



Effective Health Care Program

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

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

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

protect against distal embolization during PCI.³ These devices utilize different technologies and can be broadly classified as thrombus aspiration, mechanical



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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 and harms associated with using adjunctive devices to remove thrombi or protect against distal embolization in patients with ACS who are undergoing PCI of native vessels. The Key Questions (KQs) examined in this report are:

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

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

KQ 3. In patients with ACS who are undergoing PCI of native vessels, which patient characteristics (e.g., gender, age, ethnicity, diabetes, smoker, ejection fraction, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, ischemia time, presence of a

thrombus-containing lesion, infarct-related artery and pre-PCI TIMI flow, use of direct stenting) affect outcomes?

Analytic Framework

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

Methods

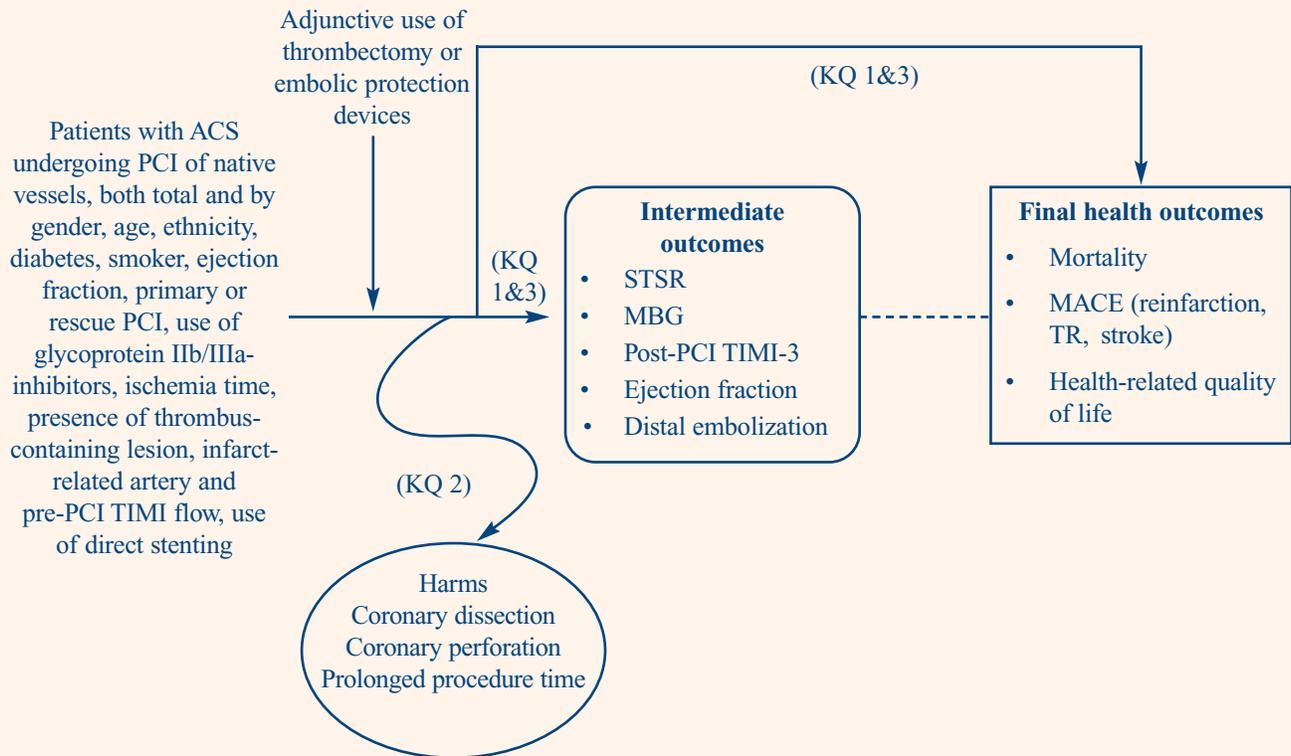
Input From Stakeholders

The University of Connecticut/Hartford Hospital Evidence-based Practice Center drafted a topic refinement document with proposed KQs after consultation with Key Informants. The Key Informants included six physicians: two provided methods expertise, two represented the payer's perspective, one provided the local interventional cardiologist's perspective, and the last provided both an interventional cardiologist and American College of Cardiology perspective. The Key Informants did not have financial or other declared conflicts. The public was invited to comment on the topic refinement document and KQs. After we reviewed the public commentary, we generated responses to public commentary, proposed revisions to the KQs, generated a preliminary protocol, and reviewed it with the Technical Expert Panel. The

aforementioned Key Informants constituted the Technical Expert Panel. They provided feedback on the feasibility and importance of our approach and provided their unique insight. Again, no conflict of

interest was identified. The draft Comparative Effectiveness Review report underwent peer and public review and was revised based on commentary.

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.

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 KQ. 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 KQ 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 studies⁵⁹⁻⁶⁵ were included in this KQ. 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} MBG₃^{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 MBG₃^{37,33,34,36-40,74,80} 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 RCT⁴⁶ and one controlled observational study⁶⁰ 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-345 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 resolution⁴⁷ and MBG₃^{34,43,47} increased ejection fraction,⁴⁷ and reduced the risk of no

reflow⁴³ 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 trial⁴⁷ 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

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
STEMI: Distal filter embolic protection devices			
Target revascularization	2 (2,0)	Increased risk (favors control); RR 1.61	Low
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 effectc	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 effectc	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 effectc	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

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
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 “insufficient” are not reported in this table but are listed in Table C.

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

^c Based on qualitative evaluation of available data.

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 study⁶² 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 study⁶² 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 time ^c	Moderate

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

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

^cBased 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

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

Population: Device Category	Outcome With Insufficient Data
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 colleagues⁸³ 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 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 colleagues⁷⁰ 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 interval (CI): 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 EXT™, FilterWire EZ™, SpideRXT™, AngioGuard™, AngioGuard™ XP, PercuSurge GuardWire®, PercuSurge GuardWire™ Plus, and Proxis™.

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

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

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

Myocardial blush grade (MBG): An angiographic method of grading myocardial tissue perfusion ranging from grade 0 to grade 3. In grade 0, the dye fails to enter the microvasculature, with either minimal or no ground-glass appearance (“blush”) or opacification of the myocardium in the distribution of the culprit artery, indicating lack of tissue-level perfusion. In grade 1, the dye slowly enters but fails to exit the microvasculature. There is the ground-glass appearance (blush) or opacification of the myocardium in the distribution of the culprit lesion that fails to clear from the microvasculature, and dye staining is present on the next injection (with approximately 30 seconds between injections). In grade 2, there is delayed entry and exit of dye from the microvasculature. There is the ground-glass appearance (blush) or opacification of the myocardium in the distribution of the culprit lesion that 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:

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

σ is the 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 (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.

Full Report

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