ACC/AHA/SCAI Practice Guideline

ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention—Summary Article

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)

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he American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) 2005 Guideline Update for Percutaneous Coronary Intervention (PCI) contains changes in the recommendations, along with supporting text. For

the purpose of comparison, this summary contains a list of the updated recommendations (middle column) alongside a list of the 2001 recommendations (left column), with each set accompanied by a comment (right column) that provides the rationale for the changes, additions, or deletions (see Table 1). References

Acknowledgment: The ACC and AHA recognize Dr J. Ward Kennedy for his dedicated service on developing ACC/AHA guidelines for PTCA and PCI since their inception in 1986 and for his counsel and advice in the preparation of this guideline.

This document was approved by the American College of Cardiology Foundation Board of Trustees in September 2005, by the American Heart Association Science Advisory and Coordinating Committee in September 2005, and by the Society for Cardiovascular Angiography and Interventions in September 2005.

The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated as changes occur. The relationship with industry information for writing committee members, as well as peer reviewers of the document, is located in an appendix of the full-text guideline, which is available on the ACC, AHA, and SCAI Web sites.

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Copies: This document is available on the World Wide Web sites of the American College of Cardiology (www.acc.org), the American Heart Association (www.americanheart.org), and the Society for Cardiovascular Angiography and Interventions (www.scai.org). Single copies of this document are available by calling I-800-253-4636 or writing the American College of Cardiology Foundation, Resource Center, at 9111 Old Georgetown Road, Bethesda, MD 20814-1699. Ask for reprint number 71-0346. To obtain a copy of the full text published in the January 3, 2006, issue of the *Journal of the American College of Cardiology*, the January 3, 2006, issue of *Circulation*, and the January 2006, issue of *Catheterization and Cardiovascular Interventions*, ask for reprint number 71-0347. To purchase bulk reprints (specify version and reprint number): Up to 999 copies, call 1-800-611-6083 US only) or fax 413-665-2671; 1000 or more copies, call 214-706-1789, fax 214-691-6342, or e-mail pubauth@heart.org.

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lished guidelines, primarily the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and the ACC/AHA 2002 Guidelander is referred de Web sites of Non–ST-Elevation Myocardial Infarction.

The classification of recommendations and levels of evidence are expressed in the ACC/AHA format as follows:

Classification of Recommendations

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

Level of Evidence

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.

Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

that support either the 2001 recommendations that have changed or the new or revised recommendations are cited in parentheses at the end of each recommendation or comment. A list of abbreviations is included in the Appendix. The reader is referred to the full-text guideline posted on the World Wide Web sites of the ACC, the AHA, and the SCAI for a more detailed explanation of the changes discussed here. Please note that we have changed the table of contents headings in the 2001 ACC/AHA Guidelines for Percutaneous Coronary Intervention from roman numerals to unique identifying numbers.

In preparing this update, the committee was guided by the following principles:

- Changes in recommendations and levels of evidence were made because of the availability of data from new randomized trials, the accumulation of new clinical evidence, and/or the development of clinical consensus.
- The committee is cognizant of the healthcare, logistic, and financial implications of recent trials and factored in these considerations in arriving at the class level of certain recommendations.
- 3. All recommendations in the PCI guideline update have been written in full sentences that express a complete thought, such that a recommendation, even if separated and presented apart from the rest of the document, will still convey the full intent of the recommendation.
- 4. The committee wishes to re-emphasize that the recommendations in the guideline apply to most patients but may require modification by existing situations that only the primary treating healthcare provider can evaluate properly.
- 5. The committee endeavored to maintain the consistency of recommendations in this and other previously pub-

218 Smith et al. ACC/AHA/SCA	2005 Guideline Update for PCI	JACC Vol. 47, No. 1, 2006 January 3, 2006:216–35		
2001 Recommendation	2005 New or Revised Recommendation	Comments		
3. Outcomes 3.2 Acute Outcome: Proced	ural Complications			
Class I	Class I			
None	All patients who have signs or symptoms suggestive of MI during or after PCI and those with complicated procedures should have CK-MB and troponin I or T measured after the procedure. (Level of Evidence: B)	This recommendation appeared in the text of the 2001 revision for CK-MB only. Troponin I or T measurement has been added, and it is now listed as a class I, level of evidence B recommendation (1–10).		
Class IIa	Class IIa			
None	Routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in all patients undergoing PCI is reasonable 8 to 12 hours after the procedure. (Level of Evidence: C)	Routine measurement of CK-MB or troponin I or T is added as a new class IIa, level of evidence C recommendation. The committee did not think that evidence regarding the clinical utility of routine measurement of biomarkers in all patients was strong enough to warrant a class I recommendation.		
4. Institutional and Operate 4.1 Quality Assurance Class I	or Competency Class I			
None	1. An institution that performs PCI should establish an ongoing mechanism for valid peer review of its quality and outcomes. Review should be conducted both at the level of the entire program and at the level of the individual practitioner. Quality-assessment reviews should take risk adjustment, statistical power, and national benchmark statistics into consideration. Quality-assessment reviews should include both tabulation of adverse event rates for comparison with benchmark values and case review of complicated procedures and some uncomplicated procedures. (Level of Evidence: C)	Quality assurance is an important responsibility for all institutions in which PCI is performed. Institutions must monitor the PCI program with respect to process, appropriateness, and outcomes and correct any circumstances in which quality falls below accepted norms. The quality assessment should be conducted at the level of both the entire program and the individual practitioner.		
	2. An institution that performs PCI should participate in a recognized PCI data registry for the purpose of benchmarking its outcomes against current national norms. (Level of Evidence: C)	Participation in a recognized PCI registry for benchmarking outcomes against current national norms is an important part of the quality-improvement process. The ACC-National Cardiovascular Data		

4.2 Operator and Institutional Volume

Class I

Class IIa

PCI done by operators with acceptable volume (greater than or equal to 75) at high-volume centers (greater than 400). (Level of Evidence: B)

- 1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with on-site cardiac surgery. (Level of Evidence: B)
- 2. Elective PCI should be performed by operators and institutions whose historical and 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. (Level of Evidence: B)

1. PCI done by operators with acceptable volume (75 or more) at low-volume centers (200-400). (Level of Evidence: C)

1. It is reasonable that operators with acceptable volume (at least 75 PCI procedures per year) perform PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery. (Level of Evidence: B)

Registry® or other databases may serve as a valuable resource in this regard.

Wording has been added to clarify this statement and emphasize that it relates to elective PCI performed at centers with on-site cardiac surgery.

This recommendation was added to emphasize that historical and current risk-adjusted outcomes for operators and institutions are an essential part of the quality-improvement process.

This recommendation is expanded based on data from the New York State registry indicating that physicians performing more than 10 primary PCI procedures per year have lower mortality rates (11-13).

Wording has been changed to comply with current recommended phrasing for class Ila recommendation. The fact that this recommendation applies to centers with on-site cardiac surgery is emphasized. Level of evidence has been changed to B based on accumulated published evidence (14).

2001 Recommendation

2005 New or Revised Recommendation

Comments

2. PCI done by low-volume operators (fewer than 75) at high-volume centers (more than 400). Note: Ideally operators with an annual procedure volume less than 75 should only work at institutions with an activity level of more than 600 procedures/year.* (Level of Evidence: C)

*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 per year.

2. It is reasonable that low-volume operators (fewer than 75 PCI procedures per year) perform PCI at high-volume centers (more than 400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume less than 75 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 per year. (Level of Evidence: B)

Wording has been changed to comply with current recommended phasing. Level of evidence has been changed to B based on accumulated published evidence (15).

Class IIb

None

Class III

PCI done by low-volume operators (fewer than 75) at low-volume centers (200-400). Note: An institution with a volume of fewer than 200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer service.* (Level of Evidence: C)

*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 per year.

Class IIb

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

It is not recommended that elective PCI be performed by low-volume operators (fewer than 75 procedures per year) at low-volume centers (200 to 400) 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. (Level of Evidence: B)

This recommendation has been added to address the issue of low-volume operators performing primary PCI. It reflects the relative lack of evidence supporting a benefit of primary PCI for low-volume operators.

Wording has been changed to reflect current preferred phrasing. Level of evidence changed to B on the basis of published data indicating poorer outcomes at low-volume centers (15).

4.3. Role of On-Site Cardiac Surgical Back-up

Class I

Class III

facilities with on-site cardiac surgery. (Level of Evidence: B)

(Level of Evidence: B)

Class I

1. Patients undergoing elective PCI in 1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available on-site emergency cardiac surgical services. (Level of Evidence: B)

2. Patients undergoing primary PCI in 2. Primary PCI for patients with STEMI should be performed in facilities with on-site cardiac surgery. (Level of Evidence: B)

Phrasing has been changed to reflect current

Class III

Patients undergoing elective PCI in facilities without on-site cardiac surgery. (Level of Evidence: C)

Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery.* (Level of Evidence: C) *Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (18-28). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg et al. found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (29). These recommendations may be subject to revision as clinical data and experience increase.

terminology and volume criteria; otherwise, no significant changes.

Phrasing has been changed to reflect current terminology and to be consistent with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.

Phrasing has been changed to reflect current terminology. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

2001 Recommendation 2005 New or Revised Recommendation Comments

Section 4.4 Primary PCI for STEMI Without On-Site Cardiac Surgery

Class IIb

Patients undergoing primary PCI in facilities without on-site cardiac surgery, but with a proven plan for rapid access (within 1 h) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with ST-segment elevation MI or new LBBB on ECG, and done in a timely fashion (balloon inflation within 90 plus or minus 30 min of admission) by persons skilled in the procedure (at least 75 PCIs/year) and only at facilities performing a minimum of 36 primary PCI procedures per year. (Level of Evidence: B)

Class III

Patients undergoing primary PCI in facilities without on-site cardiac surgery and without a proven plan for rapid access (within 1 h) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer or when performed by lower-skilled operators (fewer than 75 PCIs per year) in a facility performing fewer than 36 primary PCI procedures per year. (Level of Evidence: C)

Class IIb

Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished, including appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI), an experienced catheterization team on a 24 hours per day, 7 days per week call schedule, and a well-equipped catheterization laboratory with digital imaging equipment, a full array of interventional equipment, and intra-aortic balloon pump capability, and provided that there is a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with STEMI or MI with new or presumably new LBBB on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 primary PCI procedures per year. (Level of Evidence: B)

Class III

Primary PCI should not be performed in hospitals without on-site cardiac surgery and 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)

Phrasing has been changed to reflect current terminology. Recommendations have been added that 1) physicians perform at least 11 primary PCIs per year for STEMI, 2) a 24 hours per day, 7 days per week call schedule be maintained, and 3) the catheterization laboratory be well equipped with digital imaging equipment, a full array of interventional equipment, and intra-aortic balloon pump capability. The intent is to ensure optimal experience availability and capability to perform primary PCI in patients with STEMI (16,17).

Phrasing has been changed to reflect current terminology and to place emphasis on need for inter-institutional planning and support.

4.5 Elective PCI Without On-Site Surgery

Class III

Patients undergoing elective PCI in facilities without on-site cardiac surgery. (Level of Evidence: C)

Class III

Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery. (Level of Evidence: C) *Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (18–28). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg et al. found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (29). These recommendations may be subject to revision as clinical data and experience increase.

Repeated from previous section for consistency. Phrasing has been changed to reflect current terminology.

5.1. Patients With Asymptomatic Ischemia or Canadian Cardiovascular Society (CCS) Class I or II Angina

Class I

Patients who do not have treated diabetes with asymptomatic ischemia or mild angina with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a large area of viable myocardium. (Level of Evidence: B)

Class IIa

1. The same clinical and anatomic requirements for Class I, except the myocardial area at risk is of moderate size or the patient has treated diabetes. (Level of Evidence: B)

Class IIa

1. PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina and with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a moderate to large area of viable myocardium or be associated with a moderate to severe degree of ischemia on noninvasive testing. (Level of Evidence: B)

Phrasing has been changed to reflect current terminology. This recommendation and all of those that follow in Section 5 have been reworded to be consistent with the CCS classification system of angina. This recommendation has been changed to class lla to reflect the published data and Writing Committee consensus that not all patients in this clinical category must have PCI performed (30,31).

This recommendation has been merged with other class lla recommendations of this section, and the phrasing has been changed to reflect current terminology.

2001 Recommendation

2005 New or Revised Recommendation

Comments

- 2. PCl is reasonable for patients with asymptomatic ischemia or CCS class I or II angina, and recurrent stenosis after PCI with a large area of viable myocardium or high-risk criteria on noninvasive testing. (Level of Evidence: C)
- 3. Use of PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. (Level of Evidence: B)

This is a new recommendation dealing with the management of recurrent stenosis after PCI among patients with asymptomatic ischemia or class I or II

This recommendation for PCI among patients who are eligible for CABG who have significant left main disease has been added to reflect the favorable results noted by several trials with PCI (32-35).

This recommendation has been eliminated and replaced by the following 2 recommendations. For each, the phrasing has been constructed to reflect current terminology.

Class IIb

Patients with asymptomatic ischemia or mild angina with greater than or equal to 3 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend at least a moderate area of viable myocardium. In the physician's judgment, there should be evidence of myocardial ischemia by ECG exercise testing, stress nuclear imaging, stress echocardiography or ambulatory ECG monitoring or intracoronary physiologic measurements. (Level of Evidence: B)

Class IIb

Class III

- 1. The effectiveness of PCI for patients with asymptomatic ischemia or CCS class I or II angina who have 2- or 3-vessel disease with significant proximal LAD CAD who are otherwise eligible for CABG with 1 arterial conduit and who have treated diabetes or abnormal LV function is not well established. (Level of Evidence: B)
- 2. PCI might be considered for patients with asymptomatic ischemia or CCS class I or II angina with nonproximal LAD CAD that subtends a moderate area of viable myocardium and demonstrates ischemia on noninvasive testing. (Level of Evidence: C)

Phrasing has been changed to reflect current terminology. Among patients who are eligible, CABG with 1 arterial conduit is generally preferred for treatment of multivessel disease with significant proximal LAD obstruction in patients with treated diabetes and/or abnormal LV function (36).

Phrasing has been changed to reflect current terminology. PCI might be considered in this clinical settina.

Class III

Patients with asymptomatic ischemia or mild angina who do not meet the criteria as listed under Class I or Class Il and who have:

- a. Only a small area of viable myocardium at risk
- b. No objective evidence of ischemia
- c. Lesions that have a low likelihood of successful dilatation
- d. Mild symptoms that are unlikely
- to be due to myocardial ischemia
- e. Factors associated with increased risk of morbidity or mortality
- f. Left main disease
- g. Insignificant disease less than 50% (Level of Evidence: C)

PCI is not recommended in patients with asymptomatic ischemia or CCS class I or II angina who do not meet the criteria as listed under the class II recommendations or who have 1 or more of the following:

- a. Only a small area of viable myocardium at risk (Level of Evidence: C)
- b. No objective evidence of ischemia (Level of Evidence: C)
- c. Lesions that have a low likelihood of successful dilatation (Level of Evidence: C)
- d. Mild symptoms that are unlikely to be due to myocardial ischemia (Level of Evidence: C)
- e. Factors associated with increased risk of morbidity or mortality (Level of Evidence: C)
- f. Left main disease and eligibility for CABG (Level of Evidence: C)
- g. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C)

Phrasing has been changed to reflect current terminology. Recommendation has been reworded to be consistent with CCS classification system for angina. Level of evidence has been added for each subgroup.

5.2 Patients With CCS Class III Angina

Class I

Patients with 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality. The vessel(s) to be dilated must subtend a moderate or large area of viable myocardium and have high risk. (Level of Evidence: B)

Class IIa

1. It is reasonable that PCI be performed in patients with CCS class III angina and single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality. (Level of Evidence: B)

Phrasing has been changed to reflect current terminology. Recommendation has been reworded to be consistent with CCS classification system for angina. The recommendation class has been changed to lla to reflect published data and Writing Committee consensus. Criteria regarding viable and high-risk myocardium have been deleted from this recommendation (30, 31).

222

2001 Recommendation 2005 New or Revised Recommendation Comments Class IIa Patients with focal saphenous vein 2. It is reasonable that PCI be performed in patients with CCS Phrasing has been changed to reflect current graft lesions or multiple stenoses class III angina with single-vessel or multivessel CAD who are terminology. who are poor candidates for undergoing medical therapy with focal saphenous vein graft reoperative surgery. (Level of lesions or multiple stenoses who are poor candidates for Evidence: C) reoperative surgery. (Level of Evidence: C) 3. Use of PCI is reasonable in patients with CCS class III This recommendation for PCI among patients with angina with significant left main CAD (greater than 50% significant left main disease who are not eligible for diameter stenosis) who are candidates for revascularization but CABG has been added to reflect the favorable results are not eligible for CABG. (Level of Evidence: B) noted by several trials with PCI (32-35). Class IIb Class IIb Patient has 1 or more lesions to be 1. PCI may be considered in patients with CCS class III angina Phrasing has been changed to reflect current dilated with reduced likelihood of with single-vessel or multivessel CAD who are undergoing terminology. The 2001 recommendation has been split success or the vessel(s) subtend a medical therapy and who have 1 or more lesions to be dilated into 2 separate recommendations. less than moderate area of viable with a reduced likelihood of success. (Level of Evidence: B) myocardium. Patients with 2- or 2. PCI may be considered in patients with CCS class III angina Phrasing has been changed to reflect current 3-vessel disease, with significant and no evidence of ischemia on noninvasive testing or who terminology. The use of noninvasive testing to evaluate proximal LAD CAD and treated are undergoing medical therapy and have 2- or 3-vessel CAD for evidence of ischemia has been added. diabetes or abnormal LV function. with significant proximal LAD CAD and treated diabetes or (Level of Evidence: B) abnormal LV function. (Level of Evidence: B) Class III Class III Patient has no evidence of PCI is not recommended for patients with CCS class III angina Phrasing has been changed to reflect current myocardial injury or ischemia on with single-vessel or multivessel CAD, no evidence of terminology. Class III recommendations #2 and #3 from the 2001 guidelines have been merged into this objective testing and has not had a myocardial injury or ischemia on objective testing, and no trial trial of medical therapy, or has of medical therapy, or who have 1 of the following: recommendation. a. Only a small area of a. Only a small area of myocardium at risk (Level of myocardium at risk b. All lesions or the culprit lesion b. All lesions or the culprit lesion to be dilated with to be dilated with morphology with morphology that conveys a low likelihood of success (Level a low likelihood of success of Evidence: C) c. A high risk of procedure-related c. A high risk of procedure-related morbidity or mortality morbidity or mortality. (Level of (Level of Evidence: C) Evidence: C) d. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C) e. Significant left main CAD and candidacy for CABG (Level of Evidence: C) 2. Patients with insignificant See above. coronary stenosis (e.g., less than

5.3 Unstable Angina/Non-ST-Elevation Myocardial Infarction (UA/NSTEMI)

50% diameter). (Level of Evidence:

3. Patients with significant left main

CAD who are candidates for CABG.

(Level of Evidence: B)

(Note: Some of these recommendations have been repeated from above because the sections for the 2005 guideline were revised slightly.)

Class

An early invasive PCI strategy is indicated for patients with UA/NSTEMI who have no serious comorbidity and who have coronary lesions amenable to PCI. Patients must have any of the following high-risk features:

- a. Recurrent ischemia despite intensive anti-ischemic therapy (Level of Evidence: A)
- b. Elevated troponin level (Level of Evidence: A)
- c. New ST-segment depression (Level of Evidence: A)
- d. CHF symptoms or new or worsening MR (Level of Evidence: A)
- e. Depressed LV systolic function (Level of Evidence: A)
- f. Hemodynamic instability (Level of Evidence: A)
- g. Sustained ventricular tachycardia (Level of Evidence: A)
- h. PCI within 6 months (Level of Evidence: A)
- i. Prior CABG (Level of Evidence: A)

Added to maintain consistency with the ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non–ST-Segment Myocardial Infarction (37).

See above.

2001 Recommendation	2005 New or Revised Recommendation	Comments		
Class IIa	Class IIa			
1. Patients with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. (Level of Evidence: C)	1. It is reasonable that PCI be performed in patients with UA/NSTEMI and single-vessel or multivessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.		
	2. In the absence of high-risk features associated with UA/NSTEMI, it is reasonable to perform PCI in patients with amenable lesions and no contraindication for PCI with either an early invasive or early conservative strategy. See full-text guidelines. (Level of Evidence: B)	Added in accordance with growing evidence regarding PCI for patients with UA/NSTEMI (30, 37–39).		
	3. Use of PCI is reasonable in patients with UA/NSTEMI with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. (Level of Evidence: B)	Added in accordance with growing evidence regarding PCI for patients with UA/NSTEMI (32–35, 40–43).		
	Class IIb			
	1. In the absence of high-risk features associated with UA/NSTEMI, PCI may be considered in patients with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with reduced likelihood of success. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology. Original recommendation replaced by 2 separate recommendations as noted here and in the following recommendations.		
	2. PCI may be considered in patients with UA/NSTEMI who are undergoing medical therapy who have 2- or 3-vessel disease, significant proximal LAD CAD, and treated diabetes or abnormal LV function. (Level of Evidence: B)	See above.		
2. All patients after a non-Q-wave Ml. (Level of Evidence: C)		This recommendation was removed because it is now covered by the revised recommendations from the ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non–ST-Segment Myocardial Infarction.		
Class III	Class III			
Patient has no evidence of myocardial injury or ischemia on objective testing and has not had a trial of medical therapy, or has a. Only a small area of myocardium at risk b. All lesions or the culprit lesion to be dilated with morphology with a low likelihood of success c. A high risk of procedure-related morbidity or mortality. (Level of Evidence: C)	1. In the absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for patients with UA/NSTEMI with single-vessel or multivessel CAD and no trial of medical therapy, or who have 1 or more of the following a. Only a small area of myocardium at risk (Level of Evidence: C) b. All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success (Level of Evidence: C) c. A high risk of procedure-related morbidity or mortality (Level of Evidence: C) d. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C) e. Significant left main CAD and candidacy for CABG (Level of Evidence: B)	Phrasing has been changed to reflect current terminology and level of evidence for each subgroup. Class III recommendations #2 and #3 from the 2001 guidelines have been merged into this recommendation.		
2. Patients with insignificant coronary stenosis (e.g., less than 50% diameter). (Level of Evidence: C)		See above.		
3. Patients with significant left main CAD who are candidates for CABG.		See above.		

(Level of Evidence: B) 5.4. Patients With STEMI

The phrasing has been changed to reflect current terminology as needed for all recommendations in this section and to be consistent with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.

2001 Recommendation 2005 New or Revised Recommendation Comments

5.4.1. General and Specific Considerations

Class I

1. As an alternative to thrombolytic therapy in patients with AMI and ST-segment elevation or new or presumed new left bundle-branch block who can undergo angioplasty of the infarct artery less than or equal to 12 h from the onset of ischemic symptoms or more than 12 h if symptoms persist, if performed in a timely fashion* by individuals skilled in the procedure† and supported by experienced personnel in an appropriate laboratory environment.‡ (Level of Evidence: A) *Performance standard: balloon inflation within 90 plus or minus 30 min of hospital admission. tIndividuals who perform 75 or more PCI procedures per year. ‡Centers that perform more than 200 PCI procedures per year and have cardiac surgical capability.

2. In patients who are within 36 h of an acute ST elevation/Q-wave or new left bundle-branch block MI who develop cardiogenic shock, are less than 75 years of age, and revascularization can be performed within 18 h of the onset of shock by individuals skilled in the procedure† and supported by experienced personnel in an appropriate laboratory environment.‡ (Level of Evidence: A) †Individuals who perform 75 or more PCI procedures per year. ‡Centers that perform more than 200 PCI procedures per year and have cardiac surgical capability (193, 194).

Class I

General considerations:

1. If immediately available, primary PCI should be performed in patients with STEMI (including true posterior MI) or MI with new or presumably new LBBB who can undergo PCI of the infarct artery within 12 hours of symptom onset, if performed in a timely fashion (balloon inflation goal within 90 minutes of presentation) by persons skilled in the procedure (individuals who perform more than 75 PCI procedures per year, ideally at least 11 PCIs per year for STEMI). The procedure should be supported by experienced personnel in an appropriate laboratory environment (one that performs more than 200 PCI procedures per year, of which at least 36 are primary PCI for STEMI, and that has cardiac surgery capability). (Level of Evidence: A) Primary PCI should be performed as quickly as possible, with a goal of a medical contact—to-balloon or door-to-balloon time within 90 minutes. (Level of Evidence: B)

Phrasing has been changed to reflect current terminology to be consistent with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction. This revised recommendation reflects the evidence from several trials and a meta-analysis of 23 trials comparing PCI with fibrinolysis that confirm the advantage of PCI. The conditions under which PCI must be performed to optimize this advantage are included in the recommendation (11–13,44–47).

Specific considerations:

2. Primary PCI should be performed for patients less than 75 years old with ST elevation or presumably new LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: A)

Phrasing has been changed to reflect current terminology. The changes from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction have been included in this recommendation (48–53).

3. Primary PCI should be performed in patients with severe HF and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours. The medical contact—to-balloon or door-to-balloon time should be as short as possible (i.e., goal within 90 minutes). (Level of Evidence: B)

Class IIa

- 1. Primary PCI is reasonable for selected patients 75 years or older with ST elevation or LBBB or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B)
- 2. It is reasonable to perform primary PCI for patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:
 - a. Severe HF (Level of Evidence: C)
 - b. Hemodynamic or electrical instability (Level of Evidence: C)
 - c. Evidence of persistent ischemia (Level of Evidence: C)

The changes from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction are included in this new recommendation, which emphasizes the benefits of PCI for patients with severe CHF and onset of symptoms within 12 hours (54–56).

This recommendation, which addresses the benefit of PCI in patients at least 75 years of age with shock, is included from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction with phrasing to reflect current terminology (48–53).

This new recommendation provides guidance for use of primary PCI within 12 to 24 hours of symptom onset in certain patient subsets. Phrasing has been changed to reflect current terminology and to be consistent with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.

2001 Recommendation	2005 New or Revised Recommendation	Comments	
Class III	Class III		
1. Elective PCI of a non-infarct-related artery at the time of acute MI. (Level of Evidence: C)	1. Elective PCI should not be performed in a non–infarct-related artery at the time of primary PCI of the infarct-related artery in patients without hemodynamic compromise. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology. Important phrasing has been added to address the issue of PCI of the non-infarct-related coronary artery at the time of primary PCI.	
2. In patients with acute MI who: a. have received fibrinolytic therapy within 12 h and have no symptoms of myocardial ischemia b. are eligible for thrombolytic therapy and are undergoing primary angioplasty by an inexperienced operator (Individual who performs fewer than 75 PCI procedures per year) c. are beyond 12 h after onset of	2. Primary PCI should not be performed in asymptomatic patients more than 12 hours after onset of STEMI who are hemodynamically and electrically stable. (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 PCI procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology. Recommendation has been divided to emphasize specific points. The class IIb recommendation was upgraded in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and approved by the PCI Writing Committee.	
symptoms and have no evidence of myocardial ischemia. (Level of Evidence: C)			
5.4.2. PCI in Fibrinolytic-Ineligible P	atients		
Class IIa	Class I		
As a reperfusion strategy in candidates who have a contraindication to thrombolytic therapy. (Level of Evidence: C)	Primary PCI should be performed in fibrinolytic-ineligible patients who present with STEMI within 12 hours of symptom onset. (Level of Evidence: C)	Revised recommendation reflects the committee's opinion primary PCI should be a class I recommendation for fibrinolytic-ineligible patients within 12 hours of sympton onset. Phrasing has been changed to reflect current terminology and to be consistent with the ACC/AHA Guic for the Management of Patients With ST-Elevation Myoc Infarction.	
	Class IIa		
	It is reasonable to perform primary PCI for fibrinolytic-ineligible patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following: a. Severe HF (Level of Evidence: C) b. Hemodynamic or electrical instability (Level of Evidence: C) c. Evidence of persistent ischemia (Level of Evidence: C)	New recommendation from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction that addresses conditions under which primary PCI is reasonable for fibrinolytic-ineligible patients with onset of symptoms within the prior 12 to 24 hours.	
5.4.3. Facilitated PCI			
Class IIb	Class IIb		
None	Facilitated PCI might be performed as a reperfusion strategy in higher-risk patients when PCI is not immediately available and bleeding risk is low. (Level of Evidence: B)	New recommendation from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction addressing conditions for which facilitated PCI might be considered. Important randomized trials are under way, and more data are needed regarding outcomes resulting from this treatment strategy (57–63).	
5.4.4. PCI After Failed Fibrinolysis (Rescue PCI)		
Class I	Class I		
None	1. Rescue PCI should be performed in patients less than 75 years old with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: B)	See above (49,51).	
	2. Rescue PCI should be performed in patients with severe HF and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours. (Level of Evidence: B)	See above (54–56).	

2001 Recommendation	2005 New or Revised Recommendation	Comments
Class IIa	Class IIa	
None	Rescue PCI is reasonable for selected patients 75 years or older with ST elevation or LBBB or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B) 2. It is reasonable to perform rescue PCI for patients with 1 or	See above (49).
	more of the following: a. Hemodynamic or electrical instability (Level of Evidence: C) b. Evidence of persistent ischemia. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
Class IIb		
Recurrent angina without objective evidence of ischemia/infarction. (Level of Evidence: C)		Deleted. Recurrent angina is not applicable to rescue angioplasty. Recurrent symptoms are discussed elsewhere.
Class III	Class III	
Routine PTCA within 48 h following failed thrombolysis. (Level of Evidence: B)	Rescue PCI in the absence of 1 or more of the above class I or IIa indications is not recommended. (Level of Evidence: C)	Evidence obtained from studies of PTCA during the fibrinolytic era before the use of stents failed to show a benefit for reperfusion under these conditions. Current trials are under way to investigate the outcome of PCI with stent placement among patients with occluded arteries days after presentation with STEMI.
5.4.5. PCI After Successful Fibrinoly	sis or for Patients Not Undergoing Primary Reperfusion	
Class I	<u>Class I</u>	
1. Objective evidence for recurrent infarction or ischemia (rescue PCI). (Level of Evidence: B)	In patients whose anatomy is suitable, PCI should be performed when there is objective evidence of recurrent MI. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology. Revised to a level of evidence C.
2. Spontaneous or provocable myocardial ischemia during recovery from infarction. <i>(Level of Evidence: C)</i>	2. In patients whose anatomy is suitable, PCI should be performed for moderate or severe spontaneous or provocable myocardial ischemia during recovery from STEMI. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology. Level of evidence revised on the basis of review by the Writing Committee (64).
3. Persistent hemodynamic instability. (Level of Evidence: C)	3. In patients whose anatomy is suitable, PCI should be performed for cardiogenic shock or hemodynamic instability. See also Section 5.4.6 of the full-text guidelines. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology. Level of evidence was revised on the basis of review by the Writing Committee, and cardiogenic shock has been added (cardiogenic shock is discussed in Section 5.4.6 and is a class I, level of evidence A recommendation for patients younger than 75 years old and a class IIa, level of evidence B recommendation for those aged 75 years and older) (49).
Class IIa	Class IIa	
Patients with LV ejection fraction less than or equal to 0.4, CHF, or serious ventricular arrhythmias. <i>(Level of Evidence: C)</i>	1. It is reasonable to perform routine PCI in patients with LV ejection fraction less than or equal to 0.40, CHF, or serious ventricular arrhythmias. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
Class IIb		
1. Coronary angiography and angioplasty for an occluded infarct-related artery in an otherwise stable patient to revascularize that artery (open artery hypothesis). (Level of Evidence: C)		Recommendation deleted. Important trials are under way to provide evidence regarding outcomes associated with or resulting from this therapy.
2. Angioplasty of the infarct-related artery stenosis within hours to days (48 h) following successful thrombolytic therapy in asymptomatic patients without clinical and/or inducible evidence of ischemia. (Level of Evidence: B)		This recommendation has been merged into the upgraded class llb recommendation for PCI after fibrinolytic therapy below.

2001 Recommendation	2005 New or Revised Recommendation	Comments	
	Class IIa		
3. Clinical HF during the acute episode, but subsequent demonstration of preserved LV function (LV ejection fraction greater than 0.4). (Level of Evidence: C)	2. It is reasonable to perform PCI when there is documented clinical heart failure during the acute episode, even though subsequent evaluation shows preserved LV function (LV ejection fraction greater than 0.40). (Level of Evidence: C) Phrasing has been changed to reflect terminology. Recommendation was upon the labeled terminology.		
Class III	Class III		
1. PCI of the infarct-related artery within 48 to 72 h after thrombolytic therapy without evidence of spontaneous or provocable ischemia. (Level of Evidence: C)		This recommendation has been upgraded and me into the IIb recommendation for PCI after fibrinolyt therapy below.	
	Class IIb		
2. Routine PCI of the infarct-artery stenosis immediately after thrombolytic therapy. (Level of Evidence: A)	1. PCI might be considered as part of an invasive strategy after fibrinolytic therapy. (Level of Evidence: C)	This recommendation has been upgraded to class llb to reflect a possible benefit from improved technology. The Committee recognizes the potential benefit of this therapy but believes more data are needed to define outcomes of PCI after fibrinolytic therapy in the current era of improved antiplatelet, anticoagulant, and drug-eluting stent therapies.	
5.4.6. PCI for Cardiogenic Shock			
Class I	<u>Class I</u>		
None	Primary PCI is recommended for patients less than 75 years old with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: A)	Phrasing has been changed to reflect current terminology and the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (48–53).	
Class IIa	Class IIa		
Cardiogenic shock or hemodynamic instability. (Level of Evidence: B)	Primary PCI is reasonable for selected patients 75 years or older with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B)		
5.5. Percutaneous Intervention in Pa	atients With Prior Coronary Bypass Surgery		
Class I	Class I		
Patients with early ischemia (usually within 30 days) after CABG (194). (Level of Evidence: B)	1. When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology.	
	2. It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. (Level of Evidence: B)	New recommendation is based on several studies demonstrating efficacy of distal embolic protection devices in PCI to saphenous vein grafts (65,66).	
Class IIa	Class IIa		
1. Patients with ischemia occurring 1 to 3 years postoperatively and preserved LV function with discrete lesions in graft conduits. (Level of Evidence: B)	1. PCI is reasonable in patients with ischemia that occurs 1 to 3 years after CABG and who have preserved LV function with discrete lesions in graft conduits. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology.	
2. Disabling angina secondary to new disease in a native coronary circulation. (If angina is not typical, the objective evidence of ischemia should be obtained.) (Level of Evidence: B)	2. PCI is reasonable in patients with disabling angina secondary to new disease in a native coronary circulation after CABG. (If angina is not typical, objective evidence of ischemia should be obtained.) (Level of Evidence: B)	Phrasing has been changed to reflect current terminology.	
3. Patients with diseased vein grafts more than 3 years following CABG. (Level of Evidence: B)	3. PCI is reasonable in patients with diseased vein grafts more than 3 years after CABG. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology.	
	4. PCI is reasonable when technically feasible in patients with a patent left internal mammary artery graft who have clinically significant obstructions in other vessels. (Level of Evidence: C)	This new recommendation addresses the feasibility of PCI to native circulation in the presence of a patent left internal mammary artery graft.	

2001 Recommendation 2005 New or Revised Recommendation Comments Class III Class III 1. PCI to chronic total vein graft 1. PCl is not recommended in patients with prior CABG for Phrasing has been changed to reflect current occlusions. (Level of Evidence: B) chronic total vein graft occlusions. (Level of Evidence: B) terminology. 2. Patients with multivessel disease, 2. PCI is not recommended in patients who have multiple target lesions Phrasing has been changed to reflect current failure or multiple SVGs, and with prior CABG and who have multivessel disease, failure of multiple technology, and considerations regarding risk of

5.6.1. Intravascular Ultrasound Imaging (IVUS)

impaired LV function. (Level of

Class IIa

Evidence: B)

- 1. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent. (Level of Evidence: B) 2. Determination of the mechanism of stent restenosis (inadequate expansion vs. neointimal proliferation) and to enable selection of appropriate therapy (plaque ablation vs. repeat balloon expansion). (Level of Evidence: B) 3. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis. (Level of Evidence: C)
- Assessment of a suboptimal angiographic result following PCI. (Level of Evidence: C)
 Diagnosis and management of coronary disease following cardiac transplantation. (Level of Evidence: C)
 Establish presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated. (Level of Evidence: C)
- 7. Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy. (Level of Evidence: B)

Class IIb

1. Determine extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild CAD on angiography. (Level of Evidence: C) 2. Preinterventional assessment of lesional characteristics and vessel dimensions as a means to select an optimal revascularization device. (Level of Evidence: C)

Class III

When angiographic diagnosis is clear and no interventional treatment is planned. (Level of Evidence: C)

Class IIa

- 1. IVUS is reasonable for the following:
 - a. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent. (Level of Evidence: B)

SVGs, and impaired LV function unless repeat CABG poses excessive

risk due to severe comorbid conditions. (Level of Evidence: B)

- b. Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (vascular brachytherapy versus repeat balloon expansion). (Level of Evidence: B)
- c. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis. (Level of Evidence: C)
- d. Assessment of a suboptimal angiographic result after PCI. (Level of Evidence: C)
- e. Establishment of the presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated. (Level of Evidence: C)
- f. Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy. (Level of Evidence: B)

Phrasing has been changed to reflect current terminology. The previous class lla recommendations for IVUS have been listed together in the recommendation rather than separately, with the exception that the Writing Committee has changed the recommendation to evaluate coronary disease after transplantation to class IIb.

repeat CABG have been added (36).

Class IIb

IVUS may be considered for the following:

- a. Determination of the extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild CAD on angiography.
 (Level of Evidence: C)
- b. Preinterventional assessment of lesional characteristics and vessel dimensions as a means to select an optimal revascularization device. (Level of Evidence: C)
- c. Diagnosis of coronary disease after cardiac transplantation. (Level of Evidence: C)

Class III

IVUS is not recommended when the angiographic diagnosis is clear and no interventional treatment is planned. (Level of Evidence: C)

Phrasing has been changed to reflect current terminology. The previous class Ilb recommendations for IVUS have been listed together in this recommendation rather than separately. The use of IVUS to evaluate coronary disease in transplant patients is now a class Ilb recommendation.

Phrasing has been changed to reflect current terminology.

outcomes similar to those achieved with 325 mg per day but with

fewer side effects (67,69-71).

2001 Recommendation	2005 New or Revised Recommendation	Comments
5.6.2. Coronary Artery Pressure and	Flow: Use of Fractional Flow Reserve and Coronary Vaso	dilatory Reserve
Class IIa	Class IIa	
Assessment of the physiological effects of intermediate coronary stenoses (30 to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (Level of Evidence: B)	It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (Level of Evidence: B)	Phrasing has been changed to reflect current terminology.
Class IIb	Class IIb	
1. Evaluation of the success of percutaneous coronary revascularization in restoring flow reserve and to predict the risk of restenosis. (Level of Evidence: C)	1. Intracoronary physiologic measurements may be considered for the evaluation of the success of PCl in restoring flow reserve and to predict the risk of restenosis. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
2. Evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (Level of Evidence: C)	2. Intracoronary physiologic measurements may be considered for the evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
Class III	Class III	
Routine assessment of the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study. (Level of Evidence: C)	Routine assessment with intracoronary physiologic measurements such as Doppler ultrasound or fractional flow reserve to assess the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
6. Management of Patients Undergo 6.1. Evolution of Technologies 6.1.1. Acute Results	ing PCI	
	<u>Class I</u>	
	It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. (Level of Evidence: B)	Published clinical trials using distal embolic protection devices confirm their benefit in improving cardiovascular outcomes among patients undergoing PCI to saphenous vein grafts (65,66).
6.2. Antiplatelet and Antithrombotic 6.2.1. Oral Antiplatelet Therapy	Adjunctive Therapies for PCI	
	<u>Class I</u>	
The recommendations in this section appeared in table format in the 2001 guideline (see 2001 Table). The phrasing has been changed to reflect current terminology and to be consistent with new evidence and/or recommendations	1. Patients already taking daily chronic aspirin therapy should take 75 to 325 mg of aspirin before the PCI procedure is performed. (Level of Evidence: A)	A daily dose of 75 mg of aspirin has been shown to result in improved cardiovascular outcomes similar to daily doses of 325 mg but with fewer bleeding complications (67–69).
in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and the ACC/AHA 2002 Guideline Update for Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction.	2. Patients not already taking daily chronic aspirin therapy should be given 300 to 325 mg of aspirin at least 2 hours and preferably 24 hours before the PCI procedure is performed. (Level of Evidence: C)	Higher doses of aspirin are recommended for patients not already taking aspirin therapy immediately before PCI procedures.
	3. After the PCI procedure, in patients with neither aspirin resistance, allergy, nor increased risk of bleeding, aspirin 325 mg daily should be given for at least 1 month after bare-metal stent implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily chronic aspirin use should be continued indefinitely at a dose of 75 to 162 mg. (Level of Evidence: B)	The doses and duration of aspirin therapy recommended herein are derived from those used for US Food and Drug Administration approval of the specific stent types noted in the recommendation. Daily chronic aspirin therapy is based on recommendations in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and evidence indicating that aspirin therapy in dosages as low as 75 mg per day yields outcomes similar to those achieved with 325 mg per day but with

dose of 75 to 162 mg. (Level of Evidence: B)

2001 Recommendation

230

2005 New or Revised Recommendation

4. A loading dose of clopidogrel should be administered before PCI is performed. (Level of Evidence: A) An oral loading dose of 300 mg, administered at least 6 hours before the procedure, has the best established evidence of efficacy. (Level of Evidence: B)

best evidence of efficacy exists for 300 mg given at least 6 hours before PCl is performed (68,69,72).

Clopidogrel therapy in the dosage of 75 mg daily should be given after stent placement to all patients. The duration of thorapy price for each

5. In patients who have undergone PCl, clopidogrel 75 mg daily should be given for at least 1 month after bare-metal stent implantation (unless the patient is at increased risk for bleeding; then it should be given for a minimum of 2 weeks), 3 months after sirolimus stent implantation, and 6 months after paclitaxel stent implantation, and ideally up to 12 months in patients who are not at high risk of bleeding. (Level of Evidence: B)

Clopidogrel therapy in the dosage of 75 mg daily should be given after stent placement to all patients. The duration of therapy varies for each stent and is based on data from clinical trials used for US Food and Drug Administration approval of that stent (67,69–71).

When clopidogrel is given at the time of a PCI

procedure, supplementation with glycoprotein

Ilb/Illa receptor antagonists can be beneficial,

especially among high-risk patients (73,74).

resistance to aspirin. The strongest evidence

for clopidogrel benefit exists for doses of 300

A significant number of patients will have

mg given at least 6 hours before the

procedure.

Comments

Clopidogrel is an important adjunctive therapy for

patients undergoing PCI with stent placement. The

Class IIa

- 1. If clopidogrel is given at the time of procedure, supplementation with GP llb/llla receptor antagonists can be beneficial to facilitate earlier platelet inhibition than with clopidogrel alone. (Level of Evidence: B)
- 2. For patients with an absolute contraindication to aspirin, it is reasonable to give a 300-mg loading dose of clopidogrel, administered at least 6 hours before PCl, and/or GP Ilb/Illa antagonists, administered at the time of PCl. (Level of Evidence: C)
- 3. When a loading dose of clopidogrel is administered, a regimen of greater than 300 mg is reasonable to achieve higher levels of antiplatelet activity more rapidly, but the efficacy and safety compared with a 300-mg loading dose are less established. (Level of Evidence: C)
- Many patients receive clopidogrel therapy at the time of PCI in dosages greater than 600 mg. Although more pronounced inhibition of platelet function has been demonstrated for doses of clopidogrel greater than 300 mg, the safety of these higher doses and their benefits on clinical outcome are not fully established.
- 4. It is reasonable that patients undergoing brachytherapy be given daily clopidogrel 75 mg indefinitely and daily aspirin 75 to 325 mg indefinitely unless there is significant risk for bleeding. (Level of Evidence: C)

Subacute or later thrombosis has been observed in patients undergoing brachytherapy, and for this reason long-term antiplatelet therapy is recommended.

Class IIb

In patients in whom subacute thrombosis may be catastrophic or lethal (unprotected left main, bifurcating left main, or last patent coronary vessel), platelet aggregation studies may be considered and the dose of clopidogrel increased to 150 mg per day if less than 50% inhibition of platelet aggregation is demonstrated. (Level of Evidence: C)

Clopidogrel resistance is a significant problem, and owing to its contribution to catastrophic clinical outcomes, the Writing Committee recommends studies be performed with increases in clopidogrel dose being recommended for use in those with higher-risk lesions.

6.2.2 Glycoprotein Ilb/Illa Inhibitors

The recommendations in this section appeared in table format in the 2001 guideline (see 2001 Table). The phrasing has been changed to reflect current terminology and to be consistent with new evidence and/or recommendations in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction and the ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina/ Non-ST-Elevation Myocardial Infarction.

Class

In patients with UA/NSTEMI undergoing PCI without clopidogrel administration, a GP Ilb/Illa inhibitor (abciximab, eptifibatide, or tirofiban) should be administered. (Level of Evidence: A)§ §It is acceptable to administer the GP Ilb/Illa inhibitor before performance of the diagnostic angiogram ("upstream treatment") or just before PCI ("in-lab treatment").

This recommendation and phrasing are compatible with the ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non–ST-Segment Myocardial Infarction and current evidence from randomized clinical trials. The benefits of GP Ilb/Illa inhibition are especially efficacious when clopidogrel is not given (37).

Class IIa

1. In patients with UA/NSTEMI undergoing PCI with clopidogrel administration, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). (Level of Evidence: B)§

§It is acceptable to administer the GP IIb/IIIa inhibitor before performance of the diagnostic angiogram ("upstream treatment") or just before PCI ("in-lab treatment").

2. In patients with STEMI undergoing PCI, it is reasonable to administer abciximab as early as possible. (Level of Evidence: B)

See above (37).

Recommendation has been added for consistency with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (57,75–78).

2001 Recommendation	2005 New or Revised Recommendation	Comments
	3. In patients undergoing elective PCI with stent placement, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). (Level of Evidence: B) Class IIb	Phrasing has been changed to reflect current terminology, especially in a high-risk patient (79,80).
	In patients with STEMI undergoing PCI, treatment with eptifibatide or tirofiban may be considered. (Level of Evidence: C)	Recommendation has been added for consistency with the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction.
6.2.3. Antithrombotic The 6.2.3.1 Unfractionated He	rapy parin, Low-Molecular-Weight Heparin, and Bivalirudin	
	Class I	
The recommendations in this section appeared in table format in the 2001 guideline	1. Unfractionated heparin should be administered to patients undergoing PCI. (Level of Evidence: C)	Phrasing has been changed to reflect current terminology.
(see 2001 Table). The phrasing has been changed to reflect current terminology and to be consistent with new evidence and/or recommendations in the ACC/AHA Guidelines for the	2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace heparin. (Level of Evidence: B)	Bivalirudin and argatroban are established therapies in place of heparin among patients with heparin-induced thrombocytopenia (81, 82).
Management of Patients With ST-Elevation Myocardial Infarction and the ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina/Non-ST- Elevation Myocardial Infarction.		
Class IIa	Class IIa	
None	1. It is reasonable to use bivalirudin as an alternative to unfractionated heparin and glycoprotein Ilb/Illa antagonists in low-risk patients undergoing elective PCI. (Level of Evidence: B) 2. Low-molecular-weight heparin is a reasonable alternative to unfractionated heparin in patients with UA/NSTEMI undergoing PCI. (Level of Evidence: B)	New recommendation is based on data from a clinical trial (REPLACE-2) indicating bivalirudin is an acceptable alternative to heparin and GP Ilb/Illa antagonists in low-risk patients undergoing PCI (83). Recommendation from the ACC/AHA 2002 Guidaline Update for the Management of Patients With Unstable Angina and Non–ST-Segment Myocardial Infarction has been approved by this Writing Committee and included in those guidalines for consistency.
Class IIb	Class IIb	included in these guidelines for consistency.
None	Low-molecular-weight heparin may be considered as an alternative to unfractionated heparin in patients with STEMI undergoing PCI. (Level of Evidence: B)	Recommendation from the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction has been approved by this Writing Committee and included in these guidelines for consistency.
6.3.4. Left Main CAD		
Class IIa None	Class IIa It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI. (Level of Evidence: C)	Patients undergoing PCl to an unprotected left main coronary artery are at higher risk for adverse events and should be monitored carefully. On the basis of experience and opinion in the available reports, the Writing Committee recommends angiography be performed between 2 and 6 months after PCl.
7.3.3. Management Strate	gies for Restenosis After PTCA	
Class IIa	Class IIa	
None	It is reasonable to consider that patients who develop restenosis after PTCA or PTCA with atheroablative devices are candidates for repeat coronary intervention with intracoronary stents if anatomic factors are appropriate. (Level of Evidence: B)	This new recommendation reflects data indicating a significant reduction in target-lesion revascularization and restenosis for patients undergoing bare-metal stent placement compared with PTCA for restenosis after PTCA (84).
7.3.5. Drug-Eluting Stents	1	
Class I None	Class I A drug-eluting stent should be considered as an alternative to the bare-metal stent in subsets of patients in whom trial data suggest efficacy. (Level of Evidence: A)	New recommendation since the 2001 ACC/AHA Guidelines for Percutaneous Coronary Intervention. Evidence continues to accumulate that supports the use of drug-eluting stents (DES) versus bare-metal stents in certain subsets in which DES results and outcomes are better (70, 71, 85–97).
Class IIb None	Class IIb A drug-eluting stent may be considered for use in anatomic settings in which the usefulness, effectiveness, and safety have not been fully documented in published trials. (Level of Evidence: C)	The data that a DES can improve clinical outcomes for PCI are generally strong. However, DESs have not undergone evaluation for use in all clinical situations and anatomic settings.

situations and anatomic settings.

2001 Recommendation	2005 New or Revised Recommendation Comments		
7.3.6.2 Drug-Eluting Stents fo	r the Management of In-Stent Restenosis		
Class IIa	Class IIa		
None	It is reasonable to perform repeat PCI for in-stent restenosis with a DES or a new DES for patients who develop in-stent restenosis if anatomic factors are appropriate. (Level of Evidence: B)	This is a new recommendation. Clinical trials comparing sirolimus and paclitaxel DESs with PTCA for in-stent restenosis demonstrate improved outcomes for the DESs (97–101).	
7.3.6.3. Radiation for Resteno	sis		
Class IIa	Class IIa		
None	Brachytherapy can be useful as a safe and effective treatment for in-stent restenosis. (Level of Evidence: A)	This is a new recommendation since the 2001 ACC/AHA Guidelines for Percutaneous Coronary Intervention based on evidence supporting the efficacy of brachytherapy in the treatment of in-stent restenosis (102–109).	

2001 TABLE. Recommendations for Pharmacological Management of Patients Undergoing PCI—For Comparison Purposes Only (Deleted From 2005 Guideline)

	Clinical Status				
		Trai	nsmural Myo	cardial Infarction	1
Drugs	Class I Angina	Class II–IV Angina, Unstable Angina, NSTEMI	Acute Phase MI	After Thrombolysis	Hospital Management Phase
Aspirin	l*	I	I	I	ı
Ticlopidine,	I‡	1	1	I	I§
Clopidogrel†					
Warfarin	Ш	III	III	II	۱¶
GP blockers#	II	1	II	I	III
Abciximab					
Tirofiban					
Eptifibatide					
Unfractionated heparin**	I	1	1	II	III††

Note: This table has been deleted from the 2005 PCI Guideline Update. The recommendations in this table were updated or deleted, as determined by the writing committee, and included in the 2005 PCI Guideline Update in the recommendation list.

*Roman numerals indicate ACC/AHA class indication I, II, or III.

†In conjunction with stenting.

 \ddagger To be given 24-48 h before planned stenting, if possible.

§For 2 to 4 weeks after stent placement.

¶For patients without atrial fibrillation or other pre-existing clinical indications.

||For patients with anterior myocardial wall motion abnormalities or LV thrombus.

#Every indication may not apply to all individual agents.

**Low-molecular-weight heparin is under investigation to replace unfractionated heparin.

††Other noncoronary thrombotic complications (eg, thrombophlebitis).

Appendix. Abbreviations		left bundle-branch block
		left ventricular
coronary artery bypass graft surgery	MB	cardiac muscle isoenzyme of
coronary artery disease		creatine kinase
creatine kinase	MI	myocardial infarction
drug-eluting stent	MR	mitral regurgitation
electrocardiogram	NSTEMI	non-ST-elevation myocardial
glycoprotein		infarction
heart failure	PCI	percutaneous coronary intervention
intravascular ultrasound	STEMI	ST-elevation myocardial infarction
left anterior descending artery	UA	unstable angina
	coronary artery bypass graft surgery coronary artery disease creatine kinase drug-eluting stent electrocardiogram glycoprotein heart failure intravascular ultrasound	coronary artery bypass graft surgery coronary artery disease creatine kinase drug-eluting stent electrocardiogram glycoprotein heart failure intravascular ultrasound

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ACC/AHA/SCAI 2005 Guideline Update for PCI

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