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ACC/AHA Pocket Guideline

**Based on the ACC/AHA/SCAI 2005
Guideline Update**

Percutaneous Coronary Intervention

November 2005

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Percutaneous Coronary Intervention

November 2005

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I. Introduction

The American College of Cardiology (ACC)/American Heart Association (AHA) practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These percutaneous coronary intervention (PCI) guidelines attempt to define practices that meet the needs of most patients in most circumstances. The guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.

Although initially limited to balloon angioplasty and termed percutaneous transluminal coronary angioplasty (PTCA), PCI now includes other new techniques capable of relieving coronary narrowing. Accordingly, in this document, implantation of intracoronary stents and other catheter-based interventions for treating coronary atherosclerosis are considered components of PCI. In this context,



PTCA will be used to refer to procedures that use only balloon angioplasty, whereas PCI will refer to the broader group of percutaneous techniques.

Percutaneous coronary intervention is a technique that is being continually refined and modified; hence, continued, periodic guideline revision is anticipated. These guidelines are to be viewed as broad recommendations to aid in the appropriate application of PCI. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment and knowledge. They are intended for operators who possess the cognitive and technical skills to perform 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 and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge.

The schema for classification of recommendations and level of evidence is summarized in *Table 1*, which also illustrates how the grading system provides an estimate of the size of the treatment effect and an estimate of the certainty of the treatment effect. It is recognized that the basis for recommendations graded Level of Evidence: C is the opinion and consensus of the Writing Group. In this setting, evidence from clinical trials can provide important data to investigate the validity of the consensus opinion and to support continuing or modifying the recommendation.

Table 1. Applying Classification of Recommendations and Level of Evidence in ACC/AHA Format

		SIZE OF TREATMENT EFFECT	
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/ administered	CLASS IIa <i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple (3-5) population risk strata evaluated* General consistency of direction and magnitude of effect	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses
	LEVEL B Limited (2-3) population risk strata evaluated*	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Limited evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies
	LEVEL C Very limited (1-2) population risk strata evaluated*	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard-of-care 	<ul style="list-style-type: none"> ■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard-of-care
Suggested phrases for writing recommendations		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated

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



<p>CLASS IIb <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED</p>	<p>CLASS III <i>Risk ≥ Benefit</i> <i>No additional studies needed</i> Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL</p>
<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Limited evidence from single randomized trial or nonrandomized studies
<ul style="list-style-type: none"> ■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard-of-care 	<ul style="list-style-type: none"> ■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard-of-care

may/might be considered
 may/might be reasonable
 usefulness/effectiveness is
 unknown/unclear/uncertain
 or not well established

is not recommended
 is not indicated
 should not
 is not useful/effective/beneficial
 may be harmful



II. Outcomes

The outcomes of PCI 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 (*Table 2*). The committee recommends the use of such standards as the ACC-National Cardiovascular Data Registry[®] whenever feasible to accommodate the common database for the assessment of outcomes.

A. Definitions of PCI Success

1. Angiographic Success

With the advent of advanced adjunct technology, including coronary stents, a minimum stenosis diameter reduction to less than 20% has been the clinical benchmark of an optimal angiographic result.

2. Procedural Success

Although the occurrence of emergency coronary artery bypass surgery and death are easily identified end points, the definition of procedure-related myocardial infarction (MI) has been debated. The development of Q waves in addition to a threshold

value of creatine kinase (CK) elevation has been commonly used. The clinical significance of cardiac biomarker elevations in the absence of Q waves remains a subject of investigation and debate. An increase in CK-MB greater than 5 times is associated with worsened outcome. Thus, this degree of increase in CK-MB without Q waves is considered by most to qualify as an associated complication of PCI. Troponin T or I elevation occurs frequently after PCI. Minor elevations do not appear to have prognostic value, whereas marked (greater than 5 times) elevations are associated with worsened 1-year outcome (*Table 3*).



Table 2. Unadjusted In-Hospital Outcome Trends After PCI

Registry	Years	n
NHLBI (I) [‡]	1977–1981	3079*
NHLBI (II) [§]	1985–1986	2311*
BARI Registry	1988–1991	1189*
Northern New England [¶]	1990–1993	13 014 [†]
SCA&I [#]	1990–1994	4366 [†]
NACI ^{**}	1990–1994	4079*
New York State Database	1991–1994	62 670*
Northern New England [¶]	1994–1995	7248 [†]
NCN	1994–1997	76 904 [†]
Northern New England [¶]	1995–1997	14 490 [†]
NHLBI Dynamic Registry ⁺⁺	1997–1998	1559*
NHLBI Dynamic	1997–1999	857
ACC-NCDR	1998–2000	100 292
NY State Database	1997–2000	22 102

B. Acute Outcome: Procedural Complications

Class I 1. All patients who have signs or symptoms suggestive of MI during or after PCI and those with complicated procedures should have CK-MB and troponin I or T measured after the procedure. (*Level of Evidence: B*)

Class IIa 1. Routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in all patients undergoing PCI is reasonable 8 to 12 hours after the procedure. (*Level of Evidence: C*)

Clinical Success, %	In-Hospital Mortality, %	Q-Wave MI, %	Emergency CABG, %
61	1.2	NR	5.8
78	1.0	4.8	5.8
NR	0.7	2.8	4.1
88.8	1.0	2.4	2.2
91.5	2.5	NR	3.4
NR	1.6	1.6	1.9
NR	0.9	NR	3.4
89.2	1.1	2.1	2.3
NR	1.3	NR	1.7
91.5	1.2	2.0	1.3
92	1.9	2.8	0.4
91	0.9	0.8	1.9
96.5	1.4	0.4	1.9
NR	0.68	NR	NR

BARI = Bypass Angioplasty Revascularization Investigation; **CABG** = coronary artery bypass graft; **MI** = myocardial infarction; **NACI** = New Approaches in Coronary Interventions; **NCDR**[®] = National Cardiovascular Data Registry; **NCN** = National Cardiovascular Network; **NHLBI** = National Heart, Lung, and Blood Institute; **NR** = not reported; **SCAI** = Society for Cardiovascular Angiography and Interventions.

* n = patients.

† n = procedures.

‡ NHLBI (I), emergency CABG was defined as in-hospital CABG.

§ NHLBI (II), MI was defined as the presence of at least 2 of the 3 criteria: clinical symptoms, Q waves on electrocardiogram (Minnesota code), or elevated cardiac enzyme level (double the normal levels for CK or its MB fraction without Q waves). Emergency CABG was defined as in-hospital CABG.

|| BARI, MI was defined as the appearance of electrocardiogram changes (new pathologic Q waves) supported by abnormal CK-MB elevations.

¶ Northern New England, A new MI was defined as a clinical event, electrocardiogram changes, and a creatinine phosphokinase (CPK) rise greater than or equal to 2 times normal levels with positive isozymes. Emergency CABG was defined as surgery performed to treat acute closure, unstable angina, or heart failure requiring intravenous nitroglycerin or ABP, or tamponade resulting from the intervention.

SCAI, A new MI was defined as any significant infarction (greater than 3 times normal) rise in MB fraction.

** NACI, MI was defined as a Q-wave MI.

†† MI was defined as 2 or more of the following: 1) typical chest pain greater than 20 min not relieved by nitroglycerin; 2) serial electrocardiogram recordings showing changes from baseline or serially in ST-T and/or Q waves in at least 2 contiguous leads; or 3) serum enzyme elevation of CK-MB greater than 5% of total CK (total CK greater than 2 times normal; lactic dehydrogenase (LDH) subtype 1 greater than LDH subtype 2).

Table 3. Incidence of Troponin Elevations After PCI in the Published Literature

Study (First Author)	No. of Patients	Marker	Percent Positive	Positive Definition
Hunt	22	Troponin I	0	> 6 ng/ml
Ravkilde	23	Troponin T	13	> 0.12 ng/ml
Karim	25	Troponin T	44	> 0.2 ng/ml
La Vecchia	19 (Stent), 25 (balloon PCI)	Troponin T and troponin I	37% cTnI, 21% cTnT; 14% cTnI, 0% cTnT	N/A
Johansen	75	Troponin T	28	> 0.1 ng/ml
Shyu	59 (Stent), 61 (balloon PCI)	Troponin T	29; 13	> 0.1 ng/ml
Bertichant	105	Troponin I	22	> 0.1 ng/ml
Garbarz	109	Troponin I	27	> 0.3 ng/ml
Fuchs	1129	Troponin I	31	> 0.15 ng/ml
Cantor	481	Troponin I	48% Overall; 26% after excluding positive or unknown pre-PCI cTnI	> 1.5 ng/ml
Wu	98	Troponin T	26	> 0.1 ng/ml
Kizer	212	Troponin T	40% Positive before PCI; 18% of baseline-negative cTnT were positive after PCI	≥ 0.1 ng/ml
Ricciardi	286	Troponin I	13.6	> 2.3 ng/ml
Kini	2873	Troponin I	38.9	> 2 ng/ml

cTnI = cardiac troponin I; cTnT = cardiac troponin T; N/A = not applicable; RR = repeat revascularization.

Prognostic Information

N/A

N/A

N/A

N/A

N/A

Significantly higher incidence of elevated cTnT in patients undergoing stenting than angioplasty alone.

No difference in incidence of recurrent angina, MI, cardiac death, or RR after 12 months between patients positive or negative for cTnI. Stenting not associated with more minor myocardial damage than angioplasty.

No association between post-PCI cTnI and adverse ischemic events.

cTnT levels greater than 3x normal limit associated with increased risk of major in-hospital complications, but no association with adverse intermediate-term (8 months) clinical outcomes.

Significantly higher 90-day rates of MI and the composite of MI or death in patients with positive cTnI.

At a mean of 77 months of follow-up, no increase in risk of major adverse events detected in relation to post-PCI cTnT elevation.

Pre-PCI cTnT elevation was significantly related to event-free survival during 6-year follow-up; in baseline-negative patients, positive cTnT was the only independent predictor of major adverse events at 1 year; post-PCI elevation of cTnT greater than or equal to 5x normal was the strongest long-term predictor of major adverse events at 6 years.

cTnI elevations greater than 3-fold are predictive of future major adverse cardiac events. Increased incidence of such events is accounted for by the higher rate of early RR and not by late cardiac events.

Neither cTnI peak elevations nor any subgroup predicted mid-term mortality in low-to-medium risk patients.

C. Lesion Morphology and Classification

The Committee has revised the previous ACC/AHA lesion classification system to reflect high-risk (at least 1 type C lesion characteristic) and non-high-risk (no type C lesion characteristic) lesions (*Table 4*) in accordance with the PCI Clinical Data Standards from the ACC-National Cardiovascular Data Registry.[®]

Table 4. Lesion Classification System

Descriptions of a High-Risk Lesion (Type C Lesion)

- Diffuse (length greater than 2 cm)
 - Excessive tortuosity of proximal segment
 - Extremely angulated segments greater than 90 degrees
 - Total occlusions more than 3 months old and/or bridging collaterals*
 - Inability to protect major side branches
 - Degenerated vein grafts with friable lesions
-

* The high risk with these criteria is for technical failure and increased restenosis, not for acute complications.

D. Women

Compared with men, women undergoing PCI are older and have a higher incidence of hypertension, diabetes mellitus, hypercholesterolemia, and comorbid disease. The hope that stents would eliminate the difference in outcomes between women and men has not been realized. Gender differences in mortality have persisted for patients treated with stents both in the setting of acute MI and in non-acute settings.

In general, the risks and benefits of adjunctive pharmacotherapy in women are similar to those in men, although an increased rate of minor bleeding has been reported in women treated with abciximab. When glycoprotein IIb/IIIa platelet receptor antagonists are used with unfractionated heparin, a lower dose of the latter should be considered to decrease the risk of bleeding in women.

E. The Elderly Patient

With rare exception (primary PCI for cardiogenic shock in patients greater than 75 years old), a separate category has not been created in these Guidelines for the elderly. However, their higher incidence of comorbidities and risk for bleeding complications should be taken into account when considering the need for PCI.

F. Comparison With Bypass Surgery

Overall, 6 trials have been published comparing PCI using stents with coronary artery bypass grafting (CABG) in single-vessel or multivessel disease. Both revascularization techniques relieve angina. In aggregate, these trials have not shown a difference between CABG and PCI in terms of mortality or procedural MI among the populations studied, which have included mostly low-risk patients. Stents appear to have narrowed the late repeat revascularization difference that favored CABG in the balloon era. Some risk-adjusted registries have shown the superiority of surgery for multivessel disease patients, especially those with diabetes. Randomized trials, meta-analysis of trials, and epidemiological studies have shown the superiority of drug-eluting stents (DES) over bare-metal stents (BMS) in terms of reducing late repeat revascularization.

G. Comparison With Medicine

Given the limited data available from randomized trials comparing medical therapy with PCI, it seems prudent to consider medical therapy for the initial management of most patients with Canadian Cardiovascular Society (CCS) classification class I and II stable angina (*Table 9*, pg. 27) and reserve PCI and CABG for those patients with more severe symptoms and ischemia. The symptomatic patient who wishes to remain physically active, regardless of age, will usually require PCI or CABG to remain physically active.



III. Institutional and Operator Competency

A. Quality Assurance

Class I

1. An institution that performs PCI should establish an ongoing mechanism for valid peer review of its quality and outcomes. Review should be conducted both at the level of the entire program and at the level of the individual practitioner. Quality-assessment reviews should take risk adjustment, statistical power, and national benchmark statistics into consideration. Quality-assessment reviews should include both tabulation of adverse event rates for comparison with benchmark values and case review of complicated procedures and some uncomplicated procedures. *(Level of Evidence: C)*
 2. An institution that performs PCI should participate in a recognized PCI data registry for the purpose of benchmarking its outcomes against current national norms. *(Level of Evidence: C)*
-

Each institution that performs PCI must establish an ongoing mechanism for valid peer review of its quality and outcomes. The program should provide an opportunity for interventionalists and physicians who do not perform angioplasty but are knowledgeable about it to review its overall results on a regular basis. The review process should tabulate

the results achieved both by individual physician operators and by the overall program and compare them with national benchmark standards with appropriate risk adjustment. Valid quality assessment requires that the institution maintain meticulous records that include the patient demographic and clinical characteristics necessary to assess appropriateness and to conduct risk adjustment.

Quality assessment is a complex process that includes more than mere tabulation of success and complication rates. Components of quality in coronary interventional procedures include appropriateness of case selection, quality of procedure execution, proper response to intraprocedural problems, accurate assessment of procedure outcome, and appropriateness of postprocedure management. It is important that each of these parameters be considered when a quality-assessment review is conducted (*Table 5*).

It is recommended that an interventional cardiology operator be certified by the American Board of Internal Medicine in interventional cardiology. Ideally, board certification in interventional cardiology should be required for credentialing (*Table 6*).

**Table 5. Key Components
of a Quality Assurance Program**

Clinical proficiency	<ul style="list-style-type: none">■ General indications/contraindications■ Institutional and individual operator complication rates, mortality, and emergency CABG■ Institutional and operator procedure volumes■ Training and qualifications of support staff
Equipment maintenance and management	<ul style="list-style-type: none">■ Quality of laboratory facility
Quality improvement process	<ul style="list-style-type: none">■ 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® or other databases are strongly recommended for this purpose.
Radiation safety	<ul style="list-style-type: none">■ Educational program in the diagnostic use of X-ray■ Patient and operator exposure

ACC = American College of Cardiology; CABG = coronary artery bypass graft surgery.

B. Operator and Institutional Volume

Class I

1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with on-site cardiac surgery.

(Level of Evidence: B)

2. Elective PCI should be performed by operators and institutions whose historical and current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. *(Level of Evidence: C)*

3. Primary PCI for ST-segment elevation MI (STEMI) should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCIs for STEMI per year. *(Level of Evidence B)*

Class IIa

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

(Level of Evidence: B)

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

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

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

Table 6. 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 more than 500 PCI procedures and is board certified by the 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 III-C, Role of On-Site Cardiac Surgical Backup for discussion)
 - Establishment of a mentoring program for operators who perform fewer than 75 procedures per year by individuals who perform at least 150 procedures per year
-

Physicians

- Procedural volume of 75 per year or more
 - 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.

C. Role of On-Site Cardiac Surgical Backup

- Class I**
1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available on-site emergency cardiac surgical services. *(Level of Evidence: B)*
 2. Primary PCI for patients with STEMI should be performed in facilities with on-site cardiac surgery. *(Level of Evidence: B)*
-

- Class III**
- Elective PCI should not be performed at institutions that do not provide on-site cardiac surgery. *(Level of Evidence: C)*

Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program. A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of cardiac surgical support but cannot be managed effectively by urgent transfer. A study from the Medicare database found higher mortality for patients undergoing elective PCI in institutions without onsite cardiac surgery. These recommendations may be subject to revision as clinical data and experience increase.

The Writing Committee continues to support the recommendation that elective PCI should not be performed in facilities without on-site cardiac surgery. Mere convenience should not replace safety and efficacy in establishing an elective PCI program without on-site surgery. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

D. Primary PCI for STEMI Without On-Site Cardiac Surgery

- Class IIb** 1. Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished, including appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI), an experienced catheterization team on a 24 hours per day, 7 days per week call schedule, and a well-equipped catheterization laboratory with digital imaging equipment, a full array of interventional equipment, and intra-aortic balloon pump capability, and provided that there is a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with STEMI or MI with new or presumably new left bundle-branch block (LBBB) on electrocardiogram and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 primary PCI procedures per year. *(Level of Evidence: B)*

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



Table 7. Criteria for Performance of Primary PCI at Hospitals Without On-Site Cardiac Surgery

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

IABP = intra-aortic balloon pump; **MI** = myocardial infarction; **PCI** = percutaneous coronary intervention. 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.

There are important institutional considerations in creating an effective program of primary PCI for STEMI. An institution must commit its catheterization facility to be capable of a 24 hours per day, 7 days per week rapid response to a patient presenting with STEMI. In addition, the institution's catheterization facility staff must be sufficiently trained and experienced in the management of the seriously ill patient with STEMI (*Table 7*) (*Table 8*).

It has been demonstrated that institutions without an elective PCI program that care for a large number of patients with STEMI can create high-quality PCI for STEMI programs. These programs require the 24 hours per day, 7 days per week availability of experienced interventionalists and an institutional commitment to invest in the physical and cognitive resources needed to support a high-quality program.

Table 8. Patient Selection for Primary PCI and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:

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

Transfer for emergency aortocoronary bypass surgery patients:

- After primary PCI of occluded vessels if high-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability are present, preferably with intra-aortic balloon pump support
-

PCI = percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction.

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.



IV. Clinical Presentations

Table 9. Grading of Angina Pectoris According to Canadian Cardiovascular Society Classification

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

Adapted with permission from Campeau L. Grading of angina pectoris. *Circulation* 1976;54:522-3.

A. Patients With Asymptomatic Ischemia or CCS Angina Class I or II

- Class IIa** 1. Percutaneous coronary intervention is reasonable in patients with asymptomatic ischemia or CCS class I or II angina and with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of

morbidity and mortality. The vessels to be dilated must subtend a moderate to large area of viable myocardium or be associated with a moderate to severe degree of ischemia on noninvasive testing.

(Level of Evidence: B)

2. Percutaneous coronary intervention is reasonable for patients with asymptomatic ischemia or CCS class I or II angina, and recurrent stenosis after PCI with a large area of viable myocardium or high-risk criteria on noninvasive testing. *(Level of Evidence: C)*

3. Use of PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina with significant left main coronary artery disease (CAD; greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. *(Level of Evidence: B)*

Class IIb

1. The effectiveness of PCI for patients with asymptomatic ischemia or CCS class I or II angina who have 2- or 3-vessel disease with significant proximal left anterior descending coronary artery (LAD) CAD who are otherwise eligible for CABG with 1 arterial conduit and who have treated diabetes or abnormal left ventricular (LV) function is not well established. *(Level of Evidence: B)*

2. Percutaneous coronary intervention might be considered for patients with asymptomatic ischemia

or CCS class I or II angina with nonproximal LAD CAD that subtends a moderate area of viable myocardium and demonstrates ischemia on noninvasive testing. (*Level of Evidence: C*)

Class III

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

a. Only a small area of viable myocardium at risk
(*Level of Evidence: C*)

b. No objective evidence of ischemia
(*Level of Evidence: C*)

c. Lesions that have a low likelihood of successful dilatation (*Level of Evidence: C*)

d. Mild symptoms that are unlikely to be due to myocardial ischemia (*Level of Evidence: C*)

e. Factors associated with increased risk of morbidity or mortality (*Level of Evidence: C*)

f. Left main disease and eligibility for CABG
(*Level of Evidence: C*)

g. Insignificant disease (less than 50% coronary stenosis) (*Level of Evidence: C*)

B. Patients With CCS Angina Class III

- Class IIa**
1. It is reasonable that PCI be performed in patients with CCS class III angina and single-vessel or multi-vessel CAD who are undergoing medical therapy and who have 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality. *(Level of Evidence: B)*
 2. It is reasonable that PCI be performed in patients with CCS class III angina with single-vessel or multi-vessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. *(Level of Evidence: C)*
 3. Use of PCI is reasonable in patients with CCS class III angina with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. *(Level of Evidence: B)*
-

- Class IIb**
1. Percutaneous coronary intervention may be considered in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with a reduced likelihood of success. *(Level of Evidence: B)*

2. Percutaneous coronary intervention may be considered in patients with CCS class III angina and no evidence of ischemia on noninvasive testing or who are undergoing medical therapy and have 2- or 3-vessel CAD with significant proximal LAD CAD and treated diabetes or abnormal LV function. *(Level of Evidence: B)*

Class III

1. Percutaneous coronary intervention is not recommended for patients with CCS class III angina with single-vessel or multivessel CAD, no evidence of myocardial injury or ischemia on objective testing, and no trial of medical therapy, or who have 1 of the following:
- a. Only a small area of myocardium at risk
(Level of Evidence: C)
 - b. All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success *(Level of Evidence: C)*
 - c. A high risk of procedure-related morbidity or mortality *(Level of Evidence: C)*
 - d. Insignificant disease (less than 50% coronary stenosis) *(Level of Evidence: C)*
 - e. Significant left main CAD and candidacy for CABG *(Level of Evidence: C)*
-

C. Patients With Unstable Angina/Non-STEMI

- Class I**
1. An early invasive PCI strategy is indicated for patients with unstable angina (UA)/non-STEMI (NSTEMI) who have no serious comorbidity and who have coronary lesions amenable to PCI. Patients must have any of the following high-risk features:
 - a. Recurrent ischemia despite intensive anti-ischemic therapy (*Level of Evidence: A*)
 - b. Elevated troponin level (*Level of Evidence: A*)
 - c. New ST-segment depression (*Level of Evidence: A*)
 - d. heart failure symptoms or new or worsening mitral regurgitation (*Level of Evidence: A*)
 - e. Depressed LV systolic function (*Level of Evidence: A*)
 - f. Hemodynamic instability (*Level of Evidence: A*)
 - g. Sustained ventricular tachycardia (*Level of Evidence: A*)
 - h. Percutaneous coronary intervention within 6 months (*Level of Evidence: A*)
 - i. Prior CABG (*Level of Evidence: A*)
-

- Class IIa**
1. It is reasonable that PCI be performed in patients with UA/NSTEMI and single-vessel or multivessel CAD who are undergoing medical therapy with focal

saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery.

(Level of Evidence: C)

2. In the absence of high-risk features associated with UA/NSTEMI, it is reasonable to perform PCI in patients with amenable lesions and no contraindication for PCI with either an early invasive or early conservative strategy. See full-text guidelines. *(Level of Evidence: B)*

3. Use of PCI is reasonable in patients with UA/NSTEMI with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG.

(Level of Evidence: B)

Class IIb

1. In the absence of high-risk features associated with UA/NSTEMI, PCI may be considered in patients with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with reduced likelihood of success. *(Level of Evidence: B)*

2. Percutaneous coronary intervention may be considered in patients with UA/NSTEMI who are undergoing medical therapy who have 2- or 3-vessel disease, significant proximal LAD CAD, and treated diabetes or abnormal LV function. *(Level of Evidence: B)*

-
- Class III** 1. In the absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for patients with UA/NSTEMI with single-vessel or multivessel CAD and no trial of medical therapy, or who have 1 or more of the following:
- a. Only a small area of myocardium at risk
(Level of Evidence: C)
 - b. All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success *(Level of Evidence: C)*
 - c. A high risk of procedure-related morbidity or mortality. *(Level of Evidence: C)*
 - d. Insignificant disease (less than 50% coronary stenosis) *(Level of Evidence: C)*
 - e. Significant left main CAD and candidacy for CABG *(Level of Evidence: B)*
-

D. Patients With STEMI

1. General and Specific Considerations

- Class I** General Considerations:
- 1. If immediately available, primary PCI should be performed in patients with STEMI (including true posterior MI) or MI with new or presumably new

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

Specific Considerations:

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

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

Class IIa

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

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

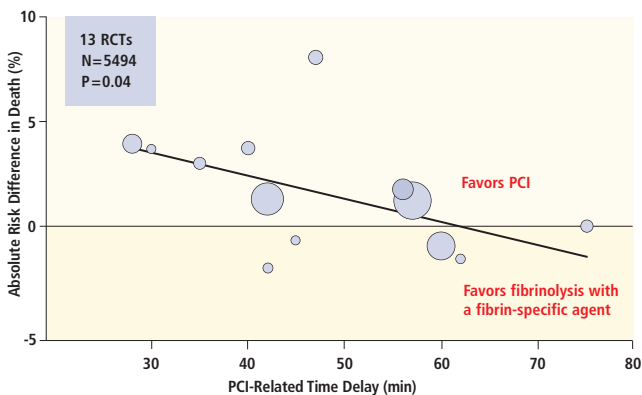
Class III 1. Elective PCI should not be performed in a non-infarct-related artery at the time of primary PCI of the infarct-related artery in patients without hemodynamic compromise. (*Level of Evidence: C*)

2. Primary PCI should not be performed in asymptomatic patients more than 12 hours after onset of STEMI who are hemodynamically and electrically stable. (*Level of Evidence: C*)

Time from symptom onset to reperfusion is an important predictor of patient outcome. An analysis of the randomized, controlled trials that compared fibrinolysis with primary PCI suggests that the mortality benefit with PCI exists when treatment is delayed by no more than 60 minutes (*Figure 1*). Mortality increases significantly with each 15-minute delay in the time between arrival and restoration of TIMI-3 flow (door-to-TIMI-3 flow time), which

further underscores the importance of timely reperfusion in patients who undergo primary PCI (Figure 2). Given that the door-to-needle time goal is 30 minutes, this Writing Committee joins the Task Force on the Management of Acute Myocardial Infarction of the European Society of Cardiology and the ACC/AHA STEMI Guidelines Writing Committee in lowering the door-to-balloon time goal from 120 to 90 minutes in an attempt to maximize the benefits of reperfusion by PCI.

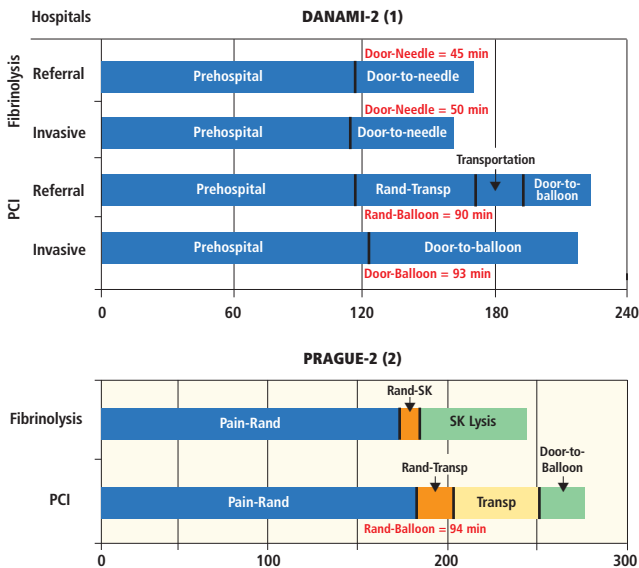
Figure 1. Percutaneous Coronary Intervention Versus Fibrinolysis with Fibrin-specific Agents: Is Timing (Almost) Everything?



N = number of patients; RCT = randomized controlled trial.

Modified with permission from Nallamothu BK, Bates E. Am J Cardiol 2003;92:824-6.

Figure 2. Comparison of Elapsed Time to Fibrinolysis Versus Primary PCI



Time is presented as a continuous variable in minutes on the horizontal axis. For DANAMI-2 (second DANISH trial in AMI), times reflect components of delay from symptom onset to randomization (vertical bar) and are further separated according to whether patients presented at community referral hospitals or those equipped for primary PCI. For those patients randomized to PCI at a referral hospital, the 3 components of delay after randomization are related to duration of stay at the referral hospital, time for transport to the PCI hospital, and delay from arrival at the PCI hospital to balloon inflation.

PCI = percutaneous coronary intervention; PRAGUE-2 = second study of Primary Angioplasty after transport of patients from General community hospitals to catheterization Units with/without Emergency thrombolytic infusion; Rand = randomization; SK = streptokinase; Transp = transportation.

Top graph reprinted with permission from Anderson et al. N Engl J Med 2003;349:733-742; (1) Copyright 2003 Massachusetts Medical Society. All rights reserved. Bottom graph reprinted from Widimsky et al. Eur Heart J 2003;24:94-104 (2) with permission from the European Society of Cardiology.

Primary stenting using BMS compared with primary PTCA in 9 studies showed no differences in mortality (3.0% versus 2.8%) or reinfarction (1.8% versus 2.1%) rates. However, subsequent target vessel revascularization rates were lower with stenting. Preliminary reports suggest that compared with conventional BMS, DES are not associated with increased risk when used for primary PCI in patients with STEMI. PCI appears to have its greatest mortality benefit in high-risk patients. In patients with cardiogenic shock, an absolute 9% reduction in 30-day mortality with mechanical revascularization instead of immediate medical stabilization was reported in the SHOCK (SHould we emergently revascularize Occluded Coronaries for cardio-genic shock?) trial.

2. Percutaneous Coronary Intervention in Fibrinolytic-Ineligible Patients (Table 10)

Class I 1. Primary PCI should be performed in fibrinolytic-ineligible patients who present with STEMI within 12 hours of symptom onset. (*Level of Evidence: C*)

Class IIa 1. It is reasonable to perform primary PCI for fibrinolytic-ineligible patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:

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

Table 10. Contraindications and Cautions for Fibrinolysis in STEMI*

Absolute contraindications

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

Relative contraindications

- History of chronic severe, poorly controlled hypertension
 - Severe, uncontrolled hypertension on presentation (SBP greater than 180 or DBP greater than 110 mm Hg)[†]
 - History of prior ischemic stroke greater than 3 months, dementia, or known intracranial pathology not covered in contraindications
 - Traumatic or prolonged (greater than 10 minutes) CPR or major surgery (less than 3 weeks)
 - Recent (within 2 to 4 weeks) internal bleeding
 - Noncompressible vascular punctures
 - For streptokinase/anistreplase: prior exposure (more than 5 days ago) or prior allergic reaction to these agents
 - Pregnancy
 - Active peptic ulcer
 - Current use of anticoagulants: the higher the INR, the higher the risk of bleeding
-

CPR = cardiopulmonary resuscitation; DBP = diastolic blood pressure; INR = international normalized ratio; SBP = systolic blood pressure; STEMI = ST-elevation myocardial infarction.

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

[†] Could be an absolute contraindication in low-risk patients with STEMI (see Section 6.3.1.6.3.2 in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction, available at: <http://www.acc.org/clinical/guidelines/stemi/index.pdf>).

Reprinted from Antman EM, et al. J Am Coll Cardiol 2004;44:e1-e211.

3. Percutaneous Coronary Intervention After Failed Fibrinolysis (Rescue PCI)

Class I

1. Rescue PCI should be performed in patients less than 75 years old with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of patient's wishes or contraindications/unsuitability for further invasive care.

(Level of Evidence: B)

2. Rescue PCI should be performed in patients with severe heart failure and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours.

(Level of Evidence: B)

Class IIa

1. Rescue PCI is reasonable for selected patients 75 years or older with ST elevation or LBBB or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. *(Level of Evidence: B)*

2. It is reasonable to perform rescue PCI for patients with 1 or more of the following:

a. Hemodynamic or electrical instability

(Level of Evidence: C)

b. Evidence of persistent ischemia. *(Level of Evidence: C)*

-
- Class III** 1. Rescue PCI in the absence of 1 or more of the above class I or IIa indications is not recommended. *(Level of Evidence: C)*
-

4. Percutaneous Coronary Intervention After Successful Fibrinolysis or for Patients Not Undergoing Primary Reperfusion

- Class I**
1. In patients whose anatomy is suitable, PCI should be performed when there is objective evidence of recurrent MI. *(Level of Evidence: C)*
 2. In patients whose anatomy is suitable, PCI should be performed for moderate or severe spontaneous or provokable myocardial ischemia during recovery from STEMI. *(Level of Evidence: B)*
 3. In patients whose anatomy is suitable, PCI should be performed for cardiogenic shock or hemodynamic instability. *(Level of Evidence: B)*
-

- Class IIa**
1. It is reasonable to perform routine PCI in patients with LV ejection fraction less than or equal to 0.40, heart failure, or serious ventricular arrhythmias. *(Level of Evidence: C)*
 2. It is reasonable to perform PCI when there is documented clinical heart failure during the acute episode, even though subsequent evaluation shows preserved LV function (LV ejection fraction greater than 0.40). *(Level of Evidence: C)*

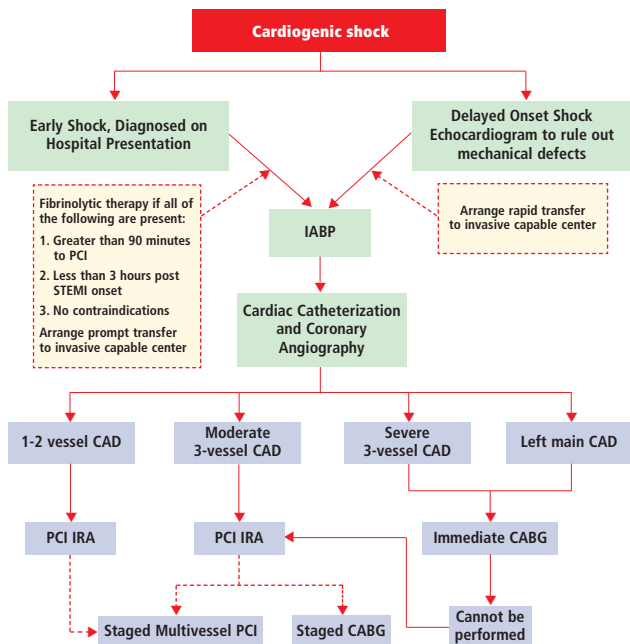
Class IIb 1. Percutaneous coronary intervention might be considered as part of an invasive strategy after fibrinolytic therapy. *(Level of Evidence: C)*

5. Percutaneous Coronary Intervention for Cardiogenic Shock (Figure 3)

Class I 1. Primary PCI is recommended for patients less than 75 years old with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. *(Level of Evidence: A)*

Class IIa 1. Primary PCI is reasonable for selected patients 75 years or older with ST elevation or LBBB who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. *(Level of Evidence: B)*

Figure 3. Recommendations for Initial Reperfusion Therapy When Cardiogenic Shock Complicates STEMI



Early mechanical revascularization with PCI/CABG is a class I recommendation for candidates less than 75 years of age with ST elevation or LBBB who develop shock less than 36 hours from STEMI and in whom revascularization can be performed within 18 hours of shock, and it is a class IIa recommendation for patients 75 years of age or older with the same criteria. Eighty-five percent of shock cases are diagnosed after initial therapy for STEMI, but most patients develop shock within 24 hours. An intra-aortic balloon pump (IABP) is recommended as a stabilizing measure for patients when shock is not quickly reversed with pharmacological therapy. **Dashed lines** indicate that the procedure should be performed in patients with specific indications only. **IRA** = infarct-related artery; **STEMI** = ST-elevation myocardial infarction.

Reprinted with permission from Hochman. *Circulation* 2003; 107:2998-3002.

E. Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

- Class I**
1. When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG. *(Level of Evidence: B)*
 2. It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. *(Level of Evidence: B)*
-

- Class IIa**
1. Percutaneous coronary intervention is reasonable in patients with ischemia that occurs 1 to 3 years after CABG and who have preserved LV function with discrete lesions in graft conduits. *(Level of Evidence: B)*
 2. Percutaneous coronary intervention is reasonable in patients with disabling angina secondary to new disease in a native coronary circulation after CABG. (If angina is not typical, objective evidence of ischemia should be obtained.) *(Level of Evidence: B)*
 3. Percutaneous coronary intervention is reasonable in patients with diseased vein grafts more than 3 years after CABG. *(Level of Evidence: B)*
 4. Percutaneous coronary intervention is reasonable when technically feasible in patients with a patent left internal mammary artery graft who have clinically significant obstructions in other vessels. *(Level of Evidence: C)*

Class III

1. Percutaneous coronary intervention is not recommended in patients with prior CABG for chronic total vein graft occlusions. *(Level of Evidence: B)*

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

F. Intravascular Ultrasound Imaging

Class IIa

1. Intravascular ultrasound is reasonable for the following:

a. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent. *(Level of Evidence: B)*

b. Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (vascular brachytherapy versus repeat balloon expansion). *(Level of Evidence: B)*

c. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis. *(Level of Evidence: C)*

d. Assessment of a suboptimal angiographic result after PCI. *(Level of Evidence: C)*

e. Establishment of the presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated. *(Level of Evidence: C)*

f. Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy. *(Level of Evidence: B)*

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

- Class III**
1. Intravascular ultrasound is not recommended when the angiographic diagnosis is clear and no interventional treatment is planned. *(Level of Evidence: C)*
-

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

Class IIa 1. It is reasonable to use intracoronary physiological measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (*Level of Evidence: B*)

Class IIb 1. Intracoronary physiological measurements may be considered for the evaluation of the success of PCI in restoring flow reserve and to predict the risk of restenosis. (*Level of Evidence: C*)

2. Intracoronary physiological measurements may be considered for the evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (*Level of Evidence: C*)

Class III 1. Routine assessment with intracoronary physiological measurements such as Doppler ultrasound or fractional flow reserve to assess the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (*Level of Evidence: C*)



V. Management of Patients Undergoing PCI

A. Oral Antiplatelet Therapy

Class I

1. Patients already taking daily chronic aspirin therapy should take 75 to 325 mg of aspirin before the PCI procedure is performed. *(Level of Evidence: A)*
2. Patients not already taking daily chronic aspirin therapy should be given 300 to 325 mg of aspirin at least 2 hours and preferably 24 hours before the PCI procedure is performed. *(Level of Evidence: C)*
3. After the PCI procedure, in patients with neither aspirin resistance, allergy, nor increased risk of bleeding, aspirin 325 mg daily should be given for at least 1 month after BMS implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily chronic aspirin use should be continued indefinitely at a dose of 75 to 162 mg. *(Level of Evidence: B)*
4. A loading dose of clopidogrel should be administered before PCI is performed. *(Level of Evidence: A)* An oral loading dose of 300 mg, administered at least 6 hours before the procedure, has the best established evidence of efficacy. *(Level of Evidence: B)*

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

Class IIa

1. If clopidogrel is given at the time of procedure, supplementation with glycoprotein (GP) IIb/IIIa receptor antagonists can be beneficial to facilitate earlier platelet inhibition than with clopidogrel alone. *(Level of Evidence: B)*

2. For patients with an absolute contraindication to aspirin, it is reasonable to give a 300-mg loading dose of clopidogrel, administered at least 6 hours, before PCI and/or GP IIb/IIIa antagonists, administered at the time of PCI. *(Level of Evidence: C)*

3. When a loading dose of clopidogrel is administered, a regimen of greater than 300 mg is reasonable to achieve higher levels of antiplatelet activity more rapidly, but the efficacy and safety compared with a 300-mg loading dose are less established. *(Level of Evidence: C)*

4. It is reasonable that patients undergoing brachytherapy be given daily clopidogrel 75 mg indefinitely and daily aspirin 75 to 325 mg indefinitely unless there is significant risk for bleeding.

(Level of Evidence: C)

Class IIb

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

(Level of Evidence: C)

Aspirin reduces the frequency of ischemic complications after PCI. A strategy of pretreatment with clopidogrel in patients who have not already had their coronary anatomy defined is controversial, because patients who undergo CABG within 5 to 7 days of clopidogrel treatment have an increased risk of bleeding.

B. Glycoprotein IIb/IIIa Inhibitors

Class I 1. In patients with UA/NSTEMI undergoing PCI without clopidogrel administration, a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban) should be administered. *(Level of Evidence: A)**

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

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

3. In patients undergoing elective PCI with stent placement, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). *(Level of Evidence: B)*

Class IIb 1. In patients with STEMI undergoing PCI, treatment with eptifibatide or tirofiban may be considered. *(Level of Evidence: C)*

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

C. Antithrombotic Therapy

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

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

- Class IIa**
1. It is reasonable to use bivalirudin as an alternative to unfractionated heparin and GP IIb/IIIa antagonists in low-risk patients undergoing elective PCI. *(Level of Evidence: B)*
 2. Low-molecular-weight heparin is a reasonable alternative to unfractionated heparin in patients with UA/NSTEMI undergoing PCI. *(Level of Evidence: B)*
-

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

D. Risk Factor Modifications

All patients should be instructed about necessary behavior and risk factor modification, and the appropriate medical therapies should be initiated for the secondary prevention

of atherosclerosis before the patient leaves the hospital. The interventional cardiologist should emphasize the importance of these measures directly to the patient, because failure to do so may suggest that secondary prevention therapies are not necessary. The interventional cardiologist should interact with the primary care physician to ensure that the necessary secondary prevention therapies initiated during hospitalization are maintained by patients after discharge from the hospital. Secondary prevention measures are an essential part of long-term therapy because they can reduce future morbidity and mortality associated with the atherosclerotic process.

E. Left Main CAD

- Class IIa** 1. It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI. (*Level of Evidence: C*)
-

Percutaneous coronary intervention is not recommended in patients with left main disease who are eligible for CABG. (See Section IV. Clinical Presentations.) In those patients with significant left main CAD (greater than 50% diameter stenosis) who are not eligible for CABG in whom PCI is performed, careful postprocedure surveillance, including coronary angiography, is needed to prevent fatal MI or sudden death that may be associated with in-stent restenosis with a large area of myocardium in jeopardy.



VI. Special Considerations

A. Management Strategies for Restenosis After PTCA

- Class IIa** 1. It is reasonable to consider that patients who develop restenosis after PTCA or PTCA with atheroablative devices are candidates for repeat coronary intervention with intracoronary stents if anatomic factors are appropriate. *(Level of Evidence: B)*

B. Drug-Eluting Stents

- Class I** 1. A DES should be considered as an alternative to the BMS in subsets of patients in whom trial data suggest efficacy. *(Level of Evidence: A)*
-
- Class IIb** 1. A DES may be considered for use in anatomic settings in which the usefulness, effectiveness, and safety have not been fully documented in published trials. *(Level of Evidence: C)*
-

C. Management Strategies for In-Stent Restenosis

1. Drug-Eluting Stents

- Class IIa** 1. It is reasonable to perform repeat PCI for in-stent restenosis with a DES or a new DES for patients if anatomic factors are appropriate.
(Level of Evidence: B)
-

2. Radiation

- Class IIa** 1. Brachytherapy can be useful as a safe and effective treatment for in-stent restenosis.
(Level of Evidence: A)
-

D. Subacute Stent Thrombosis

Issues of subacute stent thrombosis and technical issues with the paclitaxel-eluting stent balloon-delivery system were early causes for concern. After many more data have been accumulated (*Table 11*), there does not appear to be an increased incidence of early thrombosis with either the sirolimus- or paclitaxel-eluting stent.

Table 11. Published Randomized Trials and Selected Registry Experiences of Drug-Eluting Stents Compared with Bare-Metal Stents

Eluting Drug	Trial	Year	Number Active / Control	Stent	Eluting Drug Dosage
Sirolimus	FIM	2001	30 In Sao Paulo; 15 in Rotterdam	BxVelocity	140 mcg / cm ²
	FIM	2002	15 From Rotterdam	BxVelocity	140 mcg / cm ²
	RAVEL	2002	120/118	BxVelocity	140 mcg / cm ²
	SIRIUS	2004	533/525	BxVelocity	140 mcg / cm ²
	C-SIRIUS	2004	50/50	BxVelocity	140 mcg / cm ²
	E-SIRIUS	2003	175/177	BxVelocity	140 mcg / cm ²
	RESEARCH Registry Overall	2004	508/450	BxVelocity	140 mcg / cm ²
	RESEARCH Registry ACS	2003	198/301	BxVelocity	140 mcg / cm ²
	RESEARCH Registry STEMI	2004	186/183	BxVelocity	140 mcg / cm ²
	RESEARCH Registry Chronic Totals	2004	56/28	BxVelocity	140 mcg / cm ²
Paclitaxel	QuaDS-QP2	2002	15	QuaDS-QP2	2400 to 3200 mcg total dose
	ASPECT	2003	59 High dose / 58 low dose / 59 control	Supra-G	3.1 mcg / mm ² (high dose); 1.3 mcg / mm ² (low dose)
	TAXUS I	2003	31/30	NIR	1.0 mcg / mm ²
	TAXUS II	2003	266/279	NIR	1.0 mcg / mm ²
	TAXUS III	2003	28 In-stent restenosis	NIR	1.0 mcg / mm ²
	TAXUS IV	2004	662/652	Express	1.0 mcg / mm ²

ACS = acute coronary syndromes; ASPECT = ASian Paclitaxel-Eluting stent Clinical Trial; C-SIRIUS = Canadian SIRIUS trial; E-SIRIUS = European SIRIUS trial; FIM = First In Man; MACE = major adverse cardiac events; MI = myocardial infarction; NA = not applicable; QuaDS-QP2 = 7-hexanoyltaxol—eluting polymer

Death, Active / Control, %	MI, Active / Control, %	Restenosis, Active / Control, %	TLR, Active / Control, %
NA	NA	0% at 1 year	Minimal neointimal proliferation at 1 year
NA	NA	0% at 2 years	Minimal neointimal proliferation at 2 years
1.7/1.7	3.3/4.2	0/26.6 at 6 months (<i>P</i> less than 0.001)	0/22.9 at 1 year (<i>P</i> equals 0.001)
0.9/0.6	2.8/3.2	8.9/36.3 at 8 months (<i>P</i> less than 0.001)	4.9/20 at 1 year (<i>P</i> less than 0.001)
0/0	2.0/4.0	2.3/51.1	4.0/18.0 at 9 months (<i>P</i> less than 0.001)
1.1/0.6	4.6/2.3	5.9/42.3	4.0/20.9 at 9 months (<i>P</i> less than 0.001)
1.6/2.0 at 30 days	0.8/1.6 at 30 days	NA	1.0/1.8 at 30 days
3.0/3.0 at 30 days	3.0/1.0 at 30 days	NA	1.0/2.7 at 30 days
8.3/8.2 at 300 days	0.5/2.2 at 300 days	NA	1.1/8.2 at 300 days (<i>P</i> less than 0.01)
0/0 In hospital	NA	NA	12-Month MACE: 5.6/17.2 (<i>P</i> less than 0.05)
NA	NA	13.3 at 6 months; 61.5 at 1 year	20 at 6 months; 60 at 1 year
0.9/0	2.6/1.7	4/12/27 at 4 to 6 months (high dose vs control, <i>P</i> less than 0.001)	2/2/2 at 1 to 6 months
0/0	0/0	0/10 at 6 months (<i>P</i> equals 0.012)	0/10 at 1 year (<i>P</i> equals 0.237)
0/0.8	3.1/5.3	7.1/21.9 at 6 months	10.4/21.7 at 12 months
NA	NA	NA	21.4 at 1 year
1.4/1.1	3.5/3.7	7.9/26.6 at 9 months (<i>P</i> less than 0.0001)	4.4/15.1 at 1 year (<i>P</i> less than 0.0001)

stent system; **RAVEL** = RAnomized study with the sirolimus-eluting VELocity balloon expandable stent; **RESEARCH** = Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital; **SIRIUS** = SIRollmUs-coated stent in de novo native coronary lesions; **TLR** = target-lesion revascularization.

