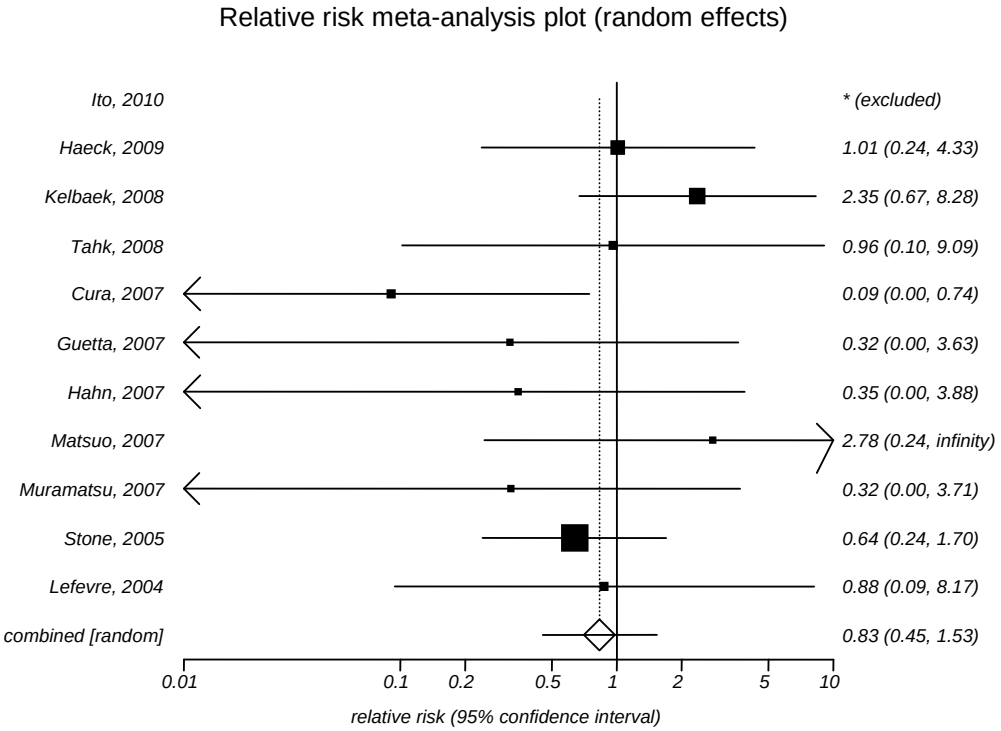
Embolic protection devices combined in patients with STEMI. *Eleven* RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on the occurrence of myocardial infarction using the maximal duration of followup.[17,18,89,95,98,101,103,107,112,133,137] One trial was excluded from the pooled analysis because no events occurred in the groups compared.[137] 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,[17,18,89,95,98,103,107,112,133,137] 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
I^2: 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^{TM} CE catheter aspiration device versus the Guardwire^{TM} Plus distal balloon embolic protection device on stroke.[160] The risk of 30-day stroke could not be calculated because no events occurred in either group during the specified time period.

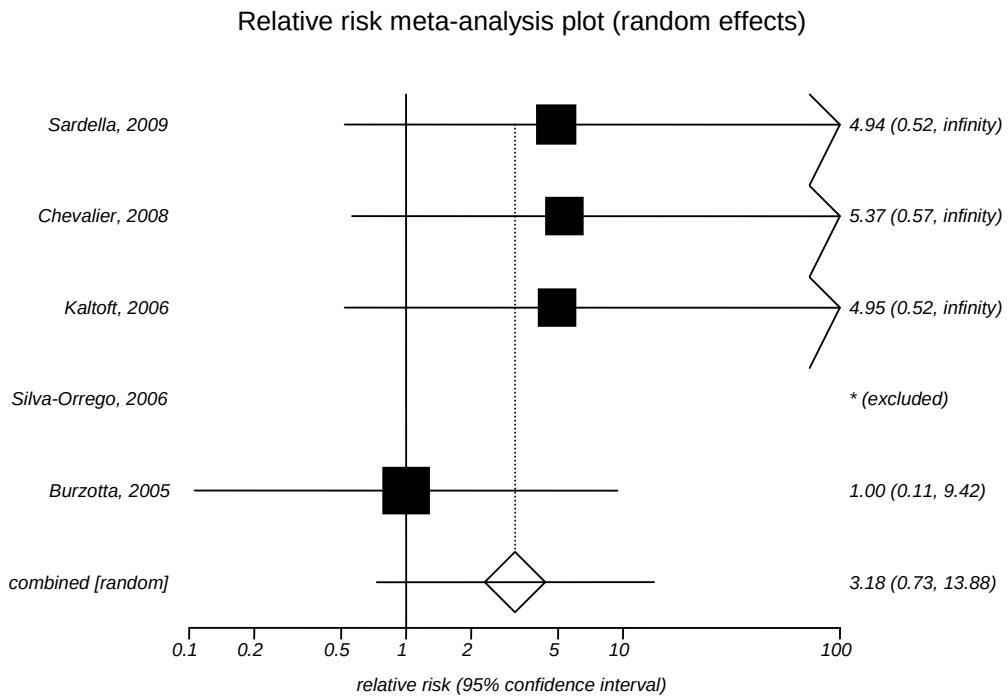
Trials Versus Control

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.[14,15,49,71,74,82,83] 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.[14,15,49,71,74,82,83]

The four trials which evaluated stroke using the maximal duration of followup are the same trials and data included in the analysis of ≤ 30 day stroke above[14,15,71,83] because the maximal duration of followup for stroke in the four trials was ≤ 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™ 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[144,152] and 365-day stoke.[144] In the first study, the Export® 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).[144] In the second study, the name of the catheter aspiration device name was not reported.[152] 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



Cochran Q: P=0.807
I^2: 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.

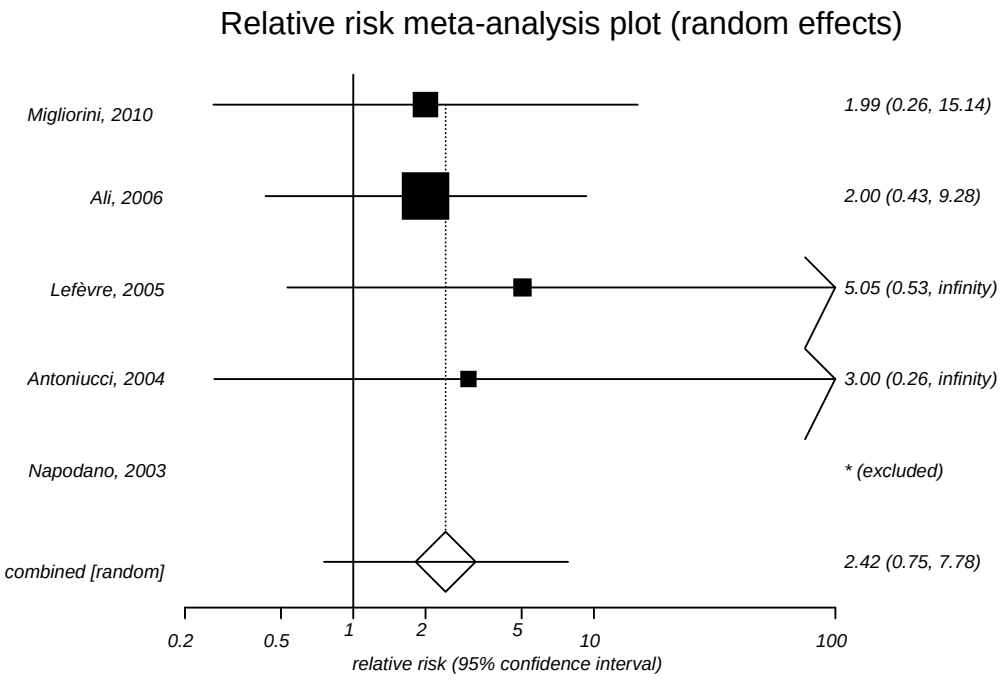
Catheter aspiration devices in other ACS populations. There were no trials or studies that evaluated catheter aspiration devices in other ACS populations.

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.[11,27,29,40,44] One trial was excluded from the pooled analysis of relative risk because no strokes occurred within the prespecified time period in either treatment group.[44] 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)][11,27,29,40] (Figure 16). The weighted-mean followup for this analysis was 5.79 months. Statistical heterogeneity and publication bias were not detected (I^2=0 percent, Egger's P=0.227). All of the pooled trials were determined to be of good methodological quality.[11,27,29,40]

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® 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



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[126] 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.[112] 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)].[112] The impact of distal balloon embolic protection devices on stroke was also evaluated in this trial at 30 days.[112] 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.

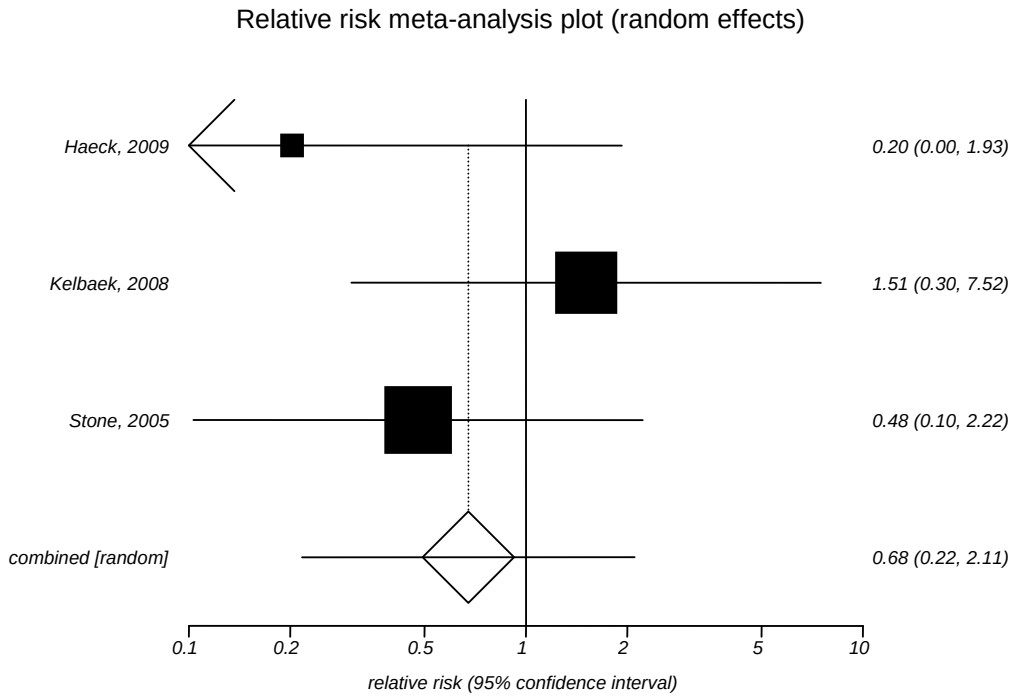
Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on stroke.[18,141] The use of a proximal balloon embolic protection device did not significantly impact the risk of having a stroke 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.[18,89,112,141] 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 (I^2=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.[18,89,112]

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
I^2: 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™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on 365-day target revascularization.[158] In this trial, the use of Diver™-Invatec did not significantly impact the risk of 365-day target revascularization [RR 1.44 (0.30, 7.00)] compared to Export®-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™ CE versus the distal balloon embolic protection device Guardwire™ Plus on 30-day

target revascularization.[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

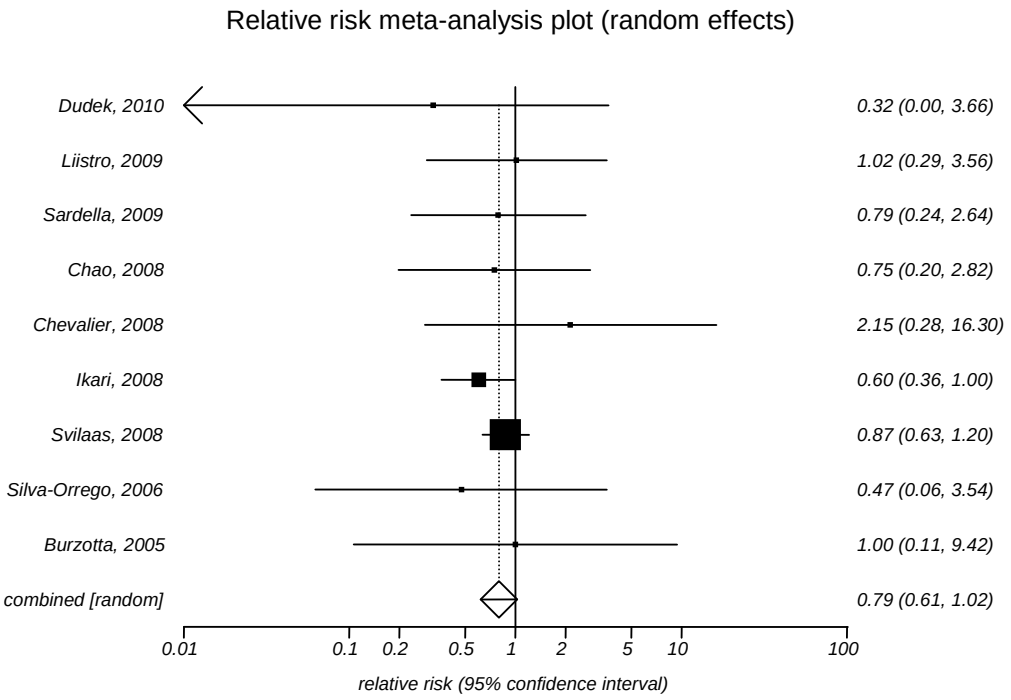
Catheter aspiration devices in patients with STEMI. Nine RCTs evaluated the impact of catheter aspiration devices versus control on target revascularization using the maximal duration of followup.[12,14-16,19,49,62,64,68,74,82,83,138] In these trials, the use of catheter aspiration devices did not significantly 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[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[144,152] and 365-day target revascularization.[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).[144] In the second study, the name of the catheter aspiration device name was not reported.[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



Cochran Q: P=0.948
I^2: 0 percent
Egger: P=0.885
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 target revascularization in other ACS populations.

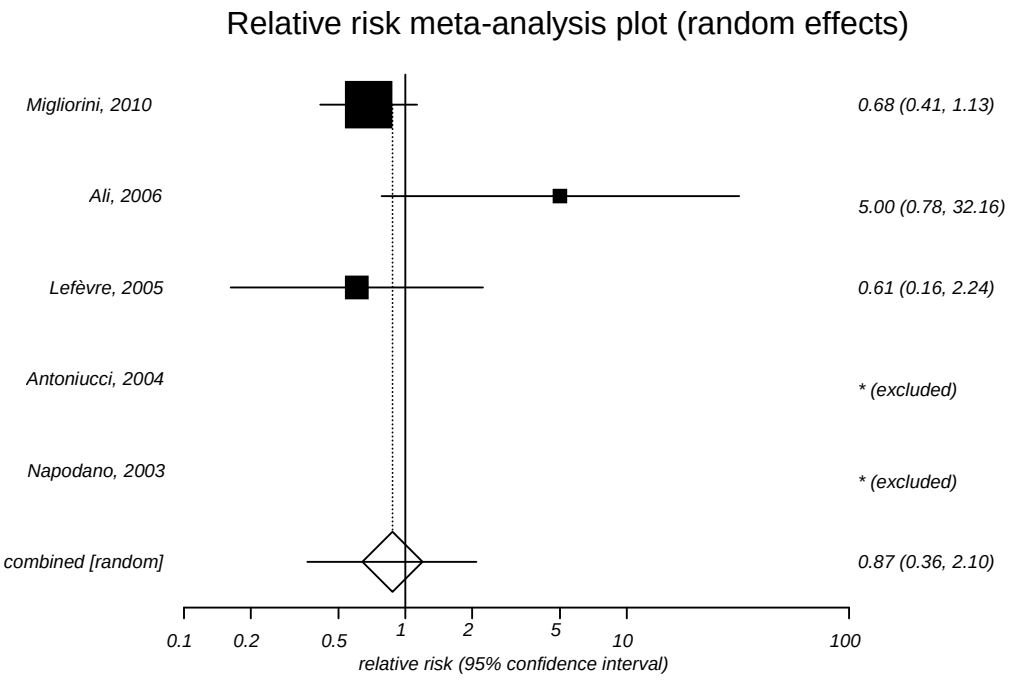
Mechanical thrombectomy in patients with STEMI. Five RCTs evaluated the impact of mechanical thrombectomy devices versus control on target revascularization using the maximal duration of followup.[11,27,29,40,44] Two trials were excluded from the pooled analysis of relative risk because no target revascularizations occurred within the prespecified time period in either treatment group.[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)][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.[11,29,40]

When the impact of mechanical thrombectomy devices versus control was assessed at ≤30 days [RR 1.62 (0.21, 12.55)], 30 days [same results as the ≤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.[145]

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 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



Cochran Q: P=0.193
I^2: 39.2 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 X-Sizer® mechanical thrombectomy device versus control on 30-day target revascularization in patients with STEMI or UA.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.[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 target revascularization was evaluated at 270 days. The use of a mechanical thrombectomy

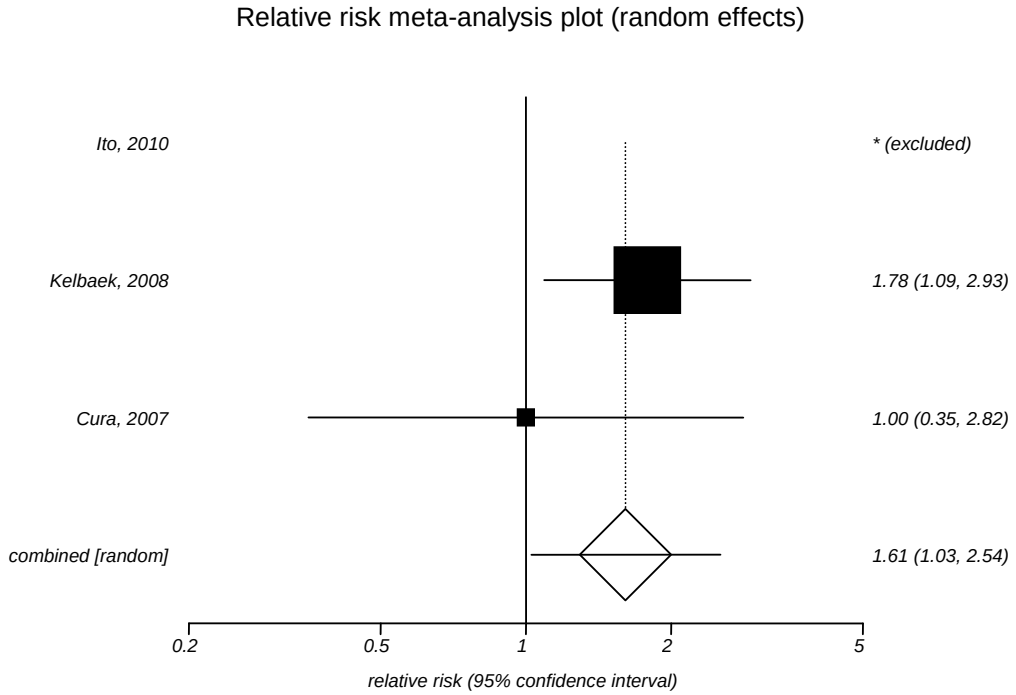
device was not associated with a significantly different rate of 180-day target revascularization compared to PCI without a mechanical thrombectomy device (5.5 percent versus 4.8 percent, p=0.72).

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 ≤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



Cochran Q: P=0.341
I^2: 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.

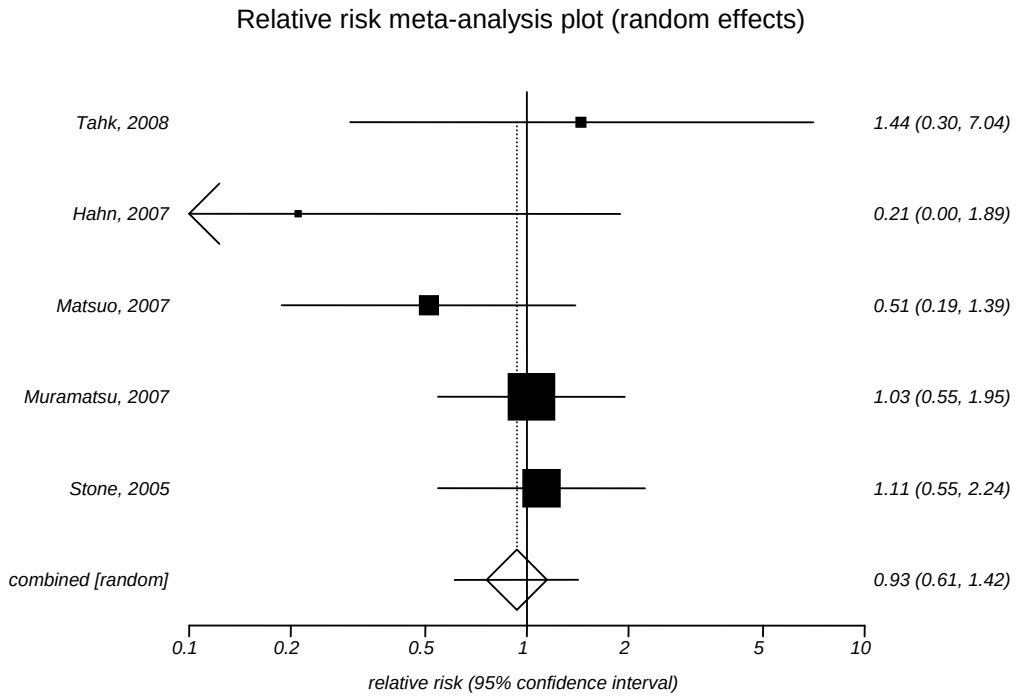
Distal filter embolic protection devices in other ACS populations. Two RCTs evaluated the impact of distal filter embolic protection devices versus control on target revascularization in patients with other ACSs using the maximal duration of followup.[126,156] These trials were not suitable for pooling because the first trial evaluated patients with either NSTEMI or STEMI[126] and the second trial evaluated patients with UA.[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.[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.[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. [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



Cochran Q: P=0.597
I^2: 0 percent
Egger: P=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.

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.[164] 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.[18,141] 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)].

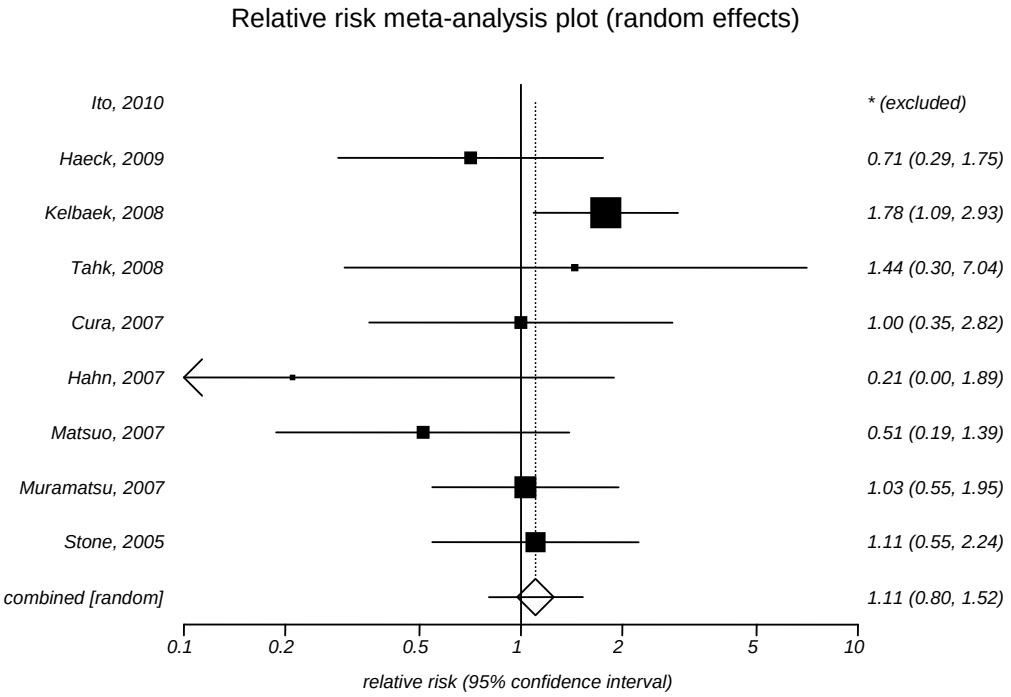
Proximal balloon embolic protection devices in other ACS populations. No trials or studies were available that evaluated the impact of proximal balloon embolic protection devices versus control on target revascularization in the population.

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.[17,18,89,95,103,107,112,133,137] One trial was excluded from the analysis because no events occurred in the groups compared.[137] 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.[17,18,89,95,103,107,112,133,]137

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)], (Appendix Figures 40-41) 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



Cochran Q: P=0.353
I^2: 10 percent
Egger: P=0.066

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 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^{TM}-Invatec catheter aspiration device versus the Export$^{®}$-Medtronic catheter aspiration device on 365-day MACE.[158] In this trial, the use of Diver^{TM}-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^{TM}-Invatec versus the Export$^{®}$-Medtronic device on 30-day MACE.[158] The use of Diver^{TM}-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^{TM} CE catheter aspiration device versus the Guardwire^{TM} Plus distal balloon embolic protection device on 30-day MACE.[160] In this trial, the use of Diver^{TM} CE did not significantly impact the risk of 30-day MACE [RR 1.33 (0.35, 5.16)] compared to Guardwire^{TM} 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 followup. [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 followup [RR 0.73 (0.61, 0.88)] (Figure 23). The weighted-mean followup for MACE using the maximal duration of followup 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[12,14-16,19,49,54,62,68,69,71,83,138] the risk of MACE using the maximal duration of followup remained significantly reduced in the catheter aspiration device group compared to control [RR 0.73 (0.61, 0.88)]. The weighted mean duration of followup 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

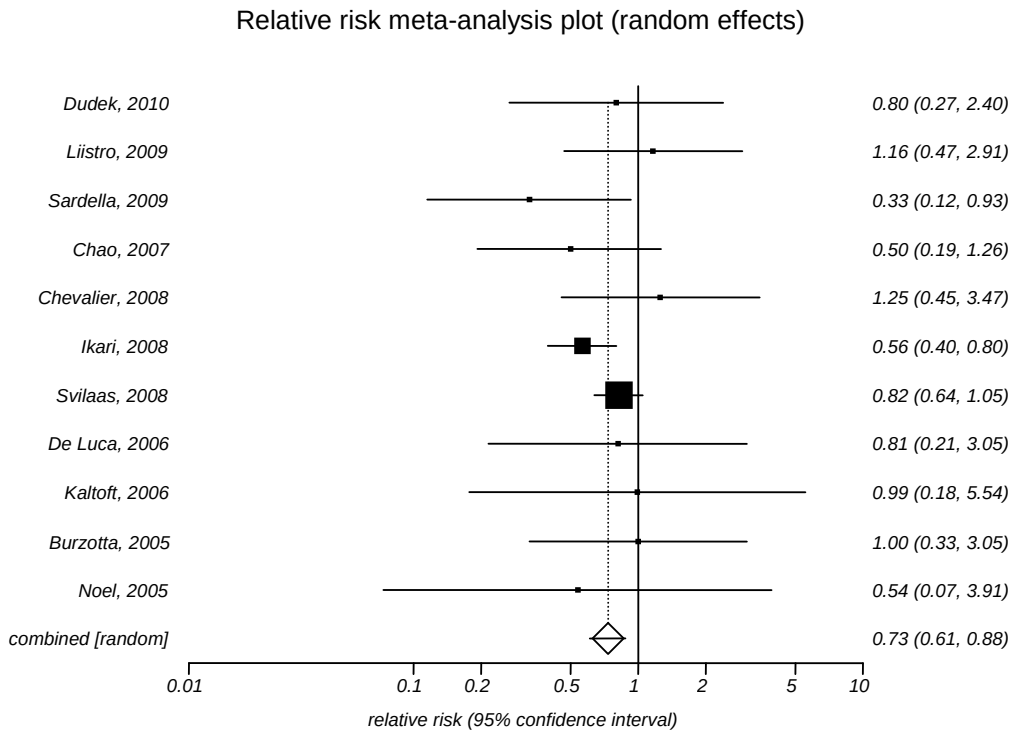
0.35)], 34 people would need to be treated with a catheter aspiration device to prevent one MACE.

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.[144,152] In the first study, the Export® aspiration catheter was compared to control.[144] 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).[144] The catheter aspiration devices included in the second study was not reported.[152]

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 followup in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.645
I^2: 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.

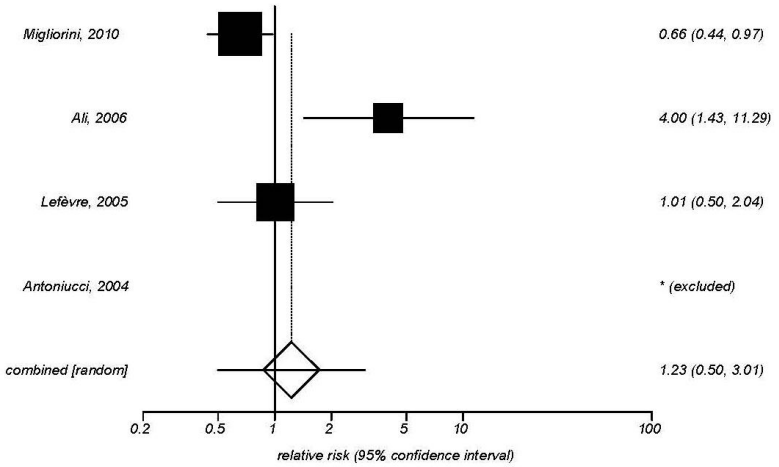
Catheter aspiration devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

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 (I2=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 ≤30 days [RR 1.28 (0.37, 4.38)], 30 days [same results as the ≤30 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® 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® 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
I^2: 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.166 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.[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 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.[89,95,98,101,137] 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 (I^2=0 percent, Egger's P=0.419).

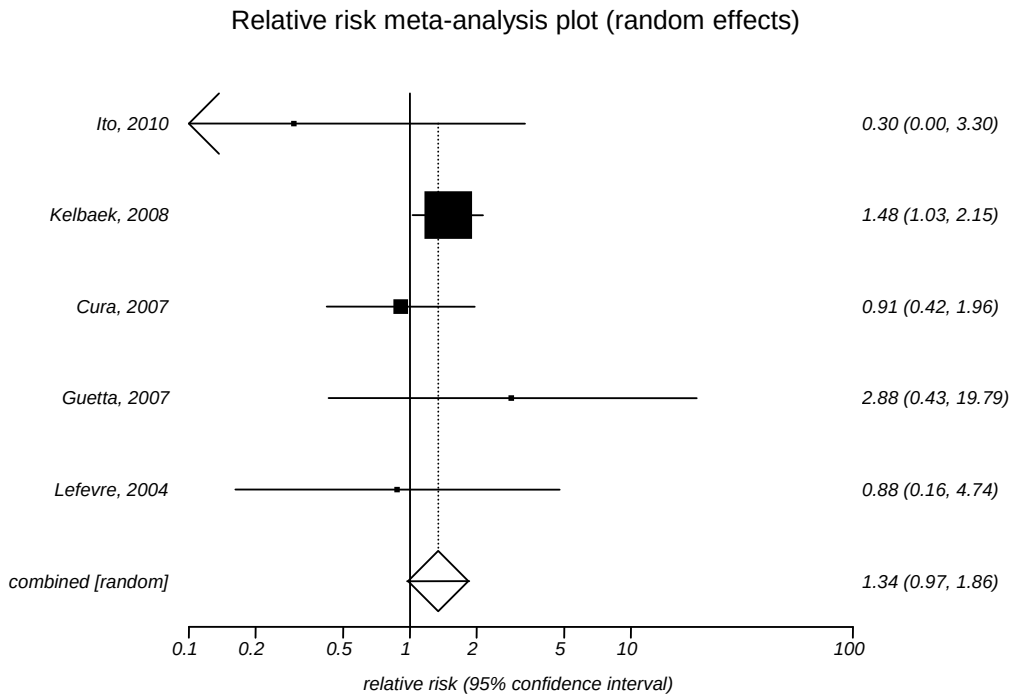
When limiting the pooled analysis to only trials of good methodological quality[89,95,98,137] the risk of MACE remained nonsignificant with distal filter embolic protection devices compared to

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 ≤30 days [RR 1.29 (0.77, 2.15)], 30 days [same results as the ≤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



Cochran Q: P=0.601
I^2: 0 percent
Egger: P=0.419
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.[126,155] These trials were not suitable for pooling because the first trial evaluated patients with either NSTEMI or UA[155] and the second trial evaluated patients with either STEMI or NSTEMI.[126] In the trial evaluating patients with NSTEMI or UA,[155] the FilterWire EZ™ 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

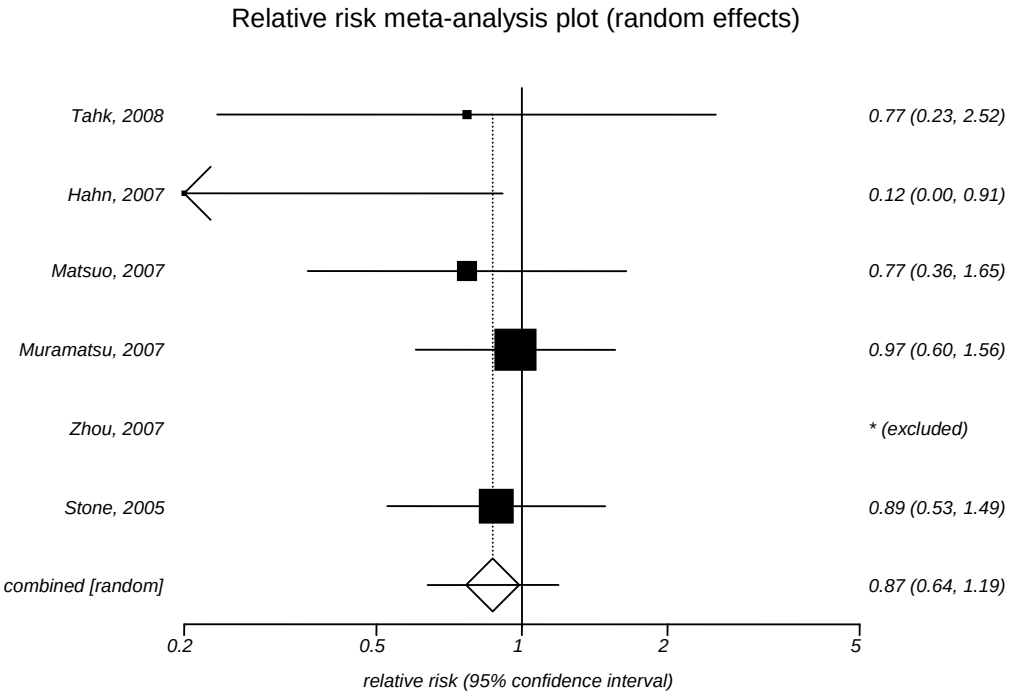
control.[155] In the trial evaluating patients with either STEMI or NSTEMI,[126] the FilterWire EX™ device was compared to control. The use of a distal filter embolic protection device did not significantly impact the risk of 180-day MACE [RR 1.08 (0.53, 2.23)] compared to control.

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.[17,103,107,111,112,133] 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.[111] 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)][17,103,107,112,133] (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.[17,103,107,111,112,133]

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



Cochran Q: P=0.685
I^2: 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.[132] 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.[18,141] 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.

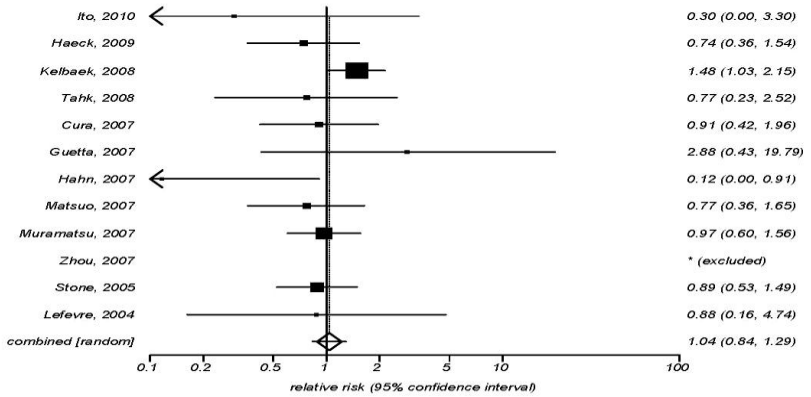
Embolic protection devices combined in patients with STEMI. Twelve RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on MACE using the maximal duration of followup.[17,18,89,95,98,101,103,107,111,112,133,137] The trial by Zhou et al 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 (I^2=0 percent, Egger's P=0.0.084). The analysis was then limited to only trials of good methodological quality[17,18,89,95,98,103,107,111,112,133,137] although one trial was excluded from the analysis because no events occurred in either group during the prespecified time period.[111] In 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 (I^2=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.[147] 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 folloup in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.494
I^2: 0 percent
Egger: P=0.084
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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	7.92	0.69 (0.47 to 1.02)	0%
Myocardial infarction	8.80	0.61 (0.36 to 1.04)	0%
Stroke	0.79	3.18 (0.73 to 13.88)	0%
Target revascularization	9.48	0.79 (0.61 to 1.02)	0%
MACE	12.43	0.73 (0.61 to 0.88)	0%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	7.80	1.19 (0.51 to 2.76)	54.9
Myocardial infarction	8.98	0.71 (0.27 to 1.85)	0%
Stroke	5.79	2.42 (0.75 to 7.78)	0%
Target revascularization	6.22	0.87 (0.36 to 2.10)	39.2%
MACE	6.22	1.23 (0.50 to 3.01)	79.9%

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

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

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	6	0.82 (0.45 to 1.51)	2.5%
Myocardial infarction	6	0.67 (0.29 to 1.57)	0%
Stroke	6	0.48 (0.10 to 2.22)*	NA
Target revascularization	6	0.93 (0.61 to 1.42)	0%
MACE	6	0.87 (0.64 to 1.19)	0%

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	6	0.51 (0.11 to 2.33)*	NA
Myocardial infarction	6	1.01 (0.24 to 4.33)*	NA
Stroke	6	0.20 (0 to 1.93)*	NA
Target revascularization	6	0.71 (0.29 to 1.75)*	NA
MACE	6	0.74 (0.36 to 1.54)*	NA

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	8.11	0.87 (0.58 to 1.30)	0%
Myocardial infarction	8.08	0.83 (0.45 to 1.53)	0%
Stroke	3.74	0.68 (0.22 to 2.11)	0%
Target revascularization	8.60	1.11 (0.80 to 1.52)	10%
MACE	7.97	1.04 (0.84 to 1.29)	0%

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.[158] 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

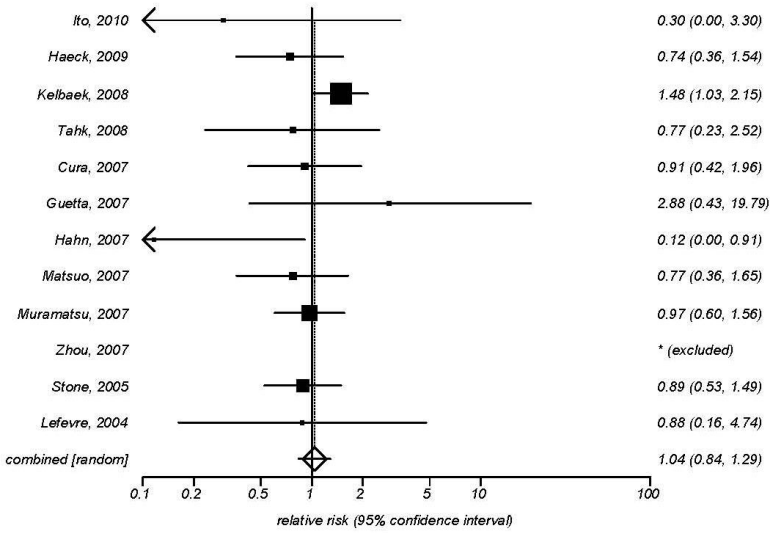
Catheter aspiration devices in patients with STEMI. Fifteen RCTs evaluated the impact of catheter aspiration devices versus control on ST-segment resolution and were included in the pooled analysis.[12,14-16,19,20,62,69,71,74,83,85-87,87,138,176] The use of a catheter aspiration device significantly 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 (I^2=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 quality[12,14-16,62,69,71,74,83,138,176] 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 (I^2=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



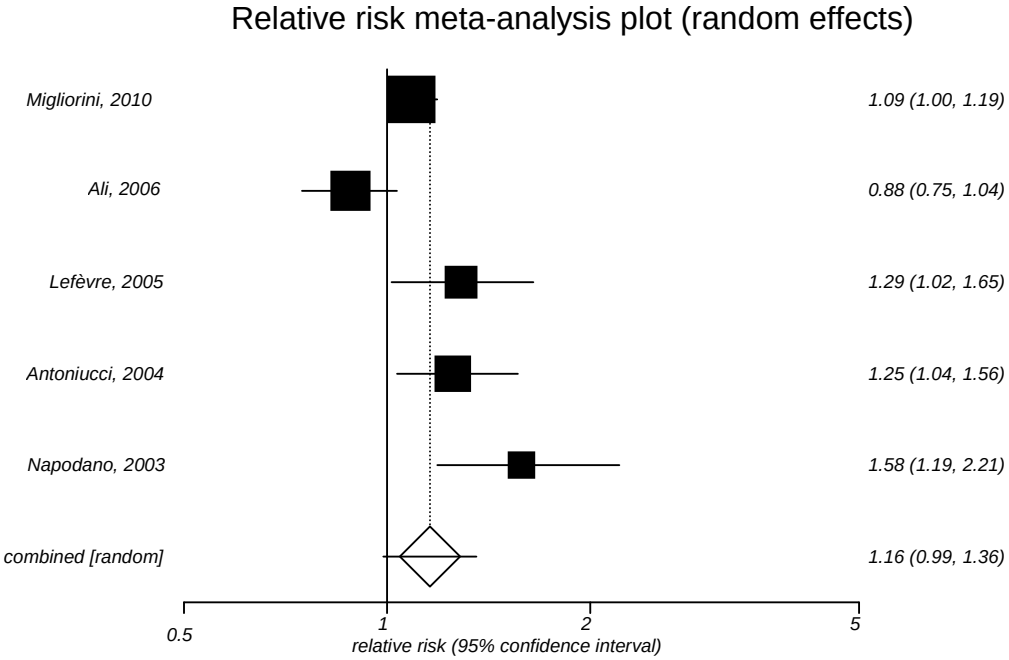
Cochran Q: P < 0.001
I^2: 64.2 percent
Egger: P=0.041
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.[11,27,29,40,44] 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 (I^2=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.[11,27,29,40,44]

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



Cochran Q: P=0.003
I^2: 75.1 percent
Egger: P=0.402
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.

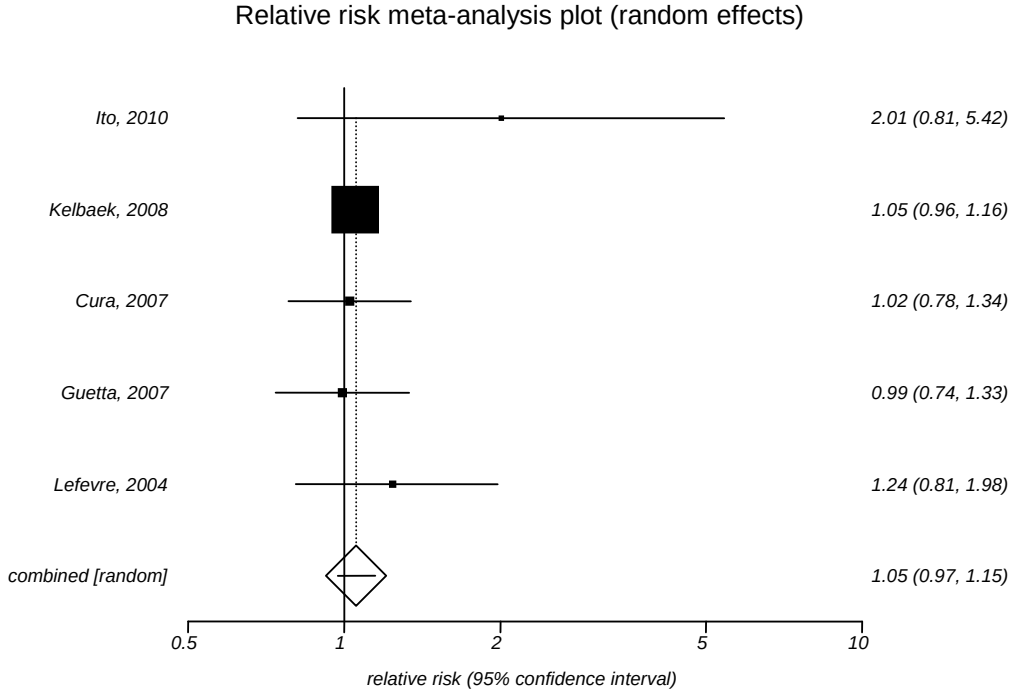
Mechanical thrombectomy devices in other ACS populations. One RCT evaluated the impact of the mechanical thrombectomy device X-Sizer® versus control on ST-segment resolution in patients with STEMI or UA.166 ST-segment resolution was defined as resolution greater than 50 percent after the procedure. The 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.[89,95,98,101,137] 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 (I^2=0 percent, Egger's P=0.279).hen limiting the pooled analysis to only trials of good methodological quality[89,95,98,137] the risk of resolving of ST-segment elevation remained nonsignificant [RR 1.05 (0.96, 1.15)]. Statistical heterogeneity was not detected (I^2=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



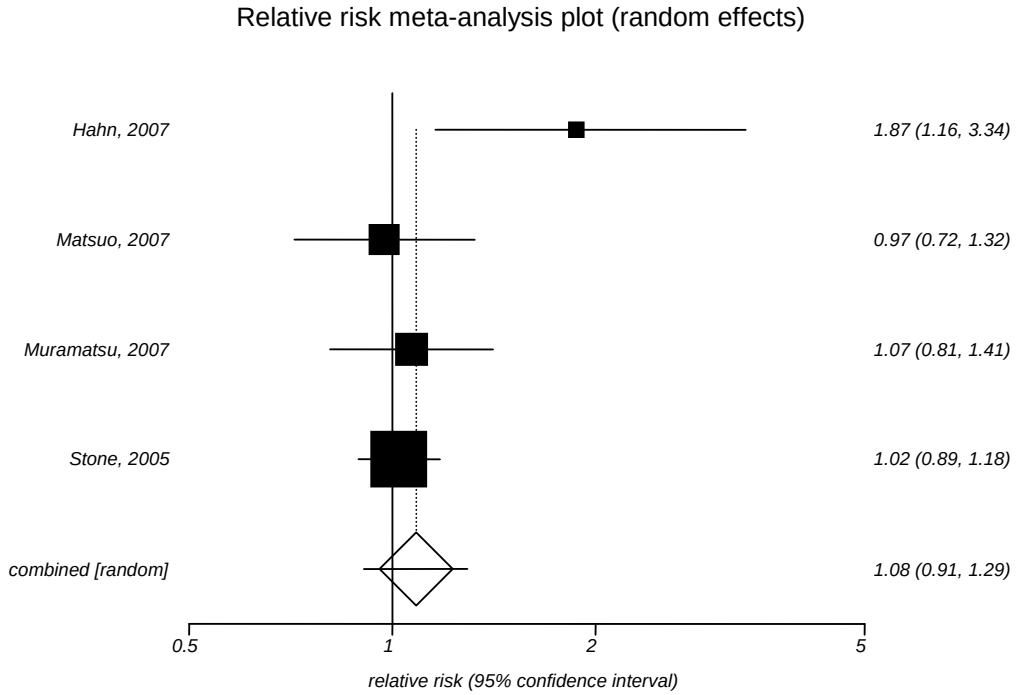
Cochran Q: P=0.651
I^2: 0 percent
Egger: P=0.279
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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



Cochran Q: P=0.164
I^2: 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.[130] 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.[130]

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.[164] 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.[18] The use of a proximal balloon embolic protection device did not

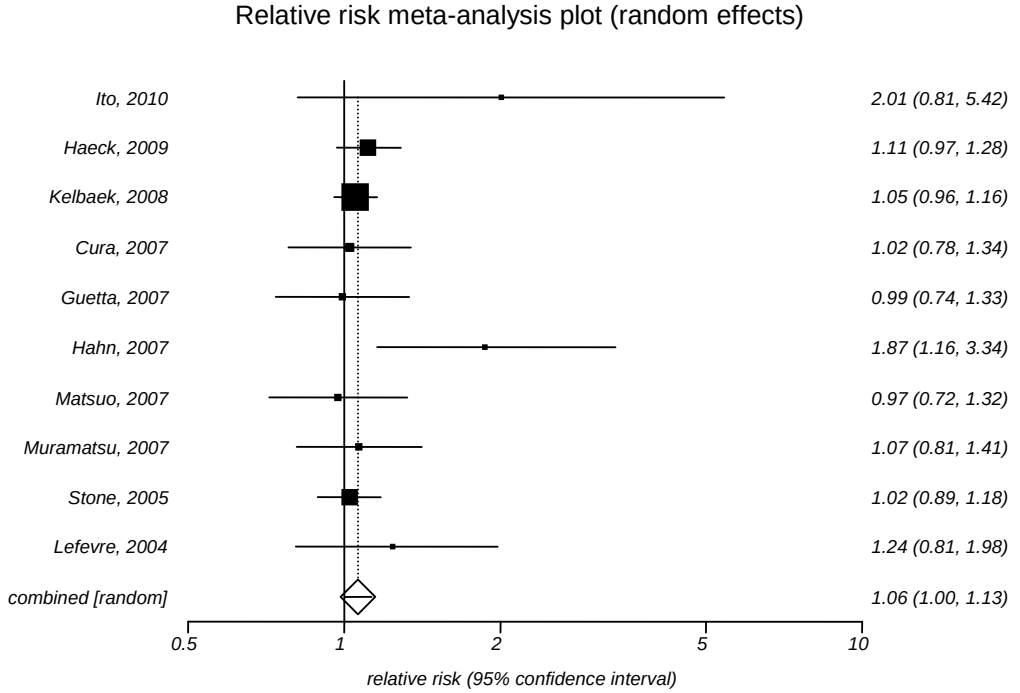
significantly impact the risk of resolving ST-segment elevation [RR 1.11 (0.97, 1.28)]. The trial was determined to be of good methodological quality.[18]

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.[18,89,95,98,101,103,107,112,133,137] 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[18,89,95,98,103,107,112,133,137] 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



Cochran Q: P=0.534
I^2: 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).[160] 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).[163] 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

Study, Year	Device Category	Group	n	Time EF Measured	Mean EF (SD)	P-value
Sardella, 2008	Catheter Aspiration Catheter Aspiration	Diver™ Invatec catheter Export® Medtronic	--- ---	---	--- ---	---
Yan, 2007	Catheter Aspiration Distal Balloon Embolic Protection	Diver™ CE catheter GuardWire™ Plus	61 61	30d	54 (12) 54 (11)	0.60
Ozaki, 2006	Catheter Aspiration Distal Balloon Embolic Protection	Rescue™ or Thrombuster® systems PercuSurge GuardWire® Control	25 24 28	180d	52 (12) 54 (11) 50 (8)	>0.05

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).[12-14,16,21,53,68,69,71,82,83,87,162] In the first trial the mean left ventricular ejection fraction at baseline did not differ between the two groups (p=0.60).[12] 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. [12] 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).[13] In the third trial a subset of patients with anterior myocardial infarction from the original trial were randomized to evaluate ejection fraction.[14] 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.[14] In the fourth trial, patients were only included in the trial if they achieved a TIMI-3 blood flow postprocedure.[162] 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).[21] 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).[16] 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).[68] 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.[69] 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).[69] 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.[83,84] Enguage 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).[83] 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).[87]

One controlled observational study evaluated the impact of catheter aspiration devices versus control on left ventricular ejection fraction.[142] 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 14. Ejection fraction in randomized controlled trials evaluating catheter aspiration devices in patients with ST-segment elevation myocardial infarction

Study, Year	Group	n	Time EF Measured	Mean EF (SD)	P-value
Dudek, 2010	Diver™ CE	---	---	---	---
	Control	---		---	
Liistro, 2009	Export® Thrombectomy Catheter	55	180d	55 (6)	<0.0001
	Control	56		49 (8)	
Lipiecki, 2009	Export® Catheter	20	7d	48 (12)	0.4
	Control	24		45 (11)	
Moura, 2009	TAC	---	---	---	---
	Control	---		---	
Sardella, 2009*	Export® Medtronic (EM)	38	3-5d	46.3 (8.6)	0.30
	Control	37		44.3 (9.5)	
Sardella, 2009*	Export® Medtronic (EM)	36	90d	49.0 (9.3)	0.3
	Control	36		46.7 (10.6)	
Wita, 2009	Diver™ CE	19	7d	50.1 (8.4)	
	Control	23		46.5 (7.9)	
Chao, 2008	Export® Aspiration Catheter	37	28d	56 (10)	0.51
	Control	37		57 (10)	
Chevalier, 2008	Export® Aspiration Catheter	---	---	---	---
	Control	---		---	
Ciszewski, 2008	Rescue™/Diver™	32	5-8d	46.7 (11.0)	0.16
	Control	31		42.5 (10.0)	
Ikari, 2008	TVAC®	103	180d	57.1 (12.5)	0.77
	Control	113		56.7 (12.3)	
Svilaas, 2008	6F Export® Aspiration Catheter	---	---	---	---
	Control	---		---	
DeLuca, 2006*	Diver™ CE	38	PostPCI	37.29 (9.97)	>0.05
	Control	38		36.67 (3.03)	
DeLuca, 2006*	Diver™ CE	35	180d	42.97 (9.97)	>0.05
	Control	36		41.28 (3.37)	
Kaltoft, 2006	Rescue™ Catheter	108	30d	51 (43-57)†	0.13
	Control	107		53 (47-58)†	
Lee, 2006	Export® Aspiration Catheter	---	---	---	---
	Control	---		---	
Silva-Orrego, 2006	Pronto™ Extraction Catheter	---	---	---	---
	Control	---		---	
Burzotta, 2005*	Diver™ CE	25	1d	50.36 (8.76)	<0.05
	Control	25		45.75 (7.49)	
Burzotta, 2005*	Diver™ CE	25	7d	53.34 (10.99)	<0.05
	Control	25		48.09 (9.4)	
Burzotta, 2005*	Diver™ CE	25	180d	53.28 (10.04)	<0.05
	Control	25		47.72 (8.28)	
Noel, 2005	Export®	---	---	---	---
	Control	---		---	
Dudek, 2004*	Rescue™	35	In-hospital	56.5 (9.1)	>0.05
	Control	32		52.8 (12.8)	
Dudek, 2004*	Rescue™	35	90d	60.3 (9.2)	>0.05
	Control	32		55.3 (14.7)	

*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).[40,44] 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).[40] 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.[44] 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).[44]

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

Study, Year	Group	n	Time EF Measured	Mean EF (SD)	P-value
Migliorini, 2010	AngioJet® Rheolytic Thrombectomy Control	--- ---	---	--- ---	---
Ali, 2006	AngioJet® Catheter Control	197 205	14-28d	51.3 (11.53) 52.3 (10.89)	0.38
Lefèvre, 2005	X-Sizer® Catheter Control	--- ---	---	--- ---	---
Antoniucci, 2004	AngioJet® Control	--- ---	---	--- ---	---
Napodano,* 2003	X-Sizer® Catheter Control	46 46	In hospital	51.0 (7.7) 48.7 (10.9)	0.29
Napodano, * 2003	X-Sizer® Catheter Control	46 46	30d	51.9 (7.9) 49.9 (8.9)	0.26

*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).[95,98] 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).[95] 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).[98]

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

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

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).[126] 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

Study, Year	Device Category	Group	n	Time EF Measured	Mean EF (SD)	P-value
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire® Control	--- ---	---	--- ---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire™ Control	100 100	3d	47.57 (10.94) 51.22 (11.75)	0.26
Sardella, 2005	Catheter Aspiration	Diver™ CE Control	--- ---	---	--- ---	---
Kunii, 2004	Catheter Aspiration	Rescue™ PT Control	--- ---	---	--- ---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire® Control	34 30	Post PCI	51.2 (14.5) 46.7 (12.2)	0.02
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire® Control	--- ---	---	--- ---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer® Control	--- ---	---	--- ---	---

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 18. Ejection fraction in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction

Study, Year	Group	n	Time EF Measured	Mean EF (SD)	P-value
Duan, 2010*	PercuSurge Guardwire™ Plus	46	90d	51.6 (3.6)	<0.05
	Control	50		49.3 (5.3)	
Duan, 2010*	PercuSurge Guardwire™ Plus	46	180d	53.0 (3.7)	<0.05
	Control	50		50.8 (5.2)	
Pan, 2010	PercuSurge Guardwire®	52	---	---	---
	Control	52			
Tahk, 2008	PercuSurge GuardWire®	48	180d	58.1 (11.4)	0.24
	Control	47		54.6 (10.3)	
Hahn, 2007*	GuardWire®	19	3d	50 (9)	0.60
	Control	20		49 (13)	
Hahn, 2007*	GuardWire®	15	180d	48 (16)	0.74
	Control	14		50 (9)	
Matsuo, 2007*	GuardWire® Distal Protection System	80	PostPCI	46.1 (9.5)	0.99
	Control	74		55.4 (13.9)	

Table 18. Ejection fraction in randomized controlled trials evaluating distal balloon embolic protection devices in patients with ST-segment elevation myocardial infarction (continued)

Study, Year	Group	n	Time EF Measured	Mean EF (SD)	P-value
Matsuo, 2007*	GuardWire® Distal Protection System	80	180d	61.9 (---)	0.36
	Control	74		62.7 (---)	
Muramatsu, 2007*	GuardWire™ Plus System	173	PostPCI	54.0 (---)	0.90
	Control	168		53.8 (---)	
Muramatsu, 2007*	GuardWire™ Plus System	133	30d	55.3 (---)	>0.05
	Control	123		55.4 (---)	
Muramatsu, 2007*	GuardWire™ Plus System	108	180d	57.1 (---)	>0.05
	Control	117		57.1 (---)	
Zhou, 2007	PercuSurge GuardWire®	---	---	---	---
	Control	---		---	
Okamura, 2005	PercuSurge GuardWire®	8	Hospital discharge (mean 22±4 d)	47 (9)	0.89
	Control	8		48 (8)	
Stone, 2005	GuardWire™ Plus	---	---	---	---
	Control	---		---	

*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).[130] 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).[164] 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

Study, Year	Device Category	Group	n	Time EF Measured	Mean EF (SD)	P-value
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge® Guardwire	57	6m	46 (45-49)*	NS
		Abciximab	63		46 (44-50)*	
Kanaya, 2003	Thrombectomy+ Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---
		Thrombectomy + Stenting	---		---	

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™ versus control on ejection fraction in patients with STEMI[190] (Table 20). There was no significant difference in ejection fraction at 4 to 6 months postPCI in the Proxis™ 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

Study, Year	Group	n	Time EF Measured	Mean EF (SD)	P-value
Haeck, 2009	Proxis™	96	4-6m	50 (11)	0.46
	Control	110		50 (12)	

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™-Invatec catheter aspiration device versus the Export®-Medtronic catheter aspiration device on MBG.[158] The use of Diver™-Invatec did not significantly impact the risk of attaining a MBG-3 [RR 0.71 (0.42, 1.18)] 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 MBG.[160] The use of Diver™ CE did not significantly impact the risk of attaining a MBG of 2 [RR 0.97 (0.77, 1.23)] compared to Guardwire™ Plus.

Trials Versus Control

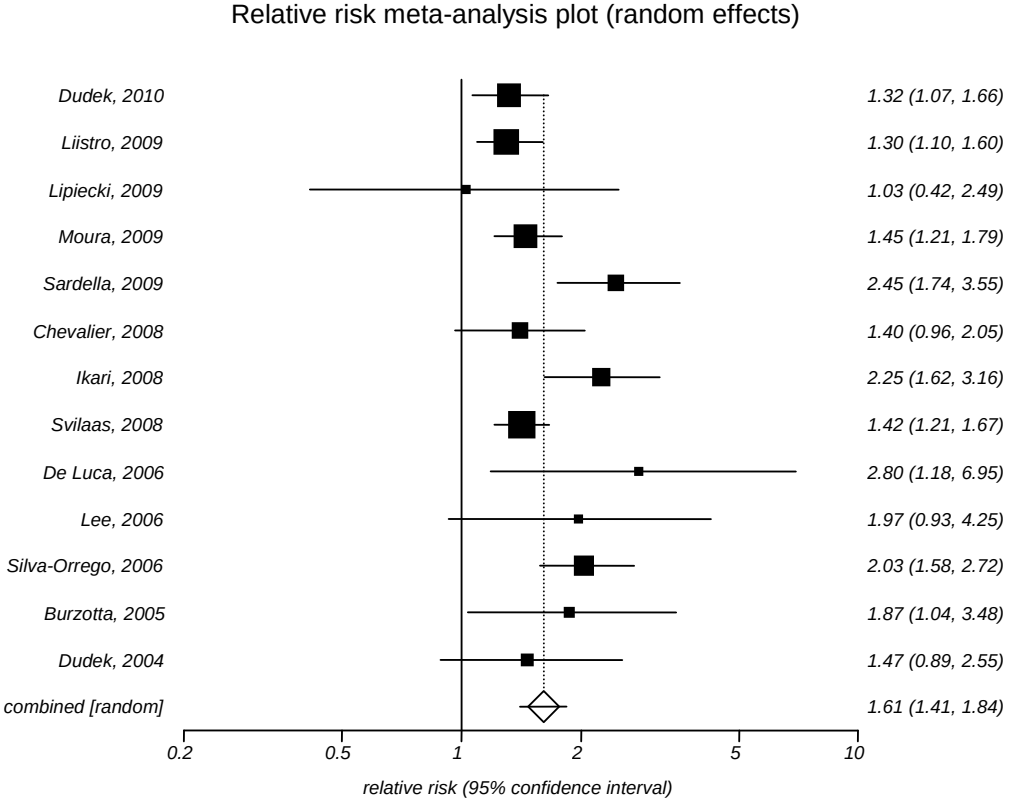
***Catheter aspiration devices in patients with STEMI*.** Thirteen RCTs evaluated the impact of catheter aspiration devices versus control on MBG and were included in the pooled analysis.[12-16,19,20,62,69,74,83,86,87,138,175,176] The use of a catheter aspiration device significantly increased the risk 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.

When limiting the pooled analysis to trials of only good methodological quality,[12,14-16,62,69,74,83,138,175,176] 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^{TM} CE versus control on MBG although was not included in the pooled analysis.[162] 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



Cochran Q: P=0.008
I²: 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^{TM}-Invatec versus control on MBG in patients with acute myocardial infarction.[127] 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

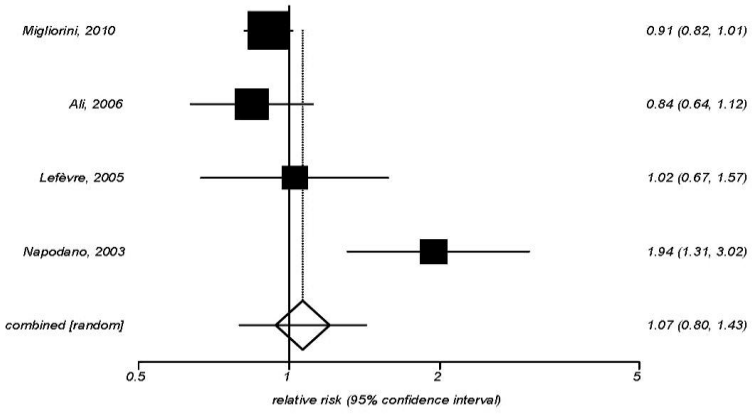
MBG-3 [RD 0.30 (0.10, 0.51), (CER 0.09)], three people would need to be treated with a catheter aspiration device to cause one person to achieve a MBG-3. This trial was determined to be of poor methodological quality.

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.[11,29,40,44] 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 (I^2=76.5 percent) but publication bias was not detected (Egger's P=0.408). All trials were determined to be of good methodological quality.[11,29,40,44]

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



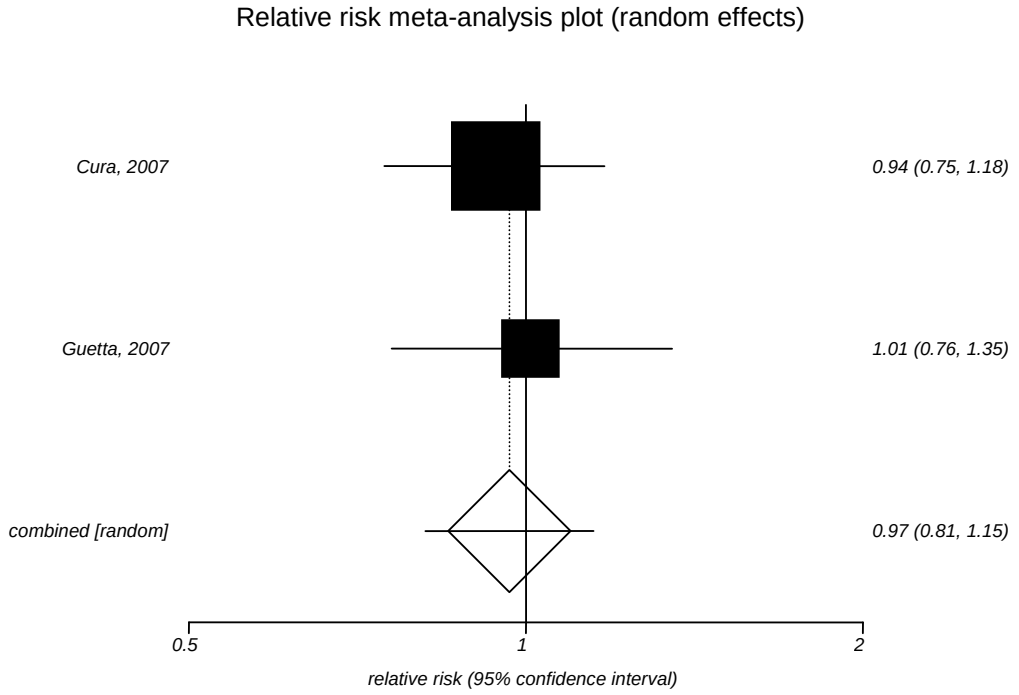
Cochran Q: P=0.005
I^2: 76.5 percent
Egger: P=0.408
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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



Cochran Q: P=0.692
I^2: 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.

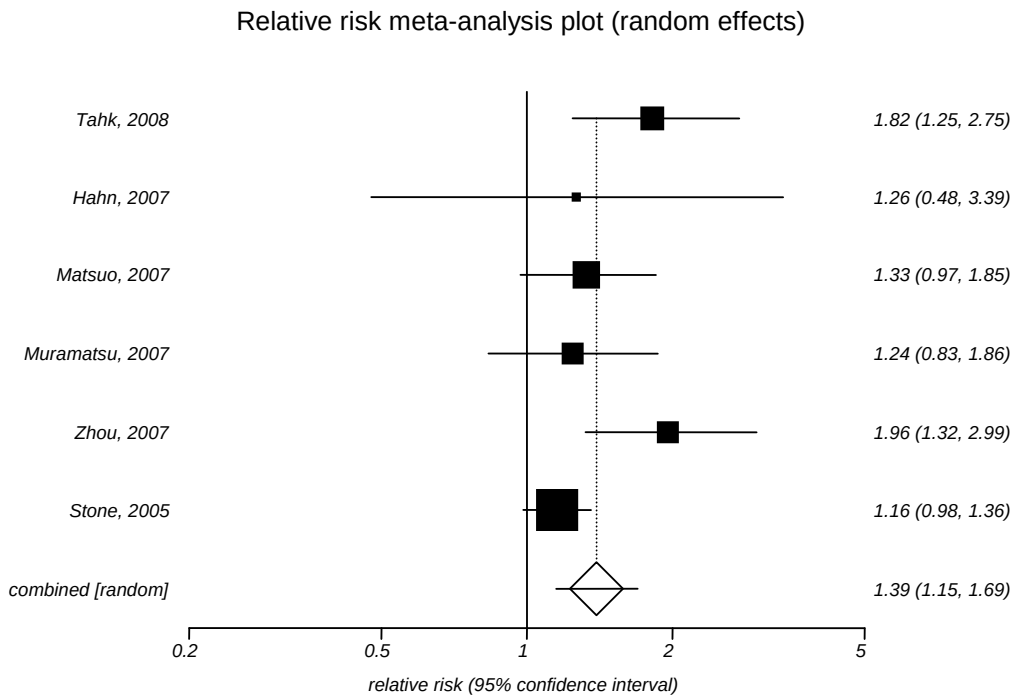
Distal filter embolic protection devices in other ACS populations. No trials or studies assessed for this endpoint in this population.

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 (I2=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.[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



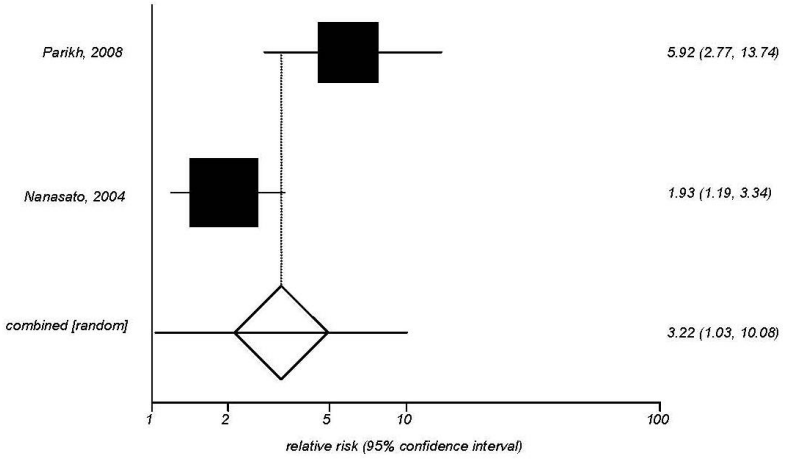
Cochran Q: P=0.115
I^2: 43.5 percent
Egger: P=0.203
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.[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.[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.[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
I^2: 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.

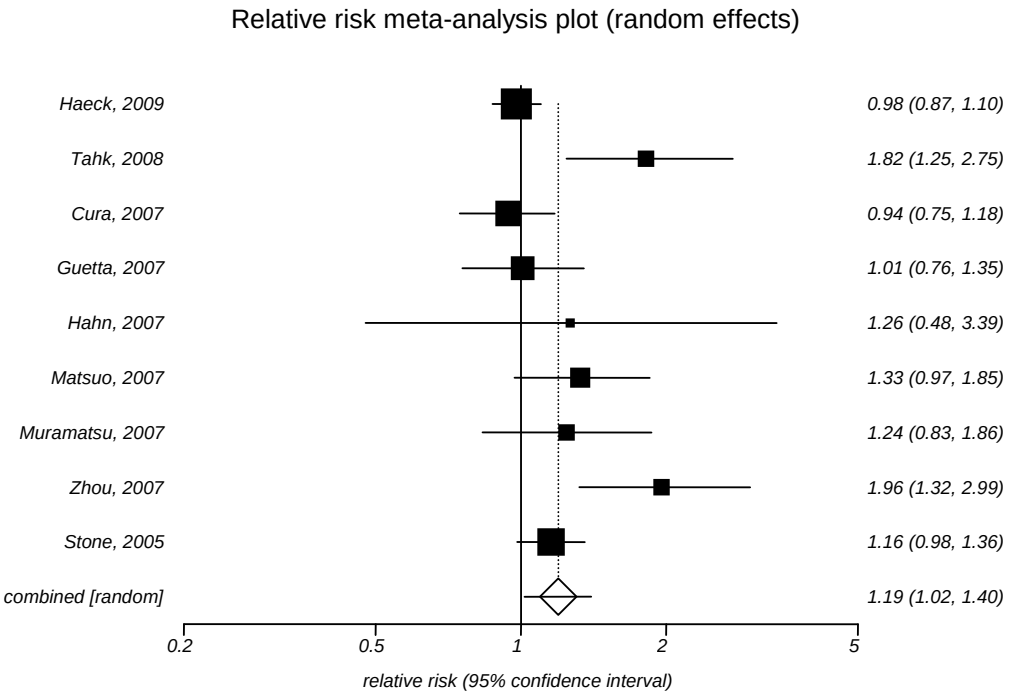
Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on MBG.[18] The use of a proximal balloon embolic protection device did not significantly impact the risk of attaining MBG-3 [RR 0.98 (0.88, 1.10)]. Limiting the analysis to trials of good methodological quality[18] 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.[17,18,95,98,103,107,111,112,133] 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 (I^2=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.[17,18,95,98,103,107,111,112,133]

Figure 38. Impact of embolic protection devices combined versus control on myocardial blush grade of 3 in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.002
I^2: 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^{TM}-Invatec catheter aspiration device versus the Export$^{®}$-Medtronic catheter aspiration device on TIMI-3 blood flow.[158] The use of Diver^{TM}-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^{TM} CE versus the distal balloon embolic protection device Guardwire^{TM} Plus on TIMI-3 blood flow.[160] The use of Diver^{TM} CE did not significantly impact the risk of attaining TIMI-3 blood flow [RR 0.98 (0.89, 1.08)] compared to Guardwire^{TM} Plus.

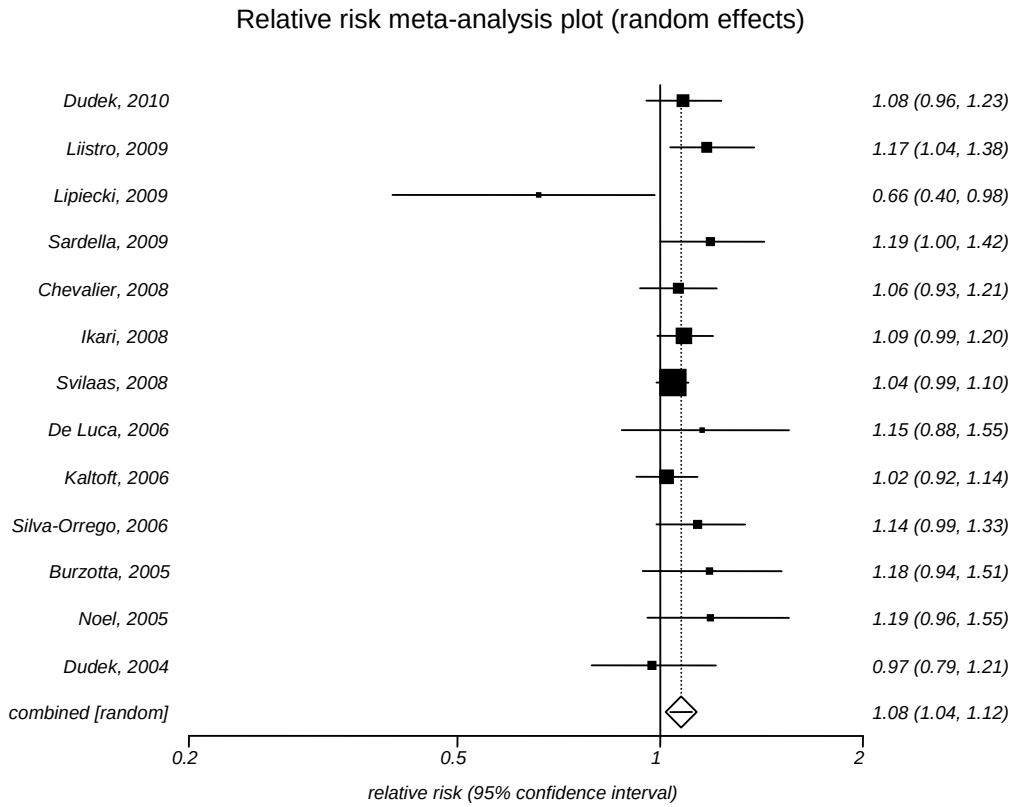
Trials Versus Control

Catheter aspiration devices in patients with STEMI. Thirteen RCTs evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow.[12-16,19,62,69,71,74,83,85,87,138,175,176] 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.[12,14-16,62,69,71,74,83,138,175,176]

Two controlled observational studies evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow.[142,144] 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).[144] 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).[142]

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



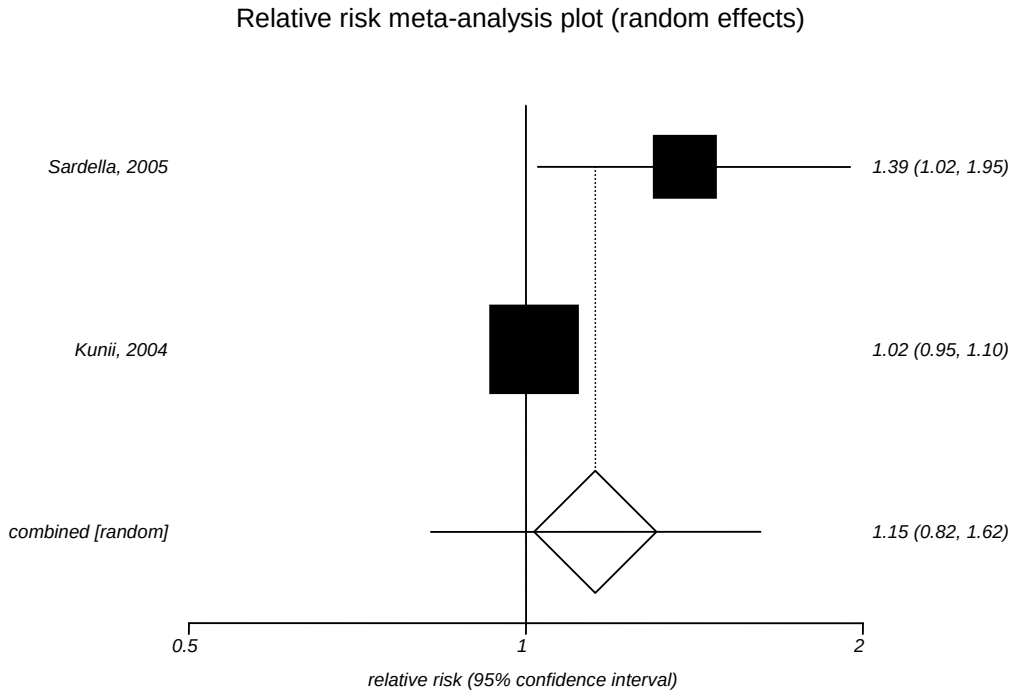
Cochran Q: P=0.329
I^2: 11.5 percent

Egger: P=0.585
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. Two RCTs evaluated the impact of catheter aspiration devices versus control on TIMI-3 blood flow in patients with acute myocardial infarction.[127,128] 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 contro[127,128] (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



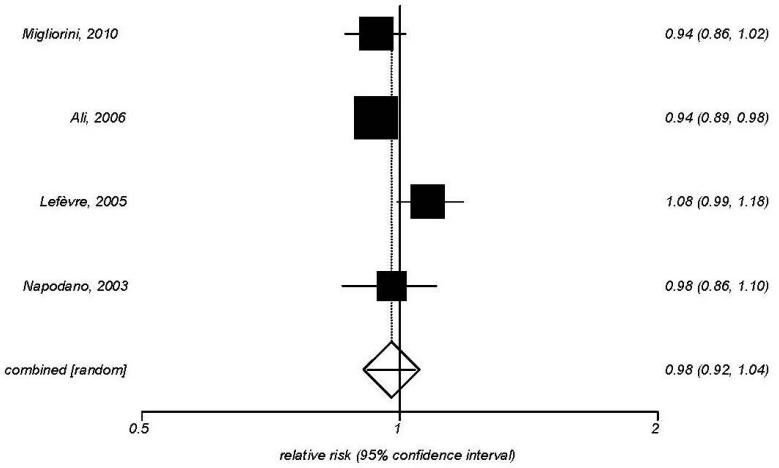
Cochran Q: P=0.027
I²: Too few strata
Egger: P=Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Mechanical thrombectomy devices in patients with STEMI. Four RCTs evaluated the impact of mechanical thrombectomy devices versus control on TIMI-3 blood flow.[11,29,40,44] 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.[11,29,40,44]

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and TIMI-3 blood flow.[145] 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



Cochran Q: P=0.026
I^2: 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.[166] 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.

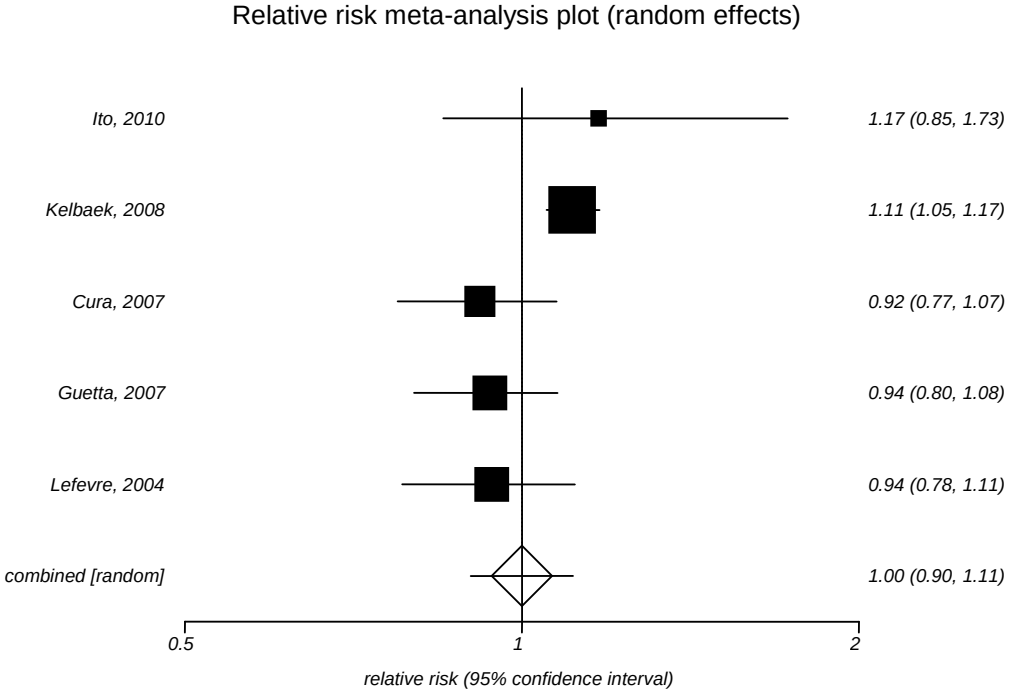
One controlled observational study evaluated the association between the use of mechanical thrombectomy devices and TIMI-3 blood flow.[153] The types of ACSs included in this study were not reported. Patients undergoing PCI with the mechanical thrombectomy device AngioJet® were compared to patients undergoing PCI without mechanical thrombectomy. 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=0.0003). 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=0.0001).

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.[89,93,98,101,137] 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,[89,95,98,137] 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



Cochran Q: P=0.011
I^2: 69.6 percent
Egger: P=0.252
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.[126,155,156] In the first trial, the FilterWire EZ™ device was compared to control in patients with NSTEMI.[155] 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.[156] The risk of attaining

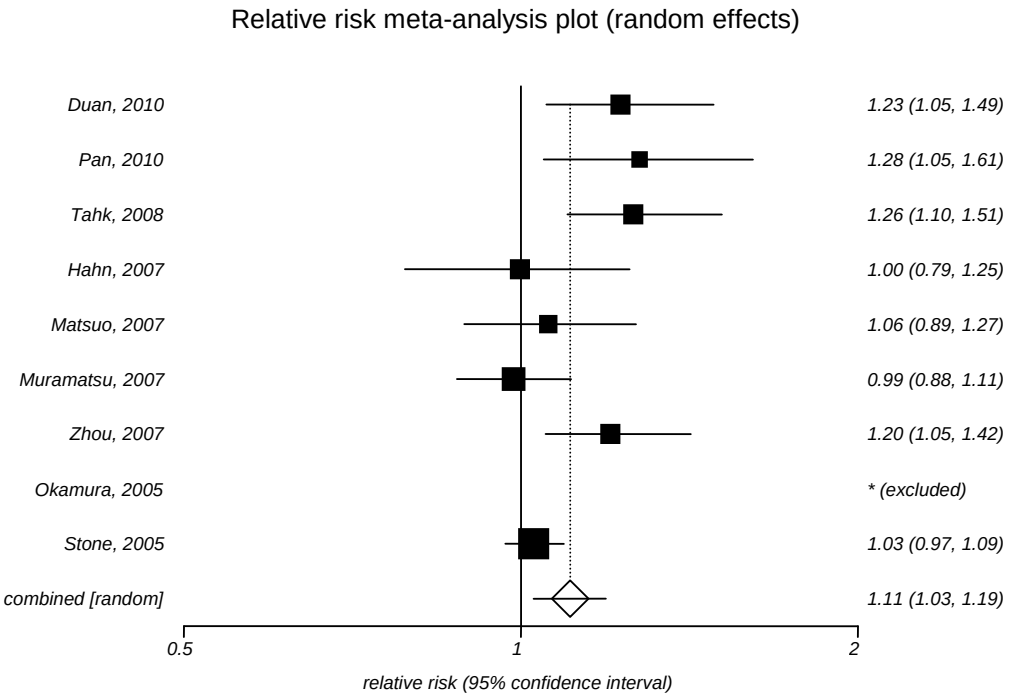
TIMI-3 blood flow could not be calculated because all patients in both groups attained TIMI-3 blood flow after the procedure. In the third trial, the FilterWire EX™ was compared to control in patients with either NSTEMI or STEMI.[126] The risk of attaining TIMI-3 blood flow was not different between 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.[17,103,107,111,112,119,133,135,136] 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.[119] 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)][17,103,107,111,112,133] (Figure 43). A higher level of statistical heterogeneity was found (I^2=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



Cochran Q: P=0.014
I^2: 60.4 percent

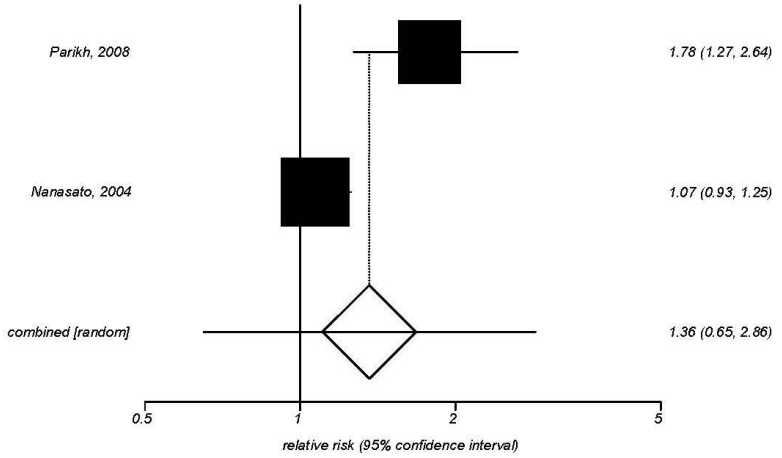
Egger: P=0.094
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical 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 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



Cochran Q: P <0.0001
I^2: 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.

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 TIMI-3 blood flow.[18] The use of a proximal balloon embolic protection device did not significantly

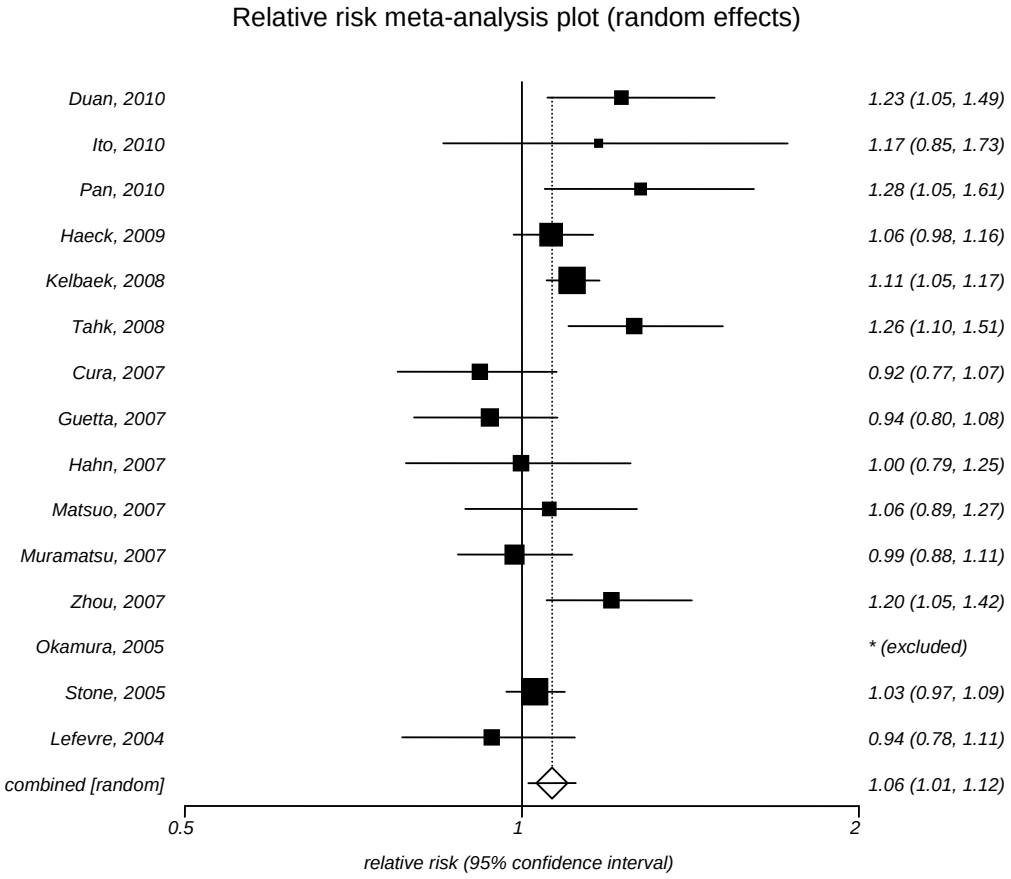
impact the risk of attaining TIMI-3 blood flow [RR 1.06 (0.98, 1.16)]. This trial was determined to be of good methodological quality.[18]

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. Fifteen RCTs evaluated the impact of embolic protection devices combined (distal or proximal; filter or balloon) versus control on TIMI-3 blood flow.[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,[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).

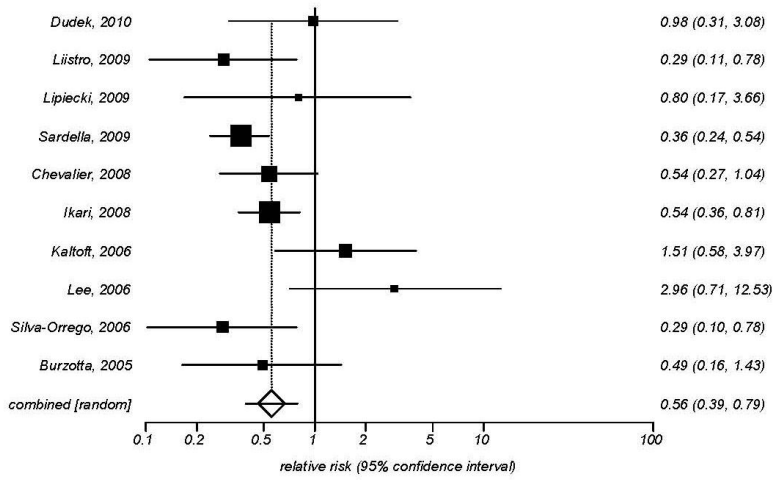
Figure 45. Impact of embolic protection devices combined versus control on TIMI-3 blood flow in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.003
I^2: 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.[125,126,130] 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[126] 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
I^2: 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.

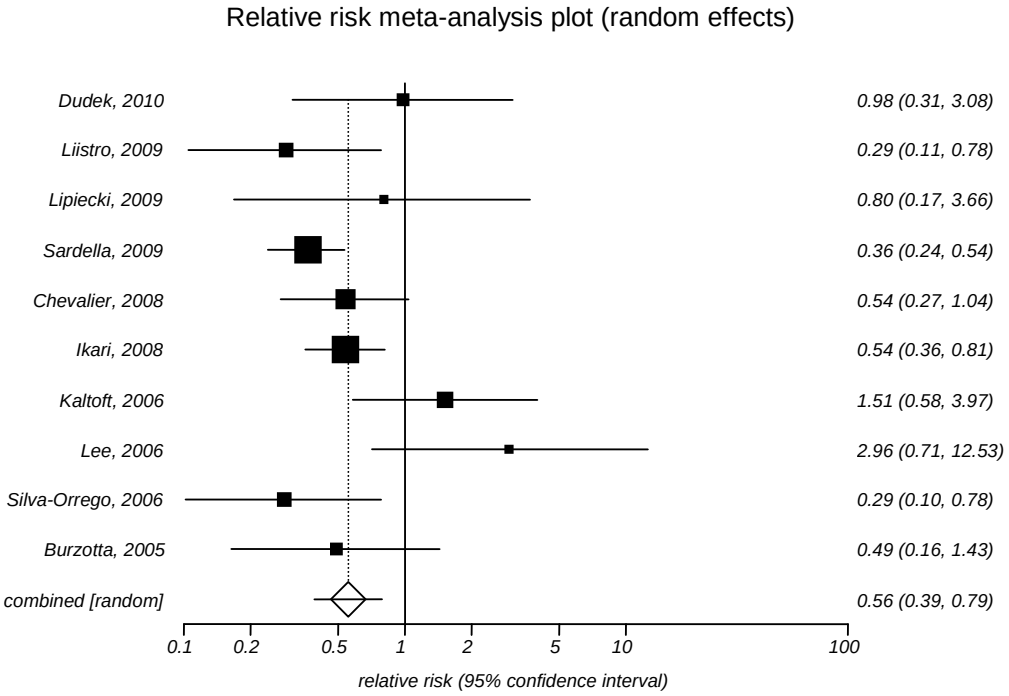
Trials Versus Control

Catheter aspiration devices in patients with STEMI. Ten RCTs evaluated the impact of catheter aspiration devices versus control on distal embolization.[12-16,19,71,74,83,86,138,176] 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 (I^2=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, [12,14-16,71,74,83,138,176] 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 (I^2=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.[152]. 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



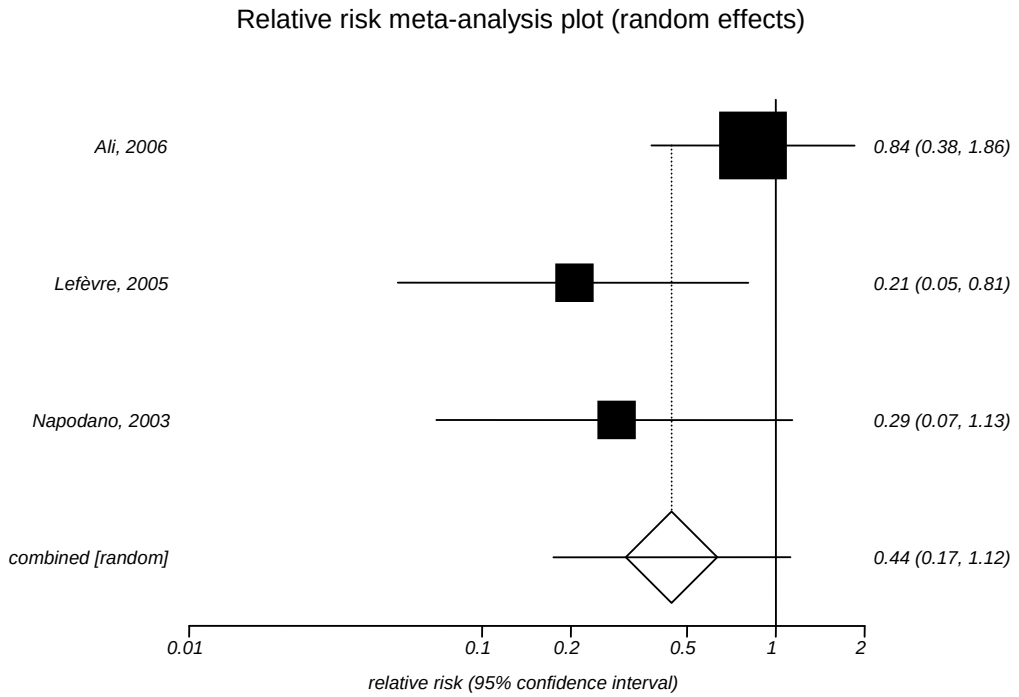
Cochran Q: P=0.069
I²: 43.4 percent
Egger: P=0.161
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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 distal embolization.[29,40,44] 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 (I^2=41.6 percent) and publication bias could not be evaluated. 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 48. Impact of mechanical thrombectomy devices versus control on distal embolization in patients with ST-segment elevation myocardial infarction



Cochran: P=0.181
I^2: 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™ 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.

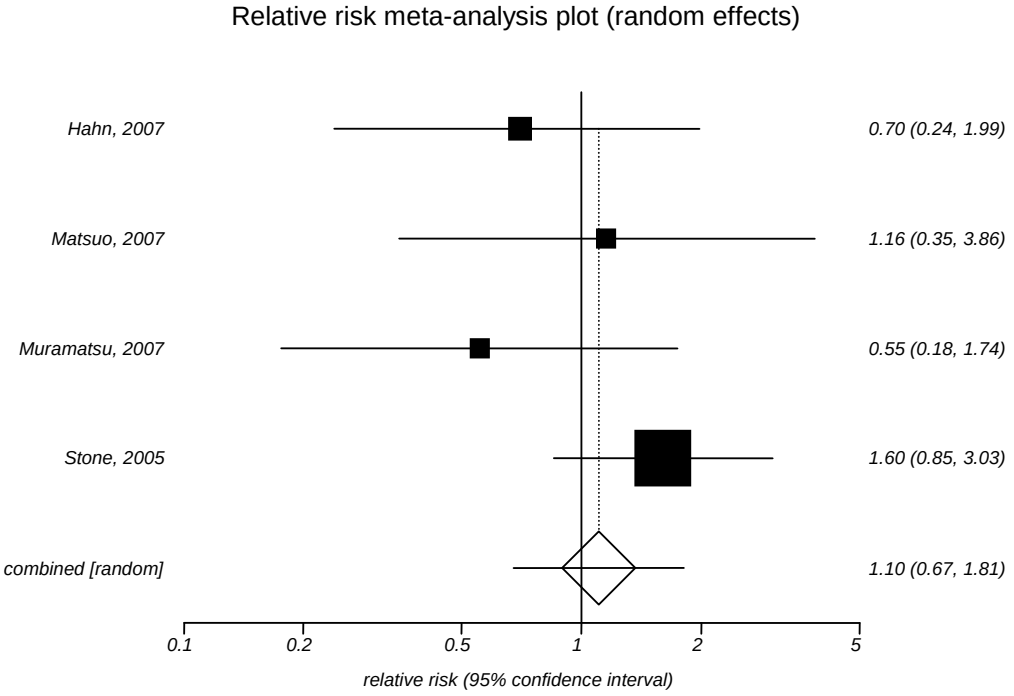
No controlled observational studies assessed for this endpoint in this population.

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



Cochran Q: P=0.364
I^2: 5.8 percent
Egger: P=0.176
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 assessed for this endpoint in this population.

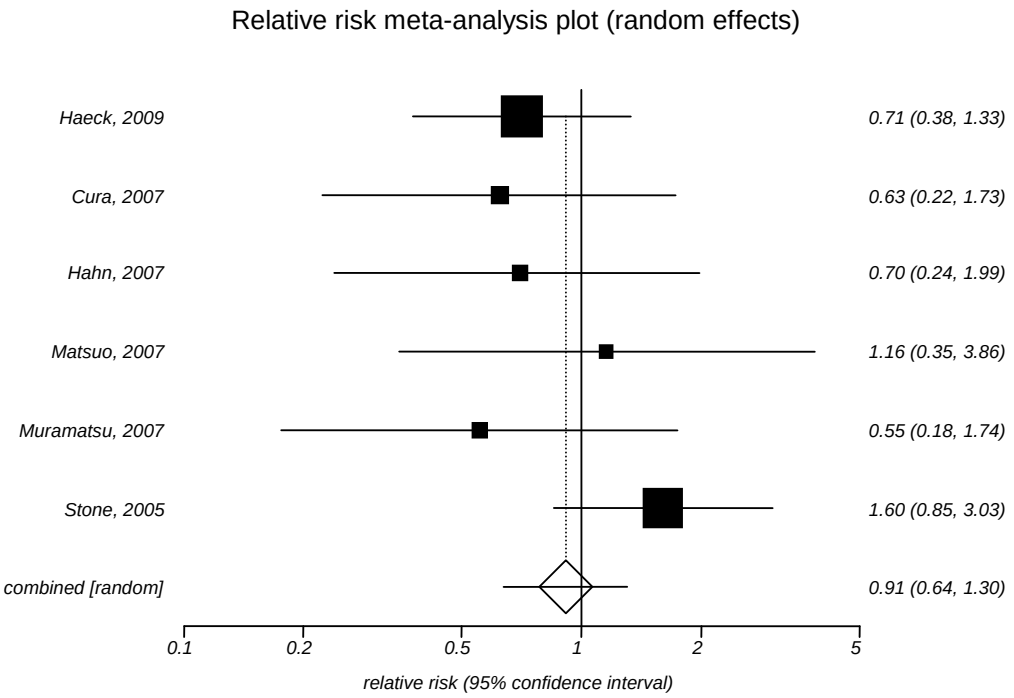
Proximal balloon embolic protection devices in patients with STEMI. One RCT evaluated the impact of the proximal balloon embolic protection device Proxis™ versus control on distal embolization.[18] The use of a proximal balloon embolic protection device did not significantly impact the risk of having 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.[18,95,103,107,112,133]

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



Cochran Q: P=0.415
I²: 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.
No Reflow

Direct Comparative Trials

Catheter aspiration device versus distal balloon protection device in STEMI. One direct comparative randomized trial evaluated the impact of the Diver^{TM} CE catheter aspiration device

versus the Guardwire™ Plus distal balloon embolic protection device on no reflow.[160] 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.

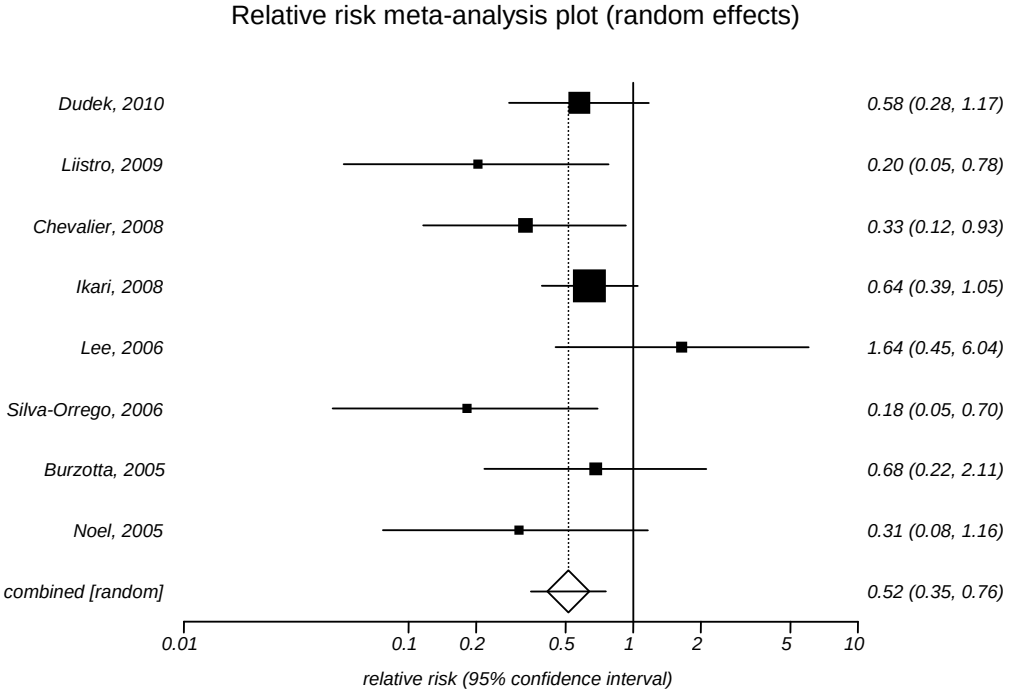
Trials Versus Control

Catheter aspiration devices in patients with STEMI. Eight RCTs evaluated the impact of catheter aspiration devices versus control on no reflow.[12,15,16,19,51,74,83,85,86,138] 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 (I^2=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,[15,16,19,48,51,74,83,138] 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 (I^2=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



Cochran Q: P=0.307
I^2: 15.7 percent
Egger: P=0.278

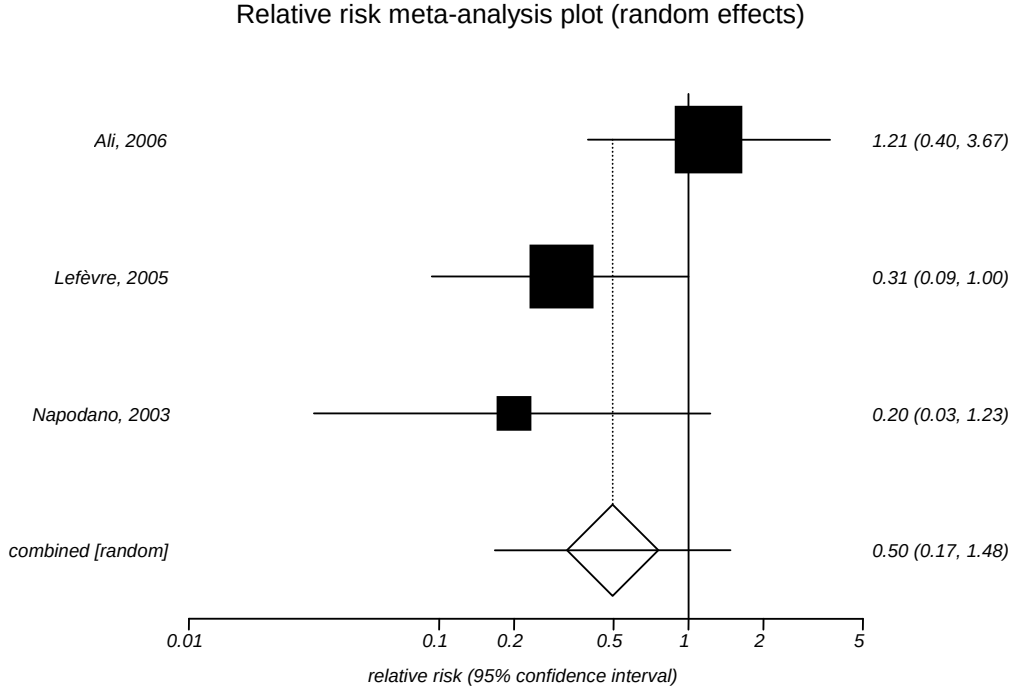
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending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



Cochran Q: P=0.180
I^2: 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.

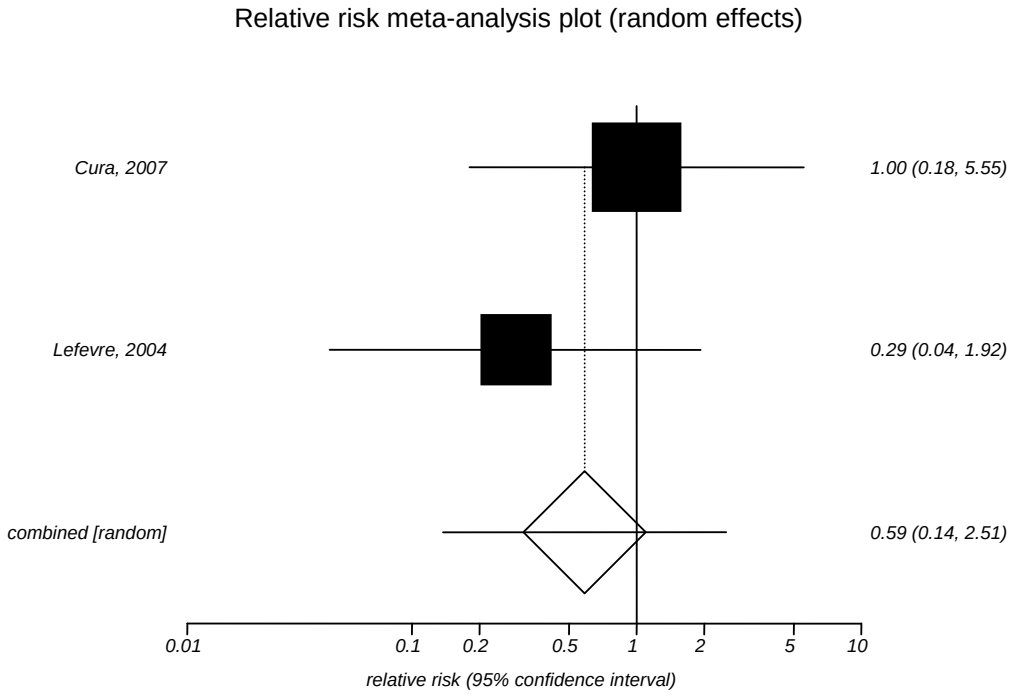
Mechanical thrombectomy devices in other ACS populations. No RCTs or controlled observational studies assessed for this endpoint in this population.

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 were determined to be of

good methodological quality.[95] 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



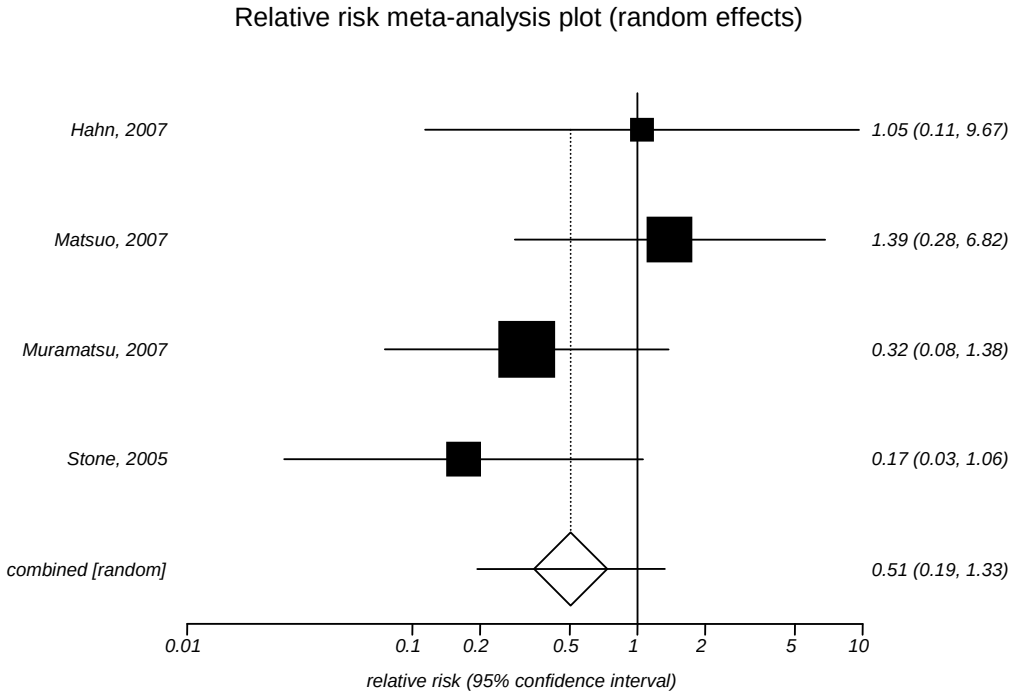
Cochran Q: P=0.409
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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[156] 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.[103,107,110,112] 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.[103,107,110,112]

Figure 54. Impact of distal balloon embolic protection devices versus control on no reflow in patients with ST-segment elevation myocardial infarction



Cochran Q: P=0.403
I^2: 0 percent
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.

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.

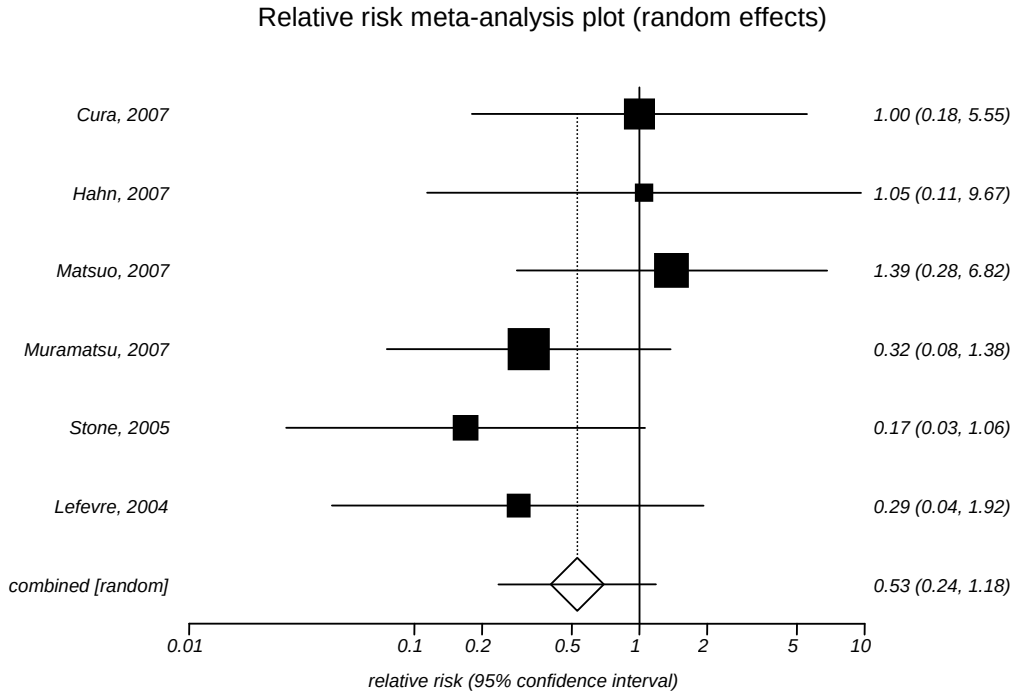
Proximal balloon embolic protection devices in patients with STEMI. No trials or studies evaluated the impact of proximal balloon embolic protection devices on this endpoint.

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.61 (1.41 to 1.84)	55.4%
TIMI-3	1.08 (1.04 to 1.12)	11.5%
Distal embolization	0.56 (0.39 to 0.79)	43.4%
No reflow	0.52 (0.35 to 0.76)	15.7%
ST-segment resolution	1.51 (1.32 to 1.73)	64.2%
HRQOL	---	---

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

Table 22. Intermediate health outcomes in randomized controlled trials evaluating mechanical thrombectomy devices in patients with ST-segment elevation myocardial infarction

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.07 (0.80 to 1.43)	76.5%
TIMI-3	0.98 (0.92 to 1.04)	67.5%
Distal embolization	0.44 (0.17 to 1.12)	41.6%
No reflow	0.50 (0.17 to 1.48)	41.7%
ST-segment resolution	1.16 (0.99 to 1.36)	75.1%
HRQOL	---	---

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

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	0.97 (0.81 to 1.15)	NA
TIMI-3	1.00 (0.90 to 1.11)	69.6%
Distal embolization	0.63 (0.22 to 1.82)*	NA
No reflow	0.59 (0.14 to 2.51)	NA
ST-segment resolution	1.05 (0.97 to 1.15)	0%
HRQOL	---	---

*Result is based on a single trial

Abbreviations: CI=confidence interval; HRQOL=health-related quality of life; MBG=myocardial blush grade; NA=not applicable; TIMI=thrombolysis in myocardial infarction

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.39 (1.15 to 1.69)	43.5%
TIMI-3	1.11 (1.03 to 1.19)	60.4%
Distal embolization	1.10 (0.67 to 1.81)	5.8%
No reflow	0.51 (0.19 to 1.33)	0%
ST-segment resolution	1.08 (0.91 to 1.29)	41.2%
HRQOL	---	---

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

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	0.98 (0.88 to 1.10)*	NA
TIMI-3	1.06 (0.98 to 1.15)*	NA
Distal embolization	0.71 (0.37 to 1.35)*	NA
No reflow	---†	---†
ST-segment resolution	1.11 (0.97 to 1.28)*	NA
HRQOL	---	---

*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; NA=not applicable; 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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.20 (1.02 to 1.40)	68.2%
TIMI-3	1.06 (1.01 to 1.12)	58.3%
Distal embolization	0.91 (0.64 to 1.30)	0.2%
No reflow	0.53 (0.24 to 1.18)	0%
ST-segment resolution	1.06 (1.00 to 1.13)	0%
HRQOL	---	---

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 significant 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.
    - 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.
    - In a RCT, the use of a distal balloon embolic protection device versus control significantly prolonged the procedure time.
    - 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

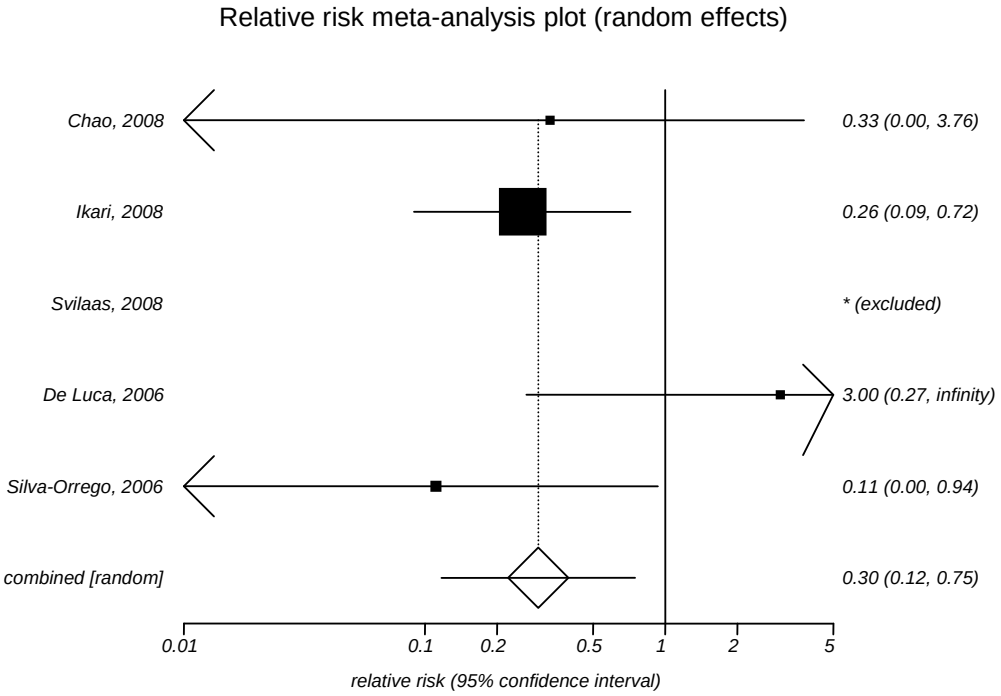
Catheter aspiration device versus catheter aspiration device in patients with STEMI. One direct comparative randomized trial evaluated the impact of the Diver^{TM}-Invatec catheter aspiration device versus the Export$^{®}$-Medtronic catheter aspiration device on coronary dissection.[158] In this trial, the use of Diver^{TM}-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.[16,62,68,69,74] 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. [16,62,68,69,74] 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.[152] 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



Cochran Q: P=0.464
I^2: 0 percent
Egger: P=0.626
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 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.[40] 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. [40]

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.[95] 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.[111] 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.[95,111] 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.[158] 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.[16] The risk of coronary

perforation could not be calculated because no events occurred in either control or treatment group.

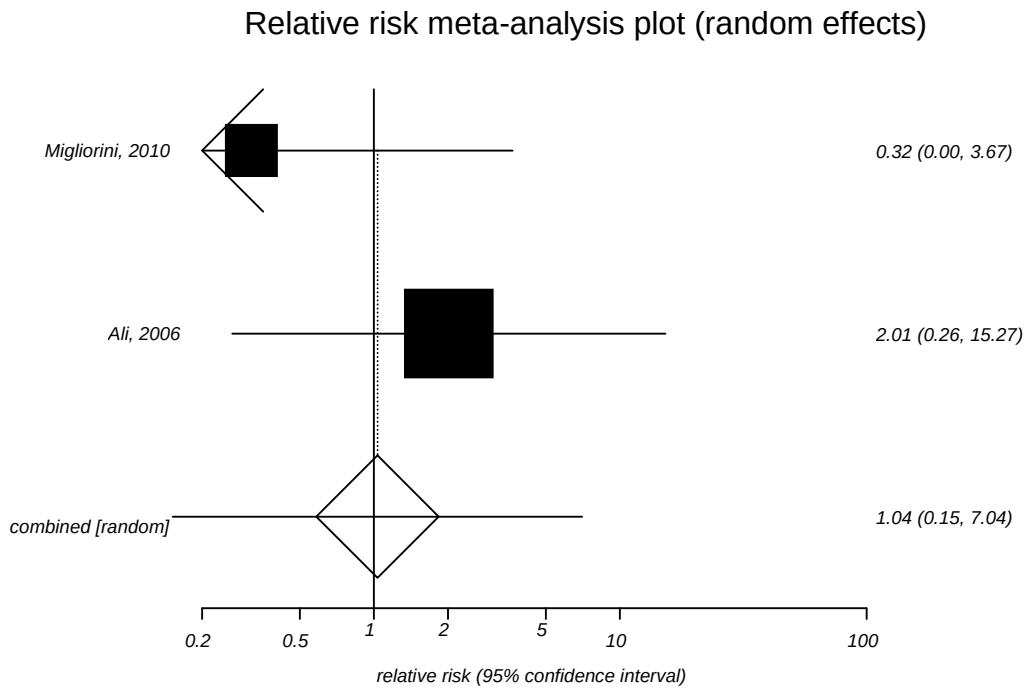
No controlled observational studies evaluated this endpoint in this population.

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.[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. [11,40]

One controlled observational study evaluated the association between the use of a mechanical thrombectomy device and coronary perforation versus control.[145] 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 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



Cochran Q: P=0.366
I^2: 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^{TM} CE catheter aspiration device versus the Guardwire^{TM} Plus distal balloon embolic protection device on procedure time.[160] In this trial, there was no significant difference in procedure time between the Diver^{TM} CE and Guardwire^{TM} 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.[12,15,16,62,68,71,74,83,162] 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).[12] In the second trial, patients were only included in the trial if they achieved a TIMI-3 blood flow postprocedure.[162] 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). [162] 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).[15] 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).[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].[62] 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).[68] 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]. [71] 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).[74] In the final trial, the mean procedure time was not significantly different between the catheter aspiration device group and control (81±43 minutes versus 72±34 minutes, p=0.41).[83] 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.[144] 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).[144]

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.[11,27,29,40] 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].[11] 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).[40] 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).[29] 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.[95] 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.[156] 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.[107,112,133] In the first trial, mean procedure time was significantly prolonged in the distal balloon embolic protection device group compared to control (75.8±30 minutes versus 53±25 minutes, p<0.01).[107] 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).[133] 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].[112] 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.[164] 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].[164] 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.[125] 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™ 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

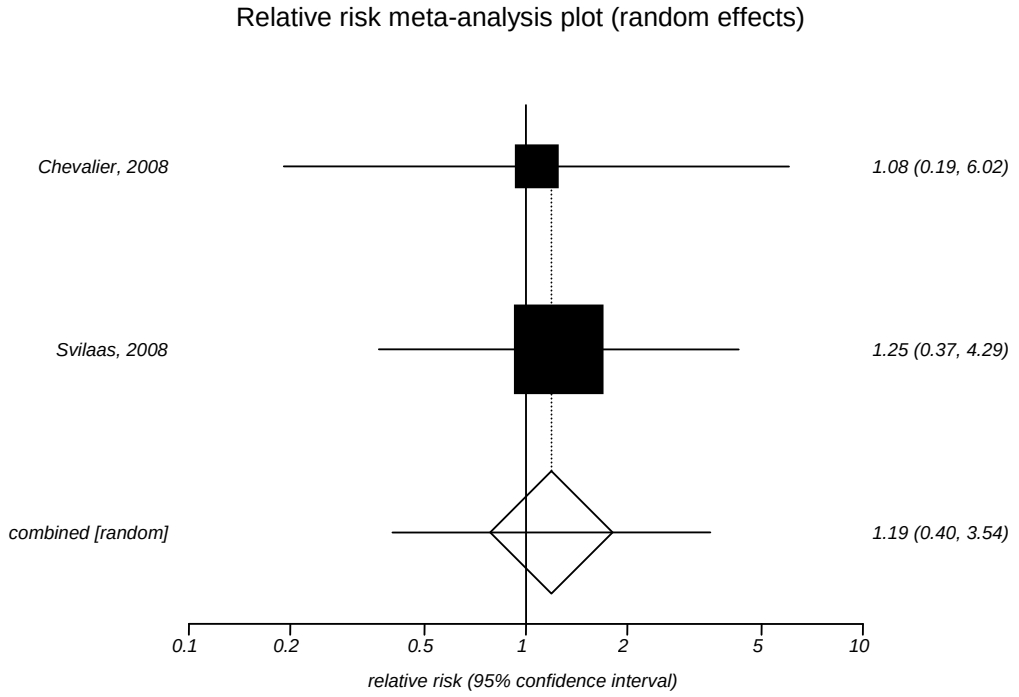
No direct comparative trials evaluated the impact of thrombectomy or embolic protection devices on this outcome.

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



Cochran Q: P=0.898
I^2: 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.

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.[44] 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.[44]

No controlled observational studies evaluated this endpoint in this population.

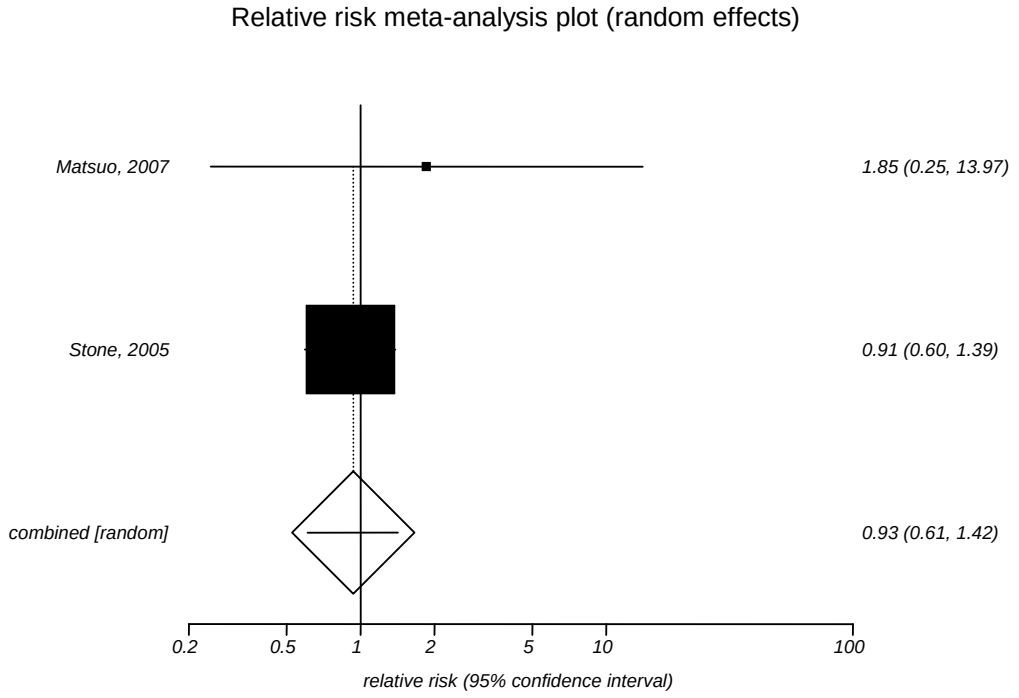
Mechanical thrombectomy devices in other ACS populations. No studies evaluated the impact of mechanical thrombectomy devices on this outcome.

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.[95] 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. [95]

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.[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. [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



Cochran Q: P=0.565
I^2: 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.

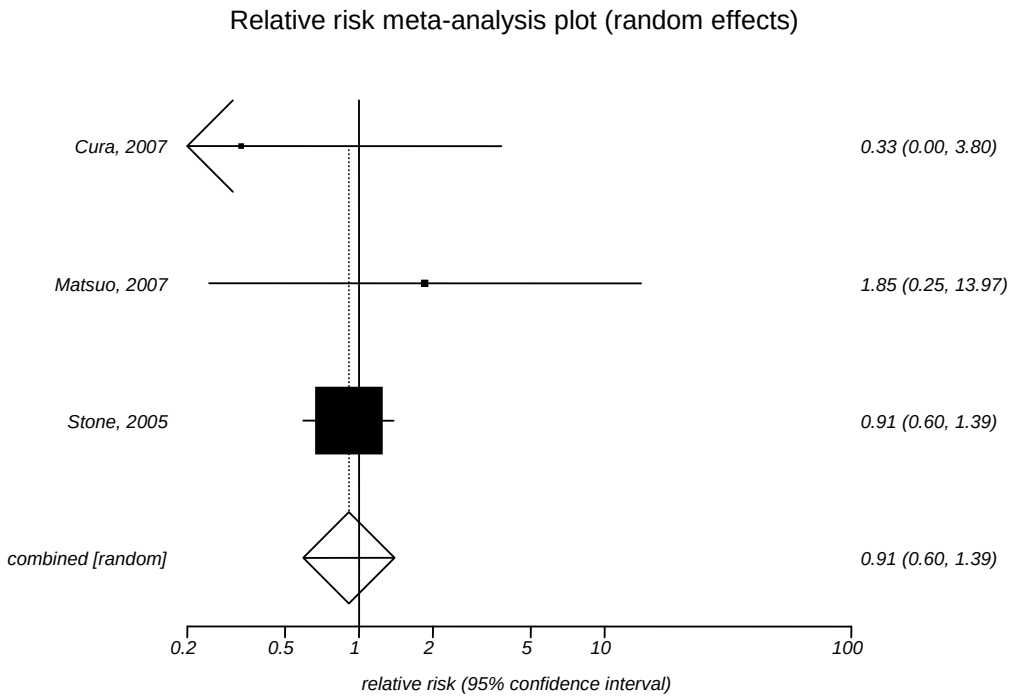
Distal balloon embolic protection devices in other ACS populations. No trials or studies evaluated the impact of distal balloon embolic protection devices on this outcome.

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.[95,107,112] 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. [95,107,112]

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



Cochran Q: P=0.697
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 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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	0.30 (0.12 to 0.75)	0%
Coronary perforation	---*	---*
Side-branch occlusion	1.19 (0.40 to 3.54)	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	1.51 (0.57 to 4.01)*	NA
Coronary perforation	1.04 (0.15 to 7.04)	NA
Side-branch occlusion	1.00 (0.11 to 9.41)*	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Coronary perforation	---*	---*
Side-branch occlusion	0.33 (0.00 to 3.80)†	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Coronary perforation	5.11 (0.53 to infinity)†	NA
Side-branch occlusion	0.93 (0.61 to 1.42)	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Coronary perforation	---*	---*
Side-branch occlusion	---*	---*

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Coronary perforation	5.11 (0.53 to infinity)†	NA
Side-branch occlusion	0.91 (0.60 to 1.39)	0%

*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 significant 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 between subgroups =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[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[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[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[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 CharacteristicsA 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).[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).[62] 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).[89]

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Male Female	RR 0.60 (0.44 to 0.82) RR 0.74 (0.49 to 1.11)	0.43
Kelbaek, 2008[89] (N=626)	Distal Filter Embolic Protection	FilterWire-EZ™ or SpiderX™	STSR ≥ 70% 90 min postPCI	Male Female	RR 1.04 (0.93 to 1.16) RR 1.08 (0.84 to 1.40)	0.79

*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;[62,83,89] however, numerical data was obtainable for only one (Table 34).[62] 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).[83] 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).[89]

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)	P-Values for Interaction Between Subgroups
Svilaas, 2008[65] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Age > 65 y/o Age ≤ 65 y/o	RR 0.74 (0.55 to 0.99) RR 0.58 (0.39 to 0.88)	0.34

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).[89,95] 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 Kelbaeck 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).[89] 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)].[95] 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.[95] 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.[171,172] 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.[171,172]

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Kelbaek, 2008[89] (N=626)	Distal Filter Embolic Protection	FilterWire-EZ™ or SpiderX™	STSR ≥ 70% 90 min postPCI	Diabetes No Diabetes	RR 0.81 (0.55 to 1.19) RR 1.07 (0.97 to 1.17)	0.17
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	Diabetes	RR 0.91 (0.65 to 1.29)	N/A

*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).[18,95,112] 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).[120] 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).[112] 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)].[95] 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 (I^2=63.3 percent).

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	Current smoking	RR 1.12 (0.93 to 1.34)	NA
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire® Plus	STSR ≥ 70% 30 min postPCI	Current smoking No current smoking	RR 0.99 (0.81 to 1.22) RR 1.05 (0.87 to 1.27)	0.68
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Protection	Proxis™	PostPCI STSR ≥ 70%	Current smoking No current smoking	RR 1.41 (1.11 to 1.80) RR 1.32 (0.90 to 1.95)	0.78

*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[83] and Stone and colleagues[112] 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).[83] 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).[112]

Table 37. Results of subgroup analysis from randomized controlled trials evaluating the effect of failed thrombolysis on clinical outcome

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire® Plus	STSR ≥ 70% 30 min postPCI	Primary angioplasty Rescue angioplasty (after failed thrombolysis)	RR 1.05 (0.90 to 1.22) RR 0.91 (0.64 to 1.29)	0.46

*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.[83] 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,[171,172] 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).[18,95] 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.[18]

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	GP2B3Ai use	RR 1.36 (1.09 to 1.69)	NA
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Protection	Proxis™	PostPCI STSR ≥ 70%	GP2B3Ai use No GP2B3Ai use	RR 1.97 (1.17 to 3.32) RR 1.20 (0.97 to 1.49)	0.08

*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 affect of ischemia time on the efficacy of adjunctive devices to improve postST-segment myocardial infarction outcomes; however, only six of the eight trials provided numerical results (Table 39).[16,18,62,68,83,89,95,112] 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].[62] 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).[16] 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)].[16] 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).[83] 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.[171,172]

One pooled analysis by De Vita and colleagues pooled data from three RCT which compared catheter aspiration to standard procedure in patients with STEMI.[143] 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 [≤3 hours (short TTT), >3 hours to <6 hours (intermediate TTT), and >6 hours to ≤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 TT 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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Total ischemic time ≥ 180min Total ischemic time < 180min	RR 0.73 (0.55 to 0.99) RR 0.45 (0.28 to 0.74)	0.09
Chao, 2008[68] (N=74)	Catheter Aspiration	Export® Aspiration Catheter	ΔTIMI	Onset-to-lab interval of 0-240min Onset-to-lab interval of 241-48 min Onset-to-lab interval of 481-720min	MD 0.30 (-0.60 to 1.20) MD 1.30 (0.46 to 2.14) MD 0.10 (-1.05 to 1.25)	0.15
Chao, 2008[68] (N=74)	Catheter Aspiration	Export® Aspiration Catheter	ΔMBG	Onset-to-lab interval of 0-240min Onset-to-lab interval of 241-480min Onset-to-lab interval of 481-72 min	MD 1.30 (0.20 to 2.40) MD 1.60 (0.84 to 2.36) MD 0.60 (-0.71 to 1.91)	0.44
Chao, 2008[68] (N=74)	Catheter Aspiration	Export® Aspiration Catheter	6m MACE	Onset-to-lab interval of 0-240 min Onset-to-lab interval of 241-480min Onset-to-lab interval of 481-720min	RR 0.35 (0.08 to 1.56) RR 0.27 (0.03 to 2.11) RR 2.29 (0.26 to 20.13)	0.30

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Chao, 2008[68] (N=74)	Catheter Aspiration	Export® Aspiration Catheter	6m mortality	Onset-to-lab interval of 0-240min Onset-to-lab interval of 241-480min Onset-to-lab interval of 481-720min	RR 0.83 (0.02 to 39.24) RR 1.07 (0.02 to 50.43) RR 2.60 (0.13 to 53.46)	0.88
Chao, 2008[68] (N=74)	Catheter Aspiration	Export® Aspiration Catheter	6m TVR	Onset-to-lab interval of 0-240 min Onset-to-lab interval of 241-480 min Onset-to-lab interval of 481-720 min	RR 0.29 (0.03 to 2.54) RR 1.08 (0.07 to 15.50) RR 3.40 (0.16 to 71.52)	0.42
Ikari, 2008[16] (N=355)	Catheter Aspiration	Trans-Vascular Aspiration Catheter®	Slow flow/No reflow	Early reperfusion (hospital arrival ≤ 6 h from symptom onset) Late reperfusion (hospital arrival 6 h to 24 h from symptom onset)	RR 0.80 (0.42 to 1.52) RR 0.23 (0.07 to 0.72)	0.07
Ikari, 2008[16] (N=355)	Catheter Aspiration	Trans-Vascular Aspiration Catheter®	Final MBG=3	Early reperfusion (hospital arrival ≤ 6 h from symptom onset) Late reperfusion (hospital arrival 6 h to 24 h from symptom onset)	RR 2.32 (1.50 to 3.58) RR 2.34 (1.21 to 4.54)	0.98
Ikari, 2008[16] (N=355)	Catheter Aspiration	Trans-Vascular Aspiration Catheter®	Final TIMI flow grade=3	Early reperfusion (hospital arrival ≤ 6 h from symptom onset) Late reperfusion (hospital arrival 6 h to 24 h from symptom onset)	RR 1.04 (0.94 to 1.15) RR 1.45 (1.12 to 1.86)	0.02
Ikari, 2008[16] (N=355)	Catheter Aspiration	Trans-Vascular Aspiration Catheter®	TLR (PCI or CABG)	Early reperfusion (hospital arrival ≤ 6 h from symptom onset) Late reperfusion (hospital arrival 6 h to 24 h from symptom onset)	RR 0.69 (0.36 to 1.31) RR 0.31 (0.09 to 1.002)	0.25
Ikari, 2008[16] (N=355)	Catheter Aspiration	Trans-Vascular Aspiration Catheter®	MACE	Early reperfusion (hospital arrival ≤ 6 h from symptom onset) Late reperfusion (hospital arrival 6 h to 24 h from symptom onset)	RR 0.74 (0.40 to 1.37) RR 0.37 (0.13 to 1.05)	0.26
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Total ischemic time ≥ 180 min Total ischemic time < 180 min	RR 0.73 (0.55 to 0.99) RR 0.45 (0.28 to 0.74)	0.09
Cura, 2007[95] (N=140)	Distal Filter Embolic Pro-tection	SpideRX™	STSR ≥ 70% 60 min postPCI	Median time to admission < 150 min Median time to admission ≥ 150 min	RR 0.89 (0.69 to 1.16) RR 1.12 (0.87 to1.45)	0.22
Stone, 2005[112] (N=501)	Distal Balloon Embolic Pro-tection	GuardWire® Plus	STSR ≥ 70% 30 min postPCI	Symptom onset to hospital arrival < 1 h Symptom onset to hospital arrival ≥ 1 h	RR 1.04 (0.82 to 1.32) RR 1.03 (0.87 to 1.24)	0.95

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Pro-tection	Proxis™	PostPCI STSR ≥ 70%	Symptom onset to balloon time < 3 h	RR 1.38 (1.06 to 1.80)	0.70
				Symptom onset to balloon time ≥ 3 h	RR 1.27 (0.90 to 1.78)	

*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) [18,62,89,95,112] 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).[62] 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 4), but not those with a lower burden (thrombus score of 1 or 2) (no numerical data reported).[83] 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).[89] 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).[18] 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.[95,112] 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), I^2=24.5 percent and RR without thrombus 1.12 (0.76 to 1.64), I^2=not estimable).

Table 40. Results of subgroup analysis from randomized controlled trials evaluating the effect of visible thrombus on clinical outcome

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Visible thrombus on angiography No visible thrombus on angiography	RR 0.61 (0.43 to 0.87) RR 0.70 (0.50 to 0.98)	0.58
Kelbaek, 2008[89] (N=626)	Distal Filter Embolic Protection	FilterWire-EZ™ or SpiderX™	STSR ≥ 70% 90 min postPCI	Visible thrombus No visible thrombus	RR 1.00 (0.89 to 1.12) RR 1.17 (1.01 to 1.37)	0.11
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	Baseline thrombosis	RR 1.02 (0.78 to 1.35)	NA
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire® Plus	STSR ≥ 70% 30 min postPCI	Baseline thrombus No baseline thrombus	RR 1.04 (0.89 to 1.22) RR 0.94 (0.70 to 1.27)	0.56
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Protection	Proxis™	PostPCI STSR ≥ 70%	Baseline thrombus No baseline thrombus	RR 1.31 (1.02 to 1.68) RR 1.39 (0.94 to 2.05)	0.80

*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) [18,62,83,89,95,112] In the trial by Svilaas 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,[171,172] 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,[89,95,112] 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)].[18] 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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Infarct-related vessel: RCA Infarct-related vessel: other	RR 0.48 (0.29 to 0.81) RR 0.71 (0.53 to 0.93)	0.19
Kelbaek, 2008[89] (N=626)	Distal Filter Embolic Protection	FilterWire-EZ™ or SpiderX™	STSR ≥ 70% 90 min postPCI	LAD treated CX/RCA treated	RR 1.16 (0.96 to 1.40) RR 1.03 (0.94 to 1.14)	0.27
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	Infarct-related vessel: LAD Infarct-related vessel: NonLAD	RR 1.14 (0.78 to1.68) RR 0.93 (0.81 to 1.08)	0.33
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire™ Plus	STSR ≥ 70% 30 min postPCI	LAD RCA or LCX	RR 0.83 (0.55 to 1.24) RR 1.09 (0.98 to 1.22)	0.20
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire™ Plus	STSR ≥ 70% 30 min postPCI	Proximal vessel (LAD, RCA, or LCX) Nonproximal vessel	RR 1.00 (0.80 to 1.25) RR 1.04 (0.86 to 1.24)	0.78
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Protection	Proxis™	PostPCI STSR ≥ 70%	Anterior artery No anterior artery	RR 2.41 (1.11 to 5.19) RR 1.20 (0.99 to 1.46)	0.09

*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 postST-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).[62] 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)].[18] 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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	Proximal lesion No proximal lesion	RR 0.60 (0.43 to 0.85) RR 0.69 (0.49 to 0.97)	0.57
Haeck, 2009[18] (N=284)	Proximal Balloon Embolic Protection	Proxis™	PostPCI STSR ≥ 70%	Proximal lesion Nonproximal lesion	RR 1.71 (1.14 to 2.55) RR 1.18 (0.92 to 1.51)	0.12

*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) [62,83,89,95,112] 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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Svilaas, 2008[62] (N=1,071)	Catheter Aspiration	6-French Export® Aspiration Catheter	PostPCI MBG 0 or 1	PrePCI TIMI flow 0 or 1 PrePCI TIMI flow 2 or 3	RR 0.72 (0.55 to 0.95) RR 0.60 (0.36 to 1.01)	0.54
Kelbaek, 2008[89] (N=626)	Distal Filter Embolic Protection	FilterWire-EZ™ or SpiderX™	STSR ≥ 70% 90 min postPCI	Baseline TIMI 0 to 1 Baseline TIMI 2 to 3	RR 1.05 (0.93 to 1.18) RR 1.09 (0.94 to 1.26)	0.70
Cura, 2007[95] (N=140)	Distal Filter Embolic Protection	SpideRX™	STSR ≥ 70% 60 min postPCI	Baseline TIMI 0/1 Baseline TIMI 2	RR 1.02 (0.79 to 1.33) RR 0.90 (0.66 to 1.23)	0.55
Stone, 2005[112] (N=501)	Distal Balloon Embolic Protection	GuardWire™ Plus	STSR ≥ 70% 30 min postPCI	Baseline TIMI 0 or 1 Baseline TIMI 2 or 3	RR 1.03 (0.86 to 1.23) RR 0.99 (0.79 to 1.25)	0.79

*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).[75] 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 ($p\geq0.20$ for both).

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

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Silva-Orrego, 2008[75] (N=148)	Catheter Aspiration	Pronto™ Extraction Catheter	PostPCI TIMI 3	Direct stenting No direct stenting	RR 1.18 (0.91 to 1.54) RR 1.23 (0.93 to 1.61)	0.83
Silva-Orrego, 2008[75] (N=148)	Catheter Aspiration	Pronto™ Extraction Catheter	MBG 3	Direct stenting No direct stenting	RR 1.41 (0.96 to 2.07) RR 2.07 (1.33 to 3.22)	0.20
Silva-Orrego, 2008[75] (N=148)	Catheter Aspiration	Pronto™ Extraction Catheter	Maximal STSR > 70%	Direct stenting No direct stenting	RR 1.41 (0.81 to 2.47) RR 1.56 (0.995 to 2.45)	0.78

Study, Year (Total N)	Device Type	Device	Outcome	Characteristic	Effect Size ("X"R 95%CI)*	P-Values for Interaction Between Subgroups*
Silva-Orrego, 2008[75] (N=148)	Catheter Aspiration	Pronto™ Extraction Catheter	DE	Direct stenting No direct stenting	RR 0.35 (0.02 to 5.35) RR 0.38 (0.09 to 1.54)	0.96
Silva-Orrego, 2008[75] (N=148)	Catheter Aspiration	Pronto™ Extraction Catheter	No Reflow	Direct stenting No direct stenting	RR 0.12 (0.01 to 2.81) RR 0.25 (0.03 to 1.80)	0.68

*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).[149] 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).[139] 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).[146] 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.[154] 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.[164]

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 blow 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?

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
STEMI- Catheter Aspiration Devices			
Mortality	13 (10,3)	No effect	L
Myocardial infarction	12 (10,2)	No effect	L
Stroke	6 (4,2)	No/limited data	I
Target revascularization	11 (9,2)	No effect	L
MACE	13 (11,2)	Decreases risk	H
HRQOL	0	No/limited data	I
ST-segment resolution	16 (15,1)	Increases risk	M
Ejection fraction	12 (11,1)	No effect	M
MBG-3	13 (13,0)	Increases risk	M
TIMI-3	15 (13,2)	Increases risk	M
Distal embolization	11 (10,1)	Decreases risk	H
No reflow	8 (8,0)	Decreases risk	H
STEMI- Mechanical Thrombectomy Devices			
Mortality	5 (4,1)	No/limited data	I
Myocardial infarction	4 (3,1)	No/limited data	I
Stroke	5 (4,1)	No/limited data	I
Target revascularization	4 (3,1)	No/limited data	I
MACE	4 (3,1)	No/limited data	I
HRQOL	0	No/limited data	I
ST-segment resolution	5 (5,0)	No effect	L
Ejection fraction	2 (2,0)	No effect	M
MBG-3	4 (4,0)	No effect	L
TIMI-3	5 (4,1)	No effect	M
Distal embolization	3 (3,0)	No effect	M
No reflow	3 (3,0)	No/limited data	I
STEMI- Distal Filter Embolic Protection Devices			
Mortality	5 (5,0)	No/limited data	I
Myocardial infarction	4 (4,0)	No/limited data	I
Stroke	1 (1,0)	No/limited data	I
Target revascularization	2 (2,0)	Increased risk	L
MACE	5 (5,0)	No effect	M
HRQOL	0	No/limited data	I
ST-segment resolution	5 (5,0)	No effect	M
Ejection fraction	2 (2,0)	No effect	L
MBG-3	2 (2,0)	No effect	M
TIMI-3	5 (5,0)	No effect	L
Distal embolization	1 (1,0)	No/limited data	I
No reflow	2 (2,0)	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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
STEMI- Distal Balloon Embolic Protection Devices			
Mortality	4 (4,0)	No/limited data	I
Myocardial infarction	5 (5,0)	No/limited data	I
Stroke	1 (1,0)	No/limited data	I
Target revascularization	5 (5,0)	No/limited data	I
MACE	5 (5,0)	No/limited data	I
HRQOL	0	No/limited data	I
ST-segment resolution	4 (4,0)	No effect	M
Ejection fraction	6 (6,0)	No effect	M
MBG-3	6 (6,0)	Increases risk	H
TIMI-3	8 (8,0)	Increased risk	L
Distal embolization	4 (4,0)	No effect	M
No reflow	4 (4,0)	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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
STEMI- Proximal balloon Embolic Protection Devices			
Mortality	1 (1,0)	No/limited data	I
Myocardial infarction	1 (1,0)	No/limited data	I
Stroke	1 (1,0)	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	1 (1,0)	No/limited data	I
Ejection fraction	0	No /limited data	I
MBG-3	1 (1,0)	No/limited data	I
TIMI-3	1 (1,0)	No/limited data	I
Distal embolization	1 (1,0)	No/limited data	I
No reflow	0	No/limited data	I
STEMI- Embolic Protection Devices Combined			
Mortality	10 (10,0)	No/limited data	I
Myocardial infarction	10 (10,0)	No/limited data	I
Stroke	3 (3,0)	No/limited data	I
Target revascularization	8 (8,0)	No/limited data	I
MACE	12 (11,1)	No effect	M
HRQOL	0	No/limited data	I
ST-segment resolution	10 (10,0)	No effect	L
Ejection fraction	9 (9,0)	No effect	M
MBG-3	9 (9,0)	Increases risk	M
TIMI-3	14 (14,0)	Increased risk	L
Distal embolization	6 (6,0)	No effect	M
No reflow	6 (6,0)	No/limited data	I
UA/NSTEMI- Catheter Aspiration 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- Mechanical Thrombectomy Devices			
Mortality	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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
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- 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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
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- Embolic Protection Devices Combined			
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
Mixed ACS- Catheter Aspiration Devices			
Mortality	2 (1, 1)	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	1 (1,0)	Increases risk	L
TIMI-3	2 (1,1)	No/limited data	I
Distal embolization	0	No/limited data	I
No reflow	0	No/limited data	I
Mixed ACS- Mechanical Thrombectomy Devices			
Mortality	2 (1,1)	No/limited data	I
Myocardial infarction	1 (1,0)	No/limited data	I
Stroke	0	No/limited data	I
Target revascularization	2(1,1)	No/limited data	I
MACE	2 (1,1)	No/limited data	I
HRQOL	0	No/limited data	I
ST-segment resolution	1 (1,0)	Increases risk	M
Ejection fraction	0	No/limited data	I
MBG-3	0	No/limited data	I
TIMI-3	2 (1,1)	No/limited data	I
Distal embolization	0	No/limited data	I
No reflow	0	No/limited data	I
Mixed ACS- Distal Filter Embolic Protection Devices			
Mortality	1 (1,0)	No/limited data	I
Myocardial infarction	1 (1,0)	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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
Stroke	1 (1,0)	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	1 (1,0)	No/limited data	I
MBG-3	0	No/limited data	I
TIMI-3	1 (1,0)	No/limited data	I
Distal embolization	1 (1,0)	No/limited data	I
No reflow	0	No/limited data	I
Mixed ACS- Distal Balloon Embolic Protection Devices			
Mortality	2 (2,0)	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	1 (1,0)	No/limited data	I
HRQOL	0	No/limited data	I
ST-segment resolution	1 (1,0)	Increases risk	M
Ejection fraction	1 (1,0)	No/limited data	I
MBG-3	2 (2,0)	Increases risk	M
TIMI-3	2 (2,0)	No/limited data	I
Distal embolization	0	No/limited data	I
No reflow	1 (1,0)	Decreases risk	H
Mixed ACS- 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
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
Mixed ACS- Embolic Protection Devices Combined			
Mortality	3 (3,0)	No/limited data	I
Myocardial infarction	1 (1,0)	No/limited data	I
Stroke	1 (1,0)	No/limited data	I
Target revascularization	1 (1,0)	No/limited data	I
MACE	2 (2,0)	No/limited data	I
HRQOL	0	No/limited data	I
ST-segment resolution	1 (1,0)	Increases risk	M
Ejection fraction	2 (2,0)	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)

Population-Device Category Outcome*	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
MBG-3	2 (2,0)	Increases risk	M
TIMI-3	3 (3,0)	No/limited data	I
Distal embolization	1 (1,0)	No/limited data	I
No reflow	1 (1,0)	Decreases risk	H

* 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?

Population- Device Category Outcome	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
STEMI- Catheter Aspiration Devices			
Coronary dissection	5 (4, 1)	Decreases risk	H
Coronary perforation	1 (1,0)	No/limited data	I
Prolonged procedure time	9 (8,1)	No effect	H
Side branch occlusion	2 (2,0)	No/limited data	NA
STEMI- Mechanical Thrombectomy Devices			
Coronary dissection	1 (1,0)	No/limited data	I
Coronary perforation	3 (2,1)	No/limited data	I
Prolonged procedure time	3 (3,0)	Prolongs time	H
Side branch occlusion	1 (1,0)	No/limited data	NA
STEMI- Distal Filter Embolic Protection Devices			
Coronary dissection	1 (1,0)	No/limited data	I
Coronary perforation	1 (1,0)	No/limited data	I
Prolonged procedure time	1 (1,0)	No/limited data	I
Side branch occlusion	1 (1,0)	No/limited data	NA
STEMI- Distal Balloon Embolic Protection Devices			
Coronary dissection	1 (1,0)	No/limited data	I
Coronary perforation	1 (1,0)	No/limited data	I
Prolonged procedure time	3 (3,0)	Prolongs time	L
Side branch occlusion	2 (2,0)	No/limited data	NA
STEMI- Proximal Balloon Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	1 (1,0)	Prolongs time	M
Side branch occlusion	0	No/limited data	NA

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)

Population- Device Category Outcome	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
STEMI- Embolic Protection Devices Combined			
Coronary dissection	2 (2,0)	No/limited data	I
Coronary perforation	1 (1,0)	No/limited data	L
Prolonged procedure time	5 (5,0)	Prolongs time	M
Side branch occlusion	3 (3,0)	No/limited data	NA
UA/NSTEMI- Catheter Aspiration Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
UA/NSTEMI- Mechanical Thrombectomy Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
UA/NSTEMI- Distal Filter Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
UA/STEMI- Distal Balloon Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
UA/STEMI- Proximal Balloon Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
UA/STEMI- Embolic Protection Devices Combined			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
Mixed ACS- Catheter Aspiration Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA

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)

Population- Device Category Outcome	Number and Type of Studies N (RCT, OBS)	Conclusion	SOE
Mixed ACS- Mechanical Thrombectomy Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
Mixed ACS- Distal Filter Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
Mixed ACS- Distal Balloon Embolic Protection Devices			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	1 (1,0)	Prolongs time	M
Side branch occlusion	0	No/limited data	NA
Mixed ACS- Proximal Balloon Embolic Protection			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	0	No/limited data	I
Side branch occlusion	0	No/limited data	NA
Mixed ACS- Embolic Protection Devices Combined			
Coronary dissection	0	No/limited data	I
Coronary perforation	0	No/limited data	I
Prolonged procedure time	1 (1,0)	Prolongs time	M
Side branch occlusion	0	No/limited data	NA

Abbreviation: ACS=acute coronary syndrome; AOE=applicability of evidence; H=high; 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

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 no 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.

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Acronyms/Abbreviations

Acronym/Abbreviation	Definition
ACC	American College of Cardiology
ACS	Acute coronary syndrome
ACT	Activated clotting time
AHRQ	Agency for Healthcare Research and Quality
AMI	Acute myocardial infarction
CAD	Coronary artery disease
CABG	Coronary artery bypass graft
CER	Comparative effectiveness review
CHF	Congestive heart failure
CI	Confidence interval
cm	centimeters
Cr	Creatinine
cTFC	Corrected TIMI frame count
Cx	Circumflex coronary artery
D	Days
DE	Distal embolization
ECG	Electrocardiogram
ECHO	Echocardiogram
EF	Ejection fraction
EPC	Evidence-based Practice Center
FHx	Family history
GI	Gastrointestinal
GP2B3Ai	Glycoprotein 2b3a inhibitor
GRADE	Grading of Recommendations Assessment, Development and Evaluation
H	Hours
HCL	Hypercholesterolemia
HD	Hemodialysis
HTN	Hypertension
IABP	Intra-aortic balloon pump
IRA	Infarct related artery
IU	International units
IV	Intravenous
IVUS	Intravascular ultrasound
Kg	Kilograms
LAD	Left anterior descending artery
LBBB	Left bundle branch block
LCX	Left circumflex
LV	Left ventricle
LVEF	Left ventricular ejection fraction
M	Month
MACE	Major adverse cardiovascular event

MACCE	Major adverse cerebrovascular and cardiovascular event
MBG	Myocardial blush grade
Mg/dL	Milligrams per deciliter
MI	Myocardial infarction
Min	Minutes
mm	Millimeters
MRI	Magnetic resonance imaging
MtPA	Mutant TPA
mV	milivolts
NR	Not reported
NSTEMI	NonST-segment elevation myocardial infarction
PCI	Percutaneous coronary intervention
PO	By mouth
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCA	Right coronary artery
RCT	Randomized controlled trials
RD	Risk difference
RR	Relative risk
S	Seconds
SCr	Serum creatinine
SPECT	Single-photon emission computerized tomography
STEMI	ST-segment elevation myocardial infarction
STSR	ST-segment resolution
SVG	Saphenous vein graft
TEP	Technical Expert Panel
TBG	TIMI blush grade
TIMI	Thrombolysis in myocardial infarction
TMPG	TIMI myocardial perfusion grade
TL	Thrombolysis
TLR	Target lesion revascularization
TS	Thrombus score
TVAC®	Transvascular aspiration catheter
TVR	Target vessel revascularization
U	Units
UA	Unstable angina
Y	Years

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

First Author: Study Name:	Year:
Language (if not English): Geographic location:	Single or Multi-center:
Funding Source Specify: ❑ Industry ❑ Government/Foundation ❑ Academia ❑ Other/Unknown	Publication form: ❑ Full-text ❑ Abstract ❑ Other (specify):

Design Characteristics

Study Design ❑ RCT ❑ Observational Random Allocation Concealment? Y N Blinded Outcome Assessment? Y N Intention to treat principle used? Y N

Study Population

Inclusion Criteria:

❑ Native vessel
❑ Acute MI within ___ hrs
❑ Angiographically visible thrombus
❑ Chest pain associated with ACS >___min
❑ TIMI 0/1
❑ Time from symptom onset:
❑ Age ≥ 18 years
❑ ST-segment elevation ≥ 0.1mV (1mm) in 2 or more ECG leads

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
❑ Cardiac tamponade
❑ Aortic dissection
❑ Myocarditis
❑ Renal Failure
❑ Pregnancy
❑ Fibrinolytic treatment

Device name:

Device category:

❑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) :

Follow-Up for primary outcome, n/N (%): Define primary outcome:	**Device Group**	**Control Group**

Baseline Characteristics

	Device Group	Control Group		Device Group	Control Group
N			Dyslipidemia, n/N (%)		
Age, years (mean± SD)			Hypertension n/N (%)		
Males, n/N (%)			Baseline TIMI 0-1 Flow, n/N (%) or mean ± SD, specify		
Anterior MI n/N (%)			DM n/N (%)		
Family history of CAD n/N (%)			Smoker n/N (%)		
Prior Myocardial Infarction n/N (%)			Failed TL n/N (%)		
Mean Ischemic Time, min (mean± SD or median±IQR, specify) Definition:			Killip Class n/N (%) Definition:		
Definition:			Thrombus Score n/N (%) Definition:		

		Device Group	Control Group			Device Group	Control Group
ACS n/N (%)	STEMI			Infarct Related Artery n/N (%)	LAD Lesion		
	N-STEMI				LCX Lesion		
	Unstable Angina				RCA Lesion		
					Other:		

Multi-vessel Disease n/N (%) Definition:				Visible lesion on angiography n/N (%) Definition:		
Pre-cTFC (mean± SD)				Pre-LVEF (mean± SD)		
Ethnicity reported?						

Concurrent Drugs Used

Anti-platelet Therapy

❑Aspirin Regimen: ❑Ticlopidine: Regimen: ❑Clopidogrel Regimen: ❑GP2B3A Regimen: ❑Other Regimen:

Antithrombotic Therapy

❑Heparin Regimen: ❑Others Regimen: ACT (or other monitoring parameter, please specify):

Vasodilators

❑ Nitrates Regimen: ❑ Nitroglycerine Regimen: ❑ Others Regimen:

Procedural Characteristics

		Device Group	**Control Group**
Procedural Time (min) mean± SD or median±IQR, specify	Definition:		
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

	Device Group	Control Group
MBG n/N (%) Definition:		
Post-PCI TIMI 3 n/N (%)		
Post cTFC (mean % ±SD)		
LVEF (mean % ±SD)		
Distal embolization n/N (%)		
Infarct size (mean % ± SD)		
Procedural Success Rate n/N (%)		
No Reflow n/N (%)		
Slow Reflow n/N (%)		
CK-MB n/N (%) or mean ± SD Definition:		

Safety Outcomes

	Device Group	Control Group
Coronary Dissection n/N (%)		
Perforation n/N (%)		
Prolonged Procedure n/N (%)		
Other (please specify):		
Other (please specify):		

ST-Segment Resolution

Post Procedure/immediate					60 Minutes			
STSR %	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Device Group n/N (%)								
Control Group n/N (%)								

90 Minutes					Others			
STSR %	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Device Group n/N (%)								
Control Group n/N (%)								

Other measures of ST resolution:

Final Health Outcomes

Composite MACE or MACCE n/N (%)	**Definition**	**Time Period**	**Device Group**	**Control Group**
Other individual endpoints included in MACE or MACCE not listed below	**Endpoint:**			
Mortality n/N (%)	**Definition**			
TVR n/N (%)				
Reinfarction n/N (%)				
Stroke n/N (%)				

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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Dudek, 2010 PHIRATE	**Publication type:** Full text and slide presentation **Geographical location:** Poland, Italy, Hungary **Funding:** Unfunded **Number of centers:** 10 **Randomization:** Sealed white envelopes with names of study groups were used, prepared beforehand, in blocks of 4 and 6 patietns to achieve balanced allocation **Outcome assessment:** Angiograms assessed by independent core laboratory **Number of participants enrolled:** 196	**Inclusion criteria:** First STEMI referred for primary PCI; within 6 hours from chest pain onsent, with ≥2mm ST-segment elevation in at least two continguous leads and ≥3mmST-segmenet elevation in at least one lead, with occluded IRA at baseline angiography and vessel reference diameter ≥2.5mm **Exclusion criteria:** Prior MI, PCI, CABG; patients in cardiogenic shock; treated with fibrinolysis before admission to catheterization lab **Intervention:** Primary PCI with Diver CE thrombectomy system followed by direct stenting **Comparator:** Standard balloon predilation followed by stenting **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3,TIMI-3, DE (post-procedure); STSR > 70% (immediately post-procedure, 60 min) **Final:** MACE (reinfarction, death) (in-hospital); MACE (mortality, reinfarction, re-PCI or re-CABG), mortality, reinfarction, TVR (in-hospital, 180 d) **Safety:** NR	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? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Liistro, 2009	**Publication type:** Full text, slide presentation **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** Computer generated random assignment number 1:1 in blocks of 10 **Outcome assessment:** Evaluated by 2 readers without the knowledge of clinical status, treatment modality, angiographic and echocardiographic data **Number of participants enrolled:** 111	**Inclusion criteria:** Symptoms associated with ACS > 30 min, < 12 h symptom onset, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads **Exclusion criteria:** 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 < 6 m **Intervention:** PCI with thrombus aspiration by Export Aspiration Catheter **Comparator:** Standard PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG ≥ 2, TIMI-3, DE, no reflow (post-procedure); EF (post-procedure and 180 d); STSR ≥ 70% (90 min) **Final:** MACE, TLR, reinfarction (180 d) **Safety:** Procedure time	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Lipiecki, 2009	**Publication type:** Full text **Geographical location:** France **Funding:** Regional Project of Clinical Research grant and Medtronic Company **Number of centers:** 1 **Randomization:** Randomized 1:1 **Outcome assessment:** Coronary flow assessment offline by 2 experienced interventional cardiologist **Number of participants enrolled:** 44	**Inclusion criteria:** Chest pain associated with ACS > 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 **Exclusion criteria:** LBBB, ventricular pacing at baseline, previous MI or CABG, Killip Class > II, contraindication to SPECT or MRI **Intervention:** PCI with Export catheter **Comparator:** PCI **Duration of followup (d):** 7 **Followup:** NR	**Intermediate:** MBG-2, TIMI-3, DE (post-procedure); EF (7 d); STSR > 70% (90 min, 24 h) **Final:** NR **Safety:** NR	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 (< 10%)? Can't tell 6. Was the overall loss to followup low (< 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Moura, 2009	**Publication type:** Abstract **Geographical location:** Brazil **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 152	**Inclusion criteria:** Acute STEMI within 6 h **Exclusion criteria:** NR **Intervention:** Thrombectomy aspiration catheter **Comparator:** Conventional PCI with stent **Duration of followup (d):** 270 **Followup:** NR	**Intermediate:** MBG ≥ 2 (post-procedure); STSR > 70% (NR) **Final:** MACE (mortality, new MI, stent thrombosis, TVR) (in-hospital, 30 d, 270 d) **Safety:** NR	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 (< 10%)? Can't tell 6. Was the overall loss to followup low (< 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Sardella, 2009 EXPIRA	**Publication type:** Full text, slide presentation **Geographical location:** NR **Funding:** NR **Number of centers:** 1 **Randomization:** Random assignment 1:1 **Outcome assessment:** Blinded operators using an off-line dedicated workstation **Number of participants enrolled:** 175	**Inclusion criteria:** First STEMI, ≤ 9 h symptom onset, IRA ≥ 2.5 mm, TS ≥ 3, TIMI ≤ 1, > 18 y **Exclusion criteria:** Previous PCI on IRA, MI or CABG, cardiogenic shock, 3-vessel or left main disease, severe valvular heart disease, thrombolysis, contraindication to GP2B3Ai **Intervention:** Primary PCI with Export Medtronic **Comparator:** Primary PCI **Duration of followup (d):** 720 **Followup:** 100%	**Intermediate:** MBG ≥ 2, TIMI ≥ 2, (post-procedure); EF (3-5 d post-procedure); STSR > 70% (90 min) **Final:** MACE (cardiac mortality, nonfatal reinfarction, TVR) (30 d, 270, 720 d); MACCE (MACE + stroke) (30 d); mortality (in-hospital, 30 d, 180 d); TVR, reinfarction (in-hospital; 30 d, 720 d); stroke (in-hospital) **Safety:** NR	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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Chao, 2008	**Publication type:** Full text **Geographical location:** Taiwan **Funding:** NR **Number of centers:** 1 **Randomization:** NR **Outcome assessment:** Coronary angiograms reviewed offline by 2I interventional cardiologists who were blinded to the clinical data **Number of participants enrolled:** 74	**Inclusion criteria:** STEMI with chest pain > 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 **Exclusion criteria:** Previous CABG, Killip IV, ventricular tachycardia, significant left main disease, culprit vessel diameter < 2mm, existing TIMI-3 flow without visible thrombus in IRA **Intervention:** Primary PCI with Export aspiration catheter **Comparator:** Primary PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG, TIMI blood flow (post-procedure); EF (30 d) **Final:** MACE (mortality, stroke, nonfatal reinfarction), mortality, TVR (180 d) **Safety:** Coronary dissection, procedure time	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? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Chevalier, 2008 EXPORT	**Publication type:** Full text, slide presentation **Geographical location:** Europe and India **Funding:** Medtronic Vascular **Number of centers:** 24 **Randomization:** Computerized telephone system on a 1:1 basis **Outcome assessment:** Three independent interventional cardiologist reviewed MACE and serious adverse device events, ECG and angiographic results analyzed by an independent core laboratory **Number of participants enrolled:** 249	**Inclusion criteria:** 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 **Exclusion criteria:** Cardiogenic shock, pacemaker, fibrinolytic treatment, cardiac arrest, treatment with GP2B3Ai, medical condition with expected survival < 1 y, participation in other investigations **Intervention:** Primary PCI with Export aspiration catheter followed by stenting **Comparator:** Conventional stenting **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 50% (60 min) **Final:** MACCE (mortality, reinfarction, emergent bypass surgery, TLR or TVR, cerebrovascular accident), mortality, TVR, TLR, reinfarction, cerebrovascular accident (30 d) **Safety:** Procedure time, side branch occlusion	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? Can't tell 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ciszewski, 2008	**Publication type:** Abstract **Geographical location:** Poland **Funding:** NR **Number of centers:** 1 **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 135	**Inclusion criteria:** TIMI < 2, ≤ 12 h from symptom onset, first anterior or inferior STEMI, LAD or RCA lesion **Exclusion criteria:** NR **Intervention:** Thrombectomy with Rescue or Diver followed by stent implantation **Comparator:** Standard primary PCI with stenting **Duration of followup (d):** 5-8 **Followup:** 96.92% in device group, 91.43% in control group	**Intermediate:** EF (5-8 d) **Final:** Mortality (3-7 d) **Safety:** NR	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? 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? Can't tell Overall quality rating: Fair

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ikari, 2008 VAMPIRE	**Publication type:** Full text, slide presentation, abstract **Geographical location:** Japan **Funding:** Nipro **Number of centers:** 23 **Randomization:** NR **Outcome assessment:** Data analysis by an independent clinical research organization, clinical events adjudicated by an independent committee **Number of participants enrolled:** 355	**Inclusion criteria:** AMI ≤ 24 h and > 30 min from symptom onset, age ≥ 21 y, ST-segment elevation ≥ 2 mm in 2 or more ECG leads or new LBBB **Exclusion criteria:** Cardiogenic shock, fibrinolytic treatment, previous CABG, chronic renal failure (Cr > 2.0 mg/dL or HD), presence of primary thrombolysis prior to randomization, history of cardiac arrest, left main disease, target vessel < 2.5 or > 5 mm in diameter **Intervention:** Primary PCI with TVAC **Comparator:** PCI without thrombectomy **Duration of followup (d):** 240 **Followup:** 98.89% in device group, 97.71% in control group	**Intermediate:** MBG-3, TIMI-3, EF (post-procedure, 180 d); DE, no reflow (post-procedure); STSR > 70% (immediately post-procedure, 3-6 h) **Final:** MACE (mortality, recurrence of MI, TLR) (in-hospital, 240 d, 720 d), mortality, recurrence of MI, TLR, (in-hospital, 240 d) **Safety:** Coronary dissection, perforation, procedure time	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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Svilaas, 2008 TAPAS	**Publication type:** Full text, slide presentation **Geographical location:** Netherlands **Funding:** Medtronic, Thorax Center of university Medical Center **Number of centers:** 1 **Randomization:** Computerized voice-response system to select randomly permuted blocks of 3-6 stratified by the interventional cardiologist **Outcome assessment:** Coronary angiogram data analyzed at an independent core laboratory **Number of participants enrolled:** 1071	**Inclusion criteria:** AMI ≤ 12 h and > 30 min from symptom onset, ST-segment elevation ≥ 0.1 mV in 2 or more ECG leads **Exclusion criteria:** Fibrinolytic therapy, inability to obtain informed consent, known existence of disease with life expectancy < 6 m **Intervention:** Primary PCI with thrombus aspiration by 6-French Export Aspiration Catheter **Comparator:** Conventional PCI **Duration of followup (d):** 30 **Followup:** 91.59% in device group, 91.42% in control group	**Intermediate:** MBG-3, TIMI-3 (post-procedure); STSR > 70% (30-60 min) **Final:** MACE (mortality, reinfarction, TVR), mortality, reinfarction, TVR (30 d, 365 d) **Safety:** Coronary dissection, procedure time, side branch occlusion	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? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
DeLuca, 2006	**Publication type:** Full text **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** Randomized on a 1:1 basis **Outcome assessment:** TIMI flow and MBG were analyzed offline **Number of participants enrolled:** 76	**Inclusion criteria:** Anterior STEMI with chest pain > 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 **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 > 50% residual stenosis in the IRA) **Intervention:** Primary PCI with Diver CE aspiration thrombectomy catheter **Comparator:** Conventional PCI **Duration of followup (d):** 180 **Followup**: 92.11% in device group, 94.74% in control group	**Intermediate:** MBG-3, TIMI-3 (post-procedure); EF (post-procedure, 180 d); STSR > 70% (90 min) **Final:** MACE (mortality, reinfarction, hospitalization for CHF), mortality, reinfarction (180 d) **Safety:** Coronary dissection	• Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No • Were outcomes assessed using a valid methodology and criteria? Yes • Were outcome assessors blind to exposure/intervention status? Partially • Were incomplete outcome data adequately addressed? Yes • Was the differential loss to followup between the compared groups low (< 10%)? Yes • Was the overall loss to followup low (< 30%)? Yes • Conflict of interest reported and insignificant? Yes • Were the methods used for randomization adequate? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Kaltoft, 2006	**Publication type:** Full text, slide presentation **Geographical location:** Denmark **Funding:** Partially by Boston Scientific **Number of centers:** 1 **Randomization:** 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 **Outcome assessment:** Angiographic measurements made by 4 experienced observers blinded to randomization **Number of participants enrolled:** 215	**Inclusion criteria:** Symptom onset > 30 min and < 12 h; ST-segment elevation ≥ 2 mm in 2 or more ECG leads, PCI indicated upon angiography, IRA suitable for thrombectomy **Exclusion criteria:** 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 **Intervention:** Primary PCI with Rescue catheter **Comparator:** Standard PCI **Duration of followup (d):** 30 **Followup:** 73.15% in device group, 83.18% in control group	**Intermediate:** TIMI-3, DE (post-procedure); EF (30 d); STSR > 70% (immediately post-procedure, 90 min, 6 h) **Final:** MACE (mortality, reinfarction, disabling stroke), mortality, reinfarction, disabling stroke (30 d) **Safety:** Procedure time	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? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Lee, 2006 TSUNAMI	**Publication type:** Abstract **Geographical location:** Korea **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 133	**Inclusion criteria:** STEMI scheduled for primary PCI **Exclusion criteria:** NR **Intervention:** Primary PCI with Export aspiration catheter **Comparator:** Primary PCI **Duration of followup (d):** In-hospital **Followup:** 100%	**Intermediate:** MBG-3, STSR, DE, no reflow (post-procedure) **Final:** NR **Safety:** NR	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 (< 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: Poor

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Silva-Orrego, 2006 DEAR-MI	**Publication type:** Full text, abstract, slide presentation **Geographical location:** Italy **Funding:** Niguarda Hospital, Milan **Number of centers:** 1 **Randomization:** Randomly assigned on a 1:1 basis **Outcome assessment:** Angiographic and ECG data analysis by 2 blinded observers **Number of participants enrolled:** 148	**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 **Exclusion criteria:** Contraindication to GP2B3Ai, cardiogenic shock, LBBB, ventricular pacing, previous MI or CABG, fibrinolytic treatment **Intervention:** Primary PCI with Pronto extractor catheter **Comparator:** Standard angioplasty with stenting **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, STSR, DE, no reflow (post-procedure) **Final:** Mortality, TVR, reinfarction, stroke (in-hospital, 180 d) **Safety:** Coronary dissection, procedure time	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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Burzotta, 2005 REMEDIA	**Publication type:** Full text **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** 1:1 by computer generated random series of numbers **Outcome assessment:** ECG analyzed by blinded cardiologist, angiographic data analyzed offline by two expert interventional cardiologists **Number of participants enrolled:** 99	**Inclusion criteria:** Acute STEMI within 12 h, eligible for primary or rescue PCI **Exclusion criteria:** No angiographic exclusion criteria were applied **Intervention:** Primary or rescue PCI with Diver CE **Comparator:** Standard PCI **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure), EF(24 h); STSR > 70% (post-procedure) **Final:** MACE (major adverse events), mortality, TLR, reinfarction, stroke (30 d); **Safety:** Procedure time	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Noel, 2005	**Publication type:** Abstract **Geographical location:** France **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 50	**Inclusion criteria:** Acute STEMI within 12 h, initial TIMI flow < 3 **Exclusion criteria:** NR **Intervention:** PCI with Export **Comparator:** PCI **Duration of followup (d):** 1 h **Followup:** In-hospital	**Intermediate:** TIMI < 3, no reflow, (post-procedure); STSR > 50%, STSR > 70% (60 min) **Final:** MACE, mortality (NR) **Safety:** NR	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 (< 10%)? Can't tell 6. Was the overall loss to followup low (< 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Dudek, 2004	**Publication type:** Full text, abstract **Geographical location:** Poland **Funding:** NR **Number of centers:** NR **Randomization:** Randomized using a computer system **Outcome assessment**: ECG data analyzed by 2 blinded investigators **Number of participants enrolled:** 72	**Inclusion criteria:** 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 **Exclusion criteria:** Cardiogenic shock, previous fibrinolytic treatment, previous GP2B3Ai, IRA reference diameter < 2.5 mm **Intervention:** Primary PCI with Rescue system **Comparator:** Primary PCI **Duration of followup (d):** 90 **Followup:** NR	**Intermediate:** MBG-3, TIMI-3 (post-procedure); EF (in-hospital, 90 d); STSR > 70% (60 min) **Final:** NR **Safety:** NR	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%)? Can't tell 6. Was the overall loss to followup low (< 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

*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; MACE=major adverse cardiac events; 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 2. Characteristics and quality assessment of randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Migliorini, 2010 JETSTENT	**Publication type:** Full text, slide presentation **Geographical location:** International **Funding:** Medrad Interventional/ Possis **Number of centers:** Multiple **Randomization:** Computer generated sequence of number and assignments were provided by a centralized telephone system **Outcome assessment:** 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 **Number of participants enrolled:** 501	**Inclusion criteria:** STEMI with chest pain > 30 min and < 12 h, ST-segment elevation > 1 mm in 2 or more ECG leads or a new LBBB, TIMI thrombus grade 3-5 after infarct artery wiring, IRA > 2.5 mm on visual assessment **Exclusion criteria:** Fribrinolytic 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 < 1 y, participation in another study, TIMI thrombus grade < 3, IRA diameter < 2.5 mm, previous stenting of IRA, inability to identify IRA **Intervention:** Rheolytic thrombectomy with AngioJet followed by direct stenting **Comparator:** Direct stenting **Duration of followup (d):** 365 **Followup:** 96.09% in device group, 97.90% in control group	**Intermediate:** MBG-3,TIMI-3 post-procedure); STSR > 50% (30 min) **Final:** MACCE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d, 180 d, 365 d) **Safety:** Perforation, procedure time	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ali, 2006 AIMI	**Publication type:** Full text, slide presentation **Geographical location:** USA, Canada **Funding:** Possis Medical, Millenium Incorporation **Number of centers:** Multiple **Randomization:** NR **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 **Number of participants enrolled:** 480	**Inclusion criteria:** < 12 h from symptom onset, age ≥ 18 y, anterior or large inferior myocardial infarction (new ST-segment elevation > 1 mm in 2 or more ECG leads in V_1 to V_6 or II, II and aVF), reference coronary artery > 2 mm in diameter **Exclusion criteria:** Contraindication to GP2B3Ai, cardiogenic shock (SBP < 80 mmHg requiring inotrope), inability to obtain informed consent, known prior EF < 35%, major surgery within last 6 w, history of stroke within 30 d, history of haemorrhagic stroke **Intervention:** Conventional PCI with AngioJet catheter **Comparator:** Conventional PCI **Duration of followup (d):** 30 **Followup:** 82.08% in device group, 85.42% in control group	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure), EF (14-28 d); STSR > 70% (90 min) **Final:** MACCE (mortality, reinfarction, emergent CABG, TLR, stroke, stent thrombosis), reinfarction, stroke, TLR (30 d); mortality (30 d, 180 d) **Safety:** Coronary dissection, perforation, procedure time	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? Yes 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Lefèvre, 2005	**Publication type:** Full text, abstract, slide presentation **Geographical location:** France, Germany, Italy, Austria, UK, and Spain **Funding:** NR **Number of centers:** 14 **Randomization:** Randomly assigned on a 1:1 basis **Outcome assessment:** Coronary angiogram, MBG, and ECG analyzed by blinded independent core laboratory **Number of participants enrolled:** 201	**Inclusion criteria:** AMI < 12 h, chest pain > 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 **Exclusion criteria:** Saphenous vein graft, LBBB, fibrinolytic treatment, Killip ≥ III, previous PCI in IRA, rescue PCI, IRA with excessive proximal tortuousity or severe calcification, osital lesion, LVEF < 30%, contraindication to emergency CABG, current participation in any other study **Intervention:** PCI with X-Sizer catheter system and stenting **Comparator:** PCI with balloon angioplasty and/or stenting **Duration of followup (d):** 180 **Followup:** 90% in device group, 94.06% in control group	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 50% (60 min) **Final:** MACCE (major adverse cardiac and cerebral events), mortality, TVR, reinfarction, stroke (30 d,180 d) **Safety:** Procedure time	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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Antoniucci, 2004	**Publication type:** Full text, abstract **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** Computer generated sequence and assignment using a closed envelope system **Outcome assessment:** Independent analysis of ECG, scintigrams, and angiograms by investigators unaware of patients' treatment assignments **Number of participants enrolled:** 100	**Inclusion criteria:** Chest pain > 30 min, ST-segment elevation ≥ 0.1 mV (1 mm) in 2 or more ECG leads **Exclusion criteria:** BBB or pacing at baseline, previous MI, fibrinolytic treatment, IRA < 2.5 mm on visual angiography, inability to obtain informed consent **Intervention:** PCI with AngioJet **Comparator**: Direct IRA stenting only **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** STSR ≥ 50% (30 min) **Final:** MACE, mortality, TVR, stroke (30 d) **Safety:** NR	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Napodano, 2003 MIRANO	**Publication type:** Full text, slide presentation **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned on 1:1 basis **Outcome assessment:** Angiographic data analyzed offline by 2 experienced operators blinded to clinical data **Number of participants enrolled:** 92	**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 **Exclusion criteria:** Contraindication to GP2B3Ai and antiplatelets, LBBB, ventricular pacing at baseline, pregnancy, left main stem lesions, IRA diameter < 2.5 mm **Intervention:** Thrombectomy with X-Sizer catheter system followed by stenting **Comparator:** Conventional stenting **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (at discharge); STSR ≥ 50% (60 min) **Final:** Mortality, TVR, reinfarction, stroke (in-hospital, 30 d) **Safety:** Side branch occlusion	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 Overall quality rating: Good

*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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ito, 2010	**Publication type:** Full text **Geographical location:** Japan **Funding:** Unfunded **Number of centers:** 1 **Randomization:** Randomly assigned to either of the two groups **Outcome assessment:** Angiography images were analyzed offline by 2 experienced interventional cardiologists who were unaware of the index of microcirculatory resistance results **Number of participants enrolled:** 36	**Inclusion criteria:** First anterior STEMI (chest pain>30min and 0.1mV ST-segment elevation in 2 contiguous ECG leads) after successful PCI within 24h of symptom onset **Exclusion criteria:** Cardiac shock, history of old MI, severe liver or renal dysfunction, history of allergic response to drugs, severe hypovolemia **Intervention:** PCI with distal filter protection (Filtrap) **Comparator:** Standard PCI **Duration of followup (d):** 30 days **Followup:** 100%	**Intermediate:** TIMI-3 (post-procedure); STSR≥70% (60 min) **Final:** MACE (mortality, MI, TLR), mortality, MI, TLR (30d) **Safety:** NR	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? Yes 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Kelbæk, 2008 DEDICATION	**Publication type:** Full text, abstract, slide presentation **Geographical location:** Denmark **Funding:** NR **Number of centers:** 2 **Randomization:** Centralized telephone randomization performed by computerized assignment stratified with regard to gender and presence of diabetes **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 **Number of participants enrolled:** 626	**Inclusion criteria:** Chest pain > 30 min presenting within 12 h, age ≥18 y, total ST-segment elevation > 4 mm in 2 or more ECG leads, high grade stenosis or occlusion of native coronary artery without excess tortuousity or calcification prohibiting advancement of of filterwire to the distal vascular bed of the vessel **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 <1 y, linguistic problems **Intervention:** Primary PCI with FilterWire EZ or SpiderX **Comparator:** Primary PCI **Duration of followup (d):** 30 **Followup:** 96.79% in device group, 95.86% in control group	**Intermediate:** TIMI-3 (post-procedure) STSR > 70% (90 min) **Final:** MACE (mortality, TLR, reinfarction, stroke) (30 d, 240 d, 450 d); mortality, TLR, reinfarction, stroke (30 d); mortality, TLR, TVR, reinfarction (450d) **Safety:** NR	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Cura, 2007 PREMAIR	**Publication type:** Full text, abstract, slide presentation **Geographical location:** Argentina, Chile, Israel **Funding:** Partial funding from ev3 **Number of centers:** 20 **Randomization:** Randomized in a 1:1 ratio according to IRA and physician's intention to use GP2B3Ai **Outcome assessment:** ST-segment resolution, reperfusion, EF and angiographic data analyzed in a blinded manner by a core laboratory, clinical events adjudicated by a blinded committee **Number of participants enrolled:** 140	**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 **Exclusion criteria:** SVG, cardiogenic shock, previous CABG or PCI within 6 m, cardiac tamponade, aortic dissection, myocarditis, known renal failure (Cr > 2 mg/dL), pregnancy, oral anticoagulation, allergy to nitinol, stainless steel, aspirin, or thienopyridibe, TIMI-3 at baseline, culprit lesion < 50% stenosis, vessel ≤ 2.5 mm, left main disease, bifurfication lesion, excessive proximal tortuousity, need for treatment of > 1 vessel during index procedure **Intervention:** PCI with SpiderX **Comparator:** PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, EF, DE, no reflow (post-procedure); STSR > 70% (60 min) **Final:** MACE (mortality, reinfarction, heart failure), mortality, TVR, reinfarction, (30 d,180 d) **Safety:** Coronary dissection, perforation, procedure time, side branch occlusion	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? Can't tell 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Guetta, 2007 UPFLOW MI	**Publication type:** Full text, slide presentation **Geographical location:** Israel **Funding:** Partial funding from Boston Scientific **Number of centers:** 5 **Randomization:** Computer-generated, permuted blocks, random sequence by a statistician unknown to the investigators and attending medical team, Patient were given opaque, sealed envelope by statistician who was not involved in the performing the study **Outcome assessment:** Angiographic data and ST-segment resolution analyzed offline by an independent angiographic core laboratory **Number of participants enrolled:** 100	**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 **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 **Intervention:** PCI with FilterWire EZ **Comparator:** PCI **Duration of followup (d):** 30 **Followup:** 96.08% in device group, 97.96% in control group	**Intermediate:** MBG-3, TIMI-3, EF (post procedure); STSR > 70% (60 min) **Final:** MACE (mortality, nonfatal MI, CHF), mortality, reinfarction (30 d) **Safety:** NR	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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Lefèvre, 2004 DIPLOMAT	**Publication type:** Abstract, slide presentation **Geographical location:** France, Italy **Funding:** CORDIS **Number of centers:** 5 **Randomization:** Randomized on a 1:1 basis **Outcome assessment:** ECG and echocardiography analyzed at a central core laboratory **Number of participants enrolled:** 60	**Inclusion criteria:** AMI within 12 h with ST-segment elevation > 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 < 5.5 mm, target lesion stenosis > 80% **Exclusion criteria:** RBBB or LBBB, fibrinolytic treatment, Killip class IV, unprotected left main with > 50% stenosis in case left coronary artery is treated, ostial target lesion, contraindication to aspirin, heparin, stainless steel or contrast media **Intervention:** PCI with Angioguard XP **Comparator:** PCI **Duration of followup (d):** 30 **Followup:** 93.75% in device group, 92.86% in control group	**Intermediate:** TIMI-3, DE, no reflow (post-procedure); STSR > 70% (NR) **Final:** MACE (mortality + MI), mortality, AMI (30 d) **Safety:** NR	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? Can't tell 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 (< 10%)? Yes 6. Was the overall loss to followup low (< 30%)? Yes 7. Conflict of interest reported and insignificant? Yes 8. Were the methods used for randomization adequate? Can't tell 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: 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 revasclarization; 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Duan, 2010	**Publication type:** Full text **Geographical location:** China **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned to either of the two groups **Outcome assessment:** Echocardiography was performed by observers who were blind to all clinical and angiographic data **Number of participants enrolled:** 96	**Inclusion criteria:** First anterior MI defined as chest pain lasting >30 min but <6h in conjunction with persistent ST-segment elevation in precordial leads; proximal lesionof LAD present and diameter of infarct lesion known or expected >3mm without extensive tortuosity or lesion/vessel calcification, with 30mm or more of distal vessel **Exclusion criteria:** 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 **Intervention:** PCI with distal balloon embolic protection (PercuSurge Guardwire Plus) **Comparator:** Standard PCI **Duration of followup (d):** 180 days **Followup:** 100%	**Intermediate:** TIMI-3; EF (post-procedure) **Final:** NR **Safety:** NR	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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Pan, 2010	**Publication type:** Full text **Geographical location:** China **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned to either of the two groups **Outcome assessment:** NR **Number of participants enrolled:** 104	**Inclusion criteria:** 65-81 years old admitted within 2-14h after symptom onset of acute STEMI (typical chest pain>30min, ST-elevation ≥1mm in 2 contiguous leads and or >2mm in precordial leads with visible thrombus) proven angiographically **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 **Intervention:** PCI with distal balloon protection (PercuSurge Guardwire) **Comparator:** Standard PCI **Duration of followup (d):** Post-procedure **Followup:** 100%	**Intermediate:** TIMI-3 (post-procedure) **Final:** NR **Safety:** NR	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? No 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Fair

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Tahk, 2008	**Publication type:** Full text, abstract **Geographical location:** Korea **Funding:** Supported in part by Medtronic Inc. **Number of centers:** 7 **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 116	**Inclusion criteria:** First-time STEMI, chest pain > 30 min, presentation within 12 h after symptom onset, ST-segment elevation > 2 mV in 2 or more ECG leads, reference vessel diameter of target lesion 2.75 - 4.5 mm, diameter stenosis > 70%, lesion length short enough to be covered by a single stent deployment **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 < 1 y **Intervention:** Primary PCI with PercuSurge GuardWire system **Comparator:** Primary PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** TMP-3; TIMI-3 (post-procedure); EF (post-procedure, 180 d) **Final:** MACE (mortality, reinfarction, ischemia-driven TVR), mortality, TVR, reinfarction (30 d,180 d) **Safety:** NR	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? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Hahn, 2007	**Publication type:** Full text, abstract **Geographical location:** South Korea **Funding:** NR **Number of centers:** 1 **Randomization:** NR **Outcome assessment:** Coronary angiograms analyzed by 2 blinded observers, MRI analyzed independently by 2 experienced radiologists blinded to the clinical information **Number of participants enrolled:** 39	**Inclusion criteria:** Chest pain > 30 min but < 12 h after symptom onset, ST-segment elevation > 1 mm in 2 or more ECG leads or presumably new LBBB, IRA lesion eligible for primary PCI with stenting, distal vessel > 2.5 mm in diameter and suitable for balloon occlusion and aspiration device **Exclusion criteria:** Previous MI, hemodynamic instability, requirement for multivessel intervention during index PCI, contraindication to aspirin, clopidogrel or heparin **Intervention:** Primary PCI with GuardWire **Comparator:** Primary PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); EF (3 d,180 d); STSR > 50% (90 min) **Final:** MACE (mortality, MI, TLR), mortality, TLR, reinfarction (180 d) **Safety:** NR	1. Were the groups similar at baseline in terms of baseline characteristics and prognostic factors? No 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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Matsuo, 2007 MICADO	**Publication type:** Full text **Geographical location:** Japan **Funding:** NR **Number of centers:** 14 **Randomization:** Randomized using envelope method **Outcome assessment:** NR **Number of participants enrolled:** 154	**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 **Exclusion criteria:** Severe blood, hepatic, or renal disease with history of internal organ bleeding within the past month, allergy to antiplatelets or anticoagulants, chronic renal failure (Cr 2.6 mg/dL or greater) **Intervention:** PCI with GuardWire Plus **Comparator:** Conventional PCI **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post procedure); EF (post procedure,180 d); STSR > 70% (30 min) **Final:** MACE (mortality, non-lethal MI, heart failure, ischemic-driven revascularization), mortality, TVR, reinfarction (30 d,180 d) **Safety:** Procedure time, side branch occlusion	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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Muramatsu, 2007 ASPARAGUS	**Publication type:** Full text **Geographical location:** Japan **Funding:** Medtronic Japan Co. Ltd **Number of centers:** 22 **Randomization:** Randomized according to envelope method **Outcome assessment:** Clinical and basic angiographic data collected and case report forms sent to and reviewed by reviewed by core laboratory **Number of participants enrolled:** 341	**Inclusion criteria:** Native vessel, AMI within 12 h of chest pain onset, age ≥ 18 y, ST-segment elevation, patients considered treatable by stenting **Exclusion criteria:** SVG, left main trunk disease, reference vessel diameter < 2.5 mm, cardio-pulmonary arrest **Intervention:** Primary PCI with GuardWire Plus **Comparator:** Primary PCI **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post- procedure); EF (post-procedure, 30 d, 180 d); STSR > 70% (90 min) **Final:** MACE (mortality, myocardial infarction or TVR) (30 d, 180 d); mortality, TVR, reinfarction (in-hospital, 30 d, 180 d) **Safety:** Procedure time	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Zhou, 2007	**Publication type:** Full text **Geographical location:** NR **Funding:** NR **Number of centers:** NR **Randomization:** Randomized using sealed envelopes **Outcome assessment:** TIMI flow grade and MBG evaluated by 2 experienced investigators who were blinded to all clinical data **Number of participants enrolled:** 112	**Inclusion criteria:** Continuous chest pain > 30 min, < 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 **Exclusion criteria:** Thrombolytic treatment before PCI, GP2B3Ai before PCI, reference vessel diameter < 3.0 mm, Killip IV or cardiogenic shock, left main coronary artery lesion **Intervention:** Primary stenting with PercuSurge GuardWire **Comparator:** Primary stenting **Duration of followup (d):** In-hospital **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3 (post-procedure) **Final:** MACE (in-hospital) **Safety:** Coronary dissection, perforation	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? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Okamura, 2005	**Publication type:** Full text **Geographical location:** Japan **Funding:** NR **Number of centers:** 1 **Randomization:** NR **Outcome assessment:** Data assessed using an offline personal computer **Number of participants enrolled:** 16	**Inclusion criteria:** Chest pain > 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 **Exclusion criteria:** Cardiogenic shock, previous CABG, atrial fribrillation **Intervention:** PCI with PercuSurge Guidewire **Comparator:** PCI **Duration of followup (d):** In-hospital until discharge, 22 ± 4 **Followup:** 100%	**Intermediate:** TIMI-3 (post-procedure); EF (discharge) **Final:** NR **Safety:** NR	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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Stone, 2005 EMERALD	**Publication type:** Full text, abstract, slide presentation **Geographical location:** USA, Canada, France, Italy, Germany, Switzerland, Japan **Funding:** Medtronic **Number of centers:** 38 **Randomization:** Telephone randomization in random blocks of 4 or 6 patients stratified by intention to use GP2B3Ai and by primary versus rescue PCI	**Inclusion criteria:** AMI > 30 min but < 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 **Exclusion criteria:** Cardiogenic shock, CABG within 30 d, unprotected left main disease, renal insufficiency (SCr > 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 (< 1000 neutrophils/mm^3), thrombocytopenia (< 100,000 platelets/mm^3), non-cardiac condition with expected survival < 1 y, current participation in another study	**Intermediate:** MBG-3, TIMI-3, DE, no reflow (post-procedure); STSR > 70% (30 min) **Final:** MACE related to ischemic complications, mortality, TVR, reinfarction, stroke (30 d, 180 d); **Safety:** Perforation**,** procedure time, side branch occlusion	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? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
	Outcome assessment: STSR by core laboratory, infarct size by a staff blinded to treatment assignment at a central core laboratory and all primary and secondary clinical endpoints adjudicated by a clinical events committee blinded to treatment allocation **Number of participants enrolled:** 501	**Intervention:** PCI GuardWire Plus **Comparator:** PCI **Duration of followup (d):** 180 **Followup:** 93.06% in device group and 89.76% in control group		

*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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Haeck, 2009 PREPARE	**Publication type:** Full text, abstract, slide presentation **Geographical location:** Netherlands and Canada **Funding:** St. Jude Medical, University of Amsterdam **Number of centers:** 2 **Randomization:** Randomized on a 1:1 basis **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 **Number of participants enrolled:** 284	**Inclusion criteria:** Symptoms of MI < 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 **Exclusion criteria:** Age < 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 > 30%, heavy proximal calcification, small infarct related artery (< 2.5 mm in diameter), proximal location of lesion with insufficient landing zone for Proxis system (generally < 10-12 mm) **Intervention:** Primary PCI with Proxis device **Comparator:** Primary PCI **Duration of followup (d):** 30 **Followup:** 89.36% in device group, 90.21% in control group	**Intermediate:** MBG-3, TIMI-3, DE, (post-procedure); STSR ≥ 70% (60 min); ejection fraction (120-180d) **Final:** MACE (death, spontaneous or procedural MI, stroke, percutaneous or surgical TVR), mortality, reinfarction, TVR, stroke (30d, 180d) **Safety:** Procedure time	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 Overall quality rating: Good

* 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; DE=distal embolization; ECG=electrocardiogram; GP2B3Ai=glycoprotein IIB IIIA inhibitor; h=hours; LBBB=left bundle branch block; MACE=major adverse cardiac events; MBG=myocardial blush grade; MI=myocardial infarction; mm=millimeters; NR=not reported; PCI=percutaneous coronary intervention; STSR=ST-segment resolution; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization; y=years; μV=microvolts

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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Webster, 2008 A-F Trial	**Publication type:** Slide presentation **Geographical location:** Canada, Australia, New Zealand **Funding:** Boston Scientific **Number of centers:** 14 **Randomization:** NR **Outcome assessment:** Unblinded design, core laboratories for ECG and angiographic data **Number of participants enrolled:** 151	**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 > 20 mm) **Exclusion criteria:** NR **Intervention:** PCI with distal filter embolic protection using BSC FilterWire EZ **Comparator:** Standard PCI **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** TIMI-3 (post-procedure) **Final:** MACE (mortality, recurrent MI, emergency CABG, repeat TVR) (in-hospital, 30 d) **Safety:** NR	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? Can't tell 3. Were outcome assessors blind to exposure/intervention status? Cant' tell 4. Were incomplete outcome data adequately addressed? Can't tell 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? Yes 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Fair

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Dudek, 2003	**Publication type:** Full text, abstract **Geographical location:** Poland **Funding:** Paper sponsored by Komitet Badan Naukowych (Scientific Research Committee) **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 31	**Inclusion criteria:** Consent to participate, unstable angina, patient qualified to single vessel coronary angioplasty with the use of stent in the vessel > 3 mm in diameter, no contraindications to GP2B3Ai **Exclusion criteria:** Recent STEMI, LVEF< 30%, complete closing of the vessel, cancer, impaired liver and kidney function, increased transferases (> 3 times the max normal values), muscle diseases, CK-MB level above normal at baseline, age > 75 y, alcohol abuse, hypersensitivity to used medication, continuation of treatment to cyclosporine and other immunosuppressant drugs, pregnancy and breast feeding **Intervention:** PCI with distal filter embolic protection using Angioguard **Comparator:** Angioplasty supported by pharmacotherapy **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** TIMI-3, no reflow (post-procedure) **Final:** Mortality, TVR, reinfarction (30 d) **Safety:** NR	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? Can't tell 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? No 8. Were the methods used for randomization adequate? Can't tell 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: ACS=Acute coronary syndrome; CABG=coronary artery bypass graft; CK-MB=creatinine 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Parikh, 2008 RAPID	**Publication type:** Full text, abstract **Geographical location:** India **Funding:** NR **Number of centers:** 1 **Randomization**: Randomly divided into 2 groups depending on whether PercuSurge was used or not **Outcome assessment**: Coronary angiograms reviewed by 2 independent cardiologists unaware of the patients' medical histories and details **Number of participants enrolled:** 67	**Inclusion criteria:** AMI patients with angiographically detected thrombotic lesions who were to undergo primary/rescue PCI within 24 h of onset of chest pain **Exclusion criteria:** NR **Intervention:** PCI with distal balloon embolic protection using PercuSurge GuardWire Plus Temporary Occlusion and Aspiration System **Comparator:** PCI **Duration of followup (d):** 720 **Followup:** 100%	**Intermediate:** TMP-3, TIMI-3, DE, no reflow (post-procedure) **Final:** Mortality (730 d) **Safety:** Procedure time	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 Overall quality rating: Fair

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Glick, 2005 PROMISE	**Publication type:** Full text, abstract **Geographical location:** Germany **Funding:** Boston Scientific **Number of centers:** 1 **Randomization:** Randomization sequence set in blocks of 20 by statistician, unknown to the investigators and medical staff **Outcome assessment:** MRI images examined by 2 experienced observers who were unaware of the patients' group assignment, angiographic images analyzed offline by independent core laboratory **Number of participants enrolled:** 200	**Inclusion criteria:** Both at least 1 episode of typical angina pain > 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 **Exclusion criteria:** Presumed distal vessel diameter < 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 **Intervention:** PCI with distal filter embolic protection using FilterWire EX **Comparator:** PCI **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG > 1, TIMI-3, DE (post-procedure); EF (3 d,180 d) **Final:** MACE (180 d); mortality, reinfarction (30 d,180 d); TVR, stroke (30 d) **Safety:** NR	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? Yes 8. Were the methods used for randomization adequate? Yes Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Sardella, 2005	**Publication type:** Abstract **Geographical location:** NR **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 62	**Inclusion criteria:** Anterior MI undergoing primary PCI of de novo coronary lesions with angiographic presence of intracoronary thrombus **Exclusion criteria:** NR **Intervention:** PCI with catheter aspiration using Diver-Invatec plus stenting **Comparator:** Conventional coronary stenting **Duration of followup (d):** 180 **Followup:** NR	**Intermediate:** MBG-3, TIMI-3 (post procedure) **Final:** NR **Safety:** NR	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 (< 10%)?Can't tell 6. Was the overall loss to followup low (< 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Kunii, 2004 NONSTOP	**Publication type:** Abstract **Geographical location:** Japan **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 258	**Inclusion criteria:** < 24 h of symptom onset, lesion diameter > 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 **Exclusion criteria:** NR **Intervention:** PCI with catheter aspiration using Rescue PT catheter **Comparator:** Primary stenting **Duration of followup (d):** In-hospital **Followup:** NR	**Intermediate:** TIMI-3 (post-procedure) **Final:** Mortality (in-hospital) **Safety:** NR	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 (< 10%)?Can't tell 6. Was the overall loss to followup low (< 30%)? Can't tell 7. Conflict of interest reported and insignificant? Can't tell 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Poor

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Nanasato, 2004	**Publication type:** Abstract **Geographical location:** Japan **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 64	**Inclusion criteria:** AMI within 12 h of onset **Exclusion criteria:** NR **Intervention:** PCI with distal balloon embolic protection using GuardWire Plus **Comparator:** Conventional PCI **Duration of followup (d):** In-hospital **Followup:** NR	**Intermediate:** MBG-3, TIMI-3, EF, (post procedure) **Final:** NR **Safety:** NR	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 (< 10%)? Can't tell 6. Was the overall loss to followup low (< 30%)? Can't tell 7. Conflict of interest reported and insignificant? Can't tell 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Poor

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Matsushita, 2003	**Publication type:** Abstract **Geographical location:** Japan **Funding:** NR **Number of centers:** NR **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 80	**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 **Exclusion criteria:** NR **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	**Intermediate:** NR **Final:** MACE (180 d); mortality (in-hospital) **Safety:** NR	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? 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 (< 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? Can't tell Overall quality rating: Poor

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Beran, 2002	**Publication type:** Full text, abstract **Geographical location:** Austria **Funding:** NR **Number of centers:** 1 **Randomization:** Randomized on a 1:1 basis **Outcome assessment:** Angiographic measurements were performed by 2 experienced observers who were blinded to randomization, ECG recording were analyzed by 2 observers blinded to randomization and angiographic findings **Number of participants enrolled:** 61	**Inclusion criteria:** STEMI with chest pain > 30 min and ST-segment elevation > 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 **Exclusion criteria:** NR **Intervention:** Mechanical thrombectomy with X-Sizer followed by stenting or PTCA **Comparator:** PTCA or stenting **Duration of followup (d):** 30 **Followup:** 90.19% in device group and 93.94% in control group	**Intermediate:** TIMI-3, STSR > 50% (post-procedure) **Final:** MACE, mortality, TVR (30 d) **Safety:** NR	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 Overall quality rating: Good

*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 8. Characteristics and quality assessment of direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Sardella, 2008 RETAMI	**Publication type:** Full text, abstract **Geographical location:** Italy **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned in a 1:1 basis **Outcome assessment:** Coronary angiograms analyzed offline by 2 expert interventional cardiologists in a blinded manner **Number of participants enrolled:** 103	**Inclusion criteria:** STEMI (chest pain > 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 > 18 y **Exclusion criteria:** Previous PCI on IRA, rescue PCI, previous MI or CABG and current participation in another study **Intervention:** Primary PCI with catheter aspiration using Diver-Invatec **Comparator:** Primary PCI with catheter aspiration using Export-Medtronic **Duration of followup (d):** 365 **Followup:** 100%	**Intermediate:** MGB-3, TIMI-3 (post-procedure); STSR > 70% (90 min) **Final:** MACE (cardiac death, Q and non-Q-wave MI, TVR), TVR, reinfarction (30 d, 365 d) **Safety:** Coronary dissection, perforation	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 Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Yan, 2007	**Publication type:** Full text **Geographical location:** China **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned on a 1:1 basis according to a computer generated random series of number **Outcome assessment:** Coronary angiograms reviewed offline by 2 experienced observers who were blinded to randomization **Number of participants enrolled:** 122	**Inclusion criteria**: Symptoms > 30 min but < 12 h, ST segment elevation ≥ 2 mV in 2 or more contiguous inferior ECG leads and total occlusion of the left coronary artery **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 **Intervention:** PCI with catheter aspiration using Diver CE **Comparator:** PCI with distal balloon embolic protection using Guardwire Plus **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG > 2, TIMI-3, no reflow/slow flow (post-procedure); STSR > 70% (90 min); EF (30 d) **Final:** MACE (mortality, MI, TVR, stroke), mortality, TVR, reinfarction, stroke (30 d) **Safety:** Procedure time	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? Yes Overall quality rating: Good

*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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Wita, 2009	**Publication type:** Full text **Geographical location:** Poland **Funding:** NR **Number of centers:** 1 **Randomization:** Randomized on a 1:1 basis **Outcome assessment:** Quantitative analysis of all images by 1 investigator blinded to the type of procedure, using a quantitative analysis tool **Number of participants enrolled:** 42	**Inclusion criteria:** Age > 18 y, chest pain > 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 **Exclusion criteria:** Cardiogenic shock, history of previous MI, hypertrophic cardiomyopathy, significant valvular disease, lack of IRA identification, residual stenosis after PCI > 50%, electrical instability, ICD or pacemaker , or females of child bearing potential **Intervention:** Catheter aspiration using Diver CE flowed by stenting **Comparator:** Stenting **Duration of followup (d):** 30 **Followup:** 100%	**Intermediate:** MBG 2-3 (post-procedure); EF (7 d, 30 d) **Final:** NR **Safety:** Procedure time	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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ozaki, 2006	**Publication type:** Full text **Geographical location:** Japan **Funding:** NR **Number of centers:** 1 **Randomization:** Randomized using envelope method **Outcome assessment:** 3 or more cardiologists evaluated the success or failure of acute stage coronary angiography, a data processing super computer was used for analysis of SPECT data **Number of participants enrolled:** 77	**Inclusion criteria:** Chest pain ≥ 30 min, ST-segment elevation ≥ 1 mm on 2 or more contiguous ECG leads, plasma creatinine level ≥ 2 times higher than normal value, abnormalities in the left ventricular wall motion on ECHO, ≤ 6 h of symptom onset **Exclusion criteria:** Fibrinolytic treatment with tissue plasminogen activator or urokinase before admission, cardiogenic shock, contraindication to aspirin or ticlopidine, coronary no-reflow/slow flow and chronic stage restenosis **Intervention A:** Stent insertion after catheter aspiration using Rescue system or Thrombuster system **Intervention B:** Stent insertion after distal balloon embolic protection using PercuSurge GuardWire catheter **Comparator:** Direct stent **Duration of followup (d):** 180 **Followup:** 80% in Rescue/Thrombuster group, 83.3% in the PercuSurge GuardWire group, 71.43% in the direct stenting group	**Intermediate:** EF (180 d) **Final:** NR **Safety:** NR	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? No 4. Were incomplete outcome data adequately addressed? Yes 5. Was the differential loss to followup between the compared groups low (< 10%)? No 6. Was the overall loss to followup low (< 30%)? No 7. Conflict of interest reported and insignificant? No 8. Were the methods used for randomization adequate? Yes 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Yamamoto, 2006	**Publication type:** Full text **Geographical location:** Japan **Funding:** NR **Number of centers:** 1 **Randomization:** Randomly assigned using the envelope method **Outcome assessment:** TMP grade assessed by single observer who was blinded to the treatment assignment and clinical outcome **Number of participants enrolled:** 44	**Inclusion criteria:** First onset STEMI, no contraindication to mutant plasminogen activator **Exclusion criteria:** Age > 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 > 180 mmHg systolic or > 100 mmHg diastolic, post cardiopulmonary resuscitation **Intervention:** PCI with catheter aspiration using Thrombuster and mutant tissue plasminogen activator **Comparator:** PCI with catheter aspiration using Thrombuster **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** TMP-3, TIMI-3 (post-procedure); EF (1-3 d, 180 d) **Final:** Mortality, TVR reinfarction, stroke (180 d) **Safety:** Procedure time	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? Yes Overall quality rating: Good

*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=creatinine 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

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ochala, 2007	**Publication type:** Full text **Geographical location:** Poland **Funding:** KBN Grant **Number of centers:** NR **Randomization:** NR **Outcome assessment:** Angiographic data analysis by independent investigator **Number of participants enrolled:** 120	**Inclusion criteria:** AMI < 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 V_1-V_2 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 **Exclusion criteria:** Lack of patients' informed consent, critical stenosis of left main artery, complex occlusive lesion (> 20 mm length or in the segment bent at 90^0 or incorporating ostium of a large side branch > 2 mm in diameter), cardiogenic shock, respiratory distress requiring intubation, previous PCI in the culprit artery, previous surgical myocardial revascularization, contraindication to abxicimab, aspirn, clopidogrel or heparin, critical lesions in other segments of coronary arteries requiring revascularization within 6 m,, valvular disease requiring surgical intervention **Intervention:** Primary PCI with distal balloon embolic protection using PercuSurge device **Comparator:** Primary PCI with abciximab **Duration of followup (d):** 180 **Followup:** 100%	**Intermediate:** MBG-3, TIMI-3 (post-procedure); EF (180 d) **Final:** Mortality (death /cardiovascular death), TVR, reinfarction (180 d) **Safety:** Procedure time	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? Yes 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Good

Study, Year	Trial Characteristics	Population, Interventions and Followup*	Outcomes of Interest (Timing)	Quality Assessment / Comments
Kanaya, 2003	**Publication type:** Abstract **Geographical location:** Japan **Funding:** NR **Number of centers:** 1 **Randomization:** NR **Outcome assessment:** NR **Number of participants enrolled:** 60	**Inclusion criteria:** AMI within 12 h of symptom onset **Exclusion criteria:** NR **Intervention:** Thrombectomy and stenting with distal protection method **Comparator:** Thrombectomy and stenting **Duration of followup (d):** In-hospital **Followup:** 100%	**Intermediate:** TIMI-3 (post-procedure) **Final:** NR **Safety:** NR	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? Can't tell 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? No 8. Were the methods used for randomization adequate? Can't tell Overall quality rating: Poor

*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

Table 12. Characteristics and quality assessment of controlled observational studies

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Beaudoin, 2010	**Publication type:** Full text **Geographical location:** Canada **Study design:** Retrospective study **Funding:** NR **Number of centers:** 1 **Outcome assessment:** Angiograms reviewed by two trained investigators **Number of participants enrolled:** 535	**Inclusion criteria:** Patients undergoing primary or rescue PCI for STEMI (chest pain or equivalent symptoms at rest >30 min, with ST-segment elevation in ≥2 contiguous leads); presenting >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 **Exclusion criteria:** NR **Intervention:** PCI with Export Aspiration Catheter **Comparator:** PCI without prior thrombectomy **Duration of followup (d):** 357 days in intervention and 363 days in control groups **Covariates/potential confounders adjusted for:** Killip class, final TIMI flow, age≥60 years, presence of three vessel disease, anterior infarction and ischemia time>4hours for the survival analysis	**Intermediate:** TIMI 3 (post-procedure) **Final:** Mortality, reinfarction, stroke, revascularization, MACE (365 d) **Safety:** Procedure time (post-procedure)	1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? Yes 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? Partially 8. Adequate followup period? Yes? 9. Completeness of followup? Yes? 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes Overall quality rating: Good

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Kim, 2010	**Publication type:** Abstract **Geographical location:** South Korea **Study design:** Propensity-matched cohort **Funding:** NR **Number of centers:** NR **Outcome assessment:** NR **Number of participants enrolled:** 858	**Inclusion criteria:** STEMI patients **Exclusion criteria:** NR **Intervention:** PCI with thrombus aspiration **Comparator:** PCI without thrombus aspiration **Duration of followup (d):** 30 days **Covariates/potential confounders adjusted for:** NR	**Intermediate:** TIMI 3, LVEF (post-procedure) **Final:** Mortality (in-hospital) **Safety:** NR	1. Unbiased selection of the cohort? Can't tell 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Can't tell 7. Outcome assessment blinded to exposure? Can't tell 8. Adequate followup period? No 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes Overall quality rating: Poor

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Ko, 2009 KAMIR	**Publication type:** Abstract **Geographical location:** Korea **Study design:** Registry **Funding:** NR **Number of centers:** NR **Outcome assessment:** NR **Number of participants enrolled:** 1050	**Inclusion criteria:** Acute STEMI, PCI within 3 h of symptom onset **Exclusion criteria:** NR **Intervention:** PCI with distal protection device (device name NR) **Comparator:** PCI without distal protection device **Duration of followup (d):** 365 **Covariates/potential confounders adjusted for:** NR, subgroup analyses based on LV dysfunction and use of GP2B3Ai	**Intermediate:** NR **Final:** MACE (365 d) **Safety:** NR	12. Unbiased selection of the cohort? Partially 13. Selection minimizes baseline differences in prognostic factors? Yes 14. Sample size calculated? No 15. Adequate description of the cohort? No 16. Validated method to ascertain exposure? Yes 17. Validated method for ascertaining clinical outcomes? Can't tell 18. Outcome assessment blinded to exposure? Can't tell 19. Adequate followup period? Yes 20. Completeness of followup? Yes 21. Analysis controls for confounding? Yes 22. Analytic methods appropriate? Yes Overall quality rating: Poor

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Nilsen, 2009	**Publication type:** Abstract **Geographical location:** NR **Study design:** Retrospective cohort **Funding:** NR **Number of centers:** 123 **Outcome assessment:** Core lab analysis[1] **Number of participants enrolled:** 3298, 3233[1]	**Inclusion criteria:** See table 2 of original study[2] **Exclusion criteria:** See table 2 of original study[2] **Intervention:** PCI with catheter aspiration (Device name NR) **Comparator:** PCI without catheter aspiration **Duration of followup (d):** 30 **Covariates/potential confounders adjusted for:** NR	**Intermediate:** DE[1], (post-procedure); STSR > 70%[1](60 min) **Final:** MACE (mortality, reinfarction, ischemic TVR, stroke), mortality, reinfarction, ischemic TVR, stroke (30 d) **Safety:** Dissection[1]	1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Can't tell 7. Outcome assessment blinded to exposure? Yes 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes Overall quality rating: Fair

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Nakatani, 2007 OACIS	**Publication type:** Full text, abstract **Geographical location:** Japan **Study design:** Prospective registry **Funding:** Government (Japanese Ministry of Education, Culture, Sports, Sciences, and Technology); Foundation (Japan Arteriosclerosis Prevention Fund) **Number of centers:** 25 **Outcome assessment:** NR **Number of participants enrolled:** 3913	**Inclusion criteria:** Undergoing PCI, AMI/symptoms within 24 h **Exclusion criteria:** Admittance > 24 h (or time unknown) after onset of AMI, treated conservatively, with thrombolytic therapy, emergent CABG, or with distal protection **Intervention:** PCI with catheter aspiration (RESCUE catheter, Thrombuster catheter, TVAC catheter, Export PercuSurge System) **Comparator:** PCI without catheter aspiration **Duration of followup (d):** 30 **Covariates/potential confounders adjusted for:** Mortality adjusted for hospital volume, age, male gender, diabetes mellitus, hypertension, hyperlipidemia, smoking, body mass index ≥ 25 kg/m^2, a history of myocardial infarction, preangina, Killip class ≥ II, ST-segment elevation myocardial infarction, onset to admission < 12 h, angiographic findings (including multivessel disease, collateral circulation, and initial TIMI grade flow), use of stenting	**Intermediate:** NR **Final:** Mortality (cardiac and non-cardiac) (30 d) **Safety:** NR	• Unbiased selection of the cohort? Yes • Selection minimizes baseline differences in prognostic factors? Yes • Sample size calculated? No • Adequate description of the cohort? Yes • Validated method to ascertain exposure? Yes • Validated method for ascertaining clinical outcomes? Yes • Outcome assessment blinded to exposure? Can't tell • Adequate followup period? Yes • Completeness of followup? Yes • Analysis controls for confounding? Yes • Analytic methods appropriate? Yes Overall quality rating: Fair

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Chinnaiyan, 2006	**Publication type:** Full text **Geographical location:** NR **Study design:** Retrospective cohort **Funding:** NR **Number of centers:** 1 **Outcome assessment:** Examined according to whether patient received mechanical thrombectomy or not **Number of participants enrolled:** 1260	**Inclusion criteria:** Undergoing primary or rescue PCI, symptoms consistent with AMI lasting < 24 h, ST-segment elevation ≥ 1 mm in two contiguous leads **Exclusion criteria:** SVG culprit, stent thrombosis **Intervention:** PCI with mechanical thrombectomy (AngioJet XMI or XVG catheter) **Comparator:** PCI without mechanical thrombectomy **Duration of followup (d):** In-hospital **Covariates/potential confounders adjusted for:** MACE and mortality adjusted for baseline clinical and angiographic characteristics	**Intermediate:** TIMI-3 (post-procedure) **Final:** MACE (mortality, reinfarction, TVR, stroke), mortality, TVR, stroke, reinfarction (in-hospital) **Safety:** Coronary artery perforation	1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? Yes 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? No 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? Yes 11. Analytic methods appropriate? Yes Overall quality rating: Fair

Study, Year	Study Characteristics	Population, Intervention, and Followup	Outcomes of Interest (Timing)	Quality Assessment / Comments
Simonton, 2006	**Publication type:** Full text **Geographical location:** United States **Study design:** Prospective registry **Funding:** Unknown **Number of centers:** 9 **Outcome assessment:** Patient contact by phone for clinical outcome assessment, physician adjudicated MACE events, routine data audits **Number of participants enrolled:** 1368	**Inclusion criteria:** Undergoing PCI, TIMI thrombus grade ≥ 3, 9 m followup available, no use of distal protection device **Exclusion criteria:** Inability to provide informed consent **Intervention:** PCI with mechanical thrombectomy (AngioJet) **Comparator:** PCI without mechanical thrombectomy or distal protection **Duration of followup (d):** 270 **Covariates/potential confounders adjusted for:** Unadjusted	**Intermediate:** TIMI-3 (post-procedure) **Final:** MACE (mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event), mortality, TVR, MI (270 d) **Safety:** NR	1. Unbiased selection of the cohort? Yes 2. Selection minimizes baseline differences in prognostic factors? Yes 3. Sample size calculated? No 4. Adequate description of the cohort? No 5. Validated method to ascertain exposure? Yes 6. Validated method for ascertaining clinical outcomes? Yes 7. Outcome assessment blinded to exposure? Can't tell 8. Adequate followup period? Yes 9. Completeness of followup? Yes 10. Analysis controls for confounding? No 11. Analytic methods appropriate? No Overall quality rating: Poor

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=transvacular aspiration catheter; TIMI=thrombolysis in myocardial infarction; TVR=target vessel revascularization

Table 13. Characteristics and quality assessment of systematic reviews with meta-analysis published as full text

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Mongeon, 2010	**Number of studies (participants):** Overall analysis: 21 (4299) Aspiration-only analysis: 16 (3365) **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) **Final:** Mortality : OR 0.94 (0.47 to 1.80) MACE: OR 1.07 (0.63 to 1.92) **Safety:** PT (min): 5.8 (-29.2 to 40.6) STBT (min): -12.8 (-116.4 to 91.4) **Aspiration-only analysis** **Intermediate:** TIMI-3: OR 1.49 (1.14 to 1.99) TMPG-3: OR 3.04 (1.74 to 5.78) No-reflow: OR 0.36 (0.11 to 0.88) DE: OR 0.47 (0.25 to 0.87) STSR ≥ 50%: OR 2.24 (1.53 to 3.46) **Final:** Mortality: OR 0.58 (0.28 to 1.22) MACE: OR 0.75 (0.42 to 1.52) **Safety:** PT (min): 2.2 (-75.6 to 80.2) STBT (min): -13.2 (-166.3 to 138.0)	**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? 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 Total 'Yes' responses (out of 11): 6

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Tamhane, 2010	**Number of studies (participants):** Overall analysis: 17 (3909) Manual Aspiration-only analysis*: 9 (2114) Vacuum Aspiration-only analysis*: 4 (911) Mechanical Aspiration-only analysis*: 5 (934) **Study design included:** RCTs only (full-text, abstracts, and expert slide presentations) **Literature search:** MEDLINE, Google Scholar, Embase, ISI Web of Knowledge, Current Contents, International Pharmaceutical Abstracts databases and the Cochrane Central Register of Randomized controlled trial from 1996 through December 2009. Abstracts from 2005 through 2009 scientific meetings of the AHA, the ACC, the ESC, published review articles, editorials, and internet-based sources (www.cardiosource.com, www.tctmd.com, www.crtonline.com, www.theherat.org, www.medscape.com) **Languages:** Not specified **Statistical methods:** Used both fixed- and random-effects models to produce across-study summary odds ratios with 95% confidence intervals however random-effect models were preferentially reported due to significant heterogeneity, although fixed-effects models gave similar results	**Population:** STEMI only **Intervention:** PCI with catheter aspiration or mechanical thrombectomy **Comparator:** PCI without thrombectomy **Outcomes (Timing):** Mortality, stroke, TVR, reinfarction (30 d); STSR > 70%; TIMI-3, MBG-0/1, MBG-3 (post-procedure)	**Overall Analysis** **Intermediate:** TIMI-3: OR 1.41 (1.10 to 1.81) MBG-0/1: OR 0.51 (0.32 to 0.82) MBG-3: OR 2.42 (1.63 to 3.61) STSR > 70%: OR 2.30 (1.64 to 3.23) **Final:** Mortality : OR 0.84 (0.54 to 1.29) Stroke: OR 2.88 (1.06 to 7.85) TVR: OR 0.92 (0.57 to 1.49) Reinfarction: OR 0.59 (0.29 to 1.22) **Manual Aspiration-only analysis*** **Intermediate:** MBG-3: OR 2.30 (1.90 to 2.79) TIMI-3: OR 1.50 (1.17 to 1.92) STSR > 70%: OR 1.95 (1.62 to 2.34) **Final:** Mortality : OR 0.59 (0.35 to 1.01) Stroke: OR 2.84 (0.51 to 15.65) **Vacuum Aspiration -only analysis*** **Intermediate:** MBG-3: OR 3.01 (1.98 to 4.60) TIMI-3: OR 1.49 (0.99 to 2.23) STSR > 70%: OR 1.80 (1.01 to 3.18) **Final:** Mortality : OR 0.75 (0.18 to 3.05) Stroke: OR 5.05 (0.24 to 106.37) **Mechanical-only analysis*** **Intermediate:** MBG-3: OR 1.06 (0.78 to 1.45) TIMI-3: OR 0.79 (0.43 to 1.45) STSR > 70%: OR 1.40 (1.02 to 1.91) **Final:** Mortality : OR 2.07 (0.95 to 4.48) Stroke: OR 2.61 (0.68 to 10.09)	**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

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Burzotta, 2009 and De Vita, 2009	**Number of studies (participants):** Overall analysis:11 (2686) **Study design(s) included:** RCTs only (full-text, abstracts, and expert slide presentations) **Literature search:** Systematic MEDLINE database search (www.ncbi.nlm.nih.gov) according to a modified Robinson and Dickersin strategy. TCT (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) websites searched for pertinent abstracts and expert slides presentations between October 2003 and February 2008 **Languages:** No restrictions **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.	**Population:** STEMI only **Intervention:** PCI with catheter aspiration or mechanical thrombectomy **Comparator:** PCI without thrombectomy **Outcomes (Timing):** TLR/TVR, MI, mortality, MACE (all-cause mortality, TLR/TVR, MI) and mortality + MI (longest available clinical outcome)	**Final:** TLR/TVR: OR 0.87 (0.67 to 1.12) 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)	**AMSTAR assessment:** 1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? No 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 Total 'Yes' responses (out of 11): 9

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Inaba, 2009	**Number of studies (participants):** Overall analysis: 25 (5919) Aspiration-only analysis: 10 (2656) Mechanical-only analysis: 5 (934) Embolic Protection-only analysis: 10 (2329) **Study design(s) included:** RCTs only (full-text, oral presentations, and expert slide presentations) **Literature search:** Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process & 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 (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) from January 2006 and December 2008. Search limited to human studies and filter for RCT applied. **Languages:** No restrictions **Statistical methods:** Dersimonian and Laird random effects model with RR and 95% CI for dichotomous variables and WMD and 95% CI for continuous variables	**Population:** AMI only **Intervention:** PCI with catheter aspiration, mechanical thrombectomy, distal balloon embolic protection, or distal filter embolic protection **Comparator:** PCI without thrombectomy **Outcomes (Timing):** MBG < 3, STSR < 70% (< 50% < 70% not available) (post-procedure); mortality (NR)	**Overall Analysis** **Intermediate:** MBG < 3: RR 0.75 (0.66 to 0.84) STSR < 70% :RR 0.77 (0.68 to 0.87) **Final:** Mortality: RR 0.78 (0.57 to 1.05) **Aspiration-only analysis** **Intermediate:** MBG < 3: RR 0.56 (0.36 to 0.87) STSR < 70%: RR 0.69 (0.58 to 0.83) **Final:** Mortality: RR 0.56 (0.36 to 0.87) **Mechanical-only analysis** **Intermediate:** MBG < 3: RR 1.98 (0.92 to 4.27) STSR < 70%: RR 0.61 (0.37 to 1.02) **Final:** Mortality: RR 1.98 (0.92 to 4.27) **Embolic Protection-only analysis** **Intermediate:** MBG < 3: RR 0.79 (0.48 to 1.31) STSR < 70%: RR 0.94 (0.84 to 1.04) **Final:** Mortality: RR 0.79 (0.48 to 1.31)	**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? 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 Total 'Yes' responses (out of 11): 10

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Amin, 2009	**Number of studies (participants):** Overall analysis: 23 (5728) Thrombectomy-only analysis‡: 16 (3848) Distal Protection-only analysis‡: 7 (1880) **Study design(s) included:** RCTs (full-text, abstracts, and expert talks and slides) **Literature search:** RCTs from pervious meta-analyses. Searched MEDLINE database and expert talks, slides, and abstracts that were not included in earlier meta-analyses **Languages:** NR **Statistical methods:** DerSimonian and Laird random effects models	**Population:** STEMI only **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):** MBG < 3, TIMI < 3 (post-procedure); failed STSR (< 50% or < 70%)	**Overall Analysis** **Intermediate:** TIMI < 3: OR 0.68 (0.58 to 0.79) MBG < 3: OR 0.66 (0.58 to 0.75) Failed STSR: OR 0.65 (0.58 to 0.73) **Thrombectomy-only Analysis‡** **Intermediate:** TIMI < 3: OR 0.66 (0.55 to 0.80) MBG < 3: OR 0.61 (0.52 to 0.71) Failed STSR: OR 0.57 (0.50 to 0.65) **Distal Protection-only Analysis‡** **Intermediate:** TIMI < 3: OR 0.71 (0.53 to 0.93) MBG < 3: OR 0.83 (0.65 to 1.05) Failed STSR: OR 0.88 (0.72 to 1.08)	**AMSTAR assessment:** 1. Was an 'a priori' design provided? No 2. Was there duplicate study selection and data extraction? No 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? No 11. Was the conflict of interest stated? No Total 'Yes' responses (out of 11): 7

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Bavry, 2008	**Number of studies (participants):** Overall analysis: 30 (6415) Aspiration-only analysis: 13 (3026) Mechanical-only analysis: 5 (934) Embolic Protection-only analysis: 12 (2442) **Study design(s) included:** RCTs only (full-text, abstracts, and oral/expert slide presentations) **Literature search:** 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 http://clincialtrials.gov and www.tctmd.com. **Languages:** No restrictions	**Population:** AMI within 12 hours **Intervention:** PCI with catheter aspiration, mechanical thrombectomy, or embolic protection device **Comparator:** PCI without thrombectomy **Outcomes (Timing):** 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)	**Overall Analysis** **Intermediate:** TBG-3: RR 1.38 (1.20 to 1.58) Complete STSR: RR 1.27 (1.15 to 1.41) **Final:** 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) **Aspiration-only analysis** **Intermediate:** TBG-3: RR 1.69 (1.26 to 2.28) Complete STSR: RR 1.41 (1.21 to 1.64) **Final:** Mortality (WMF 6.2 m): RR 0.63 (0.43 to 0.93) Mortality (WMF 0.6 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) **Mechanical-only analysis** **Intermediate:** TBG-3: RR 1.16 (0.71 to 1.90) Complete STSR: RR 1.25 (0.99 to 1.58)	**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? 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 Total 'Yes' responses (out of 11): 10

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
	Statistical methods: Mantel-Haenszel fixed effects model used to construct summary risk rations (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		**Final:** Mortality (WMF 4.6 m): RR 1.93 (1.00 to 3.72) Mortality (WMF 1.0 m): RR 2.01 (0.95 to 4.23) MI (WMF 2.1 m): RR 0.67 (0.19 to 2.33) TVR (WMF 2.1 m): RR 1.14 (0.43 to 3.01) Stroke (WMF 2.1 m): RR 2.67 (0.71 to 10.0) MACE (WMF 2.1m): RR 1.64 (0.60 to 4.44) **Embolic Protection-only analysis** **Intermediate:** TBG-3: RR 1.18 (1.02 to 1.38) Complete STSR: RR 1.07 (0.98 to 1.16) **Final:** Mortality (WMF 3.7m): RR 0.92 (0.60 to 1.40) Mortality (WMF 0.8m): RR 0.79 (0.49 to 1.29) MI (WMF 3.7m): RR 0.82 (0.44 to 1.51) TVR (WMF 3.7): RR 1.04 (0.74 to 1.47) Stroke (WMF): RR 0.99 (0.34 to 2.92) MACE (WMF 3.7m): RR 0.95 (0.69 to 1.30)	

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Burzotta, 2008	**Number of studies (participants):** Overall analysis: 18 (3180) Thrombectomy-only analysis†: 12 (1934) Distal Protection-only analysis†: 6 (1246) **Study design(s) included:** RCTs (full-texts, abstracts, and expert slides presentations) **Literature search:** MEDLINE database search according to a modified Robinson and Dickersin strategy. TCT (http://www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (http://www.americaheart.org), and ESC (www.escardio.org) websites searched **Languages:** No restrictions **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.	**Population:** STEMI only **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 or MI, MACCE (mortality, MI, TVR, stroke) (up to 30 d); DE, Absence of STSR > 70% (within 90 min); TIMI < 3, MBG < 3 (post-procedure)	**Overall Analysis** **Intermediate:** TIMI < 3: OR 0.76 (0.51 to 1.12) MBG < 3: OR 0.53 (0.37 to 0.76) DE: OR 0.54 (0.37 to 0.81) Absence of STSR > 70%: OR 0.60 (0.45 to 0.78) **Final:** Mortality or MI: OR 0.85 (0.54 to 1.33) MACCE: OR 1.01 (0.63 to 1.60) **Thrombectomy-only Analysis†** **Intermediate:** TIMI < 3: OR 0.68 (0.42 to 1.09) MBG < 3: OR 0.42 (0.23 to 0.75) DE: OR 0.51 (0.28 to 0.92) Absence of STSR > 70%: OR 0.46 (0.32 to 0.66) **Final:** Mortality or MI: OR 1.07 (0.50 to 2.32) MACCE: OR 1.09 (0.60 to 1.96) **Distal Protection-only Analysis†** **Intermediate:** TIMI < 3: OR 0.95 (0.43 to 2.12) MBG < 3: OR 0.72 (0.55 to 0.96) DE: OR 0.55 (0.28 to 1.08) Absence of STSR > 70%: OR 1.01 (0.79 to 1.29) **Final:** Mortality or MI: OR 0.68 (0.39 to 1.19) MACCE: OR 0.81 (0.40 to 1.65)	**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 Total 'Yes' responses (out of 11): 10

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
De Luca, 2008	**Number of studies (participants):** Overall analysis: 9 (2417) **Study design(s) included:** RCTs only (full-text, abstracts, and oral/expert slide presentations) **Literature search:** 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 **Languages:** No restrictions **Statistical methods:** DerSimonian and Laird random effects model	**Population:** STEMI only **Intervention:** PCI with catheter aspiration **Comparator:** PCI without thrombectomy **Outcomes (Timing):** Mortality (30 d); TIMI-3, MBG-3, DE (post-procedure)	**Intermediate:** 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) **Final:** Mortality : OR 0.58 (0.34 to 0.98)	**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

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Grines, 2008	**Number of studies (participants):** Overall analysis: 90 (25094) **Study design(s) included:** RCTs and non-RCTs **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. **Languages:** English **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	**Population:** STEMI with chest pain more than 30 min and less than 24 hours treated with primary or rescue PCI **Intervention:** PCI with mechanical thrombectomy (Angiojet) **Comparator:** PCI without thrombectomy **Outcomes (Timing):** Mortality, MACE (mortality, recurrent MI, stroke, TVR) (short-term ≤ 42 d); TIMI-3 (post-procedure)	**Intermediate:** TIMI-3: OR 1.12 (0.70 to 2.27) **Final:** Mortality : OR 0.98 (0.53 to 1.50) MACE: OR 1.25 (0.54 to 2.40)	**AMSTAR assessment:** • Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • 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 Total 'Yes' responses (out of 11): 9

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
De Luca, 2007	**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 Caridology from January 1990 to October 2006. Oral presentations and or expert slide presentation (searched on the TCT (www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (www.aha.org), and ESC (www.escardio.org) websites) from January 2002 to October 2005. **Languages:** No restrictions **Statistical methods:** DerSimonian and Laird random-effects models	**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[§]** **Intermediate:** 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)	**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

Study, Year	Review Characteristics	Population, Intervention, Comparator, Outcomes of Interest (Timing)	Outcomes ["X"R (95%CI)]	Quality Scoring/Comments
Kunadian, 2007	**Number of studies (participants):** Overall analysis: 14 (2630) **Study design(s) included:** RCTs (full-texts and abstracts) **Literature search:** 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 www.tctmd.com and www.theheart.org websites **Languages:** NR **Statistical methods:** 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.	**Population:** AMI only **Intervention:** PCI with thrombectomy (catheter aspiration or mechanical thrombectomy) or embolic protection (distal balloon or distal filter embolic protection) device **Comparator:** PCI without thrombectomy **Outcomes (Timing):** Mortality or reinfarction, mortality, reinfarction, MACE (nonfatal reinfarction, stroke, repeat TVR) (30 d)	**Overall Analysis** **Final:** Mortality or reinfarction : OR 0.82 (0.55 to 1.24) Mortality: OR 0.92 (0.56 to 1.51) Reinfarction: OR 0.78 (0.40 to 1.52) MACE: OR 1.00 (0.71 to 1.42) **Thrombectomy-only Analysis**[‖] **Final:** Mortality or reinfarction: OR 0.98 (0.53 to 1.83) Mortality: OR 1.10 (0.49 to 2.43) Reinfarction: OR 0.88 (0.37 to 2.11) MACE: OR 1.25 (0.78 to 1.99) **Distal Protection-only Analysis**[‖]**:** **Final:** Mortality or reinfarction: OR 0.68 (0.37 to 1.23) Mortality: OR 0.70 (0.34 to 1.44) Reinfarction: OR 0.67 (0.24 to 1.85) MACE: OR 0.75 (0.44 to 1.28)	**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? 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 Total 'Yes' responses (out of 11): 6

*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

Study, Year	Total Studies (Participants)	Inclusion Criteria	Outcomes (Timing)	Overall Outcomes ["X"R (95%CI)]	Outcomes of Device Subtypes ["X"R (95%CI)]
Masotti 2008 and Salazar, 2008	7 (1456)	STEMI; RCT evaluating thrombectomy, distal protection and aspiration devices	Mortality, reinfarction, mortality + reinfarction (6 m)	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)	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) Distal protection devices Mortality: OR 0.77 (0.38 to 1.53) Reinfarction: OR 0.45 (0.18 to 1.1) Mortality+reinfarction: OR 0.61 (0.35 to 1.06)
Masotti 2008	8 (2527)	RCT using embolic protection devices in patients with STEMI	Mortality (6 m)	Mortality: OR 0.60 (0.40 to 0.89)	Aspiration Mortality: OR 0.49 (0.29 to 0.82) Thrombectomy Mortality: OR 1.01 (0.25 to 4.16) Filters Mortality: OR 0.77 (0.38 to 1.53)
Mongeon 2008	16 (2944)	STEMI; RCT comparing primary PCI with and without thrombectomy	No reflow, STSR > 50%, TMPG-3, TIMI-3, DE (post-procedure)	No-reflow: OR 0.35 (0.10 to 0.95) STSR > 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)	N/A

Study, Year	Total Studies (Participants)	Inclusion Criteria	Outcomes (Timing)	Overall Outcomes ["X"R (95%CI)]	Outcomes of Device Subtypes ["X"R (95%CI)]
Masotti 2007	10 (2275)	RCT using thrombectomy or distal protection devices in conjunction with PCI	Mortality, reinfarction, mortality + reinfarction (1m)	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)	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)
Brahmbhatt 2006	11 (NR)	Thrombectomy in the setting of STEMI, RCT in full text or abstracts from TCT, AHA, ACC	MACE (30d); MBG≥2, MBG-3, TIMI-3, STSR > 50% (post-procedure)	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 > 50%: 3.5 (2.17 to 5.65) MACE: 0.94 (0.6 to 1.47)	N/A
Salazar 2006 and Salazar 2006	9 (2060)	RCT using thrombectomy or distal protection devices in conjunction with PCI	Mortality, reinfarction, mortality + reinfarction (1 m)	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)	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)
Qayyum 2006	7 (2447) Native vessel AMI population 4 (551)	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 Note: For this meta-analysis, only results for PCI for native vessel AMI are included in this table)	Mortality(30 d)	Mortality: OR 0.69 (0.39 to 1.22)	N/A

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

Reference	Reason for Exclusion
Adlbrecht C, Bonderman D, Plass C, et al. Thrombus bound endothelin and leukocytes extracted by thrombectomy in acute myocardial infarction correlate with ST-segment resolution [abstract]. *Circulation* 2006;114:458	Uncontrolled study
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	Not an RCT or an observational study enrolling more than 500 patients
Ali A, Afzal A, Kazmouz G, et al. Rheolytic thrombectomy facilitates restoration of coronary flow in patients with acute myocardial infarction [abstract]. *Am J Cardiol* 2001;88:TCT63	Not an RCT or an observational study enrolling more than 500 patients
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]. *Am J Cardiol* 2002;90:TCT268	Not an RCT or an observational study enrolling more than 500 patients
Ali A., Malik FS, Collins T, et al. Reduction in QT dispersion with rheolytic thrombectomy in acute myocardial infarction: Evidence of electrical stability with reperfusion therapy [abstract]. *Am J Cardiol* 1997;80:TCT261	Uncontrolled study
Ali A, Rehan A, Rahbar M, et al. Rheolytic thrombectomy in acute myocardial infarction results in a higher degree of ST-segment resolution [abstract]. *Am J Cardiol* 2002;90:TCT39	Not an RCT or an observational study enrolling more than 500 patients
Ali A, Schreiber TL. The role of percutaneous thrombectomy in the contemporary treatment of acute myocardial infarction. *J Invasive Cardiol* 2004;16:546-8	A narrative review, editorial or letter to the editor
Alidjan FMF, Koch KT, Henriques JP, et al. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R) device [abstract]. *Eur Heart J* 2006;27:771	Uncontrolled study
Alidjan F. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R)-device [abstract]. *Circulation* 2006;114:739	Uncontrolled study
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]. *Circulation* 2009;120:S337	Not an RCT or an observational study enrolling more than 500 patients
Amato JL, Shamoon FE, Haft JI. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2640	A narrative review, editorial or letter to the editor
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]. *J Am Coll Cardiol* 2009;53:A282	Not an RCT or an observational study enrolling more than 500 patients
Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. *J Invasive Cardiol* 2006;18:32C-34C	A narrative review, editorial or letter to the editor
Antoniucci D. Rheolytic thrombectomy in acute myocardial infarction: the Florence experience and objectives of the multicenter randomized JETSTENT trial. *J Invasive Cardiol* 2006;18:32C-34C	A narrative review, editorial or letter to the editor
Bartorelli AL. Acute thrombosis of a coronary artery aneurysm: toughing it out with the poor man's thrombectomy catheter technique. *Catheter Cardiovasc Interv* 2006;68:403-5	A narrative review, editorial or letter to the editor
Bartorelli AL, Koh TH, Di Pede F, et al. The RUBY registry: assessment of distal embolic protection during coronary angioplasty in patients with acute coronary syndrome [abstract]. *Circulation* 2004;110:3403	Uncontrolled study
Bass TA. Mechanical thrombectomy to the RESCUE. *Catheter Cardiovasc Interv* 2002;55:244	A narrative review, editorial or letter to the editor
Bates ER. Aspirating and filtering atherothrombotic debris during percutaneous coronary intervention. *JACC: Cardiovasc Interv* 2008;1:265-7	A narrative review, editorial or letter to the editor
Belardi J. Beyond the limit on percutaneous intervention of saphenous vein graft. *Catheter Cardiovasc Interv* 2005;64:387-8	A narrative review, editorial or letter to the editor
Belli G, Silva P, Pezzano A, et al. Primary protected percutaneous intervention for acute myocardial infarction with the PercuSurge system in native coronary arteries [abstract]. *Am J Cardiol* 2000;86:79	Uncontrolled study
Berger-Kucza A, Lelek M, Wita K, et al. Thrombus aspiration for microvascular	Not an RCT or an

Reference	Reason for Exclusion
protection in patients with acute MI undergoing early primary PCI [abstract]. *Circulation* 2008;118:E311	observational study enrolling more than 500 patients
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]. *Can J Cardiol* 2010; 26:106D	Not an RCT or an observational study enrolling more than 500 patients
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]. *J Thromb Haemost* 2010;8:57	Uncontrolled study
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. *Clin Appl Thromb Hemost* 2005;11:461-6	Not an RCT or an observational study enrolling more than 500 patients
Blackman DJ, Channon KM. Prevention of embolisation during percutaneous vein graft intervention using a Filter Wire distal protection device. *Heart* 2003;89:376	A narrative review, editorial or letter to the editor
Bonello L, De Labriolle A, Steinberg D, et al.Thrombus aspiration during percutaneous coronary intervention. *Lancet* 2008;372:1034	A narrative review, editorial or letter to the editor
Buellesfeld L, Gerckens U, Grube E. [Background and indications for distal protection devices in percutaneous coronary interventions]. *Dtsch Med Wochenschr* 2006;131:2160-4	A narrative review, editorial or letter to the editor
Burzotta F, Crea F. Thrombus-aspiration: a victory in the war against no reflow. *Lancet* 2008;371:1889-90	A narrative review, editorial or letter to the editor
Burzotta F, Romagnoli E, Manzoli A, et al. The outcome of PCI for stent-ThrombosIs MultIcentre Study (OPTIMIST): rationale and design of a multicenter registry. *Am Heart J* 2007;153:377e1-e5	Uncontrolled study
Carter AJ, Gregory K. Thrombo-atherectomy: hope for pesky thrombus-containing lesions? *Catheter Cardiovasc Interv* 2002;55:140-1	A narrative review, editorial or letter to the editor
Carter LI, Golzar JA, Cavendish JJ, et al. Embolic protection of saphenous vein graft percutaneous interventions. *J Interv Cardiol* 2007;20:351-8	A narrative review, editorial or letter to the editor
Chaliha BHK, Singh RS, Bahl A, et al. A study of abciximab versus distal protection device during percuteneous coronary stenting in acute coronary syndrome [abstract]. *Indian Heart J* 2004;56:417	
Choi YS, Chung WS, Park CS, et al. Angiographic improvement after thrombus aspiration concomitant with glycoprotein IIb/IIIa inhibitor therapy does not affect long-term mortality during primary PCI [abstract]. *Am J Cardiol* 2009;103:AS8	Not an RCT or an observational study enrolling more than 500 patients
Choudhury RP, Pillay P, Porto I, et al. Quantification of embolic material captured by the filterwire distal protection device during percutaneous intervention in native coronary arteries (NCA) and comparison with saphenous vein grafts (SVG) [abstract]. *Heart* 2004;90:51	Uncontrolled study
Choudhury RP, Porto I, Banning AP. Images in cardiovascular medicine. Debris trapped by a distal protection device may mimic no-reflow during percutaneous coronary intervention. *Circulation* 2004;109:803-4	Uncontrolled study
Chung WY, Cho YS, Chae IH, et al. The efficacy of distal protection device on ventricular remodeling and microvascular obstruction in ST elevation acute myocardial infarction [abstract]. *Am J Cardiol* 2006;98:M	Incomplete data and no response from author
Cohen DJ, Ramee S, Baim DS, et al. Economic assessment of rheolytic thrombectomy versus intracoronary urokinase for treatment of extensive intracoronary thrombus: Results from a randomized clinical trial. *Am Heart J* 2001;142:648-56	Outside of ACS patients
Cohen R, Faucher R, Domniez T, et al. Predictive factors of successful intracoronary thrombectomy with the export aspiration catheter before angioplasty in patients with ST-segment elevation myocardial infarction [abstract]. *Am Heart J* 2006;98:59M	Not an RCT or an observational study enrolling more than 500 patients
Costa JR, Costa R, Feres F, et al. Preliminary experience with the Novel MGuard (TM) Stent System containing a protection net to prevent distal embolization - results from a prospective, non-randomized, single center study [abstract]. *Circulation* 2008;118:S745	Uncontrolled study
Cox DA, Stuckey T, Babb J, et al. Early and late results of thrombectomy prior to stenting in acute myocardial infarction: Principal report of the EndiCOR X-SIZER AMI registry [abstract]. *J Am Coll Cardiol* 2002;39:308A	Uncontrolled study

Reference	Reason for Exclusion
Cox DA, Stuckey T, Babb J, et al. The EndiCOR X-SIZER AMI registry: Improvement in myocardial blush scores with adjunctive thrombectomy combined with stenting for AMI [abstract].*Circulation* 2001;104:2387	Uncontrolled study
Cox DA, Stuckey T, Low R, et al. Adjunctive thrombectomy combined with stenting for AMI: The Endicor X-SIZER AMI registry [abstract]. *J Am Coll Cardiol* 2001;37:306S	Uncontrolled study
Cox DA, Turco M, Stuckey T, et al. Stent placement combined with thrombectomy improves outcomes in thrombotic lesions: Results from the X-SIZER acute myocardial infarction registry [abstract]. *Am J Cardiol* 2002;90:TCT124	Uncontrolled study
Cox D, Lui H, Caputo R, et al. Lower MACE can be achieved in SVG PCI: Stenting in saphenous vein grafts with distal protection using a second generation filter-based catheter - The combined BLAZE I and BLAZE II registries [abstract]. *Am J Cardiol* 2005;96:5H	Uncontrolled study
Cox D, Stuckey T, Babb J, et al. The EndiCOR X-SIZER acute myocardial infarction (AMI) registry: Adjunctive thrombectomy combined with stenting for AMI [abstract]. *Am J Cardiol* 2001;88:TCT62	Uncontrolled study
Cox D, Stuckey T, Babb J, et al. The X-SIZER acute myocardial infarction (AMI) registry: Improvement in myocardial blush scores and ST-segment resolution with the use of thrombectomy before stenting in AMI [abstract]. *Am J Cardiol* 2002;90:TCT38	Uncontrolled study
Dangas,G. Interventional therapy for acute myocardial infarction: respect the microvasculature. *J Am Coll Cardiol* 2003;42:1403-5	A narrative review, editorial or letter to the editor
De Carlo M, Cortese B, Borelli G, et al. Successful treatment of acute myocardial infarction due to subocclusive thrombosis over a small atherosclerotic plaque with the "Rinspiration" device, a novel thrombectomy catheter. *Int J Cardiol* 2007;115:95-6	Uncontrolled study
De Carlo M, Webb JG, Grube E, et al. International Rinspiration Registry (100 patients treated with fluidic thrombectomy in the AMI setting) [abstract]. *Am J Cardiol* 2005; 96:76H-77H	Uncontrolled study
De Luca G, Suryapranata H, Chiariello M. Aspiration thrombectomy and primary percutaneous coronary intervention. *Heart* 2006;92:867-9	A narrative review, editorial or letter to the editor
De Luca L, Sardella G. Tirofiban plus sirolimus-eluting stent vs abciximab plus bare-metal stent. *JAMA* 2005;294:1617	A narrative review, editorial or letter to the editor
De Rosa S, Cirillo P, De Luca G, et al. Rheolytic thrombectomy during percutaneous coronary intervention improves long-term outcome in high-risk patients with acute myocardial infarction. *J Interv Cardiol* 2007;20:292-8	Not an RCT or an observational study enrolling more than 500 patients
De Vita M, Burzotta F, Trani C, et al. Urgent PCI in patients with stent thrombosis: an observational single-center study comparing thrombus aspiration and standard PCI. *J Invasive Cardiol* 2008;20:161-5	Uncontrolled study
De Young MB, Kazziha S. Use of a thrombus extraction catheter (Pronto) in the treatment of acute myocardial infarction after coronary embolism post mitral valve replacement. *J Invasive Cardiol* 2006;18:E273-5	Uncontrolled study
DeLago A, Papaleo R, Macina A. Initial experience with Angiojet (R) mechanical thrombectomy in the treatment of acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2000;35:19A	Uncontrolled study
Delgado A, Silva P, Klugmann S. Distal protection in native coronary arteries during primary angioplasty in acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT472	Uncontrolled study
Dixon SR. Infarct angioplasty: beyond stents and glycoprotein IIb/IIIa inhibitors. *Heart* 2005;91:2-6	A narrative review, editorial or letter to the editor
Dundon BK, Worthley MI, Worthley SG. Very late drug-eluting stent thrombosis. *Heart Lung Circ* 2008;17:144-5	Uncontrolled study
Fabbiocchi F, Calligaris G, De Martini S, et al. Comparison between 2 different distal protection devices in acute myocardial infarction treated with percutaneous coronary intervention [abstract]. *Am J Cardiol* 2002;90:TCT492	Uncontrolled study
Fabbiocchi F, Ravagnani P, Calligaris G. Combined distal protection and IIb/IIIa inhibitors vs distal protection alone during primary percutaneous coronary intervention in acute myocardial infarction: A randomized trial [abstract]. *Am J Cardiol* 2004;94:12E	Uncontrolled study
Fang HY, Hussein H, Hsueh SK, et al. Clinical Outcomes of the Routinely Used	Not evaluating an adjunctive

Reference	Reason for Exclusion
PercuSurge Device for High-Burden Thrombus Formation in the Infarct-Related Artery in Patients with ST-Segment Elevation Acute Myocardial Infarction: A Single-Center Experience [abstract]. *Am J Cardiol* 2010;105:34B	device to remove thrombus and/or protect from distal embolization prior to or in PCI
Fiorentino RP, Zuckerman B, Uchida T. Regulatory perspective on embolic protection device approval for saphenous vein graft stenting with a single-arm trial using risk-adjusted prediction model. *Circulation* 2008;117:714-6	A narrative review, editorial or letter to the editor
Fischell TA. Cleaning up the mess: new approaches to the old problem of thrombus in coronary interventions. *J Invasive Cardiol* 1999;11:485-7	A narrative review, editorial or letter to the editor
Fischell TA, Subraya RG, Ashraf K, et al. Pharmacologic distal protection using prophylactic, intragraft nicardipine to prevent no-reflow and non-Q wave MI during SVG interventions [abstract]. *Am J Cardiol* 2005;96:124H	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Frobert O, Lagerqvist B, Gudnason T, et al. Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE trial). A multicenter, prospective, randomized, controlled clinical registry trial based on the Swedish angiography and angioplasty registry (SCAAR) platform. Study design and rationale.*Am Heart J* 2010 ;160:1042-48	A narrative review, editorial or letter to the editor
Fortier S, Demaria RG, Pelletier GB, et al. Left ventricular thrombectomy in a cocaine user with normal coronary arteries. *J Thorac Cardiovasc Surg* 2003 ;125 :204-5	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Furuse Y, Muramatsu T, Tsukahara R, et al. Effectiveness of thrombectomy and distal protection for non-ST-segment elevation myocardial infarction [abstract]. *Am J Cardiol* 2005;95:6A-7A	Uncontrolled study
Galiuto L, Burzotta F, Garramone B, et al. Manual thrombus-aspiration reduces microvascular obstruction after PCI in unselected STEMI patients: MCE substudy of the randomised REMEDIA trial and insight into the pathogenesis of no-reflow [abstract]. *Eur Heart J* 2005;26:1962	Does not report outcomes of interest
Galiuto L, Burzotta F, Garramone B, et al. Manual thrombus-aspiration reduces microvascular obstruction after PCI in unselected stemi patients: MCE substudy of the randomized REMEDIA trial [abstract]. *Circulation* 2005;112:3130	Does not report outcomes of interest
Garcia E. Thrombus removal: clean the house before you settle. *Catheter Cardiovasc Interv* 2003;58:449-50	A narrative review, editorial or letter to the editor
Garcia E, Alvarez A, Cubero JM, et al. Mid-term results of thrombus extraction in patients with ST elevation myocardial infarction: One center experience with the X-SIZER catheter system [abstract]. *J Am Coll Cardiol* 2003;41:356A	Uncontrolled study
Garcia E, Datino T, Pinto J, et al. Does thrombectomy with the X-sizer catheter system improve myocardial perfusion in patients with ST-segment elevation myocardial infarction? [abstract] *Am J Cardiol* 2006;97:53D	Not an RCT or an observational study enrolling more than 500 patients
Garcia E, Valdes M, Alvarez A, et al. Thrombectomy followed by elective stent implantation in ST elevation myocardial infarction. Results from the TASMI study [abstract]. *Eur Heart J* 2002;23:506	Uncontrolled study
Gerckens U, Mueller R, Soblik S, et al. Prevention of distal embolization during interventions in CABG and native coronary lesions using a new protection filter device [abstract]. *J Am Coll Cardiol* 2000;35:10A-11A	Uncontrolled study
Gerckens U, Muller R, Rowold S, et al. The FilterWire (TM): First evaluation of a new protection catheter device for distal embolization in native coronary arteries and SVGs [abstract]. *J Am Coll Cardiol* 2001;37:34A-35A	Uncontrolled study
Ghahramani A. Rheolytic thrombectomy after suboptimal pharmacologic therapy for treatment of acute coronary syndrome. *Am J Cardiol* 2001;88:TCT181	Uncontrolled study
Golebiewski S, Bartkowiak M, Pawlowski T, et al. [Successful thrombectomy with Diver aspirator in the treatment of acute myocardial infarct of the lower heart wall]. *Kardiol Pol* 2007;2:205-7	Uncontrolled study
Gu YL, Fokkema ML, Zijlstra F. The emerging role of thrombus aspiration in the management of acute myocardial infarction. *Circulation* 2008;118:1780-2	A narrative review, editorial or letter to the editor
Gu YL, van der Horst, Iwan C, et al. The role of coronary artery bypass grafting in ST-segment elevation myocardial infarction: a substudy from the thrombus aspiration during percutaneous coronary intervention in acute myocardial infarction study [abstract]. *J Am Coll Cardiol* 2009;53:A56	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Guang HW, Guo WT, Yun LJ, et al. The Efficiency and Safety of the Seek	Does not report outcome of

Reference	Reason for Exclusion
Aspiration Thrombectomy Catheter and Tirofiban in Primary Percutaneous Coronary Intervention of Acute Myocardial Infarction [abstract]. *Heart* 2010;96:e0482	interest
Guigauri P, Dauerman HL. A novel use for a distal embolic protection device: stent retrieval. *J Invasive Cardiol* 2005;17:183-4	Uncontrolled study
Haeck JD, Koch KT, Henriques JP, et al. One-year results of combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the proxis (R)-device [abstract]. *J Am Coll Cardiol* 2007:49:32B	Uncontrolled study
Haery C, Exaire JE, Bhatt DL, et al. Use of PercuSurge GuardWire in native coronary arteries during acute myocardial infarction. *J Invasive Cardiol* 2004;16:152-4	Uncontrolled study
Heuser RR. Embolic protection pas de deux. *Catheter Cardiovasc Interv* 2004;63:310	A narrative review, editorial or letter to the editor
Hofmann R, Kypta A, Kerschner K, et al. Thrombus aspiration prior to primary angioplasty in acute myocardial infarction: estimation of rescued myocardial tissue by return of ST-segment elevation. *Clin Cardiol 2004*;27:451-4	Not an RCT or an observational study enrolling more than 500 patients
Hong GR, Kang JH, Bae JH, et al. Effectiveness of distal protection device on the protection of microvascular integrity assessed by myocardial contrast echocardiography in patients with acute myocardial infarction [abstract]. *Eur Heart J* 2005;26:P2219	Does not report outcome of interest
Horita Y, Kanaya H, Uno Y, et al. [Deterioration of cardiac function by combination therapy with mutant-tPA and guardwire plus for acute myocardial infarction: randomized study for acute myocardial infarction]. *Japanese Journal of Interventional Cardiology*;19:238-44	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Hui W, Sleik K, Cheung PK, et al. The benefit of filter wire distal protection for native vessel percutaneous coronary intervention in patients with acute coronary syndromes [abstract]. *Am J Cardiol* 2003;92:167L	Uncontrolled study
Ijiima R, Nakajima R, Tsunoda T, et al. Fate of unprotected side branches due to distal embolization during stent implantation for acute coronary syndromes using distal protection procedure [abstract]. *Circulation* 2004;110:3511	Uncontrolled study
Inoue N, Fujita H, Matsuo A, et al. Efficacy of an aspiration device with distal protection for the treatment of acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:38L-39L	Not an RCT or an observational study enrolling more than 500 patients
Ito N, Morozumi T, Nanto S, et al. Myocardial salvage in acute myocardial infarction: Thrombectomy versus addition of a distal embolic protection device to primary angioplasty [abstract]. *J Am Coll Cardiol* 2005;45:268A	Not an RCT or an observational study enrolling more than 500 patients
Ito N, Nakamura M, Komatsu H, et al. Thrombectomy with distal protection prior to stenting is a novel strategy to obtain optimal reperfusion in patients with acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2003;41:356A	Not an RCT or an observational study enrolling more than 500 patients
Ito N, Nakamura M, Nuruki H, et al. Thrombectomy prior to stenting is a novel strategy to obtain optimal reperfusion in acute myocardial infarction patients [abstract]. *Eur Heart J* 2002;23:269	Not an RCT or an observational study enrolling more than 500 patients
Ito Y, Muramatsu T, Tsukahara R, et al. Dose thrombus aspiration with distal protection using PercuSurge (TM) before stenting for acute myocardial infarction reduce no-reflow phenomenon [abstract]? *J Am Coll Cardiol* 2004;43:285A	Incomplete data and no response from author
Ito Y, Muramatsu T, Tsukahara R, et al. Effectiveness of PercuSurge for acute myocardial infarction comparison with rescue catheter for clinical and pathological effectiveness [abstract]. *Circulation* 2003;107:55	Not an RCT or an observational study enrolling more than 500 patients
Ito Y, Muramatsu T, Tsukahara R, et al. Effectiveness of the reperfusion therapy using a distal protection device guided by intravascular ultrasound for acute myocardial infarction [abstract]. *Am J Cardiol* 2006;97:8D	Incomplete data and no response from author
Ito Y, Muramatsu T, Tsukahara R, et al. Prevention of the no-reflow phenomenon and long-term prognosis of thrombus aspiration before stenting in acute myocardial infarction [abstract]. *Eur Heart J* 2004;25:420-1	Not an RCT or an observational study enrolling more than 500 patients
Ito Y, Muramatsu T, Tsukahara R, et al. Efficacy of aspiration therapy under distal protection (PercuSurge) before stenting for acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:189L	Not an RCT or an observational study enrolling more than 500 patients
Ito Y, Muramatsu T, Tsukahara R, et al.Usefulness of reperfusion therapy with a distal protection device (percusurge) for acute myocardial infarction [abstract]. *Am*	Uncontrolled study

Reference	Reason for Exclusion
J Cardiol 2002;90:TCT480	
Ito Y, Muramatsu T, Tsukahara R, et al. Efficacy of suction thrombectomy for acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT487	Uncontrolled study
Ito Y, Muramatsu T, Tsukahara R, et al. Success or lack of success of suction thrombectomy using the rescue catheter system in acute myocardial infarction and findings of intravascular ultrasound [abstract]. *Am J Cardiol* 2002;90:TCT488	Not an RCT or an observational study enrolling more than 500 patients
Finkelstein A, Schwartzenberg S, Bar L, et al. Comparative efficacy analysis of an aspiration device before primary angioplasty in patients with acute myocardial infarction: a single-center experience. *Isr Med Assoc J* 2010;12:692-6	Not an RCT or an observational study enrolling more than 500 patients
Jackson CE, Dalzell JR, Hogg KJ. Epinephrine treatment of anaphylaxis: an extraordinary case of very late acute stent thrombosis. *Circulation* 2009;2:79-81	Uncontrolled study
Javaid A, Siddiqui NH, Buch AN, et al. Does thrombus aspiration improve angiographic and clinical outcomes for patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention [abstract]? *Circulation* 2006;114:1759	Not an RCT or an observational study enrolling more than 500 patients
Jeilan M, Richardson G, Gershlick A. Transvenous pacing causing tamponade in patients receiving glycoprotein IIb/IIIa inhibitors for percutaneous coronary intervention. *J Invasive Cardiol* 2007;19;E40-2	Uncontrolled study
Kang WC, Ahn TH, Han SH, et al. Thrombosuction utilizing an export aspiration catheter during primary percutaneous coronary intervention in acute myocardial infarction. *Yonsei Med J* 2007;48:261-9	Not an RCT or an observational study enrolling more than 500 patients
Kang,WC, Ahn TH, Han SH, et al. Efficacy of thrombosuction using the export aspiration catheter before or during primary percutaneous coronary intervention in acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2005;45:86A	Not an RCT or an observational study enrolling more than 500 patients
Kang WC, Ahn TH, Han S, et al. Efficacy of thrombosuction using the export aspiration catheter before or during primary percutaneous coronary intervention in acute myocardial infarction [abstract]. *Am J of Cardiol* 2005;95:11A	Not an RCT or an observational study enrolling more than 500 patients
Kapoor N, Siddiqui T, Raza S, et al. Pharmacological distal protection using prophylactic intragraft adenosine prevent the slow-/no-reflow phenomenon. *Am J of Cardiol* 2008;102:1731-1741	Not a PCI in native vessel
Kaul U. In search of an optimal reperfusion strategy following acute myocardial infarction. *Indian Heart J* 1997;49:549-50	A narrative review, editorial or letter to the editor
Kawaguchi R, Hoshizaki H, Oshima S, et al. Does the rescue catheter improve treatment in patients with acute myocardial infarction? [abstract] *Am J Cardiol* 2003;92:113L	Not an RCT or an observational study enrolling more than 500 patients
Keeble W, Welsh R. A multifaceted approach to intracoronary thrombus: Use of pharmacology, an aspiration catheter and an embolic protection device. Can J Cardiol 2009;25:e391-2	Uncontrolled study
Kelbaek H, Thuesen L, Helqvist S, et al. Drug-eluting versus bare metal stents in patients with ST-segment–elevation myocardial infarction eight-month follow-up in the drug elution and distal protection in acute myocardial infarction (DEDICATION) Trial. *Circulation* 2008;118:1155-62	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Kelbaek H, Thuesen L, Helqvist S, et al. Drug-eluting versus bare metal stents in patients with ST-segment-elevation myocardial infarction: eight-month follow-up in the Drug Elution and Distal Protection in Acute Myocardial Infarction (DEDICATION) trial. *Circulation* 2008;118:1155-62	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Khosla S, Nemeth B. Percutaneous vascular rescue: A catheter-based approach to eliminate need for emergency vascular surgery after coronary and peripheral intervention [abstract]. *Am J Cardiol* 2001:88;TCT82	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Kikuchi T, Sakurada M, Miyake T, et al. Effectiveness of reperfusion therapy using a TVAC thrombectomy catheter system for acute myocardial infarction [abstract]. *Am J Cardiol* 2004;94:153E	Not an RCT or an observational study enrolling more than 500 patients
Kikuchi T, Sakurada M, Miyake T, et al. Effectiveness of reperfusion therapy with a distal protection device (PercuSurge) for acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:191L-192L	Not an RCT or an observational study enrolling more than 500 patients
Kim JH, Kim BO, Kim KS, et al. Thrombus Aspiration in Primary Percutaneous Coronary Intervention Improves Early Myocardial Reperfusion in Patients with ST-Segment Elevation Myocardial Infarction without Upstream Use of Glycoprotein IIb/IIIa Inhibitors. *Am J Cardiol* 2010;105:4B	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI

Reference	Reason for Exclusion
Kim BO, Kim JH, Cho SW, et al. A randomized controlled trial of upstream versus bail-out use of glycoprotein IIb/IIIa inhibitor combined with selective use of aspiration thrombectomy during primary percutaneous coronary intervention in patients with ST-segment elevation myocardial infarction [abstract]. *Am J Cardiol* 2009;104:117D-118D	Uncontrolled study
Kim BO, Lee BK, Goh CW, et al. Thrombus aspiration during primary percutaneous coronary intervention improves myocardial reperfusion with and without use of platelet glycoprotein IIb/IIIa receptor blockers [abstract]. *Am J Cardiol* 2009;103:AS98	Uncontrolled study
Kini AS, Moreno PR, Mares AM, et al. The improved outcome with AngioJet(TM) thrombectomy catheter during primary stenting in acute myocardial infarction patients with high-grade thrombus [abstract]. *Circulation* 2006;114:507	Not an RCT or an observational study enrolling more than 500 patients
Kira Y, Kosaka A, Ishihara Y, et al. [Myocardial infarction with normal coronary arteries]. *Nippon Rinsho* 2007;190:Suppl 5 Pt 2:190-3	A narrative review, editorial or letter to the editor
Kirma C, Izgi A, Dundar C et al. Clinical and procedural predictors of no-reflow phenomenon after primary percutaneous coronary interventions: experience at a single center. *Circulation* 2008;72:716-21	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Kishi T, Yamada A, Takemoto M, et al. Manual thrombectomy using a thrombuster catheter for acute myocardial infarction protects against left ventricular remodeling and congestive heart failure in cases involving the proximal left anterior descending and right coronary artery [abstract]. *Am J Cardiol* 2006;98:59M-60M	Not an RCT or an observational study enrolling more than 500 patients
Koch KT, De Winter RJ, Henriques JP, et al. Combined embolic protection and thrombectomy in percutaneous coronary intervention of acute myocardial infarction using the Proxis (R) device [abstract]. *Am J Cardiol* 2005;96:74H	Uncontrolled study
Koch K, DeWinter RJ, Henriques J, et al. Combined embolic protection and thrombectomy in percutaneous coronary intervention for acute myocardial infarction: Preliminary results using the proxis device [abstract]. *Am J Cardiol* 2004;2004:94:35E	Uncontrolled study
Koch KT, Kramer MCA, van der Wal AC, et al. Histopathological features of thrombectomy material obtained with proximal protection during primary PCI using the Proxis (R) device [abstract]. *Am J Cardiol* 2006;98:60M	Uncontrolled study
Koh TH. Proximal protection in SVG and stemi intervention [abstract]. *Int J Cardiol* 2007;122;25	A narrative review, editorial or letter to the editor
Koller D, Schuiki E, Straumann E, et al. Advantages of aspiration thrombectomy before percutaneous catheter intervention in patients with acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT123	Not an RCT or an observational study enrolling more than 500 patients
Komatsu H, Nakamura M, Ito N, et al. Primary angioplasty under distal protection is a useful strategy to obtain optimal myocardial reperfusion compared to the primary angioplasty with thrombectomy device in acute myocardial infarction patients [abstract]. *J Am Coll Cardiol* 2003;41:343A	Not an RCT or an observational study enrolling more than 500 patients
Koneru S, Pucillo A, Weiss MB, et al. Successful aspiration of occlusive coronary thrombus with intracoronary aspiration using the export catheter. *J Invasive Cardiol* 2003;15:65-7	Uncontrolled study
Kosuga K, Tamai H. [Percutaneous coronary intervention: Current status of the development of new devices and the perspective of their future]. *Nippon Rinsho* 2003;61:529-33	A narrative review, editorial or letter to the editor
Kramer MCA, van der Wal AC, Koch KT, et al. The efficacy of thrombus aspiration during primary PCI: evaluation of three eevices [abstract]. *Am J Cardiol* 2008;108:511	Uncontrolled study
Kramer MC, van der Wal AC, Kock KT, et al. Histopathological features in primary PCI: a large single-center thrombectomy study [abstract]. *J Am Coll Cardiol* 2008;51:B79	Uncontrolled study
Krstic N, Perisic Z, Pavlovic M, et al. Thrombus Aspiration during Primary Percutaneous Coronary Intervention. *Circulation* 2010;122:P782	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Kuchela A, Sutsch G, Downey WE, et al. Embolic volume retrieved during native coronary percutaneous coronary intervention with distal protection is far lower than during saphenous vein graft percutaneous coronary intervention regardless of	Not evaluating an adjunctive device to remove thrombus and/or protect from distal

Reference	Reason for Exclusion
plaque burden [abstract]. *J Am Coll Cardiol* 2003;41:71A	embolization prior to or in PCI
Kuehne C, Bollmann A, Husser D, et al. Thrombolytic therapy prior to coronary thrombectomy using the rescue PT catheter in acute myocardial infarction [abstract]. *Eur Heart J* 2002;23:723	Uncontrolled study
Kuntz RE, Baim DS, Cohen DJ, et al. A trial comparing rheolytic thrombectomy with intracoronary urokinase for coronary and vein graft thrombus (the Vein Graft AngioJet Study [VeGAS 2]). *Am J Cardiol* 2002;89:326-30	Outside of ACS patients
Kyono H, Kozuma K, Muramatsu T, et al. Angiographic impact of the GuardWire system on inflated coronary segments after six months: does the distal protection balloon of the GuardWire Plus lead to restenosis? *Eurointervention* 2010;6:257-260	Not an RCT or an observational study enrolling more than 500 patients
Lansky AJ, Cox DA, Stuckey T, et al. Improved myocardial blush score after acute myocardial infarction intervention with the X-SIZER device. Results from the X-TRACT AMI trial [abstract]. *Circulation* 2001;104:2212	Uncontrolled study
Larose E, Bertrand OF, Nguyen CM, et al. Reducing myocardial injury in late presentation acute ST-elevation myocardial infarction with proximal embolic protection [abstract]. *Circulation* 2009;120:S992	Not an RCT or an observational study enrolling more than 500 patients
Lawson C, Garcia LA. Stent thrombosis aspiration thrombectomy: is this another glimmer of hope? *J Invasive Cardiol* 2009;21:214-5	A narrative review, editorial or letter to the editor
Lee CH, Tan HC, Soon CY, et al. Does X-sizer thrombectomy abrogate the inferior outcomes in patients with impaired TIMI flow before mechanical reperfusion for acute myocardial infarction? *Int J Cardiol* 2005;103:212-3	A narrative review, editorial or letter to the editor
Lee MS, Makkar R, Singh V, et al. Pre-procedural administration of aminophylline does not prevent AngioJet rheolytic thrombectomy-induced bradyarrhythmias. *J Invasive Cardiol* 2005;17:19-22	Uncontrolled study
Lee SY, Doh JH, Namgung J, et al. Export aspiration catheter thrombosuction before actual primary angioplasty for acute myocardial infarction procedure [abstract]. *Am J Cardiol* 2005;95:29A	Uncontrolled study
Lemesle G, de Labriolle A, Bonello L, et al. Impact of thrombus aspiration use for the treatment of stent thrombosis on early patient outcomes. *J Invasive Cardiol* 2009;21:210-4	Not an RCT or an observational study enrolling more than 500 patients
Li W, Xu Y, Wang K, et al. The Applying of Aspiration Catheter in Revascularisation in Patients with St-Elevation Myocardial Infarction. *Heart* 2010;96:e0419	Uncontrolled study
Lim MJ. The AngioJet rheolytic thrombectomy system: does the end justify the means? *J Invasive Cardiol* 2005;17:23-24	A narrative review, editorial or letter to the editor
Lim MJ, Young JJ, Senter SR, et al. Determinants of embolic protection device use: case study in the acceptance of a new medical technology. *Catheter Cardiovasc Interv* 2005;65:597-9	Uncontrolled study
Limbruno U, Cortese B, Severi S. Thrombectomy for thrombus removal, filters for whatever else. *J Cardiovasc Med* 2008;9:408-9	Uncontrolled study
Limbruno U, Micheli A, Petronio AS, et al. Prevention of no-reflow during primary percutaneous coronary angioplasty with a porous distal embolic protection device [abstract]. *Circulation* 2002;106:2220	Not an RCT or an observational study enrolling more than 500 patients
Limbruno U, Michelli A, Petronio AS, et al. Adjunctive porous filter protection from distal embolization in primary percutaneous intervention for acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2003; 41:46A	Not an RCT or an observational study enrolling more than 500 patients
Lucci D, Fabbri G, Maggioni AP. [The cardiologist and first aid: the situation in Italy]. *G Ital Cardiol* 1999;29:1-3	A narrative review, editorial or letter to the editor
Maia S, Costa JR Jr, Costa RA, et al. Preliminary Experience with the Novel MGuard (TM) Stent System Containing a Protection Net to Prevent Distal Embolization - Results From a Prospective, Non-Randomized, Single Center Study [abstract]. *Am J Cardiol* 2008;102:1851	Uncontrolled study
Maia F Sr, Costa JR Sr, Costa R Sr, et al. Acute results from the INSPIRE trial with the Novel MGuard (TM) Stent system containing a protection net to prevent distal embolization [abstract]. *J Am Coll Cardiol* 2009;53:A53	Uncontrolled study
Mak KH, Phay C, Kwok V, et al. Distal protection device is superior to glycoprotein IIb/IIIa blockade in restoring myocardial perfusion during percutaneous coronary intervention for acute myocardial infarction [abstract]. *Circulation* 2003;108:3064	Not an RCT or an observational study enrolling more than 500 patients
Mak KH, Phay C, Kwok V, et al. Superiority of the distal protection device over abciximab in preserving myocardial perfusion during percutaneous coronary intervention for acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:189L	Not an RCT or an observational study enrolling more than 500 patients

Reference	Reason for Exclusion
Mak KH, Phay C, Wong A, et al. Comparison between glycoprotein IIb/IIIa blockade and distal protection device for the restoration of myocardial perfusion during percutaneous coronary intervention for acute myocardial infarction. *J Invasive Cardiol* 2004;16:694-8	Not an RCT or an observational study enrolling more than 500 patients
Mamas MA, Fraser D, Fath-Ordoubadi F. The role of thrombectomy and distal protection devices during percutaneous coronary interventions. *Eurointervention* 2008;4:115-23	A narrative review, editorial or letter to the editor
Mangiacapra F;Muller O, Trana C, et al. Adjunctive thrombus aspiration in primary percutaneous coronary intervention in real-world patients with ST-elevation myocardial infarction [abstract]. *Circulation* 2009;120:S960	Not an RCT or an observational study enrolling more than 500 patients
Mangiacapra F, Wijns W, De Luca G, et al. Thrombus aspiration in primary percutaneous coronary intervention in high-risk patients with ST-elevation myocardial infarction: a real-world registry. *Catheter Cardiovasc Interv* 2010;76:70-6	Not an RCT or an observational study enrolling more than 500 patients
McClean D, Blake J, Richards M, et al. Distal protection with combination nonocclusive porous filter and aspiration thrombectomy improves ST segment resolution in primary percutaneous coronary intervention for acute myocardial infarction [abstract]. *Am J Cardiol* 2004; 94:34E	Not an RCT or an observational study enrolling more than 500 patients
Mehta S, Oliveros E, Ishmael A, et al. Selective strategy for thrombus management in STEMI interventions. *J Invasive Cardiol* 2010;22:26B-33B	Uncontrolled study
Michels RH, vanOmmen V, Heijmen EP, et al. Thrombectomy after failure of fibrinolytic drug therapy in acute myocardial infarction [abstract]. *Circulation* 1997;96:3620	Uncontrolled study
Minocha G, Agarwal P, Chugh SK, et al. Primary thrombosuction with export aspiration catheter during percutaneous coronary intervention in acute coronary syndrome: Acute results and in-hospital outcomes [abstract]. *J Am Coll Cardiol* 2006;47:217A	Uncontrolled study
Mizote I, Kodama K, Hirayama A, et al. Distal protection device (PercuSurge) can reduce infarct size in patients with acute myocardial infarction who have ruptured culprit plaque [abstract]. *J Am Coll Cardiol* 2004;43:41A	Uncontrolled study
Mongeon FP, Eisenberg MJ, Rinfret S. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2639-40	A narrative review, editorial or letter to the editor
Morrison DA. Mechanical options to prevent distal embolization during primary percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2009;74:94-6	A narrative review, editorial or letter to the editor
Morrison DA.. Is the glass 97% full, or 3% empty? Reinfarction and stent thrombosis after STEMI. *Catheter Cardiovasc Interv* 2009;73:635-6	A narrative review, editorial or letter to the editor
Mukawa H, Sone T, Tsuboi H, et al. Reperfusion time-dependent myocardial salvage in patients with acute myocardial infarction who undergo emergent percutaneous coronary intervention with distal protection device PercuSurge [abstract]. *J Am Coll Cardiol* 2004;43:246A	Not an RCT or an observational study enrolling more than 500 patients
Murakami T, Mizuno S, Takahashi Y, et al. Intracoronary aspiration thrombectomy for acute myocardial infarction. *Am J Cardiol* 1998;82:839-44	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Nakagawa Y, Matsuo S, Tamura T, et al. AngioJet thrombectomy catheter for acute myocardial infarction [abstract]. *J Am Coll Cardiol* 1998;31:236A	Uncontrolled study
Nakamura T, Kubo N, Ikeda N, et al. Percutaneous coronary intervention with distal protection device preserves left ventricular function in patients with acute anterior myocardial infarction [abstract]. *J Am Coll Cardiol* 2004;43:246A	Not an RCT or an observational study enrolling more than 500 patients
Nakamura T, Kubo N, Seki Y, et al. Effects of a distal protection device during primary stenting in patients with acute anterior myocardial infarction. *Circulation* 2004;68:763-8	Not an RCT or an observational study enrolling more than 500 patients
Nakazato R, Moroi M, Kunimasa T, et al. Usefulness of primary percutaneous coronary intervention with distal protection for acute myocardial infarction: assessment of salvaged myocardium with a rest [abstract]. *Eur Heart J* 2004;25:267	Not an RCT or an observational study enrolling more than 500 patients
Nakazato R, Moroi M, Kunimasa T, et al. Usefulness of primary percutaneous coronary intervention with thrombectomy plus distal protection system for acute myocardial infarction: Assessment of salvaged myocardium with a rest thallium-201 and iodine-123 BMIPP SPECT [abstract]. *J Am Coll Cardiol* 2004;43:337A-338A	Not an RCT or an observational study enrolling more than 500 patients

Reference	Reason for Exclusion
Napodano M, Ramondo A, Iliceto S. Adjunctive thrombectomy in acute myocardial infarction: for some but not for all. *J Am Coll Cardiol* 2007;49:1586-7	A narrative review, editorial or letter to the editor
Napodano M, Reimers B, Sacca S, et al. Mechanical intracoronary thrombus removal during acute myocardial infarction using the X-Sizer catheter [abstract]. *Am J Cardiol* 2000;86:249	Uncontrolled study
Napodano M, Reimers B, Sacca S, et al. Coronary flow and myocardial reperfusion after thrombectomy during direct angioplasty in patients with acute myocardial infarction [abstract]. *Eur Heart J* 2001;22:119	Uncontrolled study
Nassar Y, Elghawaby H, Elnaggar A, et al. X-SIZER thrombectomy compared to acolysis ultrasound thrombolysis in improving final epicardial flow and ST-segment resolution in patients with acute coronary syndromes [abstract]. *Eur Heart J* 2004;25:417-8	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Nishihira K, Yamashita A, Ishikawa T, et al. Composition of thrombi in late drug-eluting stent thrombosis versus de novo acute myocardial infarction. *Thromb Res* 2010;126:254-57	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Nishibori Y, Tanaka A, Nishiya D, et al. Intravascular ultrasound-guided percutaneous coronary intervention with distal protection device in acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:189L-190L	Not an RCT or an observational study enrolling more than 500 patients
Oh J, Hong N, Kang SM. Thrombus aspiration during percutaneous coronary intervention. *Lancet* 2008;372:1034-5	A narrative review, editorial or letter to the editor
O'Neill WW. Coronary thrombosis during acute myocardial infarction: Roberts was right! *Am J Cardiol* 1998;82:896-7	A narrative review, editorial or letter to the editor
Okamura A, Ito H, Iwakura K, et al. Detection of embolic particles with the Doppler guide wire during coronary intervention in patients with acute myocardial infarction: efficacy of distal protection device. *J Am Coll Cardiol* 2005;45:212-5	Does not report outcomes of interest
Orrego PS, Delgado A, Piccalo G, et al. Distal protection in native coronary arteries during primary angioplasty in acute myocardial infarction: single-center experience. *Catheter Cardiovasc Interv* 2003;60:152-8	Not an RCT or an observational study enrolling more than 500 patients
Oyama N, Urasawa K, Sakai H, et al. PCI for totally occluded site consisting of huge thrombus. *J Invasive Cardiol* 2003;15:604-6	Uncontrolled study
Pan W, Wang LF, Yang SS, et al. [Efficacy of the thrombectomy on no-reflow in patients with acute myocardial infarction.] *Zhongguo Wei Zhong Bing Ji Jiu Yi Xue* 2007;19:687-90	
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]. *J Am Coll Cardiol* 2003;41:356A-357A	Not an RCT or an observational study enrolling more than 500
Parodi G, Memisha G, Bellandi B, et al. Effectiveness of primary percutaneous coronary interventions for stent thrombosis. *Am J Cardiol* 2009;103:913-6	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Porto I, Choudhury RP, Pillay P, et al. Filter no-reflow during percutaneous coronary interventions using the filtewire distal protection device [abstract]. *Eur Heart J* 2004;25:312	Uncontrolled study
Porto I, Greco F, Buffon A. Coronary arteriovenous fistula following X-sizer thrombectomy. *J Cardiovasc Med* 2007;8:973-4	Uncontrolled study
Porto I, De Maria GL, Biasucci LM, et al. Levels of platelet microparticles are increased in thrombectomy-aspirated blood of ST-elevation myocardial infarction patients and correlate with thrombus burden of the culprit lesion [abstract]. *Am J Cardiol* 2009;104:76D	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Porto I, De Maria GL, Biasucci LM, et al. Levels of endothelial progenitor cells are increased in thrombectomy-aspirated blood of ST-elevation myocardial infarction patients and correlate with microvascular damage [abstract]. *Am J Cardiol* 2009;104:79D	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Porto L, Choudhury RP, Pillay P, et al. Filter no-reflow during percutaneous coronary intervention using the FilterWire distal protection device [abstract]. *Am J Cardiol* 2004;94:153E	Uncontrolled study
Reho I, Gruner C, Roffi M. Coronary thrombectomy by retrieval of an open emboli-protection filter device. *Heart* 2008;94:274	Uncontrolled study
Remondino A, Seiler C, Rakhit R, et al. Distal embolisation protection during	Not an RCT or an

Reference	Reason for Exclusion
percutaneous coronary intervention in acute myocardial infarction protects coronary collateral flow [abstract]. *Eur Heart J* 2003;24:713	observational study enrolling more than 500
Richartz BM. [Randomized comparison of the effect of distal protection and drug eluting stent versus bare metal stent implantation during percutaneous coronary intervention for ST-elevation myocardial infarction.] *Herz* 2007;32:249	A narrative review, editorial or letter to the editor
Rigatelli G, Giordan M, Cardaioli P, et al. Peripheral devices for recanalizing a giant thrombosed aneurysmal coronary artery. *Cardiovasc Revasc Med* 2006;7:199-200	Uncontrolled study
Rittersma SZ, van der Wal AC, Koch KT, et al. Plaque disruption frequently occurs days or weeks before occlusive coronary thrombosis: A pathologic thrombectomy study in primary PCI [abstract]. *Circulation* 2004;110:1941	Uncontrolled study
Sakai T, Inoue S, Takei M, et al. Role of Inflammatory Cells Activation In Growing Thrombus: Immunohistochemical Analysis of Aspiration Samples in Acute Coronary Syndrome [abstract]. *Circulation* 2008;118:S581	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Sakuma T, Okada T, Hayashi Y, et al. Myocardial tissue protection with distal coronary protection and thrombus aspiration, or pharmacological intervention during reperfusion, which is better in patients with acute myocardial infarction? [abstract] *Eur Heart J* 2004;25:421	Uncontrolled study
Sakuma T, Okada T, Ishibashi K, et al. Myocardial tissue protection with distal coronary protection and adenosine triphosphate disodium infusion can further reduce no-reflow in acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2005;45:302A	Uncontrolled study
Sarmento-Leite R, Machado PR, Garcia,SL, et al. [Intracoronary thrombectomy. An alternative in the management of the acute ischemic syndromes.] *Arq Bras Cardiol* 2002;79:428	Uncontrolled study
Satler L. Feasibility of primary clot extraction prior to percutaneous coronary intervention in acute myocardial infarction. *Catheter Cardiovasc Interv* 2008;71:877-8	A narrative review, editorial or letter to the editor
Satler L. Improving outcomes for primary PCI. *Catheter Cardiovasc Interv* 2007;69:497-9	A narrative review, editorial or letter to the editor
Satler L. Importance of creativity: new applications of the Proxis catheter. *Catheter Cardiovasc Interv* 2009;74:446-7	A narrative review, editorial or letter to the editor
Schneider H, Ince H, Casale PN, et al. Efficacy And Safety Of A Thrombectomy Aspiration Device In Patients With High Thrombus Burden Acute Coronary Syndrome [abstract]. *Am J Cardiol* 2008;102:1201	Uncontrolled study
Schomig A, Kastrati A. Distal embolic protection in patients with acute myocardial infarction: attractive concept but no evidence of benefit. *JAMA* 2005;293:1116-8	A narrative review, editorial or letter to the editor
Sena MA., Peixoto RTS, Tedeschi AL. Thrombectomy with the X-Sizer catheter in thrombus-containing lesions during acute coronary syndrome. outcomes in-hospital and at 1year [abstract]. *Am J Cardiol* 2003;92:233L	Uncontrolled study
Seth A. Another "nail in the coffin" for protection devices in acute MI? *Catheter Cardiovasc Interv* 2008;71:E3-4	A narrative review, editorial or letter to the editor
Shah PB, Lilly CM. Interventional therapy for coronary artery disease. *Am J Respir Crit Care Med* 2002;166:791-6	A narrative review, editorial or letter to the editor
Sharma SK. Role of AngioJet rheolytic thrombectomy catheter: Mount Sinai Hospital experience. *J Invasive Cardiol* 2010;22:15B-20B	Not an RCT or an observational study enrolling more than 500
Sharma M, Yeghiazarians Y. Stent thrombosis--a complication best avoided. *J Invasive Cardiol* 2008;20:166-7	A narrative review, editorial or letter to the editor
Sharma SK, Tamburrino F, Mares AM, et al. Improved outcome with AngioJet thrombectomy during primary stenting in acute myocardial infarction patients with high-grade thrombus. *J Invasive Cardiol* 2006;18:8-11	Not an RCT or an observational study enrolling more than 500
Sheiban I, Moretti C, Prathap K, et al. Thrombus aspiration for the treatment of no-reflow phenomenon complicating primary angioplasty for acute myocardial infarction [abstract]. *J Am Coll Cardiol* 2004;43:248A	Uncontrolled study
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	Not an RCT or an observational study enrolling more than 500
Sievert H, Schuler G, Diederich K, et al. Preclinical and clinical experience with the proxis device: A novel proximal occlusion system for prevention of distal	Conducted outside of humans

Reference	Reason for Exclusion
embolization during percutaneous coronary intervention [abstract]. *Am J Cardiol* 2002;90:TCT57	
Silva JA. Percutaneous coronary intervention of thrombotic lesions: still challenging! *Catheter Cardiovasc Interv* 2002;56:8-9	A narrative review, editorial or letter to the editor
Silva JD, Seca L, Baptista R, et al. The role of thrombus aspiration in primary percutaneous coronary intervention: safety and efficacy [abstract]. *Eur Heart J* 2010; 12:F26	Not an RCT or an observational study enrolling more than 500
Silva JA, Ramee SR, Cohen D, et al. Rheolytic thrombectomy for the treatment of acute myocardial infarction in patients with angiographic large thrombus burden: One-year results of the VeGAS 2 acute myocardial infarction registry [abstract]. *J Am Coll Cardiol* 2004;43:248A	Uncontrolled study
Silva JA, Ramee SR, Kuntz R, et al. Mechanical thrombectomy using the angiojet catheter in the treatment of acute myocardial infarction [abstract]. *J Am Coll Cardiol* 1998;31:410A-411A	Uncontrolled study
Silva JA., Saucedo JF, Lanoue AS, et al. Rheolytic thrombectomy using the POSSIS AngioJet -> catheter in patients with acute myocardial infarction presenting within eight hours of symptom onset [abstract]. *Circulation* 1998;98:762	Uncontrolled study
Sison EOD, Tan HC, Lee R, et al. Thrombectomy using the thrombus vacuum catheter (Nipro (R)) in primary angioplasty for acute myocardial infarction [abstract]. *Am J Cardiol* 2005;96:75H-76H	Uncontrolled study
Skowasch M, Schofer J, Diedrich K, et al. Initial experiences with the Proxis System: A proximal occlusion device for embolic protection during percutaneous coronary intervention [abstract]. *Am J Cardiol* 2005;95:64A	Uncontrolled study
Stoel MG, von Birgelen C, Zijlstra F. Aspiration of embolized thrombus during primary percutaneous coronary intervention. *Catheter Cardiovasc Interv* 2009;73:781-6	Uncontrolled study
Stone GW, Cox DA, Babb J, et al. Prospective, randomized evaluation of thrombectomy prior to percutaneous intervention in diseased saphenous vein grafts and thrombus-containing coronary arteries. *J Am Coll Cardiol* 2003;42:2007-13	Outside of ACS patients
Stone, GW, Cox, DA, Low, R, et al. Safety and efficacy of a novel device for treatment of thrombotic and atherosclerotic lesions in native coronary arteries and saphenous vein grafts: results from the multicenter X-Sizer for treatment of thrombus and atherosclerosis in coronary applications trial (X-TRACT) study. *Catheter Cardiovasc Interv* 2003;58:419-27.	Not in native vessel
Sun Jiaan. No-Reflow Phenomenon in Primary PCI of AMI: Effect of Super-Selective Injection of Nitroprusside Combined with ZEEK Thrombus Aspiration. *Circulation* 2010;122:P1304	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Sutsch G, Metzler C, Murphy S, et al. Distal protection accelerates ST-segment resolution and improves epicardial flow in percutaneous coronary intervention for acute myocardial infarction [abstract]. *Am J Cardiol* 2002;90:TCT43	Uncontrolled study
Sutsch G, Eberli FR, Serruys PW. Evaluation of proximal embolic protection during percutaneous coronary intervention in acute myocardial infarction with Proxis.(TM) [abstract]. *Am J Cardiol* 2004;94:36E	Uncontrolled study
Sutsch G, Kiowski W, Amann W. The new reduced profile GuardWire (028) embolic protection device is feasible for percutaneous coronary intervention in native coronary arteries [abstract]. *Am J Cardiol* 2002;90:TCT90	Uncontrolled study
Sutsch G, Kiowski W, Bossard A, et al. Recanalisation in acute myocardial infarction: preliminary experiences with the PercuSurge (R)-Protection device in native coronary arteries [abstract]. *Eur Heart J* 2000;21:P1003	Uncontrolled study
Sutsch G, Murphy S, Kiowski W, et al. Does embolic protection in native coronary arteries acutely affect the outcome of percutaneous coronary intervention in acute myocardial infarction? [abstract] *Am J Cardiol* 2002;90:TCT110	Not an RCT or an observational study enrolling more than 500
Sutsch G, Puippe G, Kessel M., et al. No angiographic evidence of harm, to native coronary arteries using the GuardWire distal embolization protection device [abstract]. *Am J Cardiol* 2001;88:TCT83	Uncontrolled study
Szerlip M, Grines CL. The current role of AngioJet rheolytic thrombectomy in acute myocardial infarction. *J Invasive Cardiol* 2010;22:21B-22B	A narrative review, editorial or letter to the editor
Tamburrino F, Kini AS, Gupta S, et al. The improved outcome with AngioJet (TM)	Not an RCT or an

Reference	Reason for Exclusion
thrombectomy catheter during primary stenting in acute myocardial infarction patients with high-grade thrombus [abstract]. *Am J Cardiol* 2005;96:76H	observational study enrolling more than 500
Tarsia G;Polosa D, Biondi-Zoccai G, et al. Passive Versus Active Thrombectomy In Primary And Rescue Percutaneous Coronary Intervention For ST-elevation Acute Myocardial Infarction [abstract]. *Am J Cardiol* 2008;102:481	Not an RCT or an observational study enrolling more than 500
Testa L, Bedogni F, Biondi Zoccai GG. Letter by Testa et al regarding article, "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". *Circulation* 2009;120:e3	A narrative review, editorial or letter to the editor
Tomoda H, Izumi N, Aoki N. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2540	A narrative review, editorial or letter to the editor
Tsubotan T, Muramatsu T, Tsukahara R, et al. Clinical results of intravascular ultrasound-guided distal protection therapy for acute myocardial infarction [abstract]. *Am J Cardiol* 2005;95:9A	Not an RCT or an observational study enrolling more than 500
Turco MA, Cox DA, Stuckey T, et al. Impact of glycoprotein IIb/IIIa inhibitors in conjunction with the X-SIZER thrombectomy catheter system during acute myocardial infarction (AMI) intervention: Results from the X-SIZER AMI registry [abstract]. *Am J Cardiol* 2002;90:TCT121	Uncontrolled study
Upadhyay S, Sawar A. Device failure and acute vessel thrombosis with PercuSurge. *J Invasive Cardiol* 2008;20:E256	Uncontrolled study
Uretsky BF. Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med* 2008;358:2639	A narrative review, editorial or letter to the editor
van Ommen V, Michels R, Heymen E, van Asseldonk J, et al. Usefulness of the rescue PT catheter to remove fresh thrombus from coronary arteries and bypass grafts in acute myocardial infarction. *Am J Cardiol* 2001;88:306-8	Uncontrolled study
Vink MA, Dirksen MT, Tijsserr JGP, et al. Thrombus Aspiration During Primary Percutaneous Coronary Intervention: Post-hoc Analysis of the PASSION Trial [abstract]. *Am J Cardiol* 2009;104:197D	Uncontrolled study
Vink MA., Patterson MS, Van Etten J, et al. Thrombus Removal by Extraction or Aspiration in Primary PCI in the Treatment of ST-elevation Myocardial Infarction (TREAT-MI). A follow-up study [abstract].. *Am J Cardiol* 2009;104 :197D-198D	Uncontrolled study
Vlaar PJ, Diercks G, Svilaas T, et al. One-year follow-up of the Thrombus Aspiration during Primary percutaneous coronary intervention in Acute non-ST-elevation myocardial infarction Study (TAPAS-II) - pilot – trial [abstract]. *J Am Coll Cardiol* 2009;53:A64	Not an RCT or an observational study enrolling more than 500
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	Not an RCT or an observational study enrolling more than 500
Wang FW, Osman A, Otero J, et al. Distal myocardial protection with intracoronary propranolol during percutaneous coronary intervention is widely applicable [abstract]. *J Am Coll Cardiol* 2003;41:17A	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Wang L, Nguyen T, Yang X, et al. Distal protection with AngioGuard during PCI for acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:38L	Not an RCT or an observational study enrolling more than 500
Weisz G, Rogers C, Herrmiller J, et al. Predilatation before distal protection device placement is associated with increased procedure-related myocardial infarction: Analysis from the FIRE trial [abstract]. *J Am Coll Cardiol* 2004;43:52A	Not a PCI in native vessel
Wong A, Nait D, Phay C, et al. Rate of distal embolization in primary angioplasty in acute myocardial infarction without distal embolization prevention and thrombectomy devices [abstract]. *Am J Cardiol* 2005;95:12A	Not evaluating an adjunctive device to remove thrombus and/or protect from distal embolization prior to or in PCI
Worthley MI, Traboulsi M. Thrombectomy and acute myocardial infarction. *Intern Med J* 2006;36:470-1	Uncontrolled study
Yamaguchi K, Hiasa Y, Nada T, et al. Rescue percutaneous thrombectomy catheter is less beneficial in acute myocardial infarction with large vessel diameter [abstract]. *Eur Heart J* 2002;23:350	Uncontrolled study
Yamasaki T, Koizumi T, Iida S, et al. Benefit of thrombus aspiration for myocardial infarction with ST-segment elevation: analysis by biomarkers of thrombosis and inflammation [abstract]. *Circulation* 2009;120:S926	Uncontrolled study

Reference	Reason for Exclusion
Yang SS, Li WM, Zhou LJ, et al. [The efficacy of percutaneous coronary intervention combined percutaneous thrombectomy on coronary thrombotic lesions in patients with acute myocardial infarction]. *Zhonghua Xin Xue Guan Bing Za Zhi* 2007;35:1136-40	Does not report outcomes of interest
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	Not an RCT or an observational study enrolling more than 500
Yoon MH, Tahk SJ, Choi SY, et al. The effect of distal protection device on the protection of microvascular integrity during primary stenting in AMI [abstract]. *Circulation* 2003;108:1877	Not an RCT or an observational study enrolling more than 500
Yoon MH, Tahk SJ, Choi SY, et al. The effect of a distal protection device on the protection of microvascular integrity during primary stenting in acute myocardial infarction [abstract]. *Am J Cardiol* 2003;92:37L	Not an RCT or an observational study enrolling more than 500
Yoshida K, Oku K, Uchida Y, et al. The effect for chronic phase left ventricular ejection fraction using adjunctive distal protection during percutaneous coronary intervention in patients with acute coronary syndrome [abstract]. *Am J Cardiol* 2005;95:28A	Not an RCT or an observational study enrolling more than 500
Zalewski D, Zajdel W, El-Massri N, et al. The immediate and long-term results of successful thrombectomy during primary coronary angioplasty in acute myocardial infarction [abstract]. *Am J Cardiol* 2005;96:74H	Uncontrolled study

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

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Dudek, 2010	Diver CE	100	60.8 (10.2)	80	96.9	---	2	---	0	39	---	13	58	43	63	33
	Control	96	58.8 (10.3)	81.7	97.9	---	0	---	0	39.6	---	9.6	54	48.5	63	26
Liistro, 2009	Export Thrombectomy Catheter	55	64 (11)	78	69	189 (105)	0	---	0	38	---	20	60	34	63	38
	Control	56	65 (11)	77	76	209 (147)	0	---	0	46	---	12	53	30	64	23
Lipiecki, 2009	Export Catheter	20	59 (13)	60	100	426 (294)	0	---	15	35	---	5	25	30	35	---
	Control	24	59 (13)	75	95.83	444 (408)	0	---	8	46	---	8	33	21	38	---
Moura, 2009	TAC	76	---	---	---	---	---	---	---	---	---	---	---	---	---	---
	Control	76	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Sardella, 2009	Export Medtronic (EM)	88	66.7 (14.1)	64.7	100	372 (54)	0	43.18	0	43.2	100	23.8	67.0	---	48.8	29.5
	Control	87	64.6 (12.5)	55.1	100	366 (108)	0	42.53	0	43.7	100	18.4	49.4	---	26.4	36.8
Chao, 2008	Export Aspiration Catheter	37	60 (13)	83.78	---	312 (183)	11	60	0	56.76	81	32	57	60	41	---
	Control	37	62 (11)	86.49	---	331 (175)	3	65	0	59.46	73	22	57	57	46	---
Chevalier, 2008	Export Aspiration Catheter	120	59.2 (12.8)	80.8	99.2	321.7 (413.5)	10.83	---	0	47.5	---	16.7	41.4	36.7	42.5	32.5
	Control	129	61.2 (12.9)	81.4	100	271.4 (197.6)	10.85	---	0	51.9	---	13.2	44.2	41.9	35.7	25.6
Ciszewski, 2008	Rescue/Diver	65	64.3(12.4) †	65.19 †	---	---	---	32.28 †	0	---	---	---	---	---	---	---
	Control	70			---	---	---		0	---	---	---	---	---	---	---
Ikari, 2008	TVAC	180	63.2 (10.6)	80.6	74.6	270 (300)	---	---	0	50.3	81.11	23.3	54.8	50.0	56.6	13.9
	Control	175	63.5 (9.9)	77.7	75.3	312 (330)	---	---	0	52.0	82.29	29.9	59.0	48.5	50.9	14.4

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Svilaas, 2008	6F Export Aspiration Catheter	535	63 (13)	67.9	54.8	190 (110-270)‡	9.5	---	0	42.9	48.6§	10.6	33.1	23.7	46.0	46.2
	Control	536	63 (13)	73.1	59.5	185 (107-263)‡	10.7	---	0	43.1	44.0§	12.6	37.1	27.1	48.0	44.6
DeLuca, 2006	Diver CE	38	66.7 (14.1)	71	100	432 (114)	0	---	0	97.4	100	23.7	39.5	---	18.4	13.1
	Control	38	64.6 (12.5)	55.3	100	456 (108)	0	---	0	100	100	18.4	50	---	26.3	36.8
Kaltoft, 2006	Rescue Catheter	108	65 (11)	76	68	242 (171-321)‡	13	46.30	0	46	69	8	31	9	55	---
	Control	107	63 (13)	80	69	208 (155-329)‡	10	42.99	0	43	79	6	21	9	64	---
Lee, 2006	Export Aspiration Catheter	67	60.8(1.05)†	69.9†	---	---	---	---	0	42.9†	---	---	---	---	---	---
	Control	66			---	---	---	---	0		---	---	---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	74	57.3 (13)	84	81	206 (115)	0	42	0	43	---	21	37	34	54	---
	Control	74	58.9 (14)	76	73	199 (124)	0	51	0	51	---	15	46	25	60	---
Burzotta, 2005	Diver CE	50	61 (13)	90.0	86	274 (137)	---	40.0	32.0	40.0	---	22.0	62.0	54.0	62.0	30.0
	Control	49	60 (13)	77.6	89.8	300 (202)	---	51.0	24.5	51.0	---	18.4	57.1	34.7	53.1	22.4
Noel, 2005	Export	24	61.2(11.3)†	---	100‖	282 (186)†	---	44†	---	---	---	---	---	---	---	---
	Control	26		---	100‖		---		---	---	---	---	---	---	---	---
Dudek, 2004	Rescue System	40	56.7 (8.1)	80	79	258 (198)	15	40	0	---	---	10	75	---	45	40
	Control	32	59.1 (7.8)	69	66	236 (162)	25	56	0	---	---	19	81	---	31	50

*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

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Dudek, 2010	Diver CE Control	100 96	--- ---	99/100 (99) 93/96 (96.8)	75/100 (75) 5/96 (5.2)	62/100 (62) 60/96 (63)	Aspirin 325mg and clopidogrel 600mg pre-PCI	Heparin 70 U/kg pre-PCI
Liistro, 2009	Export Thrombectomy Catheter Control	55 56	75.7 (30.0) 75.9 (38.7)	55/55 (100) 56/56 (100)	12/55 (21) 5/56 (9)	55/55 (100) 56/56 (100)	Aspirin 500 mg and clopidogrel 600 mg load pre-PCI	Heparin 70 IU/kg pre-PCI
Lipiecki, 2009	Export Catheter Control	20 24	--- ---	19/20 (95) 22/24 (92)	10/20 (55) 6/24 (33)	5/20 (25) 15/24 (62)	Aspirin and clopidogrel 300 mg load pre-PCI	Heparin pre-PCI
Moura, 2009	TAC Control	76 76	--- ---	--- ---	--- ---	45/76 (59) 62/76 (82)	--- ---	--- ---
Sardella, 2009	Export Medtronic (EM) Control	88 87	--- ---	88/88 (100) 87/87 (100)	67/88 (76.2) 2/87 (2.3)	88/88 (100) 87/87 (100)	Aspirin 300 mg and clopidogrel 300 mg pre-PCI Aspirin and clopidogrel (for 12 m) post-PCI	Heparin 7.5 UI pre-PCI
Chao, 2008	Export Aspiration Catheter Control	37 37	49 (18)† 53 (23)†	35/37 (95) 34/37 (92)	19/37 (51) 4/37 (11)	7/37 (19) 12/37 (32	Aspirin 300 mg and clopidogrel 300 mg load pre-PCI Aspirin 100 mg/d indefinitely and clopidogrel 75 mg/d for 3 m post-PCI	Heparin 70-100 IU/kg IV (ACT >200 s) pre-PCI and for at least 24 hours
Chevalier, 2008	Export Aspiration Catheter Control	120 129	36.7 (18.0) 34.5 (21.5)	120/120 (100) 129/129 (100)	--- ---	--- ---	Aspirin and clopidogrel used at investigator's discretion	Heparin used at investigator's discretion
Ciszewski, 2008	Rescue/Diver Control	65 70	--- ---	65/65 (100) 70/70 (100)	--- ---	--- ---	--- ---	--- ---
Ikari, 2008	TVAC Control	178 180	87.0 (32.4) 93.6 (78.6)	167/178 (94.1) 160/171 (93.4)	--- ---	0/178 (0) 0/180 (0)	Aspirin pre-PCI Ticlopidine (cilostizol if intolerant to ticlopidine) and aspirin post-PCI	Heparin (ACT≥300 s) pre-PCI

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Svilaas, 2008	6F Export Aspiration Catheter	535	28 (14-42)*	442/279 (92.3)	295/535 (55.1)	469/502 (93.4)	Aspirin 500 mg bolus and clopidogrel 600mg pre-PCI and standard aspirin and clopidogrel therapy post-PCI	Heparin 5000 IU pre-PCI plus additional doses based on ACT
	Control	536	26 (12-40)*	438/476 (92.0)	---	452/503 (89.9)		
DeLuca, 2006	Diver CE	38	---	38/38 (100)	35/38 (92.1)	---	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	Heparin 8000 IU IV pre-PCI continued for 48 hours post-PCI
	Control	38	---	38/38 (100)	2/38 (5.3)	---		
Kaltoft, 2006	Rescue Catheter	108	39 (29-48)*	103/108 (95)	---	104/108 (96)	Aspirin 300 mg and clopidogrel 300 mg pre-PCI Aspirin 75 mg/d and clopidogrel 75 mg/d for 12 m post-PCI	Heparin 10,000 IE IV pre-PCI
	Control	107	29 (23-38)*	104/107 (97)	---	100/107 (93)		
Lee, 2006	Export Aspiration Catheter	67	---	---	---	---	---	---
	Control	66	---	---	---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	74	57 (19)	73/74 (99)	52/74 (70)	74/74 (100)	Aspirin pre-PCI	Heparin 60 U/kg pre-PCI
	Control	74	54 (21)	72/74 (97)	18/74 (24)	74/74 (100)		
Burzotta, 2005	Diver CE	50	81 (43)	---	33/50 (66.0)	34/50 (68.0)	Aspirin and clopidogrel (300 mg load followed by 75 mg/d) for at least 4 weeks	Heparin (ACT 250-300 s)
	Control	49	72 (34)	---	12/49 (24.4)	31/49 (63.3)		
Noel, 2005	Export	24	---	---	---	---	---	---
	Control	26	---	---	---	---	---	---
Dudek, 2004	Rescue System	40	---	---	---	---	Aspirin 75 mg/d, clopidogrel (initially 300 mg, followed by 75 mg/d) or ticlopidine (500 mg/d) for 1 m	---
	Control	32	---	---	---	---		---

*Median (interquartile range); †Lab to TIMI-3

Abbreivations: 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

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Migliorini 2010	AngioJet Rheolytic Thrombectomy	256	63.0 (12.3)	76	83.5	125 (85-221.5)†	3.9	39	0	42	---	14	47	30	---	---
	Control	245	64.3 (11.5)	81	83.9	135 (86-227)†	4.9	37	0	37	---	15	47	35	---	---
Ali, 2006	AngioJet Catheter	240	60 (51.0-69.0)†	75.8	68.4	144 (198)	---	---	14.2	38.9	20.83	16.7	42.9	22.1	44.2	---
	Control	240	59.9 (49.0 - 70.0)†	74.2	63.2	150 (192)	---	---	13.3	37.4	19.19	15.8	42.1	25.4	45.0	---
Lefèvre 2005	X-Sizer Catheter	100	61 (13)	76	100	251 (151)	10	54	0	55	---	25	54	58	52	---
	Control	101	62 (11)	73	100	264 (194)	6	50	0	48	---	18	50	61	51	---
Antoniucci 2004	AngioJet	50	63 (13)	82	76	234 (120)	---	34	0	34	---	18	36	46	38	---
	Control	50	66 (12)	78	80	264 (168)	---	46	0	46	---	16	38	48	28	---
Napodano2003	X-Sizer Catheter	46	61.3 (10.8)	82.6	73.9	202.9 (204.9)	17.4	39.1	---	---	100	13.0	60.9	50.0	45.6	---
	Control	46	63.6 (11.7)	71.7	84.7	165.7 (134.7)	6.5	43.5	---	---	100	13.0	65.2	52.1	34.8	---

*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

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Migliorini, 2010	AngioJet Rheolytic Thrombectmy Control	256 245	59.5 (44.7-70)* 46 (35-60)*	256/256 (100) 245/245 (100)	256/256 (100) 245/245 (100)	249/256 (97) 239/245 (98)	Aspirin 325 mg po or 500 mg IV and clopidogrel 600 mg load pre-PCI or immediately post-PCI Aspirin 100 to 325 mg/d indefinitely and clopidogrel 75 mg/d for 6 m post-PCI	Heparin 70 U/kg bolus with additional doses (ACT 200-250 s)
Ali, 2006	AngioJet Catheter Control	240 240	75.4 (30.9) 59.2 (26.8)	224/240 (93.7) 227/240 (94.5)	--- ---	228/240 (95.0) 226/240 (94.2)	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)	Heparin during PCI (ACT >250 s)
Lefèvre, 2005	X-Sizer Catheter Control	100 101	54 (28) 45 (25)	100/100 (100) 100/101 (99)	60/100 (60) 34/101 (34)	55/100 (55) 66/101 (65)	Aspirin pre-PCI	Heparin 70 U/kg (ACT >250 s)
Antoniucci, 2004	AngioJet Control	50 50	--- ---	49/50 (98) 49/50 (98)	47/50 (94) 41/50 (82)	49/50 (98) 49/50 (98)	Aspirin 325 mg/d indefinitely and ticlopidine (500 mg/d for 1 m) or clopidogrel (75 mg/d for 1 m)	Heparin 70 U/kg bolus and additional doses (ACT 200-300 s)
Napodano, 2003	X-Sizer Catheter Control	46 46	--- ---	43/46 (93.5) 42/46 (91.3)	28/46 (60.8) 13/46 (28.3)	20/46 (43.4) 19/46 (41.3)	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	Heparin 70 U/kg IV pre-PCI/ during PCI and 7-12 IU/kg/hour for 48 hours (ACT >250 s)

*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 19. Baseline characteristics of randomized controlled trials evaluating distal filter embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Ito, 2010	Filtrap	19	62.7 (12)	79	89	275 (223)	0	100	0	---	---	47	58	74	68	---
	Control	17	63.7 (8.4)	76	94	196 (223)	0	100	0	---	---	29	53	59	71	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	312	62 (12.3)	74.4	67	200 (26-1350)†	6.4	---	0	44	68	9.0	32.1	18.6	56.7	36.5
	Control	314	63 (12.1)	72.0	68	199 (40-996)†	6.4	---	0	38	75	11.8	34.1	20.4	50.3	37.6
Cura, 2007	SpideRX	70	60.2 (9.9)	86	85	150 (80-270)†	21	---	3	53	90	19	56	---	33	---
	Control	70	60.4 (10.4)	77	83	146 (75-236)†	13	---	4	56	97	20	49	---	47	---
Guetta, 2007	FilterWire EZ	51	60 (12)	82	78	180 (90-420)†	12	---	---	51	---	22	44	48	43	---
	Control	49	57 (10)	82	92	120 (66-180)†	11	---	---	53	---	23	51	50	44	---
Lefèvre, 2004	AngioGuardXP	32	61 (15)	81	71.88	---	---	---	---	41	100	19	50	62	---	---
	Control	28	62 (12)	83	67.86	---	---	---	---	53	100	14	43	61	---	---

*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

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Ito, 2010	Filtrap	19	---	19/19 (100)	---	---	Aspirin 200mg and ticopidine 200mg or clopidogrel 300mg pre-PCI	Heparin 8000 U IV pre-PCI
	Control	17	---	17/17 (100)	---	---		
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	312	---	307/312 (98)	---	301/312 (97)	Aspirin 300-500 mg and clopidogrel 300-600 mg pre-PCI Clopidogrel continued for 1 year and aspirin continued indefinitely	Heparin 10,000 IU pre-PCI
	Control	314	---	312/314 (99)	---	302/314 (96)		
Cura, 2007	SpideRX	70	52 (43-70)*	69/70 (99)	---	18/70 (26)	Aspirin 325 mg and clopidogrel 300-600 mg load pre- or immediately after PCI Clopidogrel recommended for 12 m and aspirin indefinitely post-PCI	Heparin IV during PCI (ACT>250 s)
	Control	70	43.5 (30-54)*	68/70 (97)	---	18/70 (26)		
Guetta, 2007	FilterWire EZ	51	---	---	---	38/51 (74)	Aspirin 500 mg IV or 200 mg orally and clopidogrel 300 mg load pre-PCI	Heparin 70 U/kg pre-PCI
	Control	49	---	---	---	38/49 (77)		
Lefèvre, 2004	AngioGuardXP	32	---	32/32 (100)	---	---	---	---
	Control	28	---	28/28 (100)	---	---	---	---

*Median (interquartile range)

Abbreivations: 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

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Duan, 2010	PercuSurge Guardwire Plus	46	55 (7)	86.96	80.4	289 (58)	---	100	0	100	---	6.5	17.4	15.2	63.0	---
	Control	50	56 (8)	82	80.0	282 (60)	---	100	0	100	---	8.0	20.0	20.0	58.0	---
Pan, 2010	PercuSurge Guardwire	52	67 (6.1)‡	61.54‡	73.1	157 (47)	0	40.4‡	---	55.8	---	32.7	55.8	---	42.3	---
	Control	52			71.1	161 (43)	0		---	51.9	---	30.7	51.9	---	46.2	---

Study, Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Tahk, 2008	PercuSurge GuardWire	60	55.9 (13.9)	85	67	339.3 (189.2)	0	53	0	53	---	20	36	---	68	---
	Control	56	58.8 (14.5)	71	76	327.8 (209.5)	0	56	0	56	---	21	54	---	57	---
Hahn, 2007	GuardWire	19	55 (45-62)†	79	95	212 (160-325)†	---	58	0	58	---	32	47	26	63	---
	Control	20	56 (45-65)†	95	75	248 (185-480)†	---	55	0	55	---	15	25	20	65	---
Matsuo, 2007	GuardWire Distal Protection System	80	65 (12)	86	78	312 (252)	5	---	---	57	---	20	51	35	47	12
	Control	74	65 (13)	76	71	264 (174)	8	---	---	40	---	25	49	39	50	7
Muramatsu, 2007	GuardWire Plus System	173	63.5 (12.3)	78.6	69	252 (168)	1.7	---	0	50	---	31.8	42.2	32.9	51.4	4.6
	Control	168	64.7 (11.1)	72.9	68	264 (204)	2.9	---	0	48	---	32.3	44.1	32.9	49.4	4.1
Zhou, 2007	PercuSurge GuardWire	52	55 (14)	62	100	310 (145)	---	---	0	54	---	23	37	---	67	---
	Control	60	57 (15)	67	100	315 (176)	---	---	0	48	---	22	35	---	60	---
Okamura, 2005	PercuSurge GuardWire	8	59 (13)	75	75	450 (348)	---	---	---	25	---	25	38	38	75	---
	Control	8	59 (8)	88	38	510 (492	---	---	---	75	---	25	63	38	63	---
Stone, 2005	GuardWire Plus	252	58.5(51.1-69.3)†	76.2	64.0	233 (178-296)†	9.5	---	18.3	40.2	72.1	7.5	35.9	20.2	40.5	---
	Control	249	59.8 (52.1-69.3)†	80.7	67.8	211 (158-273)†	12.4	---	18.9	38.5	72.1	17.3	38.2	28.5	44.6	---

*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 22. Procedural characteristics of randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Duan, 2010	PercuSurge Guardwire Plus	46	---	46/46 (100)	---	---	Aspirin 300mg and clopidogrel 300mg followed by 75mg pre-PCI	UFH 70U/kg to achieve an ACT of 300s
	Control	50	---	50/50 (100)	---	---		
Pan, 2010	PercuSurge Guardwire	52	---	---	---	52/52 (100)	Aspirin 300mg and clopidogrel 300mg pre-PCI	---
	Control	52	---	---	---	52/52 (100)		---

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Tahk, 2008	PercuSurge GuardWire	60	---	60/60 (100)	0/60 (0)	---	Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI	Heparin IV during PCI (ACT 300 s)
	Control	56	---	56/56 (100)	1/56 (1.8)	---		
Hahn, 2007	GuardWire	19	---	19/19 (100)	---	1/19 (5.3)	Appropriate antiplatelet therapy	Heparin
	Control	20	---	29/20 (100)	---	1/20 (5.0)		
Matsuo, 2007	GuardWire Distal Protection System	80	75.8 (30)	---	---	9/80 (11)	Aspirin 100 mg and ticlopidine 200 mg pre-PCI	Heaparin 5000 U (ACT >250 s)
	Control	74	53 (25)	---	---	5/74 (7)		
Muramatsu, 2007	GuardWire Plus System	173	29.7 (18.3)*	173/173 (100)	---	---	Aspirin 81-100 mg/d and ticlopidine 200 mg/d for at least 2 weeks	---
	Control	168	29.5 (18.2)*	168/168 (100)	---	---		---
Zhou, 2007	PercuSurge GuardWire	52	---	52/52 (100)	---	0/52 (0)	Aspirin 300 mg and clopidogrel 300 mg pre-PCI then aspirin 100 mg/d and clopidogrel 75 mg/d post-PCI	Heparin IV during PCI (ACT ≥300 s)
	Control	60	---	60/60 (100)	---	0/60 (0)		
Okamura, 2005	PercuSurge GuardWire	8	---	8/8 (100)	---	---	Aspirin 243 mg at least 30 min pre-PCI	Heparin 100 U/kg IV
	Control	8	---	8/8 (100)	---	---		
Stone, 2005	GuardWire Plus	252	53 (42-69)†	244/252 (96.8)	---	210/252 (83.3)	Aspirin 324 mg and clopidogrel 300 mg pre-PCI	Heparin IV 70 U/kg bolus (ACT >300 s pre-PCI or 200-300 s if GP2B3Ai used)
	Control	249	39 (29-51)†	241/249 (96.8)	---	208/249 (83.5)		

*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

Study Year	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Haeck, 2009	Proxis	141	62 (11)	80	98.58	170 (132-234)†	6	---	0	29	76	12	31	21	50	35
	Control	143	59 (11)	80	96.50	153 (126-212)†	9	---	0	29	66	6	23	13	65	38

*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

Study, Year	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Haeck, 2009	Proxis	141	45 (36-58)*	---	15/141 (11)	61/141(43)	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	Heparin 70 U/kg pre-PCI
	Control	143	31 (25-40)*	---	27 /143 (19)	50/143 (35)		

*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 cotnrol in patients with mixed acute coronary syndrome

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Parikh 2008	Distal Balloon Embolic Protection	GuardWire	30	55.17 (12)	90	---	---	---	---	---	53	100	20	20	3	17	23
		Control	37	56.16 (11.31)	95	---	---	---	---	---	62	100	41	28	8	19	27
Gick 2005	Distal Filter Embolic Protection	FilterWire	100	62.9 (11.3)	86	65	372 (210-726)†	12	---	---	45	---	21	65	---	35	---
		Control	100	60.2 (13.0)	80	57	474 (266-936)†	17	---	---	39	---	26	69	---	35	---
Sardella 2005	Catheter Aspiration	Diver CE	28	65.3 (11.2)‡	77.42‡	---	408 (138)‡	---	100	0	---	100	---	78	---	---	---
		Control	34			---		---	100	0	---	100	---	55	---	---	---
Kunii 2004	Catheter Aspiration	Rescue PT	129	64 (11.8)	79.84	---	---	---	---	0	34.1	---	---	---	---	---	---
		Control	129	65.9 (11.1)	79.84	---	---	---	---	0	45.8	---	---	---	---	---	---
Nanasato 2004	Distal Balloon Embolic Protection	GuardWire	34	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	30	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Matsushita 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	24	63 (13)	83.33	---	---	0	100	---	---	---	---	---	---	---	---
		Control	56	63 (10)	76.79	---	---	0	100	---	---	---	---	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	30	55.9 (9.9)	73	80.00	291 (177)	10	35	23	30	---	17	53	60	57	---
		Control	31	53.9 (10.0)	77	74.19	279 (185)	10	35	10	32	---	13	36	58	55	---

*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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	30	25.01 (11.89)	---	10/30 (33)	13/30 (43)	---	---
		Control	37	31.98 (15.33)	---	3/37 (8)	26/37 (70)	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	100	---	---	---	---	Aspirin 500 mg IV and clopidogrel 600 mg load pre-PCI	Heparin 100 U/kg pre-PCI
		Control	100	---	---	---	---		
Sardella, 2005	Catheter Aspiration	Diver CE	28	---	28/28 (100)	---	28/28 (100)	---	Heparin
		Control	34	---	34/34 (100)	---	34/34 (100)	---	
Kunii, 2004	Catheter Aspiration	Rescue PT	129	---	129/129 (100)	---	---	---	---
		Control	129	---	129/129 (100)	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	34	---	---	---	---	---	---
		Control	32	---	---	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	24	---	---	---	---	---	---
		Control	56	---	---	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	30	---	---	14/30 (46.67)	22/30 (73)	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	STEMI: Heparin (ACT >300 s) pre-PCI and during intervention UA: low-molecular weight heparin pre-PCI and heparin during intervention (ACT >300 s)
		Control	31	---	---	2/31 (6.45)	21/31 (68)		

*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

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Webster 2008	Distal Filter Embolic Protection	FilterWire EZ	77	58 (11)	83	---	---	---	---	---	39	---	16	39	69	71	---
		Control	74	60 (13)	89	---	---	---	---	---	32	---	26	46	62	66	---
Dudek 2003	Distal Filter Embolic Protection	AngioGuard	15	59.4 (66.6)	66.6	---	---	60	---	---	---	---	0	40	26.0	---	---
		Control	16	49.3 (8.4)	62.5	---	---	50	---	---	---	---	0	62.5	31.0	---	---

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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	77	---	---	---	---	---	---
		Control	74	---	---	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	15	63 (17)	15/15 (100)	---	---	Aspirin 75 mg and ticlopidine 500 mg/d	Heparin 60 U/kg (ACT 200-300 s)
		Control	16	---	16/16 (100)	---	---		

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

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Sardella 2008	Catheter Aspiration	Diver Invatec catheter	52	64.6 (12.5)	78.8	100	414 (60)	0	---	0	46.1	100	26.9	63.4	---	42.3	23.0
	Catheter Aspiration	Export Medtronic	51	66.7 (14.1)	78.4	100	408 (54)	0	---	0	41.2	100	23.5	66.6	---	49.0	29.4
Yan 2007	Catheter Aspiration	Diver CE catheter	61	60 (14)	82	100	350 (185)	---	0	0	0	---	31	62	54	62	30
	Distal Balloon Embolic Protection	GuardWire Plus	61	60 (13)	84	100	345 (180)	---	0	0	0	---	28	57	56	61	23

*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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Sardella 2008	Catheter Aspiration	Diver Invatec catheter	52	---	52/52 (100)	32/52 (65.3)	52/52 (100)	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	Heparin (ACT >250 s) and continued for 48 hours post-PCI
	Catheter Aspiration	Export Medtronic	51	---	51/51 (100)	39/51 (76.4)	51/51 (100)		
Yan, 2007	Catheter Aspiration	Diver CE catheter	61	60 (24)	---	39/61 (64)	7/61 (11)	Aspirin 300 mg and clopidogrel 300-600 mg pre-PCI Aspirin 300 mg/d for 4 weeks then 100 mg/d and clopidogrel 75 mg/d for greater than 9-12 m	Heparin 8000-10000 U IV during PCI and low-molecular weight heparin for 1 week if needed post-PCI
	Distal Balloon Embolic Protection	GuardWire Plus	61	65 (28)	---	41/61 (67)	8/61 (13)		

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

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Wita, 2009	Catheter Aspiration	Diver CE	19	56.6 (10.9)	79	100	268 (197)	0	100	---	100	---	5.3	42.1	10.5	68.4	---
		Control	23	58.1 (10.8)	70.9	100	323 (183)	0	100	---	100	---	16.7	39.1	8.3	83.3	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	25	68 (9)	100	---	---	0	0	0	---	---	45	45	55	50	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire	24	60 (18)	100	---	---	0	0	0	---	---	45	50	65	55	---
		Control	28	66 (13)	100	---	---	0	0	0	---	---	40	50	65	65	---

*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

Study,Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Wita, 2009	Catheter Aspiration	Diver CE Control	19 23	39.5 (10.1) 32.3 (18.6)	19/19 (100) 23/23 (100)	--- ---	19/19 (100) 23/23 (100)	Aspirin and clopidogrel load pre-PCI	Heparin (ACT >200 s)
Ozaki, 2006	Catheter Aspiration Distal Balloon Embolic Protection	Rescue or Thrombuster systems PercuSurge GuardWire Control	25 24 28	--- --- ---	25/25 (100) 24/24 (100) 28/28 (100)	--- --- ---	--- --- ---	Aspirin 162 mg and ticlopidine 200 mg pre-PCI and post-PCI	Heparin 10,000 U intra-arterial pre-PCI and 20,000 U/d IV post-PCI

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

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Beaudoin, 2010	Catheter aspiration	Export Control	165 370	60 (11) 61(13)	76 70	88 62	--- ---	14 15	37 45	9.1 19.7	--- ---	--- ---	9 15	43 44	36 42	41 44	--- ---
Kim, 2010	Thrombus Aspiration	Thrombus Aspiration Control	429 429	62 (13) 62 (13)	77.6 72.7	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---
Ko, 2009	Distal Embolic Protection	Distal Protection Device Control	1050[†] ---	58(12)[‡] ---	72.5[‡] ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter Control	381 2917	--- ---	--- ---	--- ---	--- ---	--- ---	--- ---	0 0	--- ---	25.6 14.3	--- ---	--- ---	--- ---	--- ---	--- ---
Nakatani, 2007	Catheter Aspiration	Multiple devices[§] Control	990 2923	63.3 (11.7) 64.9 (11.4)	79.8 76.7	6.4 14.6	252 (288) 282 (330)	13.9 13.6	--- ---	0 0	40.0 47.0	--- ---	31.3 34.2	53.0 53.8	47.2 43.5	66.0 66.5	--- ---

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	239	62 (13)	60	---	---	13	30.1	16	30.5	---	15	49	56	47	---
		Control	1021	61 (13)	50	---	---	11	49.8	15	50.2	---	16	53	53	38	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	200	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	1168	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Beaudoin, 2010	Catheter Aspiration	Export	165	41.2*	---	---	88	68% and 61%	---
		Control	370	36.5	---	---	79	received clopidogrel loading dose of 600mg	---
Kim, 2010	Thrombus Aspiration	Thrombus Aspiration	429	---	---	---	38.5	63.9% and	---
		Control	429	---	---	---	38.5	63.4% received clopidogrel loading dose of 600mg	---
Ko, 2009	Catheter Aspiration	Aspiration Catheter	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---
Nilsen, 2009	Distal Embolic Protection	Distal Protection Device	381	---	---	155/381 (40.7)	---	---	---
		Control	2917	---	---	855/2917(29.3)	---	---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices*	990	---	784/990 (79.2)	---	---	---	---
		Control	2923	---	1789/2923 (61.2)	---	---	---	---

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	239	---	215/239 (90)	---	132/239 (55)	---	Heparin (ACT>250 s)
		Control	1021	---	878/1021 (86)	---	639/1021 (63)	---	
Simonton, 2006	Mechanical Thrombectomy	AngioJet	200	---	---	---	---	---	---
		Control	1168	---	---	---	---	---	---

*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

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)*	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	23	58 (10)	82.61	34.78	186 (186)	0	---	---	43	---	61	48	65	74	---
		Thrombuster	21	62 (8)	80.95	90.48	126 (78)	0	---	---	48	---	19	52	90	81	---

*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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA Thrombuster	23 21	57 (22) 64 (21)	23/23 (100) 21/21 (100)	--- ---	--- ---	Aspirin 100 mg and ticlopidine 100 mg pre-PCI and both for 6m post-PCI	Heparin 60 U/kg

Abbreviations: ACT=activated clotting time; GP2B3Ai=glycoprotein IIbIIIa inhibitor; IU=International Units; kg=kilogram; m=months; mg=milligram; MtPA=mutant plasminogen activator; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; s=seconds; SD=standard deviation; U=units

Table 37. Baseline characteristics of randomized controlled trials with unique comparisons in patients with mixed acute coronary syndrome

Study, Year	Device Category	Group	N	Mean Age (SD)	Male (%)	TIMI-0/1 (%)	Mean Ischemic Time in Minutes (SD)	Prior MI (%)	Anterior MI (%)	Failed TL (%)	IRA LAD (%)	Visible Lesion (%)	DM (%)	HTN (%)	HCL (%)	Smoker (%)	FHx (%)
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	57	57.75 (6.78)	52.63	84.2	360 (240-540)[†]	22.81	43.86	0	---	57.89	26.32	63.16	49.12	49.12	---
		Abciximab	63	58.71 (7.41)	71.43	77.8	360 (300-720)[†]	20.63	41.27	0	---	71.43	30.16	61.90	50.79	49.21	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	30	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Thrombectomy + Stenting	30	---	---	---	---	---	---	---	---	---	---	---	---	---	---

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

Study, Year	Device Category	Group	N	Mean Procedure Time in Minutes (SD)	Stenting n/N (%)	Direct Stenting n/N (%)	Procedural GP2B3Ai Use n/N (%)	Anti-platelet Drugs Used	Anti-thrombotic Drugs Used
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	57	58 (35-88)*	57/57 (100)	40/57 (57)	---	Aspirin 300 mg and clopidogrel 300 mg pre-PCI	Device group: heparin 100 IU/kg (ACT >300 s) Abciximab group: heparin 70 IU/kg (ACT >250 s)
		Abciximab	63	43 (25-87)*	63/63 (100)	41/63 (65.7)	63/63 (100)		
Kanaya, 2003	Thrombectomy + Distal protection device	Thrombectomy + stenting + distal protection device	30	---	30/30 (100)	---	---	---	---
		Thrombectomy + stenting	30	---	30/30 (100)	---	---	---	---

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

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Dudek, 2010	Diver CE	Death	3/100	---	4/100	---
	Control		3/96	---	3/96	---
Liistro, 2009	Export Thrombectomy Catheter	Cardiac death	---	---	1/55	---
	Control		---	---	0/56	---
Lipiecki, 2009	Export Catheter	---	---	---	---	---
	Control		---	---	---	---
Moura, 2009	TAC	---	---	---	---	---
	Control		---	---	---	---
Sardella, 2009	Export Medtronic (EM)	Death	0/88	0/88	0/88[*]	0/88[#]
	Control	720-day: cardiac death	1/87	1/87	1/87[*]	6/87[#]
Chao, 2008	Export Aspiration Catheter	Death	---	---	1/37	---
	Control		---	---	0/34	---
Chevalier, 2008	Export Aspiration Catheter	Cardiac+ non-cardiac death	---	4/120	---	---
	Control		---	5/129	---	---
Ciszewski, 2008	Rescue/Diver	Death	5/135[†]	---	---	---
	Control			---	---	---
Ikari, 2008	TVAC	Death	1/178	---	2/170[‡]	---
	Control		1/171	---	1/158[‡]	---
Svilaas, 2008	6F Export Aspiration Catheter	Death	---	11/529	---	25/535**
	Control		---	21/531	---	41/536**
DeLuca, 2006	Diver CE	Death	---	---	0/35	2/20*
	Control		---	---	2/38	4/28*
Kaltoft, 2006	Rescue Catheter	Death	---	0/108	---	---
	Control		---	1/107	---	---
Lee, 2006	Export Aspiration Catheter	---	---	---	---	---
	Control		---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	Death	0/74	---	0/74	---
	Control		0/74	---	0/70	---
Burzotta, 2005	Diver CE	Death	1/48[§]	3/48	---	---
	Control		2/48[§]	3/48	---	---

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Noel, 2005	Export	Death	1/48[‖]	---	---	---
	Control		2/48[‖]	---	---	---
Dudek, 2004	Rescue System	Death	0/24[¶]	---	---	---
	Control		1/26[¶]	---	---	---

*270-day data; [†]3-7 days post PCI in the both the groups together; [‡]240-day data; [§]In the catheterization lab; [‖]Post-PCI; [¶]Time period not specified; [#]730-day data; **365-day data
Abbreviations: n=number; N=number of participants in the group; TAC=Thrombectomy Aspiration Catheter; TVAC=Transvascular aspiration catheter

Table 40. Mortality in randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Migliorini, 2010	AngioJet Rheolytic Thrombectomy	Death	---	4/256	7/251	7/221*
	Control		---	7/245	11/242	14/220*
Ali, 2006	AngioJet Catheter	Death independent of MACE at 30 days	---	11/240	14/24	---
	Control	Death at 6 months	---	2/240	5/240	---
Lefèvre, 2005	X-Sizer Catheter	Death	---	4/100	6/100	---
	Control		---	4/101	4/101	---
Antoniucci, 2004	AngioJet	Death	---	0/50	---	---
	Control		---	0/50	---	---
Napodano, 2003	X-Sizer Catheter	Death	3/46	3/46	---	---
	Control		3/46	3/46	---	---

*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

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Ito, 2010	Filtrap	Death	---	0/19	---	---
	Control		---	1/17	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	Death	---	8/312	---	13/312*
	Control		---	8/314	---	15/314*
Cura, 2007	SpideRX	Death	---	4/70	5/70	---
	Control		---	4/70	4/70	---
Guetta, 2007	FilterWire EZ	Death	---	2/51	---	---
	Control		---	0/49	---	---
Lefèvre, 2004	AngioGuardXP	Death	---	1/32	---	---
	Control		---	1/28	---	---

*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

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---	---
	Control		---	---	---	---
Pan, 2010	PercuSurge Guardwire	---	---	---	---	---
	Control		---	---	---	---
Tahk, 2008	PercuSurge GuardWire	Death	---	0/54	0/54	---
	Control		---	2/52	2/52	---
Hahn, 2007	GuardWire	Death	---	---	0/19	---
	Control		---	---	1/20	---
Matsuo, 2007	GuardWire Distal Protection System	Cardiac death	---	1/80	1/80	---
	Control		---	2/74	3/74	---
Muramatsu, 2007	GuardWire Plus System	Death	5/173	5/173	11/173	---
	Control		7/168	7/168	11/168	---
Zhou, 2007	PercuSurge GuardWire	---	---	---	---	---
	Control		---	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---	---
	Control		---	---	---	---

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Stone, 2005	GuardWire Plus	Death	---	5/246	8/243	---
	Control		---	7/244	8/233	---

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

Study, Year	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Haeck, 2009	Proxis	Death	---	2/141	2/141	---
	Control		---	2/143	4/143	---

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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	Death	1/30	---	---	1/30*
		Control		---	1/37	---	4/37*
Gick, 2005	Distal Filter Embolic Protection	FilterWire	Death	---	2/100	3/100	---
		Control		---	3/100	3/100	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control		---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	Death	2/129	---	---	---
		Control		2/129	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---	---
		Control		---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	Death	0/24	---	---	---
		Control		3/56	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	Death	---	2/33	---	---
		Control		---	1/33	---	---

*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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---	---
		Control		---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	---	0/15	---	---
		Control		---	0/16	---	---

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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Sardella, 2008	Catheter Aspiration Catheter Aspiration	Diver Invatec catheter Export Medtronic	Cardiac death	---	2/52	---	2/50*
				---	3/51	---	0/48*
Yan, 2007	Catheter Aspiration Distal Balloon Embolic Protection	Diver CE catheter GuardWire Plus	Death	---	2/61	---	---
				---	2/61	---	---

*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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control		---	---	---	---
Ozaki, 2006	Catheter Aspiration Distal Balloon Embolic Protection	Rescue or Thrombuster systems	---	---	---	---	---
		PercuSurge GuardWire		---	---	---	---
		Control		---	---	---	---

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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	Death	---	---	0/19	---
		Thrombuster		---	---	0/14	---

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

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	Death	---	---	0/57	---
		Abciximab		---	---	0/63	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---	---
		Thrombectomy+ Stenting		---	---	---	---

Abbreviations: n=number; N=number of participants in the group

Table 50. Mortality in observational studies

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Beaudoin, 2010	Catheter aspiration	Export	Death	---	8/164	---	9/154
		Control			16/370		26/353
Kim, 2010	Catheter Aspiration	Thrombus Aspiration	Death	22/429	---	---	---
		Control		19/429	---	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---	---
		Control		---	---	---	---
Nilsen, 2009*	Catheter Aspiration	Aspiration Catheter	Death	---	10/381	---	---
		Control		---	70/2917	---	---
Nilsen, 2009*	Catheter Aspiration	Aspiration Catheter	Cardiac death	---	10/381	---	---
		Control		---	64/2917	---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices[†]	Death	---	37/990	---	---
		Control		---	180/2923	---	---

Study, Year	Device Category	Group	Mortality definition	In-hospital mortality n/N	30-day mortality n/N	180-day mortality n/N	365-day mortality n/N
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	Death	7/239	---	---	---
		Control		55/1021	---	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	Death	---	---	10/200‡	---
		Control		---	---	76/1168‡	---

*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

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Dudek, 2010	Diver CE	0/100	---	1/100	---
	Control	1/96	---	3/96	---
Liistro, 2009	Export Thrombectomy Catheter	---	---	3/55	---
	Control	---	---	3/56	--
Lipiecki, 2009	Export Catheter	---	---	---	---
	Control	---	---	---	---
Moura, 2009	TAC	---	---	---	---
	Control	---	---	---	---
Sardella, 2009	Export Medtronic (EM)	0/88	0/88	0/88	0/88*
	Control	0/87	0/87	0/87	1/87*
Chao, 2008	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Chevalier, 2008	Export Aspiration Catheter	---	2/120	---	---
	Control	---	1/129	---	---
Ciszewski, 2008	Rescue/Diver	---	---	---	---
	Control	---	---	---	---
Ikari, 2008	TVAC	0/178	---	0/170†	---
	Control	1/171	---	1/158†	---
Svilaas, 2008	6F Export Aspiration Catheter	---	4/529	---	12/535‡
	Control	---	10/531	---	23/536‡
DeLuca, 2006	Diver CE	---	---	1/35	---
	Control	---	---	0/38	---
Kaltoft, 2006	Rescue Catheter	---	0/108	---	---
	Control	---	1/107	---	---

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Lee, 2006	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	0/74	---	0/74	---
	Control	074	---	1/7	---
Burzotta, 2005	Diver CE	---	2/48	---	---
	Control	---	2/48	---	---
Noel, 2005	Export	---	---	---	---
	Control	---	---	---	---
Dudek, 2004	Rescue System	---	---	---	---
	Control	---	---	---	---

*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

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	---	2/256	2/251	2/22*
	Control	---	3/245	3/242	3/220*
Ali, 2006	AngioJet Catheter	---	0/240	---	---
	Control	---	0/240	---	---
Lefèvre, 2005	X-Sizer Catheter	---	1/100	2/100	---
	Control	---	3/101	4/101	---
Antoniucci, 2004	AngioJet	---	0/50	---	---
	Control	---	0/50	---	---
Napodano, 2003	X-Sizer Catheter	0/46	2/46	---	---
	Control	0/46	2/46	---	---

*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

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Ito, 2010	Filtrap	---	0/19	---	---
	Control	---	0/17	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	---	5/312	---	7/312*
	Control	---	1/314	---	3/314*
Cura, 2007	SpideRX	---	0/70	0/70	---
	Control	---	5/70	5/70	---
Guetta, 2007	FilterWire EZ	---	0/51	---	---
	Control	---	1/49	---	---
Lefèvre, 2004	AngioGuardXP	---	1/32	---	---
	Control	---	1/28	---	---

*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

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---
	Control	---	---	---	---
Pan, 2010	PercuSurge Guardwire	---	---	---	---
	Control	---	---	---	---
Tahk, 2008	PercuSurge GuardWire	---	1/54	1/54	---
	Control	---	0/52	1/52	---
Hahn, 2007	GuardWire	---	---	0/19	---
	Control	---	---	1/20	---
Matsuo, 2007	GuardWire Distal Protection System	---	1/80	1/80	---
	Control	---	0/74	0/74	---
Muramatsu, 2007	GuardWire Plus System	0/173	0/173	0/173	---
	Control	1/168	1/168	1/168	---
Zhou, 2007	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Stone, 2005	GuardWire Plus	---	5/246	6/243	---
	Control	---	7/244	9/233	---

Abbreviations: n=number; N=number of participants in the group

Table 55. Myocardial infarction in randomized controlled trials evaluating proximal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Haeck, 2009	Proxis	---	2/141	3/141	---
	Control	---	3/143	3/143	---

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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	1/30	---	---	---
		Control	---	---	---	---
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	---	---	3/57	---
		Abciximab	---	---	2/63	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	---	0/100	0/100	---
		Control	---	0/100	0/100	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---
		Control	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---
		Control	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---
		Control	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	0/15	---	---
		Control	---	0/16	---	---

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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	---	0/52	---	1/50*
	Catheter Aspiration	Export Medtronic	---	0/51	---	1/48*
Yan, 2007	Catheter Aspiration	Diver CE catheter	---	1/61	---	---
	Distal Balloon Embolic Protection	GuardWire Plus	---	0/61	---	---

*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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	---	---	---	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	---	---	1/19	---
		Thrombuster	---	---	0/14	---

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

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	---	---	3/57	---
		Abciximab	---	---	2/63	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---
		Thrombectomy+ Stenting	---	---	---	---

Abbreviations: n=number; N=number of participants in the group

Table 62. Myocardial infarction in observational studies

Study, Year	Device Category	Group	In-hospital myocardial infarction n/N	30-day myocardial infarction n/N	180-day myocardial infarction n/N	365-day myocardial infarction n/N
Beaudoin, 2010	Catheter aspiration	Export	**---**	2/164	---	6/154
		Control	**---**	2/370		5/353
Kim, 2010	Catheter Aspiration	Thrombus Aspiration	---	---	---	---
		Control	---	---	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---
		Control	---	---	---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter	---	5/381	---	---
		Control	---	55/2917	---	---

Nakatani, 2007	Catheter Aspiration	Multiple devices*	---	---	---	---
		Control	---	---	---	---
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	6/239	---	---	---
		Control	10/1021	---	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	---	---	8/200	---
		Control	---	---	25/1168	---

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter
Abbreviations: n=number; N=number of participants in the group

Table 63. Stroke in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Dudek, 2008	Diver CE	---	---	---	---
	Control	---	---	---	---
Liistro, 2009	Export Thrombectomy Catheter	---	---	---	---
	Control	---	---	---	---
Lipiecki, 2009	Export Catheter	---	---	---	---
	Control	---	---	---	---
Moura, 2009	TAC	---	---	---	---
	Control	---	---	---	---
Sardella, 2009	Export Medtronic (EM)	2/88	---	---	---
	Control	0/87	---	---	---
Chao, 2008	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Chevalier, 2008	Export Aspiration Catheter	---	2/120	---	---
	Control	---	0/129	---	---
Ciszewski, 2008	Rescue/Diver	---	---	---	---
	Control	---	---	---	---
Ikari, 2008	TVAC	---	---	---	---
	Control	---	---	---	---
Svilaas, 2008	6F Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
DeLuca, 2006	Diver CE	---	---	---	---
	Control	---	---	---	---
Kaltoft, 2006	Rescue Catheter	---	2/108	---	---
	Control	---	0/107	---	---
Lee, 2006	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	---	---	0/74	---
	Control	---	---	0/70	---

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Burzotta, 2005	Diver CE	---	1/48	---	---
	Control	---	1/48	---	---
Noel, 2005	Export	---	---	---	---
	Control	---	---	---	---
Dudek, 2004	Rescue System	---	---	---	---
	Control	---	---	---	---

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

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	---	0/256	1/251	2/221*
	Control	---	1/245	1/242	1/220*
Ali, 2006	AngioJet Catheter	---	4/240	---	---
	Control	---	2/240	---	---
Lefèvre, 2005	X-Sizer Catheter	---	2/100	2/100	---
	Control	---	0/101	0/101	---
Antoniucci, 2004	AngioJet	---	1/50	---	---
	Control	---	0/50	---	---
Napodano, 2003	X-Sizer Catheter	0/46	0/46	---	---
	Control	0/46	0/46	---	---

*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**

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Ito, 2010	Filtrap	---	---	---	---
	Control	---	---	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	---	3/312	---	---
	Control	---	2/314	---	---
Cura, 2007	SpideRX	---	---	---	---
	Control	---	---	---	---

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Guetta, 2007	FilterWire EZ	---	---	---	---
	Control	---	---	---	---
Lefèvre, 2004	AngioGuardXP	---	---	---	---
	Control	---	---	---	---

Abbreviations: n=number; N=number of participants in the group

Table 66. Stroke in randomized controlled trials evaluating distal balloon embolic protection devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---
	Control	---	---	---	---
Pan, 2010	PercuSurge Guardwire	---	---	---	---
	Control	---	---	---	---
Tahk, 2008	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Hahn, 2007	GuardWire	---	---	---	---
	Control	---	---	---	---
Matsuo, 2007	GuardWire Distal Protection System	---	---	---	---
	Control	---	---	---	---
Muramatsu, 2007	GuardWire Plus System	---	---	---	---
	Control	---	---	---	---
Zhou, 2007	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Stone, 2005	GuardWire Plus	---	0/246	2/243	---
	Control	---	4/244	4/233	---

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**

Study, Year	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Haeck, 2009	Proxis	---	0/141	0/141	---
	Control	---	1/143	2/143	---

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**

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	---	---	---	---
		Control	---	---	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	---	0/100	---	---
		Control	---	0/100	---	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---
		Control	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---
		Control	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	---	---	---
		Control	---	---	---	---

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**

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---
		Control	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	---	---	---	---
	Catheter Aspiration	Export Medtronic	---	---	---	---
Yan, 2007	Catheter Aspiration	Diver CE catheter	---	0/61	---	---
	Distal Balloon Embolic Protection	GuardWire Plus	---	0/61	---	---

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

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Ozaki, 2006	Catheter Aspiration Distal Balloon Embolic Protection	Rescue or Thrombuster systems PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	---	---	0/19	---
		Thrombuster	---	---	0/14	---

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

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	---	---	---	---
		Abciximab	---	---	---	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---
		Thrombectomy+ Stenting	---	---	---	---

Abbreviations: n=number; N=number of participants in the group

Table 74. Stroke in observational studies

Study, Year	Device Category	Group	In-hospital stroke n/N	30-day stroke n/N	180-day stroke n/N	365-day stroke n/N
Beaudoin, 2010	Catheter aspiration	Export	---	0/164	---	0/154
		Control		0/370		2/353
Kim, 2010	Catheter Aspiration	Thrombus Aspiration	---	---	---	---
		Control	---	---	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---
		Control	---	---	---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter	---	5/381	---	---
		Control	---	12/2917	---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices*	---	---	---	---
		Control	---	---	---	---
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	1/239	---	---	---
		Control	5/1021	---	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	---	---	---	---
		Control	---	---	---	---

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter
Abbreviations: n=number; N=number of participants in the group

Table 75. Target revascularization in randomized controlled trials evaluating catheter aspiration devices versus control **in patients with ST-segment elevation myocardial infarction**

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Dudek, 2010	Diver CE Control	In-hospital: Re-PCI (TVR, TLR, non-infarct involved vessel or CABG) 180d: TLR	2/100 1/96	--- ---	0/100 1/96	--- ---
Liistro, 2009	Export Thrombectomy Catheter Control	TLR	--- ---	--- ---	4/55 4/56	--- ---
Lipiecki, 2009	Export Catheter Control	--- ---	--- ---	--- ---	--- ---	--- ---
Moura, 2009	TAC Control	--- ---	--- ---	--- ---	--- ---	--- ---
Sardella, 2009	Export Medtronic (EM) Control	TVR	--- ---	0/88 0/87	5/87* 0/88*	4/88† 5/87†
Chao, 2008	Export Aspiration Catheter Control	TVR	--- ---	--- ---	3/37 4/37	--- ---
Chevalier, 2008	Export Aspiration Catheter Control	TLR+TVR	--- ---	2/120 1/129	--- ---	--- ---
Ciszewski, 2008	Rescue/Diver Control	--- ---	--- ---	--- ---	--- ---	--- ---
Ikari, 2008	TVAC Control	TLR	0/178 1/171	--- ---	20/170‡ 31/158‡	--- ---
Svilaas, 2008	6F Export Aspiration Catheter Control	TVR	--- ---	24/529 31/531	--- ---	60/535§ 69/536§
DeLuca, 2006	Diver CE Control	--- ---	--- ---	--- ---	--- ---	--- ---
Kaltoft, 2006	Rescue Catheter Control	--- ---	--- ---	--- ---	--- ---	--- ---
Lee, 2006	Export Aspiration Catheter Control	--- ---	--- ---	--- ---	--- ---	--- ---
Silva-Orrego, 2006	Pronto Extraction Catheter Control	TVR	1/74 0/74	--- ---	1/74 2/70	--- ---

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Burzotta, 2005	Diver CE	TLR	---	1/48	---	---
	Control		---	1/48	---	---
Noel, 2005	Export	---	---	---	---	---
	Control	---	---	---	---	---
Dudek, 2004	Rescue System	---	---	---	---	---
	Control	---	---	---	---	---

*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**

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	TVR	---	2/256	18/251	22/221*
	Control		---	6/245	32/242	32/220*
Ali, 2006	AngioJet Catheter	TLR or sub-acute thrombosis	---	5/240	---	---
	Control		---	1/240	---	---
Lefèvre, 2005	X-Sizer Catheter	TVR	---	2/100	3/100	---
	Control		---	0/101	5/101	---
Antoniucci, 2004	AngioJet	TVR	---	0/50	---	---
	Control		---	0/50	---	---
Napodano, 2003	X-Sizer Catheter	TVR	0/46	0/46	---	---
	Control		0/46	0/46	---	---

*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

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Ito, 2010	Filtrap	TLR	---	0/19	---	---
	Control		---	0/17	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	TLR	---	6/312	---	39/312*
	Control		---	2/314	---	22/314*
Cura, 2007	SpideRX	Revascularization	---	---	6/70	---
	Control		---	---	6/70	---
Guetta, 2007	FilterWire EZ	---	---	---	---	---
	Control	---	---	---	---	---
Lefèvre, 2004	AngioGuardXP	---	---	---	---	---
	Control	---	---	---	---	---

*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**

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Tahk, 2008	PercuSurge GuardWire	TVR	---	1/54	3/54	---
	Control		---	1/52	2/52	---
Hahn, 2007	GuardWire	TLR	---	---	0/19	---
	Control		---	---	2/20	---
Matsuo, 2007	GuardWire Distal Protection System	TVR	---	---	5/80	---
	Control		---	---	9/74	---
Muramatsu, 2007	GuardWire Plus System	TLR	0/173	0/173	17/173	---
	Control		1/168	1/168	16/168	---
Zhou, 2007	PercuSurge GuardWire	---	---	---	---	---
	Control		---	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---	---
	Control		---	---	---	---
Stone, 2005	GuardWire Plus	TVR	---	9/246	15/243	---
	Control		---	6/244	13/233	---

Abbreviations: n=number; N=number of participants in the group; TLR=target lesion revascularization; TVR=target vessel revascularization

Table 79. Target revascularization in randomized controlled trials evaluating proximal balloon embolic protection device versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Haeck, 2009*	Proxis	Urgent	---	2/141	6/141	---
	Control	percutaneous TVR	---	4/143	7/143	---
Haeck, 2009*	Proxis	Urgent	---	2/141	5/141	---
	Control	percutaneous TLR	---	3/143	5/143	---
Haeck, 2009*	Proxis	Surgical TVR	---	1/141	1/141	---
	Control		---	2/143	3/143	---

*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**

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	TVR	0/30*	---	---	---
		Control		---	---	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	Revascularization	---	0/100	---	---
		Control		---	0/100	---	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control	---	---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---	---
		Control	---	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---	---
		Control	---	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---	---
		Control	---	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	0/33	---	---	---
		Control	---	1/33	---	---	---

*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

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---	---
		Control	---	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	Revascularization	---	0/15	---	---
		Control		---	0/16	---	---

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

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	TVR	---	0/52	---	3/50*
	Catheter Aspiration	Export Medtronic		---	0/51	---	2/48*
Yan, 2007	Catheter Aspiration	Diver CE catheter	TVR	---	1/61	---	---
	Distal Balloon Embolic Protection	GuardWire Plus		---	1/61	---	---

*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

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control	---	---	---	---	---

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Ozaki, 2006	Catheter Aspiration Distal Balloon Embolic Protection	Rescue or Thrombuster systems PercuSurge GuardWire Control	---	---	---	---	---
			---	---	---	---	---

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

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	Re-intervention of IRA	---	---	4/19	---
		Thrombuster		---	---	4/14	---

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

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	Re-PCI	---	---	8/57	---
		Abciximab		---	---	8/63	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---	---
		Thrombectomy+ Stenting	---	---	---	---	---

Abbreviations: n=number; N=number of participants in the group

Table 86. Target revascularization in observational studies

Study, Year	Device Category	Group	Target revascularization definition	In-hospital target revascularization n/N	30-day target revascularization n/N	180-day target revascularization n/N	365-day target revascularization n/N
Beaudoin, 2010	Catheter aspiration	Export Control	Any unplanned PCI performed for recurrent symptoms	--- ---	4/164 7/370	---	12/154 25/353
Kim, 2010	Catheter Aspiration	Thrombus Aspiration Control	---	--- ---	--- ---	--- ---	
Ko, 2009	Distal Embolic Protection	Distal Protection Device Control	---	--- ---	--- ---	--- ---	--- ---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter Control	TVR	--- ---	7/381 73/2917	--- ---	--- ---
Nakatani, 2007	Catheter Aspiration	Multiple devices* Control	---	--- ---	--- ---	--- ---	--- ---
Chinnaiyan, 2006	Mechanical thrombectomy	AngioJet XMI or XVG Catheter Control	TVR	5/239 28/1021	--- ---	--- ---	--- ---
Simonton, 2006	Mechanical Thrombectomy	AngioJet Control	TVR	--- ---	--- ---	11/200† 56/1168†	--- ---

*Rescue Catheter, Trombuster 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**

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Dudek, 2010	Diver CE Control	Mortality, reinfarction, rePCI	5/100 5/96	--- ---	5/100§ 6/96§	--- ---
Liistro, 2009	Export Thrombectomy Catheter Control	---	--- ---	--- ---	8/55 7/56	--- ---
Lipiecki, 2009	Export Catheter Control	---	--- ---	--- ---	--- ---	--- ---

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Moura, 2009	TAC	---	---	---	---	---
	Control		---	---	---	---
Sardella, 2009	Export Medtronic (EM)	Cardiac mortality, nonfatal reinfarction and TVR	2/88[*]	0/88	4/88[†]	4/88[‡]
	Control		1/87[*]	1/87	9/87[†]	12/87[‡]
Chevalier, 2008	Export Aspiration Catheter	Mortality, reinfarction, emergent bypass surgery, TLR or CVA	---	7/120	---	---
	Control		---	6/129	---	---
Chao, 2008	Export Aspiration Catheter	Mortality, stroke, non fatal reinfarction, TVR	---	---	5/37	---
	Control		---	---	10/37	---
Ciszewski, 2008	Rescue/Diver	---	---	---	---	---
	Control		---	---	---	---
Ikari, 2008	TVAC	Mortality, recurrence of MI and TLR	1/178	---	22/170[‖]	36/180[#]
	Control		2/171	---	33/158[‖]	62/175[#]
Svilaas, 2008	6F Export Aspiration Catheter	Mortality, reinfarction or TVR	---	36/529	---	89/535[**]
	Control		---	50/531	---	109/536[**]
DeLuca, 2006	Diver CE	Mortality, new onset MI, and hospitalization for CHF	---	---	3/35	---
	Control		---	---	4/38	---
Kaltoft, 2006	Rescue Catheter	Mortality, reinfarction, disabling stroke	---	2/108	---	---
	Control		---	2/107	---	---
Lee, 2006	Export Aspiration Catheter	---	---	---	---	---
	Control		---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	---	---	---	---	---
	Control		---	---	---	---
Burzotta, 2005	Diver CE	Major adverse events	---	5/48	---	---
	Control		---	5/48	---	---
Noel, 2005	Export	---	1/24[††]	---	---	---
	Control		2/26[††]	---	---	---
Dudek, 2004	Rescue System	---	---	---	---	---
	Control		---	---	---	---

[§]Reinfarction and mortality; *Cardiac Mortality, non fatal reinfarction, TVR and stroke; [†]270-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**

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	Mortality, MI, TVR, stroke	---	8/256	28/251	33/22*
	Control		---	17/245	47/242	50/220*
Ali, 2006	AngioJet Catheter	Mortality, new Q wave MI , emergent CABG, TLR, stroke, stent thrombosis	---	16/240	---	---
	Control		---	4/240	---	---
Lefèvre, 2005	X-Sizer Catheter	Major adverse cardiac and cerebral events	---	9/100	13/100	---
	Control		---	7/101	13/101	---
Antoniucci, 2004	AngioJet	---	---	0/50	---	---
	Control		---	0/50	---	---
Napodano, 2003	X-Sizer Catheter	---	---	---	---	---
	Control		---	---	---	---

*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**

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Ito, 2010	Filtrap	Mortality,MI ,TLR	---	0/19	---	---
	Control		---	1/17	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	Mortality, TLR, reinfarction, stroke	---	17/312	22/312*	59/312†
	Control		---	10/314	18/314*	40/314†
Cura, 2007	SpideRX	Mortality, reinfarction, HF	---	10/70	10/70	---
	Control		---	10/70	11/70	---
Guetta, 2007	FilterWire EZ	Mortality, non fatal MI, CHF	---	3/51	---	---
	Control		---	1/49	---	---
Lefèvre, 2004	AngioGuardXP	Mortality and MI	---	2/32	---	---
	Control		---	2/28	---	---

*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**

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---	---
	Control		---	---	---	---
Pan, 2010	PercuSurge Guardwire	---	---	---	---	---
	Control		---	---	---	---
Tahk, 2008	PercuSurge GuardWire	Mortality, reinfarction and ischemia driven TVR	---	2/54	4/54	---
	Control		---	2/52	5/52	---
Hahn, 2007	GuardWire	Mortality, MI and TLR	---	---	0/19	---
	Control		---	---	4/20	---
Matsuo, 2007	GuardWire Distal Protection System	Mortality, non lethal MI, heart failure, ischemia-driven revascularization	---	3/80	10/80	---
	Control		---	3/74	12/74	---
Muramatsu, 2007	GuardWire Plus System	Mortality, myocardial infarction or TLR	5/173	5/173	28/173	---
	Control		9/168	9/168	28/168	---
Zhou, 2007	PercuSurge GuardWire	---	0/52	---	---	---
	Control		0/60	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---	---
	Control		---	---	---	---
Stone, 2005*	GuardWire Plus	MACE related to ischemic complications	---	14/246	24/243	---
	Control		---	18/244	26/233	---
Stone, 2005*	GuardWire Plus	MACE related to LV dysfunction	---	36/246	40/243	---
	Control		---	32/244	35/233	---

*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**

Study, Year	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Haeck, 2009	Proxis	Mortality, spontaneous or procedural	---	6/141	11/141	---
	Control	MI, stroke, percutaneous or surgical TVR	---	10/143	15/143	---

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**

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	---	---	---	---	---
		Control		---	---	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	---	---	---	13/100	---
		Control		---	---	12/100	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control		---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---	---
		Control		---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---	---
		Control		---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	1/24	---
		Control		---	---	7/56	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	---	2/33	---	---
		Control		---	2/33	---	---

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**

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	Mortality, recurrent MI, emergent CABG, repeat TVR	9/77	9/77	---	---
		Control		7/74	8/74	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	---	---	---	---
		Control		---	---	---	---

Abbreviations: CABG=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

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	Cardiac mortality, Q and non Q	---	2/52	---	5/50*
	Catheter Aspiration	Export Medtronic	wave MI, TVR	---	3/51	---	2/48*
Yan, 2007	Catheter Aspiration	Diver CE catheter	Mortality,	---	4/61	---	---
	Distal Balloon Embolic Protection	GuardWire Plus	MI,TVR, stroke	---	3/61	---	---

*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

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---	---
		Control		---	---	---	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	---	---	---	---	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire		---	---	---	---
		Control		---	---	---	---

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

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	---	---	---	---	---
		Thrombuster		---	---	---	---

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

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire Abciximab	---	---	---	---	---
				---	---	---	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---	---
		Thrombectomy+ Stenting		---	---	---	---

Abbreviations: MACE=major adverse cardiac events; n=number; N=number of participants in the group

Table 98. Major adverse cardiac events in observational studies

Study, Year	Device Category	Group	MACE definition	In-hospital MACE n/N	30-day MACE n/N	180-day MACE n/N	365-day MACE n/N
Beaudoin, 2010	Catheter aspiration	Export Control	Death, reinfarction, revascularization, stroke	---	14/164 25/370	---	21/154 52/353
Kim, 2010	Catheter Aspiration	Thrombus Aspiration Control	---	---	---	---	---
			---	---	---	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device Control	---	---	---	---	---
				---	---	---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter Control	Mortality, re-infarction, TVR for ischemia, stroke	---	21/381	---	---
				---	155/2917	---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices* Control	---	---	---	---	---
				---	---	---	---
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter Control	Mortality, re-infarction, TVR, stroke	18/239	---	---	---
				92/1021	---	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet Control	Mortality, MI, TVR, stent thrombosis, stroke, peripheral vascular event	---	---	28/200[†]	---
				---	---	136/1168[†]	---

*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**

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)			60 minutes after PCI			90 minutes after PCI			Other Times after PCI		
			70%	**<30% >70%**	**30-Others**		**<30% >70%**	**30-70% Others**		**<30% >70%**	**30-70% Others**		**<30% Others**	**30-70%**	**>70%**
Dudek, 2010	Diver CE	50/100		---	---		---	---		---	---	---	---	---	---
	Control	39/96		41/98	---		52/96	---		---			---		
				---	---		---	---		---	---	---	---	---	---
				25/96	---		34/96	---		---			---		
Liistro, 2009	Export Thrombectomy Catheter	39/55		---	---		---	---	--	---	---	39/55	---	---	---
	Control	22/56		---	---	-	---			---			---		
				---	---		---	---	--	---	---	22/56	---	---	---
				---	---	-	---			---			---		
Lipiecki, 2009	Export Catheter	11/19		---	---		---	---	--	3/19	5/19	11/19	2/19†	2/19†	15/19†
	Control	11/24		---	---	-	---			---			---		
				---	---		---	---	--	6/21	4/21	11/21	3/21†	7/21†	12/21†
				---	---	-	---			---			---		
Moura, 2009	TAC	67/76		---	---		---	---	--	---	---	---	---	---	67/76‡
	Control	33/76		---	---	-	---			---			---		
				---	---		---	---	--	---	---	---	---	---	33/76‡
				---	---	-	---			---			---		

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)	60 minutes after PCI	90 minutes after PCI	Other Times after PCI
Sardella, 2009	Export Medtronic (EM) Control	70/88 34/87	**70%** **<30% >70%** **30-Others** --- --- --- --- --- --- --- ---	**<30% >70%** **30-70% Others** --- --- - --- --- --- - ---	**<30% >70%** **30-70% Others** --- --- --- --- --- ---	**<30% Others** **30-70%** **>70%** --- --- --- --- --- --- --- ---
Chao, 2008	Export Aspiration Catheter Control	--- ---	**70%** **<30% >70%** **30-Others** --- --- --- --- --- --- --- ---	**<30% >70%** **30-70% Others** --- --- - --- --- --- - ---	**<30% >70%** **30-70% Others** --- --- --- --- --- --- --- ---	**<30% Others** **30-70%** **>70%** --- --- --- --- --- --- --- ---
Chevalier, 2008	Export Aspiration Catheter Control	88/120 84/129	**70%** **<30% >70%** **30-Others** --- --- --- --- --- --- --- ---	**<30% >70%** **30-70% Others** --- --- - 88/120[§] --- --- - 88/129[§]	**<30% >70%** **30-70% Others** --- --- --- --- --- --- --- ---	**<30% Others** **30-70%** **>70%** --- --- --- --- --- --- --- ---
Ciszewski, 2008	Rescue/Diver Control	--- ---	**70%** **<30% >70%** **30-Others** --- --- --- --- --- --- --- ---	**<30% >70%** **30-70% Others** --- --- - --- --- --- - ---	**<30% >70%** **30-70% Others** --- --- --- --- --- --- --- ---	**<30% Others** **30-70%** **>70%** --- --- --- --- --- --- --- ---

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
Ikari, 2008	TVAC	37/115	**70%**	**<30% >70%**	**30-70% Others**			**<30% >70%**	**30-70% Others**			**<30% >70%**	**30-70% Others**			**<30% Others**	**30-70%**	**>70%**
	Control	28/105		39/115	39/115		-	---	---	--		---	---	---		31/113[‖]	36/113[‖]	
				37/115	---			---				---				46/113[‖]	---	
				43/105	34/105			---	---	--		---	---	---		25/105[‖]	39/105[‖]	
				28/105	---		-	---				---				41/105[‖]	---	
Svilaas, 2008	6F Export Aspiration Catheter	275/486	**70%**	**<30% >70%**	**30-70% Others**			**<30% >70%**	**30-70% Others**			**<30% >70%**	**30-70% Others**			**<30% Others**	**30-70%**	**>70%**
				---	---			---	---	--		---	---	---		61/486[¶]	150/486[¶]	
	Control	219/496		---	---		-	---				---				275/486[¶]		---
				---	---			---	---	--		---	---	---		89/496[¶]	188/496[¶]	
				---	---		-	---				---				219/496[¶]	---	
DeLuca, 2006	Diver CE	31/38	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
	Control	21/38	---	---	---	--	---	---	---	---	---	---	31/38	---	---	---	---	---
			---	---	---	--	---	---	---	---	---	---	21/38	---	---	---	---	---
Kaltoft, 2006	Rescue Catheter	37/93	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
			43/97	32/97	22/97	--	---	---	---	---	22/93	34/93	37/93	---	16/80[#]	29/80[#]	35/80[#]	---
	Control	34/89	48/91	23/91	20/91	--	---	---	---	---	25/89	30/89	34/89	---	26/79[#]	24/79[#]	29/79[#]	---
Lee, 2006	Export Aspiration Catheter	40/67	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
			---	---	---	--	---	---	---	---	---	---	---	---	---	---	---	40/67[‡§]
	Control	24/66	---	---	---	--	---	---	---	---	---	---	---	---	---	---	---	24/66[‡§]
Silva-Orrego, 2006	Pronto Extraction Catheter	50/74	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
			---	---	---	--	---	---	---	---	---	---	---	---	3/74[‡]	21/74[‡]	50/74[‡]	---
	Control	37/74	---	---	---	--	---	---	---	---	---	---	---	---	10/74[‡]	27/74[‡]	37/74[‡]	---
Burzotta, 2005	Diver CE	29/46	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
			---	---	---	--	---	---	---	---	---	---	---	---	---	---	29/46[‡]	---
	Control	18/49	---	---	---	--	---	---	---	---	---	---	---	---	---	---	18/49[‡]	---
Noel, 2005	Export	12/24	**<30%**	**30-70%**	**>70%**	**Oth**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
			---	---	---	--	---	---	12/24	21/24[§]	---	---	---	---	---	---	---	---
	Control	3/26	---	---	---	--	---	---	3/26	16/26[§]	---	---	---	---	---	---	---	---

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
			<30%	30-70%	>70%	Oth	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Dudek, 2004	Rescue System	27/40	---	---	---	--	6/40	6/40	27/40	---	---	---	---	---	---	---	---	---
	Control	8/32	---	---	---	--	8/32	16/32	8/32	---	---	---	---	---	---	---	---	---

*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 100. ST-segment resolution in randomized controlled trials evaluating mechanical thrombectomy devices versus control **in patients with ST-segment elevation myocardial infarction**

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
			<30%	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	211/246	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	211/246[†‡]
	Control	189/240	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	189/240[†‡]
Ali, 2006	AngioJet Catheter	105/176	---	---	---	---	---	---	---	---	21/176[§]	50/176[§]	105/176[§]	136/176[§‡]	---	---	---	---
	Control	111/164	---	---	---	---	---	---	---	---	18/164[§]	35/164[§]	130/164[§]	130/164[§‡]	---	---	---	---
Lefèvre, 2005	X-Sizer Catheter	61/90	---	---	---	---	---	---	---	61/90[‡]	---	---	---	---	---	---	---	---
	Control	50/95	---	---	---	---	---	---	---	50/95[‡]	---	---	---	---	---	---	---	---
Antoniucci, 2004	AngioJet	45/50	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	45/50[†‡]
	Control	36/50	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	36/50[†‡]
Napodano, 2003	X-Sizer Catheter	38/46	---	---	---	---	---	---	---	38/46[‡]	---	---	---	---	---	---	---	---
	Control	24/46	---	---	---	---	---	---	---	24/46[‡]	---	---	---	---	---	---	---	---

*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; [‡]>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 101. ST-segment resolution in randomized controlled trials evaluating distal filter embolic protection devices versus control **in patients with ST-segment elevation myocardial infarction**

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
Ito, 2010	Filtrap		**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
	Control	9/19	---	---	---	---	---	---	9/19	---	---	---	---	---	---	---	---	---
		4/17	---	---	---	---	---	---	4/17	---	---	---	---	---	---	---	---	---
			<30%	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	230/302	---	---	---	---	---	---	---	---	---	---	230/302	211/302[†]	---	---	---	---
	Control	218/301	---	---	---	---	---	---	---	---	---	---	218/301	198/301[†]	---	---	---	---
			<30%	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Cura, 2007	SpideRX	43/70	---	---	---	---	---	---	43/70	---	---	---	---	---	---	---	---	---
	Control	42/70	---	---	---	---	---	---	42/70	---	---	---	---	---	---	---	---	---
			<30%	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Guetta, 2007	FilterWire EZ	33/51	---	---	---	---	5/51	13/51	33/51	---	0/51	18/51	33/51	---	---	---	---	---
	Control	32/49	---	---	---	---	5/49	12/49	32/49	---	2/49	13/49	35/49	---	---	---	---	---
			<30%	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**	**<30%**	**30-70%**	**>70%**	**Others**
Lefèvre, 2004	AngioGuardXP	20/30	---	---	---	---	---	---	---	---	---	---	---	---	---	---	20/30[‡]	24/30[‡§]
	Control	14/26	---	---	---	---	---	---	---	---	---	---	---	---	---	---	14/26[‡]	19/26[‡§]

*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**

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
			<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
	Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Pan, 2010	PercuSurge Guardwire	61/90	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---
	Control	50/95	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Tahk, 2008	PercuSurge GuardWire	---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---
	Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Hahn, 2007	GuardWire	16/19	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others 16/19‡	<30% ---	30-70% ---	>70% ---	Others 15/19†‡
	Control	9/20	---	---	---	---	---	---	---	---	---	---	---	9/20‡	---	---	---	12/20†‡
Matsuo, 2007	GuardWire Distal Protection System	41/80	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% 41/80§	Others ---
	Control	39/74	---	---	---	---	---	---	---	---	---	---	---	---	---	---	39/74§	---
Muramatsu, 2007	GuardWire Plus System	66/173	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% 52/173	30-70% 55/173	>70% 66/173	Others ---	<30% 46/173	30-70% 49/173	>70% 78/173	Others ---
	Control	60/168	---	---	---	---	---	---	---	---	56/168	52/168	60/168	---	42/168	53/168	73/168	---
Zhou, 2007	PercuSurge GuardWire	---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---
	Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Okamura, 2005	PercuSurge GuardWire	---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---
	Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Stone, 2005	GuardWire Plus	152/240	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% ---	Others ---	<30% ---	30-70% ---	>70% 152/240	Others ---
	Control	148/239	---	---	---	---	---	---	---	---	---	---	---	---	---	---	148/239	---

*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**

Study, Year	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
			<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Haeck, 2009	Proxis	101/126	---	---	85/129	---	---	---	101/126	---	---	---	100/124	---	---	---	96/130[†]	98/126[‡]
	Control	93/129	---	---	97/131	---	---	---	93/129	---	---	---	97/131	---	---	---	87/135[†]	100/131[‡]

*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**

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	27/34[†]	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	15/30[†]	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Beran, 2002	Mechanical Thrombectomy	X-sizer	19/23	---	---	---	19/23‡	---	---	---	---	---	---	---	---	---	---	---	---
		Control	12/23	---	---	---	12/23‡	---	---	---	---	---	---	---	---	---	---	---	---

*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 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**

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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 106. ST-segment resolution in direct comparative randomized controlled trials in patients with ST-segment elevation myocardial infarction

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	34/52	---	---	---	---	---	---	---	---	---	---	34/52	---	---	---	---	---
	Catheter Aspiration	Export Medtronic	42/51	---	---	---	---	---	---	---	---	---	---	42/51	---	---	---	---	---

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Yan, 2007	Catheter Aspiration	Diver CE catheter	35/61	---	---	---	---	---	---	---	---	---	---	---	---	---	---	35/61†	---
	Distal Balloon Embolic Protection	GuardWire Plus	36/61	---	---	---	---	---	---	---	---	---	---	---	---	---	---	36/61†	---

*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

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Wita, 2009	Catheter Aspiration	Diver CE	10/19	---	---	---	---	---	---	---	10/19†	---	---	---	---	---	---	---	---
		Control	13/19	---	---	---	---	---	---	---	13/23†	---	---	---	---	---	---	---	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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

Table 108. ST-segment resolution in randomized controlled trials with unique comparisons in patients with ST-segment elevation myocardial infarction

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Yamamoto, 2006	Catheter Aspiration	Thrombuster+ MtPA	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Thrombuster	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	29/57	---	---	---	---	12/57	16/57	29/57	---	---	---	---	---	---	---	---	---
		Abciximab	25/63	---	---	---	---	19/63	19/63	25/63	---	---	---	---	---	---	---	---	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy +Stenting +Distal Protection Device	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Thrombectomy+ Stenting	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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

Study, Year	Device Category	Group	Composite STSR Definition* (n/N)	Immediately after PCI (n/N)				60 minutes after PCI				90 minutes after PCI				Other Times after PCI			
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Beaudoin, 2010	Catheter aspiration	Export	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Kim, 2010	Catheter Aspiration	Thrombus aspiration	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter	153/318	---	---	---	---	---	---	153/318	---	---	---	---	---	---	---	---	---
		Control	1466/2915	---	---	---	---	---	---	1466/2915	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Nakatani, 2007	Catheter Aspiration	Multiple devices†	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
				<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others	<30%	30-70%	>70%	Others
Simonton, 2006	Mechanical Thrombectomy	AngioJet	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
		Control	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

*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

Study, Year	Device Category	Group	n	Time EF Measured	Mean EF (SD)	P-value
Yamamoto, 2006*	Catheter Aspiration	Thrombuster+MtPA Thrombuster	17 16	1-3d	53 (12) 48 (12)	0.31
Yamamoto, 2006*	Catheter Aspiration	Thrombuster+MtPA Thrombuster	18 12	180d	59 (8) 56 (10)	0.57

*Data from a single study; †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

Study, Year	Device Category	Group	n	Time EF Measured	Mean EF (SD)	P-value
Beaudoin, 2010	Catheter aspiration	Export Control	--- ---	---	---	---
Kim, 2010	Catheter aspiration	Thrombus aspiration Control	429 429	Post-PCI	49 (11) 53 (11)	0.0005
Ko, 2009	Distal Embolic Protection	Distal Protection Device Control	--- ---	---	--- ---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter Control	--- ---	---	--- ---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices* Control	--- ---	---	--- ---	---
Chinnaiyan, 2006	Mechanical thrombectomy	AngioJet XMI or XVG Catheter Control	--- ---	---	--- ---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet Control	--- ---	---	--- ---	---

*Rescue Catheter, Trombuster 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

Study, Year	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Dudek, 2010	Diver CE	67/88	86/98	---	10/98
	Control	48/83	78/96	---	17/96
Liistro, 2009	Export Thrombectomy Catheter	51/55*	53/55	4/55	2/55
	Control	40/56*	46/56	14/56	10/56
Lipiecki, 2009	Export Catheter	6/20*	---	2/20	---
	Control	7/20*	---	3/24	---
Moura, 2009	TAC	68/75*	---	---	---
	Control	47/76*	---	---	---
Sardella, 2009	Export Medtronic (EM)	62/88	88/88	---	---
	Control	25/87	86/87	---	---
Chao, 2008	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Chevalier, 2008	Export Aspiration Catheter	43/120	98/120	11/120	4/120
	Control	33/129	99/129	22/129	13/129
Ciszewski, 2008	Rescue/Diver	---	---	---	---
	Control	---	---	---	---
Ikari, 2008	TVAC	82/178	156/178	28/178	22/178†
	Control	35/171	138/171	50/171	33/171†
Svilaas, 2008	6F Export Aspiration Catheter	224/490	431/501	---	---
	Control	158/490	409/496	---	---
DeLuca, 2006	Diver CE	14/38	30/38	---	---
	Control	5/38	26/38	---	---
Kaltoft, 2006	Rescue Catheter	---	93/104	9/104	---
	Control	---	91/104	6/105	---
Lee, 2006	Export Aspiration Catheter	16/67	---	6/67	5/67
	Control	8/66	---	2/66	3/66
Silva-Orrego, 2006	Pronto Extraction Catheter	65/74	66/74	4/74	2/74
	Control	32/74	58/74	14/74	11/74
Burzotta, 2005	Diver CE	21/50	41/50	4/50	4/48
	Control	11/49	34/49	8/49	6/49
Noel, 2005	Export	---	23/24	---	2/24‡
	Control	---	21/26	---	7/26‡
Dudek, 2004	Rescue System	22/40	30/35	---	---
	Control	12/32	28/32	---	---

*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

Study, Year	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	155/215	203/252	---	---
	Control	167/211	207/241	---	---
Ali, 2006	AngioJet Catheter	63/234	213/234	10/234	6/234
	Control	75/235	228/235	12/235	5/235
Lefèvre, 2005	X-Sizer Catheter	29/92	93/97	2/97	3/97
	Control	28/91	89/100	10/100	10/100
Antoniucci, 2004	AngioJet	---	---	---	---
	Control	---	---	---	---
Napodano, 2003	X-Sizer Catheter	33/46	43/46	2/46	1/46
	Control	17/46	44/46	7/46	5/46

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

Study, Year	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Ito, 2010	Filtrap	---	17/19	---	---
	Control	---	13/17	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	---	295/312	---	---
	Control	---	268/314	---	---
Cura, 2007	SpideRX	---	29/32	---	1/32*
	Control	---	27/28	---	3/28*
Guetta, 2007	FilterWire EZ	47/70	55/70	5/70	2/70
	Control	59/70	60/70	8/70	2/70
Lefèvre, 2004	AngioGuardXP	33/49	43/49	---	---
	Control	32/48	45/48	---	---

*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

Study, Year	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Duan, 2010	PercuSurge Guardwire Plus	---	44/46	---	---
	Control	---	39/50	---	---
Pan, 2010	PercuSurge Guardwire	---	46/52	---	---
	Control	---	36/52	---	---
Tahk, 2008	PercuSurge GuardWire	39/60	58/60	---	---
	Control	20/56	43/56	---	---
Hahn, 2007	GuardWire	6/19	18/19	4/19	1/19
	Control	5/20	19/20	6/20	1/20
Matsuo, 2007	GuardWire Distal Protection System	46/80	64/80	5/80	3/80
	Control	32/74	56/74	4/74	2/74
Muramatsu, 2007	GuardWire Plus System	42/167	133/173	4/173	2/173
	Control	32/158	131/168	7/168	6/168
Zhou, 2007	PercuSurge GuardWire	34/52	50/52	---	---
	Control	20/60	48/60	---	---
Okamura, 2005	PercuSurge GuardWire	---	8/8	---	---
	Control	---	8/8	---	---
Stone, 2005	GuardWire Plus	138/226	219/239	22/237	1/238
	Control	120/227	215/241	14/242	6/242

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

Study, Year	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Haeck, 2009	Proxis	113/141	131/141	14/141	---
	Control	117/143	125/143	20/143	---

Abbreviations: MBG=myocardial blush grade; n=number; N=number of participants in the group; PCI=percutaneous coronary intervention; TIMI=thrombolysis in myocardial infarction

Table 118. Intermediate health outcomes in randomized controlled trials evaluating thrombectomy or embolic protection devices versus control in patients with mixed acute coronary syndromes

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	24/30	26/30	0/30	9/30
		Control	5/37	18/37	---	31/37
Gick, 2005	Distal Filter Embolic Protection	FilterWire	64/100*	93/100	3/100	---
		Control	67/100*	93/100	8/100	
Sardella, 2005	Catheter Aspiration	Diver CE	11/28	24/28	---	---
		Control	3/34	21/34	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	121/129	---	---
		Control	---	119/129	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	24/34	34/34	---	---
		Control	11/30	28/30	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	27/30	---	---
		Control	---	26/31	---	---

*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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	72/77	---	---
		Control	---	70/74	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	15/15	3/15	0/15
		Control	---	16/16	---	0/16

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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	16/52	38/52	---	---
	Catheter Aspiration	Export Medtronic	22/51	42/51	---	---
Yan, 2007	Catheter Aspiration	Diver CE catheter	43/61	58/61	---	5/61*
	Distal Balloon Embolic Protection	GuardWire Plus	44/61	59/61	---	4/61*

*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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Wita, 2009	Catheter Aspiration	Diver CE	12/19	19/19	---	---
		Control	14/23 (MBG 2-3)	23/23	---	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	---	---	---	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire Control	---	---	---	---

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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	13/23	22/23	---	---
		Thrombuster	3/21	18/21	---	---

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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire Abciximab	34/55	51/57	---	---
			38/58	56/63	---	---
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	26/30	---	---
		Thrombectomy+ Stenting	---	20/30	---	---

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

Study, Year	Device Category	Group	Post-PCI MBG-3 (n/N)	Post-PCI TIMI-3 (n/N)	Distal Embolization (n/N)	No reflow (n/N)
Beaudoin, 2010	Catheter aspiration	Export	---	147/165	---	---
		Control	---	324/370	---	---
Kim, 2010	Catheter aspiration	Thrombus aspiration	---	379/429	---	---
		Control	---	371/429	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---
		Control	---	---	---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter	---	---	29/318	---
		Control	---	---	93/2915	---
Nakatani, 2007	Catheter Aspiration	Multiple devices*	---	---	---	---
		Control	---	---	---	---
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	---	205/239	---	---
		Control	---	922/1021	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	---	170/200	---	---
		Control	---	1086/1168	---	---

*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 125. Adverse outcomes in randomized controlled trials evaluating catheter aspiration devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Dudek, 2010	Diver CE	---	---	---	---
	Control	---	---	---	---
Liistro, 2009	Export Thrombectomy Catheter	---	---	---	---
	Control	---	---	---	---
Lipiecki, 2009	Export Catheter	---	---	---	---
	Control	---	---	---	---
Moura, 2009	TAC	---	---	---	---
	Control	---	---	---	---
Sardella, 2009	Export Medtronic (EM)	---	---	---	---
	Control	---	---	---	---
Chao, 2008	Export Aspiration Catheter	0/37	---	---	---
	Control	1/37	---	---	---
Chevalier, 2008	Export Aspiration Catheter	---	---	1/120	2/120
	Control	---	---	0/129	2/129
Ciszewski, 2008	Rescue/Diver	---	---	---	---
	Control	---	---	---	---
Ikari, 2008	TVAC	4/178	0/178	---	---
	Control	15/171	0/171	---	---
Svilaas, 2008	6F Export Aspiration Catheter	0/502	---	---	5/502
	Control	0/503	---	---	4/503
DeLuca, 2006	Diver CE	1/38	---	---	---
	Control	0/38	---	---	---
Kaltoft, 2006	Rescue Catheter	---	---	---	---
	Control	---	---	---	---
Lee, 2006	Export Aspiration Catheter	---	---	---	---
	Control	---	---	---	---
Silva-Orrego, 2006	Pronto Extraction Catheter	0/74	---	---	---
	Control	4/74	---	---	---
Burzotta, 2005	Diver CE	---	---	---	---
	Control	---	---	---	---
Noel, 2005	Export	---	---	---	---
	Control	---	---	---	---
Dudek, 2004	Rescue System	---	---	---	---
	Control	---	---	---	---

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

Study, Year	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Migliorini, 2010	AngioJet Rheolytic Thrombectmy	---	0/256	---	---
	Control	---	1/245	---	---
Ali, 2006	AngioJet Catheter	9/234	2/234	1/234	---
	Control	6/235	1/235	2/235	
Lefèvre, 2005	X-Sizer Catheter	---	0/100	---	---
	Control	---	---	---	---
Antoniucci, 2004	AngioJet	---	---	---	---
	Control	---	---	---	---
Napodano, 2003	X-Sizer Catheter	---	---	---	1/46
	Control	---	---	---	1/46

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

Study, Year	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Ito, 2010	Filtrap	---	---	---	---
	Control	---	---	---	---
Kelbæk, 2008	FilterWire-EZ or SpiderX protection device	---	---	---	---
	Control	---	---	---	---
Cura, 2007	SpideRX	0/70	0/70	0/70	0/70
	Control	0/70	0/70	0/70	1/70
Guetta, 2007	FilterWire EZ	---	---	---	---
	Control	---	---	---	---
Lefèvre, 2004	AngioGuardXP	---	---	---	---
	Control	---	---	---	---

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

Study, Year	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Duan, 2010	PercuSurge Guardwire Plus	---	---	---	---
	Control	---	---	---	---
Pan, 2010	PercuSurge Guardwire	---	---	---	---
	Control	---	---	---	---
Tahk, 2008	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Hahn, 2007	GuardWire	---	---	---	---
	Control	---	---	---	---
Matsuo, 2007	GuardWire	---	---	---	2/80
	Control	---	---	---	1/74
Muramatsu, 2007	GuardWire Plus	---	---	---	---
	Control	---	---	---	---
Zhou, 2007	PercuSurge GuardWire	0/52	0/52	---	---
	Control	0/60	0/60	---	---
Okamura, 2005	PercuSurge GuardWire	---	---	---	---
	Control	---	---	---	---
Stone, 2005	GuardWire	---	2/229	11/238	34/238
	Control	---	0/234	6/242	38/242

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

Study, Year	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Haeck, 2009	Proxis	---	---	---	---
	Control	---	---	---	---

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Parikh, 2008	Distal Balloon Embolic Protection	GuardWire	---	---	0/30	---
		Control	---	---	---	---
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	---	---	---	---
		Abciximab	---	---	---	---
Gick, 2005	Distal Filter Embolic Protection	FilterWire	---	---	---	---
		Control	---	---	---	---
Sardella, 2005	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Kunii, 2004	Catheter Aspiration	Rescue PT	---	---	---	---
		Control	---	---	---	---
Nanasato, 2004	Distal Balloon Embolic Protection	GuardWire	---	---	---	---
		Control	---	---	---	---
Matsushita, 2003	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---
Beran, 2002	Mechanical Thrombectomy	X-sizer	---	---	---	---
		Control	---	---	---	---

Abbreviations: n=number; N=number of participants in the group

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Webster, 2008	Distal Filter Embolic Protection	FilterWire EZ	---	---	---	---
		Control	---	---	---	---
Dudek, 2003	Distal Filter Embolic Protection	AngioGuard	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Sardella, 2008	Catheter Aspiration	Diver Invatec catheter	0/52	0/52	---	---
	Catheter Aspiration	Export Medtronic	1/51	0/51	---	---

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Yan, 2007	Catheter Aspiration	Diver CE catheter	---	---	---	---
	Distal Balloon Embolic Protection	GuardWire Plus	---	---	---	---

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Wita, 2009	Catheter Aspiration	Diver CE	---	---	---	---
		Control	---	---	---	---
Ozaki, 2006	Catheter Aspiration	Rescue or Thrombuster systems	---	---	---	---
	Distal Balloon Embolic Protection	PercuSurge GuardWire	---	---	---	---
		Control	---	---	---	---

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Yamamoto, 2006	Catheter Aspiration	Thrombuster+MtPA	---	---	---	---
		Thrombuster	---	---	---	---

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

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Ochala, 2007	Distal Balloon Embolic Protection	PercuSurge Guardwire	---	---	---	---
		Abciximab	---	---	---	---

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Kanaya, 2003	Thrombectomy + Distal Protection Device	Thrombectomy + Stenting + Distal Protection Device	---	---	---	---
		Thrombectomy+ Stenting	---	---	---	---

Abbreviations: n=number; N=number of participants in the group; vs=versus

Table 136. Adverse outcomes in observational studies

Study, Year	Device Category	Group	Coronary dissection (n/N)	Perforation (n/N)	Vessel spasm (n/N)	Side branch closure (n/N)
Beaudoin, 2010	Catheter Aspiration	Export	---	---	---	---
		Control	---	---	---	---
Kim, 2010	Catheter aspiration	Thrombus aspiration	---	---	---	---
		Control	---	---	---	---
Ko, 2009	Distal Embolic Protection	Distal Protection Device	---	---	---	---
		Control	---	---	---	---
Nilsen, 2009	Catheter Aspiration	Aspiration Catheter	21/318	---	---	---
		Control	154/2915	---	---	---
Nakatani, 2007	Catheter Aspiration	Multiple devices*	---	---	---	---
		Control	---	---	---	---
Chinnaiyan, 2006	Mechanical Thrombectomy	AngioJet XMI or XVG Catheter	---	0/239	---	---
		Control	---	2/1021	---	---
Simonton, 2006	Mechanical Thrombectomy	AngioJet	---	---	---	---
		Control	---	---	---	---

*Rescue Catheter, Trombuster Catheter, Transvascular Aspiration Catheter, Export Catheter
Abbreviations: n=number; N=number of participants in the group

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	8.08	0.70 (0.47 to 1.03)	0%
Myocardial infarction	8.80	0.61 (0.36 to 1.04)	0%
Stroke	0.79	3.18 (0.73 to 13.88)	0%
Target revascularization	9.48	0.79 (0.61 to 1.02)	0%
MACE	12.66	0.73 (0.61 to 0.88)	0%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	7.80	1.19 (0.51 to 2.76)	54.9
Myocardial infarction	8.98	0.71 (0.27 to 1.85)	0%
Stroke	5.79	2.42 (0.75 to 7.78)	0%
Target revascularization	6.22	0.87 (0.36 to 2.10)	39.2%
MACE	6.22	1.23 (0.50 to 3.01)	79.9%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	11.49	0.97 (0.53 to 1.79)	0%
Myocardial infarction	11.93	0.56 (0.06 to 5.02)	60%
Stroke	1	1.51 (0.30 to 7.52)*	NA
Target revascularization	13.36	1.61 (1.03 to 2.54)	NA
MACE	11.49	1.36 (0.98 to 1.89)	0%

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	6	0.82 (0.45 to 1.51)	2.5%
Myocardial infarction	6	0.67 (0.29 to 1.57)	0%
Stroke	6	0.48 (0.10 to 2.22)*	NA
Target revascularization	6	0.93 (0.61 to 1.42)	0%
MACE	6	0.87 (0.64 to 1.19)	0%

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	6	0.51 (0.11 to 2.33)*	NA
Myocardial infarction	6	1.01 (0.24 to 4.33)*	NA
Stroke	6	0.20 (0 to 1.93)*	NA
Target revascularization	6	0.71 (0.29 to 1.75)*	NA
MACE	6	0.74 (0.36 to 1.54)*	NA

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	8.31	0.87 (0.57 to 1.31)	0%
Myocardial infarction	8.27	0.83 (0.45 to 1.55)	0%
Stroke	3.74	0.68 (0.22 to 2.11)	0%
Target revascularization	8.60	1.11 (0.80 to 1.52)	10%
MACE	8.15	1.03 (0.82 to 1.29)	4%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	0.79	0.65 (0.39 to 1.10)	0%
Myocardial infarction	0.77	0.55 (0.24 to 1.25)	0%
Stroke	0.79	3.18 (0.73 to 13.88)	0%
Target revascularization	0.70	0.85 (0.53 to 1.38)	0%
MACE	0.79	0.80 (0.57 to 1.12)	0%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	1	1.25 (0.47 to 3.32)	48.7%
Myocardial infarction	1	0.63 (0.21 to 1.96)	0%
Stroke	1	1.89 (0.55 to 6.48)	0%
Target revascularization	1	1.62 (0.21 to 12.55)	62%
MACE	1	1.28 (0.37 to 4.38)	80.4%

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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	1	1.02 (0.50 to 2.08)	0%
Myocardial infarction	1	0.73 (0.12 to 4.44)	44.3%
Stroke	1	1.51 (0.30 to 7.52)*	NA
Target revascularization	1	3.02 (0.61 to 14.84)	NA
MACE	1	1.29 (0.77 to 2.15)	0%

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	1	0.64 (0.30 to 1.39)	0%
Myocardial infarction	1	0.85 (0.32 to 2.23)	0%
Stroke	1	0.11 (0 to 0.94)*	NA
Target revascularization	1	1.38 (0.55 to 3.50)	0%
MACE	1	0.74 (0.44 to 1.23)	0%

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I2 for Relative Risk
Mortality	1	1.01 (0.14 to 7.10)*	NA
Myocardial infarction	1	0.68 (0.11 to 3.99)*	NA
Stroke	1	0.34 (0.01 to 8.23)*	NA
Target revascularization	1	0.51 (0.13 to 1.99)*	NA
MACE	1	0.61 (0.23 to 1.63)*	NA

*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

Final Health Outcome	Weighted Mean Followup (months)	Relative Risk (95% CI)	I^2 for Relative Risk
Mortality	1	0.84 (0.50 to 1.39)	0%
Myocardial infarction	1	0.83 (0.41 to 1.69)	0%
Stroke	1	0.56 (0.11 to 2.84)	22.1%
Target revascularization	1	1.24 (0.62 to 2.48)	0%
MACE	1	0.92 (0.66 to 1.30)	0%

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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.81 (0.23 to 2.86)	0%
Mechanical Thrombectomy	1.00 (0.24 to 4.16)*	NA
Distal Filter Embolic Protection Devices	---†	---†
Distal Balloon Embolic Protection Devices	0.69 (0.24 to 2.03)*	NA
Proximal Balloon Embolic Protection Devices	---†	---†
Embolic Protection Devices Combined	0.69 (0.24 to 2.03)*	NA

*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 150. 30-day mortality in randomized controlled trials in patients with ST-segment elevation myocardial infarction

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.61 (0.35 to 1.07)	0%
Mechanical Thrombectomy	1.25 (0.47 to 3.32)	48.7%
Distal Filter Embolic Protection Devices	1.02 (0.50 to 2.08)	0%
Distal Balloon Embolic Protection Devices	0.64 (0.30 to 1.39)	0%
Proximal Balloon Embolic Protection Device	1.01 (0.18 to 5.69)*	NA
Embolic Protection Devices Combined	0.84 (0.50 to 1.39)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.89 (0.31 to 2.51)	2.8%
Mechanical Thrombectomy	1.35 (0.53 to 3.44)	58.4%
Distal Filter Embolic Protection Devices	1.25 (0.38 to 4.16)*	NA
Distal Balloon Embolic Protection Devices	0.86 (0.48 to 1.57)	0%
Proximal Balloon Embolic Protection Devices	0.51 (0.11, 2.33)	NA
Embolic Protection Devices Combined	0.87 (0.52 to 1.46)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.62 (0.39 to 0.98)	NA
Mechanical Thrombectomy	0.50 (0.21 to 1.17)	NA
Distal Filter Embolic Protection Devices	0.87 (0.43 to 1.78)†	NA
Distal Balloon Embolic Protection Devices	---*	---*
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	0.87 (0.43 to 1.78)†	NA

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.32 (0.03 to 3.06)	NA
Mechanical Thrombectomy	1.00 (0.11 to 9.41)*	NA
Distal Filter Embolic Protection Devices	---†	---†
Distal Balloon Embolic Protection Devices	0.32 (0.00 to 3.71)*	NA
Proximal Balloon Embolic Protection Devices	---†	---†
Embolic Protection Devices Combined	0.32 (0.00 to 3.71)*	NA

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.60 (0.25 to 1.45)	0%
Mechanical Thrombectomy	0.63 (0.21 to 1.96)	0%
Distal Filter Embolic Protection Devices	0.73 (0.12 to 4.44)	44.3%
Distal Balloon Embolic Protection Devices	0.85 (0.32 to 2.23)	0%
Proximal Balloon Embolic Protection Devices	0.68 (0.14 to 3.34)*	NA
Embolic Protection Devices Combined	0.83 (0.41 to 1.69)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.70 (0.24 to 1.99)	0%
Mechanical Thrombectomy	0.57 (0.17 to 1.92)	NA
Distal Filter Embolic Protection Devices	0.09 (0 to 0.74)*	NA
Distal Balloon Embolic Protection Devices	0.67 (0.29 to 1.57)	0%
Proximal Balloon Embolic Protection Device	1.01 (0.24, 4.33)	NA
Embolic Protection Devices Combined	0.65 (0.31 to 1.33)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.51 (0.26 to 1.00)	NA
Mechanical Thrombectomy	0.66 (0.13 to 3.29)	NA
Distal Filter Embolic Protection Devices	2.35 (0.61 to 8.90)†	NA
Distal Balloon Embolic Protection Devices	---*	---*
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	2.35 (0.61 to 8.90)†	NA

* 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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	4.94 (0.52 to infinity)	NA
Mechanical Thrombectomy Devices	---*	---*
Distal Filter Embolic Protection Devices	---†	---†
Distal Balloon Embolic Protection Devices	---†	---†
Proximal Balloon Embolic Protection Devices	---†	---†
Embolic Protection Devices Combined	---†	---†

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	2.77 (0.51 to 14.98)	0%
Mechanical Thrombectomy	1.89 (0.55 to 6.48)	0%
Distal Filter Embolic Protection Devices	1.51 (0.30 to 7.52)*	NA
Distal Balloon Embolic Protection Devices	0.11 (0 to 0.94)*	NA
Proximal Balloon Embolic Protection Devices	0.34 (0 to 3.87)*	NA
Embolic Protection Devices Combined	0.56 (0.11 to 2.84)	22.1%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	---*	---*
Mechanical Thrombectomy Devices	2.05 (0.27 to 15.78)	NA
Distal Filter Embolic Protection Devices	---†	---†
Distal Balloon Embolic Protection Devices	0.48 (0.10 to 2.22)‡	NA
Proximal Balloon Embolic Protection Devices	0.20 (0.00 to 1.93)	NA
Embolic Protection Devices Combined	0.39 (0.09 to 1.71)	NA

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	---*	---*
Mechanical Thrombectomy Devices	1.99 (0.26 to 15.14)	NA
Distal Filter Embolic Protection Devices	---*	---*
Distal Balloon Embolic Protection Devices	---*	---*
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	---*	---*

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	1.35 (0.26 to 6.94)	0%
Mechanical Thrombectomy Devices	---*	---*
Distal Filter Embolic Protection Devices	---†	---†
Distal Balloon Embolic Protection Devices	0.32 (0.00 to 3.71)‡	NA
Proximal Balloon Embolic Protection Devices	---†	---†
Embolic Protection Devices Combined	0.32 (0.00 to 3.71)‡	NA

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	0.82 (0.50 to 1.35)	0%
Mechanical Thrombectomy Devices	1.62 (0.21 to 12.55)	62%
Distal Filter Embolic Protection Devices	3.02 (0.70 to 13.01)*	NA
Distal Balloon Embolic Protection Devices	1.38 (0.55 to 3.50)	0%
Proximal Balloon Embolic Protection Devices	0.51 (0.14 to 1.81)*	NA
Embolic Protection Devices Combined	1.24 (0.62 to 2.48)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	0.62 (0.40 to 0.96)	0%
Mechanical Thrombectomy Devices	0.55 (0.33 to 0.92)	NA
Distal Filter Embolic Protection Devices	1.00 (0.35 to 2.82)*	NA
Distal Balloon Embolic Protection Devices	0.93 (0.61 to 1.42)	0%
Proximal Balloon Embolic Protection Devices	0.71 (0.29 to 1.75)	NA
Embolic Protection Devices Combined	0.90 (0.63 to 1.30)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration Devices	0.87 (0.63 to 1.19)	NA
Mechanical Thrombectomy Devices	0.68 (0.41 to 1.13)	NA
Distal Filter Embolic Protection Devices	1.78 (1.09 to 2.93)†	NA
Distal Balloon Embolic Protection Devices	---*	---*
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	1.78 (1.09 to 2.93)†	NA

*Risk could not be calculated because no trials evaluated this outcome

† 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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.97 (0.36 to 2.58)	0%
Mechanical Thrombectomy	---*	---*
Distal Filter Embolic Protection Devices	---*	---*
Distal Balloon Embolic Protection Devices	---†	---†
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	---†	---†

*Risk could not be calculated because no trials evaluated this outcome; †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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.79 (0.56 to 1.13)	0%
Mechanical Thrombectomy	1.28 (0.37 to 4.38)	80.4%
Distal Filter Embolic Protection Devices	1.29 (0.77 to 2.15)	0%
Distal Balloon Embolic Protection Devices	0.74 (0.44 to 1.23)	0%
Proximal Balloon Embolic Protection Devices	0.61 (0.23 to 1.57)*	NA
Embolic Protection Devices Combined	0.92 (0.66 to 1.30)	0%

*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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.66 (0.47to 0.94)	0%
Mechanical Thrombectomy	0.71 (0.41 to 1.20)	NA
Distal Filter Embolic Protection Devices	1.10 (0.68 to 1.78)	NA
Distal Balloon Embolic Protection Devices	0.87 (0.64 to 1.19)	0%
Proximal Balloon Embolic Protection Devices	0.74 (0.36 to 1.54)	NA
Embolic Protection Devices Combined	0.91 (0.71 to 1.16)	0%

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

Device Category	Relative Risk (95% CI)	I^2 for Relative Risk
Catheter Aspiration	0.61 (0.26 to 1.41)	NA
Mechanical Thrombectomy	0.66 (0.44 to 0.97)	NA
Distal Filter Embolic Protection Devices	1.48 (1.03 to 2.15)†	NA
Distal Balloon Embolic Protection Devices	---*	---*
Proximal Balloon Embolic Protection Devices	---*	---*
Embolic Protection Devices Combined	1.48 (1.03 to 2.15)†	NA

*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 cathter aspiration devices versus control on intermediate health outcomes in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.75 (1.44 to 2.14)	69.2%
TIMI-3	1.07 (1.04 to 1.11)	0%
Distal embolization	0.48 (0.34 to 0.66)	33.7%
No reflow	0.45 (0.27 to 0.75)	22.3%
ST-segment resolution	1.39 (1.21 to 1.61)	60.4%

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.07 (0.80 to 1.43)	76.5%
TIMI-3	0.98 (0.92 to 1.04)	67.5%
Distal embolization	0.44 (0.17 to 1.12)	41.6%
No reflow	0.50 (0.17 to 1.48)	41.7%
ST-segment resolution	1.16 (0.99 to 1.36)	75.1%

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	0.97 (0.81 to 1.15)	NA
TIMI-3	1.02 (0.90 to 1.15)	70.2%
Distal embolization	0.63 (0.22 to 1.82)	NA
No reflow	1.00 (0.18 to 5.55)*	NA
ST-segment resolution	1.05 (0.96 to 1.14)	0%

*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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.39 (1.15 to 1.69)	43.5%
TIMI-3	1.09 (1.01 to 1.17)	59.7%
Distal embolization	1.10 (0.67 to 1.81)	5.8%
No reflow	0.51 (0.19 to 1.33)	0%
ST-segment resolution	1.08 (0.91 to 1.29)	41.2%

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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	0.98 (0.88 to 1.10)*	NA
TIMI-3	1.06 (0.98 to 1.16)*	NA
Distal embolization	0.71 (0.38 to 1.33)*	NA
No reflow	---†	---†
ST-segment resolution	1.11 (0.97 to 1.28)*	NA

*Result is based on a single trial; †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

Intermediate health outcomes	Relative Risk (95% CI)	I^2 for Relative Risk
MBG-3	1.20 (1.02 to 1.40)	68.2%
TIMI-3	1.06 (1.01 to 1.12)	55.4%
Distal embolization	0.91 (0.64 to 1.30)	0.2%
No reflow	0.58 (0.25 to 1.37)	0%
ST-segment resolution	1.06 (1.00 to 1.13)	0%

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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	0.30 (0.12 to 0.75)	0%
Perforation	---*	---*
Side-branch occlusion	1.19 (0.40 to 3.54)	NA

*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 trhombectomy devices versus control on adverse events in randomized controlled trials of good methodological quality in patients with ST-segment elevation myocardial infarction

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	1.51 (0.57 to 4.01)*	NA
Perforation	1.04 (0.15 to 7.04)	NA
Side-branch occlusion	1.00 (0.11 to 9.41)*	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Perforation	---*	---*
Side-branch occlusion	0.33 (0.00 to 3.80)†	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Perforation	5.11 (0.53 to infinity)†	NA
Side-branch occlusion	0.93 (0.61 to 1.42)	NA

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Perforation	---*	---*
Side-branch occlusion	---*	---*

*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

Adverse event	Relative Risk (95% CI)	I^2 for Relative Risk
Coronary dissection	---*	---*
Perforation	5.11 (0.53 to infinity)†	NA
Side-branch occlusion	0.91 (0.60 to 1.39)	0%

*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

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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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	NA	No serious indirectness	NA	None	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Ejection fraction	2	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Myocardial blush grade 3	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Thrombolysis in myocardial infarction -3	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	1	RCT	No serious limitation	NA	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Thrombolysis in myocardial infarction -3	1	RCT	No serious limitation	NA	No serious indirectness	No imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

Abbreviation: RCT=randomized controlled trials

Table 183. Strength of evidence for intermediate and final health outcomes for catheter aspiration devices versus control in ST-segment elevation myocardial infarction patients under key question 1

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	13	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Myocardial infarction	12	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Stroke	6	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Target revascularization	11	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Major adverse cardiac events	13	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	16	RCTs and Observational study	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate	Important
Ejection fraction	12	RCTs and Observational study	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate	Important
Myocardial blush grade 3	13	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate	Important
Thrombolysis in myocardial infarction -3	15	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Distal embolization	11	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important
No reflow	8	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	5	RCTs and Observational study	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Insufficient	Important
Myocardial infarction	4	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Stroke	5	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Target revascularization	4	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Major adverse cardiac events	4	RCTs and Observational study	No serious limitation	Serious Inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	5	RCTs	No serious limitation	Serious Inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Ejection fraction	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Myocardial blush grade 3	4	RCTs	No serious limitation	Serious Inconsistency	No serious indirectness	Serious imprecision	None	Low	Important
Thrombolysis in myocardial infarction-3	5	RCTs and Observational study	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate	Important
Distal embolization	3	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
No reflow	3	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Myocardial Infarction	4	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Target revascularization	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Major adverse cardiac events	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Ejection fraction	2	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Low	Important
Myocardial blush grade 3	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Thrombolysis in myocardial infarction-3	5	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Low	Important
Distal Embolization	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
No reflow	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important

Abbreviation: RCT=randomized controlled trials

Table 186. Strength of evidence for intermediate and final health outcomes for distal balloon embolic protection devices versus control in ST-segment elevation myocardial infarction patients under key question 1

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	4	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Myocardial infarction	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Target revascularization	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Major adverse cardiac events	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	4	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Ejection fraction	6	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Myocardial blush grade 3	6	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important
Thrombolysis in myocardial infarction-3	8	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Low	Important
Distal embolization	4	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
No reflow	4	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Major adverse cardiac events	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
Thrombolysis in myocardial infarction-3	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Distal Embolization	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

			QualityAssessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	10	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	Insufficient	Important
Myocardial Infarction	10	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Stroke	3	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Target revascularization	8	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	Insufficient	Important
Major adverse cardiac events	12	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	10	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low	Important
Ejection fraction	9	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Myocardial blush grade 3	9	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate	Important
Thrombolysis in myocardial infarction-3	14	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Low	Important
Distal Embolization	6	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious inconsistency	None	Moderate	Important
No reflow	6	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	2	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
St-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Low	Important
Thrombolysis in myocardial infarction-3	2	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	2	RCT and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	Observational study	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	2	RCT and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	2	RCT and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	2	RCT and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Target revascularization	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Distal embolization	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Health-related quality of life	0	---	---	---	---	---	---	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important
Ejection fraction	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
Myocardial blush grade 3	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important
Thrombolysis in myocardial infarction-3	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Distal Embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	High	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	0	-	-	-	-	-	-	Insufficient	Important
Distal Embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	3	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important
Ejection fraction	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial blush grade 3	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Thrombolysis in myocardial infarction-3	3	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Distal Embolization	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
No reflow	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	High	Important

Abbreviation: RCT=randomized controlled trials

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	0	-	-	-	-	-	-	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	0	-	-	-	-	-	-	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Mortality	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Major adverse cardiac events	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Thrombolysis in myocardial infarction-3	0	-	-	-	-	-	-	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	0	-	-	-	-	-	-	Insufficient	Important
Myocardial infarction	0	-	-	-	-	-	-	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	0	-	-	-	-	-	-	Insufficient	Important
Major adverse cardiac events	0	-	-	-	-	-	-	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	0	-	-	-	-	-	-	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	0	-	-	-	-	-	-	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Mortality	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Myocardial infarction	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Stroke	0	-	-	-	-	-	-	Insufficient	Important
Target revascularization	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Major adverse cardiac events	1	RCT	No Serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Insufficient	Important
Health-related quality of life	0	-	-	-	-	-	-	Insufficient	Important
ST-segment resolution	0	-	-	-	-	-	-	Insufficient	Important
Ejection fraction	0	-	-	-	-	-	-	Insufficient	Important
Myocardial blush grade 3	0	-	-	-	-	-	-	Insufficient	Important
Thrombolysis in myocardial infarction-3	1	RCT	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Distal embolization	0	-	-	-	-	-	-	Insufficient	Important
No reflow	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

Abbreviation: RCT=randomized controlled trials

Table 202. Strength of evidence for adverse outcomes for catheter aspiration devices versus catherter aspiration devices in patients with ST-segment elevation myocardial infarction under key question 2

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	1	RCT	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Insufficient	Important
Perforation	1	RCT	No serious limitation	NA	No serious indirectness	NA	None	Insufficient	Important
Prolonged procedure time	1	RCT	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	5	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important
Perforation	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Prolonged procedure time	9	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Perforation	3	RCTs and Observational study	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Prolonged procedure time	3	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	High	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
Perforation	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
Prolonged procedure time	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	1	RCT	No serious limitation	Not graded	No serious indirectness	No serious imprecision	None	Insufficient	Important
Perforation	1	RCT	No serious limitation	Not graded	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Prolonged procedure time	3	RCTs	No serious limitation	Serious inconsistency	No serious indirectness	Serious imprecision	None	Low	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	None	Insufficient	Important
Perforation	2	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Insufficient	Important
Prolonged procedure time	5	RCTs	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate	Important

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

			Quality Assessment					Summary of Findings	
Outcome	**Number of Studies**	**Design**	**Limitations**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality**	**Importance**
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	1	RCT	No serious limitation	Not graded	No serious indirectness	Serious imprecision	None	Moderate	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

		Quality Assessment						Summary of Findings	
Outcome	Number of Studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other Considerations	Quality	Importance
Coronary dissection	0	-	-	-	-	-	-	Insufficient	Important
Perforation	0	-	-	-	-	-	-	Insufficient	Important
Prolonged procedure time	0	-	-	-	-	-	-	Insufficient	Important

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Dudek, 2010	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Intervention, Outcomes, Setting	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
Liistro, 2009	Study Designation: Efficacy study Composite Score: 4 of 7	Enrolled primary care population Assessed final health outcomes Assessed adverse outcomes Used intention to treat analysis	Population, Setting	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
Lipiecki, 2009	Study Designation: Efficacy study Composite Score: 1 of 7	Enrolled primary care population	Population, Outcomes, Setting	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
Moura, 2009	Study Designation: Efficacy study Composite Score: 2 of 7	Less stringent eligibility criteria Assessed final health outcomes	Population, Intervention, Outcomes, Setting	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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Sardella, 2009	Study Designation: Efficacy study Composite Score: 3 of 7	Enrolled primary care population Assessed final health outcomes Adequate study duration with clinically relevant treatments	Population, Outcomes, Setting	Only patients undergoing primary PCI Adverse outcomes not reported Small sample size (N =175) Use of ITT analysis not reported
Chao, 2008	Study Designation: Efficacy study Composite Score: 3 of 7	Enrolled primary care population Assessed final health outcomes Assessed adverse outcome	Population, Setting	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
Chevalier, 2008	Study Designation: Effectiveness study Composite Score: 5 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis	Population, Setting	• High male to female ratio (80-81%) • Only patients undergoing primary PCI • Short duration of followup (30 d) • Conducted in Europe and India
Ciszewski, 2008	Study Designation: Efficacy study Composite Score: 2 of 7	1. Assessed final health outcomes 2. Used intention to treat analysis	Population, Intervention, Outcomes, Setting	• 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
Ikari, 2008	Study Designation: Effectiveness study Composite Score: 5 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis	Population, Intervention, Setting	• 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
Svilaas, 2008	Study Designation: Effectiveness study Composite Score: 6 of 7	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	Population, Setting	• High male to female ratio (67.9-73.1%) • Only patients undergoing primary PCI • Conducted in Europe

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
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
Kaltoft, 2006	Study Designation: Effectiveness study Composite Score: 5 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis	Population, Intervention, Setting	• High male to female ratio (76- 80%) • 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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Noel, 2005	Study Designation: Efficacy study Composite Score: 1 of 7	1. Assessed final health outcomes	Population, Outcomes, Setting	• 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
Dudek, 2004	Study Designation: Efficacy study Composite Score: 1 of 7	1. Less stringent eligibility criteria	Population, Intervention, Outcomes, Setting	• 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

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 222. Evaluation of applicability for individual randomized controlled trials evaluating mechanical thrombectomy devices versus control in patients with ST-segment elevation myocardial infarction

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Migliorini, 2010	Study Designation: Effectiveness study Composite Score: 5 of 7	Enrolled primary care population Assessed final health outcomes Adequate study duration with clinically relevant treatments Assessed adverse outcome Adequate sample size	Population	High male to female ratio (76- 81%) Only patients undergoing primary PCI Use of ITT analysis not reported
Ali, 2006	Study Designation: Effectiveness study Composite Score: 5 of 7	Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Adequate sample size Used intention to treat analysis	Population	High male to female ratio (74.2-75.8%) Short duration of followup (30 -180 d)
Lefèvre, 2005	Study Designation: Efficacy study Composite Score: 4 of 7	Assessed final health outcomes Assessed adverse outcome Adequate sample size Used intention to treat analysis	Population, Setting	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
Antoniucci, 2004	Study Designation: Efficacy study Composite Score: 4 of 7	Enrolled primary care population Less stringent eligibility criteria Assessed final health outcomes Used intention to treat analysis	Outcome, Setting	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
Napodano, 2003	Study Designation: Efficacy study Composite Score: 3 of 7	Assessed final health outcomes Assessed adverse outcomes Used intention to treat analysis	Population, Setting	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

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Ito, 2010	Study Designation: Effiacy study Composite Score: 4 of 7	Enrolled primary care population Less stringent inclusion criteria Assessed final health outcomes Used intention to treat analysis	Intervention, Outcomes, Setting	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
Kelbæk, 2008	Study Designation: Effectiveness study Composite Score: 5 of 7	Enrolled primary care population Assessed final health outcomes Adequate study duration with clincally relevant treatments Adequate sample size Used intention to treat analysis	Population, Intervention, Outcomes, Setting	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
Cura, 2007	Study Designation: Efficacy study Composite Score: 4 of 7	Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis	Population, Intervention, Setting	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
Guetta, 2007	Study Designation: Efficacy study Composite Score: 2 of 7	Assessed final health outcomes Used intention to treat analysis	Population, Outcomes, Setting	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
Lefèvre, 2004	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Outcomes, Setting	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

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Duan, 2010	Study Designation: Efficacy study Composite Score: 2 of 7	Adequate study duration with clinically relevant treatments Used intention to treat analysis	Population, Outcomes, Setting	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
Pan, 2010	Study Designation: Efficacy study Composite Score: 3 of 7	Enrolled primary care population Adequate study duration with clinically relevant treatments Used intention to treat analysis	Outcomes, Intervention, Setting	Final health outcomes not reported Adverse outcomes not reported Small sample size (n=104) Guardwire not available in the US Conducted in Asia
Tahk, 2008	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Intervention, Outcomes, Setting	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
Hahn, 2007	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Intervention, Outcomes, Setting	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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Matsuo, 2007	Study Designation: Efficacy study Composite Score: 3 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome	Population, Intervention, Setting	• 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
Muramatsu, 2007	Study Designation: Efficacy study Composite Score: 4 of 7	1. Assessed final health outcomes 2. Assessed adverse outcome 3. Adequate sample size 4. Used intention to treat analysis	Population, Setting	• 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
Zhou, 2007	Study Designation: Efficacy study Composite Score: 3 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome	Population, Intervention, Outcomes, Setting	• 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
Okamura, 2005	Study Designation: Efficacy study Composite Score: 0 of 7		Population, Intervention, Outcomes, Setting	• 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
Stone, 2005	Study Designation: Effectiveness study Composite Score: 5 of 7	1. Enrolled primary care population 2. Assessed final health outcomes 3. Assessed adverse outcome 4. Adequate sample size 5. Used intention to treat analysis	Population	• Younger population (58.5- 59.8 y) • High male to female ratio (76.2-80.7%) • Short duration of followup (180 d)

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Haeck, 2009	Study Designation: Efficacy study Composite Score: 4 of 7	Assessed final health outcomes Assessed adverse outcome Adequate sample size Used intention to treat analysis	Population, Setting	Younger population (59-62 y) High male to female ratio (80%) Only patients undergoing primary PCI Short duration of followup (30 d) Conducted in Europe and North America

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Parikh, 2008	Study Designation: Efficacy study Composite Score: 3 of 7	Assessed final health outcomes Assessed adverse outcome Adequate study duration with clinically relevant treatments	Population, Intervention, Setting	Younger population (55.17-56.16 y) High male to female ratio (90-95%) Percentage of primary PCI versus rescue PCI not reported Use of antiplatelets and antithrombotic not reported GuardWire device no longer available Small sample size (N =67) Use of ITT analysis not used Conducted in Asia
Gick, 2005	Study Designation: Efficacy study Composite Score: 4 of 7	Enrolled primary care population Assessed final health outcomes Adequate sample size Used intention to treat analysis	Population, Intervention, Outcomes, Setting	High male to female ratio (80-86%) Percentage of primary PCI versus rescue PCI not reported Short duration of followup (30 - 180 d) FilterWire device no longer available Adverse outcomes not reported Conducted in Europe

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
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	1. Assessed final health outcomes 2. Adequate sample size	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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Webster, 2008	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Outcomes, Setting	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 Americ
Dudek, 2003	Study Designation: Efficacy study Composite Score: 1 of 7	Assessed final health outcomes	Population, Outcomes, Setting	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

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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Sardella, 2008	Study Designation: Effectiveness study Composite Score: 4 of 7	Enrolled primary care population Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis	Population, Intervention, Setting	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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Yan, 2007	Study Designation: Efficacy study Composite Score: 3 of 7	Assessed final health outcomes Assessed adverse outcome Used intention to treat analysis	Population, Intervention, Setting	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

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 229. Evaluation of applicability for individual randomized controlled trials with selective inclusion/exclusion criteria in patient with ST-segment elevation myocardial infarction

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Wita, 2009	**Study Designation:** Efficacy study **Composite Score:** 1 of 7	Assessed adverse outcome	Population, Intervention, Outcomes, Setting	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
Ozaki, 2006	**Study Designation:** Efficacy study **Composite Score:** 0 of 7		Population, Intervention, Outcomes, Setting	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

Abbreviations: d=days; 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 230. Evaluation of applicability for individual observational studies

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
Beaudoin, 2010	Study Designation: Effectiveness study Composite Score: 6 of 7	Enrolled primary care population Less stringent inclusion criteria Assessed final health outcomes Adequate study duration with clinically relevant treatments Asssessed adverse health outcome Adequate sample size	Population	High male to female ratio (70-76%) IRA not reported Conducted in Canada ITT analysis not used
Kim, 2010	Study Designation: Efficacy study Composite Score: 3 of 7	Less stringent inclusion criteria Assessed final health outcomes Adequate sample size	Intervention, Outcomes, Setting	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
Ko, 2009	Study Designation: Efficacy study Composite Score: 2 of 7	Assessed final health outcomes Adequate sample size	Population, Intervention, Outcomes, Setting	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
Nilsen, 2009	Study Designation: Efficacy study Composite Score: 3 of 7	Assessed final health outcomes Assessed adverse outcome Adequate sample size	Population, Intervention, Setting	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

Study, Year	Effectiveness Study Designation and Composite Score	Effectiveness Study Criteria Met	Applicability Limitation Category	Specific Factors Limiting Applicability
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 231. Strength of applicability for the body of evidence evaluating mortality in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	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.
Catheter aspiration versus distal balloon embolic protection device	Low	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 on the right coronary artery.
Catheter aspiration devices versus control	Moderate	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.
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 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.
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Moderate	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.
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 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.

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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States;Y=years

Table 232. Strength of applicability for the body of evidence evaluating myocardial infarction in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	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. Data is not applicable to patients with other ACS or undergoing rescue PCI.
Catheter aspiration versus distal balloon embolic protection device	Low	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 durtation. Data is highly applicable to Asian male patients with STEMI undergoing primary PCI on the right coronary artery.
Catheter aspiration devices versus control	Moderate	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.
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 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.
Distal filter embolic protection devices versus control	Moderate	Compared with control, patients who undergo native vessel PCI with a distal filter embolic protection device do not have a difference in the risk off 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Distal balloon embolic protection devices versus control	Moderate	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.
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 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.
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 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.

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

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration devices versus control	Moderate	Compared with control, patients who undergo native vessel PCI with a catheter aspiration device do not have a difference in the risk of stroke. Applicability is limited by duration of followup as the majority of studies did not allow for adequate duration to stroke. 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.
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 stroke. Overall, the majority of studies were conducted outside of the US and did not allow for adequate duration of followup to stroke. 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.
Distal filter embolic protection devices versus control	Low	Compared with control, patients undergoing native vessel PCI with a distal filter embolic protection device do not have a difference in the risk of stroke. Data has limited applicability because all studies were conducted in Europe and mostly devices evaluated are not available in the US. The majority of studies did not allow for adequate duration of followup to assess stroke. 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.
Distal balloon embolic protection devices versus control	High	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 stroke. Overall applicability of data is limited because the study did not allow for adequate duration to assess stroke. The data is highly applicable to male patients with STEMI undergoing primary or rescue PCI. The data is moderately applicable to female patients and not applicable to patients with other ACS.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
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 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.
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 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.

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

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	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.
Catheter aspiration versus distal balloon embolic protection device	Low	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.
Catheter aspiration devices versus control	Moderate	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.
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 target revascularization. Overall, the majority of studies were conducted outside of the US and 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.
Distal filter embolic protection devices versus control	Moderate	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 in patients with other ACS, although low in patients undergoing rescue PCI.
Distal balloon embolic protection devices versus control	Moderate	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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
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 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.
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 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.

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

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus distal balloon embolic protection device	Low	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.
Catheter aspiration devices versus control	Moderate	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.
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 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Moderate	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.
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 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.
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 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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 236. Strength of applicability for the body of evidence evaluating resolution of ST-segment elevation in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	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 resolving ST-segment elevation. 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus distal balloon embolic protection device	Low	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.
Catheter aspiration devices versus control	Moderate	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.
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 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.
Distal filter embolic protection devices versus control	Low	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 ST segment elevation myocardial infarction undergoing primary PCI and moderately applicable in female patients. Data is not applicable to patients with other ACS.
Distal balloon embolic protection devices versus control	Moderate	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.
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 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.
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 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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 237. Strength of applicability for the body of evidence evaluating ejection fraction in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration devices versus control	Low	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.
Catheter aspiration versus distal balloon embolic protection device	Low	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.
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 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.
Distal filter embolic protection devices versus control	Low	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.
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 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.
Embolic protection devices combined versus control	Low	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

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 238. Strength of applicability for the body of evidence evaluating myocardial blush grade of 3 in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	**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.**
Catheter aspiration versus distal balloon embolic protection device	Low	**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.**
Catheter aspiration devices versus control	Moderate	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.
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 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 in patients with other ACS.
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Low	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.
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 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
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 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

Abbreviations: ACS=Acute coronary syndrome; MBG= Myocardial blush grade; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States; Y=years

Table 239. Strength of applicability for the body of evidence evaluating TIMI-3 blood flow in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus catheter aspiration	Low	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. Data is not applicable to patients with other ACS or undergoing rescue PCI.
Catheter aspiration versus distal balloon embolic protection device	Low	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.
Catheter aspiration devices versus control	Moderate	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.
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 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.
Distal filter embolic protection devices versus control	Low	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.

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. The data has low applicability in patients with other ACS or undergoing rescue PCI

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 240. Strength of applicability for the body of evidence evaluating distal embolization in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration devices 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Moderate	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.
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 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.
Embolic protection devices combined versus control	Moderate	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

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation 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

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration devices versus control	Low	Compared with control, patients who undergo native vessel PCI with a catheter aspiration device have a decreased risk of no reflow. Overall applicability is limited because all studies were conducted outside of the US and almost half of the data is derived from studies which evaluate devices that are 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 undergoing rescue PCI and is not applicable in patients with other ACS.
Catheter aspiration versus distal balloon embolic protection device	Low	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 no reflow. 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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
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 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.
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Moderate	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.
Embolic protection devices combined versus control	Moderate	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

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

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration device versus catheter aspiration device	Low	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.
Catheter aspiration devices versus control	Moderate	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.
Mechanical thrombectomy devices versus control	High	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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 243. Strength of applicability for the body of evidence evaluating coronary perforation in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Mechanical thrombectomy devices versus control	High	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.
Distal balloon embolic protection devices versus control	Low	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.
Embolic protection devices combined versus control	Low	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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

Table 244. Strength of applicability for the body of evidence evaluating prolonged procedure time in patients with acute coronary syndromes

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration device versus distal balloon embolic protection device	Low	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.
Catheter aspiration versus control	Moderate	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.
Mechanical thrombectomy devices versus control	High	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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Distal filter embolic protection devices versus control	Low	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.
Distal balloon embolic protection devices versus control	Moderate	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.
Proximal balloon embolic protection device versus control	Low	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.
Embolic protection devices combined versus control	Low	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.

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

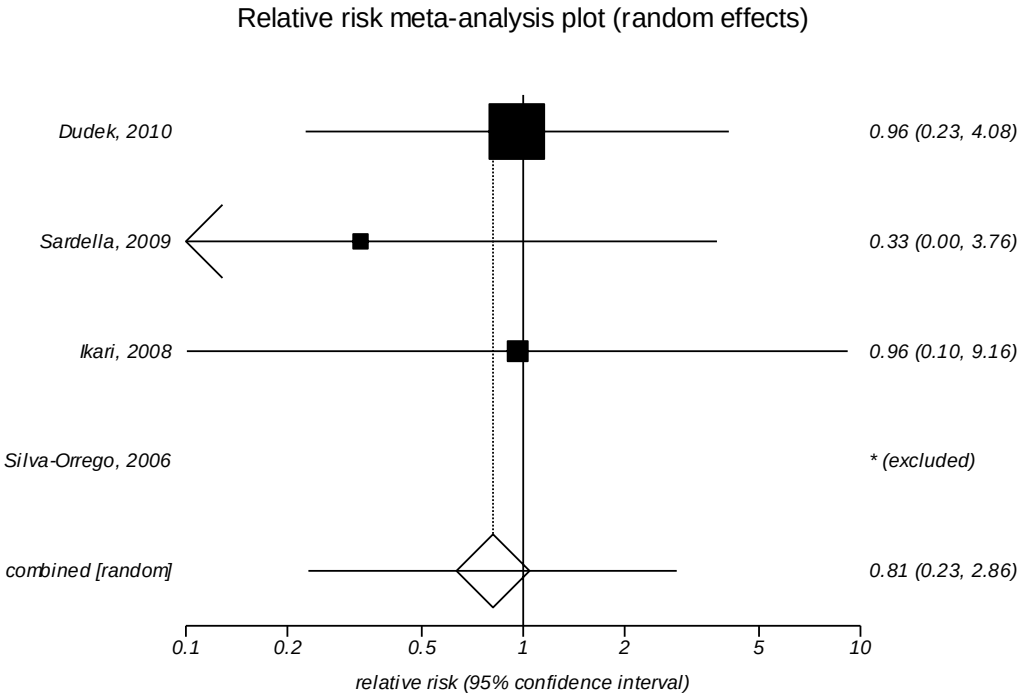
Comparison	Strength of Applicability	Conclusion with Description of Applicability
Catheter aspiration versus control	Moderate	Compared with control, patients undergoing native vessel PCI with a catheter aspiration device do not have a difference in the risk of side branch occlusion. Overall applicability 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.
Mechanical thrombectomy devices versus control	Low	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.
Distal filter embolic protection devices versus control	Low	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.

Comparison	Strength of Applicability	Conclusion with Description of Applicability
Distal balloon embolic protection devices versus control	Moderate	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.
Embolic protection devices combined versus control	Moderate	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.

Abbreviations: ACS=Acute coronary syndrome; PCI=Percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction; US=United States

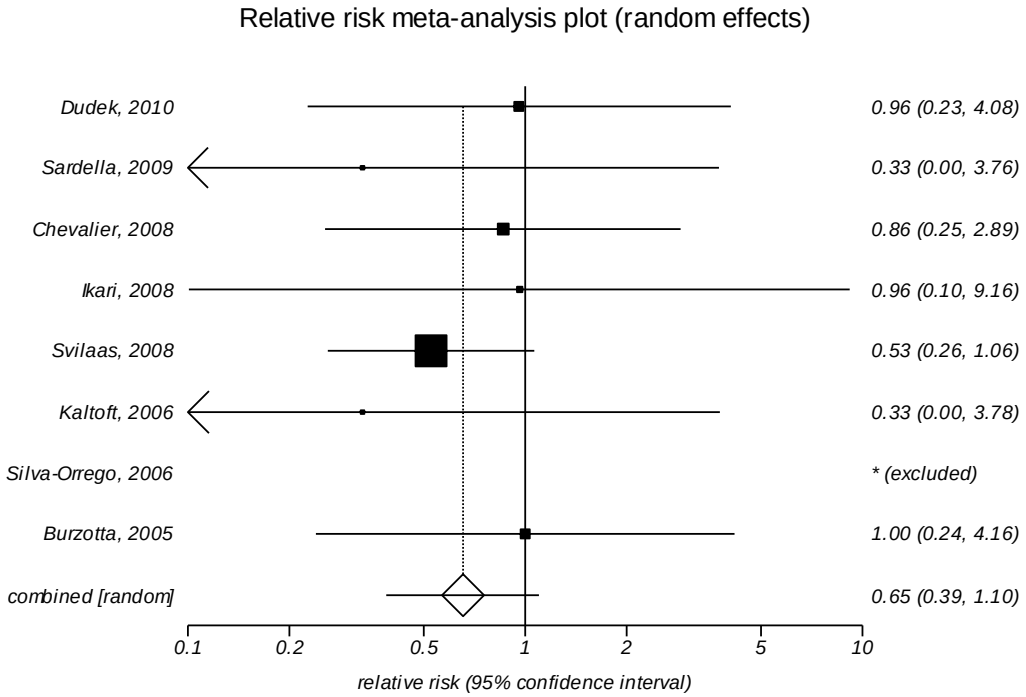
Appendix I: Forest Plots for Results of Final Health Outcomes Analyzed at Individual Time Points

Figure 1. Impact of catheter aspiration devices versus control on in-hospital mortality.



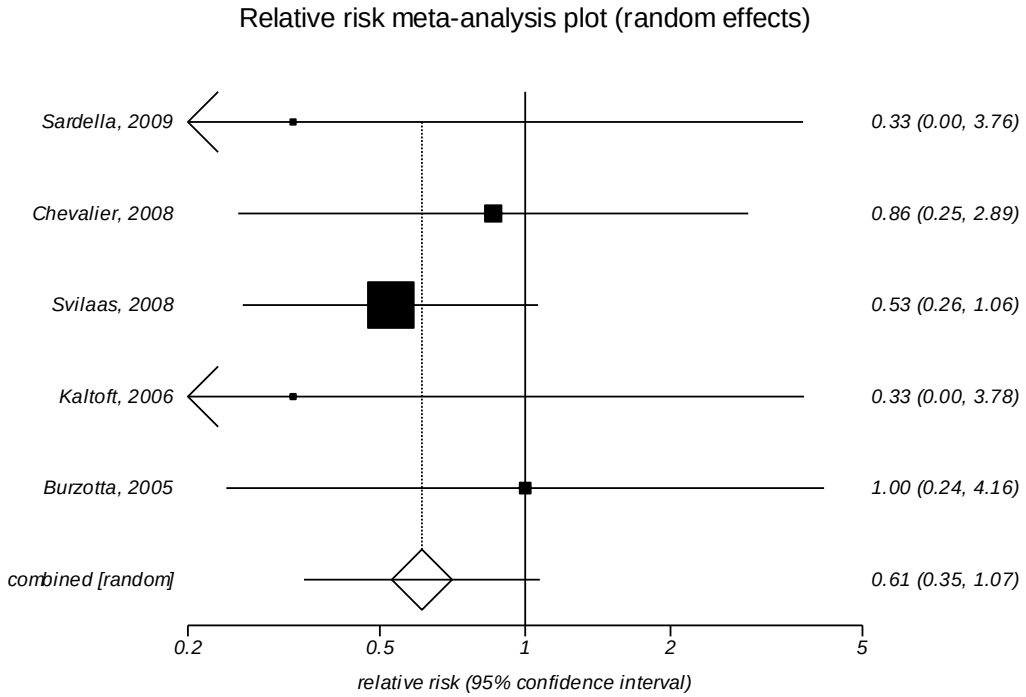
Cochran Q: P = 0.832
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 2. Impact of catheter aspiration devices versus control on ≤30 day mortality.



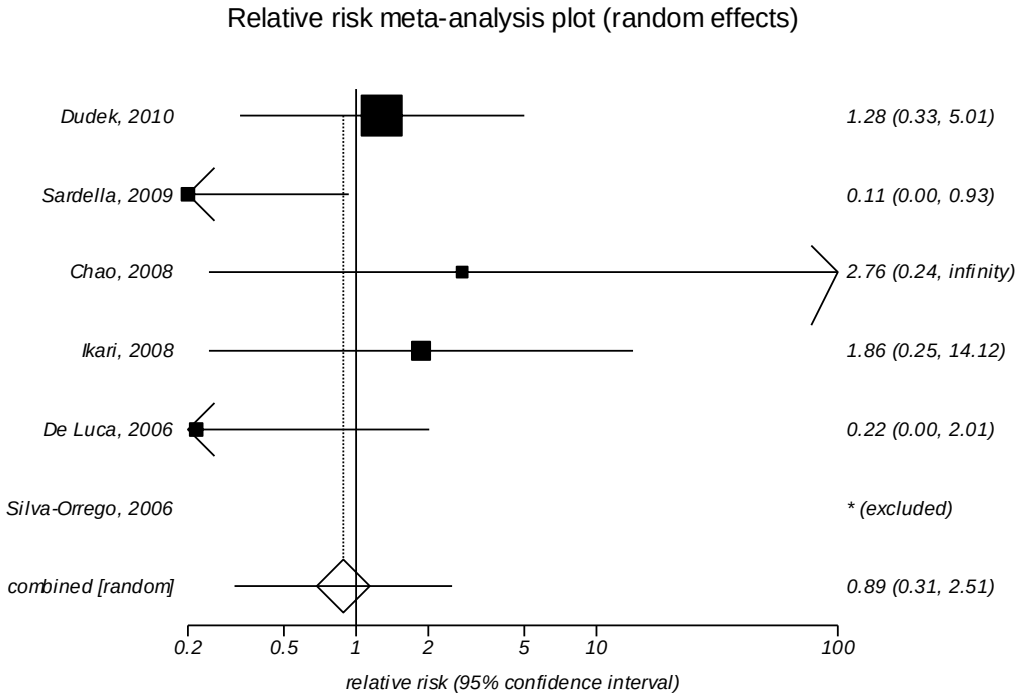
Cochran Q: P = 0.961
I^2: 0%
Egger: P = 0.689
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



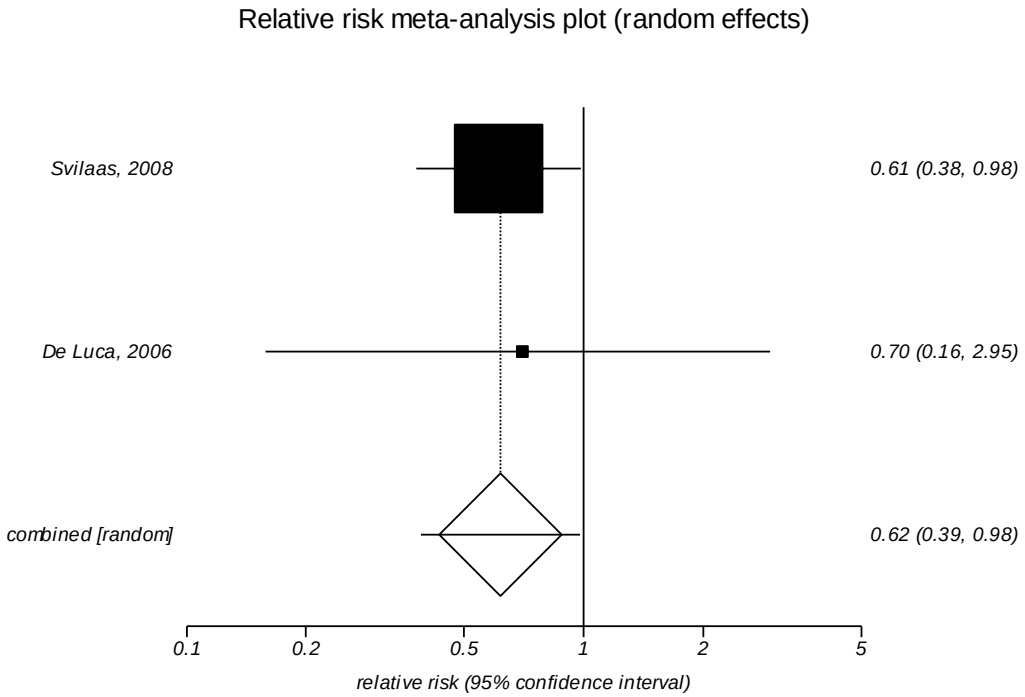
Cochran Q: P = 0.892
I^2: 0%
Egger: P = 0.976
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 4. Impact of catheter aspiration devices versus control on 180-day mortality.



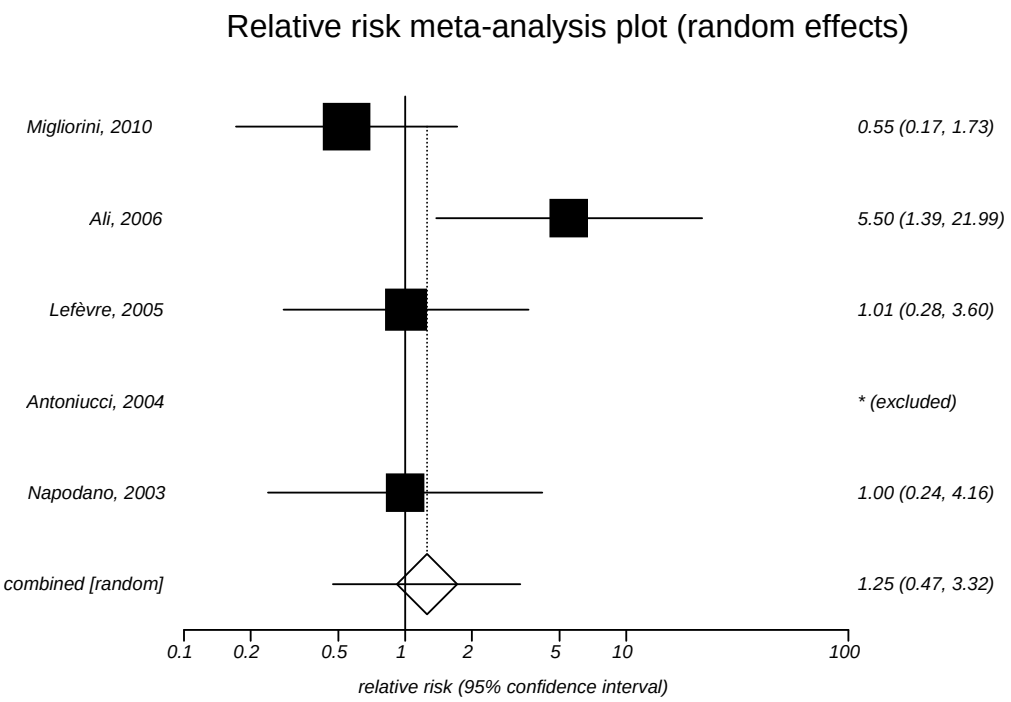
Cochran Q: P = 0.391
I^2: 2.8%
Egger: P = 0.487
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



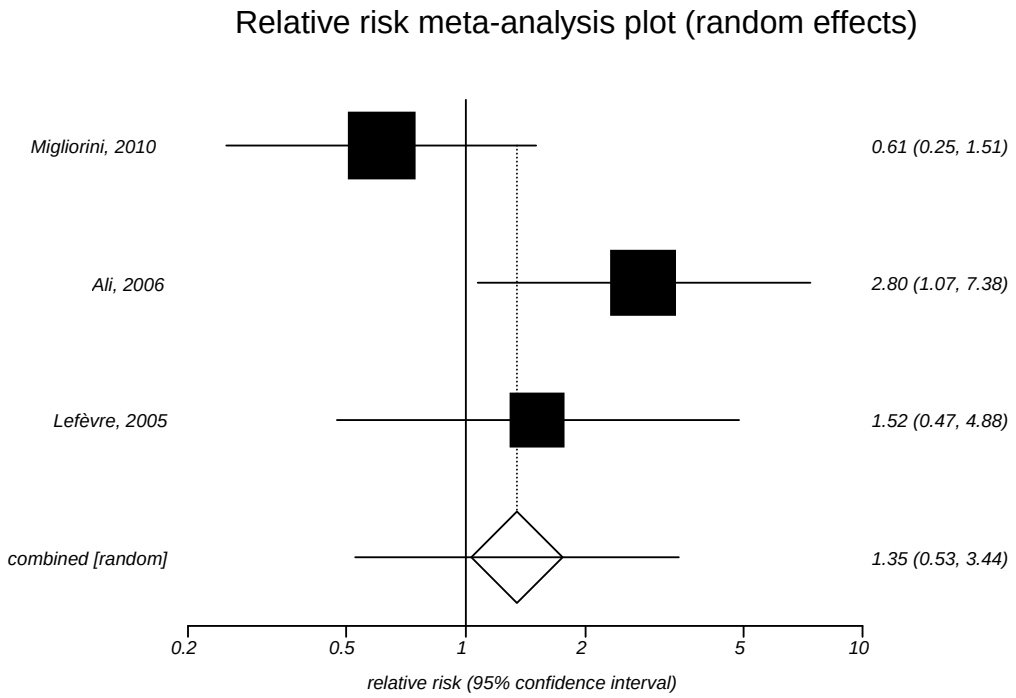
Cochran Q: P = 0.873
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



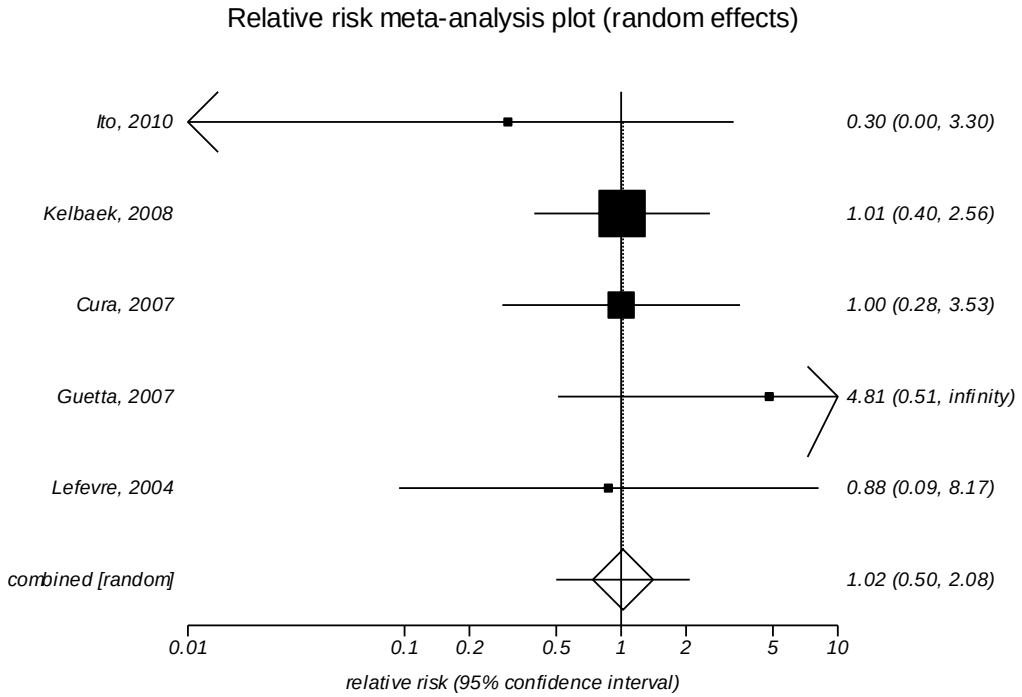
Cochran Q: P = 0.120
I^2: 48.7%
Egger: P = 0.329
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



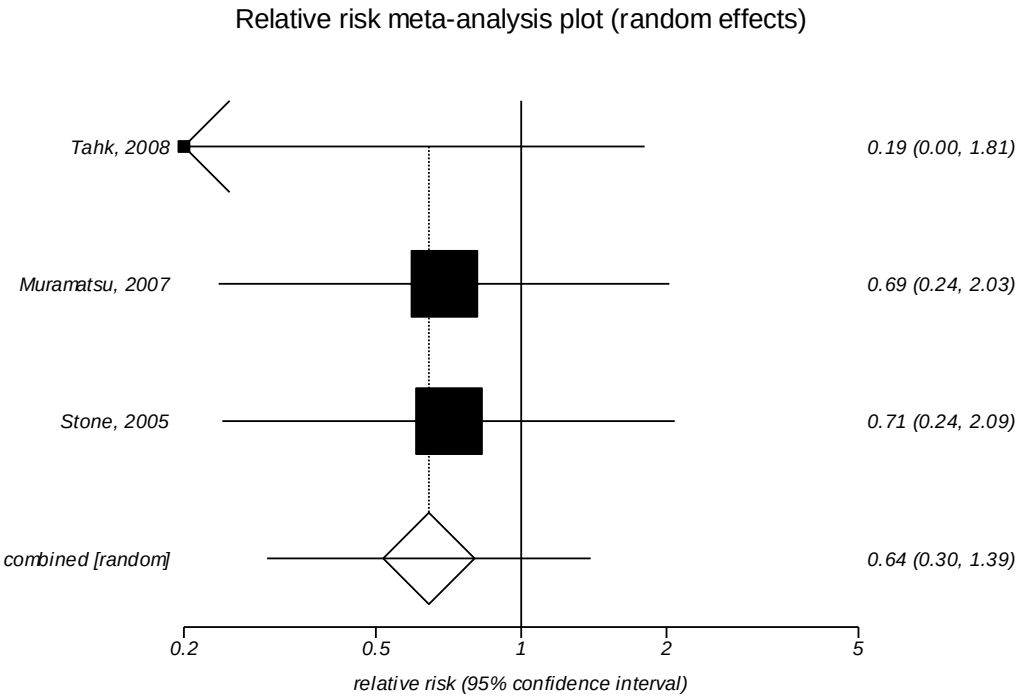
Cochran Q: P = 0.090
I^2: 58.4%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 8. Impact of distal filter embolic protection devices versus control on ≤30 day mortality.



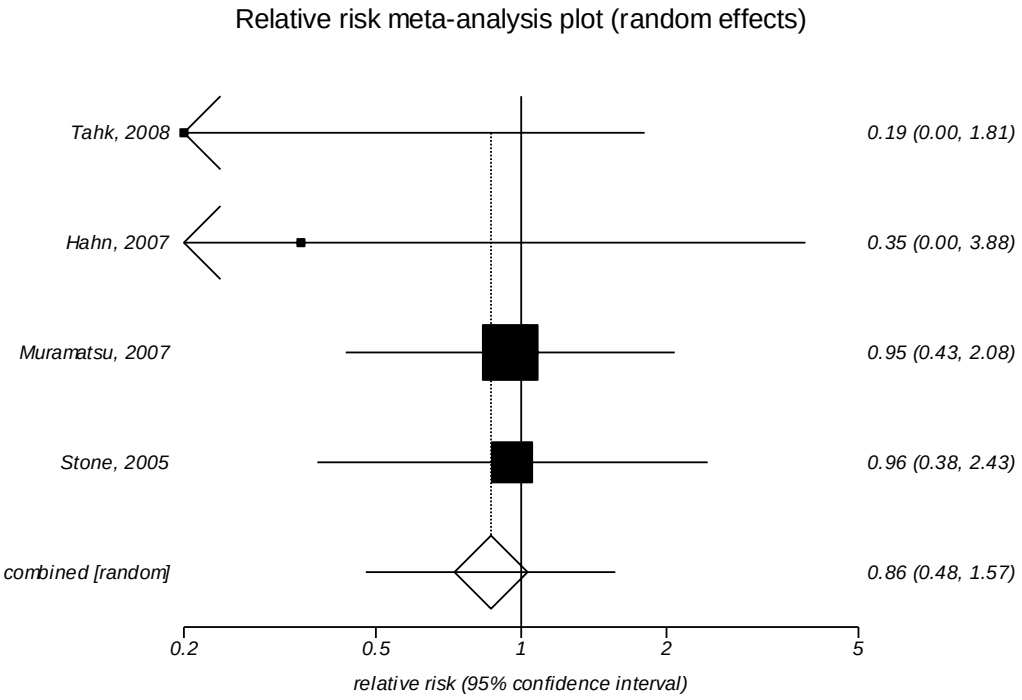
Cochran Q: P = 0.805
I^2: 0%
Egger: P = 0.925
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



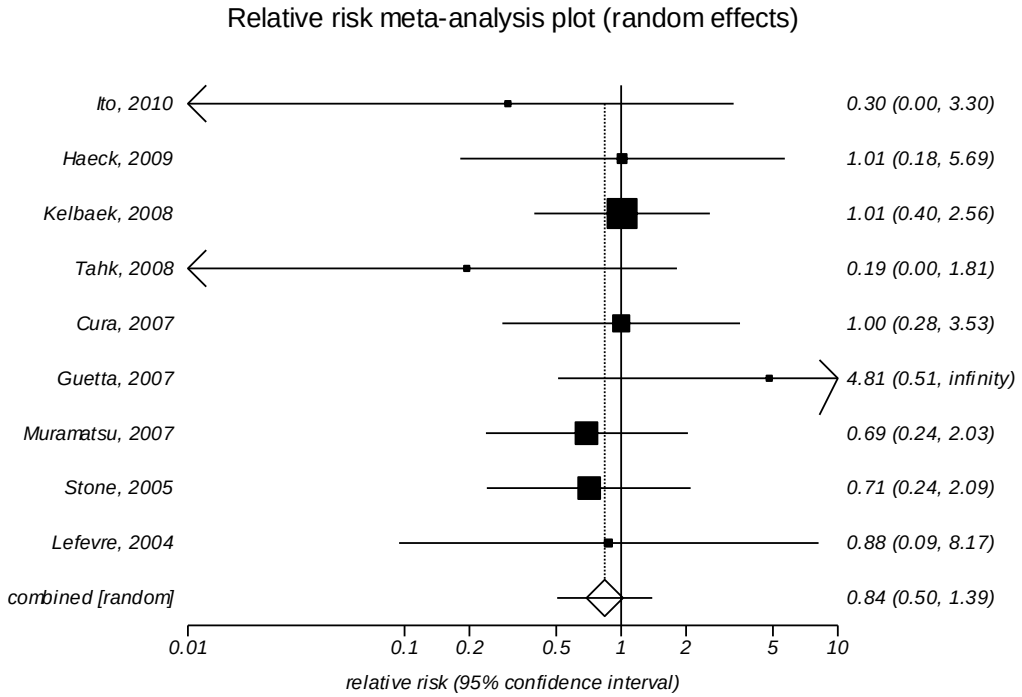
Cochran Q: P = 0.716
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 10. Impact of distal balloon embolic protection devices versus control on 180-day mortality.



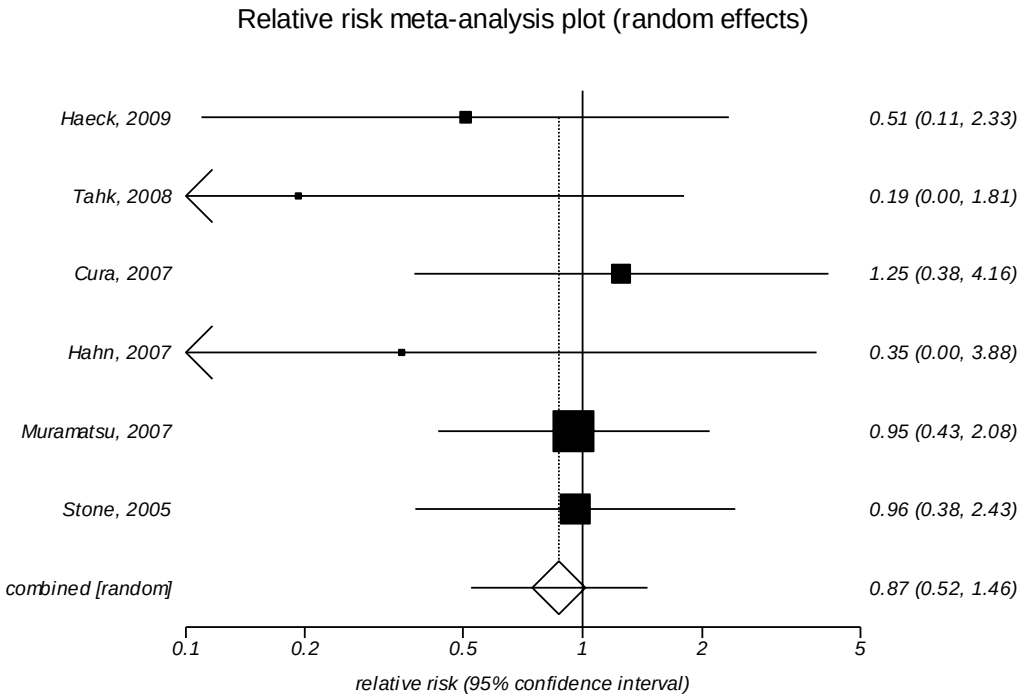
Cochran Q: P = 0.709
I^2: 0%
Egger: P = 0.044
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



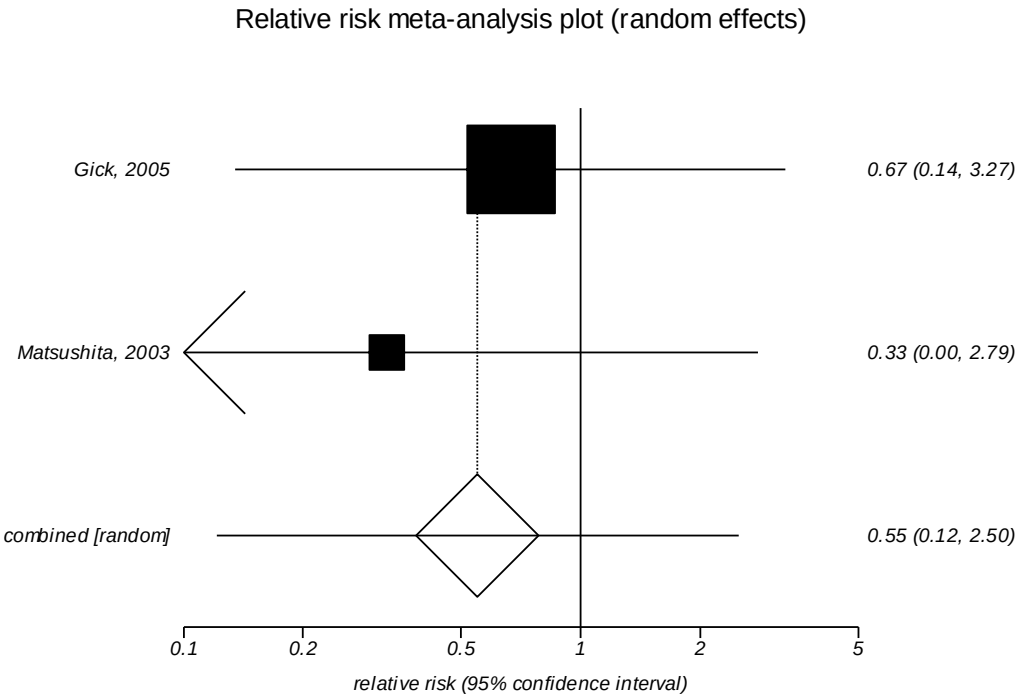
Cochran Q: P = 0.931
I^2: 0%
Egger: P = 0.794
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



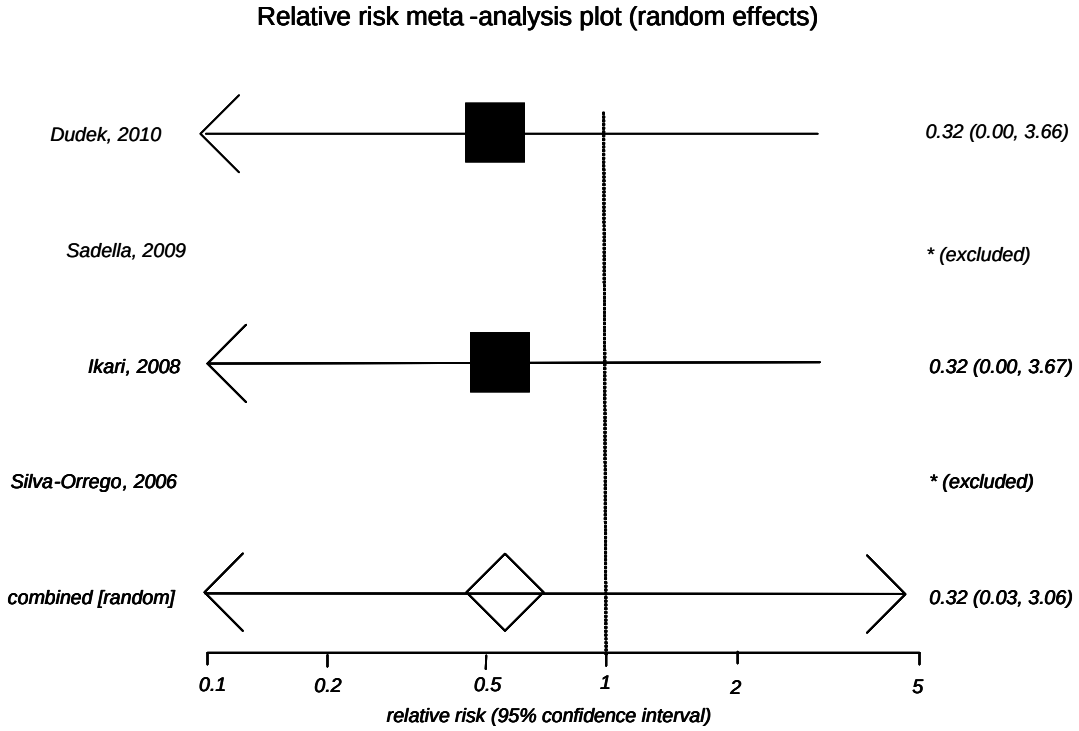
Cochran Q: P = 0.836
I^2: 0%
Egger: P = 0.031
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



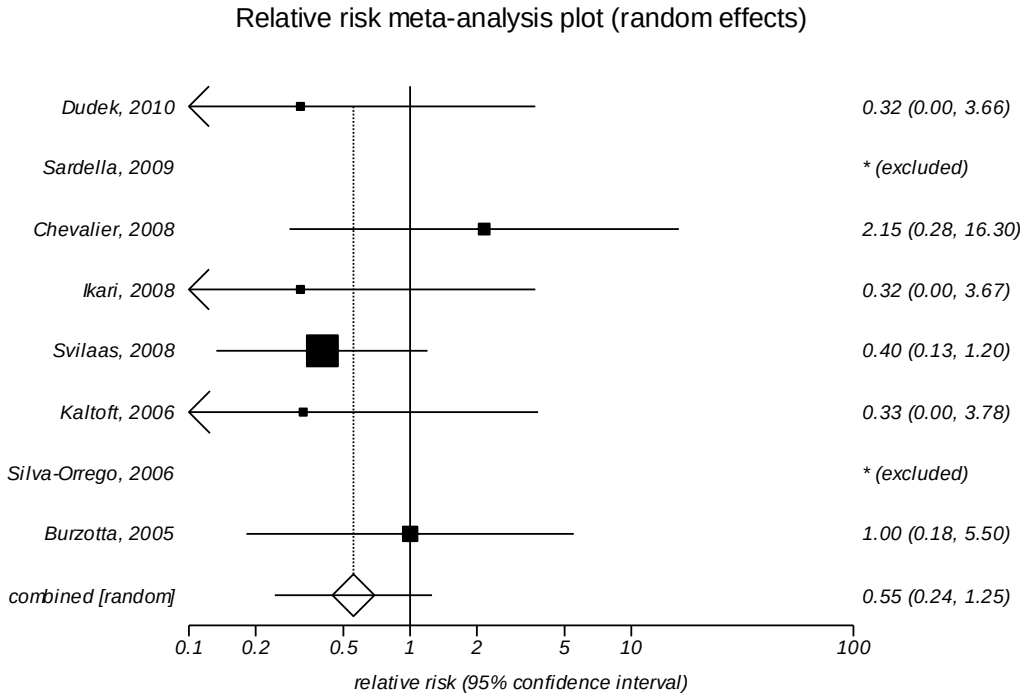
Cochran Q: P = 0.677
I^2: Too few strata
Egger: P = Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond 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.



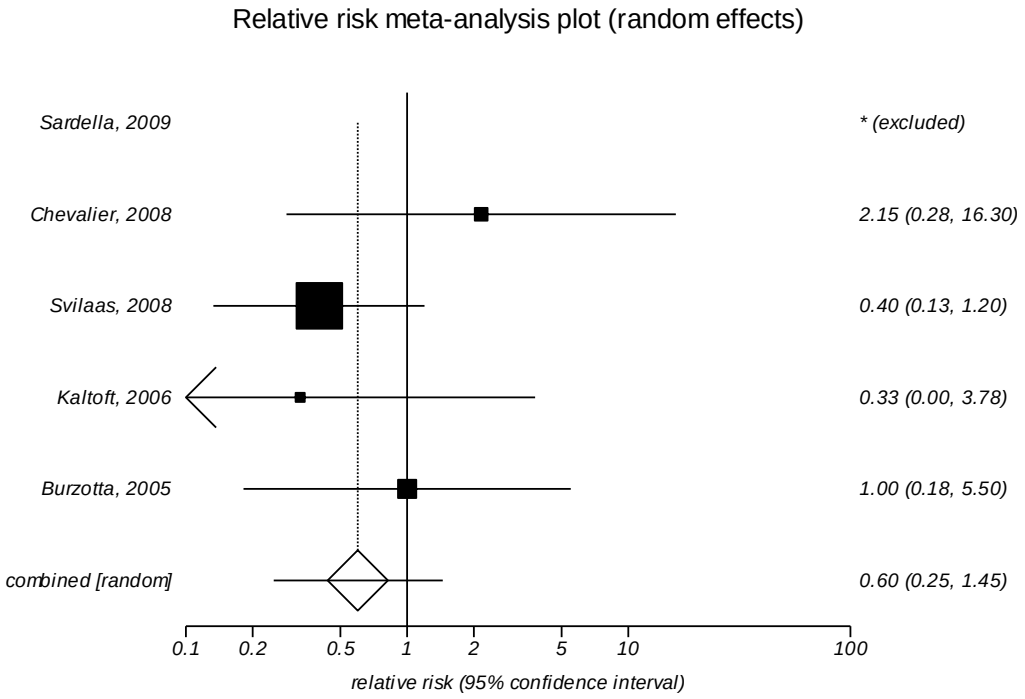
Cochran Q: P = 1.000
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



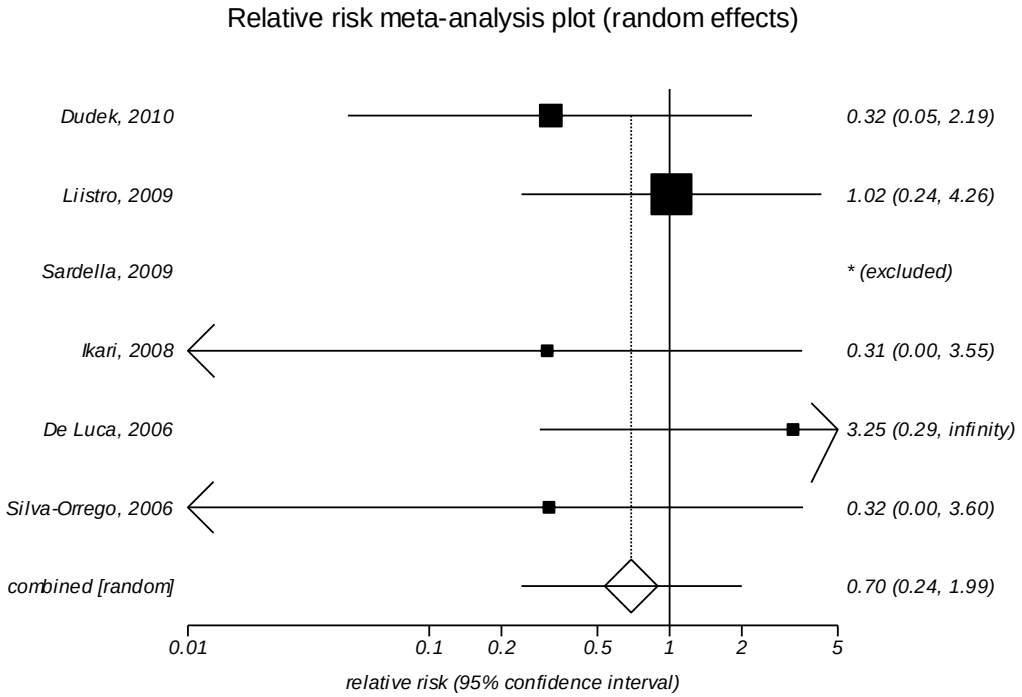
Cochran Q: P = 0.816
I^2: 0%
Egger: P = 0.809
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



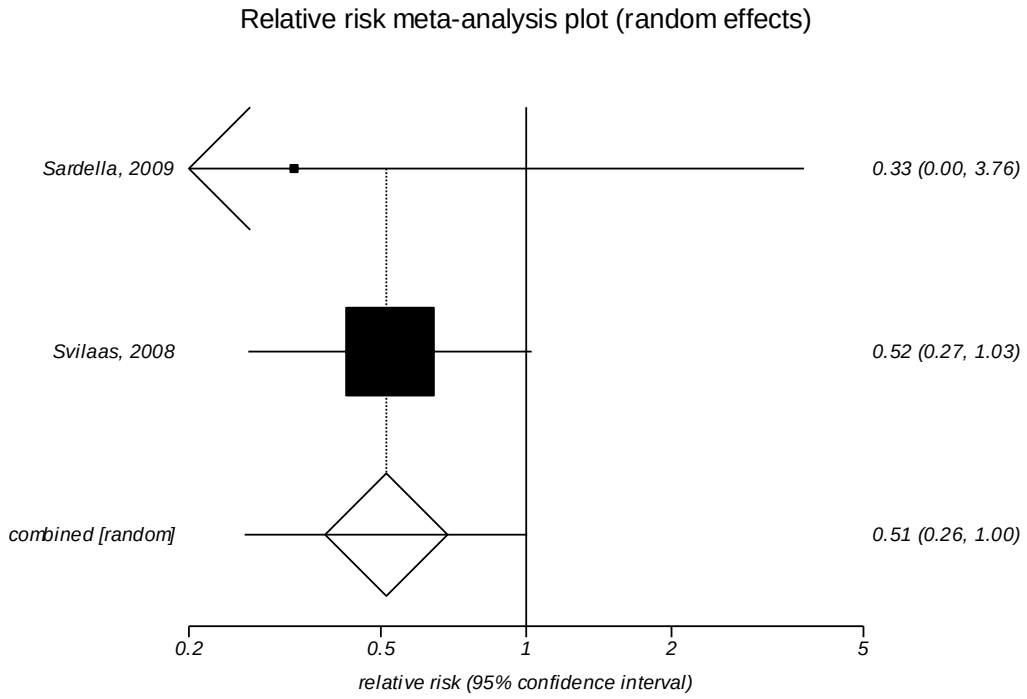
Cochran Q: P = 0.578
I^2: 0%
Egger: P = 0.499
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



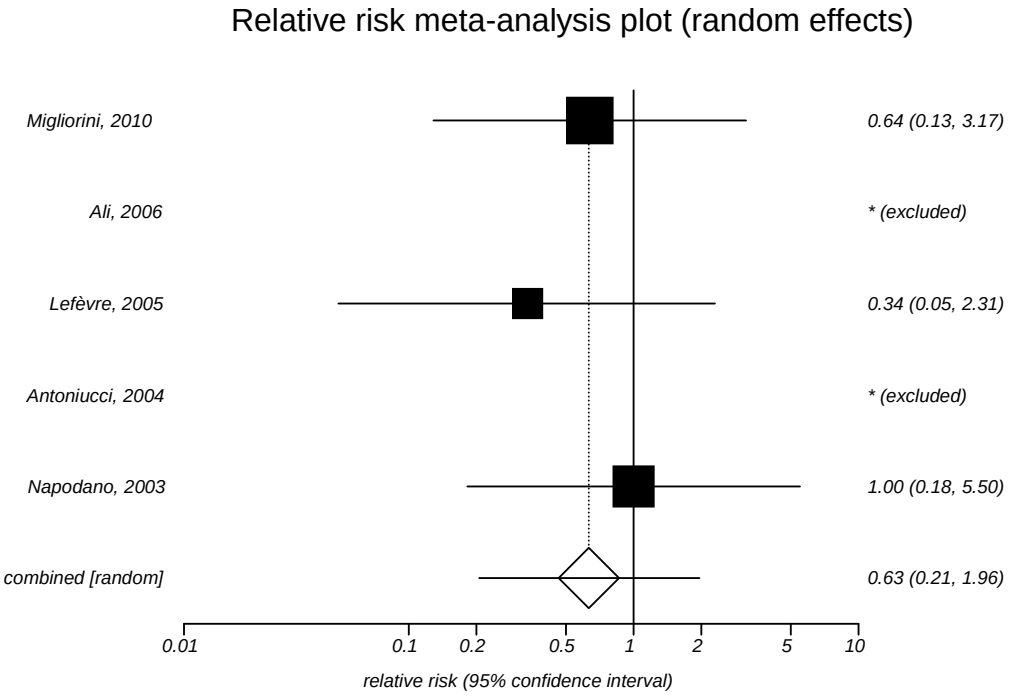
Cochran Q: P = 0.721
I^2: 0%
Egger: P = 0.708
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



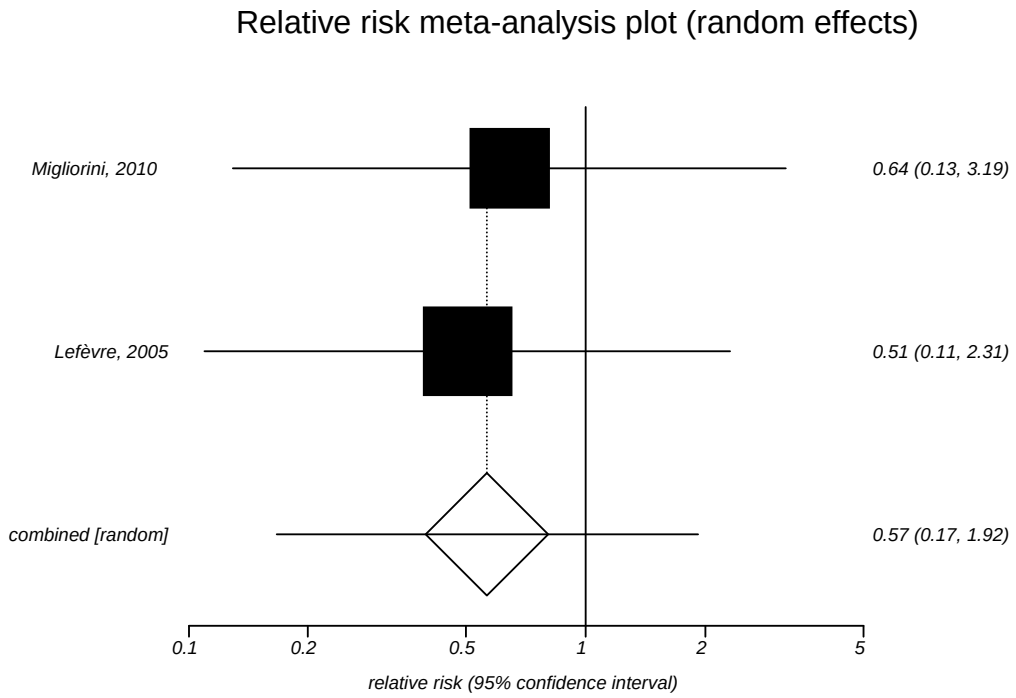
Cochran Q: P = 0.782
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



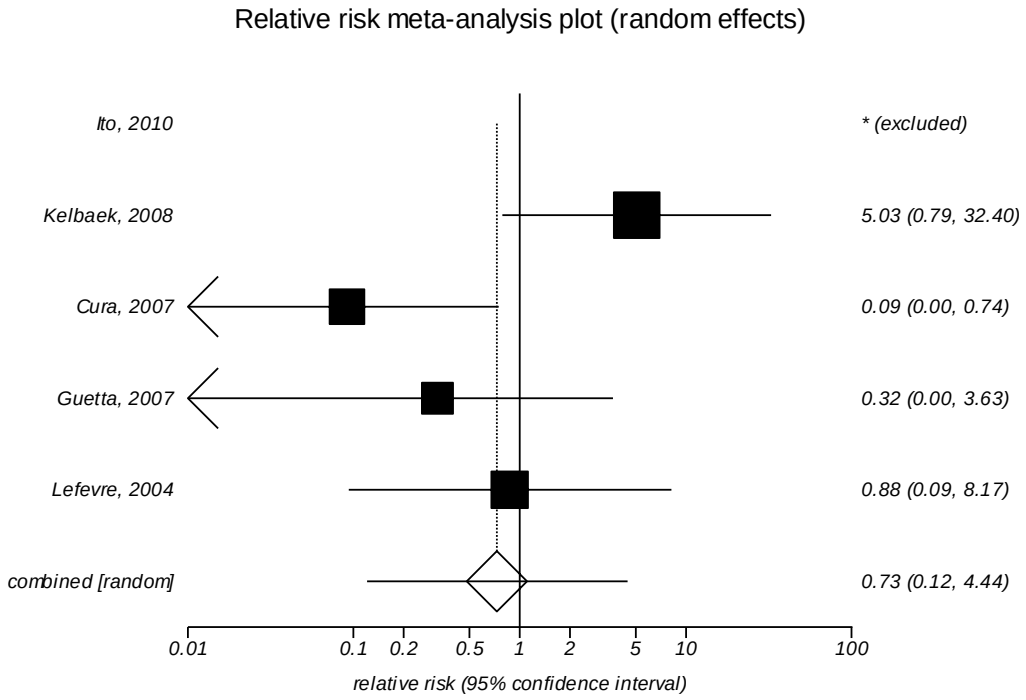
Cochran Q: P = 0.769
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



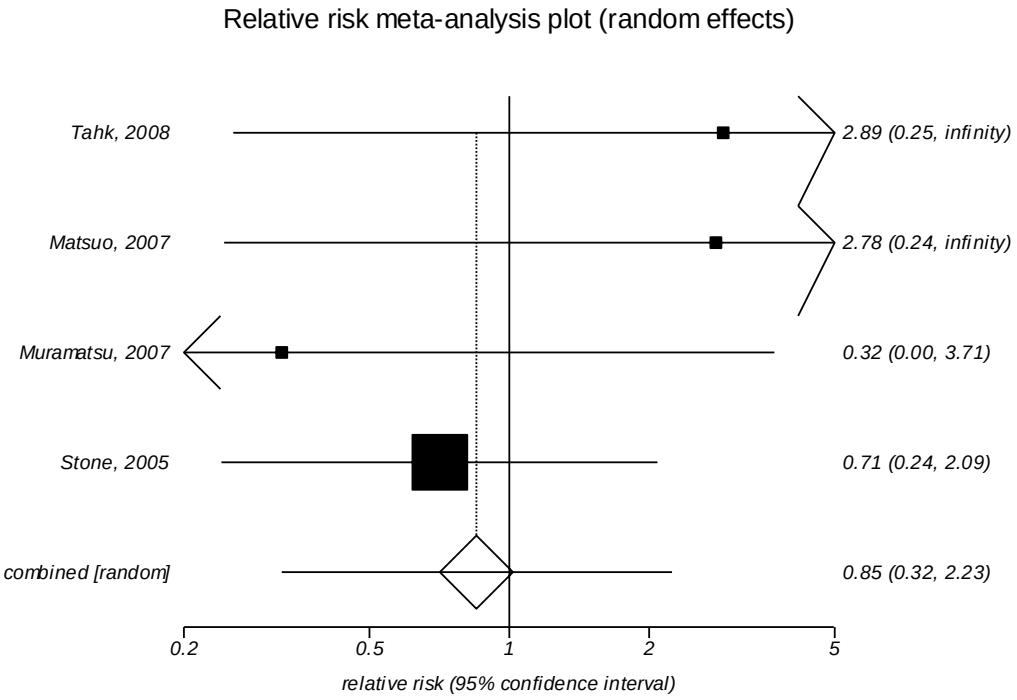
Cochran Q: P = 0.847
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 21. Impact of distal filter embolic protection devices versus control on ≤30-day myocardial infarction.



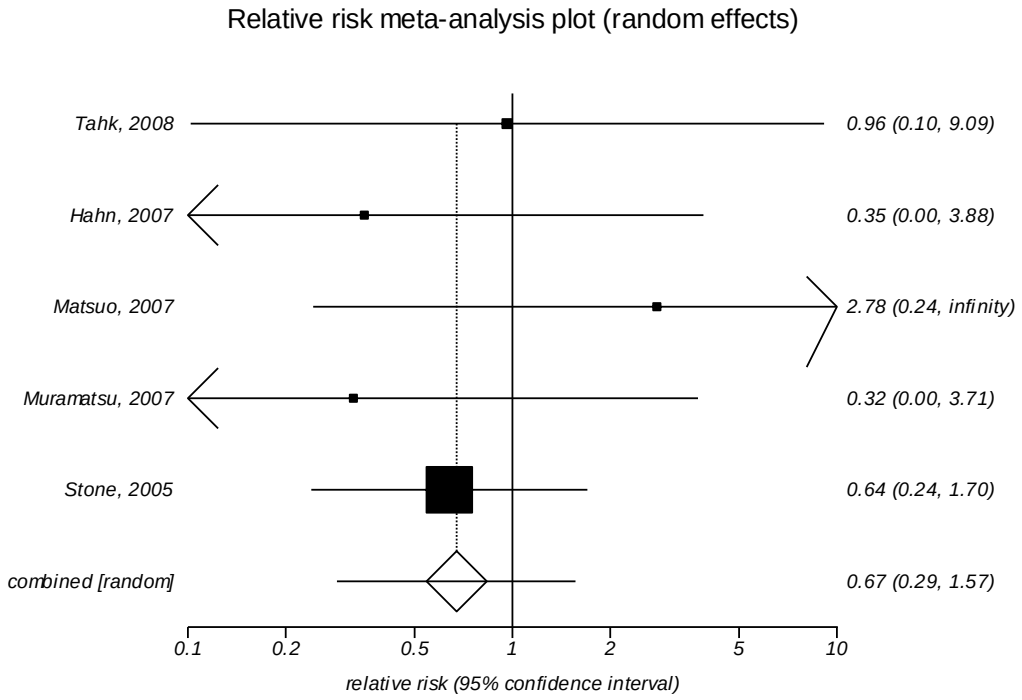
Cochran Q: P = 0.146
I^2: 44.3 percent
Egger: 0.128
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



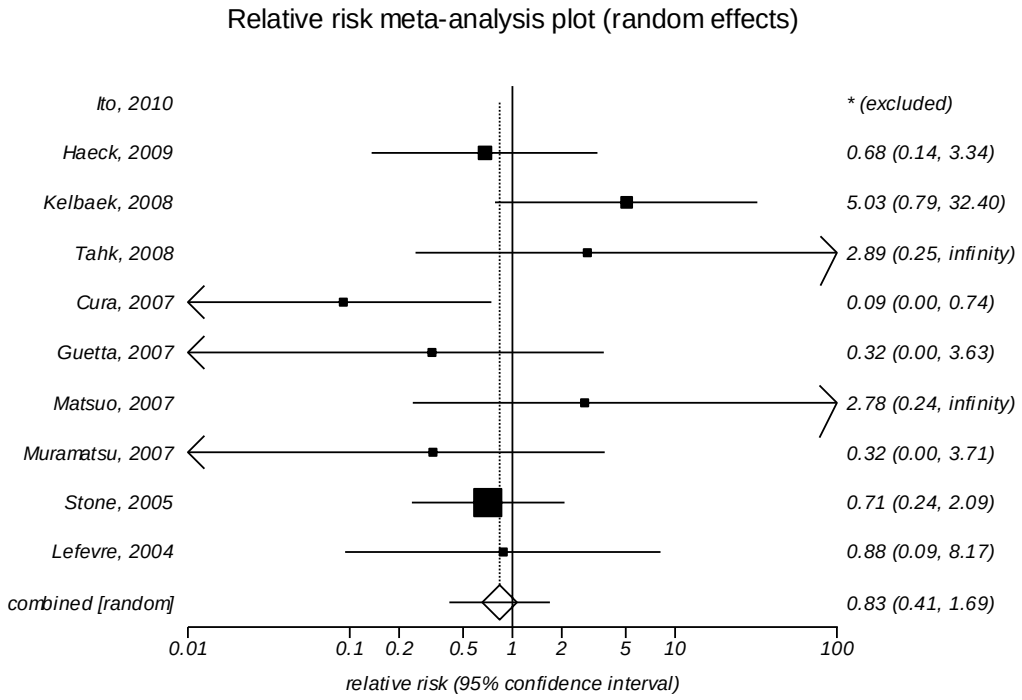
Cochran Q: P = 0.670
I^2: 0%
Egger: P = 0.517
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 23. Impact of distal balloon embolic protection devices versus control on 180-day myocardial infarction.



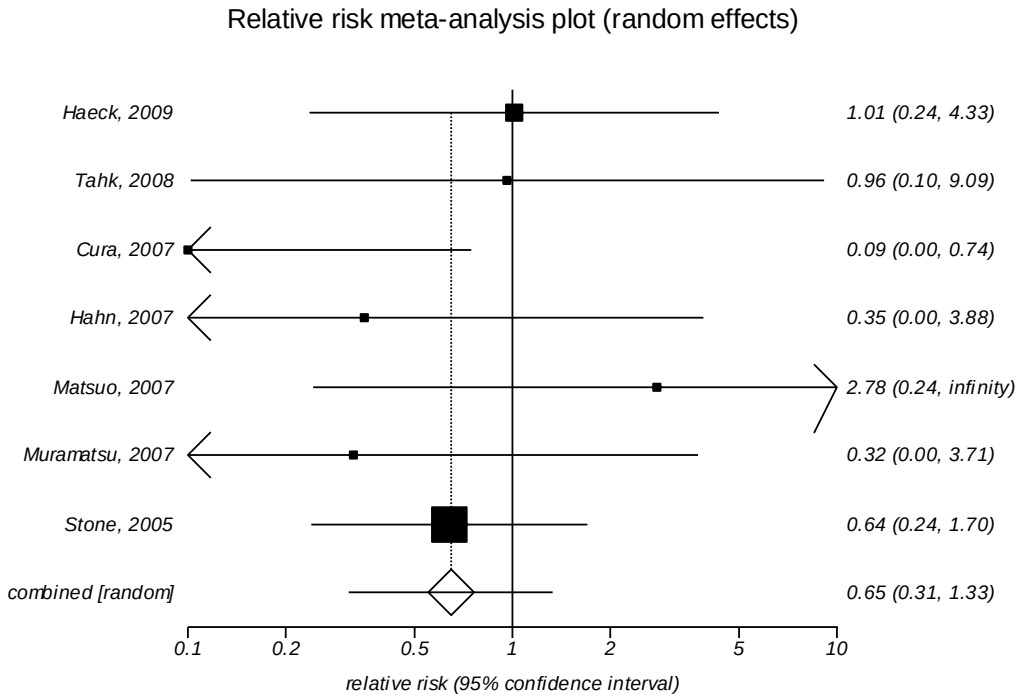
Cochran Q: P = 0.877
I^2: 0%
Egger: P = 0.820
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



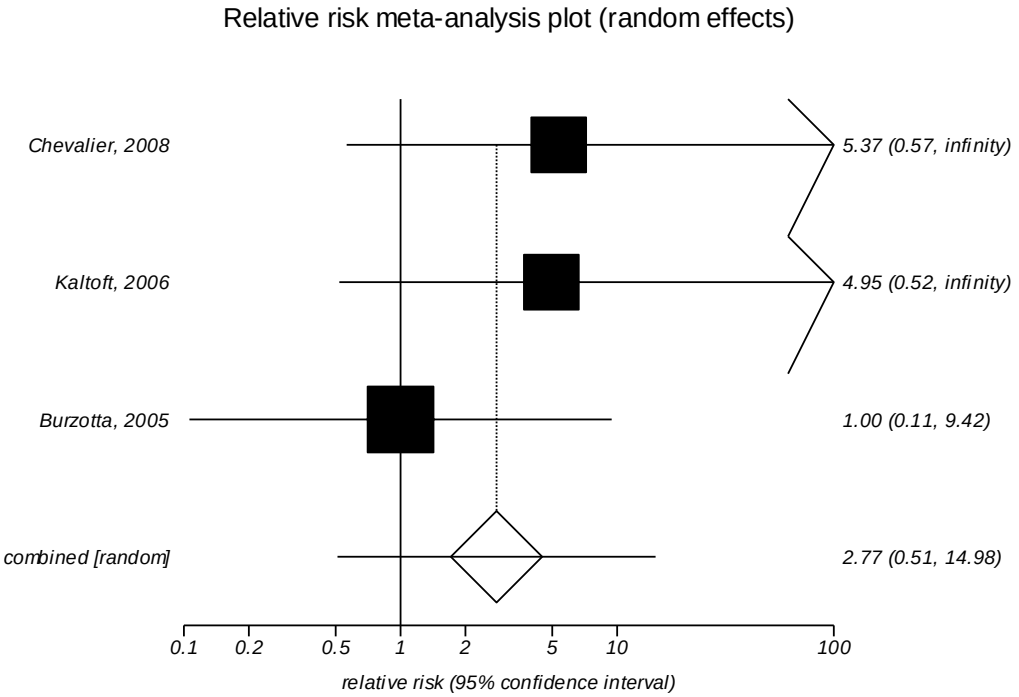
Cochran Q: P = 0.542
I^2: 0%
Egger: P = 0.982
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 25. Impact of embolic protection devices combined versus control on 180-day myocardial infarction.



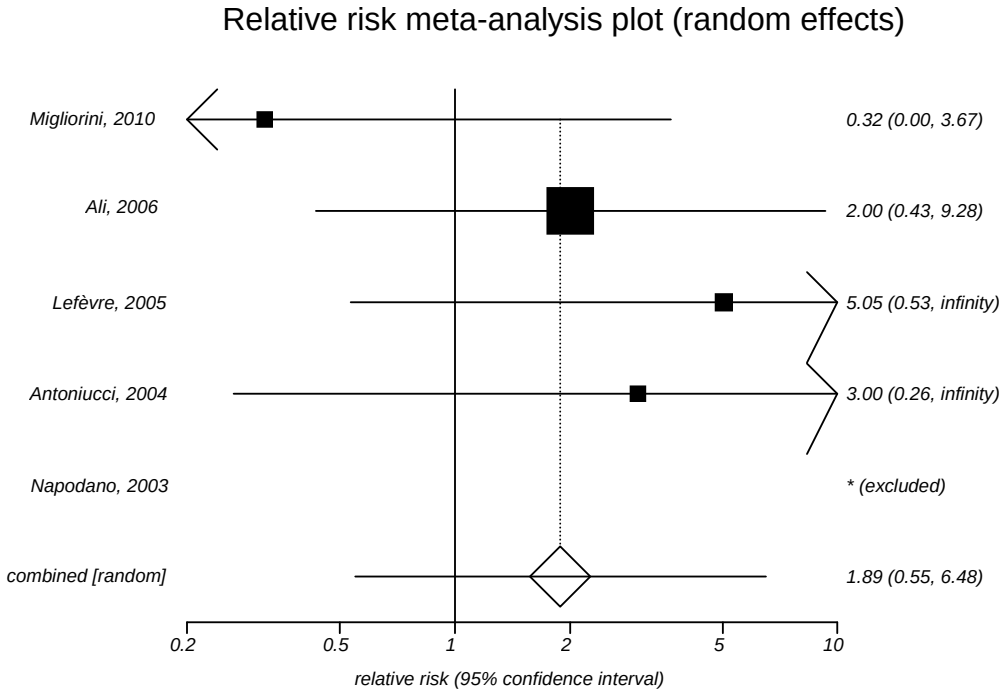
Cochran Q: P = 0.756
I^2: 0%
Egger: P = 0.880
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



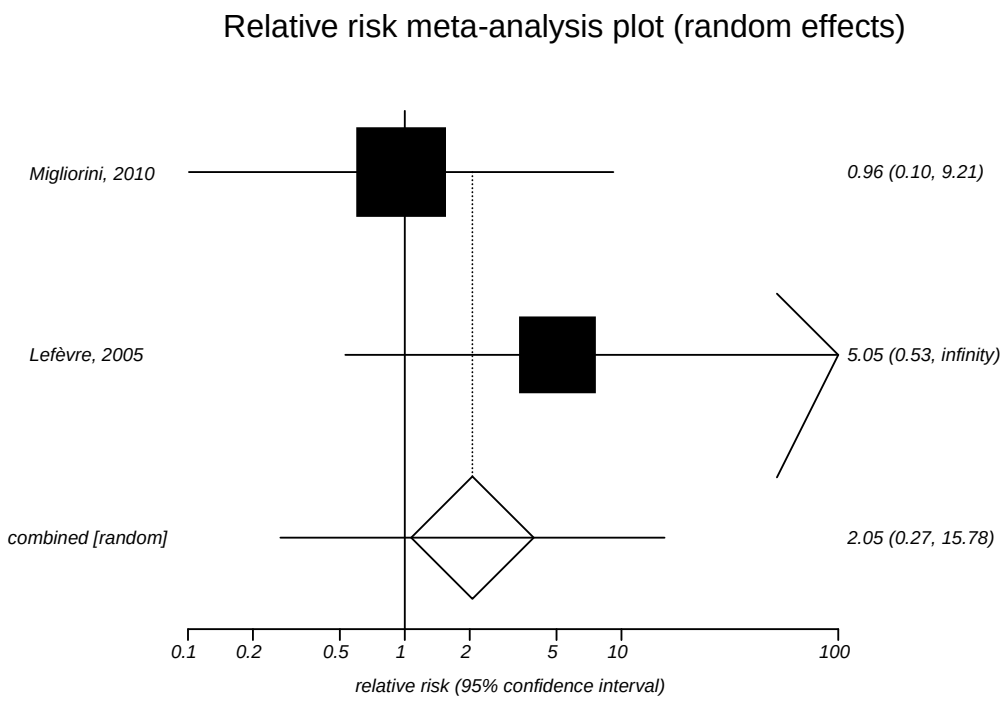
Cochran Q: P = 0.647
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 27. Impact of mechanical thrombectomy devices versus control on ≤ 30-day stroke.



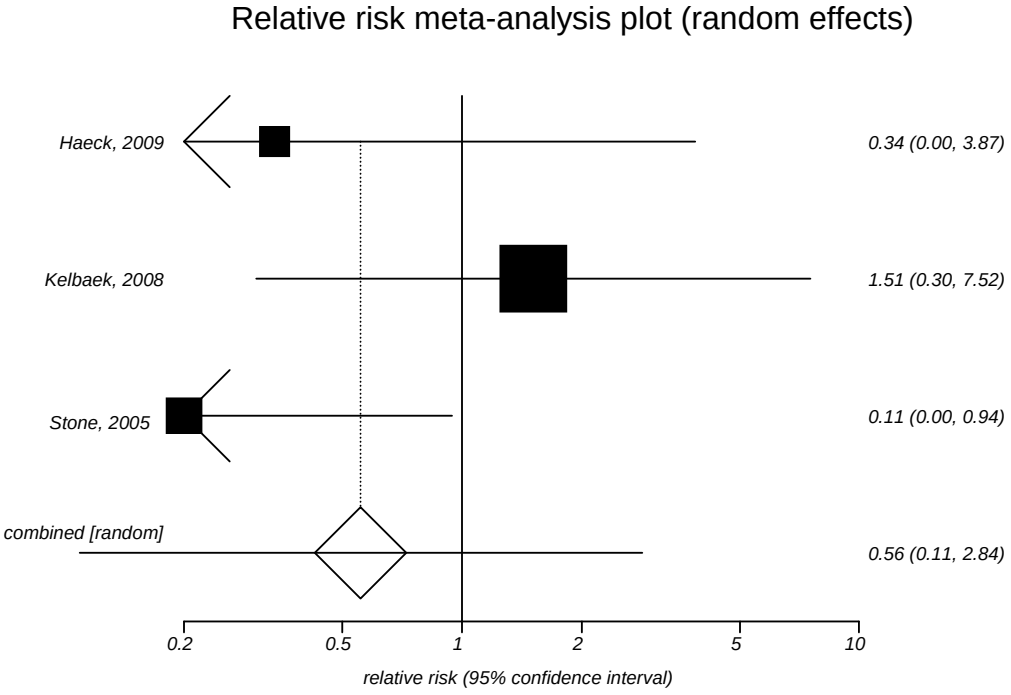
Cochran Q: P = 0.641
I^2: 0%
Egger: P = 0.870
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



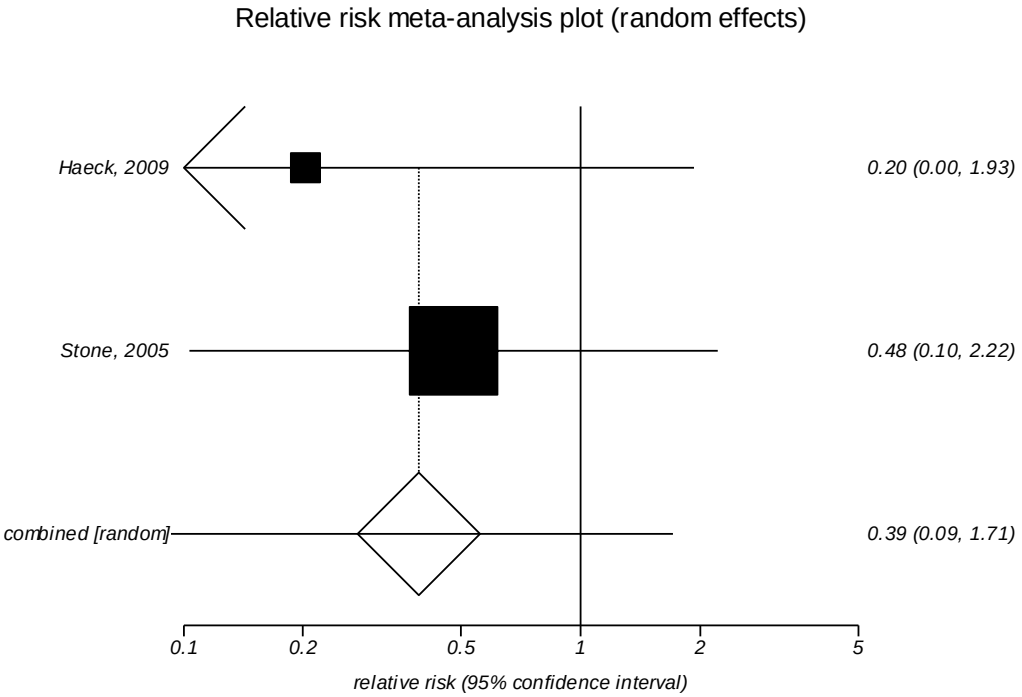
Cochran Q: P = 0.424
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



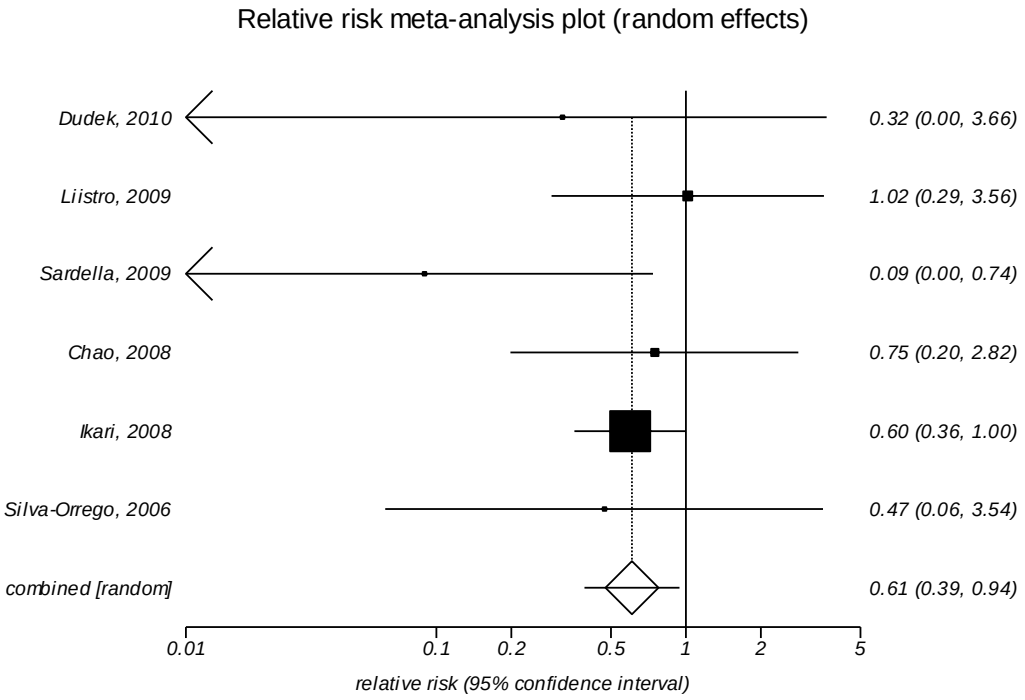
Cochran Q: P = 0.277
I^2: 22.1%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



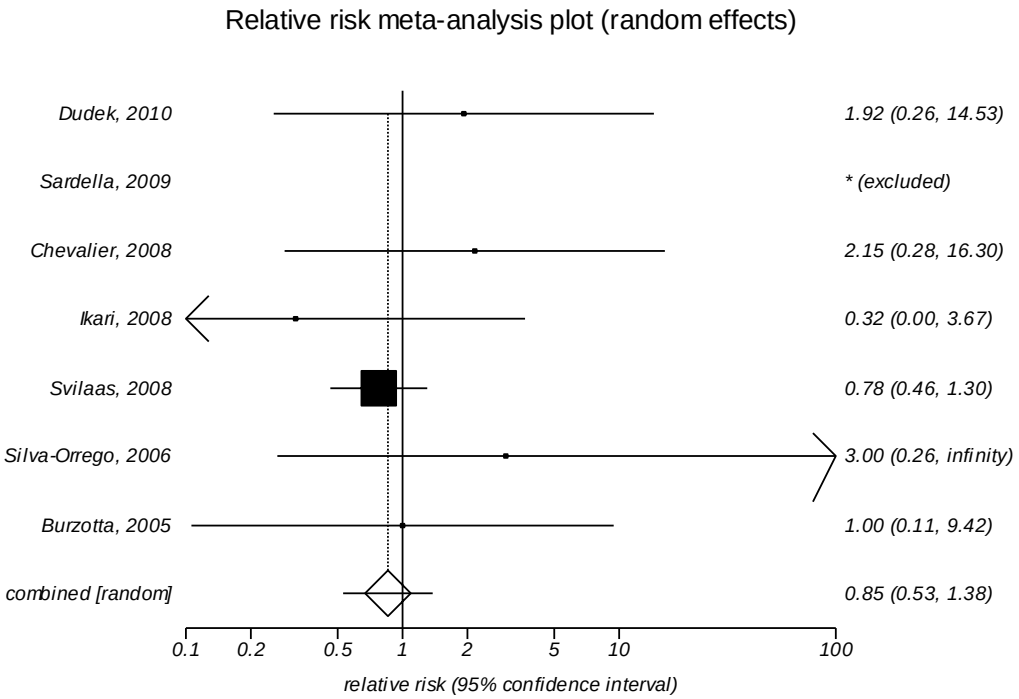
Cochran Q: P = 0.624
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 31. Impact of catheter aspiration devices versus control on 180-day target revascularization.



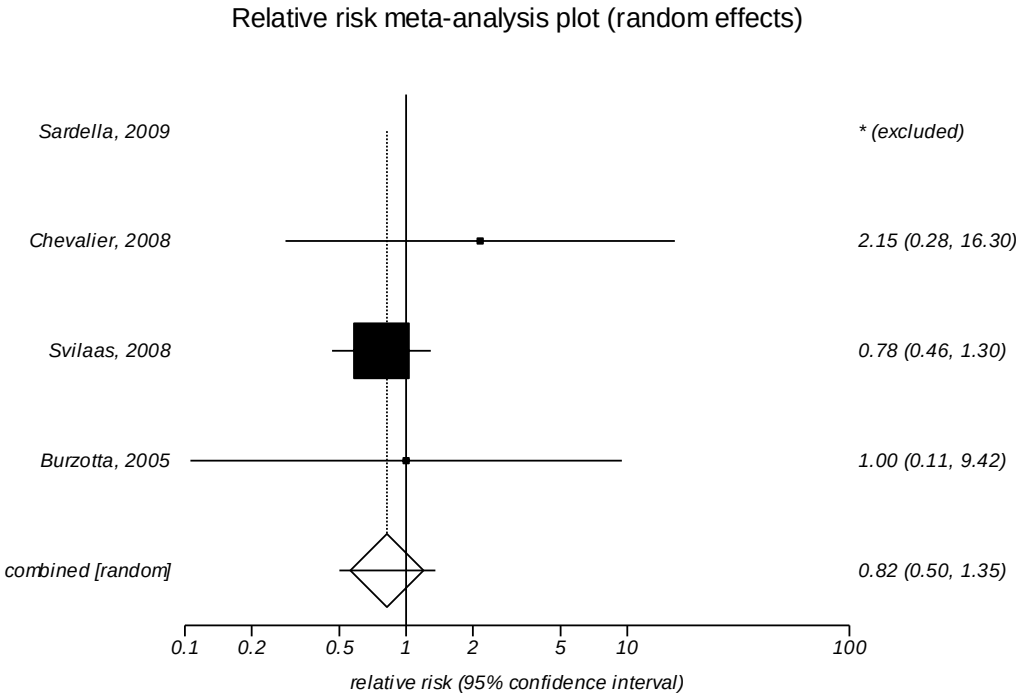
Cochran Q: P = 0.759
I^2: 0%
Egger: P = 0.444
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



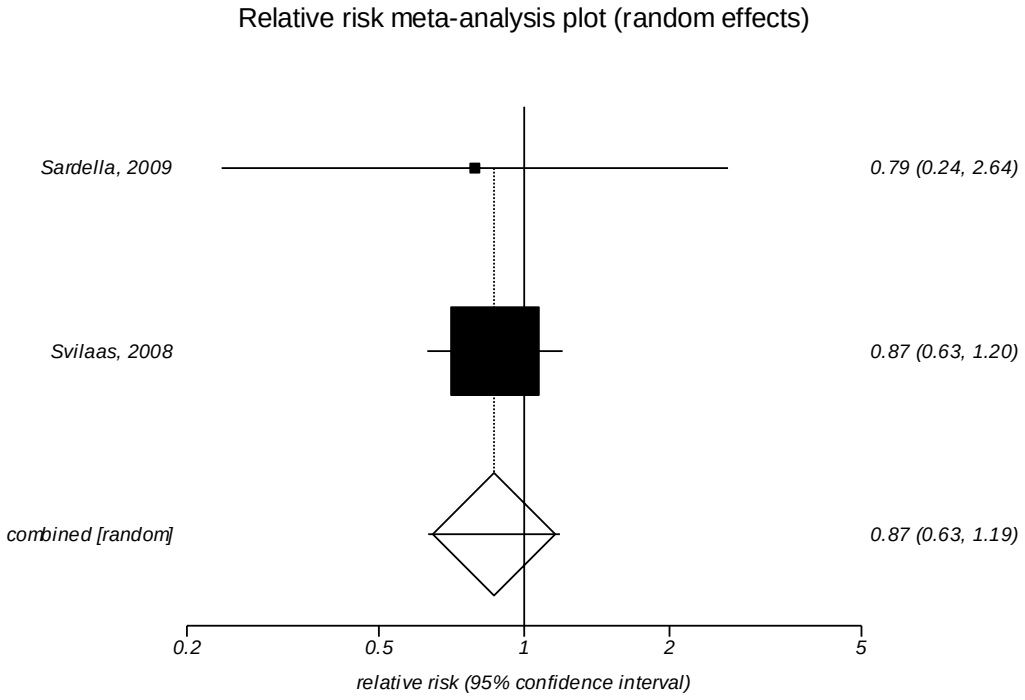
Cochran Q: P = 0.832
I^2: 0%
Egger: P = 0.254
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



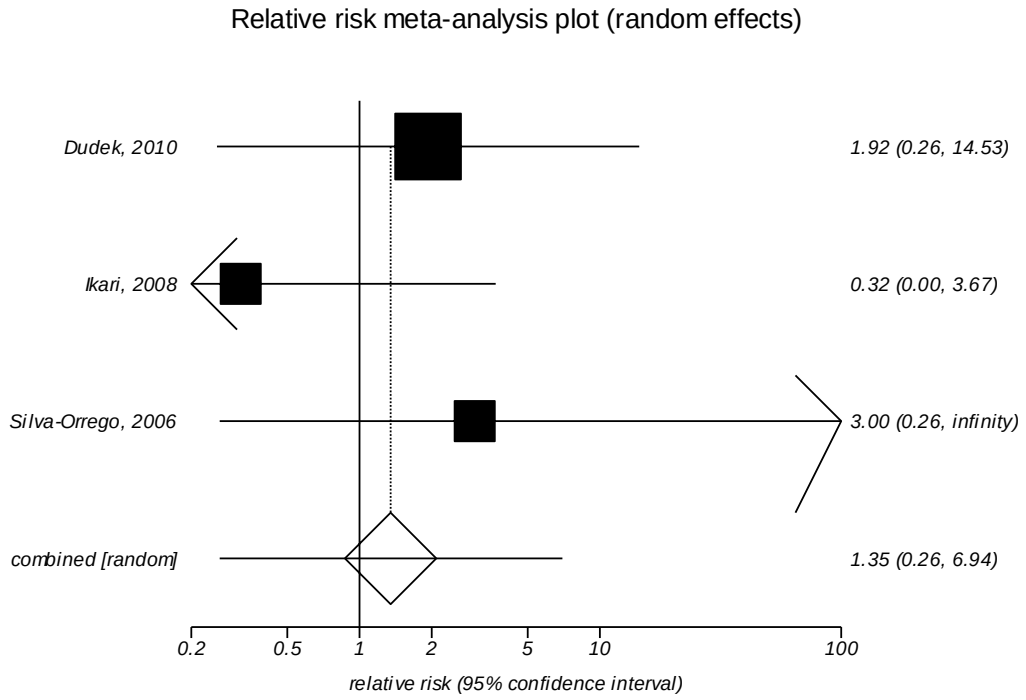
Cochran Q: P = 0.709
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



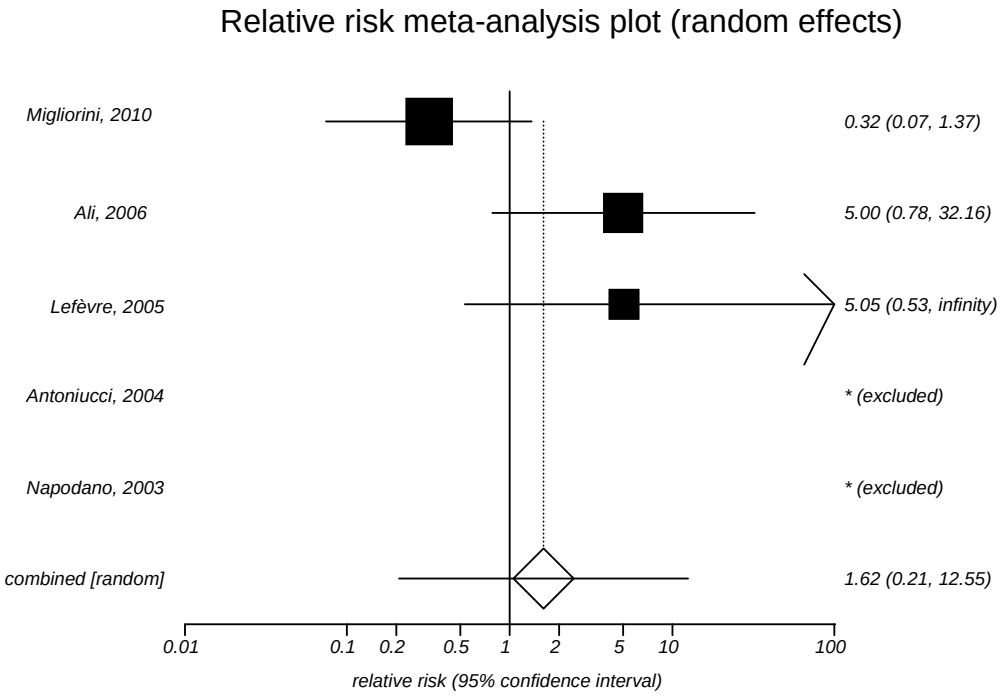
Cochran Q: P = 0.886
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



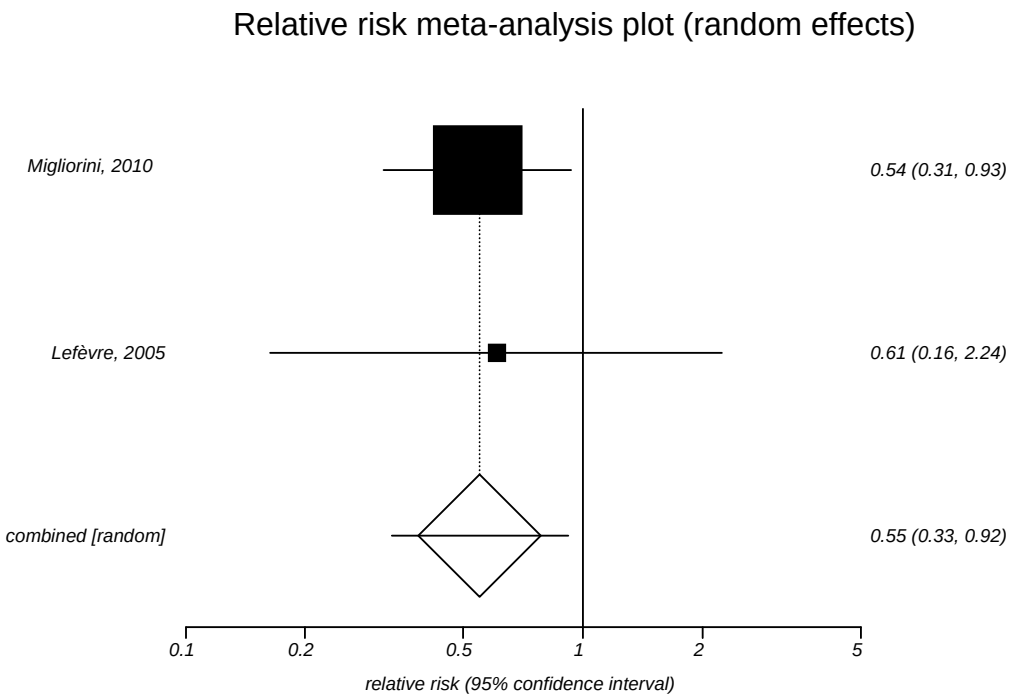
Cochran Q: P = 0.575
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



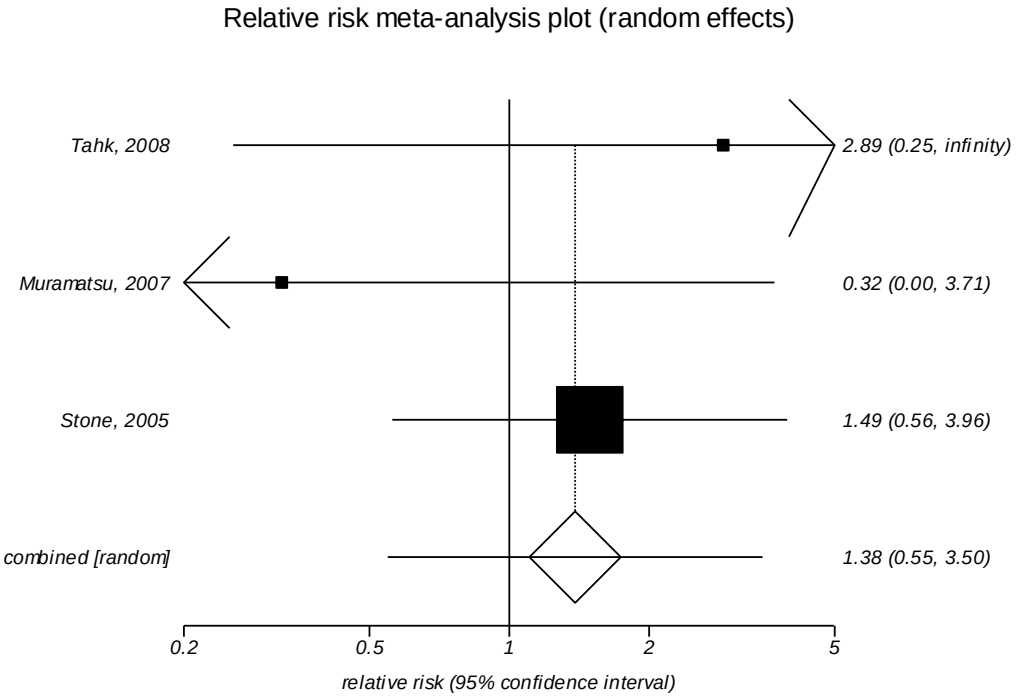
Cochran Q: P = 0.072
I^2: 62%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



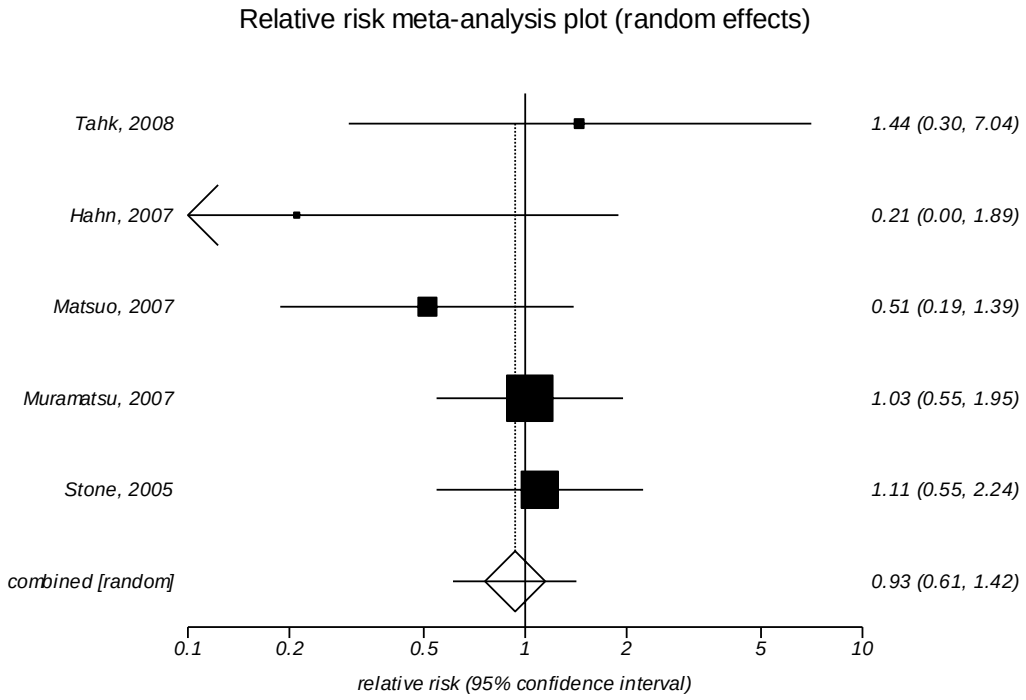
Cochran Q: P = 0.885
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



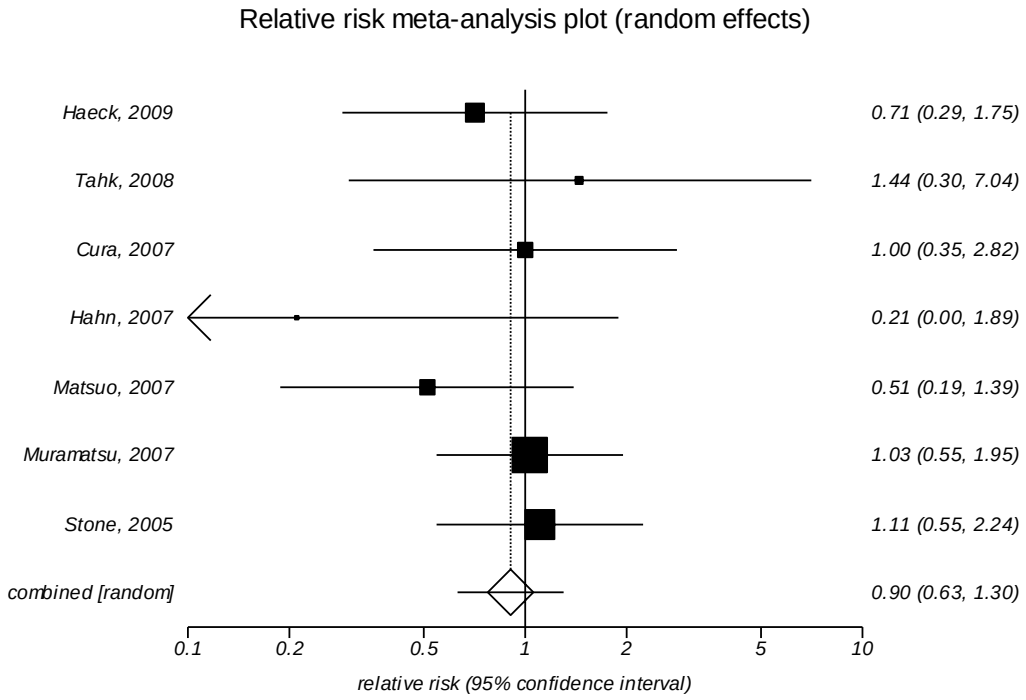
Cochran Q: P = 0.600
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the 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.



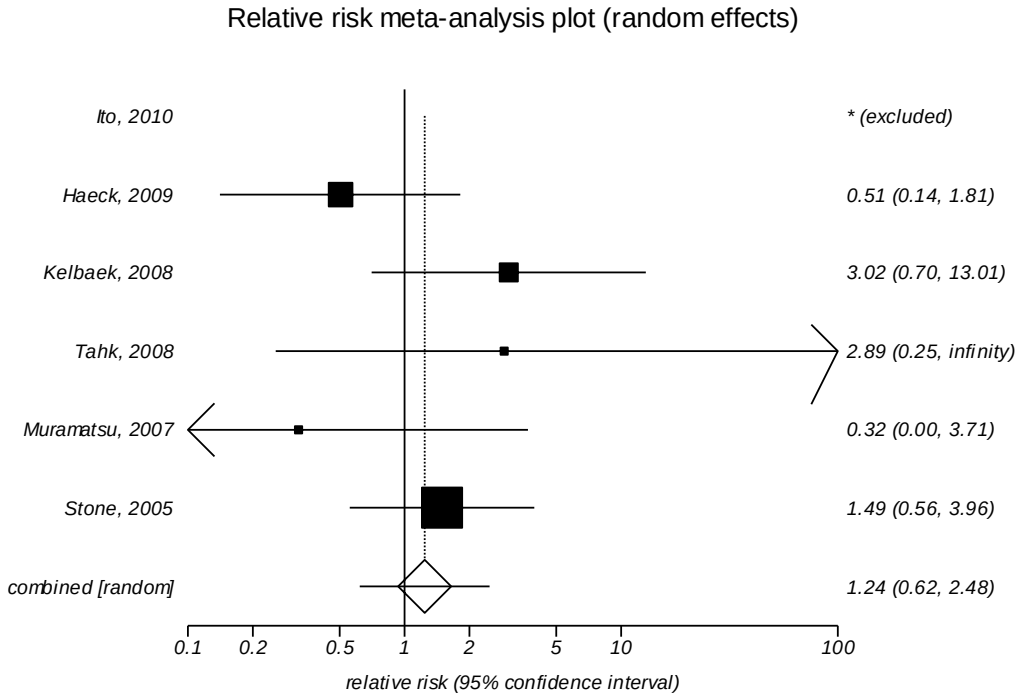
Cochran Q: P = 0.600
I^2: 0%
Egger: 0.369
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 40. Impact of embolic protection devices combined versus control on 180-day target revascularization.



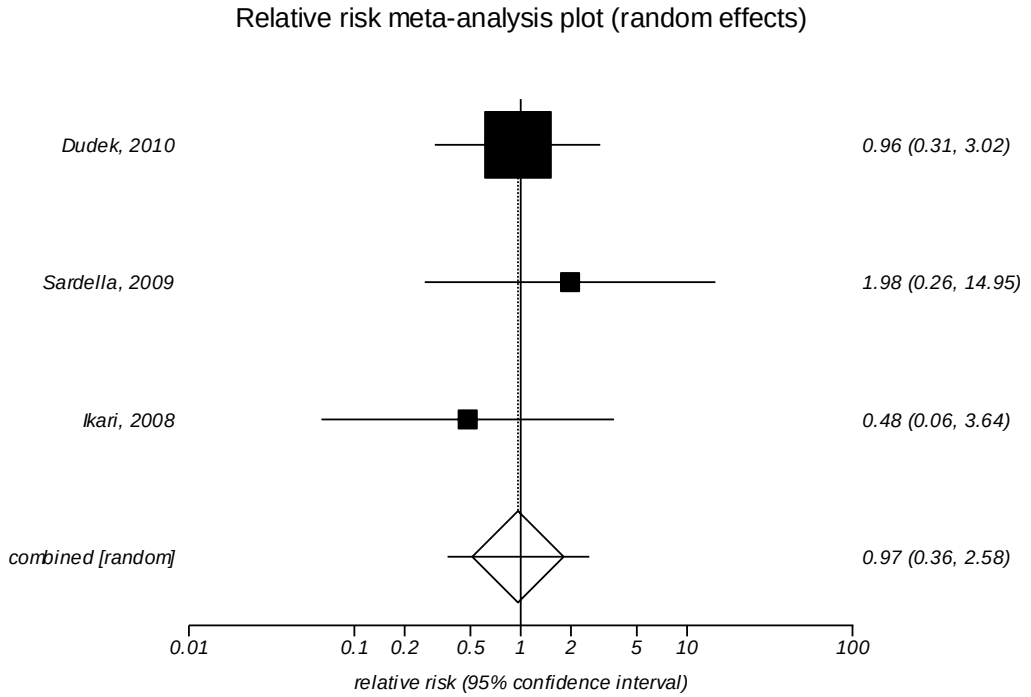
Cochran Q: P = 0.799
I^2: 0%
Egger: P = 0.268
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



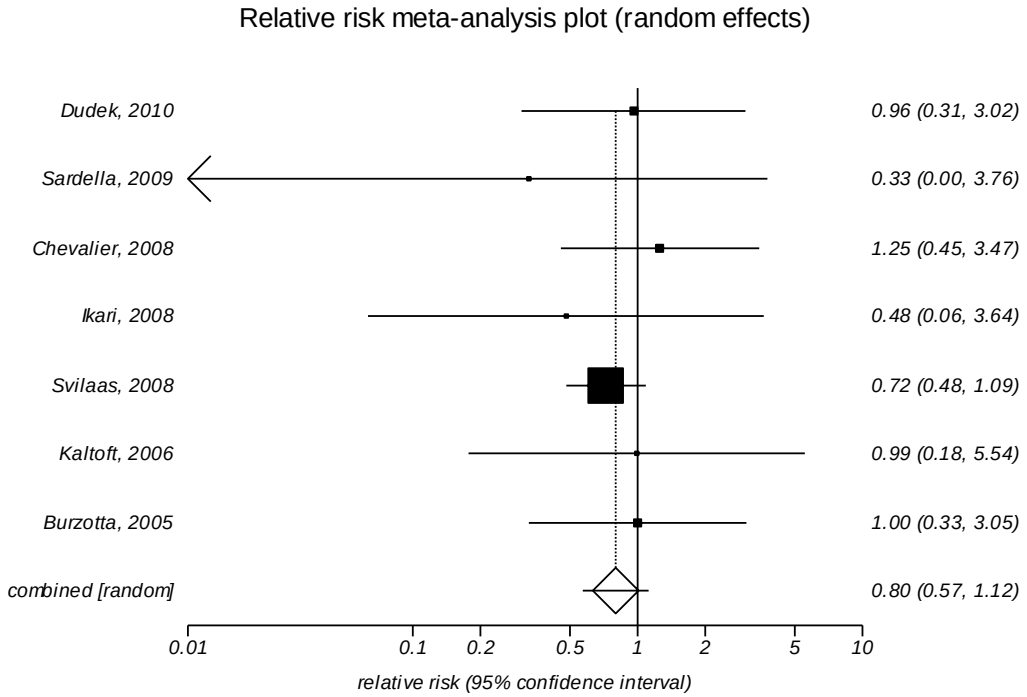
Cochran Q: P = 0.417
I^2: 0%
Egger: P = 0.900
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 42. Impact of catheter aspiration devices versus control on in-hospital MACE.



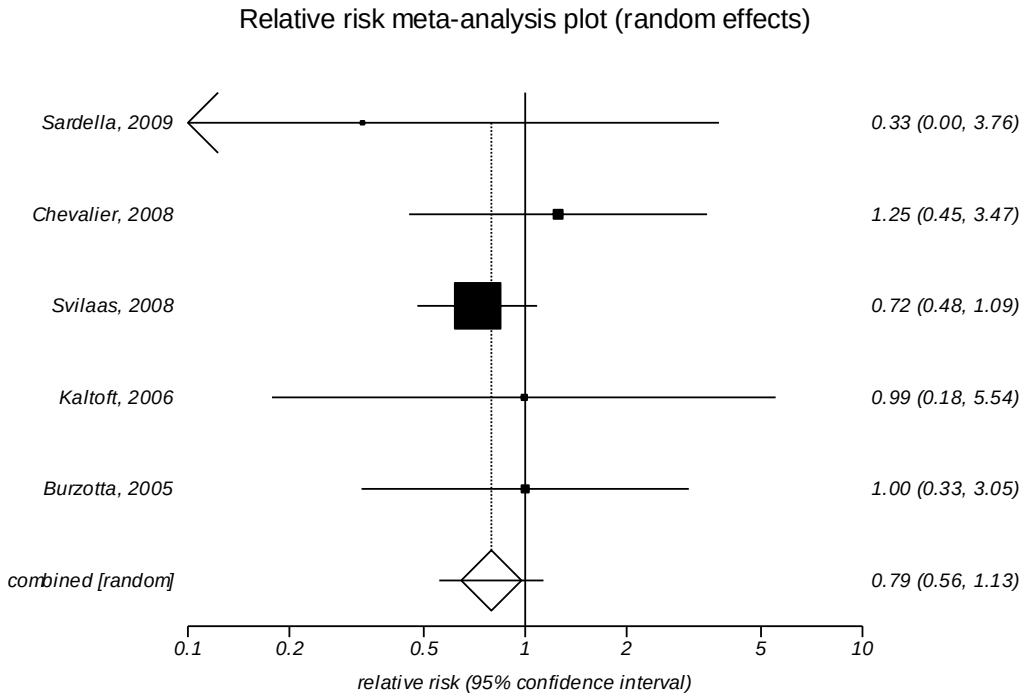
Cochran Q: P = 0.713
I^2: 0%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 43. Impact of catheter aspiration devices versus control on ≤ 30 day MACE.



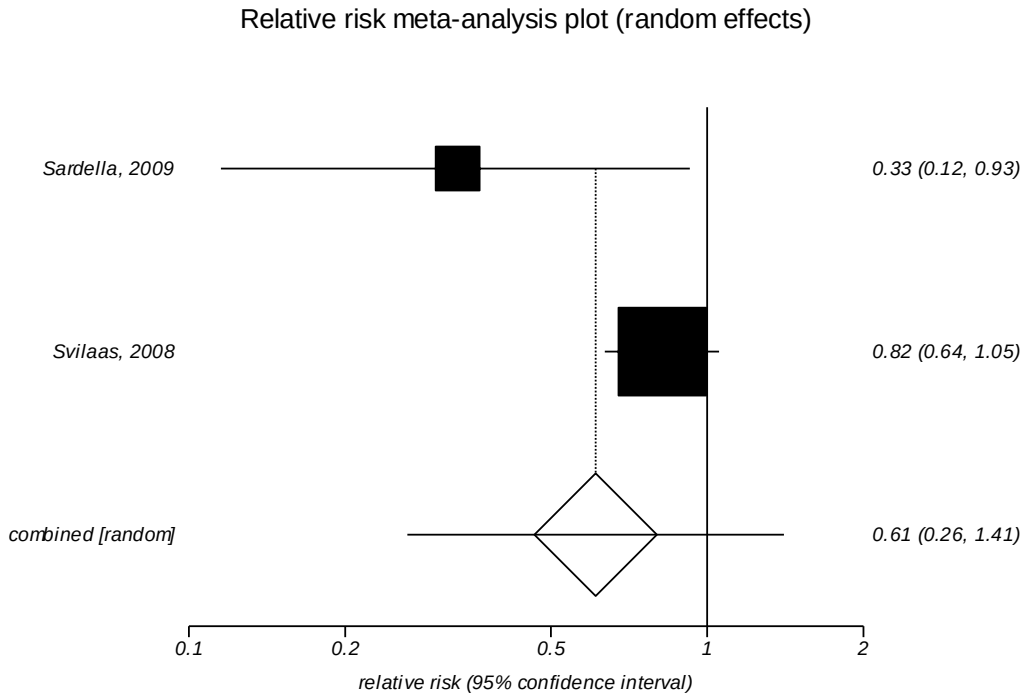
Cochran Q: P = 0.948
I^2: 0%
Egger: P = 0.739
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



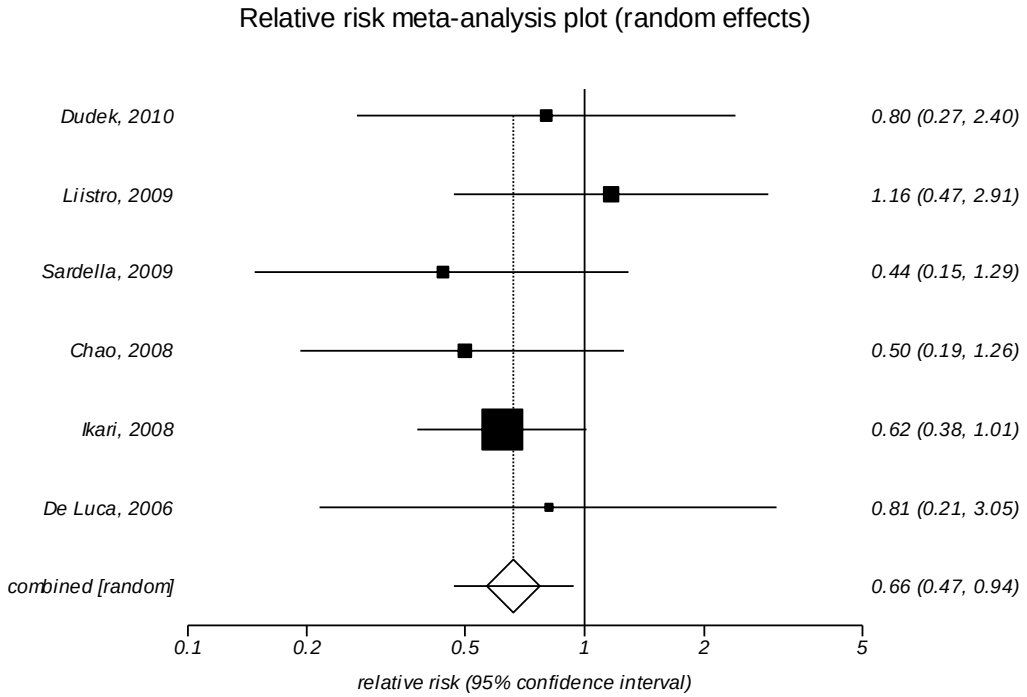
Cochran Q: P = 0.844
I^2: 0%
Egger: P = 0.61
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



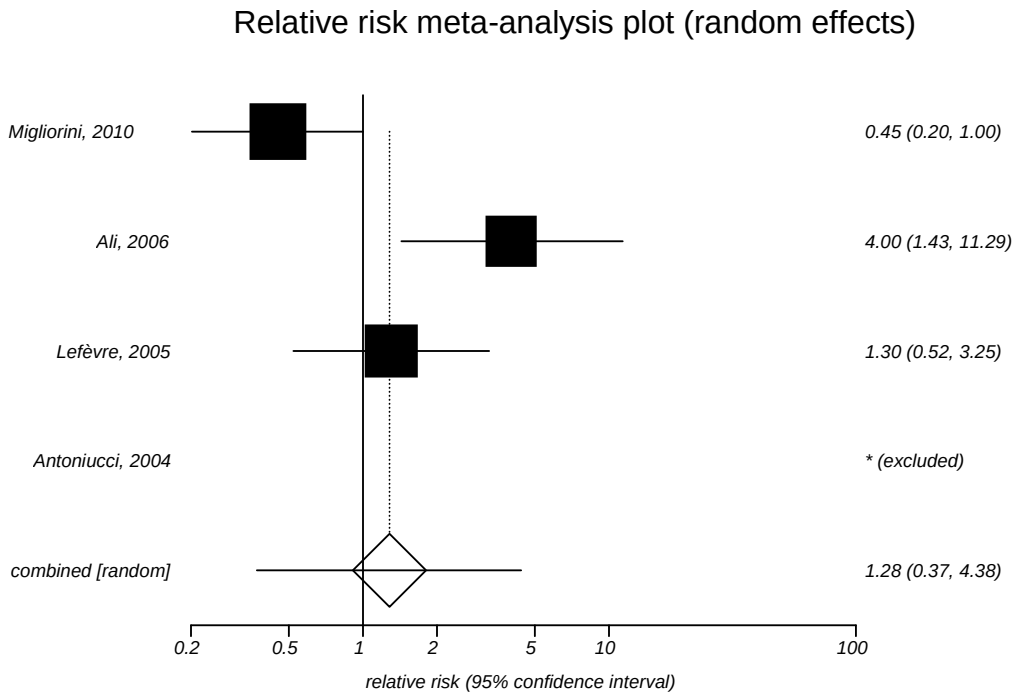
Cochran Q: 0.111
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 46. Impact of catheter aspiration devices versus control on 180-day MACE.



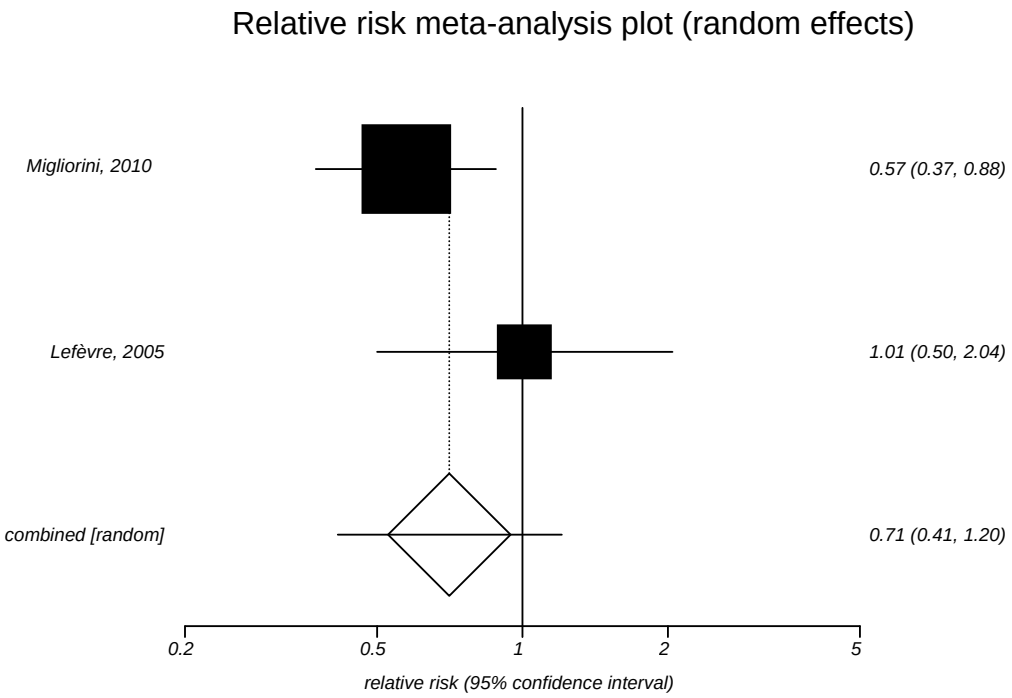
Cochran Q: P = 0.785
I^2: 0%
Egger: P = 0.733
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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.



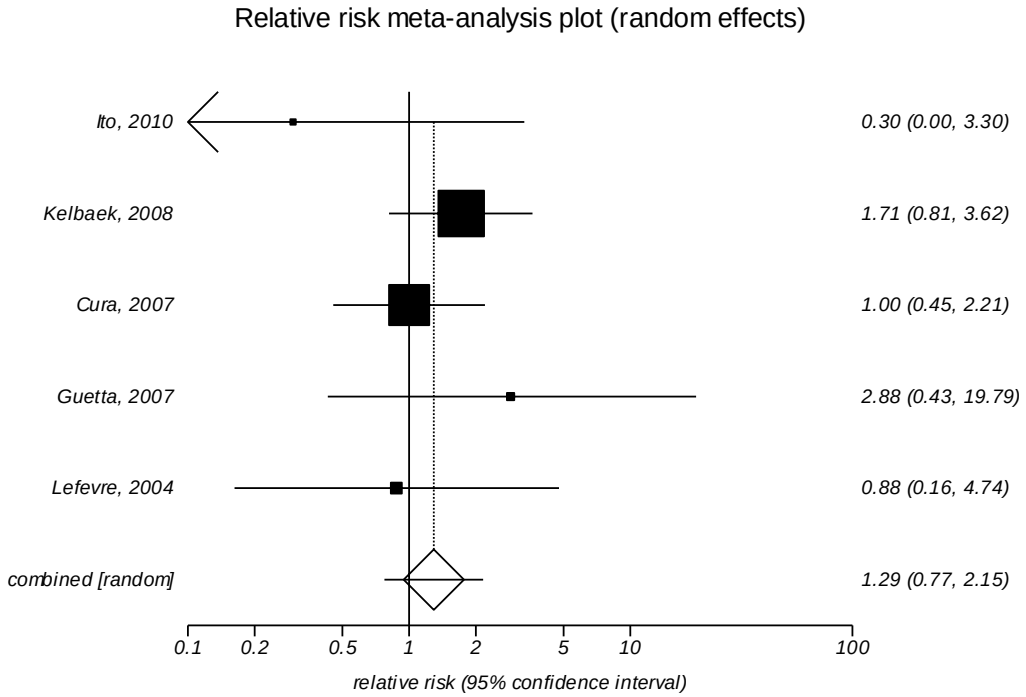
Cochran Q: P = 0.006
I^2: 80.4%
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



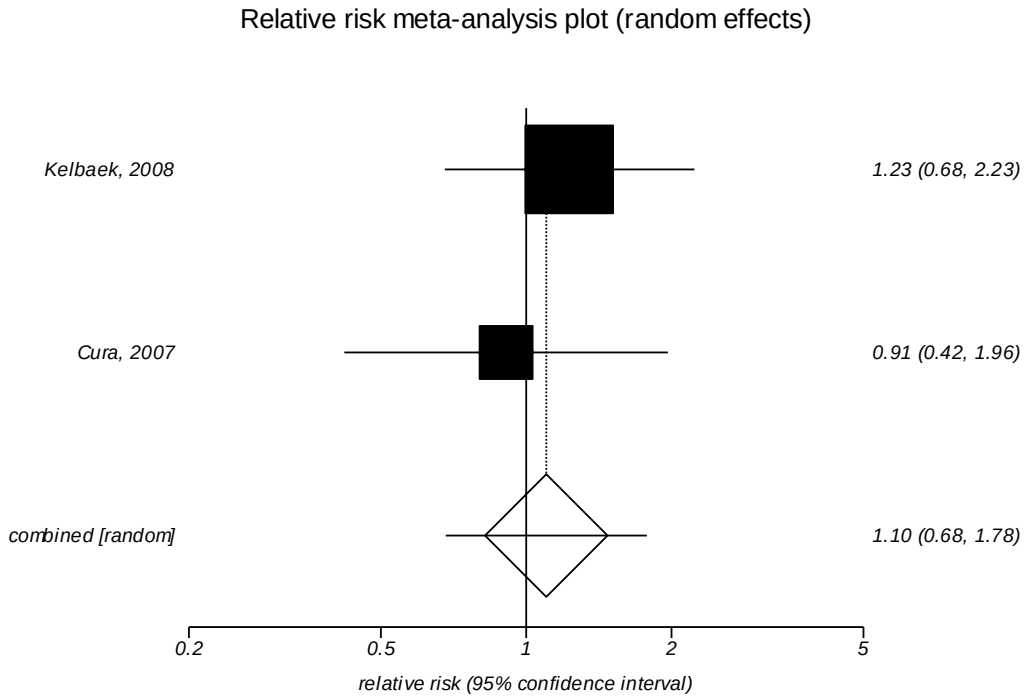
Cochran Q: P = 0.187
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



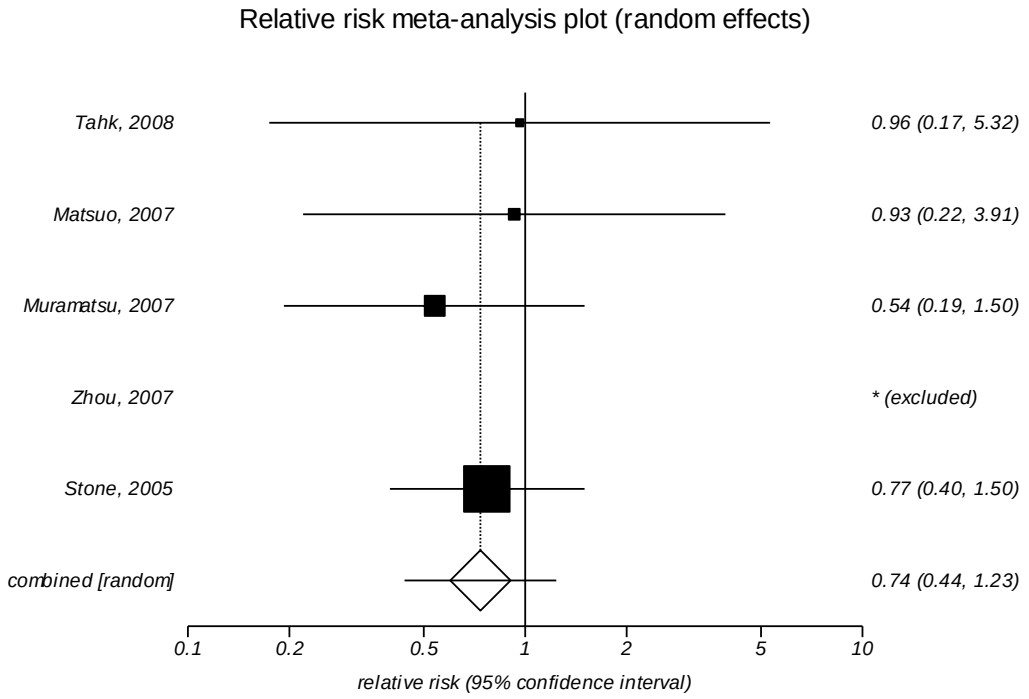
Cochran Q: P = 0.664
I^2: 0%
Egger: P = 0.449
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 50. Impact of distal filter embolic protection devices versus control on 180-day MACE events.



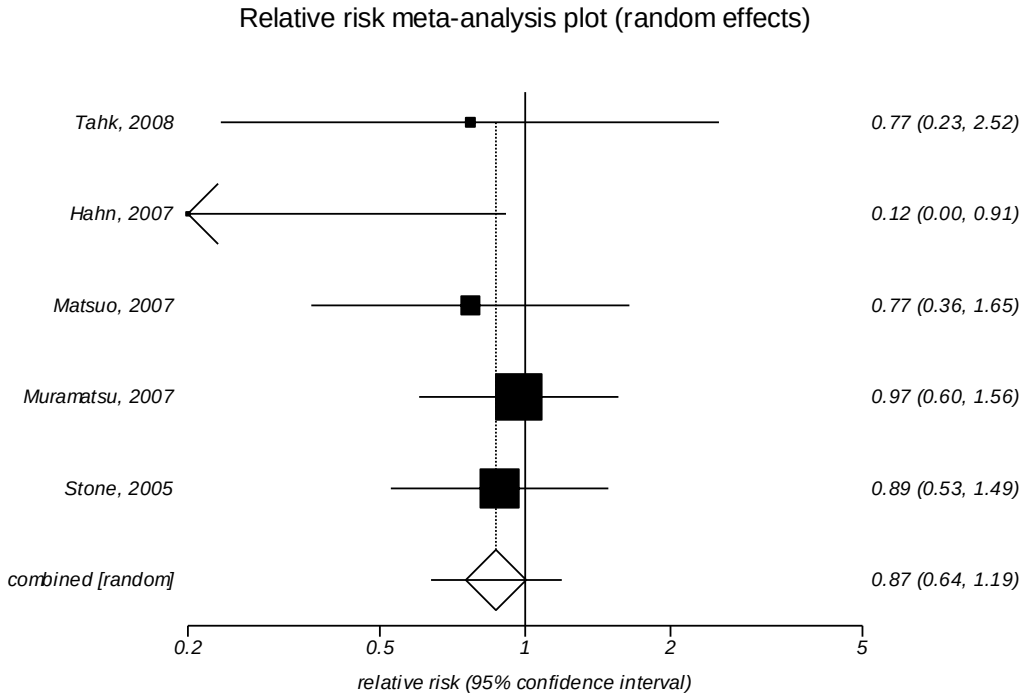
Cochran Q: P = 0.550
I^2: Too few strata
Egger: Too few strata
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents 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.



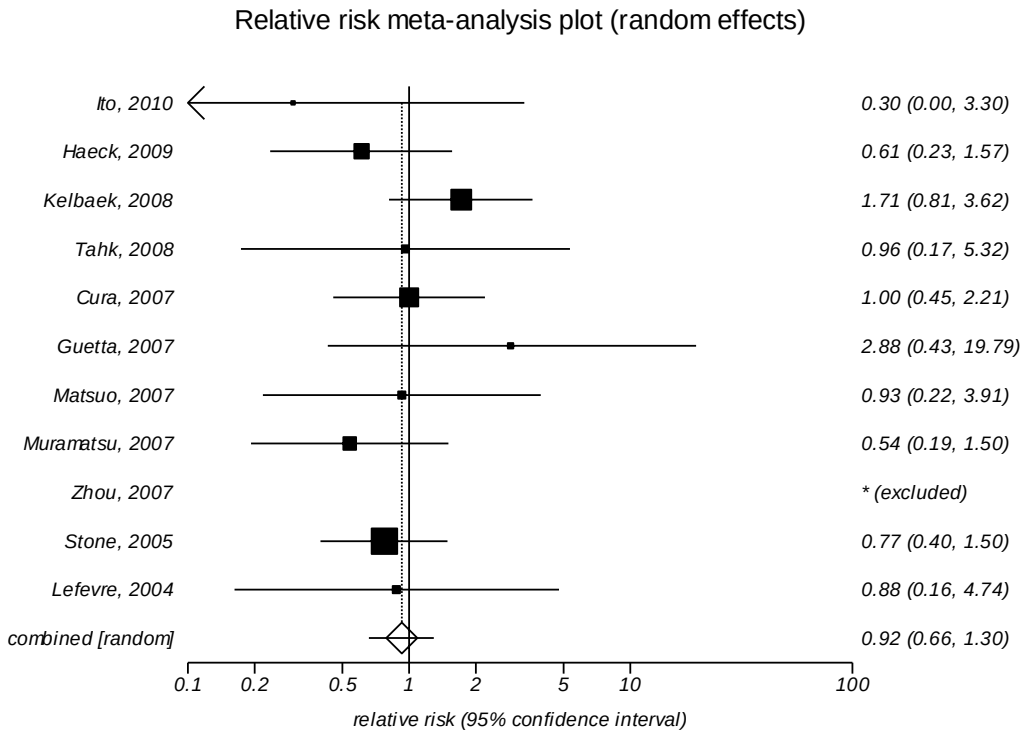
Cochran Q: P = 0.919
I^2: 0%
Egger: P = 0.758
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined results. The solid vertical line extending from 1 is the null value.

Figure 52. Impact of distal balloon embolic protection devices combined versus control on 180-day MACE.



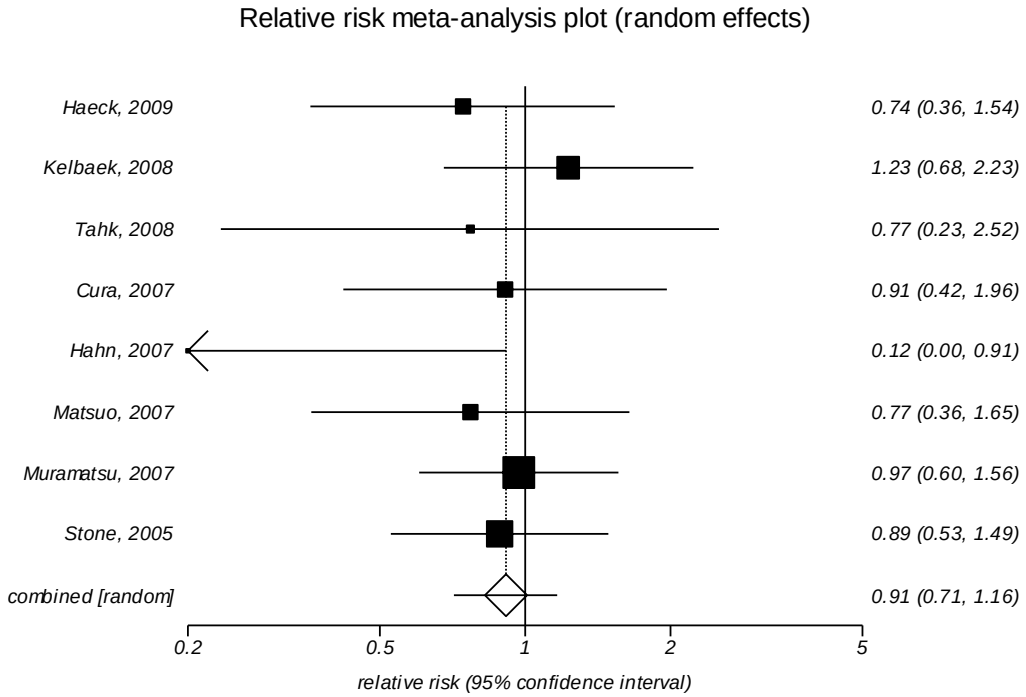
Cochran Q: P = 0.685
I^2: 0%
Egger: P = 0.032
Legend: The squares represent individual point estimates. The size of the square represents the weight given to each study in the meta-analysis. Horizontal lines through each square represent 95 percent confidence intervals. The diamond represents the combined 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



Cochran Q: P = 0.744
I^2: 0%
Egger: P = 0.821
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 54. Impact of embolic protection devices combined versus control on 180-day MACE.



Cochran Q: P = 0.828
I^2: 0%
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.

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.

$\mathbf{I^2}$: Measure of degree of variation due to statistical heterogeneity. Usually reported as a percent ranging from 0 to100.

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:

$$\sigma = ((\sum(x-x_m))^2/N)^{0.5}$$

σ 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 myocardiam caused by either atherosclerotic narrowing or constriction of the coronary arteries or partial blockage of the coronary arteries by a blood clot.