### Accepted Manuscript



2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

Glenn N. Levine, MD, FACC, FAHA, Chair, PCI Writing Committee, Patrick T. O'Gara, MD, FACC, FAHA, Chair, STEMI Writing Committee, Eric R. Bates, MD, FACC, FAHA, FSCAI, Vice Chair, PCI Writing Committee, James C. Blankenship, MD, FACC, FAHA, FSCAI, Vice Chair, PCI Writing Committee, Frederick G. Kushner, MD, FACC, FAHA, FSCAI, Vice Chair, STEMI Writing Committee, Steven R. Bailey, MD, FACC, FSCAI, PCI Writing Committee, John A. Bittl, MD, FACC, PCI Writing Committee, Ralph G. Brindis, MD, MPH, MACC, FSCAI, FAHA, STEMI Writing Committee, Donald E. Casey, Jr., MD, MPH, MBA, FAHA, STEMI Writing Committee, Bojan Cercek, MD, FACC, FAHA, PCI Writing Committee, Charles E. Chambers, MD, FACC, FSCAI, PCI Writing Committee, Mina K. Chung, MD, FACC, FAHA, STEMI Writing Committee, James A. de Lemos, MD, FACC, STEMI Writing Committee, Deborah B. Diercks, MD, MSc, STEMI Writing Committee, Stephen G. Ellis, MD, FACC, PCI Writing Committee, James C. Fang, MD, FACC, FAHA, STEMI Writing Committee, Barry A. Franklin, PhD, FAHA, STEMI Writing Committee, Christopher B. Granger, MD, FACC, FAHA, STEMI Writing Committee, Robert A. Guyton, MD, FACC, PCI Writing Committee, Steven M. Hollenberg, MD, FACC, PCI Writing Committee, Umesh N. Khot, MD, FACC, PCI Writing Committee, Harlan M. Krumholz, MD, SM, FACC, FAHA, STEMI Writing Committee, Richard A. Lange, MD, FACC, FAHA, PCI Writing Committee, Jane A. Linderbaum, MS, CNP-BC, STEMI Writing Committee, Laura Mauri, MD, MSc, FACC, FSCAI, PCI Writing Committee, Roxana Mehran, MD, FACC, FAHA, FSCAI, PCI Writing Committee, David A. Morrow, MD, MPH, FACC, FAHA, STEMI Writing Committee, Issam D. Moussa, MD, FACC, FAHA, FSCAI, PCI Writing Committee, Debabrata Mukherjee, MD, FACC, FAHA, FSCAI, PCI Writing Committee, L. Kristin Newby, MD, MHS, FACC, FAHA, STEMI Writing Committee, Joseph P. Ornato, MD, FACC, FAHA, FACP, FACEP, STEMI Writing Committee, Narith Ou, PharmD, STEMI Writing Committee, Martha J. Radford, MD, FACC, FAHA, STEMI Writing Committee, Jacqueline E. Tamis-Holland, MD, FACC, FSCAI, STEMI Writing Committee, Henry H. Ting, MD, FACC, FAHA, PCI Writing Committee, Carl L. Tommaso, MD, FACC, FAHA, MSCAI, STEMI Writing Committee, Cynthia M. Tracy, MD, FACC, FAHA, STEMI Writing Committee, Y. Joseph Woo, MD, FACC, FAHA, STEMI Writing Committee, David X. Zhao, MD, FACC, STEMI Writing Committee

PII: S0735-1097(15)06797-2

DOI: 10.1016/j.jacc.2015.10.005

Reference: JAC 21889

To appear in: Journal of the American College of Cardiology

Please cite this article as: Levine GN, O'Gara PT, Bates ER, Blankenship JC, Kushner FG, Bailey SR, Bittl JA, Brindis RG, Casey Jr DE, Cercek B, Chambers CE, Chung MK, de Lemos JA, Diercks DB, Ellis SG, Fang JC, Franklin BA, Granger CB, Guyton RA, Hollenberg SM, Khot UN, Krumholz HM, Lange RA, Linderbaum JA, Mauri L, Mehran R, Morrow DA, Moussa ID, Mukherjee D, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Ting HH, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, 2015 ACC/AHA/ SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction, *Journal of the American College of Cardiology* (2015), doi: 10.1016/j.jacc.2015.10.005.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

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

### **PCI WRITING COMMITTEE\***

Glenn N. Levine, MD, FACC, FAHA, Chair† Eric R. Bates, MD, FACC, FAHA, FSCAI, Vice Chair\*† James C. Blankenship, MD, FACC, FAHA, FSCAI, Vice Chair\*: Steven R. Bailey, MD, FACC, FSCAI\*: Umesh N. Khot, MD, FACC\*† John A. Bittl, MD, FACC<sup>†</sup> Richard A. Lange, MD, FACC, FAHA<sup>†</sup> Bojan Cercek, MD, FACC, FAHA<sup>†</sup> Laura Mauri, MD, MSc, FACC, FSCAI\*† Charles E. Chambers, MD, FACC, FSCAI‡ Roxana Mehran, MD, FACC, FAHA, FSCAI\*; Stephen G. Ellis, MD, FACC\*† Issam D. Moussa, MD, FACC, FAHA, FSCAI: Robert A. Guyton, MD, FACC§ Debabrata Mukherjee, MD, FACC, FAHA, FSCAI<sup>+</sup> Steven M. Hollenberg, MD, FACC\*† Henry H. Ting, MD, FACC, FAHA<sup>†</sup>

### **STEMI WRITING COMMITTEE\***

Patrick T. O'Gara, MD, FACC, FAHA, Chairt Frederick G. Kushner, MD, FACC, FAHA, FSCAI, Vice Chair+ Ralph G. Brindis, MD, MPH, MACC, FSCAI, FAHA§ David A. Morrow, MD, MPH, FACC, FAHA\*† Donald E. Casey, Jr, MD, MPH, MBA, FAHA L. Kristin Newby, MD, MHS, FACC, FAHA\*† Joseph P. Ornato, MD, FACC, FAHA, FACP, FACEP\*† Mina K. Chung, MD, FACC, FAHA\*\* James A. de Lemos, MD, FACC\*† Narith Ou, PharmD<sup>†</sup> Deborah B. Diercks, MD, MSc<sup>+</sup> Martha J. Radford, MD, FACC, FAHA<sup>†</sup> James C. Fang, MD, FACC, FAHA\*† Jacqueline E. Tamis-Holland, MD, FACC, FSCAI<sup>†</sup> Barry A. Franklin, PhD, FAHA<sup>†</sup> Carl L. Tommaso, MD, FACC, FAHA, MSCAI‡ Christopher B. Granger, MD, FACC, FAHA\*† Cynthia M. Tracy, MD, FACC, FAHA<sup>†</sup> Y. Joseph Woo, MD, FACC, FAHA<sup>†</sup> Harlan M. Krumholz, MD, SM, FACC, FAHA\*† Jane A. Linderbaum, MS, CNP-BC<sup>†</sup> David X. Zhao, MD, FACC\*†

Page 1 of 28

### ACC/AHA TASK FORCE MEMBERS

Jonathan L. Halperin, MD, FACC, FAHA, Chair Glenn N. Levine, MD, FACC, FAHA, Chair-Elect Jeffrey L. Anderson, MD, FACC, FAHA, Immediate Past Chair Nancy M. Albert, PhD, RN, FAHA¶ Mark A. Hlatky, MD, FACC John Ikonomidis, MD, PhD, FAHA Sana M. Al-Khatib, MD, MHS, FACC, FAHA Kim K. Birtcher, PharmD, MS, AACC Jose Joglar, MD, FACC, FAHA Biykem Bozkurt, MD, PhD, FACC, FAHA Richard J. Kovacs, MD, FACC, FAHA¶ E. Magnus Ohman, MD, FACC¶ Ralph G. Brindis, MD, MPH, MACC Joaquin E. Cigarroa, MD, FACC Susan J. Pressler, PhD, RN, FAHA Lesley H. Curtis, PhD, FAHA Frank W. Sellke, MD, FACC, FAHA¶ Lee A. Fleisher, MD, FACC, FAHA Win-Kuang Shen, MD, FACC, FAHA¶ Federico Gentile, MD, FACC Duminda N. Wijeysundera, MD, PhD Samuel Gidding, MD, FAHA

\*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendixes 1 and 2 for detailed information.

\*ACC/AHA Representative. \*SCAI Representative. \*ACC/AHA Task Force on Clinical Practice Guidelines Liaison. ACP Representative. \*Force member; current member during the writing effort.

This document was approved by the American College of Cardiology Board of Trustees and Executive Committee, the American Heart Association Science Advisory and Coordinating Committee, and the Society of Cardiovascular Angiography and Interventions in September 2015, and the American Heart Association Executive Committee in October 2015.

The American College of Cardiology requests that this document be cited as follows: Levine GN, O'Gara PT, Bates ER, Blankenship JC, Kushner FG, Bailey SR, Bittl JA, Brindis RG, Casey DE Jr, Cercek B, Chambers CE, Chung MK, de Lemos JA, Diercks DB, Ellis SG, Fang JC, Franklin BA, Granger CB, Guyton RA, Hollenberg SM, Khot UN, Krumholz HM, Lange RA, Linderbaum JA, Mauri L, Mehran R, Morrow DA, Moussa ID, Mukherjee D, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Ting HH, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2015 ACC/AHA/SCAI focused update on primary percutaneous coronary intervention for patients with ST-elevation myocardial infarction: an update of the 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention and the 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2015; ••:••••-

This article has been copublished in Circulation and Catheterization and Cardiovascular Interventions.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (www.acc.org), the American Heart Association (my.americanheart.org), and the Society for Cardiovascular Angiography and Interventions (www.scai.org). For copies of this document, please contact the Elsevier Inc. Reprint Department via fax (212-633-3820) or e-mail (<u>reprints@elsevier.com</u>).

Permissions: Multiple copies, modification, alteration, enhancement, and/or distribution of this document are not permitted without the express permission of the American College of Cardiology. Requests may be completed online via the Elsevier site (http://www.elsevier.com/about/policies/author-agreement/obtaining-permission).

© 2015 by the American College of Cardiology Foundation, the American Heart Association, Inc., and the Society for Cardiovascular Angiography and Interventions.

### **Table of Contents**

Preamble	4
1. Introduction	7
1.1. Methodology and Evidence Review	7
1.2. Organization of the GWC	7
1.3. Review and Approval	7
2. Culprit Artery–Only Versus Multivessel PCI	9
3. Aspiration Thrombectomy	11
Appendix 1. Author Relationships With Industry and Other Entities (Relevant)	
Appendix 2. Author Relationships With Industry and Other Entities (Relevant)	16
Appendix 3. Reviewer Relationships With Industry and Other Entities (Relevant)-2015 Focused Update	e on
Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction (Com	bined
Peer Reviewers From 2011 PCI and 2013 STEMI Guidelines)	
References	26

Ý

Page 3 of 28

### 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

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

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

(http://jaccjacc.acc.org/Clinical\_Document/2015\_Focused\_Update\_on\_Primary\_PCI in STEMI\_Comprehensive \_RWI\_Table.pdf). 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)

### **CLASS (STRENGTH) OF RECOMMENDATION**

Suggested phrases for writing recommendations:

Is recommended

CLASS I (STRONG)

- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

#### LASS IIa (MODERATE)

Suggested phrases for writing recommendations:

- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
- It is reasonable to choose treatment A over treatment B

#### CLASS IIb (WEAK)

lenefit ≥ Ris

Benefit >>> Risk

Suggested phrases for writing recommendations:

- May/might be reasonable
- May/might be considered

CLASS III: No Benefit (MODERATE)

 Usefulness/effectiveness is unknown/unclear/uncertain or not well established

#### Benefit = Risk

Suggested phrases for writing recommendations:

Is not recommended

(Generally, LOE A or B use only

- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

#### CLASS III: Harm (STRONG)

### Risk > Benefit

Suggested phrases for writing recommendations:

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

### **LEVEL (QUALITY) OF EVIDENCE**<sup>‡</sup>

### LEVEL A

- High-quality evidence<sup>‡</sup> from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

#### LEVEL B-R

- Moderate-quality evidence<sup>‡</sup> from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

#### LEVEL B-NR

#### (Nonrandomized)

(Limited Data)

(Randomized)

- 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**

- 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

(http://jaccjacc.acc.org/Clinical\_Document/2015\_Focused\_Update\_on\_Primary\_PCI\_in\_STEMI\_Data\_Suppleme nts.pdf).

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.)

2013 Recommendation	2015 Focused Update Recommendation	Comment
<u>Class III: Harm</u>	Class IIb	
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). ( <i>Level of Evidence: B</i> )	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). (Level of Evidence: B-R)	Modified recommendation (changed class from "III: Harm" to "IIb" and expanded time frame in which multivessel PCI could be performed).

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

Levine GN, et al.

2015 ACC/AHA/SCAI Focused Update on Primary PCI

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.

Page 10 of 28

### 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.)

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

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

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

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).

### **Presidents and Staff**

### American College of Cardiology

Kim A. Williams, Sr, MD, FACC, FAHA, President Shalom Jacobovitz, Chief Executive Officer William J. Oetgen, MD, MBA, FACC, Executive Vice President, Science, Education, Quality, and Publications Amelia Scholtz, PhD, Publication Manager, Science, Education, and Quality

### American College of Cardiology/American Heart Association

Lisa Bradfield, CAE, Director, Science and Clinical Policy Abdul R. Abdullah, MD, Associate Science and Medicine Advisor Allison Rabinowitz, Project Manager, Science and Clinical Policy

### American Heart Association

Mark A. Creager, MD, FAHA, FACC, President Nancy Brown, Chief Executive Officer Rose Marie Robertson, MD, FAHA, Chief Science Officer Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations Jody Hundley, Production Manager, Scientific Publications, Office of Science Operations

**Key Words**: ACC/AHA Clinical Practice Guidelines, focused update, primary PCI, culprit vessel, multivessel, thrombectomy

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

# 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)

Committee Member	Employer/Title	Consultant	Speakers Bureau	Ownership/ Partnership / Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness	Voting Recusals by Section*
Glenn N. Levine (Chair)	Baylor College of Medicine— Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates (Vice Chair)	University of Michigan— Professor of Medicine	<ul><li>Merck</li><li>Sanofi-aventis</li></ul>	None	None	None	None	None	2 and 3
James C. Blankenship (Vice Chair)	Geisinger Medical Center— Director of Cardiology and Cardiac Catheterization Laboratories	None	None	None	<ul> <li>Abbott Vascular†</li> <li>Abiomed†</li> <li>Boston Scientific†</li> <li>Volcano†</li> </ul>	None	None	2 and 3
Steven R. Bailey	University of Texas Medical Center—Professor of Medicine and Radiology	None	None	None	None	None	None	None
John A. Bittl	Munroe Heart—Interventional Cardiologist	None	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center— Director, Coronary Care Unit	None	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical Center—Professor of Medicine and Radiology	None	None	None	None	None	None	None
Stephen G. Ellis	Cleveland Clinic Foundation— Section Head, Invasive and Interventional Cardiology	<ul> <li>Abbott</li> <li>Boston Scientific</li> <li>Medtronic</li> </ul>	None	None	None	None	None	2 and 3
Robert A. Guyton	Emory Clinic, Inc.—Professor and Chief, Division of Cardiothoracic Surgery	•Medtronic‡	None	None	None	None	None	2 and 3
Steven M. Hollenberg	Cooper Medical School of Rowan University—Professor	None	None	None	None	None	None	None

Page 13 of 28

### Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

	of Medicine							
Umesh N. Khot	Cleveland Clinic—Vice Chairman, Department of Cardiovascular Medicine	AstraZeneca	None	None	None	None	None	None
Richard A. Lange	Texas Tech University Health Sciences Center El Paso— President	None	None	None	None	None	None	None
Laura Mauri	Brigham & Women's Hospital—Associate Professor of Medicine, Harvard Medical School	•Medtronic •St. Jude Medical	None	None	None	<ul> <li>Abbott‡</li> <li>Boston Scientific‡</li> <li>Bristol-Myers Squibb‡</li> <li>Cordis‡</li> <li>Medtronic Cardiovascular‡</li> <li>Sanofi-aventis‡</li> </ul>	None	2 and 3
Roxana Mehran	Columbia University Medical Center—Associate Professor of Medicine; Director, Data Coordinating Analysis Center	<ul> <li>Abbott Vascular</li> <li>Boston Scientific</li> <li>Janssen (Johnson &amp; Johnson)‡</li> <li>Merck</li> <li>Sanofi-aventis‡</li> </ul>	None	None	<ul> <li>BMS/Sanofi- aventis‡</li> <li>Regado</li> <li>STENTYS†</li> </ul>	None	None	2 and 3
Issam D. Moussa	University of Central Florida College of Medicine— Professor of Medicine; First Coast Cardiovascular Institute—Chief Medical Officer	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
Henry H. Ting	New York–Presbyterian Hospital, The University Hospital of Columbia and Cornell—Senior Vice President and Chief Quality Officer	None	None	None	None	None	None	None

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

### Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

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  $\geq$ 5% of the voting stock or share of the business entity, or ownership of  $\geq$ \$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 makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household* has a reasonable potential for financial, professional, or 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.

CERTER

Page 15 of 28

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

# 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)

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness	Voting Recusals by Section*
Patrick T. O'Gara ( <i>Chair</i> )	Harvard Medical School— Professor of Medicine	None	None	None	None	None	None	None
Frederick G. Kushner (Vice Chair)	Tulane University School of Medicine—Clinical Professor of Medicine; Heart Clinic of Louisiana—Medical Director	None	None	None	None	None	None	None
Ralph G. Brindis	UCSF Philip R. Lee Institute for Health Policy Studies— Clinical Professor of Medicine	None	None	None	None	None	None	None
Donald E. Casey, Jr.	Thomas Jefferson College of Population Health—Adjunct Faculty; Alvarez & Marsal IPO4Health—Principal and Founder	None	None	None	None	None	None	None
Mina K. Chung	Cleveland Clinic Foundation—Professor of Medicine	<ul> <li>Boston Scientific‡</li> <li>Medtronic‡</li> <li>St. Jude‡</li> </ul>	None	None	<ul> <li>Biosense Webster‡</li> <li>Boston Scientific‡</li> <li>Medtronic‡</li> <li>St. Jude†</li> </ul>	None	None	2 and 3
James A. de Lemos	UT Southwestern Medical Center—Professor of Medicine	<ul> <li>Abbott Diagnostics</li> <li>Novo Nordisc</li> <li>St. Jude Medical</li> </ul>	None	None	Abbott     Diagnostics†	None	None	2 and 3
Deborah B. Diercks	UT Southwestern Medical Center—Audre and Bernard Rapoport Distinguished Chair in Clinical Care and Research; Department of Emergency	None	None	None	None	None	None	None

Page 16 of 28

	Medicine—Professor and Chair							
James C. Fang	University of Utah— Cardiovascular Division	Boston     Scientific	None	None	None	None	None	2 and 3
Barry A. Franklin	William Beaumont Hospital— Director, Cardiac Rehabilitation and Exercise Laboratories	None	None	None	None	None	None	None
Christopher B. Granger	Duke Clinical Research Institute—Director, Cardiac Care Unit; Professor of Medicine	None	None	None	<ul> <li>Medtronic Foundation†</li> <li>Merck†</li> </ul>	None	None	2 and 3
Harlan M. Krumholz	Yale University School of Medicine—Professor of Epidemiology and Public Health	None	None	None	<ul> <li>Johnson &amp; Johnson†</li> <li>Medtronic†</li> </ul>	None	None	2 and 3
Jane A. Linderbaum	Mayo Clinic—Assistant Professor of Medicine	None	None	None	None	None	None	None
David A. Morrow	Harvard Medical School— Professor of Medicine	• Abbott • Merck	None	None	<ul> <li>Abbott†</li> <li>GlaxoSmith- Kline†</li> <li>Johnson &amp; Johnson†</li> <li>Merck†</li> </ul>	None	None	2 and 3
L. Kristin Newby	Duke University Medical Center, Division of Cardiology—Professor of Medicine	• Philips	None	None	• Merck†	None	None	2 and 3
Joseph P. Ornato	Department of Emergency Medicine Virginia Commonwealth University— Professor and Chairman	None	None	None	None	None	None	None
Narith Ou	Mayo Clinic— Pharmacotherapy Coordinator, Cardiology	None	None	None	None	None	None	None
Martha J. Radford	NYU Langone Medical Center—Chief Quality	None	None	None	None	None	None	None

### Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

	Officer; NYU School of Medicine—Professor of Medicine (Cardiology)							
Jacqueline E. Tamis-Holland	Mount Sinai Saint Luke's Hospital and The Icahn School of Medicine—Program Director, Interventional Cardiology Fellowship Program	None	None	None	None	None	None	None
Carl L. Tommaso	Skokie Hospital—Director of Catheterization Laboratory; NorthShore University HealthSystems—Partner	None	None	None	None	None	None	None
Cynthia M. Tracy	George Washington University Medical Center— Associate Director, Division of Cardiology	None	None	None	None	None	None	None
Y. Joseph Woo	Stanford University— Professor and Chair, Cardiothoracic Surgery	None	None	None	None	None	None	None
David X. Zhao	Wake Forest Baptist Health— Professor of Medicine, Heart and Vascular Center of Excellence Director	None	None	None	<ul><li>St. Jude‡</li><li>Medtronic‡</li></ul>	None	None	2 and 3

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  $\geq$ 5% of the voting stock or share of the business entity, or ownership of  $\geq$ 55,000 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 makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.

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

Page 18 of 28

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

\*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. ‡No financial benefit.

ACC indicates American College of Cardiology; AHA, American Heart Association; NYU, New York University; UCSF, University of California San Francisco; and UT, Utah.

Page 19 of 28

Ath MAR

Levine GN, et al. 2015 ACC/AHA/SCAI Focused Update on Primary PCI

## 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)

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Elliott M. Antman	Official Reviewer—AHA	Harvard Medical School— Professor of Medicine, Associate Dean for Clinical and Translational Research	None	None	None	None	None	None
Deepak L. Bhatt	Official Reviewer—AHA	Harvard Medical School— Professor; Interventional Cardiovascular Programs—Executive Director	None	None	None	<ul> <li>Bristol-Myers Squibb*</li> <li>Ischemix*</li> <li>Medtronic*</li> <li>St. Jude Medical</li> </ul>	• Regado Biosciences†	None
Christopher P. Cannon	Official Reviewer—AHA	Harvard Medical School— Professor of Medicine; Brigham and Women's Hospital—Senior Investigator, TIMI Study Group, Cardiovascular Division	<ul> <li>Bristol-Myers Squibb</li> <li>Merck</li> <li>Regeneron/ Sanofi- aventis*</li> </ul>	None	None	• Merck*	None	None
Joaquin E. Cigarroa	Official Reviewer— ACC/AHA Task Force on Clinical Practice Guidelines	Oregon Health & Science University—Clinical Professor of Medicine	None	None	None	None	None	None
George Dangas	Official Reviewer—ACC Board of Trustees	Icahn School of Medicine—Professor of Cardiology and Vascular Surgery; Mount Sinai Medical Center—Director, Cardiovascular Innovation	<ul> <li>Abbott</li> <li>Biosensors</li> <li>Boston Scientific</li> <li>Johnson &amp; Johnson*</li> <li>Merck</li> </ul>	None	None	None	<ul><li>Abbott</li><li>Medtronic</li><li>Osprey</li></ul>	None

Page 20 of 28

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
			<ul> <li>Osprey Medical*</li> <li>Regado Biosciences</li> </ul>					
Charles J. Davidson	Official Reviewer— SCAI	Northwestern University Feinberg School of Medicine—Professor of Medicine, Director of Cardiac Catheterization Lab	None	None	None	• Baxter International†	None	None
Kirk N. Garratt	Official Reviewer— SCAI	Hofstra University Medical School—Associate Chair of Quality and Research; Professor of Medicine	<ul> <li>Abbott</li> <li>Boston Scientific</li> <li>The Medicines Company</li> <li>Daiichi- Sankyo/Eli Lilly</li> <li>AstraZeneca</li> </ul>	None	<ul> <li>LifeCuff Technologies</li> <li>Global Delivery Systems</li> </ul>	None	• Boston Scientific	None
Steven L. Goldberg	Official Reviewer— SCAI	University of Washington Medical Center—Cath Lab Director	• Terumo†	None	None	None	None	None
G. B. John Mancini	Official Reviewer—ACC Board of Governors	Vancouver Hospital Research Pavilion— Professor of Medicine	Merck     Sanofi-aventis/     Regeneron	None	None	None	None	None
Jonathan M. Tobis	Official Reviewer— SCAI	University of California Los Angeles—Professor of Medicine and Cardiology	• St. Jude Medical	None	None	None	None	None
Jeffrey L. Anderson	Content Reviewer— ACC/AHA Task Force on Clinical Practice	Intermountain Medical Center—Associate Chief of Cardiology	None	None	None	None	None	None

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
	Guidelines							
Thomas M.	Content	Duke University—	None	None	None	None	None	None
Bashore	Reviewer	Professor of Medicine						
James A.	Content	Lehigh Valley Heart	None	None	None	None	None	None
Burke	Reviewer—ACC	Specialists—Associate						
	Interventional	Chief, Division of			C Y			
	Scientific	Cardiology						
	Council				C			
Jeffrey J.	Content	Kaiser Permanente	None	None	None	None	• Abbott	None
Cavendish	Reviewer—ACC	Cardiology—						
	Prevention of	Interventional Cardiologist						
	Cardiovascular							
	Disease							
<u> </u>	Committee		NY.			NY.		NY.
Gregory J.	Content	Texas A&M College of	None	None	None	None	None	None
Dehmer	Reviewer—ACC	Medicine—Professor of						
	Appropriate Use	Medicine; Scott & White		×				
11.0	Criteria	Healthcare	N	NT.	N		N	N
John S.	Content	Emory University	None	None	None	• Abbott	None	None
Douglas, Jr.	Reviewer	Hospital—Professor of Medicine				Medtronic		
John P. Erwin	Content	Texas A&M College of	None	None	None	None	None	None
III	Reviewer-	Medicine—Associate						
	ACC/AHA Task	Professor; Scott & White						
	Force on	Healthcare—Vice-Chair of						
	Performance	the Department of						
	Measures	Medicine						
T. Bruce	Content	East Carolina Institute	None	None	None	None	None	None
Ferguson	Reviewer—ACC	Brody School of						
	Surgeons'	Medicine—Professor of						
	Scientific	Surgery and Physiology						
	Council	· · · · · · · · · · · · · · · · · · ·						
Anthony	Content	University Hospitals of	• Abbott	• Abbott†	None	None	None	None
Gershlick	Reviewer	Leicester, Department of	Boston					

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
		Cardiology	Scientific • Cordis • Medtronic					
Jonathan L. Halperin	Content Reviewer— ACC/AHA Task Force on Clinical Practice Guidelines	Mt. Sinai Medical— Professor of Medicine	<ul> <li>Bayer Healthcare</li> <li>Boston Scientific</li> <li>Johnson &amp; Johnson</li> <li>Medtronic</li> </ul>	None	None	None	None	None
Howard C. Herrmann	Content Reviewer	University of Pennsylvania Perelman School of Medicine—Professor of Medicine, Director of Interventional Cardiology Program	<ul> <li>Seimens Medical</li> <li>St. Jude Medical</li> </ul>	None	None	<ul> <li>Abbott*</li> <li>Medtronic</li> <li>Siemens Medical*</li> <li>St. Jude Medical</li> </ul>	None	None
Morton J. Kern	Content Reviewer	University of California Irvine—Professor of Medicine, Associate Chief of the Division of Cardiology	<ul> <li>Acist Medical</li> <li>Merit Medical*</li> </ul>	• St. Jude Medical*	None	None	None	None
Fred M. Kosumoto	Content Reviewer	Mayo Clinic—Director, Pacing and Electrophysiology Service	None	None	None	None	None	None
David J. Maron	Content Reviewer	Stanford University School of Medicine—Professor of Medicine and Emergency Medicine	None	None	None	None	None	None
Douglass A. Morrison	Content Reviewer	University of Arizona— Professor of Medicine; Southern Arizona VA Health Care System— Cardiac Catheterization	None	None	None	None	None	None

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
		Laboratories, Director						
Manesh R. Patel	Content Reviewer—ACC Appropriate Use Criteria	Duke University Medical Center—Associate Professor of Medicine	<ul> <li>Bayer Healthcare*</li> <li>Janssen Pharmaceutica ls*</li> </ul>	None	None	• Johnson & Johnson*	None	None
M. Eugene Sherman	Content Reviewer—ACC Board of Governors	Aurora Denver Cardiology	None	None	None	None	<ul> <li>Bristol-Myers Squibb*</li> <li>Hospira*</li> </ul>	None
Daniel I. Simon	Content Reviewer	University Hospitals Case Medical Center—Professor of Cardiovascular Research	<ul> <li>Cordis/Johnson &amp; Johnson*</li> <li>Janssen Pharmaceutica ls/Johnson &amp; Johnson</li> <li>Medtronic Vascular</li> <li>Merck</li> </ul>	• Abbott	None	None	None	None
Richard W. Snyder	Content Reviewer—ACC Board of Governors	HeartPlace	None	None	None	None	None	None
William A. Tansey III	Content Reviewer	Summit Medical Group— Cardiologist	None	None	None	None	None	None
David D. Waters	Content Reviewer	San Francisco General Hospital—Chief, Division of Cardiology	None	None	None	None	Merck	None
Patrick L. Whitlow	Content Reviewer	Cleveland Clinic Foundation—Director, Interventional Cardiology	None	None	None	• Abbott	Medtronic*	
David O. Williams	Content Reviewer	Harvard Medical School— Professor of Medicine;	None	None	None	None	None	None

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
		Brigham and Women's Hospital						
Clyde W. Yancy	Content Reviewer— ACC/AHA Task Force on Practice Guidelines	Northwestern University Feinberg School of Medicine—Vice Dean for Diversity and Inclusion, Chief of Medicine- Cardiology, Professor	None	None	None	None	None	None
Yerem Yeghiazarians	Content Reviewer	University of California San Francisco—Associate Professor	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant to this document. It 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  $\geq 5\%$  of the voting stock or share of the business entity, or ownership of  $\geq 5,000$  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. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review.

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 makes a competing drug or device addressed in the *document*; or c) the *person or a member of the person's household* has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the *document*.

\*Significant relationship. †No financial benefit.

ACC indicates American College of Cardiology; AHA, American Heart Association; HF, heart failure; SCAI, Society for Cardiovascular Angiography and Interventions; STEMI, ST-elevation myocardial infarction; PCI, percutaneous coronary interventions; TIMI, Thrombolysis In Myocardial Infarction; and VA, Veteran's Affairs.

### References

- 1. ACCF/AHA Task Force on Practice Guidelines. *Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines*. American College of Cardiology and American Heart Association. 2010. Available at: <a href="http://assets.cardiosource.com/Methodology\_Manual\_for\_ACC\_AHA\_Writing\_Committees.pdf">http://assets.cardiosource.com/Methodology\_Manual\_for\_ACC\_AHA\_Writing\_Committees.pdf</a> and <a href="http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm\_319826.pdf">http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm\_319826.pdf</a>. Accessed January 23, 2015.
- 2. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Institute of Medicine (U.S.). *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press; 2011.
- 3. Committee on Standards for Systematic Reviews of Comparative Effectiveness Research, Institute of Medicine (U.S.). *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press; 2011.
- 4. Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2304-22.
- Arnett DK, Goodman RA, Halperin JL, et al. AHA/ACC/HHS strategies to enhance application of clinical practice guidelines in patients with cardiovascular disease and comorbid conditions: from the American Heart Association, American College of Cardiology, and U.S. Department of Health and Human Services. J Am Coll Cardiol. 2014;64:1851-6.
- 6. Jacobs AK, Kushner FG, Ettinger SM, et al. ACCF/AHA clinical practice guideline methodology summit report: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;61:213-65.
- Jacobs AK, Anderson JL, Halperin JL. The evolution and future of ACC/AHA clinical practice guidelines: a 30year journey: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;64:1373-84.
- 8. Halperin JL, Levine GN, Al-Khatib SM, et al. Further evolution of the ACC/AHA clinical practice guideline recommendation classification system: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. In press.
- 9. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58:e44-122.
- 10. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;61:e78-140.
- 11. Hannan EL, Samadashvili Z, Walford G, et al. Culprit vessel percutaneous coronary intervention versus multivessel and staged percutaneous coronary intervention for ST-segment elevation myocardial infarction patients with multivessel disease. JACC Cardiovasc Interv. 2010;3:22-31.
- Toma M, Buller CE, Westerhout CM, et al. Non-culprit coronary artery percutaneous coronary intervention during acute ST-segment elevation myocardial infarction: insights from the APEX-AMI trial. Eur Heart J. 2010;31:1701-7.
- 13. Vlaar PJ, Mahmoud KD, Holmes DR Jr, et al. Culprit vessel only versus multivessel and staged percutaneous coronary intervention for multivessel disease in patients presenting with ST-segment elevation myocardial infarction: a pairwise and network meta-analysis. J Am Coll Cardiol. 2011;58:692-703.
- 14. Cavender MA, Milford-Beland S, Roe MT, et al. Prevalence, predictors, and in-hospital outcomes of non-infarct artery intervention during primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (from the National Cardiovascular Data Registry). Am J Cardiol. 2009;104:507-13.
- 15. Corpus RA, House JA, Marso SP, et al. Multivessel percutaneous coronary intervention in patients with multivessel disease and acute myocardial infarction. Am Heart J. 2004;148:493-500.
- 16. Dziewierz A, Siudak Z, Rakowski T, et al. Impact of multivessel coronary artery disease and noninfarct-related artery revascularization on outcome of patients with ST-elevation myocardial infarction transferred for primary

Page 26 of 28

Levine GN, et al.

2015 ACC/AHA/SCAI Focused Update on Primary PCI

percutaneous coronary intervention (from the EUROTRANSFER Registry). Am J Cardiol. 2010;106:342-7.

- 17. Engstrøm T, Kelbæk H, Helqvist S, et al. Complete revascularisation versus treatment of the culprit lesion only in patients with ST-segment elevation myocardial infarction and multivessel disease (DANAMI 3-PRIMULTI): an open-label, randomised controlled trial. Lancet. 2015;386:665–71.
- 18. Gershlick AH, Khan JN, Kelly DJ, et al. Randomized trial of complete versus lesion-only revascularization in patients undergoing primary percutaneous coronary intervention for STEMI and multivessel Disease: the CvLPRIT trial. J Am Coll Cardiol. 2015;65:963-72.
- 19. Kornowski R, Mehran R, Dangas G, et al. Prognostic impact of staged versus "one-time" multivessel percutaneous intervention in acute myocardial infarction: analysis from the HORIZONS-AMI (harmonizing outcomes with revascularization and stents in acute myocardial infarction) trial. J Am Coll Cardiol. 2011;58:704-11.
- 20. Manari A, Varani E, Guastaroba P, et al. Long-term outcome in patients with ST segment elevation myocardial infarction and multivessel disease treated with culprit-only, immediate, or staged multivessel percutaneous revascularization strategies: insights from the REAL registry. Catheter Cardiovasc Interv. 2014;84:912-22.
- 21. Politi L, Sgura F, Rossi R, et al. A randomised trial of target-vessel versus multi-vessel revascularisation in STelevation myocardial infarction: major adverse cardiac events during long-term follow-up. Heart. 2010;96:662-7.
- 22. Roe MT, Cura FA, Joski PS, et al. Initial experience with multivessel percutaneous coronary intervention during mechanical reperfusion for acute myocardial infarction. Am J Cardiol. 2001;88:170-3, A6.
- 23. Varani E, Balducelli M, Aquilina M, et al. Single or multivessel percutaneous coronary intervention in STelevation myocardial infarction patients. Catheter Cardiovasc Interv. 2008;72:927-33.
- 24. Wald DS, Morris JK, Wald NJ, et al. Randomized trial of preventive angioplasty in myocardial infarction. N Engl J Med. 2013;369:1115-23.
- 25. Sorajja P, Gersh BJ, Cox DA, et al. Impact of multivessel disease on reperfusion success and clinical outcomes in patients undergoing primary percutaneous coronary intervention for acute myocardial infarction. Eur Heart J. 2007;28:1709-16.
- 26. Park D-W, Clare RM, Schulte PJ, et al. Extent, location, and clinical significance of non-infarct-related coronary artery disease among patients with ST-elevation myocardial infarction. JAMA. 2014;312:2019-27.
- 27. Hlinomaz O. Multivessel coronary disease diagnosed at the time of primary PCI for STEMI: complete revascularization versus conservative strategy. PRAGUE 13 trial. Available at: <u>http://sbhci.org.br/wp-content/uploads/2015/05/PRAGUE-13-Trial.pdf</u>. Accessed September 10, 2015.
- 28. Vlaar PJ, Mahmoud KD, Holmes DR, Jr., et al. Culprit vessel only versus multivessel and staged percutaneous coronary intervention for multivessel disease in patients presenting with ST-segment elevation myocardial infarction: a pairwise and network meta-analysis. J Am Coll Cardiol. 2011;58:692-703.
- 29. Vlaar PJ, Svilaas T, van der Horst IC, et al. Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study. Lancet. 2008;371:1915-20.
- 30. Bavry AA, Kumbhani DJ, Bhatt DL. Role of adjunctive thrombectomy and embolic protection devices in acute myocardial infarction: a comprehensive meta-analysis of randomized trials. Eur Heart J. 2008;29:2989-3001.
- 31. Sardella G, Mancone M, Bucciarelli-Ducci C, et al. Thrombus aspiration during primary percutaneous coronary intervention improves myocardial reperfusion and reduces infarct size: the EXPIRA (thrombectomy with export catheter in infarct-related artery during primary percutaneous coronary intervention) prospective, randomized trial. J Am Coll Cardiol. 2009;53:309-15.
- 32. Svilaas T, Vlaar PJ, van der Horst IC, et al. Thrombus aspiration during primary percutaneous coronary intervention. N Engl J Med. 2008;358:557-67.
- 33. Elgendy IY, Huo T, Bhatt DL, et al. Is aspiration thrombectomy beneficial in patients undergoing primary percutaneous coronary intervention? Meta-analysis of randomized trials. Circ Cardiovasc Interv. 2015;8:e002258.
- 34. Fröbert O, Lagerqvist B, Olivecrona GK, et al. Thrombus aspiration during ST-segment elevation myocardial infarction. N Engl J Med. 2013;369:1587-97.
- 35. Jolly SS, Cairns JA, Yusuf S, et al. Randomized trial of primary PCI with or without routine manual thrombectomy. N Engl J Med. 2015;372:1389-98.
- 36. Lagerqvist B, Fröbert O, Olivecrona GK, et al. Outcomes 1 year after thrombus aspiration for myocardial infarction. N Engl J Med. 2014;371:1111-20.
- 37. Stone GW, Maehara A, Witzenbichler B, et al. Intracoronary abciximab and aspiration thrombectomy in patients with large anterior myocardial infarction: the INFUSE-AMI randomized trial. JAMA. 2012;307:1817-26.
- 38. Napodano M, Dariol G, Al Mamary AH, et al. Thrombus burden and myocardial damage during primary

Page 27 of 28

Levine GN, et al.

2015 ACC/AHA/SCAI Focused Update on Primary PCI

percutaneous coronary intervention. Am J Cardiol. 2014;113:1449-56.

- Sianos G, Papafaklis MI, Daemen J, et al. Angiographic stent thrombosis after routine use of drug-eluting stents in ST-segment elevation myocardial infarction: the importance of thrombus burden. J Am Coll Cardiol. 2007;50:573-83.
- 40. Yip HK, Chen M-C, Chang H-W, et al. Angiographic morphologic features of infarct-related arteries and timely reperfusion in acute myocardial infarction: predictors of slow-flow and no-reflow phenomenon. Chest. 2002;122:1322-32.
- 41. Brener SJ, Dambrink J-H, Maehara A, et al. Benefits of optimising coronary flow before stenting in primary percutaneous coronary intervention for ST-elevation myocardial infarction: insights from INFUSE-AMI. EuroIntervention. 2014;9:1195-201.
- 42. Costa RA, Abizaid A, Lotan C, et al. Impact of thrombus burden on outcomes after standard versus mesh-covered stents in acute myocardial infarction (from the MGuard for acute ST elevation reperfusion trial). Am J Cardiol. 2015;115:161-6.
- 43. Ali A, Cox D, Dib N, et al. Rheolytic thrombectomy with percutaneous coronary intervention for infarct size reduction in acute myocardial infarction: 30-day results from a multicenter randomized study. J Am Coll Cardiol. 2006;48:244-52.
- 44. Migliorini A, Stabile A, Rodriguez AE, et al. Comparison of AngioJet rheolytic thrombectomy before direct infarct artery stenting with direct stenting alone in patients with acute myocardial infarction. The JETSTENT trial. J Am Coll Cardiol. 2010;56:1298-306.

Page 28 of 28