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ACC/AHA PRACTICE GUIDELINES

ACC/AHA Guidelines for Percutaneous Coronary Intervention (Revision of the 1993 PTCA Guidelines)—Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty)

Endorsed by the Society for Cardiac Angiography and Interventions

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I. INTRODUCTION

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines was formed to gather information and make recommendations about appropriate use of technology for the diagnosis and treatment of patients with cardiovascular disease. Percutaneous coronary interventions (PCI) are an important group of technologies in this regard. Although initially limited to PTCA, and termed percutaneous transluminal coronary angioplasty (PTCA), PCI now includes other new techniques capable of relieving coronary narrowing. Accordingly, in this document, rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents and other catheter devices for treating coronary atherosclerosis are considered components of PCI. In this context PTCA will be used to refer to those studies using primarily PTCA while PCI will refer to the broader group of percutaneous techniques. These new technologies have impacted the effectiveness and safety profile initially established for PTCA. Moreover, important advances have occurred in the use of adjunctive medical therapies such as glycoprotein (GP) IIb/IIIa receptor blockers. In addition, since publication of the previous Guidelines in 1993, greater experience in the performance of PCI in patients with acute coronary syndromes and in community hospital settings has been gained. In view of these developments, further review and revision of the guidelines is warranted. This document reflects the opinion of the third ACC/AHA committee charged with revising the guidelines for PTCA to include the broader group of technologies now termed PCI.

Several issues relevant to the Committee's process and the interpretation of the Guidelines have been noted previously and are worthy of restatement. First, PCI is a technique that has been continually refined and modified; hence continued, periodic Guideline revision is anticipated. Second, 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. As in the past, the indications are categorized as Class I, II, or III based on a multifactorial assessment of risk as well as expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. Initially, this document describes the background information that forms the foundation for specific indications. Topics fundamental to coronary intervention are reviewed followed by separate discussions relating to unique technical and operational issues. **Formal recommendations for the use of angioplasty are included in Section V.** Indications are organized according to clinical presentation. This format is designed to enhance the usefulness of this document for the assessment and care of patients with coronary artery disease (CAD).

This document employs the ACC/AHA style classification as Class I, II, or III. These classes summarize the indications for PCI as follows:

Class I: **Conditions for which there is evidence for and/or general agreement that the procedure or treatment is 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.

The weight of evidence in support of the recommendation for each listed indication is presented as follows:

Level of Evidence A: **Data derived from multiple randomized clinical trials.**

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

Level of Evidence C: **Consensus opinion of experts.**

The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated as changes occur.

II. GENERAL CONSIDERATIONS AND BACKGROUND

More than 500,000 PCI procedures are performed yearly in the U.S., and it has been estimated that more than 1,000,000 procedures are performed annually worldwide. New coronary devices have expanded the clinical and anatomical indications for revascularization initially limited by balloon catheter angioplasty. For example, stents reduce both the acute risk of major complications and late-term restenosis. The success of new coronary devices in meeting these goals is in part represented by the less frequent use of PTCA alone (<30%) and the high (>70%) penetration of coronary stenting in the current practice of interventional cardiology. Atherectomy devices and stenting, associated with improved acute angiographic and clinical outcomes compared to PTCA, in specific subsets, continue to be applied to a wider patient domain that includes multivessel disease and complex coronary anatomy. However, strong evidence (level A data from multiple randomized clinical trials) is only available for stenting in selected patients undergoing single-vessel PCI. These Guidelines will focus on the Food and Drug Administration (FDA) approved balloon-related and nonballoon coronary revascularization devices.

III. OUTCOMES

The outcomes of coronary interventional procedures are measured in terms of success and complications and are related to the mechanisms of the employed devices, as well as the clinical and anatomic patient-related factors. With increased operator experience, new technology, and adjunctive pharmacotherapy, the overall success and complication rates of angioplasty have improved.

A. Definitions of PCI Success

The success of a PCI procedure may be defined by angiographic, procedural, and clinical criteria.

1. Angiographic Success. A successful PCI produces substantial enlargement of the lumen at the target site. The consensus definition prior to the widespread use of stents was the achievement of a minimum stenosis diameter reduction to <50% in the presence of grade 3 TIMI flow (assessed by angiography). However, with the advent of advanced adjunct technology, including coronary stents, a minimum stenosis diameter reduction to <20% has been the clinical benchmark of an optimal angiographic result.

2. Procedural Success. A successful PCI should achieve angiographic success without in-hospital major clinical complications (e.g., death, myocardial infarction [MI], emergency coronary artery bypass surgery [CABG]) during hospitalization. Although the occurrence of emergency artery coronary bypass surgery and death are easily identified end points, the definition of procedure-related MI has been debated. The development of Q-waves in addition to a threshold value of CK elevation has been commonly used. However, the significance of enzyme elevations in the absence of Q-waves remains a subject of investigation and debate. Several reports have identified non–Q-wave MIs with CK-MB elevations 3 to 5 times the upper limit of normal as having clinical significance. Thus a significant increase in CK-MB without Q-waves is considered by most to qualify as an associated complication of PCI.

If serial determinations are performed after PCI, an abnormally high value (CK-MB >1 times normal) can be expected in 10 to 15% of PTCA procedures, 15 to 20% of stent procedures, 25 to 35% of atherectomy procedures, and >25% for any device used in saphenous vein grafts (SVGs) or long lesions with a high atherosclerotic burden, even in the absence of other signs and symptoms of MI. There is no accepted consensus on what level of CK-MB index (with or without clinical or electrocardiographic [ECG] findings) is indicative of a clinically important MI following the interventional procedure. Cardiac troponin T and I have now been introduced as measurements of myocardial necrosis and have been proven to be more sensitive and specific than CK-MB. However, prognostic criteria after PCI based on troponin T and I have not yet been developed. The Writing Committee recommends that CK-MB determination be performed on all patients who have signs or symptoms suggestive of MI following the procedure or in patients in

Table 1. Definitions of Procedural Complications

Procedural Complications	Definitions
Primary cause of death	Patient died during this hospitalization
Periprocedural MI	The NEW presence of an MI as documented by at least 1 of the following criteria: 1. Evolutionary ST-segment elevations, development of new Q-waves in 2 or more contiguous ECG leads, or new or presumably new LBBB pattern on the ECG 2. Biochemical evidence of myocardial necrosis; this can be manifested as 1) CK-MB ≥3 × the upper limit of normal or if CK-MB not available (2) total CK ≥3 × upper limit of normal. Because normal limits of certain blood tests may vary, please check with your lab for normal limits for CK-MB and total CK
CABG during this admission	If the patient had a CABG during this admission indicate the CABG status using the following categories: I. Elective: The procedure could be deferred without increased risk of compromised cardiac outcome II. Urgent: All of the following conditions are met: A. Not elective B. Not emergency C. Procedure required during same hospitalization in order to minimize chance of further clinical deterioration III. Emergency: The patient's clinical status includes any of the following: A. Ischemic dysfunction (any of the following): 1. Ongoing ischemia including rest angina despite maximal medical therapy (medical and/or IABP) 2. Acute evolving MI within 24 hours before intervention 3. Pulmonary edema requiring intubation B. Mechanical dysfunction (either of the following): 1. Shock with circulatory support 2. Shock without circulatory support IV. Salvage: The patient is undergoing CPR en route to the Operating Room
CVA/Stroke	Patient experienced a cerebrovascular accident (CVA) as documented by a loss of neurological function caused by an ischemic event with residual symptoms at least 24 hours after onset
Vascular complications	
Bleeding	Blood loss at the site of arterial or venous access or due to perforation of a traversed artery or vein requiring transfusion and/or prolonging the hospital stay, and/or causing a drop in hemoglobin >3.0 gm/dl. Bleeding attributable to the vascular site could be retroperitoneal, a local hematoma >10 cm diameter or external
Occlusion	A total obstruction of the artery usually at the site of access requiring surgical repair. Occlusion is defined as total obstruction of the artery by thrombus, dissection or other mechanism, usually at the site of access, requiring surgical repair. Occlusion may be accompanied by absence of palpable pulse or Doppler signal and associated with signs and symptoms of an ischemic limb requiring surgical intervention
Dissection	A dissection occurred at the site of percutaneous entry. Dissection is defined as disruption of an arterial wall resulting in splitting and separation of the intimal (or subintimal) layers
Pseudoaneurysm	Pseudoaneurysm is defined as the occurrence of an aneurysmal dilatation of the artery at the site of catheter entry demonstrated by arteriography or ultrasound
AV fistula	AV fistula is defined as a connection between the access artery (e.g., femoral) and access vein (e.g., femoral) that is demonstrated by an imaging study (arteriography or ultrasound) and most often characterized by a continuous bruit
Renal failure	After the lab visit—but before any subsequent lab visits only: Indicate if the patient experienced acute renal insufficiency resulting in an increase in serum creatinine to more than 2.0 mg/dl (or a 50% or greater increase over an abnormal baseline) measured prior to procedure, or requiring dialysis

CABG = coronary artery bypass graft; CK = creatine kinase; CPR = cardiopulmonary resuscitation; ECG = electrocardiographic; IABP = intra-aortic balloon pump; LBBB = left bundle-branch block; MI = myocardial infarction.

whom there is angiographic evidence of abrupt vessel closure, important side branch occlusion, or new and persistent slow coronary flow. In patients in whom a clinically driven CK-MB determination is made, a CK-MB of >3 times the upper limit of normal would constitute a clinically significant MI.

3. Clinical Success. In the short term, a clinically successful PCI includes anatomic and procedural success with relief of signs and/or symptoms of myocardial ischemia after the patient recovers from the procedure. The long-term clinical success requires that the short-term clinical success remains durable and that the patient has persistent relief of signs and symptoms of myocardial ischemia for more than 6 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success when a short-term clinical success has been achieved.

B. Definitions of Procedural Complications

As outlined in the 1998 coronary interventional document, procedural complications are divided into six basic categories: death, MI, emergency CABG, stroke, vascular access site complications, and contrast agent nephropathy. Key data elements and definitions to measure the clinical management and outcomes of patients undergoing diagnostic catheterization and/or PCI have been defined in the Clinical Data Standards document and the ACC-National Cardiovascular Data Registry™ Catheterization Laboratory

Table 2. Selected Trials of Pharmacologic and Mechanical Approaches to Limit Restenosis

Study	Year	N	Agent	Restenosis Rate (%)	
				Placebo or Control	Agent
Schwartz	1988	376	Aspirin and Dipyridamole	39	38
Ellis	1989	416	Heparin	37	41
Pepine	1990	915	Methylprednislone	39	40
CARPORT	1991	649	Vapiprost	19	21
O'Keefe	1991	197	Colchicine	22	22
MERCATOR	1992	735	Cilazapril	28	28
CAVEAT*	1993	500	DCA vs. PTCA	57	50
CCAT	1993	136	DCA vs. PTCA	43	46
Serruys	1993	658	Ketanserin	32	32
BENESTENT*	1994	520	Stent vs. PTCA	32	22
ERA	1994	458	Enoxaparin	51	52
Leaf	1994	551	Fish Oil	46	52
STRESS*	1994	410	Stent vs. PTCA	42	32
Weintraub	1994	404	Lovastatin	42	39
BOAT*	1996	492	DCA vs. PTCA	40	31
Wantanabe*	1996	118	Probucol	40	20
Tardif*	1997	317	Probucol	39	21
BENESTENT II*	1998	823	Stent vs. PTCA	31	17
TREAT*	1999	255	Tranilast	39	18
PRESTO*	2000	192	DCA and Tranilast	26	11

*$p < 0.05$.
DCA = Directional Coronary Atherectomy; PTCA = percutaneous transluminal coronary angioplasty.

Module version 2.0. These rigorous definitions for key adverse events are endorsed by this Writing Committee for inclusion in the present PCI Guidelines (Table 1).

C. Acute Outcome

Improvements in balloon technology coupled with the increased use of nonballoon devices, particularly stents (which are effective in treating abrupt vessel closure) and GP IIb/IIIa platelet receptor antagonists have favorably influenced acute procedural outcome. This combined balloon/device/pharmacologic approach to coronary intervention in elective procedures has resulted in angiographic success rates of 96 to 99%, with Q-wave MI rates of 1 to 3%, emergency coronary bypass surgery rates of 0.2 to 3%, and unadjusted in-hospital mortality rates of 0.5 to 1.4%.

D. Long-Term Outcome and Restenosis

Although improvements in technology, including stents and new pharmacologic therapy, have resulted in an improved acute outcome of the procedure, the impact of these changes on long-term (5 to 10 years) outcome may be less dramatic where factors such as advanced age, reduced left ventricular (LV) function, and complex multivessel disease in patients currently undergoing PCI may have a more important influence. In addition, available data on long-term outcome are mostly limited to patients undergoing PTCA. Ten-year follow-up of the initial cohort of patients treated with PTCA revealed an 89.5% survival rate (95% in patients with single-vessel disease, 81% in patients with multivessel disease). In patients within the 1985–1986 NHLBI PTCA Registry, 5-year survival was 92.9% for patients with single-vessel disease, 88.5% for those with 2-vessel disease, and 86.5% for those with 3-vessel disease. In patients with multivessel disease undergoing PTCA in BARI, 5-year survival was 86.3% and infarct-free survival was 78.7%. Specifically, 5-year survival was 84.7% in patients with 3-vessel disease and 87.6% in patients with 2-vessel disease.

In addition to the presence of multivessel disease, other clinical factors adversely impact late mortality. In randomized patients with treated diabetes in BARI, the 5-year survival was 65.5%, and the cardiac mortality was 20.6% in comparison to 5.8% cardiac mortality in patients without treated diabetes, although among eligible but not randomized diabetic patients, the 5-year cardiac mortality was 7.5%. In the 1985–1986 NHLBI PTCA Registry, 4-year survival was significantly lower in women (89.2%) in comparison to men (93.4%). In addition, although LV dysfunction was not associated with an increase in in-hospital mortality or nonfatal MI in patients undergoing PTCA in the same registry, it was an independent predictor of a higher long-term mortality.

A major determinant of event-free survival following coronary intervention is the incidence of restenosis which had, until the development of stents, remained fairly constant, despite multiple pharmacologic and mechanical approaches to limit this process (Table 2). Depending on the definition, (i.e., whether clinical or angiographic restenosis or target lesion revascularization is measured), the incidence of restenosis following coronary intervention had been 30 to 40%, and higher in certain clinical and angiographic subsets.

Although multiple clinical factors (diabetes, unstable angina, acute MI, prior restenosis), angiographic factors (proximal left anterior descending artery, small vessel diameters, total occlusion, long lesion length, SVG), and procedural factors (higher post-procedure percent diameter ste-

Table 3. Studies Comparing Balloon Angioplasty With Stents for Native Coronary Artery Lesions

Study	Year	Follow-Up, Month	N, Stent/ Angioplasty	Angiographic Restenosis, %			Target-Vessel Revascularization (TVR), %			Death, MI, or TVR, %	
				Stent	Angioplasty	p Value	Stent	Angioplasty	p Value	Stent	Angioplasty
STRESS	1994	6	205/202	31.6	42.1	0.046	10.2	15.4	0.06	19.5	23.8
BENESTENT*	1996	12	259/257	—	—	—	10	21	0.001	23.2	31.5
TASC I	1995	6	270 (Overall)†	31	46	0.01	—	—	—	—	—
Versaci et al.	1997	12	60/60	19	40	0.02	6.6	22	—	—	—
STRESS II	1998	12	100/89	—	—	—	10	20	—	17	34
BENESTENT II	1998	6	413/410	16	31	<0.001	8‡	13.7	0.02	12.8	19.3
OCBAS	1998	7	57/59	18.8	16.6	—	17.5	9.2	—	19.2	16.9
EPISTENT§	1998	6	1603/796	—	—	—	8.7	15.4	<0.001	13	20.5
START	1999	6/48‖	229/223	22	37	<0.002	12	24.6	<0.002	16.9	29.9
OPUS	2000	6	479 (Overall)	—	—	—	3.0	10.1	0.003	6.1	14.9

*Any event at one year; †122 patients in the TASC I trial had treated restenotic lesions; ‡any repeat procedure; §stent plus abciximab vs. percutaneous transluminal coronary angioplasty plus abciximab; ‖6 months angiographic follow-up and 48 months clinical follow-up.

MI = myocardial infarction; dashes (—) = data not reported for that category. Data are for lesions in coronary arteries with vessel diameter ≥3.0 mm. Adapted from Suwaidi MB, et al. JAMA 2000;284:1828–36.

nosis, smaller minimal lumen diameter, and smaller acute gain), have been associated with an increased incidence of restenosis, the ability to integrate these factors and predict the risk of restenosis in individual patients following the procedure remains difficult. The most promising potential approaches to favorably impact the restenosis process relate to: 1) the ability to decrease elastic recoil and remodeling using intracoronary stents, and 2) to the ability to reduce intimal hyperplasia using catheter-based ionizing radiation. More than 6,300 patients have been studied in 12 randomized clinical trials to assess the efficacy of PTCA vs. stents to reduce restenosis (Table 3).

In addition, randomized studies in patients with in-stent restenosis have shown that both intracoronary gamma and beta radiation significantly reduced the rate of subsequent angiographic and clinical restenosis by 30 to 50%.

E. Predictors of Success/Complications

1. Anatomic Factors. The risk of PTCA in the pre-stent era relative to anatomic subsets has been identified in previous NHLBI PTCA Registry data and by the ACC/AHA Task Force. The lesion classification based on severity of characteristics proposed in the past has been principally altered using the present PCI techniques, which capitalize on the ability of stents to manage initial and subsequent complications of coronary interventions. As a result the Committee has revised the previous ACC/AHA lesion classification system to reflect low, moderate, and high risk (Table 4) in accordance with the PCI Clinical Data Standards from the ACC-National Cardiovascular Data Registry™.

2. Clinical Factors. Coexistent clinical conditions can increase the complication rates for any given anatomic risk factor. The clinical risk factors associated with in-hospital adverse events have been further evaluated with additional experience during the PCI era and summarized based on odds ratio >2.0 or results of multivariate analysis (Table 5).

3. Risk of Death. In the majority of patients undergoing elective PCI, death as a result of PCI is directly related to the occurrence of coronary artery occlusion and is most frequently associated with pronounced LV failure. The clinical and angiographic variables associated with increased mortality include advanced age, female gender, diabetes, prior MI, multivessel disease, left main or equivalent coronary disease, a large area of myocardium at risk, pre-existing

Table 4. Lesion Classification System

Anatomic Risk Groups* 2000 PCI Stent Era
Low Risk
Discrete (length <10 mm)
Concentric
Readily accessible
Nonangulated segment (<45°)
Smooth contour
Little or no calcification
Less than totally occlusive
Not ostial in location
No major side branch involvement
Absence of thrombus
Moderate Risk
Tubular (length 10–20 mm)
Eccentric
Moderate tortuosity of proximal segment
Moderately angulated segment (>45°, <90°)
Irregular contour
Moderate or heavy calcification
Total occlusions <3 months old
Ostial in location
Bifurcation lesions requiring double guidewires
Some thrombus present
High Risk
Diffuse (length >20 mm)
Excessive tortuosity of proximal segment
Extremely angulated segments >90°
Total occlusions >3 months old and/or bridging collaterals
Inability to protect major side branches
Degenerated vein grafts with friable lesions

*This classification of lesion risk is cited from the ACC-National Cardiovascular Data Registry™ Catheterization Laboratory Module version 2.0. This classification scheme is also cited in the ACC Clinical Data Standards.

PCI = percutaneous coronary interventions.

Table 5. Clinical Risk Factors Associated With In-Hospital Adverse Events*

Variables	Definitions
Age	Date of birth as stated by the patient or family
Gender	Male or female
LVEF-calculated	Calculated by LV gram, echo, blood pool scan
LVEF-estimated	Estimated by LV gram, echo, blood pool scan
No. of vessels >70%	By angiography measured, quantified or estimated diameter stenosis; "vessel" defined as RCA and its branches, proximal LAD (before 1st diagonal), mid/distal LAD and its branches, and Cx and its branches
Unstable angina	Progressive or new onset or occurs at rest accompanied by ECG changes, hypotension or pulmonary congestion
CCS Class IV	Highest CCS angina class leading to hospital admission and/or intervention: 0 = no angina by Hx
CHF	Hx of CHF before intervention
MI at this admission	Within 24 h of AMI
Previous MI	>1 day; <7 days of AMI
Urgency of the procedure	*Elective:* patient clinically stable; procedure routinely scheduled *Urgent:* unstable patient: procedure scheduled before discharge *Emergent/ongoing ischemia:* ongoing ischemia including rest angina despite maximal therapy (medical or IABP) *Emergent/salvage:* arrest with CPR immediately before entering lab
Cardiogenic shock	Hypoperfusion with SBP <80 mm Hg and central filling pressure >20 mm Hg or cardiac index <1.8 liters/min/m^2; also present if inotropes or IABP needed to maintain these values
Preprocedural IABP/CPS	IABP/CPS assisted device placed before intervention
Aortic valve disease	Aortic valve area <1.0 cm^2 and/or Aortic regurgitation >2+
Mitral regurgitation >2+	Presence of mitral regurgitation >2+
Diabetes (treated)	Clinical diagnosis of diabetes treated either with oral agents or insulin with or without sequelae
PVD	Presence of occlusive disease in the aorta, iliac, or femoral artery sufficient to cause symptoms
Stroke	Hx of presence of fixed neurological deficit
Creatinine	If creatinine preintervention known, list creatinine
Creatinine >2 mg/dl	Creatinine >2 mg/dl known in past
Dialysis	Patient on dialysis
Cholesterol >225 mg/dl (reduced risk)	Measure cholesterol > 225 mg/dl before intervention
Same vessel intervention (reduced risk)	Any previous intervention on same vessel
Type C lesions attempted	Type A: concentric noncalcified, <10 mm in length, not bifurcated or angulated. Type C: total occlusion. Type B: all others (ACC/AHA)
LMCA attempted-unprotected	Intervention involving all or part of LMCA
LMCA attempted-protected	"Protected" LMCA stenosis by patent bypass conduit
Vein graft intervention	Any intervention to SVG or IMA
Thrombus	Intraluminal filling defect, haziness or contrast staining in artery before intervention

*Note: More than 50% of databases that evaluated the variable showed an odds ratio >2.0 or variable chosen on multivariable analysis. The definition of variables defined herein varies slightly from those agreed upon in the ACC Clinical Data Standards.

AMI = acute myocardial infarction; CCS = Canadian Cardiovascular Society; CHF = congestive heart failure; CPR = cardiopulmonary resuscitation; CPS = cardiopulmonary support; Cx = circumflex; ECG = electrocardiogram; Hx = history; IABP = intra-aortic balloon pump; IMA = internal mammary artery; LAD = left anterior descending coronary artery; LMCA = left main coronary artery; LV = left ventricle; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PVD = peripheral vascular disease; RCA = right coronary artery; SBP = systolic blood pressure; SVG = saphenous vein graft. Adapted with permission from Block P, et al. J Am Coll Cardiol. 2000;32:275–82.

impairment of LV or renal function, and collateral vessels supplying significant areas of myocardium that originate distal to the segment to be dilated (Table 5).

4. Women. In comparison to men, women undergoing PCI are older and have a higher incidence of hypertension, diabetes mellitus, hypercholesterolemia, and comorbid disease. Early reports of patients undergoing PTCA revealed a lower procedural success rate in women; however, more recent studies have noted similar angiographic outcome and incidence of MI and emergency coronary bypass surgery in women and men. Although reports have been inconsistent, in several large-scale registries, in-hospital mortality is significantly higher in women and an independent effect of gender on acute mortality following PCI persists after adjustments for the baseline higher-risk profile in women.

5. The Elderly Patient. Age >75 years is one of the major clinical variables associated with increased risk of complications. In the elderly population, the morphologic and clinical variables are compounded by advanced years with the very elderly having the highest-risk of adverse outcomes. In the stent era, procedural success rates and short-term outcomes are comparable to those for nonoctogenarians. Thus, with rare exception (primary PCI for cardiogenic shock for patients >75 years), a separate category has not been created in these Guidelines for the elderly. However, their higher incidence of comorbidities should be taken into account when considering the need for PCI.

6. Diabetes Mellitus. In the TIMI-IIB study of MI, patients with diabetes mellitus had significantly higher 6-week (11.6% vs. 4.7%), 1-year (18.0% vs. 6.7%), and 3-year (21.6% vs. 9.6%) mortality rates compared to nondiabetic patients. The BARI trial, in which stents and abciximab were not used, showed that survival was better for patients with treated diabetes undergoing CABG with an arterial conduit than for those undergoing angioplasty. Stenting decreases the need for target revascularization

procedures in diabetic patients compared with PTCA. The efficacy of stenting with GP IIb/IIIa inhibitors was assessed in the diabetic population compared to those without diabetes in a substudy of the EPISTENT trial. Irrespective of revascularization strategy abciximab significantly reduced 6-month death and MI rates in patients with diabetes for all strategies. Likewise, 6-month target-vessel revascularization was reduced in the stent/abciximab group approach.

7. Coronary Angioplasty After Coronary Artery Bypass Surgery. Although speculated to be at higher risk, patients having PCI of native vessels after prior coronary bypass surgery have, in recent years, nearly equivalent interventional outcomes and complication rates compared to patients having similar interventions without prior surgery. For PCI of SVG, studies indicate that the rate of successful angioplasty exceeds 90%, death <1.2%, Q-wave MI <2.5%. The incidence of non–Q-wave MI may be higher than that associated with native coronary arteries.

Use of GP IIb/IIIa blockers has not been shown to improve results of angioplasty in vein grafts. The native vessels should be treated with PCI if feasible. Patients with older and/or severely diseased SVGs may benefit from elective repeat coronary artery bypass graft surgery rather than PCI.

8. Specific Technical Considerations. Certain outcomes of PCI may be specifically related to the technology utilized for coronary recanalization. Antecedent unstable angina appears to be a clinical predictor of slow flow and periprocedural infarction following ablative technologies and direct platelet activation has been demonstrated to occur with both directional and rotational atherectomy.

Coronary perforation may occur more commonly following the use of ablative technologies including rotational, directional or extraction atherectomy, and excimer laser coronary angioplasty. Coronary perforation complicates PCI more frequently in the elderly and in women. While 20% of perforations may be secondary to the coronary guidewire, most are related to the specific technology used.

9. Issues of Hemodynamic Support in High-Risk Angioplasty. Elective high-risk PCI can be performed safely without intra-aortic balloon pump (IABP) or cardiopulmonary support (CPS) in most circumstances. Emergency high-risk PCI such as direct PCI for acute MI can usually be performed without IABP or CPS. CPS for high-risk PCI should be reserved only for patients at the extreme end of the spectrum of hemodynamic compromise, such as those patients with extremely depressed LV function and patients in cardiogenic shock. However, it should be noted that in patients with borderline hemodynamics, ongoing ischemia, or cardiogenic shock, insertion of an intra-aortic balloon just prior to coronary instrumentation has been associated with improved outcomes. Furthermore, it is reasonable to obtain vascular access in the contralateral femoral artery prior to the procedure in patients in whom the risk of hemodynamic compromise is high, thereby facilitating intra-aortic balloon insertion, if necessary.

In patients having a higher-risk profile, consideration of alternative therapies, particularly CABG, formalized surgical standby, or periprocedural hemodynamic support should be addressed before proceeding with PCI.

F. Comparison With Bypass Surgery

The major advantage of PCI is its relative ease of use, avoiding general anesthesia, thoracotomy, extracorporeal circulation, CNS complications, and prolonged convalescence. Repeat PCI can be performed more easily than repeat bypass surgery, and revascularization can be achieved more quickly in emergency situations. The disadvantages of PCI are early restenosis and the inability to relieve many totally occluded arteries and/or those vessels with extensive atherosclerotic disease.

Coronary artery bypass surgery has the advantages of greater durability (graft patency rates exceeding 90% at 10 years with arterial conduits) and more complete revascularization irrespective of the morphology of the obstructing atherosclerotic lesion. Generally speaking, the greater the extent of coronary atherosclerosis and its diffuseness, the more compelling the choice of CABG, particularly if LV function is depressed. Patients with lesser extent of disease and localized lesions are good candidates for endovascular approaches.

Percutaneous transluminal coronary angioplasty and CABG have been compared in many nonrandomized and randomized studies. The most accurate comparisons of outcomes are best made from prospective randomized trials of patients suitable for either treatment. Although results of these trials provide useful information for selection of therapy in several patient subgroups, prior studies of PTCA may not reflect outcome of current PCI practice, which includes frequent use of stents and antiplatelet drugs. Similarly, many previous studies of CABG may not reflect outcome of current surgical practice in which arterial conduits are used whenever practicable. Beating heart bypass operations are also employed for selected patients with single-vessel disease with reduced morbidity. In addition, patients are selected for PCI (with or without stenting) because of certain lesion characteristics, and these anatomical criteria are not required for CABG.

Despite these limitations, some generalizations can be made from comparative trials of PTCA and CABG. First, for most patients with single-vessel disease, late survival is similar with either revascularization strategy, and this might be expected given the generally good prognosis of most patients with single-vessel disease managed medically.

In the ARTS trial, the first trial to compare stenting with surgery, there was no significant difference in mortality between PCI and surgical groups at one year. The main difference compared to previous PTCA and CABG trials was an approximate 50% reduction in the need for repeat revascularization in a group randomized to PCI with stent placement.

Direct comparison of initial strategies of PCI or CABG

in patients with multivessel coronary disease is possible only by randomized trials because of selection criteria of patients for PCI. There have been five large (>300 patients) randomized trials of PTCA versus CABG and two smaller studies. These trials demonstrate that in appropriately selected patients with multivessel coronary disease, an initial strategy of standard PTCA yields similar overall outcomes (e.g., death, MI) compared to initial revascularization with coronary artery bypass.

An important exception to the conclusion of the relative safety of PCI in multivessel disease is the subgroup of patients with treated diabetes mellitus. Among treated diabetic patients in BARI assigned to PTCA, 5-year survival was 65.5% compared to 80.6% for patients having CABG ($p = 0.003$); the improved outcome with CABG was due to reduced cardiac mortality (5.8% vs. 20.6%, $p = 0.0003$), which was confined to those receiving at least one internal mammary artery graft.

G. Comparison With Medicine

There has been a considerable effort made to evaluate the relative effectiveness of bypass surgery as compared to PCI for coronary artery revascularization. In contrast to this, very little effort has been directed toward comparing medical therapy with PCI for the management of stable and unstable angina.

Based on the limited data available from randomized trials (Table 6) comparing medical therapy with PTCA, it seems prudent to consider medical therapy for the initial management of most patients with Canadian Cardiovascular Society Classification Class I and II and reserve PTCA and CABG for those patients with more severe symptoms and ischemia. The symptomatic individual patient who wishes to remain physically active, regardless of age, will more often require PCI. The results of the ACIP trial indicate that higher-risk patients with asymptomatic ischemia and significant CAD who undergo complete revascularization with CABG or PTCA may have a better outcome as compared to those with medical management.

IV. INSTITUTIONAL AND OPERATOR COMPETENCY

A. Quality Assurance

A mechanism for valid peer review must be established and ongoing at each institution performing PCI. Interventional cardiology procedures are associated with complications that in general are inversely related to operator and institutional volume. The mechanism for institutional review should provide an opportunity for interventionalists as well as physicians who do not perform angioplasty, but are knowledgeable about it, to review overall results of the program on a regular basis. The responsible supervising authority should monitor the following issues as outlined in Table 7.

The institutional credentialing committee should document that an interventionalist wishing to start practice meets the established training criteria, including those of the ACC Task Force on Training in Cardiac Catheterization and Interventional Cardiology. This Writing Committee agrees with the ACC Task Force recommendations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures. Institutions performing PCI should meet the following standards as outlined in Tables 8 and 9.

B. Operator and Institutional Volume

The proliferation of small angioplasty or small surgical programs to support such angioplasty programs is strongly discouraged. Several studies have identified procedural volume as a determining factor for frequency of complications with PCI.

Although some investigators have suggested that low procedure volume does not contribute to poor outcomes, these studies are small in number and underpowered for analysis. Development of small cardiovascular surgical programs to support angioplasty is a poor use of resources that will likely lead to suboptimal results.

Given the concerns regarding operator volume and surgical standby, it is recommended that PCI be performed by higher volume operators (≥75 cases/year) with advanced technical skills (e.g., subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Similar concerns have been identified and supported by the Task Force for Practice Guidelines for Coronary Angiography.

This Committee acknowledges that not every cardiologist desiring to do PCI should perform these procedures and not every hospital anxious to have an interventional program should start one. This caveat is particularly true where there are high-volume programs and operators nearby. In these situations, operators should be subspecialty board certified.

Recommendations for PCI Institutional and Operator Volumes at Centers With On-Site Cardiac Surgery

Class I

1. **PCI done by operators with acceptable volume (≥75) at high-volume centers (>400).** ***(Level of Evidence: B)***

Class IIa

1. **PCI done by operators with acceptable volume (≥75) at low-volume centers (200 to 400).** ***(Level of Evidence: C)***
2. **PCI done by low volume operators (<75) at high-volume centers (>400). Note: Ideally operators with annual procedure volume <75 should only work at institutions with an activity level of >600 procedures/year.*** ***(Level of Evidence: C)***

Class III

1. **PCI done by low volume operators (<75) at low-volume centers (200 to 400). Note: An institution**

Table 6. PCI Comparison With Medical Therapy

Study	Year	N	Patient Population	Treatment	Follow-Up	Results			Comments
						PCI	Medical Therapy	Significance	
ACME	1992	212	Patients with single-vessel disease	Medical therapy vs. balloon angioplasty		64% less angina	46% less angina	$p < 0.01$	The PTCA group had less angina, better exercise performance and more improvement in quality of life scores, but had more complications (emergency bypass 2 patients, MI in 5, and repeat PTCA in 16).
VA ACME	1997	328	Patients with documented chronic stable angina 227 single-vessel disease 101 double-vessel disease	Medical therapy vs. balloon angioplasty	3 years	63% less angina	48% less angina	$p = 0.02$	Among patients with single-vessel disease, the PTCA group had less angina, better exercise performance, and more improvement in quality of life scores.
RITA-2	1997	1018	53% with Class II angina 47% with prior angina 7% triple-vessel disease	Medical therapy vs. balloon angioplasty	2.7 years	6.3% death or MI	3.3% death or MI	$p = 0.02$	The PTCA group had increased rates of death and MI, but had 7% less Class II angina at 2 years and longer exercise treadmill test time at 3 months.
ACIP	1997	558	Patients with documented CAD and asymptomatic ischemia 183 angina-guided drug therapy 183 angina plus ischemia-guided drug therapy 192 revascularization by PTCA or CABG	Angina-guided drug therapy vs. angina plus ischemia-guided drug therapy vs. revascularization	2 years	4.7% death or MI	8.8% death or MI for ischemia-guided drug therapy 12.1% death or MI for angina-guided drug therapy	$p < 0.01$	40% of patients had previous MI, 23% had prior PTCA or CABG and 38% had triple-vessel disease.
AVERT	1999	341	Patients with stable CAD, normal LV function and angina Class I/II	Medical therapy with atorvastatin vs PTCA	18 months	21% ischemic events	13% ischemic events	$p = 0.048$	$p = 0.045$ needed for significance due to interim analysis. Patients required to complete 4 minutes on Bruce protocol. Only 2 deaths among 341 patients in 18 months. Significant improvement in angina in patients treated with PTCA compared with medical therapy.

CABG = coronary artery bypass graft; CAD = coronary artery disease; LV = left ventricular; MI = myocardial infarction; PCI = percutaneous coronary intervention; PTCA = percutaneous transluminal coronary angioplasty.

Table 7. Key Components of a Quality Assurance Program

Clinical proficiency	• General indications/contraindications • Institutional and individual operator complication rates, mortality and emergency bypass surgery • Institutional and individual operator procedure volumes • Training and qualifications of support staff
Equipment maintenance and management	• Quality of laboratory facility (See ACC/SCA&I Expert Consensus Document on Cardiac Catheterization Laboratory Standards)
Quality improvement process	• Establishment of an active concurrent database to track clinical and procedural information as well as patient outcomes for individual operators and the institution. The ACC-National Cardiovascular Data Registry™ is strongly recommended for this purpose
Radiation safety	• Educational program in the diagnostic use of X-ray • Patient and operator radiation exposure

Table 8. Considerations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures

Institutions
- Quality assessment monitoring of privileges and risk stratified outcomes
- Provide support for a quality assurance staff person (e.g., nurse) to monitor complications
- Minimal institutional performance activity of 200 interventions per year with the ideal minimum of 400 interventions per year
- Interventional program director who has a career experience of >500 PCI procedures and is board certified by ABIM in interventional cardiology
- Facility and equipment requirements to provide high resolution fluoroscopy and digital video processing
- Experienced support staff to respond to emergencies (See Section IV, C. Need for Surgical Backup for discussion)
- Establishment of a mentoring program for operators who perform <75 procedures per year by the individuals who perform ≥150 procedures per year

Physicians
- Procedural volume of ≥75 per year
- Continuation of privileges based on outcome benchmark rates with consideration of not granting privileges to operators who exceed adjusted case mix benchmark complication rates for a 2-year-period
- Ongoing quality assessment comparing results with current benchmarks with risk stratification of complication rates
- Board Certification by ABIM in interventional cardiology

ABIM = American Board of Internal Medicine; PCI = percutaneous coronary intervention.

with a volume <200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer service.* ***(Level of Evidence: C)***

C. On-Site Cardiac Surgical Backup

Cardiac surgical backup for PCI has evolved from the formal surgical standby in the 1980s to an informal arrangement of first available operating room and, in some cases, off-site surgical backup. With the advent of intracoronary stenting, there has been a decrease in the need for emergency coronary bypass, ranging between 0.4 and 2%.

1. Primary PCI Without On-Site Cardiac Surgery. Although thrombolytic trials demonstrated that early reperfusion saves myocardium and reduces mortality, the superiority and greater applicability of primary PCI for the treatment of acute MI has raised the question of whether primary PCI should be performed at institutions with diagnostic cardiac catheterization laboratories that do not perform elective PCI or have on-site cardiac surgery. For this reason, the establishment of PCI programs at institutions without on-site cardiovascular surgery has been promoted as necessary to maintain quality of care. It must be realized that PCI in the early phase of an acute MI can be difficult and requires even more skill and experience than routine PCI in the stable patient. The need for an experienced operator and experienced laboratory technical support with availability of a broad range of catheters, guidewires, stents, and other devices (e.g., IABP) that are required for optimum results in an acutely ill patient is of major importance (Table 9). If these complex patients are treated by interventionalists with limited experience at institutions with low volume, then the gains of early intervention may be lost because of increased complications. In such circumstances, transfer to a center that routinely performs complex PCI will often be a more effective and efficient course of action. Thrombolysis is still an acceptable form of therapy and is preferable to acute PCI by an inexperienced team.

Criteria have been suggested for the performance of primary PCI at hospitals without on-site cardiac surgery (Tables 9 and 10). Of note, large-scale registries have shown an inverse relationship between the number of primary angioplasty procedures performed and in-hospital mortality. The data suggest that both door-to-balloon time and in-hospital mortality are significantly lower in institutions performing a minimum of 36 primary angioplasty procedures per year. Communities may identify a unique qualified and experienced center wherein the on-site intervention for acute MI could be performed. Suboptimal results may relate to operator/staff inexperience and capabilities and delays in performing angioplasty for logistical reasons. From clinical data and expert consensus, the Committee recommends that primary PCI for acute MI performed at hospitals without established elective PCI programs should be restricted to those institutions with a proven plan for rapid and effective PCI as well as rapid access to cardiac surgery in a nearby facility (Table 11).

2. Elective PCI Without On-Site Surgery. Technical improvements in interventional cardiology have led to the development of elective angioplasty programs without on-

*Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume >150 procedures/year.

Table 9. Criteria for the Performance Angioplasty at Hospitals Without On-Site Cardiac Surgery

1. The operators must be experienced interventionalists who regularly perform elective intervention at a surgical center (≥75 cases/year). The institution must perform a minimum of 36 primary PCI procedures per year.
2. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-h, 365-day call schedule.
3. The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, intra-aortic. balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
4. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
5. The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
6. There must be formalized written protocols in place for immediate (within 1 h) and efficient transfer of patients to the nearest cardiac surgical facility which are reviewed/tested on a regular (quarterly) basis.
7. Primary intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes.
8. Case selection for the performance of primary angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown in Table 10.
9. There must be an ongoing program of outcomes analysis and formalized periodic case review.
10. 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 establishing standards, training staff, detailed logistic development, and creation of a quality assessment and error management system.

Adapted with permission from Wharton TP Jr, McNamara NS, Fedele FA, Jacobs MI, Gladstone AR, Funk EJ. Primary angioplasty for the treatment of acute myocardial infarction: experience at two community hospitals without cardiac surgery. J Am Coll Cardiol 1999;33:1257–65.

AMI = acute myocardial infarction; IABP = intra-aortic balloon pump; PCI = percutaneous coronary intervention.

site surgical coverage. Caution is warranted before endorsing an unrestricted policy for PCI in hospitals without appropriate facilities. Several outstanding and critically important clinical issues, such as timely management of ischemic complications, adequacy of specialized post-interventional care, logistics for managing cardiac surgical or vascular complications and operator/laboratory volumes, and accreditation must be addressed. At this time, the Committee, therefore, continues to support the recommendation that elective PCI should not be performed in facilities without on-site cardiac surgery (Table 11). As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

Recommendations for PCI With and Without On-Site Cardiac Surgery (Table 11)

Class I

1. **Patients undergoing elective PCI in facilities with on-site cardiac surgery.** ***(Level of Evidence: B)***
2. **Patients undergoing primary PCI in facilities with on-site cardiac surgery.** ***(Level of Evidence: B)***

Class IIb

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

Class III

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

V. INDICATIONS

A broad spectrum of clinical presentations exists wherein patients may be considered candidates for PCI, ranging from asymptomatic to severely symptomatic or unstable, with variable degrees of jeopardized myocardium. Each time that a patient is considered for revascularization, the potential risk and benefits of the particular procedure under consideration must be weighed against alternative therapies.

Table 10. Patient Selection for Angioplasty and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:
- Significant (≥60%) stenosis of an unprotected left main (LM) 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 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
- Lesions in other than the infarct artery

Transfer for emergent aortocoronary bypass surgery patients with:
- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability
  —After angioplasty or occluded vessels
  —Preferably with intraaortic balloon pump support

Adapted with permission from Wharton TP Jr, McNamara NS, Fedele FA, Jacobs MI, Gladstone AR, Funk EJ. Primary angioplasty for the treatment of acute myocardial infarction: experience at two community hospitals without cardiac surgery. J Am Coll Cardiol 1999;33:1257–65.

Table 11. Recommendations For PCI With and Without On-Site Cardiac Surgery

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

ECG = electrocardiography; LBBB = left bundle-branch block; MI = myocardial infarction; PCI = percutaneous coronary intervention.

The initial simplicity and associated low morbidity of PCI as compared to surgical therapy is always attractive, but the patient and family must understand the limitations inherent in current PCI procedures, including a realistic presentation of the likelihood of restenosis and the potential for incomplete revascularization as compared with CABG surgery. In patients with CAD who are asymptomatic or have only mild symptoms, the potential benefit of antianginal drug therapy along with an aggressive program of risk reduction must also be understood by the patient before a revascularization procedure is performed.

A. Asymptomatic or Mild Angina

In the previous ACC/AHA Guidelines for PTCA, specific recommendations were made separately for patients with single- or multivessel disease. The current techniques of PCI have matured to the point where, in patients with favorable anatomy, the competent practitioner can perform either single- or multivessel PCI at low risk and with a high likelihood of initial success. For this reason, in this revision of the Guidelines, recommendations will be made largely based upon the patients' clinical condition, specific coronary lesion morphology and anatomy, LV function, and associated medical conditions, and less emphasis will be placed on the number of lesions or vessels requiring PCI. The CCS Class of angina (I to IV) is used to define the severity of symptoms. The categories described in this section refer to an initial PCI procedure in a patient without prior CABG surgery.

The Committee recognizes that the majority of patients with asymptomatic ischemia or mild angina should be treated medically. The published ACIP study casts some doubt on the wisdom of medical management for those higher-risk patients who are asymptomatic or have mild angina, but have objective evidence by both treadmill testing and ambulatory monitoring of significant myocardial ischemia and CAD. In addition, there is a substantial portion of the middle and older age populations in this country that remains physically active, participating in sports, such as tennis and skiing, or performing regular and vigorous physical exercise, such as jogging, who have CAD. For such individuals with moderate or severe ischemia and few symptoms, revascularization with PCI or CABG surgery may reduce their risk of serious or fatal cardiac events. For this reason, patients in this category of higher-risk asymptomatic ischemia or mild symptoms and severe anatomic CAD are placed in Class I or II. PCI may be considered if there is a high likelihood of success and a low risk of morbidity or mortality. The judgment of the experienced physician is deemed valuable in assessing the extent of ischemia.

Recommendations for PCI in Asymptomatic or Class I Angina Patients

Class I

1. **Patients who do not have treated diabetes with asymptomatic ischemia or mild angina with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a large area of viable myocardium (Table 12).** ***(Level of Evidence: B)***

Class IIa

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

Table 12. Noninvasive Risk Stratification: High Risk (>3% Annual Mortality Rate)

- High-risk treadmill score (score ≤-11)
- Stress-induced large perfusion defect (particularly if anterior)
- Stress-induced perfusion defects of moderate size
- Stress-induced multiple perfusion defect with LV dilation or increased lung uptake (thallium-201)
- Echocardiographic wall motion abnormality (involving >2 segments) developing at a low dose of dobutamine (≤10 $mg \cdot kg^{-1} \cdot min^{-1}$) or at a low heart rate (120 bpm)
- Stress echocardiographic evidence of extensive ischemia

Adapted with permission from Gibbons RJ, Chatterjee K, Daley J, et al. ACC/AHA/ACP-ASIM guidelines for the management of patients with chronic stable angina. J Am Coll Cardiol 1999;33:2092–197.

Class IIb

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

Class III

1. **Patients with asymptomatic ischemia or mild angina who do not meet the criteria as listed under Class I or Class II and who have:**
    a. **Only a small area of viable myocardium at risk.**
    b. **No objective evidence of ischemia.**
    c. **Lesions that have a low likelihood of successful dilation.**
    d. **Mild symptoms that are unlikely to be due to myocardial ischemia.**
    e. **Factors associated with increased risk of morbidity or mortality.**
    f. **Left main disease.**
    g. **Insignificant disease <50%.** ***(Level of Evidence: C)***

B. Angina Class II to IV or Unstable Angina

Many patients with moderate or severe stable angina or unstable angina do not respond adequately to medical therapy and often have significant coronary artery stenoses that are suitable for revascularization with CABG surgery or PCI. In addition, a proportion of these patients have reduced LV systolic function which places them in a group that is known to have improved survival with CABG surgery and possibly with revascularization by PCI. In nondiabetic patients with 1- or 2-vessel disease in whom angioplasty of 1 or more lesions has a high likelihood of initial success, PCI is the preferred approach. In a minority of such patients, CABG surgery may be preferred, particularly for those in whom the left anterior descending coronary artery can be revascularized with the internal mammary artery or in those with left main coronary disease. In patients with unstable angina or non–Q-wave MI, intensive medical therapy should be initiated prior to revascularization with PCI or CABG surgery. Patients with unstable angina and non–ST-segment elevation MI have been randomized to medical therapy or PCI in the FRISC II and TACTICS TIMI 18 trials. These trials utilizing stenting as the primary therapy have favored the invasive approach.

The indications for coronary angiography are summarized in the ACC/AHA Coronary Angiography Guidelines and recommendations for PCI are summarized in the ACC/AHA Unstable Angina Guidelines. Indications for PCI for patients with angina Class II to IV, unstable angina, or non–Q-wave infarction follow.

Recommendations for Patients With Moderate or Severe Symptoms (Angina Class II to IV, Unstable Angina or Non–ST-Elevation MI) With Single- or Multivessel Coronary Disease on Medical Therapy

Class I

1. **Patients with 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality (Table 5). The vessel(s) to be dilated must subtend a moderate or large area of viable myocardium and have high risk (Table 12).** ***(Level of Evidence: B)***

Class IIa

1. **Patients with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery.** ***(Level of Evidence: C)***

Class IIb

1. **Patient has 1 or more lesions to be dilated with reduced likelihood of success (Table 5) or the vessel(s) subtend a less than moderate area of viable myocardium. Patients with 2- or 3-vessel disease, with significant proximal LAD CAD and treated diabetes or abnormal LV function.** ***(Level of Evidence: B)***

Class III

1. **Patient has no evidence of myocardial injury or ischemia on objective testing and has not had a trial of medical therapy, or has:**
    a. **Only a small area of myocardium at risk.**
    b. **All lesions or the culprit lesion to be dilated with morphology with a low likelihood of success.**
    c. **A high risk of procedure-related morbidity or mortality.** ***(Level of Evidence: C)***
2. **Patients with insignificant coronary stenosis (e.g., <50% diameter).** ***(Level of Evidence: C)***

3. Patients with significant left main CAD who are candidates for CABG. ***(Level of Evidence: B)***

It is recognized by the Committee that the assessment of risk of unsuccessful PCI or serious morbidity or mortality must always be made with consideration of the alternative therapies available for the patient, including more intensive or prolonged medical therapy or surgical revascularization (Table 13), especially in patients with unstable angina pectoris.

When CABG surgery is a poor option because of high risk due to special considerations or other organ system disease, patients otherwise in Class IIb may be appropriately managed with PCI. Under these special circumstances formal surgical consultation is recommended.

C. Myocardial Infarction

The results of randomized clinical trials of intravenous thrombolysis and subsequent management strategies of immediate, delayed, and deferred PCI have established the benefits of early pharmacologic and mechanical reperfusion therapies for patients with acute MI.

Percutaneous coronary intervention is a very effective method for re-establishing coronary perfusion and is suitable for ≥90% of patients. Considerable data support the use of PCI for patients with acute MI. Reported rates of achieving TIMI 3 flow, the goal of reperfusion therapy, range from 70 to 90%. Late follow-up angiography demonstrates that 87% of infarct arteries remain patent. Although most evaluations of PCI have been in patients who are eligible to receive thrombolytic therapy, considerable experience supports the value of PCI for patients who may not be suitable for thrombolytic therapy due to an increased risk of bleeding.

Intracoronary stents appear to augment the results of PCI for MI (Table 14). Preliminary results suggest that stenting achieves a better immediate angiographic result with a larger arterial lumen, less reclosure of the infarct-related artery, and fewer subsequent ischemic events than PTCA alone. Results from a randomized clinical trial suggest that stenting enhances late clinical outcomes (reduction in composite end point attributable to a decrease in target-vessel revascularization) when compared to PTCA alone. However an increase in mortality at 1 year among the stent group has been reported in the Stent-PAMI trial.

Primary PTCA performed without routine stenting has been compared to thrombolytic therapy in several randomized clinical trials. These investigations consistently demonstrate that PTCA-treated patients experience less recurrent ischemia or infarction than those treated by thrombolysis. Trends favoring a survival benefit with PTCA are noted. Two meta-analyses showed superiority of PCI over thrombolysis for mortality with risk reductions of 0.34 and 0.56. It is important to note that these results of PCI have been achieved in medical centers with experienced

Table 13. Invasive vs Conservative Strategies in Unstable Angina Patients

Study	Year	N	Patient Population	Treatment	Follow-Up	Results			Comments
						PCI	Medical Therapy	Significance	
TIMI-IIIB	1995	1473	Patients 21–76 years of age presenting within 24 h of ischemic discomfort at rest consistent with unstable angina or non-Q-wave MI	Medical therapy (tPA vs. placebo) and early invasive or conservative strategy	6 weeks	16.2% combined primary endpoints	18.1% combined primary endpoints	NS	While no difference was found in combined primary endpoints (death, MI, positive ETT), the early invasive strategy was associated with shorter hospital stay and lower incidence of rehospitalization
					1 year	12.4%	10.6%	NS	
VANQWISH	1998	920	Patients with an evolving MI	Invasive vs conservative	Avg 23 months	32.9% death and MI	30.3% death and MI	p = 0.35	Fewer patients treated conservatively had death plus MI or death at hospital discharge at 1 month and at 1 year. The invasive group had a higher CABG mortality rate (11.6% vs. 3.4%)
FRISC II	1999	2,457	Patient's ischemic symptoms in previous 48 h accompanied by ECG changes or elevated markers	Early invasive therapy or noninvasive treatment strategy. Patients also received dalteparin or placebo for 3 months	6 months	9.4% death or MI	12.1% death or MI	p = 0.031	Invasive strategy was associated with 50% lower recurrent angina and hospital readmission rates

CABG = coronary artery bypass graft; ECG = electrocardiography; ETT = exercise treadmill test; MI = myocardial infarction; NS = no significance; PCI = percutaneous coronary intervention.

Table 14. Studies Comparing PTCA With Stents In Acute Myocardial Infarction

Study	Year	Follow-Up Month	N, Stent/ Angioplasty	Success %	Crossover %	Early Events (0–30 days), %				Late Events (Cumulative), %			
						Death	Reinfarction	TVR	Any Event	Restenosis	Death	Reinfarction	TVR	Any Event
GRAMI	1998	12	52/52	98/94.2	25*	3.8/7.6	0/7.6	0/5.7	3.8/19.2	—	—	—	14/21	17/35
FRESCO	1998	6	75/75	99†	—	0/0	1.3/2.6	1.3/12	3/15	17/43	1/0	1/3	7/25	13/32
STENTIM 2	2000	12	101/110	95/94.5	3/36.4	1/0	4/3.6	5/5.4	5/5.4	25.3/39.6	3/1.9	4.0/5.5	17.8/28.2	12.9/20.0
Suryapranata et al.	1998	6	112/115	98/96	2/13	2/3	1/4	—	—	—	2/3	1/7	4/17	5/20
PASTA	1999	12	67/69	99/97	1/10	3/7	3/4	6/13	6/19	17/37.5	5/9	—	—	22/49
PSAAMI	2001	710 ± 282 days	44/44	—	1/27	2/5	0/2	0/9	5/11	24/61	9/18	2/9	16/34	23/43
Stent-PAMI	1999	6	452/448	89.4/92.7	1.5/15	3.5/1.8	0.4/1.1	1.8/3.8	4.6/5.8	20.3/33.5	4.2/2.7	2.4/2.2	7.7/17	12.6/20.1

*Values for crossovers from angioplasty to stent treatment; †Success rate of 99% before randomization
Dashes — = data not gathered for that category; TVR = target-vessel revascularization. All data are presented as values for stent/angioplasty groups. Adapted from Suwaidi MB, et al. JAMA 2000;284:1828–1836.

Table 15. Contraindications and Cautions for Thrombolytic Use in Myocardial Infarction*

Contraindications
- Previous hemorrhagic stroke at any time, other strokes or cerebrovascular events within 1 year
- Known intracranial neoplasm
- Active internal bleeding (does not include menses)
- Suspected aortic dissection

Caution/relative contraindications
- Severe uncontrolled hypertension on presentation (blood pressure >180/110 mm Hg)†
- History of prior cerebrovascular accident or known intracerebral pathology not covered in contraindications
- Current use of anticoagulants in therapeutic doses (INR ≥2–3); known bleeding diathesis
- Recent trauma (within 2–4 weeks) including head trauma or traumatic or prolonged (>10 min) CPR or major surgery (3 weeks)
- Noncompressible vascular punctures
- Recent (within 2 to 4 weeks) internal bleeding
- For streptokinase/anistreplase: prior exposure (especially within 5 days–2 years) or prior allergic reaction
- Pregnancy
- Active peptic ulcer
- History of chronic severe hypertension

*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 myocardial infarction.
INR = International Normalized Ratio; CPR = cardiopulmonary resuscitation.
Reproduced with permission from Ryan TJ, Antman EM, Brooks NH, et al. ACC/AHA guidelines for the management of patients with acute myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). J Am Coll Cardiol 1999;34:890–911.

providers and under circumstances where angioplasty can be performed immediately following patient presentation.

1. PCI in Thrombolytic-Ineligible Patients. Randomized, controlled clinical trials evaluating the outcome of PCI for patients who present with ST-segment elevation but who are ineligible for thrombolytic therapy and for patients who experience infarction without ST-segment elevation have not been performed. Nevertheless, there is a general consensus that PCI is an appropriate means for achieving reperfusion in patients who cannot receive thrombolytics because of increased risk of hemorrhage. Other reasons also exclude acute MI patients from thrombolytic therapy and the outcome of PCI in these patients may differ from those eligible for lytic therapy. For example, patients who present without ST-elevation are more often older and female and have higher in-hospital mortality than those with ST-segment elevation. Little data are available to characterize the value of primary PCI for this subset of acute MI patients (Table 15).

2. Post-Thrombolysis PCI. In asymptomatic patients, the strategies of routine PCI of the stenotic infarct-related artery immediately after successful thrombolysis show no benefit with regard to salvage of jeopardized myocardium or prevention of reinfarction or death. In some studies this approach was associated with increased incidence of adverse events, which include bleeding, recurrent ischemia, emergency coronary artery surgery, and death. Routine PCI immediately after thrombolysis may increase the chance for

vascular complications at the catheterization access site and hemorrhage into the infarct-related vessel wall.

3. Rescue PCI. Rescue (also known as salvage) PCI is defined as PCI after failed thrombolysis for patients with continuing or recurrent myocardial ischemia. Rescue PCI has resulted in higher rates of early infarct-artery patency, improved regional infarct zone wall motion, and greater freedom from adverse in-hospital clinical events compared to a deferred PCI strategy. The randomized evaluation of rescue PCI with combined utilization end points trial (RESCUE) demonstrated a reduction in rates of in-hospital death and combined death and congestive heart failure maintained up to 1 year after study entry for patients presenting with anterior wall MI who failed thrombolytic therapy. Improvement in TIMI grade flow from ≤2 to 3 may offer additional clinical benefit.

4. PCI for Cardiogenic Shock. Observational studies support the value of PCI for patients who develop cardiogenic shock in the early hours of MI. For patients who do not have mechanical causes of shock, such as acute mitral regurgitation or septal or free wall rupture, mortality among those having PCI is lower than those treated by medical means.

A randomized clinical trial has further clarified the role of emergency revascularization (ERV) in acute MI complicated by cardiogenic shock. This multicenter trial supports the use of ERV with PCI in appropriate candidates for patients <75 years old with acute MI complicated by cardiogenic shock. After 6 months, there was significant survival benefit to early revascularization. These data strongly support the approach that patients <75 years with acute MI complicated by cardiogenic shock should undergo emergency revascularization and support measures.

5. PCI Hours to Days After Thrombolysis. Patients who achieve reperfusion and myocardial salvage following thrombolytic therapy may experience reocclusion of the infarct artery and recurrent MI. This concern has prompted the routine use of catheterization and PCI prior to hospital discharge to identify and dilate the culprit lesion. The SWIFT study examined 800 patients with acute MI randomly assigned to PCI within 2 to 7 days after thrombolysis or to conservative management with intervention for spontaneous or provocable ischemia. There were no differences in the two treatment strategies regarding LV function, incidence of reinfarction, in-hospital survival, or 1-year survival rate. These data indicate that routine PCI of the infarct-related artery in the absence of spontaneous or provoked ischemia is not warranted.

Initial studies of late (>6 to 12 h) PCI in asymptomatic survivors of MI indicate that opening an occluded artery does not appear to alter the process of LV dilation, the incidence of spontaneous and inducible arrhythmias, or prognosis. Although data supporting the argument to open occluded infarct-related arteries are persuasive, at least for large arteries subtending large areas of myocardium, there are few randomized trials supporting this approach. It should be noted that the overwhelming majority of trials were performed prior to the widespread use of stents and platelet IIb/IIIa receptor blockade and thus, the potential impact and benefit of these newer therapies in this clinical setting needs re-evaluation.

6. PCI After Thrombolysis in Selected Patient Subgroups. a. YOUNG AND ELDERLY POST-INFARCT PATIENTS. Although not supported by randomized trials, routine cardiac catheterization following thrombolytic therapy for AMI has been a frequently performed strategy in all age groups. Young (<50 years) patients often undergo cardiac catheterization after thrombolytic therapy due to a "perceived need" to define coronary anatomy and thus establish psychological as well as clinical outcomes. In contrast, older (>75 years) patients have higher in-hospital and long-term mortality rates and enhanced clinical outcomes when treated with primary PCI. Confirmatory studies to determine quality-of-life aspects of care in younger patients and to define the potential of other modes of coronary revascularization in older patient groups are not yet available. Based on the current data, with the exception of patients presenting with cardiogenic shock, PCI should be based on clinical need without special consideration of age.

b. PATIENTS WITH PRIOR MYOCARDIAL INFARCTION. A prior MI is an independent predictor of death, reinfarction, and need for urgent coronary bypass surgery. In the TIMI-II study, patients with a history of prior MI had a higher 42-day mortality (8.8% vs. 4.3%; $p < 0.001$), higher prevalence of multivessel CAD (60% vs. 28%; $p < 0.001$), and a lower LV ejection fraction (42% vs. 48%; $p < 0.001$) compared to patients with a first MI. Mortality tended to be lower among patients with a prior MI undergoing the invasive compared to the conservative strategy, a benefit which persisted up to 1 year following study entry.

Based on the earlier findings in this document and current practice, PCI should be based on clinical need. The presence of prior MI places the patient in a higher risk subset and should be considered in the PCI decision.

Recommendations for Primary PCI for Acute Transmural MI Patients as an Alternative to Thrombolysis

Class I

1. **As an alternative to thrombolytic therapy in patients with AMI and ST-segment elevation or new or presumed new left bundle branch block who can undergo angioplasty of the infarct artery ≤12 h from the onset of ischemic symptoms or >12 h if symptoms persist, if performed in a timely fashion* by individuals skilled in the procedure† and supported by experienced personnel in an appropriate laboratory environment.‡** ***(Level of Evidence: A)***
2. **In patients who are within 36 h of an acute ST elevation/Q-wave or new left bundle branch block MI who develop cardiogenic shock, are <75 years**

of age, and revascularization can be performed within 18 h of the onset of shock by individuals skilled in the procedure† and supported by experienced personnel in an appropriate laboratory environment.‡ ***(Level of Evidence: A)***

Class IIa

1. **As a reperfusion strategy in candidates who have a contraindication to thrombolytic therapy.** ***(Level of Evidence: C)***

Class III

1. **Elective PCI of a non–infarct-related artery at the time of acute MI.** ***(Level of Evidence: C)***
2. **In patients with acute MI who:**
   a. **have received fibrinolytic therapy within 12 h and have no symptoms of myocardial ischemia.**
   b. **are eligible for thrombolytic therapy and are undergoing primary angioplasty by an inexperienced operator (individual who performs <75 PCI procedures/year).**
   c. **are beyond 12 h after onset of symptoms and have no evidence of myocardial ischemia.** ***(Level of Evidence: C)***

Recommendations for PCI After Thrombolysis

Class I

1. **Objective evidence for recurrent infarction or ischemia (rescue PCI).** ***(Level of Evidence: B)***

Class IIa

1. **Cardiogenic shock or hemodynamic instability.** ***(Level of Evidence: B)***

Class IIb

1. **Recurrent angina without objective evidence of ischemia/infarction.** ***(Level of Evidence: C)***
2. **Angioplasty of the infarct-related artery stenosis within hours to days (48 h) following successful thrombolytic therapy in asymptomatic patients without clinical and/or inducible evidence of ischemia.** ***(Level of Evidence: B)***

Class III

1. **Routine PCI within 48 h following failed thrombolysis.** ***(Level of Evidence: B)***
2. **Routine PCI of the infarct-artery stenosis immediately after thrombolytic therapy.** ***(Level of Evidence: A)***

Recommendations for PCI During Subsequent Hospital Management After Acute Therapy for AMI Including Primary PCI

Class I

1. **Spontaneous or provocable myocardial ischemia during recovery from infarction.** ***(Level of Evidence: C)***
2. **Persistent hemodynamic instability.** ***(Level of Evidence: C)***

Class IIa

1. **Patients with LV ejection fraction ≤0.4, CHF, or serious ventricular arrhythmias.** ***(Level of Evidence: C)***

Class IIb

1. **Coronary angiography and angioplasty for an occluded infarct-related artery in an otherwise stable patient to revascularize that artery (open artery hypothesis).** ***(Level of Evidence: C)***
2. **All patients after a non–Q-wave MI.** ***(Level of Evidence: C)***
3. **Clinical HF during the acute episode, but subsequent demonstration of preserved LV function (LV ejection fraction >0.4).** ***(Level of Evidence: C)***

Class III

1. **PCI of the infarct-related artery within 48 to 72 h after thrombolytic therapy without evidence of spontaneous or provocable ischemia.** ***(Level of Evidence: C)***

D. Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

Ischemic symptoms recur in 4% to 8% of patients/year following CABG. Recurrence of symptoms can be attributed to progression of native vessel coronary disease (5%/year) and bypass conduit occlusion, particularly SVG failure (7% in week 1; 15 to 20% in first year; 1 to 2%/year during the first 5 to 6 years and 3 to 5%/year in years 6 to 10 postoperatively). At 10 years postoperatively, approximately half of all SVG conduits are occluded and only half of the remaining patent grafts are free of significant disease. The requirement for repeat revascularization procedures increases over time from the initial revascularization, particularly in younger patients. Although arterial conduits exhibit improved long-term patency, stenosis or occlusion of these grafts can occur. Thus, patients with recurrent ischemic symptoms following CABG may require repeat revascularization due to diverse anatomic problems.

Risk of repeat surgical revascularization is higher (hospital mortality 7 to 10%) than initial CABG and both long-term relief of angina and bypass graft patency are lower than that of the first procedure. In addition, patients with prior bypass surgery may have limited graft conduits, impaired LV function, advanced age, and coexisting medical conditions (cerebrovascular disease; renal and pulmonary insufficiency) which may complicate repeat surgical coronary revascularization and prompt consideration for catheter-based intervention.

1. Early Ischemia After CABG. Recurrent ischemia early (<30 days) postoperatively usually reflects graft failure, often secondary to thrombosis, and may occur in both saphenous vein and arterial graft conduits. Incomplete revascularization and unbypassed native vessel stenoses or

*Performance standard: balloon inflation within 90 (±30) min of hospital admission; †Individuals who perform ≥75 PCI procedures/year; ‡Centers that perform >200 PCI procedures/year and have cardiac surgical capability.

stenoses distal to a bypass graft anastomosis may also precipitate recurrent ischemia. Urgent coronary angiography is indicated to define the anatomic cause of ischemia and to determine the best course of therapy. Emergency PCI of a focal graft stenosis (venous or arterial) or recanalization of an acute graft thrombosis may successfully relieve ischemia in the majority of patients. Balloon dilation across suture lines has been accomplished safely within days of surgery. Adjunctive therapy with abciximab for percutaneous intervention during the first week following bypass surgery has been limited but intuitively may pose less risk for hemorrhage than fibrinolysis. As flow in vein graft conduits is pressure dependent, intra-aortic balloon pump support should be considered in the context of systemic hypotension and/or severe LV dysfunction. If feasible, PCI of both bypass graft and native vessel offending stenoses should be attempted, particularly if intracoronary stents can be successfully deployed.

When ischemia occurs 1 to 12 months following surgery, the etiology is usually peri-anastomotic graft stenosis. Distal anastomotic stenoses (both arterial and venous) respond well to balloon dilation alone and have a more favorable long-term prognosis than stenoses involving the mid-shaft or proximal vein graft anastomosis. The immediate results of PCI in mid-shaft ostial or distal anastomotic vein graft stenoses may be enhanced by coronary stent deployment.

Percutaneous transluminal coronary angioplasty with or without stent deployment can be successfully performed in patients with distal anastomotic stenoses involving the gastroepiploic artery bypass graft and in patients with free radial artery bypass grafts as well. Percutaneous intervention has also been effective in relieving ischemia for patients with the stenosis of the subclavian artery proximal to the origin of a patent left internal mammary artery bypass graft.

2. Late Ischemia After CABG. Ischemia occurring more than 1 year postoperatively usually reflects the development of new stenoses in graft conduits and/or native vessels that may be amenable to PCI. Slow-flow occurs more frequently in grafts having diffuse atherosclerotic involvement, angiographically demonstrable thrombus, irregular or ulcerative lesion surfaces, and with long lesions having large plaque volume.

Final patency after PTCA is greater for distal SVG lesions than for ostial or mid-SVG lesions, and stenosis location appears to be a better determinant of final patency than graft age or the type of interventional device used.

Percutaneous intervention for chronic vein graft occlusion has been problematic. Percutaneous transluminal coronary angioplasty alone has been associated with high complication rates and low rates of sustained patency. Favorable results have been obtained with both local "targeted" and more prolonged infusion of fibrinolytic agents for nonocclusive intragraft thrombus. Thrombolytic catheter-based systems appear to successfully treat SVG thrombosis as well as or better than thrombolytic agents.

3. Early and Late Outcomes of Percutaneous Intervention. Patients with prior bypass surgery who undergo successful PCI have a long-term outcome that is dependent on patient age, the degree of LV dysfunction, and the presence of multivessel coronary atherosclerosis. The best long-term results are observed after recanalization of distal anastomotic stenoses occurring within 1 year of operation. Conversely, event-free survival is less favorable following angioplasty of totally occluded SVGs, ostial vein graft stenoses, or grafts with diffuse or multicentric disease. Coexistent multisystems disease, the presence of which may have prompted the choice of a percutaneous revascularization strategy, may also influence long-term outcomes in this population.

4. Surgery Versus Percutaneous Reintervention. Aged, diffuse, friable and degenerative SVG disease in the absence of a patent arterial conduit to the left anterior descending artery represents a prime consideration for repeat surgical revascularization. The overall risk of repeat operation, especially the presence of comorbidities such as concomitant cerebrovascular, renal, or pulmonary disease and the potential for jeopardizing patent, nondiseased bypass conduits must be carefully considered. Isolated, friable stenoses in vein grafts may be approached with primary stenting or the combination of extraction atherectomy and stenting in an attempt to reduce the likelihood of distal embolization.

In general, patients with multivessel disease, failure of multiple SVGs, and moderately impaired LV function, derive the greatest benefit from the durability provided by surgical revascularization with arterial conduits. Regardless of repeat revascularization strategy, risk-factor modification with cessation of smoking and lipid-lowering therapy should be implemented in patients with prior CABG surgery. An aggressive lipid-lowering strategy that targets a low-density lipoprotein level of less than 90 mg/L can be effective in reducing recurrent ischemic events and the need for subsequent revascularization procedures.

Recommendations for PCI With Prior CABG

Class I

1. **Patients with early ischemia (usually within 30 days) after CABG.** ***(Level of Evidence: B)***

Class IIa

1. **Patients with ischemia occurring 1 to 3 years postoperatively and preserved LV function with discrete lesions in graft conduits.** ***(Level of Evidence: B)***
2. **Disabling angina secondary to new disease in a native coronary circulation. (If angina is not typical, the objective evidence of ischemia should be obtained.)** ***(Level of Evidence: B)***
3. **Patients with diseased vein grafts >3 years following CABG.** ***(Level of Evidence: B)***

Class III

1. **PCI to chronic total vein graft occlusions.** ***(Level of Evidence: B)***

2. **Patients with multivessel disease, failure or multiple SVGs, and impaired LV function.** ***(Level of Evidence: B)***

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

The limitations of coronary angiography for diagnostic and interventional procedures can be reduced by employing adjunctive technology of intracoronary ultrasound imaging, flow velocity, and pressure. Information obtained from the adjunctive modalities of intravascular imaging and physiology can improve PCI methods and outcomes.

1. Intravascular Ultrasound Imaging (IVUS). IVUS is not necessary for all stent procedures. The results of the French Stent Registry study of 2900 patients treated without coumadin and without IVUS reported a subacute closure rate of 1.8%. In the STARS trial, a subacute closure rate of 0.6% in patients having optimal stent implantation supports the approach that IVUS does not appear to be required routinely in all stent implantations. However, the use of IVUS for evaluating results in high-risk procedures (i.e., those patients with multiple stents, impaired TIMI grade flow or coronary flow reserve, and marginal angiographic appearance) appears warranted.

In the context of published data and growing clinical experience, the Writing Committee has modified prior recommendations for the use of IVUS as follows.

Recommendations for Coronary Intravascular Ultrasound

Class IIa

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

Class IIb

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

Class III

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

2. Coronary Flow Velocity and Coronary Vasodilatory Reserve. Coronary flow velocity reserve (CVR), the ratio of hyperemic to basal flow, reflects flow resistance through the epicardial artery and the corresponding myocardial bed. For lesion assessment, a normal CVR indicates a nonphysiologically significant stenosis. An abnormal CVR indicates that the stenosis in the epicardial artery is significant when the microcirculation is normal, confirmed by measuring rCVR. Several studies report that deferring PCI of non–flow-limiting lesions is safe, with <10% rate of lesion progression.

3. Coronary Artery Pressure and Fractional Flow Reserve. Fractional flow reserve (FFR) of the myocardium is the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia, which represents the fraction of normal blood flow through the stenotic artery. The normal FFR value for all vessels under all hemodynamic conditions, regardless of the status of microcirculation is 1.0. FFR values <0.75 are associated with abnormal stress tests. FFR does not use measurements in a reference vessel and is thought to be epicardial lesion-specific.

Reports indicate that a physiologic assessment can determine whether PTCA alone has achieved a satisfactory result with 6-month outcome equivalent to that reported with elective stenting. The DEBATE trial in 224 patients found that when a final diameter stenosis <35% and an excellent physiologic result (CVR >2.5) were obtained after PTCA (44/224 patients), the intermediate-term (6 months) target lesion revascularization and angiographic restenosis rates were 16%. Similar data have been reported for FFR. The application of coronary physiologic adjunctive modalities can facilitate decision making for moderate lesions, the appropriateness of PTCA, and the use of provisional stenting.

Recommendations for Intracoronary Physiologic Measurements (Doppler Ultrasound, FFR)

Class IIa

1. **Assessment of the physiological effects of intermediate coronary stenoses (30 to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive func-**

tional 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. **Evaluation of the success of percutaneous coronary revascularization in restoring flow reserve and to predict the risk of restenosis.** ***(Level of Evidence: C)***
2. **Evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion.** ***(Level of Evidence: C)***

Class III

1. **Routine assessment of the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study.** ***(Level of Evidence: C)***

VI. MANAGEMENT OF PATIENTS UNDERGOING PCI

A. Experience With New Technologies

The introduction of coronary stents and atherectomy devices has broadened the scope of patients that can be approached by PCI beyond those that could be safely treated by PTCA alone.

1. Acute Results. Significant reduction in the acute complication rate for PTCA has resulted from the adjunctive use of GP receptor IIb/IIIa blockers, which have been shown to reduce abrupt closure and periprocedural MI rates compared to placebo. Improved acute outcomes (in terms of abrupt closure rates and reduced target lesion residual diameter stenosis) have also been seen with the use of coronary stents, DCA, and adjunctive rotational atherectomy.

2. Late-Term Results. PCI devices offer the possibility of lower restenosis compared to PTCA in the native coronary circulation. Lower restenosis rates have been demonstrated for balloon-expandable slotted tubular stents in large ($\geq$3 mm) native coronary arteries but are variable depending on lesion length for SVG lesions. Initial trials of DCA showed no benefit compared to PTCA for elective single-lesion treatment. Despite the improvement in acute results seen for rotational atherectomy and excimer laser, there is no evidence that these devices improve the late outcomes in lesions than can be feasibly treated by PTCA or stenting alone.

B. Antiplatelet and Antithrombotic Therapies and Coronary Angioplasty

1. Aspirin, Ticlopidine, Clopidogrel. Aspirin reduces the frequency of ischemic complications after coronary angioplasty. Although the minimum effective aspirin dosage in the setting of coronary angioplasty has not been established, an empiric dose of aspirin, 80 to 325 mg, given at least 2 h before PCI is generally recommended. While other antiplatelet agents have similar antiplatelet effects to aspirin, only the thienopyridine derivatives, ticlopidine and clopidogrel, have been routinely used as alternative antiplatelet agents in aspirin-sensitive patients during coronary angioplasty.

Ticlopidine has a number of important side effects. The most severe side effect is severe neutropenia, occurring in approximately 1% of patients. Clopidogrel, 300 mg loading dose followed by 75 mg daily, may be used as an alternative to ticlopidine in patients undergoing stent placement. A number of nonrandomized trials and a randomized trial have failed to show a difference in the clinical outcomes among patients treated with ticlopidine and clopidogrel after stent placement. A small number of cases of thrombocytopenia purpura have been reported in patients treated with clopidogrel; therefore, patients should be monitored during treatment for occurrence of this untoward effect.

2. GP IIb/IIIa Inhibitors. The binding of fibrinogen and other adhesive proteins to adjacent platelets by means of the GP IIb/IIIa receptor serves as the "final common pathway" of platelet-thrombus formation and can be effectively attenuated by GP IIb/IIIa antagonists. These agents have reduced the frequency of ischemic complications after coronary angioplasty.

Based on the numerous trials to date (Fig. 1), intravenous GP IIb/IIIa receptor inhibitors should be considered in patients undergoing coronary angioplasty, particularly those with unstable angina or with other clinical characteristics of high-risk. There is no consistent evidence that the GP IIb/IIIa inhibitors reduce the frequency of late restenosis in the nondiabetic patient. In EPISTENT, diabetic patients who received abciximab therapy in conjunction with stent deployment had a 51% reduction in target-vessel revascularization at 6 months. This trial is the only one that has shown a reduction in target-vessel revascularization in the diabetic group. It will be important to determine if supporting evidence is found from other trials using this agent and other GP IIb/IIIa antagonists.

3. Heparin. Heparin is an important component for PCI, despite dosing uncertainties and an unpredictable therapeutic response with the unfractionated preparation. Higher levels of anticoagulation with heparin are roughly correlated with therapeutic efficacy in the reduction of complications during coronary angioplasty, albeit at the expense of bleeding complications at very high levels of heparin dosing. It appears that weight-adjusted heparin dosing may provide a clinically superior anticoagulation method over fixed heparin dosing, although definitive studies are lacking.

Some patients with unstable angina are treated with low-molecular-weight heparin (LMWH) prior to coronary angioplasty. Anticoagulation monitoring is not routinely possible with LMWH, and conventional dosages of unfractionated heparin are currently recommended. Conventional ACT monitoring methods may underestimate the true degree of periprocedural anticoagulation with LMWH. Use of LMWH as the sole anticoagulant during PCI is not supported at this time in the absence of absolute or relative contraindications to unfractionated heparin, although data

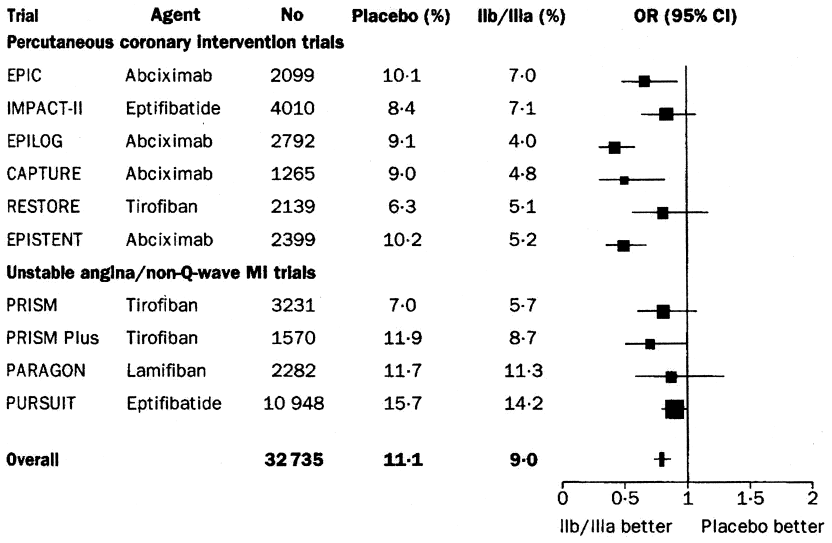

Figure 1. Death or nonfatal MI outcomes at 30 days in 10 randomized, placebo-controlled trials of GP IIb/IIIa blockers. Data and acronyms from references 30–39 (these numbers coincide with references in the original article). Risk ratio with 95% CI, size of RR box being proportional to total sample size. Frequency of death or nonfatal MI in columns 4 and 5. Overall (all 10 trials) benefit of GP IIb/IIIa blockade highly significant (RR = 0.79 [95% CI 0.73–0.85; $p < 10^{-9}$). GP = glycoprotein; OR = odds ratio; CI = confidence interval; MI = myocardial infarction. Reproduced with permission from Topol EJ, et al. Lancet 1999;353:227–31.

from clinical trials of these agents administered alone or in conjunction with GP IIb/IIIa blockade are forthcoming.

In those patients who do not receive GP IIb/IIIa inhibitors, sufficient unfractionated heparin should be given during coronary angioplasty to achieve an ACT of 250 to 300 s with the HemoTec device and 300 to 350 s with the Hemochron device.

The unfractionated heparin bolus should be reduced to 50 to 70 IU/kg when GP IIb/IIIa inhibitors are given in order to achieve a target ACT of 200 s using either the HemoTec or Hemochron device.

C. Post-PCI Management

Following PCI, in-hospital care should focus on monitoring the patient for recurrent myocardial ischemia, achieving hemostasis at the catheter insertion site, and detecting and preventing contrast-induced renal failure. Attention should also be directed toward implementing appropriate secondary atherosclerosis prevention programs. The patient should understand and adhere to recommended medical therapies and behavior modifications known to reduce subsequent morbidity and mortality from coronary heart disease.

Most patients can be safely discharged from the hospital within 24 h after an uncomplicated elective PCI. Special skilled nursing units have been developed by many institutions to facilitate post-PCI management. Specific protocols for sheath removal, continuation of anticoagulation or antiplatelet therapies, and observation for recurrent myocardial ischemia/infarction and contrast-induced renal failure are of particular assistance in ensuring appropriate outcomes during this period. Pilot studies suggest that selected patients may be discharged on the same day after PCI especially when the procedure is performed by the percutaneous radial or brachial approach. However, confirmation by larger studies is necessary prior to widespread endorsement of this strategy.

1. Post-Procedure Evaluation of Ischemia. After PCI, chest pain may occur in as many as 50% of patients. ECG evidence of ischemia identifies those with significant risk for acute vessel closure. When angina pectoris or ischemic ECG changes occur after PCI, the decision to proceed with further interventional procedures, CABG surgery, or medical therapy should be individualized based on factors such as hemodynamic stability, amount of myocardium at risk, and the likelihood that the treatment will be successful.

Patients with renal dysfunction and diabetes should be monitored for contrast-induced nephropathy. In addition, those patients receiving higher contrast loads or a second contrast load within 72 h should have renal function assessed. Whenever possible, nephrotoxic drugs (certain antibiotics, nonsteroidal anti-inflammatory agents, and cyclosporine) and metformin (especially in those with preexisting renal dysfunction) should be withheld for 24 to 48 h prior to performing PCI and for 48 h afterwards.

2. Risk-Factor Modifications. All patients should be instructed about necessary behavior and risk-factor modification and the appropriate medical therapies for the secondary prevention of atherosclerosis prior to leaving the hospital. The interventional cardiologist should emphasize the importance of these measures directly to the patient as failure to do so may suggest that secondary prevention therapies are not necessary. The interventional cardiologist should interact with the primary care physician to assure that necessary secondary prevention therapies are initiated and maintained. Secondary prevention measures are an essential part of long-term therapy because they can reduce future morbidity and mortality associated with the atherosclerotic process.

Depending on the risk factors and contraindications present, advice should include aspirin therapy, hypertensive control, diabetic management, aggressive control of serum lipids to a target LDL goal <100 mgm/dl following AHA guidelines, abstinence from tobacco use, weight control, regular exercise, and ACE inhibitor therapy as recommended in the AHA/ACC consensus statement on secondary prevention.

3. Exercise Testing After PCI. Although restenosis remains the major limitation of PCI, symptom status is an unreliable index to development of restenosis with 25% of asymptomatic patients documented as having ischemia on exercise testing.

Because myocardial ischemia, whether painful or silent, worsens prognosis, some authorities have advocated routine testing. However, the ACC/AHA practice guidelines for exercise testing favor selective evaluation in patients considered to be at particularly high risk (e.g., patients with decreased LV function, multivessel CAD, proximal left anterior descending disease, previous sudden death, diabetes mellitus, hazardous occupations, and suboptimal PCI results). The exercise ECG is an insensitive predictor of restenosis, with sensitivities ranging from 40 to 55%, significantly less than those obtainable with SPECT or exercise echocardiography. This lower sensitivity of the exercise ECG and its inability to localize disease limits its usefulness in patient management both before and after PCI. For those reasons, stress imaging is preferred to evaluate symptomatic patients after PCI. If the patient's exertional capacity is significantly limited, coronary angiography may be more expeditious to evaluate symptoms of typical angina. Exercise testing after discharge is helpful for activity counseling and/or exercise training as part of cardiac rehabilitation. Neither exercise testing nor radionuclide imaging is indicated for the routine, periodic monitoring of asymptomatic patients after PCI without specific indications.

VII. SPECIAL CONSIDERATIONS

A. Ad-Hoc Angioplasty—PCI at the Time of Initial Cardiac Catheterization

Ad-hoc coronary intervention is PCI performed at the same time as diagnostic cardiac catheterization. Since the last revision of these Guidelines, there has been an increase in ad-hoc interventions with reported incidence ranging from 52 to 83%.

Ad-hoc coronary intervention is particularly suitable for patients with clinical evidence of restenosis 6 to 12 months following the initial procedure, patients undergoing primary angioplasty for MI, and patients with refractory unstable angina in need of urgent revascularization. Ad-hoc PCI should be performed only in a well-informed patient, particularly in the setting of single-vessel disease without morphologic features predictive of an adverse outcome, when it is clear that this treatment strategy is the best alternative. This committee endorses the recommendations from the Society for Cardiac Angiography and Interventions that ad-hoc PCI be individualized and not be a standard or required strategy for all patients.

B. PCI in Cardiac Transplant Patients

Although high procedural success can be achieved and PCI may be applied in a selected cardiac transplant population with comparable success and complication rates to the routine patient population, it remains unknown whether PCI prolongs allograft survival. Coronary stenting in cardiac allograft vascular disease has been performed in small numbers of patients with favorable results. Long-term survival effects remain under examination.

C. Management of Clinical Restenosis

Although atheroablation devices have been developed in an attempt to lower the second restenosis risk in patients, none has shown an incremental benefit over PTCA. It is recommended that patients who develop restenosis following an initially successful PTCA be considered for repeat PCI with stent placement. Factors that may influence this decision include the technical difficulty of the initial procedure, the potential for the lesion to be treated successfully with a stent, and the severity and extent of the restenotic process. Each time restenosis recurs, consideration should be given to alternate methods of revascularization, particularly CABG surgery, as well as continued medical therapy.

D. Restenosis After Stent Implantation (In-stent Restenosis)

Intracoronary vascular radiation for in-stent restenosis with either gamma or beta radiation is the most promising therapy for in-stent restenosis at this time, reducing the chance for repeat restenosis by other methods from 50 to 60% to 25 to 35%. In the absence of vascular radiation for in-stent restenosis, there appears to be little difference in outcome between angioplasty alone as compared to combination with ablative techniques.

E. Cost-Effectiveness Analysis for PCI

While there is no established cost-effectiveness ratio threshold, cost-effectiveness ratios of <$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.

In patients with severe angina, normal LV function, and single-vessel disease of the left anterior descending artery, the cost-effectiveness ratio for PTCA, directional coronary atherectomy, or coronary stenting that can be expected to provide >90% success rate with <3% major acute complication rate is very favorable (<$20,000 per QALY) compared to medical therapy. In patients with 3-vessel coronary disease who have comorbidities that increase operative risk for CABG surgery, PCI that is felt to be safe and feasible is

reasonably acceptable ($20,000 to $60,000 per QALY). In patients in the post-MI setting, a strategy of routine, nonsymptom-driven coronary, angiography and PCI performed for critical (>70% diameter stenosis) culprit coronary lesions amenable to PTCA 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, while PTCA or CABG surgery has been shown to be cost-effective when compared to 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.

Because CEA research is new in the field of percutaneous coronary intervention, CEA results are limited. The Committee underscores the need for cost containment and careful decision making regarding the use of PCI strategies.

VIII. FUTURE DIRECTIONS

An exciting arena of active investigation relates to methods of distal protection of the coronary vascular bed during PCI. It is now recognized that distal embolization is an important contributor to complications in patients undergoing SVG intervention. Distal embolization is often due to dislodgement of large, macroparticles from the friable graft, rather than release of platelet-mediated aggregates. This complication can be prevented by the use of distal occlusion balloons, such as the PercuSurge Guardwire, or with the use of distal filters that trap the debris and remove it from the distal circulation. A number of filter devices are currently undergoing clinical evaluation, particularly in saphenous vein graft disease and during carotid intervention.

Restenosis has also remained a vexing problem, despite the benefits achieved with stent implantation. Novel therapies have been developed, such as the application of therapeutic ultrasound, photodynamic therapy, and systemic administration of the anti-inflammatory agent tranilast. An area of active investigation involves the use of balloon-expandable stents coated with rapamycin, paclitaxol, or its derivative. The local delivery of these agents has shown promise in early clinical trials, and longer-term studies are currently underway.