Complete Summary

GUIDELINE TITLE

(1) ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention. 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). (2) 2007 focused update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

BIBLIOGRAPHIC SOURCE(S)

King SB 3rd, Smith SC Jr, Hirshfeld JW Jr, Jacobs AK, Morrison DA, Williams DO, Feldman TE, Kern MJ, O'Neill WW, Schaff HV, Whitlow PL, ACC/AHA/SCAI, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Halperin JL, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura R, Page RL, Riegel B, Tarkington LG, Yancy CW. 2007 focused update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. J Am Coll Cardiol 2008 Jan 15;51(2):172-209. [161 references] PubMed

Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Assoc Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for PCI). Bethesda (MD): American College of Cardiology Foundation (ACCF); 2005. 122 p. [926 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun;37(8):2239i-lxvi.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s)/intervention(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin products sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- August 16, 2007, Coumadin (Warfarin): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Coronary artery disease, including:

- Asymptomatic ischemia or Canadian Cardiovascular Society (CCS) class I or II angina
- CCS class III angina
- Unstable angina/non-ST-elevation myocardial infarction (NSTEMI)
- ST-elevation myocardial infarction (STEMI)
- Ischemia (early or late) after coronary artery bypass graft

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice

Geriatrics
Internal Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

2005 Guideline

To make recommendations regarding the appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

2007 Focused Update

To revise the 2005 guideline recommendations that are affected by evolving data and opinion

TARGET POPULATION

Patients with coronary artery disease

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

1. Percutaneous coronary interventions (PCI), including percutaneous transluminal coronary angioplasty (PTCA), balloon expandable stents, drug-eluting stents, extraction atherectomy, directional coronary atherectomy, rotational atherectomy, rheolytic thrombectomy catheter, proximal and distal embolic protection devices, excimer laser coronary atherectomy, and local radiation devices to reduce in-stent restenosis
2. Insurance of institutional and operator competency in performing PCI (quality assurance programs, high-volume operators in high-volume institutions, availability of onsite cardiac surgical back-up or access to cardiac surgical back-up)
3. Antiplatelet and antithrombotic adjunctive therapies (aspirin, clopidogrel, glycoprotein IIb/IIIa Inhibitors, unfractionated heparin, low-molecular-weight heparin, bivalirudin) in patients undergoing PCI
4. Special considerations (for example, management of clinical restenosis, ad hoc PCI, PCI in the cardiac transplant patient, and restenosis after stent implantation)
5. Post-PCI management (postprocedural evaluation of ischemia, risk factor modification, exercise testing, follow-up coronary angiography)

Evaluation/Follow-up

1. Angiographic assessment
2. Use of adjunctive technologies

- Coronary intravascular ultrasound imaging (IVUS)
- Measurement of coronary flow velocity and coronary vasodilatory reserve
- Measurement of coronary artery pressure and fractional flow reserve (FFR)

3. Measurement of creatine kinase-MB isoenzyme and troponins I or T

MAJOR OUTCOMES CONSIDERED

- Success rates of percutaneous coronary intervention procedures as defined by angiographic (minimum stenosis diameter reduction to <20%), procedural, and clinical criteria (relief of signs and symptoms, rate of restenosis)
- Rates of procedural complications of percutaneous coronary intervention, such as: death, myocardial infarction, emergency coronary artery bypass graft (CABG), stroke, vascular access site complications, and contrast agent nephropathy
- Long-term (5- and 10-year) survival rates and event-free survival rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

2005 Guideline

The committee conducted comprehensive searching of the scientific and medical literature on percutaneous coronary intervention (PCI), with special emphasis on randomized controlled trials and meta-analyses published since 2001. In addition to broad-based searching on PCI, specific targeted searches were performed on the following subtopics: catheter-based intervention, stents (drug-eluting and bare-metal), cardiac biomarkers (e.g., creatine kinase and troponins), pharmacological therapy (aspirin, thienopyridines, GP IIb/IIIa inhibitors, heparin, and direct thrombin inhibitors), special populations (women, patients with diabetes, elderly), coronary artery bypass grafting (CABG), high-risk PCI, quality, outcomes, volume, left main PCI (protected and unprotected), distal embolic protection, intravascular ultrasound (IVUS), fractional flow reserve (FFR), vascular closure, and secondary prevention/risk factor modification. The complete list of keywords is beyond the scope of this section. The committee reviewed all compiled reports from computerized searches and conducted additional searching by hand. Literature citations were generally restricted to published manuscripts appearing in journals listed in Index Medicus. Because of the scope and importance of certain ongoing clinical trials and other emerging information, published abstracts were cited when they were the only published information available. Additionally, the Committee reviewed and incorporated recommendations and/or text from published American College of Cardiology/American Heart Association (ACC/AHA) or Society for Cardiovascular

Angiography and Interventions (SCAI) documents to maintain consistency, as appropriate.

2007 Focused Update

These updated guideline recommendations reflect a consensus of expert opinion following a thorough review primarily of late-breaking clinical trials identified through a broad-based vetting process as important to the relevant patient population and of other new data deemed to have an impact on patient. It is important to note that this focused update is not intended to represent an update based on a full literature review from the date of the previous guideline publication. Specific criteria/considerations for inclusion of new data include:

- Publication in a peer-reviewed journal
- Large, randomized, placebo-controlled trial(s)
- Nonrandomized data deemed important on the basis of results that impact current safety and efficacy assumptions
- Strengths/weakness of research methodology and findings
- Likelihood of additional studies influencing current findings
- Impact on current performance measure(s) and/or likelihood of the need to develop new performance measure(s)
- Requests and requirements for review and update from the practice community, key stakeholders, regulatory agencies, and other sources free of relationships with industry or other potential bias
- Number of previous trials showing consistent results
- Need for consistency with other new guidelines or guideline revisions

Evidence Review

Selected late-breaking clinical trials presented at the 2005 and 2006 annual scientific meetings of the American College of Cardiology (ACC), American Heart Association (AHA), and European Society of Cardiology, as well as selected other data, were reviewed by the standing guideline writing committee along with the parent Task Force and other experts to identify those trials and other key data that might impact guideline recommendations. On the basis of the criteria/considerations noted above, recent trial data and other clinical information were considered important enough to prompt a focused update of the ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) 2005 Guideline Update for Percutaneous Coronary Intervention.

To provide clinicians with a comprehensive set of data, whenever possible, the exact event rates in various treatment arms of clinical trials are presented to permit calculation of the absolute risk difference (ARD) and number needed to treat (NNT) or harm (NNH); the relative treatment effects are described either as odds ratio (OR), relative risk (RR), or hazard ratio (HR), depending on the format in the original publication.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

2004 Guideline

Levels of Evidence

A: Data derived from multiple randomized clinical trials or meta-analyses

B: Data derived from a single randomized trial, or nonrandomized studies

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

2007 Focused Update

Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT		
		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 objectives needed/ registry data woul helpful* Procedure/Treatm **MAY BE CONSID**
Estimate of Certainty (Precision) of Treatment Effect	**LEVEL A** Multiple (3–5) population risk strata evaluated* General consistency of direction and magnitude of effect	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment of procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommen usefulness/ less well es • Greater cor evidence fr multiple ra trials or me analyses
	LEVEL B	• Recommendation	• Recommendation in	• Recommen

		SIZE OF TREATMENT EFFECT		
	Limited (2–3) population risk strata evaluated*	• that procedure or treatment is useful/effective • Limited evidence from single randomized trial or nonrandomized studies	• favor of treatment of procedure being useful/effective • Some conflicting evidence from single randomized trial or nonrandomized studies	• usefulness/ less well es • Greater cor evidence fr randomized nonrandom studies
	LEVEL C Very limited (1–2) population risk strata evaluated*	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard-of-care	• Recommendation in favor of treatment of procedure being useful/effective • Only diverging expert opinion, case studies, or standard-of-care	• Recommen usefulness/ less well es • Only diverg opinion, cas or standard

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. 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. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

NOTE: In 2003, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All guideline recommendations 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 (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level. (See Table 1 in the Focused Update document for a list of suggested phrases for writing recommendations.)

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

2005 Guideline

Writing groups were specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might

influence the choice of particular tests or therapies are considered, along with frequency of follow-up and cost-effectiveness.

2007 Focused Update

In analyzing the data and developing updated recommendations and supporting text, the focused update writing group used evidence-based methodologies developed by the American College Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines, which are described elsewhere.

The schema for class of recommendation and level of evidence is summarized in Table 1 in the focused update document (see also the "Rating Scheme for the Strength of the Evidence" field in this summary), which also illustrates how the grading system provides estimates of the size of the treatment effect and the certainty of the treatment effect. Note that a recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although randomized trials may not be available, there may be a very clear clinical consensus that a particular test or therapy is useful and effective. Both the class of recommendation and level of evidence listed in the focused updates are based on consideration of the evidence reviewed in previous iterations of the guidelines as well as the focused update. Of note, the implications of older studies that have informed recommendations but have not been repeated in contemporary settings are carefully considered.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

2005 Guideline

Experts in the subject under consideration are selected from the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions (SCAI) to examine subject-specific data and write guidelines. The process includes additional representatives from other medical specialty groups where appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness.

2007 Focused Update

In an effort to respond more quickly to new evidence, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines has created a new "focused update" process to revise the existing guideline recommendations that are affected by evolving data or opinion. Before

the initiation of this focused approach, periodic updates and revisions of existing guidelines required up to 3 years to complete. Now, however, new evidence will be reviewed in an ongoing fashion to more efficiently respond to important science and treatment trends that could have a major impact on patient outcomes and quality of care. Evidence will be reviewed at least twice a year, and updates will be initiated on an as needed basis as quickly as possible while maintaining the rigorous methodology that the ACC and AHA have developed during their more than 20 years of partnership.

For this focused update, all members of the 2005 Percutaneous Coronary Intervention (PCI) writing committee were invited to participate; those who agreed (referred to as the 2007 focused update writing group) were required to disclose all relationships with industry (RWI) relevant to the data under consideration. Focused update writing group members who had no significant relevant RWI wrote the first draft of the focused update; the draft was then reviewed and revised by the full writing group. Each recommendation required a confidential vote by the writing group members before external review of the document. Any writing committee member with a significant (greater than $10,000) RWI relevant to the recommendation was recused from voting on that recommendation.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

2005 Guideline

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

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

2007 Focused Update

See "Rating Scheme for the Strength of the Evidence" field, above.

COST ANALYSIS

Among all diseases worldwide, ischemic heart disease currently ranks fifth in disability burden, and is projected to rank first by the year 2020. As healthcare delivery systems in countries with established economic markets continue to incorporate new and expensive technologies, the costs of medical care have seemingly escalated beyond the revenue historically allotted to health care. Given limited healthcare resources, a cost-effectiveness analysis is appropriate to

evaluate percutaneous coronary revascularization strategies. The results of cost-effectiveness analyses for any comparable treatment are reported in terms of the incremental cost per unit of health gained, such as 1 year of life adjusted to perfect health (quality-adjusted life year, QALY) compared with the standard of care. By modeling different treatments, different patient subsets, and different levels of disease, a series of cost-effectiveness ratios may be constructed to show the tradeoffs associated with choosing among competing interventions.

Although there is no established cost-effectiveness ratio threshold, cost-effectiveness ratios of less than $20,000 per QALY (such as seen in the treatment of severe diastolic hypertension or cholesterol lowering in patients with ischemic heart disease) are considered highly favorable and consistent with well accepted therapies. Incremental cost-effectiveness ratios that range between $20,000 and $60,000 per QALY may be viewed as reasonably cost-effective and thus acceptable in most countries, whereas ratios greater than $60,000 to $80,000 may be considered too expensive for most healthcare systems. The Committee defines useful and efficacious treatments, in terms of cost-effectiveness, as treatments with acceptable or favorable cost-effectiveness ratios. Cost-effectiveness analysis is not by itself sufficient to incorporate all factors necessary for medical decision making on an individual patient basis, nor is it sufficient to dictate the broad allocation of societal resources for health care. Rather, cost-effectiveness analysis aims to serve mainly as an aid to medical decision making on the basis of comparison with other evaluated therapies.

The results of cost-effectiveness analysis in the field of percutaneous revascularization for ischemic heart disease have been derived from decision models that incorporate literature-based procedure-related morbidity and mortality, coronary disease related mortality, and estimates of the benefit of selected revascularization procedures. When available, results from randomized trials (levels of evidence A and B) are used to estimate the outcomes of each decision tree branch within the decision-analytical model, for example, using data estimating the restenosis rate after uncomplicated coronary stenting of a single, simple, lesion. Cost-effectiveness analyses have been used to compare medical therapy with percutaneous transluminal coronary angioplasty (PTCA) with coronary artery bypass graft (CABG), balloon angioplasty with coronary stenting, and routine coronary angiography following acute myocardial infarction (MI) with symptom-driven coronary angiography.

In patients with severe angina, normal left ventricle (LV) function, and single-vessel disease of the left anterior descending artery (LAD), the cost-effectiveness ratio for PTCA, directional coronary atherectomy, or coronary stenting that can be expected to provide greater than 90% success rate with less than 3% major acute complication rate is very favorable (less than $20,000 per QALY) compared to medical therapy. The rating also applies to patients with symptomatic angina or documented ischemia and 2-vessel coronary disease in which percutaneous coronary revascularization can be expected to provide a more than 90% success rate with a less than 3% major acute complication rate. In patients with 3-vessel coronary disease who have comorbidities that increase operative risk for CABG surgery, percutaneous coronary intervention (PCI) that is believed to be safe and feasible is reasonably acceptable ($20,000-$60,000 per QALY). In patients in the post-MI setting, a strategy of routine, nonsymptom-driven, coronary angiography and PCI performed for critical (greater than 70% diameter stenosis) culprit

coronary lesions amenable to balloon angioplasty or stenting has been proposed to be reasonably cost-effective in many subgroups.

In patients with symptomatic angina or documented ischemia and 3-vessel coronary disease, for which bypass surgery can be expected to provide full revascularization and an acute complication rate of less than 5%, the cost-effectiveness of PCI is not well established. Although PTCA for 2- and 3-vessel coronary disease appears to be as safe, but initially less expensive than CABG surgery, the costs of PTCA converge towards the higher costs of bypass surgery after 3 to 5 years. Thus, whereas PTCA or CABG surgery has been shown to be cost-effective compared with medical therapy, there is no evidence for incremental cost-effectiveness of PTCA over bypass surgery for 2- or 3-vessel coronary disease in patients who are considered good candidates for both procedures. For patients with 1- or 2-vessel coronary disease who are asymptomatic or have only mild angina, without documented left main disease, the estimated cost-effectiveness ratios for PCI are greater than $80,000 per QALY compared with medical therapy, and are thus considered less favorable.

The initial mean cost of angioplasty was 65% that of surgery, but need for repeat interventions increased medical expenses so that after 5 years the total medical cost of PTCA was 95% that of surgery ($56,225 vs. $58,889), a significant difference of $2,664 ($p = 0.047$). Compared with CABG, PTCA appeared less costly for patients with 2-vessel disease, but not for patients with 3-vessel disease.

The use of drug-eluting stents (DES) is affecting the cost-effectiveness of PCI. In the SIRIUS (Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions) trial, there were 21 fewer repeat revascularization procedures per 100 patients treated with the sirolimus stent. Although the DES group's hospital costs were $2800 more, much of that was negated in follow-up by the high reintervention rate in the bare-metal stent (BMS) group. However, the number of repeat procedures in such trials with routine angiographic follow-up is inflated compared with registries of BMS, which suggests only 6 to 7 repeat procedures are avoided by routinely using DES. The ultimate cost effectiveness of drug-eluting stenting will depend on the cost of the stents, how many are implanted per patient, and how many repeat procedures are avoided.

Because cost-effectiveness analysis research is new in the field of PCI, its results are limited. The Committee underscores the need for cost containment and careful decision making regarding the use of PCI strategies.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed by two official reviewers nominated by the American College of Cardiology (ACC), two official reviewers nominated by the American Heart Association (AHA); two official reviewers nominated by the Society for

Cardiac Angiography and Interventions (SCAI); one official reviewer from the ACC/AHA Task Force of Practice Guidelines; and eight content reviewers, including members from the AHA Committee on Diagnostic and Interventional Cardiac Catheterization and the American College of Cardiology Foundation (ACCF) Cardiac Catheterization and Intervention Committee.

2007 Focused Update

This document was reviewed by 2 outside reviewers nominated by each cosponsoring organization (ACC, AHA, and SCAI) and 24 individual content reviewers. All reviewer relationship with industry (RWI) information was collected and distributed to the writing committee and is published in the focused update document.

This focused update was approved for publication by the governing bodies of the American College of Cardiology Foundation, the AHA, and SCAI.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the weight of the evidence (A-C) and classes of recommendations (I-III) are provided at the end of the "Major Recommendations" field.

Note from the National Guideline Clearinghouse (NGC) and the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines: In 2007, the ACC/AHA Task Force performed a focused update of the 2005 guidelines for percutaneous coronary interventions to revise existing guideline recommendations that are affected by evolving data or opinion. The updated recommendations are presented below, along with the original 2005 recommendations. Sections affected by the focused update are labeled "2007 Update," and new or modified recommendations are labeled as such. All other recommendations remain current in their 2005 form.

Outcomes

Acute Outcome: Procedural Complications

Class I

All patients who have signs or symptoms suggestive of myocardial infarction (MI) during or after percutaneous coronary interventions (PCI) and those with complicated procedures should have creatine kinase-MB isoenzyme (CK-MB) and troponin I or T measured after the procedure. (*Level of Evidence: B*)

Class IIa

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*)

Institutional and Operator Competency

Quality Assurance

Class I

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*)
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*)

Operator and Institutional Volume

Class I

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 onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) (*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 ST-segment elevation myocardial infarction (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*)

Class IIa

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 onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) (*Level of Evidence: B*)
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 onsite 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*)

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*)

Class III

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 onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) 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*)

Role of Onsite Cardiac Surgical Back-Up

Class I

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 onsite emergency cardiac surgical services. (*Level of Evidence: B*)
2. Primary PCI for patients with STEMI should be performed in facilities with onsite cardiac surgery. (*Level of Evidence: B*)

Class III

Elective PCI should not be performed at institutions that do not provide onsite 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. A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. One study found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery. This recommendation may be subject to revision as clinical data and experience increase.

Primary PCI for STEMI Without Onsite Cardiac Surgery

Class IIb

Primary PCI for patients with STEMI might be considered in hospitals without onsite 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 left bundle-branch block on electrocardiogram (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 performing a minimum of 36 primary PCI procedures per year. (*Level of Evidence: B*)

Class III

Primary PCI should not be performed in hospitals without onsite 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*)

Criteria for the Performance of Primary PCI at Hospitals Without On-Site Cardiac Surgery

- The operators must be experienced interventionalists who regularly perform elective PCI at a surgical center (greater than or equal to 75 cases per year). The catheterization laboratory must perform a minimum of 36 primary PCI procedures per year.
- The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hours-per-day, 365-days-per-year call schedule.
- The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
- The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
- The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
- There must be formalized written protocols in place for immediate and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.
- Primary PCI must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction (AMI), to ensure streamlined care paths and increased case volumes.
- Case selection for the performance of primary PCI must be rigorous. Criteria for the types of lesions appropriate for primary PCI and for the selection for transfer for emergency aortocoronary bypass surgery are shown in Table 14 of the original guideline document.
- There must be an ongoing program of outcomes analysis and formalized periodic case review.
- Institutions should participate in a 3- to 6-month period of implementation,

during which time development of a formalized primary PCI program is instituted that includes establishment of standards, training of staff, detailed logistic development, and creation of a quality-assessment and error-management system.

Patient Selection for Primary PCI and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:

- Significant (greater than or equal to 60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
- Extremely long or angulated infarct-related lesions with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow
- Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease
- Infarct-related lesions of small or secondary vessels
- Hemodynamically significant lesions in other than the infarct artery

Transfer for emergency aortocoronary bypass surgery patients with:

- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability present after primary PCI of occluded vessels, preferably with IABP support.

Elective PCI Without Onsite Surgery

Class III

Elective PCI should not be performed at institutions that do not provide onsite 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. A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. One study found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery. This recommendation may be subject to revision as clinical data and experience increase.

Clinical Presentations

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

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*)
2. PCI 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 coronary artery disease (CAD) (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for coronary artery bypass grafting (CABG). (*Level of Evidence: B*)

Class IIb

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 left anterior descending (LAD) artery 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*)

Class III

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*)

Grading of Angina Pectoris According to Canadian Cardiovascular Society (CCS) Classification

Class	Description of Stage

Class	Description of Stage
I	"Ordinary physical activity does not cause…angina," such as walking or climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
II	"Slight limitation of ordinary activity." Angina occurs on walking or climbing stairs rapidly; walking uphill; walking or stair climbing after meals; in cold, in wind, or under emotional stress; or only during the few hours after awaking. Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and under normal conditions.
III	"Marked limitations of ordinary physical activity." Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs under normal conditions and at a normal pace.
IV	"Inability to carry on any physical activity without discomfort--anginal symptoms may be present at rest."

Provider Checklist: Key Areas for Consideration

Patients at High Risk

- Assess key clinical and anatomic variables.
- Consider alternative therapies such as CABG in consultation with the patient.
- Ensure that formalized surgical standby is available.
- Ensure periprocedural hemodynamic support is available.

Patients at Low Risk

- Assess key clinical and anatomic variables.
- Consider alternative therapies such as medical therapy in consultation with the patient.

Patients With CCS Class III Angina

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*)
2. It is reasonable that PCI be performed in patients with CCS class III angina with 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*)
3. Use of PCI is reasonable in patients with CCS class III 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*)

Class IIb

1. PCI may be considered in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with a reduced likelihood of success. (*Level of Evidence: B*)
2. PCI may be considered in patients with CCS class III angina and no evidence of ischemia on noninvasive testing or who are undergoing medical therapy and have 2- or 3-vessel CAD with significant proximal LAD CAD and treated diabetes or abnormal LV function. (*Level of Evidence: B*)

Class III

PCI is not recommended for patients with CCS class III angina with single-vessel or multivessel CAD, no evidence of myocardial injury or ischemia on objective testing, and no trial of medical therapy, or who have 1 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: C*)

Patients With Unstable Angina (UA)/Non-ST-Segment Elevation Myocardial Infarction (NSTEMI) (2007 Update)*

Class I

1. 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 and who have characteristics for invasive therapy (see Table 3 and Section 3.3 of the ACC/AHA 2007 UA/NSTEMI Guidelines*). *(Level of Evidence: A*) (Modified recommendation*)
2. Percutaneous coronary intervention (or CABG) is recommended for UA/NSTEMI patients with 1- or 2-vessel CAD with or without significant proximal left anterior descending CAD but with a large area of viable myocardium and high-risk criteria on noninvasive testing. *(Level of Evidence: B*) (New recommendation*)
3. Percutaneous coronary intervention (or CABG) is recommended for UA/NSTEMI patients with multivessel coronary disease with suitable coronary anatomy, with normal LV function, and without diabetes mellitus. (*Level of Evidence: A*) (New recommendation*)
4. An intravenous platelet glycoprotein (GP) IIb/IIIa inhibitor is useful in UA/NSTEMI patients undergoing PCI. (*Level of Evidence: A*) See Section 3.2.3 and Table 13 of the 2007 ACC/AHA 2007 UA/NSTEMI Guidelines*. (New recommendation*)
5. An early invasive strategy (i.e., 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). (*Level of Evidence: B*) (New recommendation*)

Class IIa

1. Percutaneous coronary intervention is reasonable for focal saphenous vein graft lesions or multiple stenoses in UA/NSTEMI patients who are undergoing medical therapy and who are poor candidates for reoperative surgery. (*Level of Evidence: C*) (Modified recommendation*)
2. Percutaneous coronary intervention (or CABG) is reasonable for UA/NSTEMI patients with 1- or 2-vessel CAD with or without significant proximal left anterior descending CAD but with a moderate area of viable myocardium and ischemia on noninvasive testing. (*Level of Evidence: B*) (New recommendation*)
3. Percutaneous coronary intervention (or CABG) can be beneficial compared with medical therapy for UA/NSTEMI patients with 1-vessel disease with significant proximal left anterior descending CAD. (*Level of Evidence: B*) (New recommendation*)
4. 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 or who require emergency intervention at angiography for hemodynamic instability. (*Level of Evidence: B*) (2005 recommendation remains current, but received additional wording.)

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*) (Modified recommendation*)
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 left ventricular (LV) function, with anatomy suitable for catheter-based therapy. (*Level of Evidence: B*) (2005 recommendation remains current but receives additional wording.)
3. In initially stabilized patients, an initially conservative (i.e., a selectively invasive) strategy may be considered as a treatment strategy for UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures**) who have an elevated risk for clinical events (see Table 3 in the 2007 Update document) including those who are troponin positive. (*Level of Evidence: B*). The decision to implement an initial conservative (versus initial invasive) strategy# in these patients may be made by considering physician and patient preference. (*Level of Evidence: C*) (New recommendation*)
4. An invasive strategy may be reasonable in patients with chronic renal insufficiency. (*Level of Evidence: C*) (New recommendation*)

Class III

1. Percutaneous coronary intervention (or CABG) is not recommended for patients with 1- or 2-vessel CAD without significant proximal left anterior descending CAD with no current symptoms or symptoms that are unlikely to be due to myocardial ischemia and who have no ischemia on noninvasive testing. (*Level of Evidence: C*) (New recommendation*)

2. In the absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for patients with UA/NSTEMI who have 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*)

    (2005 recommendation remains current.)

3. PCI strategy in stable patients (see Class III recommendation number 1 in the "PCI After Fibrinolysis or for Patients Not Undergoing Primary Reperfusion" section below for specific recommendations) with persistently occluded infarct related coronary arteries after STEMI/NSTEMI is not indicated. (*Level of Evidence: B*) (New recommendation*)

*Based on the ACC/AHA 2007 UA/NSTEMI guidelines (see the National Guideline Clearinghouse (NGC) summary of the ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction.)

**For example, severe hepatic, pulmonary, or renal failure, or active/inoperable cancer. Clinical judgment is required in such cases

#Diagnostic angiography with intent to perform revascularization.

Chronic Kidney Disease **(2007 Update)**

1. Creatinine clearance should be estimated in UA/NSTEMI patients, and the doses of renally cleared drugs should be adjusted appropriately. (*Level of Evidence: B*) (New recommendation*)
2. In chronic kidney disease patients undergoing angiography, isosmolar contrast agents are indicated and are preferred. (*Level of Evidence: A*) (New recommendation*)

    *Based on the ACC/AHA 2007 UA/NSTEMI guidelines (see the NGC summary of the ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction.)

Patients With STEMI

General and Specific Considerations

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 left bundle-branch block 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*)

Specific Considerations

2. Primary PCI should be performed for patients less than 75 years old with ST elevation or presumably new left bundle-branch block 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*)
3. Primary PCI should be performed in patients with severe congestive heart failure 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 left bundle-branch block 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 congestive heart failure (*Level of Evidence: C*)
    b. Hemodynamic or electrical instability (*Level of Evidence: C*)
    c. Evidence of persistent ischemia (*Level of Evidence: C*)

Class IIb

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*)

Class III

1. Elective PCI should not be performed in a noninfarct-related artery at the time of primary PCI of the infarct related artery in patients without hemodynamic compromise. (*Level of Evidence: C*)
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*)

PCI in Fibrinolytic-Ineligible Patients

Class I

Primary PCI should be performed in fibrinolytic-ineligible patients who present with STEMI within 12 hours of symptom onset. (*Level of Evidence: C*)

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 congestive heart failure. (*Level of Evidence: C*)
b. Hemodynamic or electrical instability. (*Level of Evidence: C*)
c. Evidence of persistent ischemia. (*Level of Evidence: C*)

Facilitated PCI **(2007 Update)**

Class IIb

1. Facilitated PCI using regimens other than full-dose fibrinolytic therapy might be considered as a reperfusion strategy when all of the following are present:
    a. Patients are at high risk
    b. PCI is not immediately available within 90 minutes
    c. Bleeding risk is low (younger age, absence of poorly controlled hypertension, normal body weight).

    (*Level of Evidence: C*) (Modified recommendation [changed Level of Evidence and text])

Class III

1. A planned reperfusion strategy using full-dose fibrinolytic therapy followed by immediate PCI may be harmful. (*Level of Evidence: B*) (New recommendation)

PCI After Failed Fibrinolysis (Rescue PCI) **(2007 Update)**

Class I

1. A strategy of coronary angiography with intent to perform PCI (or emergency CABG) is recommended for patients who have received fibrinolytic therapy and have any of the following:

a. Cardiogenic shock in patients less than 75 years who are suitable candidates for revascularization. (*Level of Evidence: B*)
b. Severe congestive heart failure and/or pulmonary edema (Killip class III). (*Level of Evidence: B*)
c. Hemodynamically compromising ventricular arrhythmias. (*Level of Evidence: C*)

(Modified recommendation [changes Level of Evidence and text])

Class IIa

1. A strategy of coronary angiography with intent to perform PCI (or emergency CABG) is reasonable in patients 75 years of age or older who have received fibrinolytic therapy and are in cardiogenic shock, provided that they are suitable candidates for revascularization. (*Level of Evidence: B*) (Modified recommendation [changed text])
2. It is reasonable to perform rescue PCI for patients with 1 or more of the following:
    a. Hemodynamic or electrical instability. (*Level of Evidence: C*)
    b. Persistent ischemic symptoms. (*Level of Evidence: C*) (2005 recommendation remains current.)
3. A strategy of coronary angiography with intent to perform rescue PCI is reasonable for patients in whom fibrinolytic therapy has failed (ST-segment elevation less than 50% resolved after 90 minutes following initiation of fibrinolytic therapy in the lead showing the worst initial elevation) and a moderate or large area of myocardium at risk (anterior MI, inferior MI with right ventricular involvement or precordial ST-segment depression). (*Level of Evidence: B*) (New recommendation)

Class IIb

1. A strategy of coronary angiography with intent to perform PCI in the absence of 1 or more of the above Class I or IIa indications might be reasonable in moderate- and high-risk patients, but its benefits and risks are not well established. The benefits of rescue PCI are greater the earlier it is initiated after the onset of ischemic discomfort. (*Level of Evidence: C*) (Modified recommendation [changed classification of recommendation from III to IIb and changed text])

Class III

1. A strategy of coronary angiography with intent to perform PCI (or emergency CABG) is not recommended in patients who have received fibrinolytic therapy if further invasive management is contraindicated or the patient or designee does not wish further invasive care. (*Level of Evidence: C*) (New recommendation)

PCI After Successful Fibrinolysis or for Patients Not Undergoing Primary Reperfusion **(2007 Update)**

Class I

1. In patients whose anatomy is suitable, PCI should be performed when there is objective evidence of recurrent MI. (*Level of Evidence: C*) (2005 recommendation remains current.)
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*) (2005 recommendation remains current)
3. In patients whose anatomy is suitable, PCI should be performed for cardiogenic shock or hemodynamic instability. (*Level of Evidence: B*) (2005 recommendation remains current)

Class IIa

1. It is reasonable to perform routine PCI in patients with LV ejection fraction less than or equal to 0.40, HF, or serious ventricular arrhythmias. (*Level of Evidence: C*) (2005 recommendation remains current)
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*) (2005 recommendation remains current)

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. (*Level of Evidence: B*) (Modified recommendation [changed classification of recommendation/Level of Evidence and text])

Class III

1. PCI of a totally occluded infarct artery greater than 24 hours after STEMI is not recommended in asymptomatic patients with 1- or 2-vessel disease if they are hemodynamically and electrically stable and do not have evidence of severe ischemia. (*Level of Evidence: B*) (New recommendation)

PCI for Cardiogenic Shock

Class I

Primary PCI is recommended for patients less than 75 years old with ST elevation or left bundle-branch block 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*)

Class IIa

Primary PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block 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*)

Ancillary Therapy for Patients Undergoing (PCI) for STEMI **(2007 Update)**

Class I

1. For patients undergoing PCI after having received an anticoagulant regimen, the following dosing recommendations should be followed:
    a. For prior treatment with UFH, administer additional boluses of UFH as needed to support the procedure, taking into account whether GP IIb/IIIa receptor antagonists have been administered. (*Level of Evidence: C*) Bivalirudin may also be used in patients treated previously with UFH. (*Level of Evidence: C*) (New recommendation*)
    b. For prior treatment with enoxaparin, if the last subcutaneous dose was administered at least 8 to 12 hours earlier, an IV dose of 0.3 mg/kg of enoxaparin should be given; if the last subcutaneous dose was administered within the prior 8 hours, no additional enoxaparin should be given. (*Level of Evidence: B*) (New recommendation*)
    c. For prior treatment with fondaparinux, administer additional intravenous treatment with an anticoagulant possessing anti-IIa activity, taking into account whether GP IIb/IIIa receptor antagonists have been administered. (*Level of Evidence: C*) (New recommendation*)

Class III

1. Because of the risk of catheter thrombosis, fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered. (*Level of Evidence: C*) (New recommendation*)

    *Based on 2007 STEMI Focused Update (see the NGC summary of 2007 focused update of the ACC/AHA 2004 guidelines for the management of patients with ST-elevation myocardial infarction.

Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

Class I

1. When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG. (*Level of Evidence: B*)
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*)

Class IIa

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*)
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*)
3. PCI is reasonable in patients with diseased vein grafts more than 3 years after CABG. (*Level of Evidence: B*)
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*)

Class III

1. PCI is not recommended in patients with prior CABG for chronic total vein graft occlusions. (*Level of Evidence: B*)
2. PCI is not recommended in patients who have multiple target lesions with prior CABG and who have multivessel disease, failure of multiple saphenous vein grafts (SVGs), and impaired LV function unless repeat CABG poses excessive risk due to severe comorbid conditions. (*Level of Evidence: B*)

Use of Adjunctive Technology (Intracoronary Ultrasound Imaging, Flow Velocity, and Pressure)

Intravascular Ultrasound Imaging (IVUS)

Class IIa

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*)
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*)

Class IIb

Intravascular ultrasound (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*)

Coronary Artery Pressure and Flow: Use of Fractional Flow Reserve and Coronary Vasodilatory Reserve

Class IIa

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*)

Class IIb

1. Intracoronary physiologic measurements may be considered for the evaluation of the success of PCI in restoring flow reserve and to predict the risk of restenosis. (*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*)

Class III

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*)

Management of Patients Undergoing PCI

Evolution Technologies

Acute Results

Class I

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*)

Antiplatelet and Antithrombotic Adjunctive Therapies for PCI

Oral Antiplatelet Therapy **(2007 Update)**

Class I

1. Patients already taking daily long-term aspirin therapy should take 75 to 325 mg of aspirin before PCI is performed. (*Level of Evidence: A*) (2005 recommendation remains current.)
2. Patients not already taking daily long-term aspirin therapy should be given 300 to 325 mg of aspirin at least 2 hours and preferably 24 hours before PCI is performed. (*Level of Evidence: C*) (2005 recommendation remains current.)
3. After PCI, in patients without allergy or increased risk of bleeding, aspirin 162 to 325 mg daily should be given for at least 1 month after bare-metal stent (BMS) implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily long-term aspirin use should be continued indefinitely at a dose of 75 to 162 mg. (*Level of Evidence: B*) (Modified recommendation [changed text])
4. A loading dose of clopidogrel* generally 600 mg, should be administered before or when PCI is performed. (*Level of Evidence: C*) In patients undergoing PCI within 12 to 24 hours of receiving fibrinolytic therapy, a clopidogrel oral loading dose of 300 mg may be considered. (*Level of Evidence: C*) (Modified recommendation [changed Level of Evidence and text])
5. For all post-PCI patients receiving a drug-eluting stent (DES), clopidogrel 75 mg daily should be given for **at least 12 months** if patients are not at high risk of bleeding. For post PCI patients receiving a BMS, 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). (*Level of Evidence: B*) (Modified recommendation [changed text])

Class IIa

1. If clopidogrel is given at the time of procedure, supplementation with GP IIb/IIIa receptor antagonists can be beneficial. (*Level of Evidence: B*) (Modified recommendation [changed text])
2. For patients with an absolute contraindication to aspirin, it is reasonable to give a 300-mg to 600-mg loading dose of clopidogrel, administered at least 6 hours before PCI, and/or GP IIb/IIIa antagonists, administered at the time of PCI. (*Level of Evidence: C)* (Modified recommendation [changed text])
3. In patients for whom the physician is concerned about risk of bleeding, a lower dose of 75 to 162 mg of aspirin is reasonable during the initial period after stent implantation. (*Level of Evidence: C*) (New recommendation)
4. 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*)

5. 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*)

Class IIb

1. Continuation of clopidogrel therapy beyond 1 year may be considered in patients undergoing DES placement. (*Level of Evidence: C*) (New recommendation)

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*)

* Some uncertainty exists about optimal loading dose of clopidogrel. Randomized trials establishing its efficacy and providing data on bleeding risks used a loading dose of 300 mg orally followed by a daily oral dose of 75 mg. Higher oral loading doses such as 600 mg or 900 mg of clopidogrel more rapidly inhibit platelet aggregation and achieve a higher absolute level of inhibition of platelet aggregation, but the additive clinical efficacy and safety of higher oral loading doses have not been rigorously established.

Glycoprotein IIb/IIIa Inhibitors

Class I

In patients with UA/NSTEMI undergoing PCI without clopidogrel administration, a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban) should be administered. (*Level of Evidence: A*)*

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

In patients with STEMI undergoing PCI, treatment with eptifibatide or tirofiban may be considered. (*Level of Evidence: C*)

*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").

Recommendations for Use of GP IIb/IIIa Inhibitors in Patients Undergoing PCI

UA/NSTEMI and Clopidogrel Used	UA/NSTEMI and Clopidogrel Not Used	STEMI	Elective PCI
Abciximab, eptifibatide, or tirofiban *Class IIa; LOE: B*	Abciximab, eptifibatide, or tirofiban *Class I; LOE: A*	Abciximab *Class IIa; LOE: B* Eptifibatide or tirofiban *Class IIb; LOE: C*	Abciximab, eptifibatide, or tirofiban *Class IIa; LOE: B*

LOE indicates level of evidence

Antithrombotic Therapy

Unfractionated Heparin, Low-Molecular-Weight Heparin, and Bivalirudin

Class I

1. Unfractionated heparin should be administered to patients undergoing PCI. (*Level of Evidence: C*)
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace heparin. (*Level of Evidence: B*)

Class IIa

1. It is reasonable to use bivalirudin as an alternative to unfractionated heparin and glycoprotein IIb/IIIa 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*)

Class IIb

Low-molecular-weight heparin may be considered as an alternative to unfractionated heparin in patients with STEMI undergoing PCI. (*Level of Evidence: B*)

Post-PCI Management

Left Main CAD

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*)

Comprehensive Risk Reduction for Patients With Coronary and Other Vascular Disease After PCI (2007 Update)

ACC/AHA has revised its recommendation for risk reduction and secondary prevention for patients with coronary and other vascular disease after PCI, based on the 2006 AHA/ACC secondary prevention guidelines for patients with coronary and other atherosclerotic vascular diseases (see the NGC summary of AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update). Classes of recommendation and a corresponding level of evidence have been added for all recommendations. See Table 17 in the 2007 Focused Update document (see "Guideline Availability" field in this summary).

Special Considerations

Clinical Restenosis: Background and Management

Management Strategies for Restenosis After PTCA

Class IIa

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*)

Drug-Eluting and Bare-Metal Stents **(2007 Update)**

Class I

1. A DES should be considered as an alternative to a BMS in those patients for whom clinical trials indicate a favorable effectiveness/safety profile. (*Level of Evidence: A*) (Modified recommendation [changed text])
2. Before implanting a DES, the interventional cardiologist should discuss with the patient the need for and duration of dual antiplatelet therapy (DAT) and confirm the patient's ability to comply with the recommended therapy for DES. (*Level of Evidence: B*) (New recommendation)
3. In patients who are undergoing preparation for PCI and are likely to require invasive or surgical procedures for which DAT must be interrupted during the next 12 months, consideration should be given to implantation of a BMS or performance of balloon angioplasty with a provisional stent implantation instead of the routine use of a DES. (*Level of Evidence: C*) (New recommendation)

Class IIa

1. In patients for whom the physician is concerned about the risk of bleeding, a lower dose of 75 to 162 mg of aspirin is reasonable. (*Level of Evidence: C*) (New recommendation)

Class IIb

1. A DES may be considered for clinical and anatomic settings in which the effectiveness/safety profile appears favorable but has not been fully confirmed by clinical trials. (*Level of Evidence: C*) (Modified recommendation [changed text])

Management Strategies for In-Stent Restenosis (ISR)

Drug-Eluting Stents (DES)

Class IIa

It is reasonable to perform repeat PCI for ISR with a DES or a new DES for patients who develop ISR if anatomic factors are appropriate. (*Level of Evidence: B*)

Radiation

Class IIa

Brachytherapy can be useful as a safe and effective treatment for ISR. (*Level of Evidence: A*)

Exclusion Criteria for Invasive Cardiac Procedures in Settings Without Full-Support Services

Location	Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Hospitals	Adult	Age greater than 75 years NYHA class III or IV heart failure Acute, intermediate, or high-risk ischemic syndromes Recent MI with postinfarction ischemia Pulmonary edema thought to be caused by ischemia Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease	All valvuloplasty procedures, complex adult congenital heart disease diagnostic or therapeutic procedures Diagnostic pericardiocentesis when the effusion is small or moderate in size and there is no tamponade Elective coronary intervention

Location	Type of Patient	Diagnostic Procedures	Therapeutic Procedures
		Known left main coronary artery disease Severe valvular dysfunction, especially in the setting of depressed LV performance	
	Pediatric	No procedures approved	No procedures approved
Freestanding laboratories	Adult	All of the above plus high-risk patients by virtue of comorbid conditions, including need for anticoagulation, poorly controlled hypertension or diabetes, contrast allergy, or renal insufficiency	
	Pediatric	No procedures approved	No procedures approved

Definitions:

2005 Guideline

Strength of Recommendation

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.

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

Levels 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.

2007 Focused Update

Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT		
		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 objectives needed, registry data woul helpful* Procedure/Treatm **MAY BE CONSID**
Estimate of Certainty (Precision) of Treatment Effect	**LEVEL A** Multiple (3–5) population risk strata evaluated* General consistency of direction and magnitude of effect	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment of procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommen usefulness/ less well es • Greater cor evidence fr multiple ra trials or me analyses
	LEVEL B Limited (2–3) population risk strata evaluated*	• Recommendation that procedure or treatment is useful/effective • Limited evidence from single randomized trial or nonrandomized studies	• Recommendation in favor of treatment of procedure being useful/effective • Some conflicting evidence from single randomized trial or nonrandomized studies	• Recommen usefulness/ less well es • Greater cor evidence fr randomized nonrandom studies
	LEVEL C Very limited (1–2) population risk strata	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or	• Recommendation in favor of treatment of procedure being useful/effective • Only diverging expert opinion, case studies, or	• Recommen usefulness/ less well es • Only diverg opinion, ca or standard

		SIZE OF TREATMENT EFFECT		
	evaluated*	standard-of-care	standard-of-care	

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. 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. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

NOTE: In 2003, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All guideline recommendations 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 (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level. (See Table 1 in the Focused Update document for a list of suggested phrases for writing recommendations.)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

POTENTIAL HARMS

- Potential procedural complications of percutaneous coronary interventions (PCI) have been categorized as major (death, myocardial infarction [MI], and stroke) or minor (transient ischemic attack, access site complications, renal insufficiency, or adverse reactions to radiographic contrast). Additional specific complications include intracoronary thrombosis, coronary perforation, tamponade, and arrhythmias.

- Compared with bypass surgery, the disadvantages of percutaneous coronary intervention are early restenosis and the inability to relieve many totally occluded arteries and/or those vessels with extensive atherosclerotic disease.

Subgroups Most Likely to be Harmed

Coexistent clinical conditions can increase the complication rates for any given anatomic risk factor. For example, complications occurred in 15.4% of patients with diabetes versus 5.8% of patients without diabetes undergoing balloon angioplasty in a multicenter experience. Several studies have reported specific factors associated with increased risk of adverse outcome after percutaneous transluminal coronary angioplasty (PTCA). These factors include advanced age, female gender, unstable angina (UA), congestive heart failure (HF), diabetes, and multivessel coronary artery disease (CAD). Elevated baseline C-reactive protein (CRP) has recently also been shown to be predictive of 30-day death and MI. Other markers of inflammation, such asinterleukin-6 and other cytokines, have also been shown to be predictive of outcome.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications and Cautions for Fibrinolysis in ST-Elevation Myocardial Infarction (STEMI)*

Absolute Contraindications

- Any prior intracranial hemorrhage
- Known structural cerebral vascular lesion (e.g., indicates arteriovenous malformation [AVM])
- Known malignant intracranial neoplasm (primary or metastatic)
- Ischemic stroke within 3 months, EXCEPT acute ischemic stroke within 3 hours
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- Significant closed head or facial trauma within 3 months

Relative Contraindications

- History of chronic severe, poorly controlled hypertension
- Severe uncontrolled hypertension on presentation (systolic blood pressure (SBP) greater than 180 mm Hg or diastolic blood pressure (DBP) greater than 110 mm Hg)**
- History of prior ischemic stroke greater than 3 months, dementia, or known intracranial pathology not covered in contraindications
- Traumatic or prolonged (greater than 10 minutes) cardiopulmonary resuscitation (CPR) or major surgery (less than 3 weeks)
- Recent (within 2 to 4 weeks) internal bleeding
- Noncompressible vascular punctures
- For streptokinase/anistreplase: prior exposure (more than 5 days ago) or prior allergic reaction to these agents

- Pregnancy
- Active peptic ulcer
- Current use of anticoagulants: the higher the INR, the higher the risk of bleeding

*Viewed as advisory for clinical decision making and may not be all inclusive or definitive.

**Could be an absolute contraindication in low-risk patients with STEMI

2007 Focused Update

Acute fibrinolytic therapy is contraindicated for acute coronary syndrome (ACS) patients without ST-segment elevation, except for those with electrocardiographic true posterior myocardial infarction (MI) manifested as ST-segment depression in 2 contiguous anterior precordial leads and/or isolated ST-segment elevation in posterior chest lead.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

2005 Guideline

- These practice guidelines are intended to assist healthcare providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.
- Percutaneous coronary intervention (PCI) is a technique that has been continually refined and modified; hence, continued periodic guideline revision is anticipated. These guidelines are to be viewed as broad recommendations to aid in the appropriate application of PCI. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment and knowledge. They are intended for operators who possess the cognitive and technical skills for performing PCI and assume that facilities and resources required to properly perform PCI are available.

2007 Focused Update

- The American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines address patient populations (and health care providers) residing in North America. As such, drugs that are not currently available in

North America are discussed in the text without a specific class of recommendation. For studies performed in large numbers of subjects outside of North America, each writing committee reviews the potential impact of different practice patterns and patient populations on the treatment effect and on the relevance to the ACC/AHA target population to determine whether the findings should form the basis of a specific recommendation.

- The ACC/AHA practice guidelines are intended to assist health care providers in clinical decision making by describing a range of generally acceptable approaches for 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 health care provider and patient in light of all the circumstances presented by that patient. Thus, there are circumstances in which deviations from these guidelines may be appropriate. Clinical decision making should consider the quality and availability of expertise in the area where care is provided. These guidelines may be used as the basis for regulatory or payer decisions, but the ultimate goal is quality of care and serving the patient's best interests.
- Prescribed courses of treatment in accordance with these recommendations are only effective if they are followed by the patient. Because lack of patient adherence may adversely affect treatment outcomes, health care providers should make every effort to engage the patient in active participation with prescribed treatment.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

King SB 3rd, Smith SC Jr, Hirshfeld JW Jr, Jacobs AK, Morrison DA, Williams DO, Feldman TE, Kern MJ, O'Neill WW, Schaff HV, Whitlow PL, ACC/AHA/SCAI, Adams CD, Anderson JL, Buller CE, Creager MA, Ettinger SM, Halperin JL, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura R, Page RL, Riegel B, Tarkington

LG, Yancy CW. 2007 focused update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. J Am Coll Cardiol 2008 Jan 15;51(2):172-209. [161 references] PubMed

Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Assoc Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for PCI). Bethesda (MD): American College of Cardiology Foundation (ACCF); 2005. 122 p. [926 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jun (revised 2005; addendum released 2008 Jan)

GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association
Society for Cardiovascular Angiography and Interventions - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Cardiology Foundation and the American Heart Association. No outside funding is accepted.

GUIDELINE COMMITTEE

2005 Guideline

ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

2007 Focused Update

2007 Writing Group to Review New Evidence and Update the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention, Writing on Behalf of the 2005 Writing Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

2005 Guideline

Writing Committee Members: Sidney C. Smith, Jr, MD, FACC, FAHA, *Chair*; Ted E. Feldman, MD, FACC, FSCAI*; John W. Hirshfeld, Jr, MD, FACC, FSCAI*; Alice K. Jacobs, MD, FACC, FAHA, FSCAI; Morton J. Kern, MD, FACC, FAHA, FSCAI*; Spencer B. King, III, MD, MACC, FSCAI; Douglass A. Morrison, MD, PhD, FACC, FSCAI*; William W. O'Neill, MD, FACC, FSCAI; Hartzell V. Schaff, MD, FACC, FAHA; Patrick L. Whitlow, MD, FACC, FAHA; David O. Williams, MD, FACC, FAHA, FSCAI

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2007 Focused Update

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Task Force Members: Sidney C. Smith, JR, MD, FACC, FAHA, *Chair*; Alice K. Jacobs, MD, FACC, FAHA, *Vice-Chair*; Cynthia D. Adams, MSN, PHD, FAHA**; Jeffrey L. Anderson, MD, FACC, FAHA**; Christopher E. Buller, MD, FACC; Mark A. Creager, MD, FACC, FAHA; Steven M. Ettinger, MD, FACC; Jonathan L. Halperin, MD, FACC, FAHA**; Sharon A. Hunt, MD, FACC, FAHA**; Harlan M. Krumholz, MD, FACC, FAHA; Frederick G. Kushner, MD, FACC, FAHA; Bruce W. Lytle, MD, FACC, FAHA; Rick Nishimura, MD, FACC, FAHA; Richard L. Page, MD, FACC, FAHA; Barbara Riegel, DNSC, RN, FAHA**; Lynn G. Tarkington, RN; Clyde W. Yancy, MD, FACC

*Society for Cardiovascular Angiography and Interventions Representative

**Former Task Force member during this writing effort

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

2005 Guideline

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or

perceived 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 and reviewed by the writing committee as changes occur.

Table: ACC/AHA/SCAI Committee to Update 2002 Guidelines for Percutaneous Coronary Intervention--Relationships with Industry

Committee Member	Research Grant	Speakers Bureau/ Honoraria	Stock Ownership	Consultant
Dr. Ted E. Feldman	Abbot; Boston Scientific; Cardia; EV3; Evalve; Guidant	Boston Scientific	None	None
Dr. John W. Hirshfeld, Jr	None	None	None	None
Dr. Alice K. Jacobs	None	None	None	Wyeth
Dr. Morton J. Kern	None	None	None	None
Dr. Spencer B. King, III	Guidant	BMS-Sanofi; Guidant	None	Medtronic; Novoste
Dr. Douglass A. Morrison	None	None	None	None
Dr. William W. O'Neill	None	None	None	None
Dr. Hartzell V. Schaff	None	None	None	None
Dr. Sidney C. Smith, Jr	Merck	Bayer	Johnson & Johnson; Medtronic	Bristol-Myers; Squibb; Eli Lilly; Pfizer; Sanofi-Aventis
Dr. Patrick L. Whitlow	Abbot; Cordis, Inc; Fox Hollow Technologies; Lumend, Inc	None	Medtronic	None
Dr. David O.	None	None	None	None

Committee Member	Research Grant	Speakers Bureau/ Honoraria	Stock Ownership	Consultant
Williams				

Note: This table represents the relevant relationships of authors with industry that were reported orally at the initial writing committee meeting in July 2002 and updated in conjunction with all meetings and conference calls of the writing committee. It does not reflect any actual or potential relationships at the time of publication.

See Appendix 2 in the original 2005 guideline document for information about relationships with industry of the external peer reviewers of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention.

2007 Focused Update

Table. Author Relationships with Industry—Writing Group to Develop the 2007 Percutaneous Coronary Intervention Focused Update of the ACC/AHA/SCAI 2005 Guidelines for Percutaneous Coronary Intervention

Committee Member	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Board of Directors	Consultant/ Advisory Membe
Dr. John W. Hirshfeld, Jr.	None	None	None	None	None
Dr. Alice K. Jacobs	None	None	None	None	None
Dr. Spencer B. King III*	None	None	None	None	• Medtronic** • Sanofi-Aventis**
Dr. Douglass A. Morrison	None	None	None	None	None
Dr. Sidney C. Smith, Jr.*	None	• Bayer (Speaking Honorarium) • Sanofi-Aventis (Honorarium)	None	None	• Bristol-Myers Squibb • Eli Lilly • GlaxoSmith Kline • Pfizer • Sanofi-Avent
Dr. David O.	• Abbott • Boston	None	None	None	• Abbott**

Committee Member	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Board of Directors	Consultant/ Advisory Membe
Williams#	• Scientific • Cordis				• Cordis**

Note: This table represents the actual or potential relationships with industry that were reported as of September 24, 2007. This table was updated in conjunction with all conference calls of this writing committee. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of $10,000 or more 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 in this table are modest unless otherwise noted.

*Recused from voting on Section 7: Antiplatelet Therapy.
**Significant (greater than $10,000) relationship
#Recused from voting on Section 8: Bare-Metal and Drug-Eluting Stents.

See Appendix 2 in the 2007 focused update document for information about relationships with industry of the external peer reviewers of the 2007 percutaneous coronary intervention focused update of the ACC/AHA/SCAI 2005 guidelines for percutaneous coronary intervention.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun;37(8):2239i-lxvi.

GUIDELINE AVAILABILITY

2005 Guideline

Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology (ACC) Web site, the American Heart Association (AHA) Web site, and the Society for Cardiovascular Angiography and Interventions (SCAI) Web site.

2007 Focused Update

Electronic copies: Available in Portable Document Format (PDF) from the American College of Cardiology (ACC) Web site, the American Heart Association (AHA) Web site, and the Society for Cardiovascular Angiography and Interventions (SCAI) Web site.

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- 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). J Am Coll Cardiol 2006; 47:216-35. Available from the American College of Cardiology (ACC) Web site.

Also available in Circulation 2006 Feb; 113:e166-e286 and Catheter Cardiovasc Interv 2006 Jan;67(1):87-112.

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 17, 2001. The information was verified by the guideline developer on January 18, 2002. This summary was updated by ECRI on January 13, 2006. The updated information was verified by the guideline developer on March 22, 2006. This summary was updated by ECRI on March 6, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin sodium). This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on July 12, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Troponin-1 Immunoassay. This summary was updated by ECRI Institute on September 7, 2007 following the revised U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin). This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This NGC summary was updated by ECRI Institute on March 25, 2008. The updated information was verified by the guideline developer on August 4, 2008.

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Date Modified: 9/22/2008