
A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

Developed in Collaboration With the American College of Emergency Physicians

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Preamble
To ensure that guidelines reflect current knowledge, available treatment options, and optimum medical care, existing clinical practice guideline recommendations are modified and new recommendations are added in response to new data, medications or devices. To keep pace with evolving evidence, the American College of Cardiology (ACC) / American Heart Association (AHA) Task Force on Clinical Practice Guidelines (“Task Force”) has issued this focused update to revise guideline recommendations on the basis of recently published data. This update is not based on a complete literature review from the date of previous guideline publications, but it has been subject to rigorous, multilevel review and approval, similar to the full guidelines. For specific focused update criteria and additional methodological details, please see the ACC/AHA guideline methodology manual (1).

Modernization
In response to published reports from the Institute of Medicine (2,3) and ACC/AHA mandates (4-7), processes have changed leading to adoption of a “knowledge byte” format. This entails delineation of recommendations addressing specific clinical questions, followed by concise text, with hyperlinks to supportive evidence. This approach better accommodates time constraints on busy clinicians, facilitates easier access to recommendations via electronic search engines and other evolving technology (e.g., smart phone apps), and supports the evolution of guidelines as “living documents” that can be dynamically updated as needed.

Intended Use
Practice guidelines provide recommendations applicable to patients with or at risk of developing cardiovascular disease. The focus is on medical practice in the United States, but guidelines developed in collaboration with other organizations may have a broader target. Although guidelines may inform regulatory or payer decisions, they are intended to improve quality of care in the interest of patients.

Class of Recommendation and Level of Evidence
The Class of Recommendation (COR) and Level of Evidence (LOE) are derived independently of one another according to established criteria. The COR indicates the strength of recommendation, encompassing the estimated magnitude and certainty of benefit of a clinical action in proportion to risk. The LOE rates the quality of scientific evidence supporting the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources (Table 1) (1,7,8).

Relationships With Industry and Other Entities
The ACC and AHA sponsor the guidelines without commercial support, and members volunteer their time. The
Task Force zealously avoids actual, potential, or perceived conflicts of interest that might arise through relationships with industry or other entities (RWI). All Guideline Writing Committee (GWC) members and reviewers are required to disclose current industry relationships or personal interests from 12 months before initiation of the writing effort. Management of RWI involves selecting a balanced GWC and assuring that the chair and a majority of committee members have no relevant RWI (Appendixes 1 and 2). Members are restricted with regard to writing or voting on sections to which their RWI apply. For transparency, members’ comprehensive disclosure information is available online (link). Comprehensive disclosure information for the Task Force is available at http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/guidelines-and-documents-task-forces. The Task Force strives to avoid bias by selecting experts from a broad array of backgrounds representing different geographic regions, sexes, ethnicities, intellectual perspectives/biases, and scopes of clinical practice, and by inviting organizations and professional societies with related interests and expertise to participate as partners or collaborators.

Related Issues

For additional information pertaining to the methodology for grading evidence, assessment of benefit and harm, shared decision making between the patient and clinician, structure of evidence tables and summaries, standardized terminology for articulating recommendations, organizational involvement, peer review, and policies for periodic assessment and updating of guideline documents, we encourage readers to consult the ACC/AHA guideline methodology manual (1).

The recommendations in this focused update represent the official policy of the ACC and AHA until superseded by published addenda, statements of clarification, focused updates, or revised full-text guidelines. To ensure that guidelines remain current, new data are reviewed biannually to determine whether recommendations should be modified. In general, full revisions are posted in 5-year cycles (1).

Jonathan L. Halperin, MD, FACC, FAHA
Chair, ACC/AHA Task Force on Clinical Practice Guidelines
Table 1. Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care* (Updated August 2015)

<table>
<thead>
<tr>
<th>CLASS (STRENGTH) OF RECOMMENDATION</th>
<th>LEVEL (QUALITY) OF EVIDENCE‡</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLASS I (STRONG)</strong></td>
<td>Benefit &gt;&gt; Risk</td>
</tr>
<tr>
<td>Suggested phrases for writing recommendations:</td>
<td>High-quality evidence‡ from more than 1 RCT</td>
</tr>
<tr>
<td>Is recommended</td>
<td>Meta-analyses of high-quality RCTs</td>
</tr>
<tr>
<td>Is indicated/useful/effective/beneficial</td>
<td>One or more RCTs corroborated by high-quality registry studies</td>
</tr>
<tr>
<td>Should be performed/administered/other</td>
<td></td>
</tr>
<tr>
<td>Comparative-Effectiveness Phrases†:</td>
<td></td>
</tr>
<tr>
<td>Treatment/strategy A is recommended/indicated in preference to treatment B</td>
<td></td>
</tr>
<tr>
<td>Treatment A should be chosen over treatment B</td>
<td></td>
</tr>
</tbody>
</table>

| LEVEL B-R | (Randomized) |
| Moderate-quality evidence‡ from 1 or more RCTs |
| Meta-analyses of moderate-quality RCTs |

| LEVEL B-NR | (Nonrandomized) |
| Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies |
| Meta-analyses of such studies |

| LEVEL C-LD | (Limited Data) |
| Randomized or nonrandomized observational or registry studies with limitations of design or execution |
| Meta-analyses of such studies |
| Physiological or mechanistic studies in human subjects |

| LEVEL C-EO | (Expert Opinion) |
| Consensus of expert opinion based on clinical experience |

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.
1. Introduction

The scope of this focused update is limited to considerations relevant to multivessel percutaneous coronary intervention (PCI) and thrombus aspiration in patients with ST-elevation myocardial infarction (STEMI) undergoing primary PCI.

1.1. Methodology and Evidence Review

Clinical trials presented at the major cardiology organizations’ 2013 to 2015 annual scientific meetings and other selected reports published in a peer-reviewed format through August 2015 were reviewed by the 2011 PCI and 2013 STEMI GWCs and the Task Force to identify trials and other key data that might affect guideline recommendations. The information considered important enough to prompt updated recommendations is included in evidence tables in the Online Data Supplement (link).

Consult the full-text versions of the 2011 PCI and 2013 STEMI guidelines (9,10) for recommendations in clinical areas not addressed in the focused update. The individual recommendations in this focused update will be incorporated into future revisions or updates of the full-text guidelines.

1.2. Organization of the GWC

For this focused update, representative members of the 2011 PCI and 2013 STEMI GWCs were invited to participate. Members were required to disclose all RWI relevant to the topics under consideration. The entire membership of both GWCs voted on the revised recommendations and text. The latter group was composed of experts representing cardiovascular medicine, interventional cardiology, electrophysiology, heart failure, cardiac surgery, emergency medicine, internal medicine, cardiac rehabilitation, nursing, and pharmacy. The GWC included representatives from the ACC, AHA, American College of Physicians, American College of Emergency Physicians, and Society for Cardiovascular Angiography and Interventions (SCAI).

1.3. Review and Approval

This document was reviewed predominantly by the prior reviewers from the respective 2011 and 2013 guidelines. These included 8 official reviewers jointly nominated by the ACC and AHA, 4 official/organizational reviewers nominated by SCAI, and 25 individual content reviewers. Reviewers’ RWI information was distributed to the GWC and is published in this document (Appendix 3).

This document was approved for publication by the governing bodies of the ACC, the AHA, and the SCAI and was endorsed by the (TBD).
2. Culprit Artery–Only Versus Multivessel PCI
(See Section 5.2.2.2 of 2011 PCI guideline and Section 4.1.1 of 2013 STEMI guideline for additional recommendations.)

<table>
<thead>
<tr>
<th>2013 Recommendation</th>
<th>2015 Focused Update Recommendation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class III: Harm</strong></td>
<td><strong>Class IIb</strong></td>
<td></td>
</tr>
<tr>
<td>PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI who are hemodynamically stable (11-13). <em>(Level of Evidence: B)</em></td>
<td>PCI of a noninfarct artery may be considered in selected patients with STEMI and multivessel disease who are hemodynamically stable, either at the time of primary PCI or as a planned staged procedure (11-24). <em>(Level of Evidence: B-R)</em></td>
<td>Modified recommendation (changed class from “III: Harm” to “IIb” and expanded time frame in which multivessel PCI could be performed).</td>
</tr>
</tbody>
</table>

PCI indicates percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

Approximately 50% of patients with STEMI have multivessel disease (25,26). PCI options for patients with STEMI and multivessel disease include: 1) culprit artery–only primary PCI, with PCI of nonculprit arteries only for spontaneous ischemia or intermediate- or high-risk findings on predischarge noninvasive testing; 2) multivessel PCI at the time of primary PCI; or 3) culprit artery–only primary PCI followed by staged PCI of nonculprit arteries. Observational studies, randomized controlled trials (RCTs), and meta-analyses comparing culprit artery–only PCI with multivessel PCI have reported conflicting results (11,12,14-24,27,28), likely because of differing inclusion criteria, study protocols, timing of multivessel PCI, statistical heterogeneity, and variable endpoints (Data Supplement).

Previous clinical practice guidelines recommended against PCI of nonculprit artery stenoses at the time of primary PCI in hemodynamically stable patients with STEMI (9,10). Planning for routine, staged PCI of noninfarct artery stenoses on the basis of the initial angiographic findings was not addressed in these previous guidelines, and noninfarct artery PCI was considered only in the limited context of spontaneous ischemia or high-risk findings on predischarge noninvasive testing. The earlier recommendations were based in part on safety concerns, which included increased risks for procedural complications, longer procedural time, contrast nephropathy, and stent thrombosis in a prothrombotic and proinflammatory state (9,10), and in part on the findings from many observational studies and meta-analyses of trends toward or statistically significant worse outcomes in those who underwent multivessel primary PCI (12-16,21-23).

Four RCTs have since suggested that a strategy of multivessel PCI, either at the time of primary PCI or as a planned, staged procedure, may be beneficial and safe in selected patients with STEMI (17,18,24,27) (Data Supplement). In the PRAMI (Preventive Angioplasty in Acute Myocardial Infarction) trial (n=465) (24), the composite primary outcome of cardiac death, nonfatal myocardial infarction (MI), or refractory angina occurred in 21 patients (9%) treated with multivessel primary PCI, compared with 53 patients (22%) treated with culprit
artery–only PCI (HR: 0.35; 95% CI: 0.21 to 0.58; p<0.001). In the CvLPRIT (Complete Versus Culprit-Lesion Only Primary PCI) trial (18), 296 patients were randomized to culprit artery–only or multivessel PCI during the index hospitalization (72% underwent multivessel primary PCI). The composite primary outcome of death, reinfarction, heart failure, and ischemia-driven revascularization at 12 months occurred in 15 patients (10%) who underwent multivessel PCI, compared with 31 patients (21%) receiving culprit artery–only PCI (HR: 0.49; 95% CI: 0.24 to 0.84; p=0.009). In the DANAMI 3 PRIMULTI (Third Danish Study of Optimal Acute Treatment of Patients with ST-segment Elevation Myocardial Infarction) trial (17), the composite primary outcome of all-cause death, nonfatal MI, or ischemia-driven revascularization of nonculprit artery disease occurred in 40 of 314 patients (13%) who underwent multivessel staged PCI guided by angiography and fractional flow reserve before discharge, versus 68 of 313 patients (22%) treated with culprit artery–only PCI (HR: 0.56; 95% CI: 0.38 to 0.83; p=0.004). In the PRAGUE-13 (Primary Angioplasty in Patients Transferred From General Community Hospitals to Specialized PTCA Units With or Without Emergency Thrombolysis) trial (27), 214 patients with STEMI were randomized to staged (3 to 40 days after the index procedure) revascularization of all ≥70% diameter stenosis noninfarct lesions or culprit-only PCI. Preliminary results at 38 months’ mean follow-up showed no between-group differences in the composite primary endpoint of all-cause death, nonfatal MI, and stroke.

On the basis of these findings (17,18,24,27), the prior Class III (Harm) recommendation with regard to multivessel primary PCI in hemodynamically stable patients with STEMI has been upgraded and modified to a Class IIb recommendation to include consideration of multivessel PCI, either at the time of primary PCI or as a planned, staged procedure. The writing committee emphasizes that this change should not be interpreted as endorsing the *routine* performance of multivessel PCI in all patients with STEMI and multivessel disease. Rather, when considering the indications for and timing of multivessel PCI, physicians should integrate clinical data, lesion severity/complexity, and risk of contrast nephropathy to determine the optimal strategy.

The preceding discussion and recommendations apply to the strategy of *routine* PCI of noninfarct related arteries in hemodynamically stable patients. Recommendations in the 2013 STEMI guideline with regard to PCI of a non–infarct-related artery at a time separate from primary PCI in patients who have spontaneous symptoms and myocardial ischemia or who have intermediate- or high-risk findings on noninvasive testing (Section 6.3 of that guideline) remain operative.

Although several observational studies (19,20) and a network meta-analysis (13) have suggested that multivessel staged PCI may be associated with better outcome than multivessel primary PCI, there are insufficient observational data and no randomized data at this time to inform a recommendation with regard to the optimal timing of nonculprit vessel PCI. Additional trial data that will help further clarify this issue are awaited. Issues related to the optimal method of evaluating nonculprit lesions (e.g., percent diameter stenosis, fractional flow reserve) are beyond the scope of this focused update.
3. Aspiration Thrombectomy
(See Section 5.5.2 of the 2011 PCI guideline and Section 4.2 of the 2013 STEMI guideline for additional recommendations.)

<table>
<thead>
<tr>
<th>2011/2013 Recommendation</th>
<th>2015 Focused Update Recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class IIa</strong></td>
<td><strong>Class IIb</strong></td>
<td></td>
</tr>
<tr>
<td>Manual aspiration</td>
<td>The usefulness of selective and</td>
<td>Modified recommendation (Class changed from “IIa” to “IIb” for selective and bailout aspiration thrombectomy before PCI).</td>
</tr>
<tr>
<td>thrombectomy is</td>
<td>bailout aspiration thrombectomy in</td>
<td></td>
</tr>
<tr>
<td>reasonable for patients</td>
<td>patients undergoing primary PCI is</td>
<td></td>
</tr>
<tr>
<td>undergoing primary PCI</td>
<td>not well established (33-37).</td>
<td></td>
</tr>
<tr>
<td>(29-32). (Level of</td>
<td><em>(Level of Evidence: C-LD)</em></td>
<td></td>
</tr>
<tr>
<td>Evidence: B)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Class III: No Benefit</strong></td>
<td><em>Routine</em> aspiration thrombectomy</td>
<td>New recommendation (“Class III: No Benefit” added for <em>routine</em> aspiration thrombectomy before PCI).</td>
</tr>
<tr>
<td>before primary PCI is</td>
<td>before primary PCI is not useful</td>
<td></td>
</tr>
<tr>
<td>not useful (33-37).</td>
<td><em>(Level of Evidence: A)</em></td>
<td></td>
</tr>
</tbody>
</table>

PCI indicates percutaneous coronary intervention; and LD, limited data.

The 2011 PCI and 2013 STEMI guidelines’ (9,10) Class IIa recommendation for aspiration thrombectomy before primary PCI was based on the results of 2 RCTs (29,31,32) and 1 meta-analysis (30) and was driven in large measure by the results of TAPAS (Thrombus Aspiration During Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction Study), a single-center study that randomized 1,071 patients with STEMI to aspiration thrombectomy before primary PCI or primary PCI only (29,32). Three multicenter trials, 2 of which enrolled significantly more patients than prior aspiration thrombectomy trials, have prompted reevaluation of this recommendation. In the INFUSE-AMI (Intracoronary Abciximab and Aspiration Thrombectomy in Patients With Large Anterior Myocardial Infarction) trial (37) of 452 patients with anterior STEMI due to proximal or mid-left anterior descending occlusion, infarct size was not reduced by aspiration thrombectomy before primary PCI. The TASTE (Thrombus Aspiration During ST-Segment Elevation Myocardial Infarction) trial (n=7,244) incorporated a unique design that allowed randomization within an existing national registry, resulting in enrollment of a remarkably high proportion of eligible patients (34,36). No significant 30-day or 1-year differences were found between the group that received aspiration thrombectomy before primary PCI and the group that received primary PCI only with regard to death, reinfarction, stent thrombosis, target lesion revascularization, or a composite of major adverse cardiac events. The TOTAL (Trial of Routine Aspiration Thrombectomy With PCI Versus PCI Alone in Patients With STEMI) trial randomized 10,732 patients with STEMI to aspiration thrombectomy before primary PCI or primary PCI only (35). Bailout thrombectomy was performed in 7.1% of the primary PCI–only group, whereas the rate of crossover from aspiration thrombectomy before primary PCI to primary PCI only was 4.6%. There were no differences between the 2 treatment groups, either in the primary composite endpoint of cardiovascular death, recurrent MI, cardiogenic shock, or New York Heart Association class IV heart failure at 180 days, or in the individual components of the primary endpoint, stent thrombosis, or target-vessel...
revascularization. There was a small but statistically significant increase in the rate of stroke in the aspiration thrombectomy group. An updated meta-analysis that included these 3 trials among a total of 17 trials (n=20,960) found no significant reduction in death, reinfarction, or stent thrombosis with routine aspiration thrombectomy. Aspiration thrombectomy was associated with a small but nonsignificant increase in the risk of stroke (33).

Several previous studies have found that higher thrombus burden in patients with STEMI is independently associated with higher risks of distal embolization, no-reflow phenomenon, transmural myocardial necrosis, major adverse cardiac events, stent thrombosis, and death (38-42). However, subgroup analyses from the TASTE and TOTAL trials did not suggest relative benefit from aspiration thrombectomy before primary PCI in patients with higher thrombus burden or in patients with initial Thrombolysis in Myocardial Infarction (TIMI) flow grade 0-1 or left anterior descending artery / anterior infarction (34,35).

On the basis of the results of these studies, the prior Class IIa recommendation for aspiration thrombectomy has been changed. Routine aspiration thrombectomy before primary PCI is now not recommended (Class III: No Benefit, LOE A). There are insufficient data to assess the potential benefit of a strategy of selective or bailout aspiration thrombectomy (Class IIb, LOE C-LD). “Bailout” aspiration thrombectomy is defined as thrombectomy that was initially unplanned but was later used during the procedure because of unsatisfactory initial result or procedural complication, analogous to the definition of “bailout” glycoprotein IIb/IIIa use.

It should be noted that the preceding recommendations and text apply only to aspiration thrombectomy; no clinical benefit for routine rheolytic thrombectomy has been demonstrated in patients with STEMI undergoing primary PCI (30,43,44).

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**Key Words**: ACC/AHA Clinical Practice Guidelines, focused update, primary PCI, culprit vessel, multivessel, thrombectomy
Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction (Percutaneous Coronary Intervention Writing Committee) (November 2014)

<table>
<thead>
<tr>
<th>Committee Member</th>
<th>Employer/Title</th>
<th>Consultant</th>
<th>Speakers Bureau</th>
<th>Ownership/Partnership/Principal</th>
<th>Personal Research</th>
<th>Institutional, Organizational or Other Financial Benefit</th>
<th>Expert Witness</th>
<th>Voting Recusals by Section*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenn N. Levine (Chair)</td>
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<td>None</td>
<td>None</td>
<td>None</td>
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<td>None</td>
<td>None</td>
<td>None</td>
</tr>
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<td>Eric R. Bates (Vice Chair)</td>
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<td>• Merck</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<tr>
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<td>None</td>
<td>None</td>
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<td>• Abbott Vascular†• Abiomed†• Boston Scientific†• Volcano†</td>
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<td>University of Texas Medical Center—Professor of Medicine and Radiology</td>
<td>None</td>
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<td>John A. Bittl</td>
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<td>Bojan Cercek</td>
<td>Cedars-Sinai Medical Center—Director, Coronary Care Unit</td>
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<td>Charles E. Chambers</td>
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<td>Stephen G. Ellis</td>
<td>Cleveland Clinic Foundation—Section Head, Invasive and Interventional Cardiology</td>
<td>• Abbott • Boston Scientific • Medtronic</td>
<td>None</td>
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<td>Robert A. Guyton</td>
<td>Emory Clinic, Inc.—Professor and Chief, Division of Cardiothoracic Surgery</td>
<td>• Medtronic‡</td>
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<td>Cooper Medical School of Rowan University—Professor</td>
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</table>

*Voting Recusals by Section*
This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not
necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 
≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the 
business entity exceed 5% of the person’s gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of 
transparency. Relationships in this table are modest unless otherwise noted.

According to the ACC/AHA, a person has a relevant relationship IF: a) the relationship or interest relates to the same or similar subject matter, intellectual property or asset, 
topic, or issue addressed in the document; or b) the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or 
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other personal gain or loss as a result of the issues/content addressed in the document.

*Writing group members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may 
apply.
†No financial benefit.
‡Significant relationship.

ACC indicates American College of Cardiology; AHA, American Heart Association; and SCAI, Society for Cardiovascular Angiography and Interventions.
### Appendix 2. Author Relationships With Industry and Other Entities (Relevant)—2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction (ST-Elevation Myocardial Infarction Writing Committee) (February 2014)

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Dr. Deborah D. Ascheim was not eligible to continue on the writing committee due to her employment by Capricor Therapeutics effective August 2015.
Writing group members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply.

*Significant relationship.

ACC indicates American College of Cardiology; AHA, American Heart Association; NYU, New York University; UCSF, University of California San Francisco; and UT, Utah.
### Appendix 3. Reviewer Relationships With Industry and Other Entities (Relevant)—2015 Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction (Combined Peer Reviewers From 2011 PCI and 2013 STEMI Guidelines)

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References


### Author Relationships With Industry and Other Entities (Comprehensive)—2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction (Percutaneous Coronary Intervention Writing Committee) (November 2014)

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<td>Narith Ou</td>
<td>Mayo Clinic—Pharmacotherapy Coordinator, Cardiology</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Martha J. Radford</td>
<td>NYU Langone Medical Center—Chief Quality Officer; NYU School of Medicine—Professor of Medicine (Cardiology)</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Jacqueline E. Tamis-Holland</td>
<td>Mount Sinai Saint Luke's Hospital and The Icahn School of Medicine—Program Director, Interventional Cardiology Fellowship Program</td>
<td>None</td>
<td>Impact of English Comprehension on Delays to Presentation and Treatment of Patients with an Acute ST-Elevation Infarction†</td>
</tr>
<tr>
<td>Carl L. Tommaso</td>
<td>Skokie Hospital—Director of Catheterization Laboratory; NorthShore University HealthSystems—Partner</td>
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<td>None</td>
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</tr>
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<td>David X. Zhao</td>
<td>Wake Forest Baptist Health—Professor of Medicine, Heart and Vascular Center of</td>
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</tbody>
</table>

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Dr. Deborah D. Ascheim was not eligible to continue on the writing committee due to her employment by Capricor Therapeutics effective August 2015.

*Significant relationship.
†No financial benefit.

AHRQ indicates Agency for Healthcare Research and Quality; ABIM indicates American Board of Internal Medicine; ACC indicates American College of Cardiology; AHA, American Heart Association; DSMB, Data Safety Monitoring Board; HRS, Heart Rhythm Society; ISCHEMIA, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches; NYU, New York University; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; PARTNER II trial, Placement of Aortic Transcatheter Valves; PCORI, Patient-Centered Outcomes Research Institute; SCAI, Society for Cardiovascular Angiography and Interventions; UCSF, University of California San Francisco; U.S. Food and Drug Administration; and UT, Utah.
## Data Supplement 1-A. Observational Studies Comparing Culprit Artery-Only Revascularization Versus Multivessel PCI (Section 2)

<table>
<thead>
<tr>
<th>Study Acronym Author Year</th>
<th>Aim</th>
<th>Study Type; Study Size (N)</th>
<th>Patient Population</th>
<th>Primary Endpoint and Results</th>
<th>Relevant 2&lt;sup&gt;nd&lt;/sup&gt; Endpoint (if any); Study Limitations; Adverse Events and Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iqbal MB, et al., 2014 (1)</td>
<td>To investigate mortality for COR vs. MV PCI at the time of PPCI for patients presenting with STEMI</td>
<td>Observational. Used multivariate analysis and propensity matching</td>
<td>Inclusion criteria: STEMI and PPCI MVD defined as &gt;50% stenosis in ≥2 epicardial coronary arteries Exclusion criteria: LM &gt;50% stenosis Cardiogenic shock</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; endpoint: 1-y mortality</td>
<td>Total study population: 7.4% (COR) vs.10.1% (MV) (p=0.031) Adjusted HR Total population: 0.65 (95% CI: 0.47-0.91; p=0.011) Propensity matched cohort: 164/2418 (6.8%) vs. 41/403 (10.2%), p=0.059 Adjusted propensity matched cohort HR: 0.64 (95% CI: 0.45-0.90; p=0.010) Inverse probability treatment weighted analyses also confirmed COR as an independent predictor for reduced in-hospital MACE (odds ratio, 0.38; 95% CI, 0.15–0.96; p=0.040) and survival at 1 year (hazard ratio, 0.44; 95% CI, 0.21–0.93; p=0.033).</td>
</tr>
<tr>
<td>Santos AR, et al., 2014 (2)</td>
<td>To assess the impact of a MV PCI at the time of PPCI on in-hospital morbidity and mortality in patients with STEMI undergoing PCI</td>
<td>Observational: Portuguese Society of Cardiology’s Registry of Acute Coronary Syndromes (ACS)</td>
<td>Inclusion criteria: STEMI Enrolled in Portuguese Society of Cardiology Registry MVD defined as ≥50% Exclusion criteria: Staged MV PCI History of prior CABG</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; endpoint: In-hospital mortality COR vs. MV PCI at time of PPCI: In-hospital Mortality: 14/180 (7.8%) vs. 2/77 (2.6%), p=NS Adjusted mortality OR: 12.92, 95% CI 0.67-248.4, p=0.09</td>
<td></td>
</tr>
<tr>
<td>Jeger R, et al., 2014 (3)</td>
<td>To assess whether MV PCI at time of PPCI vs. COR in patients with STEMI and MVD influences 1-y outcome</td>
<td>Observational: Swiss Nationwide Acute Myocardial Infarction in Switzerland Plus Registry (AMIS)</td>
<td>Inclusion criteria: STEMI or new LBBB MVD defined as a ≥50% in ≥2 different major epicardial coronary arteries and/or involving the LM. Written informed consent to enroll</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; endpoint: 1-y all-cause mortality MV PCI 12/442 (2.7%) vs COR: 40/1467 (2.7%), p&gt;0.99 MACCE at 1 y (all-cause death, re-MI, any cardiac re-intervention, re-hospitalization due to any cardiovascular diagnosis, and CVA): Adjusted OR for MV PCI vs COR=0.69, 95% CI 0.51–0.93, p=0.017</td>
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| **Manari A, et al., 2014**<sup>(4)</sup> | **Size:** 1909 (MV PCI at time of PPCI 442 vs. COR 1467)<br>**Aim:** To examine the differences in cardiac outcomes for patients with STEMI and MVD as a function of whether they underwent COR or MV PCI, either at the time of PPCI or as a staged procedure.<br>**Study type:** Observational retrospective: REAL registry<br>**Size:** 2061 (MV PCI at time of PPCI 367, Staged MV PCI within 60 d 988, COR 706) | **Exclusion criteria:**<br>• Absence of follow-up data<br><br>**Inclusion criteria:**<br>• STEMI and MVD enrolled in REAL registry<br><br>1<sup>st</sup> **endpoint:**<br>Mortality at 30 d and 2 y COR vs. staged MV PCI<br>• 30-d mortality: adjusted HR: 2.81 (95% CI: 1.34-5.89; p=0.006)<br>• 2-y mortality: adjusted HR: 1.93 (95% CI: 1.35-2.74; p=0.0002)<br><br>MV PCI at time of PPCI vs. staged MV PCI:<br>• 30-d mortality adjusted HR: 2.58 (95% CI: 1.06-6.26; p=0.03)<br>• 2-y adjusted HR: 1.08 (95% CI: 0.64-1.82; p=0.76)<br><br>MV PCI at time of PPCI vs. COR<br>• 2-y unadjusted mortality: 127/706 (18.0%) vs. 26/367 (7.1%), p=0.0002<br><br>• Study looked at timing of MV PCI and showed that staged MV PCI was associated with better outcomes than either COR or MV PCI at the time of PPCI<br> |<br>**Jaguszewski M, et al., 2013**<sup>(5)</sup> | **Size:** 4941 (MV PCI at time of PPCI-1108 vs. COR-3833)<br>**Aim:** To compare the outcomes with MV PCI at the time of PPCI with COR<br>**Study type:** Observational: Swiss Nationwide Acute Myocardial Infarction in Switzerland Plus Registry (AMIS)<br>**Size:** 4941 (MV PCI at time of PPCI-1108 vs. COR-3833) | **Exclusion criteria:**<br>• N/A<br><br>**Inclusion criteria:**<br>• STEMI<br>• MVD: stenosis ≥50% in at least two of three major coronary arteries and/or involving the LM (in pts with prior CABG)<br><br>1<sup>st</sup> **endpoint:** In-hospital mortality<br><br>MV PCI at time of PPCI vs. COR:<br>• 81/1108 (7.3%) vs. 168/3833 (4.4%), p<0.001<br>• Low risk pts: 2.0% vs.2.0% (p=1.00)<br>• High risk pts: 22.2% vs. 21.7% (p=1.00)<br><br>MV PCI during single procedure vs. COR:<br>• 6/419 (1.4%) vs. 72/2118 (3.4%), p=0.03<br>• In-hospital mortality adjusted OR: 0.48 (95% CI: 0.21-1.13; p=0.73)<br><br>• Non-fatal MI: higher with MV PCI (8.8% vs. 1.6%, p<0.0001)<br><br>• Study looked at timing of MV PCI and showed that staged MV PCI was associated with better outcomes than either COR or MV PCI at the time of PPCI |<br>**Bauer T, et al., 2013**<sup>(6)</sup> | **Size:** 2537 (MV PCI during a single procedure 419 vs. COR 2118)<br>**Aim:** To evaluate the impact of MV-PCI during a single procedure on in-hospital outcomes of patients with MVD presenting with ACS<br>**Study type:** Observational: Euro Heart Survey Registry with STEMI<br>**Size:** 2537 (MV PCI during a single procedure 419 vs. COR 2118) | **Exclusion criteria:**<br>• N/A<br><br>**Inclusion criteria:**<br>• Hemodynamically stable patients with ACS<br>• MVD defined as ≥2 vessels with ≥70% stenosis<br>• Undergoing PCI<br><br>1<sup>st</sup> **endpoint:** In-hospital mortality<br><br>MV PCI during single procedure vs. COR:<br>• 6/419 (1.4%) vs. 72/2118 (3.4%), p=0.03<br>• In-hospital mortality adjusted OR: 0.48 (95% CI: 0.21-1.13; p=0.73)<br><br>• Non-fatal MI: higher with MV PCI (8.8% vs. 1.6%, p<0.0001)<br> |<br>**Dziewierz A, et al., 2010**<sup>(7)</sup> | **Size:** 1077 (MV PCI at time of PPCI vs COR in pts with STEMI and MVD)<br>**Aim:** To assess the impact of MV PCI at time of PPCI vs COR in pts with STEMI and MVD<br>**Study type:** Observational: Euro-Transfer Registry<br>**Size:** 2537 (MV PCI during a single procedure 419 vs. COR 2118) | **Exclusion criteria:**<br>• N/A<br><br>**Inclusion criteria:**<br>• Patients with STEMI included in Euro-transfer registry<br>• MVD on cath<br><br>1<sup>st</sup> **endpoint:** 1-y mortality<br><br>MV PCI at time of PPCI vs. COR:<br>• 11/70 (15.7%) vs. 57/707 (8.1%), p=0.043<br>• Adjusted OR: 2.04 (95% CI: 0.89–4.68; p=0.09)<br><br>• 30-d mortality: 12.9% vs.5.9% (p=0.039)<br>• Adjusted 30-d mortality: OR: 2.42 (95% CI: 0.96-6.06; p=0.06)
<table>
<thead>
<tr>
<th>Study</th>
<th>Aim</th>
<th>Study type</th>
<th>Size</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; endpoint</th>
<th>Notes</th>
</tr>
</thead>
</table>
| APEX-AMI Toma M, et al., 2010 (8) 20530505 | To evaluate the 90-d outcomes for MV PCI performed at the time of PPCI | Observational: APEX AMI | 2201 (MV PCI at time of PPCI 217 vs. COR 1984) | ≥18 y  
Ischemic symptoms <6 h  
STEMI undergoing PPCI  
MVD with ≥70% stenosis of another major epicardial vessel and/or requiring PCI | • PCI following lytics  
• Limited IWMI  
• LM PCI | 90-d mortality and composite of death, CHF, and cardiogenic shock | • Limited inclusion of only STEMI pts that met the APEX-AMI trial criteria. |
| Hannan EL, et al., 2010 (9) 20129564 | To examine the differences in inhospital and longer-term mortality for patients with STEMI and MVD as a function of whether they underwent COR or MV PCI, either at the time of PPCI or as a staged procedure | Observational; NY State Registry | 4,024 (MV PCI at time of PPCI=503; Staged MV PCI =259; COR=3,521) | STEMI within 24 h undergoing PCI  
MVD  
NY State resident | • Missing data on EF  
• Thrombolytic therapy  
• Shock  
• Prior CAGB | In hospital, 12-, 24-, and 42-mo mortality | • Used propensity matched data to evaluate the outcome of MV PCI at various time points compared with COR.  
• Of note, for the subgroup of patients without shock, low EF or arrhythmias, MV PCI at the time of PPCI as compared with COR resulted in a higher in hospital mortality (2.4% vs.0.9%,p=0.04) and trends toward higher 24-mo (7.2% vs.4.9%, p=0.07) and 42-mo (10.4% vs.6.7%, p=0.08) mortality |
| Cavender MA et al., 2010 (9) 20129564 | To examine the outcomes of patients | Observational; NY State Registry | 4,024 (MV PCI at time of PPCI=503; Staged MV PCI =259; COR=3,521) | In-hospital mortality. | In-hospital mortality. | Bleeding (non-shock patients): 6.71% |
2009 (10) 19660603

with STEMI undergoing MV PCI at time of PPCI vs. patients undergoing COR

Study type: Observational: NCDR Registry

Size: 28,936 (MV PCI at time of PPCI 3,134 vs. COR 25,802)

Exclusion criteria:
- STEMI treated with PPCI
- ≥1 additional major artery with significant stenosis.

MV PCI at time of PPCI vs. COR:
- In hospital mortality: 246/3134 (7.85%) vs. 1321/25802 (5.12%), p<0.01
- Patients without shock: 25% vs 28%, p=0.06
- Re-infarction: 14% vs. 13%, p=0.88
- Major bleeding: 6.2% vs 5.7%, p=0.08
- Revascularization: 25% vs 15%, p=0.007
- MACE: 14.68, 95% CI: 3.03–71.12, p=0.001

(MV at time of PPCI) vs.5.30% (COR), p<0.01
- Trend towards more renal failure with MV PCI at time of PPCI 2.31% vs. COR 1.81% (p=0.09)
- Very large registry also analyzed outcomes according to presence or absence of shock.

Varani E, et al., 2008 (11) 18798239

Aim: To examine a strategy of COR vs. MV PCI on clinical outcomes in a cohort of patients with STEMI treated with PPCI and compare the outcomes of MVD patients according to the type of revascularization (MV PCI at the time of PPCI vs. staged MV PCI vs. COR)

Study type: Observational: single center

Inclusion criteria:
- Ongoing symptoms within 24 h
- Symptom onset <12 h
- MVD (≥2 major epicardial coronary arteries or their major branches with stenosis ≥70%)

Exclusion criteria:
- PCI for acute occlusion after angiography
- Cardiogenic shock
- LM ≥50%

Endpoints:
- Death from any cause and any revascularization. Time point not specified.
- In-hospital mortality for COR vs. MV PCI at time of PPCI: 8/156 (5.1%) vs. 12/147 (8.2%), p<0.05
- 1-year mortality for MV PCI vs. COR: 8/156 (5.1%) vs. 12/147 (8.2%), p<0.05

Complete revascularization in 46% of patients with MVD

Corawani D, et al., 2008 (12) 17428557

Aim: To compare outcomes with two strategies used for treating MVD and acute MI

Study type: Observational: Single center

Size: 120 (MV PCI at time of PPCI 95 vs. COR 25)

Exclusion criteria:
- Cardiogenic shock
- LM ≥50%

1st endpoint: In-hospital MACE (re-ischemia, re-MI, acute CHF and mortality)

MV PCI vs. COR:
- 16.7% vs. 52%, p=0.0001
- Adjusted OR for In-hospital MACE:14.68, 95% CI: 3.03–71.12, p=0.001

In-hospital mortality for MV PCI vs. COR: 9/95 (9.5%) vs. 12/147 (8.2%), p=0.06
- 1-year mortality for MV PCI vs. COR: 9/95 (9.5%) vs. 22/275 (8.0%), p=0.06
- MV PCI associated with improved hospital survival when compared with COR even after adjusting for other factors.
- MV PCI had higher rates of transient renal failure (8.4% vs. 4.0%, p=0.01) and trend toward higher 1-y mortality (9.4% vs. 8.0%, p=0.06)
- MV PCI (either at time of PPCI or staged) vs COR:
  - Death 11% vs 12 %, p=0.82
  - Re-infarction: 13.0% vs 2.8%, p<0.001
  - Revascularization: 25% vs 15%, p=0.007

Corpus RA, et al., 2004 (13) 15389238

Aim: To compare outcomes between an aggressive MV PCI strategy either at time of PPCI or before hospital discharge and COR

Study type: Observational: Single Center

Size: 506 (MV PCI 152 [Divided into 2 groups: MV PCI at the time of PPCI=26, staged in hospital PCI=126]) vs.

Exclusion criteria:
- PCI of vein graft or LM

1st endpoint: Numerous endpoints at 1 year

MV PCI (either at time of PPCI or staged) vs COR:
- Death 11% vs 12 %, p=0.82
- Re-infarction: 13.0% vs 2.8%, p<0.001
- Revascularization: 25% vs 15%, p=0.007
- MACE: 40% vs 28%, p=0.006
- Multivessel PCI was an independent predictor of MACE at 1 year (odds ratio=1.67, 95% CI 1.10-2.54, p=0.01).
**COR 354)**

- PCI for acute occlusion after coronary angioplasty or arteriography;
- MVD and staged revascularization procedures of the non-IRA after discharge from the hospital.

1-yr mortality MV PCI at time of PPCI vs staged MV PCI vs COR:
5/26 (19.2%) vs. 12/126 (9.5%) vs. 42/354 (11.9%), p=0.36

Roe MT, et al., 2001 (14) 11448417

**Aim:** To determine the feasibility and safety of MV PCI at the time of PPCI

**Study Type:** Case Controlled

**Size:** 158 (MV PCI at the time of PPCI 79 [Divided into 2 Groups: MV PCI at time of PPCI=68; Rescue PCI=11] vs. COR 79 (PPCI 61, Rescue PCI=18))

**Inclusion Criteria:**
- Patients with AMI undergoing PCI
- ≥1 coronary stenosis ≥50% in a non-culprit vessel)

**Exclusion criteria:**
- PCI of branch vessels of IRA
- PCI of LM

**1° endpoint:** Death, re-MI, repeat PCI or CABG at 6 mo
MV PCI at time of PPCI vs. COR: 35.3% vs 27.9% p=NS

**Study found higher mortality for MV PCI vs. COR in the primary PCI group at 30 d but no difference in events at 6 mo**

**Study involved a mix of POBA and stents**

**6-mo mortality for MV PCI at time of PPCI vs. COR: 19/79 (24.1%) vs.13/79 (16.1%), p=NS**

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### Data Supplement 1-B. RCTs Comparing Culprit Artery-Only Revascularization Versus Multivessel PCI (Section 2)

<table>
<thead>
<tr>
<th>Study Acronym</th>
<th>Author</th>
<th>Year</th>
<th>Aim of Study; Study Type; Study Size (N)</th>
<th>Patient Population</th>
<th>Study Intervention</th>
<th>Primary Endpoint and Results</th>
<th>Relevant 2° Endpoint (if any); Study Limitations; Adverse Events and Summary</th>
</tr>
</thead>
</table>
| DANAMI 3-PRIMULTI | Engstrom T, et al., 2015 (15) (Not yet in PubMed) | | Aim: To determine whether staged angiographic or FFR guided revasc in STEMI patients with MVD reduces the primary endpoint of all cause death, reinfarction and repeat revascularisation compared with COR | STEMI ≤12 h; Successful IRA PCI; >50% stenosis >2mm in non-IRA suitable for PCI; Hemodynamic instability or ischemia in non IRA territory; CTO of non-IRA | Intervention: Complete in-hospital revasc with staged MV PCI for lesions >90% and staged FFR-guided MV PCI for lesions of 50-90% severity(n=314) | MV PCI vs. COR: 40/314 (13%) patients treated with staged MV PCI vs 68 of 313 (22%) patients treated with COR, p=0.004; (HR 0.56, 95% CI 0.38-0.83, p=0.001) | - 12-mo mortality: 15/314 (5%) vs. 11/313 (4%)  
- This study used FFR guidance for lesions of 50%-90% severity.  
- Benefit was driven by a significant reduction in ischemia-driven revascularization; death and MI rates were similar |
| CvLPRIT | Gershlick AH, et al., 2015 (16) 25766941 | | Aim: To compare differences in outcome for patients with STEMI and MVD randomized to MV PCI or COR | STEMI <12 h; Referred for PCI; MVD on cath with ≥1vessel >2mm in diameter with >70% stenosis in 1 plane or >50% stenosis in 2 planes; Non IRA suitable for stent implantation | Intervention: MV PCI either at time of PPCI or as a staged in-hospital procedure (n=150) | MV PCI vs. COR: 10.0% vs.21.2% (HR: 0.45; 95% CI: 0.24-0.84; p=0.009) | - 65% of pts underwent MV PCI at time of PPCI  
- Benefit was driven by sum of individual endpoints; no statistically significant difference in outcome in individual components of primary endpoint  
- Total 12-mo mortality: 4/150 (2.7%) vs. 10/146 (6.9%) (HR: 0.38; 95% CI: 0.12- 1.20; p=0.09) |
<table>
<thead>
<tr>
<th>Exclusion criteria:</th>
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<tbody>
<tr>
<td>• Indication for or contraindication to complete revasc</td>
</tr>
<tr>
<td>• Prior Q wave MI</td>
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<tr>
<td>• Prior CABG</td>
</tr>
<tr>
<td>• Shock, VSD or Moderate to severe mitral regurgitation</td>
</tr>
<tr>
<td>• Chronic kidney disease</td>
</tr>
<tr>
<td>• Stent thrombosis</td>
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<tr>
<td>• CTO of the only non-IRA</td>
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</table>

<table>
<thead>
<tr>
<th>PRAMI Wald DS, et al., 2013 (17)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong>: To compare the outcomes of MV PCI at the time of PPCI with COR and an ischemia guided approach to non-culprit artery disease.</td>
</tr>
<tr>
<td><strong>Study type</strong>: Randomized</td>
</tr>
<tr>
<td><strong>Size</strong>: 465 (234 MV PCI at time of PPCI, 231 COR)</td>
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<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
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<tr>
<td>• Acute STEMI (incl LBBB)</td>
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<tr>
<td>• Successful PPCI</td>
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<tr>
<td>• MVD with ≥50% stenosis in ≥1 other artery suitable for PCI</td>
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</table>

| Intervention: MV PCI at the time of PPCI (n=234) |
| Comparator: COR with ischemia guided approach to non-culprit artery disease (n=231) |

| 1° endpoint: MACE: (death from cardiac causes, nonfatal MI, or refractory angina). Results assessed after mean f/u of 23 mo MV PCI at the time of PPCI vs. COR |
| • 9.0% vs. 22.9%, (HR 0.35, 95% CI 0.21–0.58, <0.001) |
| • Trial stopped early by DSMB |
| • HR for components of primary endpoint (MV PCI vs PPCI only): |
| o Death from cardiac causes: 0.34 (95% CI, 0.11 to 1.08) |
| o Non-fatal MI: 0.32 (95% CI, 0.13 to 0.75) |
| o Refractory angina: 0.35 (95% CI, 0.18 to 0.69) |
| o All-cause mortality: 12/234 (5.1%) vs 16/231 (6.9%), p=NS |

<table>
<thead>
<tr>
<th>Dambrink JH, et al., 2010 (18)</th>
</tr>
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<tbody>
<tr>
<td><strong>Aim</strong>: To compare effect of early invasive FFR guided management vs. COR and ischemia-guided management on LV EF</td>
</tr>
<tr>
<td><strong>Study type</strong>: Randomized</td>
</tr>
<tr>
<td><strong>Size</strong>: 121 (FFR-guided MV PCI 80; COR 41)</td>
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</table>

<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
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<tbody>
<tr>
<td>• STEMI patients undergoing successful PPCI</td>
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<tr>
<td>• MVD</td>
</tr>
<tr>
<td>• with ≥1 additional major artery or branch</td>
</tr>
<tr>
<td>• with ≥50% disease and at least 2.5 mm diameter</td>
</tr>
</tbody>
</table>

| Intervention: PPCI and elective (within 3 wk) FFR guided management of non IRA disease (n=80) |
| Comparator: COR with conservative ischemia-guided management of non IRA (n=41) |

| 1° endpoint: EF at 6 mo FFR guided staged PCI vs. COR and ischemia-guided approach: EF 59± 9% vs. 57± 9%, p=0.362 |
| • MACE at 6 mo: 21% vs. 22%, p=0.929 |
| • MACE at 3 years: 35.4% vs 35.0%, p=0.96 |
| • Death or MI at 3 years: 20.3% vs 0%, p=0.002 |
| • Death at 3 years: 2/80 vs. 0/41 |
Aim: To compare long-term outcomes of three different strategies during PPCI in patients with STEMI and MVD: COR vs. staged MV PCI vs. MV PCI at the time of PPCI

Study type: Randomized

Size: 214 (65 MV PCI at time of PPCI; 65 staged MV PCI; 84 COR)

Inclusion criteria:
- Chest pain within 12 h
- STEMI

Exclusion criteria:
- Cardiogenic shock
- LM ≥50%
- Prior CABG
- Severe valvular heart disease
- Unsuccessful PPCI

Intervention: PPCI plus staged MV PCI: 65; MV PCI at the time of PPCI (n=65)

Comparator: COR (n=84)

1° endpoint: MACE at mean f/u 2.5 y: (death, re-MI, re-hospitalization for ACS and repeat coronary revasc)

MV PCI at the time of PPCI vs. staged MV PCI vs. COR:
- 23.1% vs. 20% vs. 50% p<0.001
- Adjusted HR for MACE for MV PCI at the time of PPCI vs COR: 0.495, 95% CI 0.262 to 0.933, p=0.030
- Adjusted HR for MACE for Staged MV PCI vs COR: 0.377, 95% CI 0.194 to 0.732 p=0.004

There were no differences in outcomes for staged MV PCI vs. MV PCI at time of PPCI but small number of enrolled patients

Mortality for MV PCI vs COR:
- 10/130 (7.7%) vs. 13/84 (15.5%)

ACS indicates acute coronary syndrome; AMI, acute myocardial infarction; BRAVE-2, Beyond 12 hours Reperfusion Alternative Evaluation trial; C, coronary; CAD, coronary artery disease; Cath, catheterization; CHF, congestive heart failure; CI, confidence interval; Contra, contraindications; COR, culprit artery-only (or infarct related artery-only) PCI; CR, complete revascularizations; CTO, chronic total occlusion; CV, cardiovascular; CVA, stroke; EF, ejection fraction; FFR, Fractional Flow Reserve; f/u, follow up; Fx, fibrinolysis; gp, group; HR, hazard ratio; IR, incomplete revascularization; IRA, infarct related artery; LAD, left anterior descending artery; LBBB, left bundle branch block; LM, left main; LV, left ventricle; MACE, major adverse cardiac events; MI, myocardial infarction; MVD; multivessel disease; MV PCI, multivessel PCI; NY, New York; Occ, occlusion; OR, odds ratio; PA, pulmonary artery; PCI, percutaneous coronary intervention; PCWP, pulmonary-capillary wedge pressure; POBA, balloon angioplasty; PPCI, primary PCI; pts., patients; RCT, randomized control trial; re-MI, recurrent MI; RCT; randomized controlled trial; revasc, revascularization; RR, relative risk; SK, streptokinase; SPECT, single-photon emission computed tomography; STE, ST elevation; STEMI, ST elevation myocardial infarction; sx, symptoms; THC, thrombocytopenia; TIA, transient ischemic attack; TIMI, thrombolysis in myocardial infarction; tPA, tissue plasminogen activator; TVR, target vessel revascularization; tx, treatment; and VSD, ventricular septal defect.
### Data Supplement 2. RCTs for Aspiration Thrombectomy (Section 3)

<table>
<thead>
<tr>
<th>Study Acronym</th>
<th>Aim of Study; Study Type; Study Size (N)</th>
<th>Patient Population</th>
<th>Study Intervention</th>
<th>Primary Endpoint and Results</th>
<th>Relevant 2° Endpoint (if any); Study Limitations; Adverse Events and Summary</th>
</tr>
</thead>
</table>
| TOTAL | To assess whether thrombus aspiration reduces MACE in patients with STEMI | **Inclusion criteria:**
- Symptoms of myocardial ischemia lasting for ≥ 30 min
- Definite ECG changes indicating STEMI
- Patients referred for primary PCI
- Randomized within 12 h of symptom onset and prior to diagnostic angiography

**Exclusion criteria:**
- Prior CABG
- Life expectancy <6 mo due to non-cardiac condition
- Treatment with fibrinolytic therapy for qualifying index STEMI event |
| Intervention: Thrombus aspiration before PCI (5033)  
Comparator: PCI alone (5030) | **1° endpoint:** Composite of CV death, re-MI, cardiogenic shock, NYHA heart failure within 180 d  
Thrombectomy vs PCI alone: 6.9% vs. 7.0% (HR: 0.99; 95% CI: 0.85-1.15; p=0.86) |
| | Safety endpoint: Stroke within 30 d; thrombectomy 0.7% vs. 0.3% PCI alone (HR: 2.06; 95% CI: 1.13-3.75; p=0.02)  
CV death: thrombectomy 3.1% vs. 3.5% PCI alone (HR: 0.90; 95% CI 0.73-1.12; p=0.34)  
Primary outcome + stent thrombosis +TVR: thrombectomy 9.9% vs. 9.8% PCI alone, (HR: 1.00; 95% CI: 0.89-1.14; p=0.95) |

**Summary:**
- No group differences with respect to re-MI, shock, NYHA heart failure, stent thrombosis, TVR, major bleeding, net clinical benefit (primary efficacy outcome or stroke).
- No differences in rate of primary outcome in pre-specified subgroups, including extent of thrombus burden.
- Improved ST resolution and lower rates of distal embolization with thrombectomy
- Bailout thrombectomy rate 7.1% among patients randomized to PCI alone.
- No or possible thrombus present (TIMI thrombus grade 0-1) in 6.7% thrombectomy patients, 8.1% PCI-alone patients. |

| TASTE | To assess if thrombus aspiration reduces mortality in STEMI pts at 1 y in the TASTE study | **Inclusion criteria:**
- Chest pain, at least for 30 min, onset of sx to admission <24 h  
- STEMI or LBBB

**Exclusion criteria:**
- Need for CABG  
- Previous randomization in TASTE trial |
| Intervention: Thrombus aspiration before PCI (3621)  
Comparator: PCI only (3623) | **1° endpoint:** N/A (previously reported in TASTE) |
| | Events at 1 year f/u:
- Death from any cause 5.3% vs. 5.6% (HR: 0.94; 95% CI: 0.78-1.15; p=0.57),
- Rehospitalization for MI 2.7% vs. 2.7% (HR: 0.97; 95% CI: 0.73-1.28; p=0.81), stent thrombosis 0.7% vs. 0.9% (HR: 0.84; 95% CI: 0.50-1.40; p=0.51)
- Incidence of composite of death, rehospitalization for MI, or stent thrombosis: 8.0% v. 8.5% (HR: 0.94; 95% CI: 0.8-1.11; p=0.48).
- Outcome events were recorded on the... |
<table>
<thead>
<tr>
<th>Study</th>
<th>Authors</th>
<th>Year</th>
<th>Volume</th>
<th>PMID</th>
<th>Aim</th>
<th>Study type</th>
<th>Size</th>
<th>Inclusion criteria</th>
<th>Intervention</th>
<th>1st endpoint</th>
<th>Comparator</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASTE</td>
<td>Frobert O et al., 2013 (23)</td>
<td>23991656</td>
<td></td>
<td></td>
<td>To assess if thrombus aspiration reduces mortality in STEMI pts.</td>
<td>Randomized</td>
<td>7244 (3621 thrombectomy, 3623 PCI alone)</td>
<td>• Chest pain, at least for 30 min • Onset of sx to admission&lt;24 h • STEMI or LBBB</td>
<td>Thrombus aspiration before PCI (3621)</td>
<td>All-cause mortality at 30 d</td>
<td>PCI only (3623)</td>
<td>2.8% vs 3.0%; HR: 0.94; 95% CI: 0.72-1.22; p=0.63</td>
<td>Bias due to the treating physician being aware of the group to which pt was assigned and entering the angiographic variables. No adjudication of events and no blinded review of angiograms</td>
</tr>
<tr>
<td>INFUSE-AMI</td>
<td>Stone GW, et al., 2012 (24)</td>
<td>22447998</td>
<td></td>
<td></td>
<td>To evaluate reduction of infarct size by IC abciximab, manual aspiration thrombectomy or both (with bivalirudin anticoagulation)</td>
<td>Randomized, 2x2 factorial design</td>
<td>353 with evaluable MRI in thrombectomy arms (thrombectomy=174; no thrombectomy=179)</td>
<td>• STEMI &gt;30 min and ≥1 mm • PPCI sx-onset-to-device time of ≤5 h</td>
<td>Thrombectomy (174)</td>
<td>Infarct size at 30 d as assessed by cardiac MRI</td>
<td>No thrombectomy (179)</td>
<td>Infarct size 17.0% vs 17.3% (p=0.51)</td>
<td>There were also no significant differences in absolute infarct mass or abnormal wall motion score</td>
</tr>
<tr>
<td>EXPIRA</td>
<td>Sardella G, et al., 2009 (25)</td>
<td>19161878</td>
<td></td>
<td></td>
<td>To determine the effects of manual thrombectomy device on myocardial perfusion and infarct size assessed by CE-MRI</td>
<td>Randomized</td>
<td>175</td>
<td>• 1st STEMI &lt;9 h from sx onset • Infarct-related artery ≥2.5 mm in diameter • Thrombus score ≥3 • TIMI flow grade ≤1</td>
<td>Manual thrombectomy-PCI (88)</td>
<td>Occurrence of final myocardial blush grade ≥2</td>
<td>PCI alone (87)</td>
<td>Manual thrombectomy vs PCI alone 88% vs. 60%; p=0.001</td>
<td>Rate of rehospitalization for recurrent MI at 30 d: HR:0.61; 95% CI:0.34-1.07; p=0.09</td>
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<table>
<thead>
<tr>
<th>Study Type</th>
<th>Size</th>
<th>Aim</th>
<th>Inclusion Criteria</th>
<th>Intervention</th>
<th>Comparator</th>
<th>1st endpoint</th>
<th>Exclusion Criteria</th>
<th>1st endpoint Details</th>
</tr>
</thead>
</table>
| TAPAS Vlaar PJ, et al., 2008 (26) | 1071 | To determine cardiac death or reinfarction rate at 1y | • AMI sx >30 min  
• Time from sx onset <12 h, STE >0.1mV in ≥2 leads | Thrombus aspiration (535); 1 y f/u (530) | PCI (536); 1 y f/u PCI (530) | Combined cardiac death or non-fatal re-MI at 1y; | Rescue PCI after thrombolysis  
Known concomitant disease with life expectancy <6 mo | Thrombus aspiration vs. PCI alone: 5.6% vs. 9.9% [HR: 1.81; 95% CI: 1.16-2.84; p=0.009] |
| Svilaas T, et al., 2008 (27) | 1071 | To assess whether manual thrombus aspiration is superior to conventional treatment during primary PCI | • AMI sx >30 min  
• Time from sx onset <12  
• STE >0.1 mV in ≥2 leads | Thrombus aspiration (535) | PCI alone (536) | Post procedure myocardial blush grade of 0 (no myocardial blush) or 1 (minimal myocardial blush or contrast density). | Rescue PCI after thrombolysis  
Known concomitant disease with life expectancy <6 mo | Thrombus aspiration vs. PCI alone: 17.1% vs. 26.3% [RR: 0.65; 95% CI: 0.51-0.83; p<0.001] |

CABG indicates coronary artery bypass graft; CE-MRI, contrast enhanced MRI; CI, confidence interval; cMRI, cardiac magnetic resonance imaging; Contra, contraindications; CrCl, creatinine clearance; CV, cardiovascular; ECG, electrocardiogram; EM, Export Medtronic; GP2B/3A, glycoprotein IIb/IIIa; Hgb, hemoglobin; Hosp., hospitalization; HR, hazard ratio; IC, intracoronary; ITT, intention-to-treat; LVF, Left ventricular function; MACE, major adverse cardiac events; MACCE, major adverse cardiac and cerebrovascular events; MI, myocardial infarction; MVO, microvascular obstruction; NYHA, New York Heart Association; OR, odds ratio; PCI, percutaneous coronary intervention; PL, platelet count; RCT, randomized controlled trial; RR, relative risk; STEMI, ST-elevation myocardial infarction; STR, ST-segment resolution; SVG, Saphenous venous graft; TIMI, Thrombolysis In Myocardial Infarction; TS, thrombus score; and TVR, target vessel revascularization.
References


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