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2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: **Executive Summary: 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

Glenn N. Levine, Eric R. Bates, James C. Blankenship, Steven R. Bailey, John A. Bittl, Bojan Cercek, Charles E. Chambers, Stephen G. Ellis, Robert A. Guyton, Steven M. Hollenberg, Umesh N. Khot, Richard A. Lange, Laura Mauri, Roxana Mehran, Issam D. Moussa, Debabrata Mukherjee, Brahmajee K. Nallamothu and Henry H. Ting

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## **ACCF/AHA/SCAI Practice Guideline**

## 2011 ACCF/AHA/SCAI Guideline for Percutaneous **Coronary Intervention: Executive Summary**

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** 

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<sup>\*</sup>Writing committee members are required to recuse themselves from voting on sections where their specific relationship with industry and other entities may apply; see Appendix 1 for recusal information.

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## **Preamble**

The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and

Table 1. Applying Classification of Recommendations and Level of Evidence

	CLASS I  Benefit >>> Risk  Procedure/Treatment SHOULD be performed/ administered	CLASS IIa  Benefit >> Risk  Additional studies with focused objectives needed  IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb  Benefit ≥ Risk  Additional studies with broad  objectives needed; additional  registry data would be helpful  Procedure/Treatment  MAY BE CONSIDERED	CLASS III No Benefit or CLASS III Harm  Procedure/ Test Treatmen  COR III: Not No Proven No benefit Helpful Benefit COR III: Excess Cost Harmful W/O Benefit to Patients or Harmful
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	Recommendation that procedure or treatment is not useful/effective and may be harmful Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: COR III:  No Benefit Harm  is not potentially recommended harmful is not indicated causes harm should not be associated w
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		should not be associated v associated v associated v administered/ other should not be performed/ beneficial/ effective other

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

\*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

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

write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force.<sup>1</sup> The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recom-

mendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the Class III recommendations to delineate if the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another have been added for COR I and IIa, LOE A or B only.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term guideline-directed medical therapy (GDMT) to represent optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I). This new term, GDMT, will be used herein and throughout all future guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and be involved in

shared decision making whenever feasible, particularly for COR IIa and IIb, where the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing committee. All writing committee members and peer reviewers of the guideline are required to disclose all such current relationships, as well as those existing 12 months previously. In December 2009, the ACCF and AHA implemented a new policy for relationships with industry and other entities (RWI) that requires the writing committee chair plus a minimum of 50% of the writing committee to have no relevant RWI (Appendix 1 for the ACCF/AHA definition of relevance). These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee and are updated as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members are not permitted to write, and must recuse themselves from voting on, any recommendation or section to which their RWI apply. Members who recused themselves from voting are indicated in the list of writing committee members, and section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at www.cardiosource.org/ACC/About-ACC/ Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI) without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a focus on summary and evidence tables (with references linked to abstracts in PubMed), and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011 the Institute of Medicine released 2 reports: Finding What Works in Health Care: Standards for Systematic Reviews and Clinical Practice Guidelines We Can Trust.<sup>2,3</sup> It is noteworthy that the ACCF/AHA guidelines are cited as being compliant with many of the proposed standards. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Alice K. Jacobs, MD, FACC, FAHA Chair. ACCF/AHA Task Force on Practice Guidelines

#### 1. Introduction

## 1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. An extensive evidence review was conducted through November 2010, as well as selected other references through August 2011. Searches were limited to studies, reviews, and other evidence conducted in human subjects and that were published in English. Key search words included but were not limited to the following: ad hoc angioplasty, angioplasty, balloon angioplasty, clinical trial, coronary stenting, delayed angioplasty, meta-analysis, percutaneous transluminal coronary angioplasty, randomized controlled trial, percutaneous coronary intervention (PCI) and angina, angina reduction, antiplatelet therapy, baremetal stents (BMS), cardiac rehabilitation, chronic stable angina, complication, coronary bifurcation lesion, coronary calcified lesion, coronary chronic total occlusion, coronary ostial lesions, coronary stent (BMS and drug-eluting stents [DES]; and BMS versus DES), diabetes, distal embolization, distal protection, elderly, ethics, late stent thrombosis, medical therapy, microembolization, mortality, multiple lesions, multivessel, myocardial infarction, non-ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor, return to work, same-day angioplasty and/or stenting, slow flow, stable ischemic heart disease (SIHD), staged angioplasty, STEMI, survival, and unstable angina (UA). Additional searches cross-referenced these topics with the following subtopics: anticoagulant therapy, contrast nephropathy, PCI-related vascular complications, unprotected left main PCI, multivessel coronary artery disease (CAD), adjunctive percutaneous interventional devices, percutaneous hemodynamic support devices, and secondary prevention. Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

Because the executive summary contains only the recommendations, the reader is encouraged to consult the full-text guideline<sup>4</sup> for additional detail on the recommendations and guidance on the care of the patient undergoing PCI.

## 1.2. Organization of the Writing Committee

The committee was composed of physicians with expertise in interventional cardiology, general cardiology, critical care cardiology, cardiothoracic surgery, clinical trials, and health services research. The committee included representatives from the ACCF, AHA, and SCAI.

## 1.3. Document Review and Approval

This document was reviewed by 2 official reviewers nominated by the ACCF, AHA, and SCAI, as well as 21 individual content reviewers (including members of the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All information on reviewers' RWI was distributed to the writing committee and is published in this document (Appendix 2). This document was approved for publication by the governing bodies of the ACCF, AHA, and SCAI.

#### 1.4. PCI Guideline Scope

The evolution of the PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, intravascular ultrasound (IVUS) and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. The 2011 iteration of the guideline continues this process, addressing ethical aspects of PCI, vascular access considerations, CAD revascularization including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support devices, no-reflow therapies, and vascular closure devices. Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations. The focus of this guideline is the safe, appropriate, and efficacious performance of PCI. The risks of PCI must be balanced against the likelihood of improved survival, symptoms, or functional status. This is especially important in patients with SIHD.

In a major undertaking, the STEMI, PCI, and coronary artery bypass graft (CABG) surgery guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing greater collaboration between the different writing committees on topics such as PCI in STEMI and revascularization strategies in patients with CAD (including unprotected left main PCI, multivessel disease revascularization, and hybrid procedures).

In accordance with direction from the Task Force and feedback from readers, in this iteration of the guideline, the text has been shortened, with an emphasis on summary statements rather than detailed discussion of numerous individual trials. Online supplemental evidence and summary tables have been created to document the studies and data considered for new or changed guideline recommendations.

#### 2. CAD Revascularization: Recommendations

Recommendations and text in this section are the result of extensive collaborative discussions between the PCI and CABG writing committees, as well as key members of the SIHD and UA/NSTEMI writing committees. Certain issues, such as older versus more contemporary studies, primary analyses versus subgroup analyses, and prospective versus post hoc analyses, have been carefully weighed in designating COR and LOE; they are addressed in the appropriate corresponding text.<sup>4</sup> The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms. The following text contains recommendations for revascularization to improve survival and symptoms, and they are presented in Tables 2 and 3.

Revascularization recommendations in this section are predominantly based on studies of patients with symptomatic SIHD and should be interpreted in this context. As discussed later in this section, recommendations on the type of revascularization are, in general, applicable to patients with UA/NSTEMI. In some cases (eg, unprotected left main CAD), specific recommendations are made for patients with UA/NSTEMI or STEMI.

Table 2. Revascularization to Improve Survival Compared With Medical Therapy

Anatomic Setting	COR	LOE	References
UPLM or complex CAD			
CABG and PCI	I—Heart Team approach recommended	С	5–7
CABG and PCI	Ila—Calculation of STS and SYNTAX scores	В	7–14
UPLM*			
CABG	The state of the s	В	15–21
PCI	Ila—For SIHD when both of the following are present:	В	8, 10, 11, 22–40, 106
	<ul> <li>Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (eg, a low SYNTAX score of ≤22, ostial or trunk left main CAD)</li> </ul>		
	<ul> <li>Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (eg, STS-predicted risk of operative mortality ≥5%)</li> </ul>		
	Ila—For UA/NSTEMI if not a CABG candidate	В	11, 27, 29–31, 36, 37, 39–4
	lla—For STEMI when distal coronary flow is TIMI flow grade $<$ 3 and PCI can be performed more rapidly and safely than CABG	С	24, 42, 43
	IIb—For SIHD when both of the following are present:	В	8, 10, 11, 22–40, 44
	<ul> <li>Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (eg, low-intermediate SYNTAX score of &lt;33, bifurcation left main CAD)</li> </ul>		
	<ul> <li>Clinical characteristics that predict an increased risk of adverse surgical outcomes (eg, moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality &gt;2%)</li> </ul>		
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	В	8, 10,11, 15–23
3-vessel disease with or	without proximal LAD artery disease*		
CABG	The second secon	В	17, 21, 45–48
	lla—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (eg, SYNTAX score >22) who are good candidates for CABG	В	23, 38, 48, 63, 64
PCI	Ilb—Of uncertain benefit	В	17, 45, 48, 74
2-vessel disease with pr	oximal LAD artery disease*		
CABG	The second secon	В	17, 21, 45–48
PCI	IIb—Of uncertain benefit	В	17, 45, 48, 74
2-vessel disease without	proximal LAD artery disease*	iation	
CABG	Ila—With extensive ischemia	В	52–55
	IIb—Of uncertain benefit without extensive ischemia	С	48
PCI	IIb—Of uncertain benefit	В	17, 45, 48, 74
1-vessel proximal LAD a	rtery disease	-41	9
CABG	Ila—With LIMA for long-term benefit	В	21, 48, 61, 62
PCI	IIb—Of uncertain benefit	В	17, 45, 48, 74
1-vessel disease without	proximal LAD artery involvement		-80-
CABG	III: Harm	В	21, 45, 52, 53, 86–90
PCI	III: Harm	В	21, 45, 52, 53, 86–90
LV dysfunction			
CABG	IIa—EF 35% to 50%	В	21, 56–60
CABG	IIb—EF $<$ 35% without significant left main CAD	В	21, 56–60, 75, 76
PCI	Insufficient data		N/A
Survivors of sudden card	liac death with presumed ischemia-mediated VT		
CABG	The state of the s	В	49–51
PCI	The state of the s	С	49
No anatomic or physiolog	gic criteria for revascularization		_
CABG	III: Harm	В	21, 45, 52, 53, 86–90
PCI	III: Harm	В	21, 45, 52, 53, 86–90

\*In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI.54,66-73 (Class Ila; LOE: B).

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; COR, class of recommendation; EF, ejection fraction; LAD, left anterior descending; LIMA, left internal mammary artery; LOE, level of evidence; LV, left ventricular; N/A, not applicable; PCI, percutaneous coronary intervention; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; STS, Society of Thoracic Surgeons; SYNTAX, Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery; TIMI, Thrombolysis In Myocardial Infarction; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; UPLM, unprotected left main disease; and VT, ventricular tachycardia.

Table 3. Revascularization to Improve Symptoms With Significant Anatomic (≥50% Left Main or ≥70% Non-Left Main CAD) or Physiological (FFR ≤0.80) Coronary Artery Stenoses

Clinical Setting	COR	LOE	References
≥1 significant stenoses amenable to revascularization and unacceptable angina despite GDMT	I-CABG	Α	74, 91–100
	I-PCI		
≥1 significant stenoses and unacceptable angina in whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences	IIa-CABG	С	N/A
	Ila-PCI		
Previous CABG with $\geq \! 1$ significant stenoses associated with ischemia and unacceptable	Ila-PCI	С	78, 81, 84
angina despite GDMT	IIb-CABG	С	85
Complex 3-vessel CAD (eg, SYNTAX score $>$ 22) with or without involvement of the proximal LAD artery and a good candidate for CABG	Ila-CABG preferred over PCI	В	23, 38, 48, 63, 64
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb-TMR as an adjunct to CABG	В	101–105
No anatomic or physiologic criteria for revascularization	III: Harm-CABG	С	N/A
	III: Harm-PCI		

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COR, class of recommendation; FFR, fractional flow reserve; GDMT, guideline-directed medical therapy; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and TMR, transmyocardial laser revascularization.

## 2.1. Heart Team Approach to Revascularization Decisions

#### Class I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.<sup>5-7</sup> (Level of Evidence: C)

#### Class IIa

1. Calculation of the Society of Thoracic Surgeons and SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) scores is reasonable in patients with unprotected left main and complex CAD.<sup>7-14</sup> (Level of Evidence: B)

## 2.2. Revascularization to Improve Survival

## Left Main CAD Revascularization

#### Class I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis.¹5-2¹ (Level of Evidence: B)

#### Class IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (eg, a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (eg, Society of Thoracic Surgeons-predicted risk of operative mortality ≥5%).8,10,11,22-40,106 (Level of Evidence: B)

- 2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG.<sup>11,27,29–31,36,37,39–41</sup> (Level of Evidence: B)
- 3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG.<sup>24,42,43</sup> (Level of Evidence: C)

### Class IIb

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (eg, low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (eg, moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; Society of Thoracic Surgeons-predicted risk of operative mortality >2%).8,10,11,22-40,44 (Level of Evidence: B)

#### Class III: HARM

1. PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG.<sup>8,10,11,15-23</sup> (Level of Evidence: B)

## Non-Left Main CAD Revascularization

#### Class I

- 1. CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal left anterior descending [LAD]) or in the proximal LAD plus 1 other major coronary artery. 17,21,45-48 (Level of Evidence: B)
- 2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. (CABG Level of Evidence: B49-51; PCI Level of Evidence: C<sup>49</sup>)

#### Class IIa

- 1. CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (eg, high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium.52-55 (Level of Evidence: B)
- 2. CABG to improve survival is reasonable in patients with mild-moderate left ventricular systolic dysfunction (ejection fraction 35% to 50%) and significant (≥70% diameter stenosis) multivessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization.<sup>21,56-60</sup> (Level of Evidence: B)
- 3. CABG with a left internal mammary artery graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia.21,48,61,62 (Level of Evidence: B)
- 4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (eg, SYNTAX score >22) with or without involvement of the proximal LAD artery who are good candidates for CABG.23,38,48,63,64 (Level of Evidence: B)
- 5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a left internal mammary artery graft can be anastomosed to the LAD artery. 54,66-73 (Level of Evidence: B)

#### Class IIb

- 1. The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia.48 (Level of Evidence: C)
- 2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease. 17,45,48,74 (Level of Evidence: B)

- 3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe left ventricular systolic dysfunction (ejection fraction <35%) whether or not viable myocardium is present.<sup>21,56-60,75,76</sup> (Level of Evidence: B)
- 4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing.77-85 (Level of Evidence: B)

#### Class III: HARM

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (eg, <70% diameter non-left main coronary artery stenosis, fractional flow reserve >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium.<sup>21,45,52,53,86-90</sup> (Level of Evidence: B)

## 2.3. Revascularization to Improve Symptoms

#### Class I

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT.74,91-100 (Level of Evidence: A)

American Heart #

## Class IIa

- 1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. (Level of Evidence: C)
- 2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT.<sup>78,81,84</sup> (Level of Evidence: C)
- 3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (eg, SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG. 23,38,48,63,64 (Level of Evidence: B)

#### Class IIb

- 1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT.85 (Level of Evidence: C)
- 2. Transmyocardial laser revascularization performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting. 101-105 (Level of Evidence: B)

Table 4. Summary of Recommendations for Preprocedural Considerations and Interventions in Patients Undergoing PCI

Recommendations	COR	LOE	References
Contrast-induced AKI			
Patients should be assessed for risk of contrast-induced AKI before PCI.	1	С	118, 119
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	1	В	120–123
In patients with CKD (creatinine clearance $<$ 60 mL/min), the volume of contrast media should be minimized.	1	В	124–126
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	А	127–131
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	T T	В	132–135
In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.	III: No Benefit	С	136–138
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of	lla	A: Statin naïve	139–145
periprocedural MI.		B: Chronic statin therapy	146
Bleeding risk			
All patients should be evaluated for risk of bleeding before PCI.	T	С	N/A
CKD			
In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.	T T	В	147–149
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	T.	В	150-153
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	1	В	150, 152, 153

AKI indicates acute kidney injury; CKD, chronic kidney disease; COR, class of recommendation; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; and PCI, percutaneous coronary intervention.

#### Class III: HARM

 CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% left main or ≥70% non-left main stenosis) or physiological (eg, abnormal fractional flow reserve) criteria for revascularization. (Level of Evidence: C)

## **2.4.** Clinical Factors That May Influence the Choice of Revascularization

2.4.1. Dual Antiplatelet Therapy Compliance and Stent Thrombosis

## Class III: HARM

 PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with dual antiplatelet therapy (DAPT) for the appropriate duration of treatment based on the type of stent implanted.<sup>107-110</sup> (Level of Evidence: B)

### 2.5. Hybrid Coronary Revascularization

#### Class IIa

 Hybrid coronary revascularization (defined as the planned combination of left internal mammary arteryto-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following<sup>111–117</sup> (Level of Evidence: B):

- a. Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);
- b. Lack of suitable graft conduits;
- c. Unfavorable LAD artery or PCI (ie, excessive vessel tortuosity or chronic total occlusion).

#### Class IIb

 Hybrid coronary revascularization (defined as the planned combination of left internal mammary artery-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures. (Level of Evidence: C)

## 3. Preprocedural Considerations: Recommendations

Table 4 contains recommendations for preprocedural considerations and interventions in patients undergoing PCI.

## 3.1. Radiation Safety

#### Class I

1. Cardiac catheterization laboratories should routinely record relevant available patient procedural

radiation dose data (eg, total air kerma at the international reference point  $[K_{a,r}]$ , air kerma air product  $[P_{KA}]$ , fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. (Level of Evidence: C)

## 3.2. Contrast-Induced Acute Kidney Injury

#### Class I

- 1. Patients should be assessed for risk of contrastinduced acute kidney injury before PCI.<sup>118,119</sup> (*Level* of Evidence: C)
- 2. Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration. 120-123 (Level of Evidence: B)
- 3. In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized. 124-126 (Level of Evidence: B)

#### Class III: NO BENEFIT

 Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced acute kidney injury.<sup>127-131</sup> (Level of Evidence: A)

## 3.3. Anaphylactoid Reactions

#### Class I

1. Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration. 132-135 (Level of Evidence: B)

#### Class III: NO BENEFIT

1. In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial. 136-138 (Level of Evidence: C)

## 3.4. Statin Treatment

#### Class IIa

1. Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural myocardial infarction. (Level of Evidence: A for statin-naïve patients<sup>139-145</sup>; Level of Evidence: B for those on chronic statin therapy<sup>146</sup>)

## 3.5. Bleeding Risk

#### Class I

1. All patients should be evaluated for risk of bleeding before PCI. (Level of Evidence: C)

## 3.6. PCI in Hospitals Without On-Site Surgical Backup

#### Class IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate

planning for program development has been accomplished. 155,156 (Level of Evidence: B)

#### Class IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. 156-158 (Level of Evidence: B)

#### Class III: HARM

1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

## 4. Procedural Considerations: Recommendations

#### 4.1. Vascular Access

#### Class IIa

1. The use of radial artery access can be useful to decrease access site complications. 159-167 (Level of Evidence: A)

## 4.2. PCI in Specific Clinical Situations

4.2.1. Unstable Angina/Non–ST-Elevation Myocardial Infarction

#### Class

- 1. An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures). 168-170 (Level of Evidence: B)
- 2. An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events. 169-172 (Level of Evidence: A)
- 3. The selection of PCI or CABG as the means of revascularization in the patient with acute coronary syndrome (ACS) should generally be based on the same considerations as those without ACS.<sup>45,170,173,174</sup> (Level of Evidence: B)

#### **Class III: NO BENEFIT**

- 1. An early invasive strategy (ie, diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (eg, liver or pulmonary failure, cancer) in whom (Level of Evidence: C)
  - a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,

Table 5. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	1	А	155, 175–178
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	1	В	179, 180
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	lla	В	181, 182
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	lla	Α	183–187
Coronary angiography before hospital discharge			
Stable patients	llb	С	N/A
Coronary angiography at any time			
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	С	N/A

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

- There is a low likelihood of ACS despite acute chest pain, or
- c. Consent to revascularization will not be granted regardless of the findings.

#### 4.2.2. ST-Elevation Myocardial Infarction

Table 5 contains indications for coronary angiography in STEMI.

## 4.2.2.1. Coronary Angiography Strategies in STEMI

## Class I

- 1. A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for:
  - a. Patients who are candidates for primary PCI. 155,175–178 (Level of Evidence: A)
  - b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization. (Level of Evidence: B)

#### Class IIa

- 1. A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis. [181,182] (Level of Evidence: B)
- 2. A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame.<sup>183–187</sup> (Level of Evidence: A)

#### Class IIb

1. A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset. (Level of Evidence: C)

#### **Class III: NO BENEFIT**

1. A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care. (Level of Evidence: C)

## 4.2.2.2. Primary PCI of the Infarct Artery

## Class I

- 1. Primary PCI should be performed in patients within 12 hours of onset of STEMI. 175-178 (Level of Evidence: A)
- 2. Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal. 188,189 (Level of Evidence: B)
- 3. Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal. 190-192 (Level of Evidence: B)
- 4. Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay. 179,180 (Level of Evidence: B)
- 5. Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for less than 12 hours. 193,194 (Level of Evidence: B)

## Class IIa

1. Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset. 195–197 (Level of Evidence: B)

Table 6. Indications for PCI in STEMI

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Indications	COR	L0E	References
Primary PCI*			
STEMI symptoms within 12 h	1	Α	175–178
Severe heart failure or cardiogenic shock	1	В	179, 180
Contraindications to fibrinolytic therapy with ischemic symptoms $<$ 12 h	1	В	193, 194
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	lla	В	195–197
Asymptomatic patients presenting between 12 and 24 h after symptom onset and higher risk	llb	С	N/A
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	В	198–202
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	lla	В	181, 182
Patent infarct artery 3 to 24 h after fibrinolytic therapy	lla	В	186, 187
Ischemia on noninvasive testing	lla	В	203, 204
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	llb	В	205–209
Totally occluded infarct artery $>$ 24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	В	210–212

<sup>\*</sup>Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability. 188,189 (Class I; LOE: B) and within 120 min when the patient presents to a hospital without PCI capability. 190–192 (Class I; LOE: B).

#### Class IIb

1. Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. (Level of Evidence: C)

### Class III: HARM

1. PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise. (Level of Evidence: B)

## 4.2.2.3. Delayed or Elective PCI in Patients With STEMI

## Class IIa

- 1. PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion. 181,182 (Level of Evidence: B)
- 2. PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy. 186,187 (Level of Evidence: B)
- 3. PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing. (Level of Evidence: B)

#### Class IIb

1. PCI of a hemodynamically significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy.<sup>205–209</sup> (Level of Evidence: B)

#### **Class III: NO BENEFIT**

1. PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia. 210-212 (Level of Evidence: B)

Table 6 contains indications for PCI in STEMI.

#### 4.2.3. Cardiogenic Shock

#### Class 1

- 1. PCI is recommended for patients with acute myocardial infarction who develop cardiogenic shock and are suitable candidates. 180,213-215 (Level of Evidence: B)
- 2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy. 180,216-219 (Level of Evidence: B)

## 4.2.4. Revascularization Before Noncardiac Surgery

#### Class IIa

- 1. For patients who require PCI and are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable.<sup>220–226</sup> (Level of Evidence: B)
- 2. For patients with DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the P2Y<sub>12</sub> inhibitor as soon as possible in the immediate postoperative period.<sup>222,227</sup> (Level of Evidence: C)

#### Class III: HARM

- 1. Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery. 228,229 (Level of Evidence: B)
- 2. Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the P2Y<sub>12</sub> inhibitor will need to be discontinued perioperatively. <sup>107,225,230,231</sup> (Level of Evidence: B)

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

## 4.3. Coronary Stents

#### Class I

- Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT.<sup>232</sup> (Level of Evidence: C)
- 2. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT (Level of Evidence: A for elective PCI<sup>233-237</sup>; Level of Evidence: A for STEMI<sup>235</sup>; Level of Evidence: A for STEMI<sup>235,236,238-240</sup>).
- 3. Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted. (Level of Evidence: B)

#### Class III: HARM

- 1. PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT.<sup>107-110</sup> (Level of Evidence: B)
- 2. DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation. 107,241-243 (Level of Evidence: B)

#### 4.4. Adjunctive Diagnostic Devices

#### 4.4.1. Fractional Flow Reserve

#### Class IIa

1. Fractional flow reserve is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD.<sup>89,244–247</sup> (Level of Evidence: A)

## 4.4.2. Intravascular Ultrasound

### Class I

- 1. Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT.<sup>232</sup> (Level of Evidence: C)
- 2. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT (Level of Evidence: A for elective PCI<sup>233-237</sup>; Level of Evidence: A for STEMI.<sup>235</sup>; Level of Evidence: A for STEMI.<sup>235,236,238-240</sup>
- 3. Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted. 107,241-243 (Level of Evidence: B)

#### Class III: HARM

1. PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT. 107-110 (Level of Evidence: B)

2. DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation. 107,241-243 (Level of Evidence: B)

## 4.4. Adjunctive Diagnostic Devices

### 4.4.1. Fractional Flow Reserve

#### Class IIa

1. Fractional flow reserve is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD.<sup>89,244-247</sup> (Level of Evidence: A)

## Class IIa

- 1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD.<sup>248–250</sup> (Level of Evidence: B)
- 2. IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information.<sup>251–253</sup> (Level of Evidence: B)
- 3. IVUS is reasonable to determine the mechanism of stent restenosis.<sup>254</sup> (Level of Evidence: C)

#### Class IIb

- 1. IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis). 248,255,256 (Level of Evidence: B)
- 2. IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting. 249,254,257 (Level of Evidence: B)
- 3. IVUS may be reasonable to determine the mechanism of stent thrombosis.<sup>254</sup> (Level of Evidence: C)

## **Class III: NO BENEFIT**

1. IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. (Level of Evidence: C)

## 4.5. Adjunctive Therapeutic Devices

## 4.5.1. Coronary Atherectomy

#### Class IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation. <sup>258,259</sup> (Level of Evidence: C)

## **Class III: NO BENEFIT**

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis. 260-263 (Level of Evidence: A)

## 4.5.2. Thrombectomy

#### Class IIa

1. Aspiration thrombectomy is reasonable for patients undergoing primary PCL<sup>264–266</sup> (Level of Evidence: B)

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Table 7. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	1	В		N/A
P2Y <sub>12</sub> Inhibitors	1	А	279–283	<ul> <li>A loading dose of a P2Y<sub>12</sub> inhibitor should be given to patients undergoing PCI with stenting.</li> </ul>
<ul> <li>Clopidogrel</li> </ul>	1	В	279–281	<ul> <li>600-mg loading dose now recommended.</li> </ul>
<ul> <li>Prasugrel</li> </ul>	ı	В	282	<ul> <li>Contraindicated in patients with prior TIA/CVA: Class III: Harm; LOE: B.</li> <li>Generally not recommended in patients &gt;75 years of age (see Section 5.7.2 in full text).</li> <li>Consideration of using a lower maintenance dose in persons weighing &lt;60 kg suggested by FDA (Section 5.7.2 in full text).</li> </ul>
<ul> <li>Ticagrelor</li> </ul>	1	В	283	<ul> <li>Issues of patient compliance may be especially important.</li> </ul>
GP Ilb/Illa inhibitors (abcix	rimab, double-bolus e	ptifibatide	, high-bolus dose tir	rofiban)
<ul> <li>No clopidogrel</li> </ul>	STEMI: IIa	Α	292–298	<ul> <li>UA/NSTEMI recommendation applies to those with high-risk features.</li> </ul>
pretreatment	UA/NSTEMI: I	Α	321–326	GPI use in STEMI may be most appropriate in those with large anterior MI  and a large throughout burden.
	SIHD: IIa	В	327–329	and/or large thrombus burden.  IC abciximab administration in STEMI: Class IIb; LOE: B.
<ul> <li>Clopidogrel</li> </ul>	STEMI: IIa	С	292–298	<ul> <li>Precatheterization laboratory GPI administration in STEMI: Class III: No</li> </ul>
pretreatment	UA/NSTEMI: IIa	В	324, 327	Benefit; LOE: B.
	SIHD: IIb	В	327, 330–332	<ul> <li>Recommendations apply to those not at high risk for bleeding complications.</li> </ul>
Antithrombin agents				
UFH	1	С	N/A	<ul> <li>Dosing based on whether or not GPI was administered.</li> </ul>
Bivalirudin	1	В	333–342	<ul> <li>Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.</li> </ul>
Enoxaparin	llb	В	343–347	<ul> <li>Recommendations apply to administration of IV enoxaparin at the time of PCI for those who have not received prior antithrombin therapy or who have received "upstream" SC enoxaparin therapy for UA/NSTEMI.</li> <li>An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received &lt;2 therapeutic SC doses (eg, 1 mg/kg) or received the last SC enoxaparin dose 8 to 12 h before PCI: Class I; LOE: B.</li> <li>Patients treated with SC enoxaparin within 12 h of PCI should not receive additional treatment with UFH during PCI ("stacking"): Class III: Harm; LOE: B.</li> </ul>
Anti-Xa inhibitors	No			1
Fondaparinux	III: Harm	С	348, 349	<ul> <li>PCI should not be performed with fondaparinux as the sole antithrombin agent in patients treated with upstream fondaparinux. An additional anticoagulant with anti-lla activity should be admin istered.</li> </ul>

ACT indicates activated clotting time; COR, class of recommendation; CVA, cerebrovascular accident; FDA, U.S. Food and Drug Administration; GP, glycoprotein; GPI, glycoprotein Ilb/Illa inhibitor; IC, intracoronary; IV, intravenous; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction; and UFH, unfractionated heparin.

## 4.5.3. Laser Angioplasty

#### Class IIb

 Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty.<sup>267</sup> (Level of Evidence: C)

#### Class III: NO BENEFIT

1. Laser angioplasty should not be used routinely during PCI.<sup>260,262,268</sup> (Level of Evidence: A)

#### 4.5.4. Cutting Balloon Angioplasty

#### Class IIb

 Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches.  $^{269}$  (Level of Evidence: C)

#### **Class III: NO BENEFIT**

1. Cutting balloon angioplasty should not be performed routinely during PCI.<sup>260,269,270</sup> (Level of Evidence: A)

## 4.5.5. Embolic Protection Devices

#### Class 1

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible.<sup>271–274</sup> (*Level of Evidence: B*)

## 4.6. Percutaneous Hemodynamic Support Devices

Table 7 contains recommendations for antiplatelet and antithrombin pharmacotherapy at the time of PCI.

#### Class IIb

1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients. (Level of Evidence: C)

#### 4.6.1. Oral Antiplatelet Therapy

#### Class I

- 1. Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI.<sup>150–153</sup> (Level of Evidence: B)
- 2. Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI. 150,152,153 (Level of Evidence: B)
- 3. After PCI, use of aspirin should be continued indefinitely.<sup>275-278</sup> (Level of Evidence: A)
- 4. A loading dose of a P2Y<sub>12</sub> receptor inhibitor should be given to patients undergoing PCI with stenting<sup>279–283</sup> (Level of Evidence: A). Options include
  - a. Clopidogrel 600 mg (ACS and non-ACS patients). 279-281 (Level of Evidence: B)
  - b. Prasugrel 60 mg (ACS patients).<sup>282</sup> (Level of Evidence: B)
  - c. Ticagrelor 180 mg (ACS patients).<sup>283</sup> (Level of Evidence: B)
- 5. The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy. (Level of Evidence: C)
- 6. Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT.<sup>107</sup> (Level of Evidence: C)
- 7. The duration of P2Y<sub>12</sub> inhibitor therapy after stent implantation should generally be as follows:
  - a. In patients receiving a stent (BMS or DES) during PCI for ACS, P2Y<sub>12</sub> inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily,<sup>285</sup> prasugrel 10 mg daily,<sup>282</sup> and ticagrelor 90 mg twice daily.<sup>283</sup> (Level of Evidence: B)
  - b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.<sup>107,232,286</sup> (Level of Evidence: B)
  - c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks). 107,287 (Level of Evidence: B)

#### Class IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses. 151,288-291 (Level of Evidence: B)

2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of P2Y<sub>12</sub> inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 months) of P2Y<sub>12</sub> inhibitor therapy is reasonable. (Level of Evidence: C)

#### Class IIb

1. Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation. (282,283) (Level of Evidence: C)

#### **Class III: HARM**

1. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack.<sup>282</sup> (Level of Evidence: B)

#### 4.6.2. Intravenous Antiplatelet Therapy

**STEMI** 

#### Class IIa

1. In patients undergoing primary PCI treated with unfractionated heparin (UFH), it is reasonable to administer a glycoprotein (GP) IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel. <sup>292–298</sup> (For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel, Level of Evidence: A; for GP IIb/IIIa inhibitor administration in patients pretreated with clopidogrel, Level of Evidence: C)

## Class IIb

1. In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab.<sup>297,299–312</sup> (Level of Evidence: B)

American Heart

## Class III: NO BENEFIT

1. Routine precatheterization laboratory (eg, ambulance or emergency room) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial.<sup>313–320</sup> (Level of Evidence: B)

## UA/NSTEMI

#### Class I

1. In UA/NSTEMI patients with high-risk features (eg, elevated troponin level) not treated with bivalirudin and not adequately pretreated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH.<sup>321–326</sup> (Level of Evidence: A)

#### Class IIa

1. In UA/NSTEMI patients with high-risk features (eg, elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).<sup>324,327</sup> (Level of Evidence: B)

SIHD

#### Class IIa

1. In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).<sup>327-329</sup> (Level of Evidence: B)

#### Class IIb

1. In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).<sup>327,330-332</sup> (Level of Evidence: B)

### 4.6.3. Anticoagulant Therapy

4.6.3.1. Use of Parenteral Anticoagulants During PCI

#### Class

1. An anticoagulant should be administered to patients undergoing PCI. (Level of Evidence: C)

4.6.3.2. Unfractionated Heparin

#### Class

1. Administration of IV UFH is useful in patients undergoing PCI. (Level of Evidence: C)

4.6.3.3. Enoxaparin

#### Class 1

1. An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received fewer than 2 therapeutic subcutaneous doses (eg, 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI.<sup>346,350-353</sup> (Level of Evidence: B)

#### Class IIh

1. Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/NSTEMI or who have not received prior antithrombin therapy and are administered IV enoxaparin at the time of PCI.<sup>343–347</sup> (Level of Evidence: B)

### Class III: HARM

1. UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin. 46,354 (Level of Evidence: B)

4.6.3.4. Bivalirudin and Argatroban

#### Class I

- 1. For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH.<sup>333–342</sup> (Level of Evidence: B)
- 2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH. 355,356 (Level of Evidence: B)

4.6.3.5. Fondaparinux

#### **Class III: HARM**

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis, 348,349 (Level of Evidence: C)

#### 4.6.4. No-Reflow Pharmacological Therapies

#### Class IIa

1. Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI.<sup>357–372</sup> (Level of Evidence: B)

## 4.7. PCI in Specific Anatomic Situations

#### 4.7.1. Chronic Total Occlusions

## Class IIa

1. PCI of a chronic total occlusion in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise.<sup>373–377</sup> (Level of Evidence: B)

## 4.7.2. Saphenous Vein Grafts

#### Class I

1. Embolic protection devices should be used during saphenous vein graft PCI when technically feasible. <sup>271–274</sup> (*Level of Evidence: B*)

## Class III: NO BENEFIT

1. Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during saphenous vein graft PCI.<sup>232,286,378,379</sup> (Level of Evidence: B)

### Class III: HARM

1. PCI is not recommended for chronic saphenous vein graft occlusions.<sup>380–382</sup> (*Level of Evidence: C*)

## 4.7.3. Bifurcation Lesions

#### Class I

1. Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium. 383-386 (Level of Evidence: A)

#### Class IIa

 It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low.<sup>387–390</sup> (Level of Evidence: B)

#### 4.7.4. Aorto-Ostial Stenoses

#### Class IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD.<sup>391,392</sup> (Level of Evidence: B)

Table 8. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations	COR	LOE	References
Aspirin			
After PCI, use of aspirin should be continued indefinitely.	1	Α	275–278
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.	lla	В	151, 288–291
P2Y <sub>12</sub> inhibitors			
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.	1	В	282, 283, 285
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.	1	В	107, 232, 286
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).	1	В	287
Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.	1	С	107
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.	1	С	402
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.	lla	С	N/A
Use of PPIs is reasonable in patients with an increased risk of GI bleeding (eg, advanced age, concomitant use of warfarin, steroids, NSAIDs, <i>Helicobacter pylori</i> infection) who require DAPT.	lla	С	402
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.	llb	С	282, 283
Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.	III: No Benefit	С	402
Exercise testing			
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.	lla	С	N/A
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.	III: No Benefit	С	403
Cardiac rehabilitation			
Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for patients at moderate to high risk for whom supervised exercise training is warranted.	I	Α	404–412
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Rules of the Lipid management with lifestyle modification and lipid-lowering pharmacotherapy	eduction Therapy	Guidel	ine). <sup>413</sup>
Lifestyle modification		В	414, 415
Statin therapy	i	A	414, 416–419, 419a
Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	1	С	414–419, 419a
Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	lla	С	416–418, 419a, 420–422
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)			•
Lifestyle modification	1	В	423–427
Pharmacotherapy	1	Α	423, 428, 429
Diabetes management (eg, lifestyle modification and pharmacotherapy) coordinated with the patient's primary care physician and/or endocrinologist	1	С	N/A
Complete smoking cessation		Α	430–433

<sup>\*</sup>Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides  $\geq$ 200 mg/dL plus non-HDL-cholesterol  $\geq$ 130 mg/dL with low HDL-cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

ACS indicates acute coronary syndromes; BMS, bare-metal stent(s); COR, class of recommendation; DAPT, dual antiplatelet therapy; DES, drug-eluting stent(s); GI, gastrointestinal; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LOE, level of evidence; N/A, not applicable; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; and PPI, proton pump inhibitor.

2. Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis.<sup>393,394</sup> (*Level of Evidence: B*)

### 4.7.5. Calcified Lesions

#### Class IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation. 258,259,395 (Level of Evidence: C)

## 4.8. PCI in Specific Patient Populations

#### 4.8.1. Chronic Kidney Disease

#### Class I

In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted. (Level of Evidence: B)

## 4.9. Periprocedural Myocardial Infarction Assessment

#### Class I

 In patients who have signs or symptoms suggestive of myocardial infarction during or after PCI or in asymptomatic patients with significant persistent angiographic complications (eg, large side-branch occlusion, flowlimiting dissection, no-reflow phenomenon, or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured. (Level of Evidence: C)

#### Class IIb

 Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable. (Level of Evidence: C)

## 4.10. Vascular Closure Devices

#### Class I

1. Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment. (Level of Evidence: C)

#### Class IIa

1. The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression.<sup>396–399</sup> (Level of Evidence: B)

## Class III: NO BENEFIT

1. The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding.<sup>396–401</sup> (Level of Evidence: B)

## 5. Postprocedural Considerations: Recommendations

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 8. Some recommendations and text regarding DAPT in Section 5.7.2 of the full-text guideline<sup>4</sup> are intentionally repeated in this section for reader ease of use.

## 5.1. Postprocedural Antiplatelet Therapy

#### Class I

- 1. After PCI, use of aspirin should be continued indefinitely.<sup>275–278</sup> (Level of Evidence: A)
- 2. The duration of P2Y<sub>12</sub> inhibitor therapy after stent implantation should generally be as follows:
  - a. In patients receiving a stent (BMS or DES) during PCI for ACS, P2Y<sub>12</sub> inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily,<sup>285</sup> prasugrel 10 mg daily,<sup>282</sup> and ticagrelor 90 mg twice daily,<sup>283</sup> (Level of Evidence: B)
  - b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding.<sup>107,232,286</sup> (Level of Evidence: B)
  - c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).<sup>287</sup> (Level of Evidence: B)
- 3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist. (Level of Evidence: C)

#### Class IIa

- 1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses. 151,288-291 (Level of Evidence: B)
- 2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of  $P2Y_{12}$  inhibitor therapy after stent implantation, earlier discontinuation (eg, <12 months) of  $P2Y_{12}$  inhibitor therapy is reasonable. (Level of Evidence: C)

#### Class IIb

1. Continuation of clopidogrel, prasugrel or ticagrelor beyond 12 months may be considered in patients undergoing placement of DES.<sup>282,283</sup> (*Level of Evidence: C*)

#### 5.1.1. Proton Pump Inhibitors and Antiplatelet Therapy

#### Class 1

1. Proton pump inhibitors should be used in patients with a history of prior gastrointestinal bleeding who require DAPT.<sup>402</sup> (Level of Evidence: C)

## Class IIa

1. Use of proton pump inhibitors is reasonable in patients with an increased risk of gastrointestinal bleeding (eg, advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT.<sup>402</sup> (Level of Evidence: C)

## **Class III: NO BENEFIT**

1. Routine use of a proton pump inhibitor is not recommended for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy.<sup>402</sup> (Level of Evidence: C)

## 5.1.2. Clopidogrel Genetic Testing

#### Class IIb

- 1. Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel. (Level of Evidence: C)
- 2. When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate P2Y<sub>12</sub> inhibitor (eg, prasugrel or ticagrelor) might be considered.<sup>434</sup> (Level of Evidence: C)

#### Class III: NO BENEFIT

1. The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended.<sup>434</sup> (Level of Evidence: C)

## 5.1.3. Platelet Function Testing

#### Class IIb

- 1. Platelet function testing may be considered in patients at high risk for poor clinical outcomes. 434 (Level of Evidence: C)
- In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered.<sup>434</sup> (Level of Evidence: C)

#### **Class III: NO BENEFIT**

 The routine clinical use of platelet function testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended.<sup>434</sup> (Level of Evidence: C)

#### 5.2. Restenosis

#### Class I

- 1. Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT.<sup>435</sup> (Level of Evidence: B)
- 2. Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT. 436-438 (Level of Evidence: A)

### Class IIa

1. IVUS is reasonable to determine the mechanism of stent restenosis.<sup>254</sup> (Level of Evidence: C)

#### Class IIb

1. Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT.<sup>254</sup> (Level of Evidence: C)

## 5.2.1. Exercise Testing

#### Class IIa

1. In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable. (Level of Evidence: C)

#### **Class III: NO BENEFIT**

1. Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed. (Level of Evidence: C)

## 5.2.2. Cardiac Rehabilitation

#### Class I

1. Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted. 404-412 (Level of Evidence: A)

## 6. Quality and Performance Considerations: Recommendations

## 6.1. Quality and Performance

#### Class I

- 1. Every PCI program should operate a quality-improvement program that routinely 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews. (Level of Evidence: C)
- 2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms. (Level of Evidence: C)

## 6.2. Certification and Maintenance of Certification

#### Class IIa

1. It is reasonable for all physicians who perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program. (Level of Evidence: C)

## **6.3. Operator and Institutional Competency and Volume**

#### Class I

- 1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery.<sup>439,440</sup> (Level of Evidence: C)
- 2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. (Level of Evidence: C)
- 3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. 439,441-444 (Level of Evidence: C)

#### Class IIa

- 1. It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery. (439 (Level of Evidence: C)
- 2. It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures. (Level of Evidence: C)

#### Class IIb

1. The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (<11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)

#### Class III: NO BENEFIT

1. It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service.<sup>439</sup> (Level of Evidence: C)

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KEY WORDS: AHA Scientific Statements ■ acute coronary syndromes ■ anticoagulants ■ antiplatelet agents, arrhythmias, cardiac ■ coronary angiography ■ coronary artery revascularization interventions: stents ■ drug therapy ■ heart diseases ■ myocardial revascularization ■ platelet aggregation inhibitor ■ ultrasound

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusais by Section Number*
Glenn N. Levine ( <i>Chair</i> )	Baylor College of Medicine-Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates	University of Michigan-Professor	Bristol-Myers Squibb	None	None	None	None	None	5.7.2
(Vice Chair)	of Medicine	<ul> <li>Daiichi-Sankyo</li> </ul>						5.7.3
		<ul><li>Datascope</li><li>Eli Lilly</li></ul>						5.7.4.1
		<ul><li>Merck</li></ul>						5.7.4.2
		<ul> <li>Sanofi-aventis</li> </ul>						5.7.4.3
								5.7.4.4
								5.7.4.5
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								6.1.2
								6.1.3
James C.	Geisinger Medical	None	None	None	<ul> <li>Abiomed</li> </ul>	None	None	2.1
Blankenship	Center-Director of Cardiology				AstraZeneca     Denter Scientific			2.2
Vice Chair)	and Cardiac Catheterization Laboratories				<ul><li>Boston Scientific</li><li>Conor Medsystems</li></ul>			2.3
					Kai Pharmaceutical			2.9.7
					<ul> <li>Schering-Plough</li> </ul>			2.11
								5.2.4
								5.3
								5.4.1
								5.4.2
								5.8.4
								6.3
Steven R.	University of Texas Medical	<ul> <li>Volcano</li> </ul>	None	None	Boston Scientific	None	None	5.4.1
Bailey	Center-Professor of Medicine and Radiology					American H Associa		5.4.2
John A. Bittl Bojan Cercek	Munroe Heart-Interventional Cardiologist Cedars-Sinai Medical Center-	None	None	None	None		None None	None None
Charles E.	Director, Coronary Care Unit Penn State Milton S. Hershey	None	None	None None	None	None None	None	None
Chambers	Medical Center-Professor of Medicine and Radiology	None	None	None	Notic	None	None	None
Stephen G.	Cleveland Clinic	Abbott Vascular	None	None	<ul> <li>Abbott Vascular</li> </ul>	None	None	2.2
Ellis	Foundation—Section Head, Invasive and Interventional	<ul><li>Boston Scientific</li><li>Cordis</li></ul>						2.11
	Cardiology	<ul> <li>Daiichi-Sankyo</li> </ul>						5.7.2
		• Eli Lilly						6.1
Robert A.	Emory Clinic, Inc.—Professor	None	None	None	<ul> <li>Edwards Lifesciences</li> </ul>	None	None	2.1
Guyton	and Chief, Division of Cardiothoracic Surgery							2.2
	· ,							2.3
								2.9.7
								2.11
								5.2.4
								5.3
								5.5.5
								6.2
Steven M.	Cooper University Hospital—	• Eisai	None	None	None	None	None	6.3 5.7.4.3
Hollenberg	Director, Coronary Care Unit							4.5
Umesh N. Khot	CV Research Innovations, LLC—President/CEO	None	None	<ul><li>Merck†</li></ul>	None	None	None	4.6 5.7.3
Richard A. Lange	University of Texas Health Science Center at San Antonio—Professor of Medicine	None	None	None	None	None	None	None

## Appendix 1. Continued

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusais by Section Number*
Laura Mauri	Brigham and Women's Hospital—Associate Professor of Medicine, Harvard Medical School	Abbott     Conor Medsystems (Johnson & Johnson)     Cordis     Medtronic	None	None	• Lutonix	Abbott Abbott Abiomed Boston Scientific Bristol-Myers Squibb Conor Medsystems Cordis Daiichi-Sankyo Eli Lilly Medtronic Cardiovascular Sanofi-aventis	Defendant, Conor, interpretation of clinical trial results, 2010	2.9.7 5.2.3 5.3 5.4.2 5.5.1 5.5.2 5.5.4 5.5.5 5.6 5.7.2 5.7.3 5.8.2 5.8.4 5.8.5 5.11 6.1 6.1.2 6.1.3 6.2
Roxana Mehran	Columbia University Medical Center—Associate Professor of Medicine; Director, Data Coordinating Analysis Center	Abbott Vascular     Abiomed     AlphaMedical     AstraZeneca     Bracco     BMS/sanofiaventis     DataScope     Eli Lilly/Daichii-Sankyo     Guerbet     The Medicines Company     Medtronic Vascular     St. Jude	None	None		None  American He  Associal	tion=	4.7 5.1 5.2.4 5.3 5.4.1 5.4.2 5.5.1 5.5.2 5.6 5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4
	JOURS						108	5.7.4.5 5.8.3 5.8.4 5.11 6.1 6.1.1 6.1.2 6.1.3
Issam D. Moussa	Mayo Clinic—Professor of Medicine; Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
								(Continued)

## Appendix 1. Continued

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, o Other Financial Benefit		Voting Recusais by Section Number*
Brahmajee K. Nallamothu	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	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 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  $\geq$ \$10 000 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 ACCF/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 committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply. Section numbers apply to the full-text guideline.

†Significant relationship.



Appendix 2. Reviewer Relationships With Industry and Other Entities (Relevant)—2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Paar Rovious	Panracantation	Conquite=+	Snagkar'a Duran	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial	Eyport Wiltness
eer Reviewer	Representation	Consultant	Speaker's Bureau			Benefit	Expert Witness
eepak L. hatt	Official Reviewer—AHA	None	None	None	AstraZeneca* Bristol-Myers Squibb* Eisai* Eli Lilly Ethicon* The Medicines Company* PLx Pharma† Sanofi-aventis*	None	None
Mauricio G. Cohen	Official Reviewer—AHA	<ul><li>AstraZeneca*</li><li>Momenta Pharma</li><li>Xoma</li></ul>	Terumo Medical	None	• Invitrox*	None	None
lohn P. Erwin II	Official Reviewer—ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kirk Garratt	Official Reviewer—SCAI	Boston Scientific     Cordis/Johnson &     Johnson     The Medicines     Company	Boston Scientific     BMS/sanofiaventis*     Daiichi-Sankyo/Eli     Lilly*     Medtronic     The Medicines Company	<ul><li>Abbott Vascular</li><li>Boston Scientific</li></ul>	None	None	None
Steven L. Goldberg	Official Reviewer—SCAI	• AGA	<ul><li>Bristol-Myers Squibb</li><li>Sanofi-aventis</li></ul>	None	None	None	<ul> <li>Plaintiff, patier litigation, 2010</li> </ul>
Alice K. Jacobs	Official Reviewer—ACCF/AHA Task Force on Practice Guldelines	None	None	• Wyeth*	Abbott Vascular* Abiomed* Accumetrics* Cardiovascular Research Foundation (DSMB)† Harvard Clinical Research Institute† TIMI Study Group (DSMB)†		None
i.B. John Mancini	Official Reviewer—ACCF Board of Governors	<ul><li>GlaxoSmithKline</li><li>Merck</li><li>Pfizer</li><li>Sanofi-aventis</li></ul>	None	None	Merck*		None
V. Douglas	Official Reviewer—ACCF	None	None	None	Boehringher Ingelheim     DOMB)	None	None
Weaver	Board of Trustees	1r(	CU.	la	(DSMB)  Boston Scientific (DSMB)  Duke Clinical Research Institute (Johnson & Johnson/Schering Plough)*  GlaxoSmithKline  NHLBI (DSMB)  TIMI Study Group (Johnson &	<u>n</u>	
Thomas M. Bashore	Content Reviewer	None	None	None	Johnson/Bayer-DSMB) None	None	None
Christopher E. Buller	Content Reviewer	<ul><li>Abbott Vascular</li><li>Toshiba Medical</li></ul>	None	None	<ul><li>Novartis</li><li>Regado Biosciences</li></ul>	None	None
ames A. Jurke	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
lohn G. Byrne	Content Reviewer—ACCF Surgeons' Scientific Council	Edwards Lifesciences	None	None	None	None	None
. Bruce Ferguson	Content Reviewer—ACCF Surgeons' Scientific Council	None	None	None	<ul> <li>Novadaq Technologies*</li> </ul>	None	None
/ictor A. Ferrari	Content Reviewer	None	None	None	<ul><li>NHLBI (DSMB)†</li><li>National Institute for Aging/NIH (DSMB)†</li></ul>	None	None

### Appendix 2. Continued

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
John G. Harold	Content Reviewer	None	None	None	None	None	None
Biswajit Kar	Content Reviewer	None	None	None	<ul><li>AstraZeneca†</li><li>Boston Scientific†</li><li>Medtronic†</li></ul>	<ul> <li>Veterans Affairs Cooperative Study†</li> </ul>	None
Morton J. Kern	Content Reviewer	<ul><li>Infraredex</li><li>Merit Medical*</li></ul>	<ul><li>St. Jude Medical*</li><li>Volcano Therapeutics*</li></ul>	None	None	None	None
Spencer B. King III	Content Reviewer	• Celonova Biosciences†	None	None	<ul><li>Merck (DSMB)</li><li>Wyeth (DSMB)</li></ul>	None	None
Frederick G. Kushner	Content Reviewer	None	None	None	<ul><li>Novartis†</li></ul>	None	None
David J. Maron	Content Reviewer	None	None	<ul> <li>Cardiovascular</li> <li>Care Affiliates*</li> </ul>	None	None	<ul> <li>Plaintiff, acute coronary syndrome, 2010</li> </ul>
Douglass A. Morrison	Content Reviewer	None	None	None	None	None	None
Thomas C. Piemonte	Content Reviewer—ACCF Board of Governors	None	None	None	None	None	<ul> <li>Defendant, stent perforation, 2010</li> </ul>
Peter K. Smith	Content Reviewer	• Eli Lilly	None	None	None	None	None
Sidney C. Smith	Content Reviewer	None	None	None	None	None	None
Richard W. Snyder	Content Reviewer—ACCF Board of Governors	None	None	None	None	<ul> <li>Hospital Corporation of America</li> </ul>	None
Patrick L. Whitlow	Content Reviewer	<ul><li>Edwards Lifesciences*</li><li>eValve*</li><li>Medtronic*</li></ul>	None	None	None	• ICON	None
David 0. Williams	Content Reviewer	<ul> <li>Light Lab/St. Jude Medical</li> </ul>	None	None	None	None	None
R. Scott Wright	Content Reviewer	<ul> <li>Hoffman LaRoche*</li> </ul>	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. 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  $\geq$ \$10 000 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.

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\*Significant relationship.

†No financial benefit.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; DSMB, data safety and monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

# 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention—ONLINE AUTHOR LISTING OF COMPREHENSIVE RELATIONSHIPS WITH INDUSTRY AND OTHERS (October 2011)

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	<b>Expert Witness</b>
Glenn N. Levine (Chair)	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None
Eric R. Bates (Vice Chair)  Top  http://circ.ahaic	University of Michigan—Professor of Medicine	<ul> <li>Bristol-Myers Squibb</li> <li>Daiichi Sankyo</li> <li>Datascope</li> <li>Eli Lilly</li> <li>Merck</li> <li>sanofi-aventis</li> <li>Takeda</li> </ul>	None	None	None	None	None
James C. Blankenship (Vice Chair)	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratory	None	None	None	<ul> <li>Abiomed</li> <li>AstraZeneca</li> <li>Boston Scientific</li> <li>Conor Medsystems</li> <li>Kai Pharmaceutical</li> <li>Novartis</li> <li>Schering-Plough</li> </ul>	None	None
Steven R. Bailey	University of Texas Medical Center— Professor of Medicine and Radiology	• Volcano	None	None	Boston Scientific	None	None
John A. Bittl	Munroe Heart— Interventional Cardiologist	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center—Director, Coronary Care Unit	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical	None	None	None	None	None	None

	Center—Professor of Medicine and Radiology						
Stephen G. Ellis	Cleveland Clinic Foundation—Director, Sones Cardiac Catheterization Laboratory	<ul> <li>Abbott Vascular</li> <li>AcelleRX         <ul> <li>Therapeutics</li> </ul> </li> <li>Boston Scientific</li> <li>CardioDX</li> <li>Celera Diagnostic</li> <li>Cordis</li> <li>Viacor</li> </ul>	None	None	None	None	None
Robert A. Guyton	Emory Clinic, Inc— Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None
Steven M. Hollenberg	Cooper University Hospital—Director, Coronary Care Unit	• Eisai	None	None	None	None	None
Umesh N. Khot	CV Research Innovations, LLC— President/CEO	None	None	• Merck*	• St. Francis Hospital and Health Centers*	None	None
Laura Mauri	Brigham & Women's Hospital—Assistant Professor of Medicine, Harvard Medical School	• Conor Medsystems (Johnson & Johnson) • Cordis	None	None	• Lutonix	<ul> <li>Abbott</li> <li>Abiomed</li> <li>Boston Scientific</li> <li>Bristol-Myers Squibb</li> <li>Conor Medsystems</li> <li>Cordis</li> <li>Daiichi Sankyo</li> <li>Eli Lilly</li> <li>Medtronic Cardiovascular</li> <li>sanofi-aventis</li> </ul>	Defendant, Interpretation of clinical trial results, 2010
Roxana Mehran	Columbia University Medical Center— Associate Professor of Medicine; Director, Data Coordinating Analysis	<ul><li>Abbott Vascular</li><li>Abiomed</li><li>Accumetrics</li><li>AlphaMedical</li><li>AstraZeneca</li></ul>	None	None	None	• Endothelix	None

Downloaded f	Center	Bracco DataScope Eli Lilly/Daichii Sankyo Gilead Guerbet The Medicines Company Medtronic Vascular Regado Biosciences sanofi-aventis/BMS St. Jude Medical Therox					
Issam D. Moussa	Weill Medical College of Cornell University— Associate Professor of Medicine	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University— Chief, Cardiovascular Medicine	None	None	None	None	None	None
Brahmajee K.	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. 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  $\geq$ \$10,000 of the fair market yalue 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 financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to <a href="http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx">http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx</a> for definitions of disclosure categories or additional information about the ACCF/AHA Disclosure Policy for Writing Committees.

<sup>\*</sup>Indicates significant relationship