

ACC/AHA TASK FORCE REPORT

Guidelines for Percutaneous Transluminal Coronary Angioplasty

A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Percutaneous Transluminal Coronary Angioplasty)

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Preamble

It is becoming more apparent each day that despite a strong national commitment to excellence in health care, the resources and personnel are finite. It is therefore appropriate that the medical profession examine the impact of developing technology and new therapeutic modalities on the practice of cardiology. Such analyses, carefully conducted, could potentially have an impact on the cost of medical care without diminishing the effectiveness of that care.

To this end, in 1980 the American College of Cardiology and the American Heart Association established the Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures with the following charge:

The task force of the American College of Cardiology and the American Heart Association shall develop guidelines relating to the role of new therapeutic approaches and of specific noninvasive and invasive procedures in the diagnosis and management of cardiovascular disease.

The task force shall address, when appropriate, the contribution, uniqueness, sensitivity, specificity, indications, contraindications, and cost-effectiveness of such diagnostic procedures and therapeutic modalities.

The task force shall emphasize the role and values of the guidelines as an educational resource.

The task force shall include a chair and six members, three representatives from the American Heart Association and three representatives from the American College of Car-

diology. The task force may select ad hoc members as needed upon the approval of the presidents of both organizations. Recommendations of the task force are forwarded to the president of each organization.

The members of the task force are George A. Beller, MD; Robert A. O'Rourke, MD; J. Ward Kennedy, MD; Robert C. Schlant, MD; Sylvan Lee Weinberg, MD; William L. Winters, Jr, MD; and Charles Fisch, MD, chair.

This document was reviewed by the officers and other responsible individuals of the two organizations and received final approval in June 1993. It is being published simultaneously in *Circulation* and the *Journal of the American College of Cardiology*. The potential effect of this document on the practice of cardiology and some of its unavoidable shortcomings are clearly set out in the introduction.

Charles Fisch, MD, FACC

Introduction

The American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures was formed to gather information and make recommendations about appropriate use of technology in the diagnosis and treatment of patients with cardiovascular disease. Coronary angioplasty is one such important technique. We are currently witnessing an extraordinary expansion of the use of coronary angioplasty as an alternative means of achieving myocardial revascularization. An estimated 300 000 angioplasty procedures were performed in the United States in 1990, a more than tenfold increase over the past decade (1). Such growth is attributable not only to demonstrated clinical benefit but also to continuing technical advances that have led to improved techniques

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and higher success rates over time. There was some concomitant broadening of the indications for both coronary angiography and angioplasty, which led the task force to promulgate guidelines for coronary angiography in 1987 (2) and guidelines for percutaneous transluminal coronary angioplasty (PTCA) in 1988 (3). In view of the continuing advances and expanding role of interventional cardiology in clinical practice today, it was recommended that this committee review current indications and procedures governing the performance of angioplasty in the United States and determine whether any alterations in the previously published guidelines are warranted. Such a review was anticipated and recommended in the original committee report (3). This document presents the summary opinion of the reconvened committee with its newly constituted membership.

These recommendations were shaped over the course of 9 months' deliberation and reflect much thoughtful discussion and broad consultation, as well as a detailed review of the world literature. The committee proceeded on the premise that angioplasty is an effective means of achieving myocardial revascularization and its appropriate use is to be broadly encouraged. At the same time, the committee is mindful of the many forces that can affect the performance of any specific procedure and recognizes the potential for a variety of inappropriate and expedient considerations to influence the performance of angioplasty in this country. Accordingly, the committee offers these recommendations with a heightened awareness of the need for the cardiology community at large, and institutional programs specifically, to police themselves in the use of coronary angioplasty.

The technique of angioplasty is in evolution and the long-term results are not yet fully elucidated; therefore, even these revised recommendations are likely to change over subsequent years. Because multiple variables must be weighed in selecting balloon angioplasty treatment, this report is not intended to provide strict indications or contraindications for the procedure. Relevant considerations include occupational needs, the family setting, associated illnesses, and lifestyle preferences. Rather, the report is intended to provide a statement of general consensus that may be helpful to the practitioner as well as to health care administrators and other professionals interested in the delivery of medical care. The American College of Cardiology and the American Heart Association recognize that the ultimate judgment regarding the appropriateness of any specific procedure is the responsibility of the physician caring for the patient. The guidelines should not be considered all-inclusive or exclusive of other methods that may be available for the care of the individual patient. The committee will not offer detailed recommendations about the specific resources required to perform coronary angioplasty or to train those performing the procedure. It is essential that physicians performing angioplasty and related procedures are adequately trained, that facilities and equipment used are capable of obtaining the necessary radiographic information, and that the safety record of the laboratory is acceptable.

This report includes some general considerations that provide a brief review of the growth and development of the procedure, identification of contraindications to its use, and a statement acknowledging general risks associated with angioplasty. A brief discussion of considerations unique to angioplasty follows with an enumeration of those factors currently recognized as influencing the outcome, the requirement for surgical backup, performance of angioplasty at the time of initial catheterization, management of the patient after angioplasty, the problems of restenosis and incomplete revascularization, the need for periodic institutional credentialing, and institutional mortality and morbidity review. Lastly, specific guidelines for the application of coronary angioplasty are presented; these were developed according to anatomic (single versus multivessel disease), clinical (asymptomatic versus symptomatic patients), and physiological (presence or absence of inducible ischemia) considerations. The indications derived from consensus for angioplasty are judged to be either Class I, II, or III (defined in "Indications for Angioplasty"), based primarily on multifactorial risk assessment weighed against expected outcome, judgments of feasibility, appropriateness to the clinical setting, and overall efficacy viewed in the light of current knowledge and technology.

General Considerations

Background

Symptomatic coronary artery disease is present in more than 6 million people in the United States. Despite the availability of effective medical therapy, a significant proportion of patients are candidates for a revascularization procedure because of unacceptable symptoms or potentially life-threatening lesions. An estimated 300 000 coronary artery bypass operations and 300 000 coronary angioplasty procedures were performed in 1990 (1). Although coronary angioplasty is still performed most often in patients with single-vessel coronary disease, increasing numbers of patients with multivessel disease and those who have undergone surgical bypass are also being treated. Coronary bypass surgery is used most often to treat multivessel coronary disease, with a majority of patients receiving three or more bypass grafts. Use of the internal mammary artery as a conduit has risen dramatically in recent years, from less than 4% of the total number of procedures (an estimated 6000) in 1983 to more than 60% of all operations in 1990 (1). The leading indication for surgery continues to be relief of angina, an approach supported by findings of randomized trials, that have shown that, compared with medical therapy, surgical revascularization significantly reduces symptoms and improves quality of life (4). At the same time there has been an expansion of the patients for whom it is recognized that bypass surgery improves survival. This improvement in survival (5-12) has been established in patients with left main coronary disease (5), certain patients with three-vessel disease (6-8), some

patients with two-vessel disease when the proximal anterior descending coronary artery is involved (7,9), as well as in subsets of patients with severe symptoms (10) or with a positive exercise test (11). Although PTCA has been effective in alleviating angina in many classes of patients, there have not yet been trials comparing angioplasty with medical therapy in the subsets shown to have improved survival with surgery.

Immediate and Long-Term Results

Coronary angioplasty was first introduced by Andreas Gruentzig in 1977 (13) as an alternative form of revascularization. During the early years of its application Gruentzig and others used angioplasty predominantly to treat patients with discrete proximal noncalcified subtotal occlusive lesions in a single coronary artery. In subsequent years the technique has been used successfully in patients with multivessel disease, multiple subtotal stenoses in the same vessel, certain complete occlusions, partial occlusion of saphenous vein or internal mammary artery grafts, or recent total thrombotic occlusions associated with acute myocardial infarction.

By 1980 Gruentzig had performed the procedure on 169 symptomatic patients, 40% of whom had multivessel disease. The 10-year follow-up of those patients showed persistent long-term benefit, with 89.5% of the patients surviving and 75% remaining asymptomatic. Ten-year survival in patients with single-vessel disease (95%) exceeded that in patients with multivessel disease (81%). Repeat angioplasty was required by 31% and coronary bypass surgery by 31% (14). Five-year survival in patients treated at Emory University in 1981, most of whom had single-vessel disease, was 97% (15) and at 10 years was 92%. The National Heart, Lung, and Blood Institute established a PTCA registry in 1979 to help evaluate the technique. Through 1982 a total of 3079 patients were entered into the voluntary registry, and numerous analyses from this data bank have substantiated the effectiveness and safety of angioplasty (16). Because technical advances resulted in improved success rates and expanded application, a new registry was opened by the NHLBI in 1985 to evaluate more recent trends in angioplasty. Sixteen centers agreed to voluntarily collect data on an additional 2500 patients. The primary clinical success rate increased from 61% in the initial cohort to 78% (17). Despite a change in complexity, with half of the cases in the second registry having multivessel disease, the rate of nonfatal myocardial infarction decreased from 4.9% to 4.3% and that of emergency coronary artery surgery from 5.8% to 3.4%; the mortality rate remained unchanged (1.2% and 1.0%). Five-year follow-up of the data from the second registry indicates an overall survival rate of 90% (18).

Investigators in a recently completed trial, Angioplasty Compared to Medical Therapy (19), compared angioplasty with medical therapy in patients with single-vessel disease. Although improved symptoms and a modest increase in

exercise performance were documented among the patients randomly assigned to PTCA, there was no demonstrable effect on survival, a feature also similar to surgical trials in patients with single-vessel disease. This study is also noteworthy for the observation that nearly 50% of the patients randomly assigned to medical therapy became angina-free during the 6-month period of observation.

In recent years, angioplasty in multivessel disease has been associated with a mortality risk of approximately 1% to 2% (20-23), although it is recognized that the procedure can have a higher risk in patients with more severe disease. In the NHLBI registry, double-vessel disease angioplasty was associated with a 0.9% in-hospital mortality rate, while triple-vessel disease was associated with a 2.8% mortality rate. The 5-year survival for patients with single-vessel disease was 93.2%, for those with double-vessel disease, 88.8%, and for those with triple-vessel disease, 86% (18). In one report from a single institution, involving 700 patients with multivessel disease (53% having double-vessel disease and 47% having triple-vessel disease), the 5-year overall survival rate was 88%. Event-free survival, defined as freedom from death, Q-wave infarction, and coronary bypass surgery, was 74% (23).

Influence of New Devices

Two aspects of balloon angioplasty have motivated cardiologists to seek alternative methods of improving flow through obstructed arteries: the acute complications resulting from the angioplasty procedure itself and the occurrence of late restenosis following the procedure. Although atherectomy, laser angioplasty, and stenting have improved initial results in certain anatomic situations, the overall rates of acute complication and restenosis with use of these devices have not differed from those with balloon angioplasty (24,25). Although in certain situations an operator may use an approved new interventional device, it is to be noted that these devices have been approved only for specific indications that are more restrictive than those for balloon angioplasty. These guidelines are based principally on experience with balloon angioplasty, and throughout this document the term "angioplasty" will be used to describe the procedure of endovascular enlargement of the coronary lumen by a balloon or other device.

Comparison With Bypass Surgery

Coronary angioplasty and coronary bypass grafting are both intended to improve myocardial blood flow. Both are palliative rather than curative and should be seen as complementary rather than competitive procedures. Both are associated with potential risks, including stroke, myocardial injury, and death.

The major advantage of coronary angioplasty is its relative ease of use, avoiding general anesthesia, thoracotomy, extracorporeal circulation, mechanical ventilation, and pro-

longed convalescence. Repeat angioplasty can be performed more easily than repeat bypass surgery and revascularization can be achieved more quickly in emergency situations. The disadvantages of angioplasty are high early restenosis rates and the inability to relieve many stenoses because of the nature and extent of the coronary lesion.

Coronary 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 through the vessel wall, the more compelling the choice of coronary artery bypass surgery, particularly if left ventricular function is depressed. Patients with lesser extent of disease and localized lesions are good candidates for endovascular approaches. The use of either technique assumes the presence of clinical indications such as failure of medical treatment to control symptoms or a potential survival benefit.

The use of the two technologies in terms of patient selection and comparisons of outcome await the completion of several ongoing randomized clinical trials (26) (the Bypass Angioplasty Revascularization Investigation, the Coronary Angioplasty Versus Bypass Revascularization Investigation, the Emory Angioplasty Surgery Trial, the German Angioplasty Bypass Investigation, and Randomized Intervention Treatment of Angina) (27) in which the two treatments are compared in patients eligible for both techniques. Changing technology, institutional and operator experience, and patient preference will continue to influence choice of treatment.

The increasing use of angioplasty in suitable patients has materially affected the indications for the coronary bypass operation. This has resulted in a change in the case mix of patients undergoing bypass surgery in recent years: they are generally older, have diffuse, extensive coronary disease, often with impaired left ventricular function, and are higher-risk patients than formerly (28,29). There is also a recognized paucity of proper risk-adjusted comparisons between coronary artery bypass surgery, PTCA, and medical treatment. Based on data available in 1989, Wong et al. (30) constructed a decision analytic model that addresses the question of when myocardial revascularization is indicated for chronic stable angina. The model considers angioplasty in addition to bypass surgery and medical therapy and supports the recommendation that revascularization is not indicated unless severe symptoms, other markers of substantial ischemia, or severe multivessel disease are present. The analysis also suggests that angioplasty may be preferable to bypass surgery in patients with one- and two-vessel disease. In a recent nonrandomized study of consecutive patients treated with PTCA or coronary artery bypass graft surgery (CABG) for multivessel disease and left ventricular dysfunction, in-hospital mortality rates were comparable (5% for CABG and 3% for PTCA) (31). Although stroke was

more common in CABG patients (7% compared with 0%, $p = .01$), there was a trend toward improved 5-year survival for patients who had undergone bypass grafting compared with those who had undergone PTCA (75% and 67%, $p = .09$). Age and incomplete revascularization, but not method of revascularization, were found upon multivariate analysis to correlate with late mortality. For a more detailed comparison of CABG with PTCA, the reader is referred to the ACC/AHA guidelines and indications for coronary artery bypass surgery (12).

Contraindications to Angioplasty

In general, the contraindications to angioplasty include all of the relative contraindications enumerated for the performance of coronary angiography as outlined in the guidelines of an earlier ACC/AHA report (2). Before undergoing angioplasty, it is imperative that the patient clearly understand the procedure, its potential complications, and the alternatives of medical therapy or bypass surgery and have a truly informed understanding of the risk-benefit ratio. The importance of a relative contraindication to angioplasty will vary with the symptomatic state as well as the general medical condition of the individual patient. Certain risks may be appropriate in severely symptomatic individuals who, for example, are not candidates for bypass surgery, whereas these risks would be inadvisable for an asymptomatic or mildly symptomatic individual. The currently accepted contraindications to the performance of *elective* coronary angioplasty are the following.

1. Absolute contraindications

- a. There is no significant obstructing lesion.*
- b. There is a significant obstruction (>50%) in the left main coronary artery and this main segment is not protected by at least one nonobstructed bypass graft to the left anterior descending or left circumflex artery.
- c. There is no formal cardiac surgical program within the institution.

2. Relative contraindications

- a. A coagulopathy is present: conditions associated with bleeding abnormalities or hypercoagulable states may be associated, respectively, with unacceptable risks of serious bleeding or thrombotic occlusion of a recently dilated vessel.
- b. The patient has diffusely diseased saphenous vein grafts without a focal dilatable lesion.
- c. The patient has diffusely diseased native coronary arteries with distal vessels suitable for bypass grafting.

*For the purpose of this report, a significant stenosis is defined as one that results in a $\geq 50\%$ reduction in coronary diameter as determined by caliper method.

- d. The vessel in question is the sole remaining circulation to the myocardium.
- e. The patient has chronic total occlusions with clinical and anatomic features that result in a very low anticipated success rate of dilation.
- f. The lesion under consideration is a borderline stenotic lesion (usually <50% stenosis).
- g. The procedure is proposed for a non-infarct-related artery in patients with multivessel disease who are undergoing direct angioplasty for acute myocardial infarction.

In addition to these generally accepted relative contraindications, there are other risks that cause clinicians to have considerable reservations about the risk-benefit ratio of angioplasty. These risks include those of abrupt vessel closure, those associated with emergency bypass surgery compared with elective surgery, as well as those of restenosis. These risks are viewed as being on a continuum, and their aggregate weight should ultimately determine whether a specific procedure should or should not be undertaken.

Patients with chronic renal failure may have increased morbidity following coronary angioplasty due to contrast-induced increased renal failure and subsequent prolonged hospitalization. Although coronary angioplasty can be performed successfully in patients on dialysis, the restenosis rate has been high (81% in one report) and the long-term outcome has been unfavorable (32). Whether the long-term results of patients undergoing renal transplantation are better if coronary angioplasty is performed before or after the procedure is unresolved.

Risks Associated With Angioplasty

Because coronary angioplasty requires visualization of the coronary anatomy as well as systemic arterial and venous access, patients undergoing the procedure are at risk for the same complications associated with diagnostic cardiac catheterization (2).

Despite major improvements in angioplasty equipment and operator skill, abrupt vessel closure remains the major cause of morbidity and mortality, occurring in 3% to 8% of procedures, depending on the definition used (33-39). Coronary artery dissection, with or without thrombus, is the major cause of abrupt vessel closure. Although coronary artery spasm appears occasionally to be a contributing factor (40), in a number of studies hypotension during or immediately after an angioplasty procedure preceded abrupt vessel closure (36,41), with a lack of adequate perfusion pressure presumably contributing to the abrupt closure. Intra-aortic balloon pumping (42) and vasopressors may restore coronary artery perfusion pressure. Although successful resolution of abrupt vessel closure has been accomplished with percutaneous techniques in as many as two thirds of patients (37), the condition is associated with a substantial mortality rate (4% to 10%), and 20% to 30% of patients require

emergency bypass surgery, with 9% experiencing Q-wave infarction (35,39,41).

In the event of abrupt vessel closure, recrossing the occluded segment and repeating balloon inflation, inserting a perfusion catheter, or using thrombolytic or vasodilator agents can frequently reestablish coronary artery patency and relieve ischemia (37,41,43,44). Directional coronary atherectomy has been successful in managing selected cases with bulky plaque separation that produces vessel obstruction (45). The preliminary results of intracoronary stents have shown promise in the management of the dissected coronary artery (46-50). The subsequent management of patients with stents requires a careful balance between adequate prolonged anticoagulation to prevent thrombosis and avoidance of bleeding complications. Prolonged maneuvers to reestablish coronary patency are discouraged if they delay needed surgical intervention and risk further myocardial damage due to prolonged ischemia.

Peripheral vascular complications (particularly false aneurysms and access site bleeding) may occur and are usually associated with large guiding catheters, prolonged procedures, advanced age of the patient, and periprocedural use of heparin or fibrinolytic agents (51). The large doses of contrast material required for complex angioplasty procedures may also contribute to morbidity by causing hemodynamic and renal dysfunction in some patients. Other infrequent complications unique to coronary angioplasty include intracoronary embolization of atherosclerotic or thrombotic material, coronary perforation, laceration or rupture of a coronary artery with subsequent hemopericardium, and tamponade.

Certain high-risk patients who may have contraindications to coronary bypass surgery may be candidates for coronary angioplasty. Hemodynamic support may be necessary in these patients and multiple devices have been used (52). The most experience is with intra-aortic balloon pump counterpulsation; this technique has been used with relatively low rates of morbidity and mortality (53). Emergency cardiopulmonary support has been used in some centers but has the disadvantage of an increased number of associated complications (54,55). In addition, although the systemic circulation is supported by this method, coronary perfusion is not provided during hemodynamic collapse, and cardiopulmonary support is not cardioprotective against global and regional myocardial dysfunction (56). The indications for cardiopulmonary support need further clarification, and at present the technique should not be used to extend the use of coronary angioplasty for higher-risk patients.

Need for Surgical Backup

Surgical backup, a service that was thought to be essential during the developmental stages of angioplasty, is still provided in one form or another in most cases of elective PTCA.

At present, 2% to 5% of patients undergoing PTCA will

sustain damage (dissection, intimal disruption, perforation, or embolization) to the coronary arteries, requiring emergency surgical intervention. Emergency coronary artery bypass grafting under these circumstances can be done effectively but with an operative mortality higher than that encountered in comparable patients managed with primary elective surgery (12,29,57). Many of these patients have one- or two-vessel disease and would be uncomplicated surgical patients under elective circumstances. The perioperative myocardial infarction rate remains high, however, and the opportunity to use arterial conduits is reduced. The mortality and myocardial infarction rates following emergency surgery for failed PTCA increase with the extent of coronary disease, the occurrence of cardiac arrest, hemodynamic instability, and the need for cardiopulmonary resuscitation, which is often required in these circumstances. Also contributing to the increased mortality and morbidity rates of emergency bypass surgery for failed angioplasty are all the factors that prolong the time to surgical reperfusion. These factors come into play in patients who have had prior heart surgery, those in whom conduit material is lacking, and especially in those for whom the decision to proceed with emergency surgical revascularization is delayed. Although no prospective studies have been done to indicate which patients experiencing failed angioplasty should have emergency surgical revascularization, it is assumed that most patients will benefit from an attempt at surgically restoring myocardial blood flow under these circumstances. The indications for emergency CABG following failed PTCA should follow the guidelines outlined in the ACC/AHA task force report (12).

Because of the variation in institutional practices of cardiology and cardiac surgery, there is no standard surgical backup for angioplasty. Surgical backup varies from informal arrangements in which emergencies are managed without prior planning or preparation to formal standby in which an operating room is kept open and an entire surgical team is immediately available. However, there is concern that the universal requirement that angioplasty be done only in hospitals having cardiac surgical capability is leading to the proliferation in the United States of small-volume cardiac surgical programs whose major role is to provide surgical backup for angioplasty.

Data from centers in Canada and Europe, where surgical programs are limited in number, suggest that elective angioplasty can be performed in hospitals without cardiac surgical capability with results comparable to those of centers having this capability (58-60). It must be acknowledged, however, that with more than 900 surgical/angioplasty units available in the United States, the relative lack of surgical facilities in Canada and abroad does not pertain here. This gives rise to the current opinion in this country that to do elective angioplasty without surgical backup exposes both the patient and physician to unnecessary risk and should not be done routinely (61).

Formal surgical standby that necessitates the expenditure

of enormous resources to provide an operating room, equipment, supplies, and highly trained personnel for a procedure that will be used less than 5% of the time is both expensive and inefficient (62). For this reason, surgical backup for angioplasty is increasingly provided on a more informal basis. Better selection of patients and lesions for angioplasty, better catheter systems, improved technical competence, more stringent credentialing, case-load requirements for those who perform angioplasty, and various "bail-out" techniques have made formal surgical standby less necessary than during the developmental phase of coronary angioplasty (63,64). The sine qua non for optimal patient care is good communication among cardiologist, cardiac surgeon, cardiac anesthesiologist, and support personnel in the cardiac catheterization laboratory and operating room.

The current national standard of accepted medical practice for coronary angioplasty requires that an experienced cardiovascular surgical team be available within the institution* to perform emergency coronary bypass surgery should the clinical need arise (3,12). Although technical advances, operator experience, and alternative reperfusion strategies have somewhat lessened the rate of emergency bypass surgery after failed elective angioplasty, surgical backup has proved life-saving and has effectively reduced subsequent morbidity such that it is deemed *mandatory* by this committee for all *elective* angioplasty procedures. After reviewing all the available evidence, being aware of the experience abroad where on-site surgical backup is not a requirement and mindful of the economic pressures to alter this standard of practice, this subcommittee affirms its conviction that such a policy is in the best interest of the patient.

For patients in whom angioplasty is clearly the most appropriate method of therapy, formal surgical consultation is not deemed necessary and will likely increase costs and may result in longer hospitalizations. For patients with high-risk features or in whom the extent of the disease may indicate that bypass surgery is an equally or more effective method of therapy, a surgical consultation is advisable. This is especially true for patients for whom a high rate of complications of either angioplasty or bypass surgery may be anticipated.

The exact arrangement for surgical backup will vary from one institution to another, depending on such obvious factors as the number of operating rooms available for cardiac surgery and the number of surgeons, perfusionists, nurses, and other personnel on hand. The essential requirement is the capacity to provide surgery promptly when angioplasty fails; otherwise, optimal patient care may be seriously compromised.

The requirement for on-site surgical backup for patients

*"Within the institution" is generally intended to mean within the same hospital. When two hospitals are physically connected such that emergency transport by stretcher or gurney can be achieved rapidly and effectively, the transport of patients between the two hospitals for emergency cardiac surgical services would not be considered off site.

undergoing emergency angioplasty for the management of acute myocardial infarction presents a special problem. The committee recognizes that the requirement for on-site surgical backup greatly restricts the use of this effective form of reperfusion therapy that may provide survival benefit for certain high-risk patients suffering acute myocardial infarction. Both elective angioplasty and emergency procedures for unstable ischemic syndromes and acute myocardial infarction have generally been carried out in tertiary hospitals with in-house cardiac surgical programs. Some cardiologists have performed angioplasty procedures in patients with acute infarction in hospitals that do not have surgical programs because of the need for early reperfusion in critically ill patients (65,66). In some cases, transfer to a tertiary facility would result in a longer period of myocardial ischemia, which would reduce the benefits resulting from reperfusion in these patients. It is clear that very early reperfusion is of greater benefit than later reperfusion, as demonstrated with thrombolytic therapy initially in the GISSI-1 (67) and ISIS-2 (68) trials and more recently in the MITI Study (69) and the GUSTO Trial (70). For this reason, the more widespread availability of angioplasty for the management of acute infarction would potentially provide improved care for some patients, particularly those with absolute contraindications to thrombolytic therapy. At the same time, it must also be recognized that angioplasty carried out during the early hours of acute myocardial infarction is frequently difficult and requires even more skill and experience than routine angioplasty performed in stable patients. However, the need for experienced operators in this setting (71) is not the only concern. It should be emphasized that the experience of the laboratory technical staff and the availability of a broad range of catheters, guidewires, and other devices are required for optimal results in these acutely ill patients. Limiting angioplasty in acute myocardial infarction to laboratories with in-house surgical backup ensures that these procedures are performed in laboratories that have ongoing and regular experience with angioplasty. In point of fact, surgical backup has become a surrogate for experienced, well-equipped laboratories. This consideration is far more important than the presence of surgical backup, especially in light of the recognized difference in the risk-benefit ratio of angioplasty performed in the setting of an acute myocardial infarction.

Data from observational studies indicate that certain high-risk patients with acute myocardial infarction, such as those developing hypotension or congestive heart failure or those in frank cardiogenic shock, benefit from emergency angioplasty of the infarct-related artery (72,73). Such patients are considered to be in Class IIa in the ACC/AHA task force guidelines for the early management of patients with acute myocardial infarction (74). Thus, there may be patients at very high risk suffering acute myocardial infarction, who may or may not be suitable for thrombolytic therapy, in whom emergency angioplasty without on-site surgical backup is acceptable treatment *if the ability to transfer the*

patient to an established angioplasty center on a timely basis is not possible or attendant with additional risk. When such an approach is undertaken in the management of patients with acute myocardial infarction, it is imperative that both the operator and the supporting laboratory team be highly experienced. In this setting the acute illness of the patient and the nature of the procedure are acknowledged to be beyond the capability of a purely diagnostic catheterization laboratory. If experienced angioplasty personnel can be quickly assembled in a laboratory with full equipment for performing angioplasty, then the high-risk acute myocardial infarction patient could benefit from urgent catheterization and angioplasty at a site remote from a laboratory where the procedure is performed routinely. Transfer to a center with full support, including surgical capability, will often be the more effective and efficient course of action. In allowing exception for the need of on-site surgical backup (angioplasty/surgical centers) in the management of select, high-risk patients suffering acute myocardial infarction, the committee feels compelled to underscore its conviction that angioplasty/surgical centers constitute the best venue for *all* angioplasty procedures.

Although many angioplasty procedures are scheduled as clinically urgent or emergent (nonelective) therapy, for example in patients with unstable angina, such procedures should be undertaken only at institutions with on-site surgical backup, ie, PTCA/surgical centers. Because current medical practice dictates that unstable angina should be managed initially by vigorous efforts to stabilize the condition with medical therapy, there is ample time to transfer such patients to institutions with experienced cardiovascular surgeons on site. Indeed, the view has long been held that patients with unstable angina, especially those who are refractory to intense medical therapy, should be transferred to institutions with existing cardiac surgical programs for their initial cardiac catheterization. In addition, recent data suggest that immediate angioplasty in patients with unstable angina may increase the risk of complications (75,76).

There are those who argue that patients who refuse bypass surgery as a therapeutic option or those who are considered nonsurgical candidates could reasonably undergo angioplasty at institutions without on-site surgical backup. The committee views such reasoning as specious and believes that truly informed judgments of this kind are best made when such patients are in institutions with experienced cardiovascular surgical teams, so that all options can be adequately considered.

Need for Institutional Review

A rigorous mechanism for valid peer review must be established and ongoing in each institution performing coronary angioplasty because 1) angioplasty is an interventional procedure associated with known risks of serious complications, including death, 2) it is a therapeutic modality whose efficacy has a recognized association with operator skill and

Table 1. Recommendations for Clinical Competence in Percutaneous Transluminal Coronary Angiography: Minimum Recommended Number of Cases Per Year

	Bethesda Conference 17 (79)	Society for Cardiac Angiography (78)	ACC/AHA (3)	ACP/ACC/AHA (77)	ACC/AHA (1993)
Training					
Total number of cases	125	125	125	125	125
Cases as primary operator	75	75	75	75	75
Practicing					
Number of cases per year to maintain competency	. . .	50	52	75	75

experience, and 3) in certain instances, the procedure can be viewed as a remunerative undertaking performed by the same physician who initiates and interprets the diagnostic studies leading to the procedure itself.

Although institutional review can take many forms and will vary according to such factors as the size of institutions and departments, the number of staff, and the volume of procedures, there are basic requirements for a meaningful review. At a minimum, there must be the opportunity for physicians, including those who do not perform PTCA's but are knowledgeable about the procedure, to review the overall results of the program on a regular basis. Specific attention should be paid to the general indications, the success and failure rates of individual operators, the number of procedures performed per operator, their rates of complications (including emergency surgical procedures), and mortality rates. The review process should examine and document the quality and accuracy of cinearteriographic studies and the appropriateness of indications, and it should include discussion of contraindications. An active database for quality assessment issues should be established.

The committee also identifies a critical need for the institutional review process to ascertain that individual operators meet national credentialing standards as promulgated by the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology in its statement on clinical competence in PTCA (77) (Table 1). Documentation of training in a structured fellowship program during which a minimum of 125 coronary angioplasty procedures, including 75 performed with the trainee as the primary operator, is required to ascertain competence in the procedure (77-79). A major concern is the reality that a majority of operators fail to meet the requirements for maintenance of competence, which is a minimum of 75 PTCA procedures performed per year as the primary operator (3,77). While acknowledging that minimums do not guarantee competence, the committee strongly endorses the recommendations of the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology and believes the proliferation of small-volume operators should be curtailed by appropriate institutional review. To this end, the committee recommends that angioplasty operators who fail to meet these requirements be required to discontinue the performance of the procedure.

Maintenance of competence is important not only for physicians performing PTCA but also for the institution offering this service. A significant number of cases per institution—at least 200 PTCA procedures annually—is essential for the maintenance of quality and safe care (80). Exceptions to this minimum must be based on documentation of high-quality performance of appropriate procedures within the institution (77).

Institutions with medical or surgical groups, or both, that cannot adequately meet the obligation of appropriate institutional review should undertake regional review with cooperating institutions or terminate their program in angioplasty.

Specific Considerations

Successful Angioplasty and Its Determinants

A successful angioplasty procedure is defined as one in which a $\geq 20\%$ change in luminal diameter is achieved, with the final-diameter stenosis $< 50\%$ and without the occurrence of death, acute myocardial infarction, or the need for emergency bypass operation during hospitalization. While this is the technically accepted definition and the one used for the NHLBI registry, it is conventional practice to reduce most lesions to a final-diameter stenosis of $< 30\%$. Atherosclerotic coronary stenoses are considered significant if they have the potential to impair coronary blood flow under physiological circumstances. The visual assessment of coronary narrowing on cineangiograms is associated with substantial inter-observer and intraobserver variability. Although independent quantitative angiographic techniques have become the gold standard for evaluating coronary obstructions, determination of coronary narrowing by caliper techniques is a readily available technique that correlates closely with computer quantitative methods for assessing percent stenosis (81). For the purpose of this report, a significant stenosis is defined as one that results in a 50% reduction in coronary diameter as determined by caliper method or other quantitative angiographic technique.

After a decade of experience, it is now reasonable to expect of any angioplasty program an overall initial success rate of $\geq 90\%$ for single lesion dilations. In addition to

operator experience, procedural success relates to certain patient characteristics and, very importantly, to angiographic characteristics of the lesion or lesions to be dilated.

Patient-related factors influencing a successful dilation are primarily younger age and male gender, but clinical variables such as diabetes, prior myocardial infarction, prior bypass surgery, and impairment of left ventricular function are associated with procedural morbidity and mortality.

Angiographic patterns outlining the morphological characteristics of vessels and defining lesion-specific characteristics have now been identified that may influence the likelihood of a successful dilation. Recognizing the uniquely technical aspects of angioplasty and in an attempt to risk-stratify any given procedure, the committee proposes that patients be stratified into low- and increased-risk categories based on clinical and angiographic variables. These variables may serve as a guide for estimating the likelihood of a successful procedure and, more importantly, the likelihood for abrupt coronary occlusion or cardiovascular collapse should PTCA fail.

Low-risk profile. Features associated with relatively low risk for the angioplasty procedure are age <70 years, male gender, single-vessel and single-lesion coronary artery disease, no history of congestive heart failure, left ventricular ejection fraction >40%, stable angina, and <90% type A coronary stenosis (3,34,39,82-85). Type A coronary stenoses are discrete (≤ 10 mm in length) and concentric, and have the characteristics of ready accessibility; location in a nonangulated segment ($<45^\circ$); smoothness of contour; little or no calcification; and absence of total occlusion, ostial location, major side branch involvement, or thrombus (Table 2).

Increased-risk profile. Features associated with increased risk for PTCA include advanced age, female gender, multivessel and multilesion PTCA, diabetes mellitus, history of congestive heart failure, degree of left ventricular dysfunction, left main equivalent coronary disease, inadequate antiplatelet therapy, unstable angina pectoris, PTCA immediately following thrombolytic therapy, and PTCA at the time of initial catheterization for unstable angina pectoris (82-91). Lesion-specific variables include stenoses $\geq 90\%$ in severity, stenosis bend angulation $>45^\circ$, excessive proximal vessel tortuosity, intraluminal thrombus, and type B or C characteristics as enumerated in Table 2. Although many experienced operators, using both conventional and newer technologies, have success rates of $\geq 90\%$ for PTCA in lesions with type B or C characteristics (92-95), an important note of caution has been sounded regarding the interpretation and implications of such data, particularly as applied to the evaluation of newer technologies (93). Chronic total occlusions are the most significant predictor of procedural failure but usually do not pose a high risk to the patient.

Abrupt vessel closure. Although the correlates of procedural complications noted above may serve to stratify groups of patients according to anticipated risk, they generally have a low positive and negative predictive value.

Table 2. Characteristics of Type A, B, and C Lesions

Lesion-Specific Characteristics
Type A lesions (minimally complex)
Discrete (length <10 mm)
Concentric
Readily accessible
Nonangulated segment ($<45^\circ$)
Smooth contour
Little or no calcification
Less than totally occlusive
Not ostial in location
No major side branch involvement
Absence of thrombus
Type B lesions (moderately complex)*
Tubular (length 10 to 20 mm)
Eccentric
Moderate tortuosity of proximal segment
Moderately angulated segment ($>45^\circ$, $<90^\circ$)
Irregular contour
Moderate or heavy calcification
Total occlusions <3 mo old
Ostial in location
Bifurcation lesions requiring double guide wires
Some thrombus present
Type C lesions (severely complex)
Diffuse (length >2 cm)
Excessive tortuosity of proximal segment
Extremely angulated segments $>90^\circ$
Total occlusions >3 mo old and/or bridging collaterals
Inability to protect major side branches
Degenerated vein grafts with friable lesions

*Although the risk of abrupt vessel closure may be moderately high with Type B lesions, the likelihood of a major complication may be low in certain instances such as in the dilation of total occlusions <3 mo old or when abundant collateral channels supply the distal vessel.

Abrupt vessel closure during PTCA will occur in 3% to 8% of procedures and is largely unforeseeable (33-39,41,96). Multivariate analyses have identified branch vessel location, lesion length >10 mm, right coronary artery stenosis, and coronary thrombus score as independent preprocedural predictors of abrupt vessel closure (97). Thrombus scores are determined by adding up the number of angiographic features (haziness, contrast stain, filling defect) that suggest the presence of thrombus. Clinical and angiographic variables associated with abrupt coronary artery occlusion are summarized in Table 3. Recent data have suggested that the presence of thrombus is the most significant factor associated with untoward events during PTCA (84,92).

Cardiovascular collapse. Certain variables may be useful in prospectively identifying patients at risk for cardiovascular collapse if abrupt vessel closure complicates PTCA (83,84,96). A composite four-variable scoring system, prospectively validated to be both sensitive and specific in predicting cardiovascular collapse if PTCA fails, includes 1) percentage of myocardium at risk, 2) pre-PTCA percent diameter stenosis, 3) multivessel coronary artery disease, and 4) diffuse disease in the dilated segment (96). This index

Table 3. Factors Predictive of Abrupt Vessel Closure**Preprocedure****Clinical factors**

- Female gender
- Unstable angina
- Insulin-dependent diabetes mellitus
- Inadequate antiplatelet therapy

Angiographic factors

- Intracoronary thrombus
- >90% stenosis
- Stenosis length 2 or more luminal diameters
- Stenosis at branch point
- Stenosis on bend ($\geq 45^\circ$)
- Right coronary artery stenosis

Postprocedure

- Intimal dissection >10 mm
- Residual stenosis >50%
- Transient in-lab closure
- Residual transstenotic gradient ≥ 20 mm Hg

proved highly sensitive and specific when prospectively compared with previously described risk factors such as >50% viable myocardium at risk and left ventricular ejection fraction of <25%. Similarly, a myocardial jeopardy score has been devised to help determine the degree of viable myocardium at risk for ischemic dysfunction (98,99). This score divides the coronary tree into six segments and assigns two points to coronary segments subtended by stenoses of $\geq 75\%$ severity. Added weight is given to the left anterior descending coronary distribution, which comprises three segments (Figure). Patients with higher preprocedural jeopardy scores have a greater likelihood of cardiovascular collapse should abrupt vessel closure occur (84).

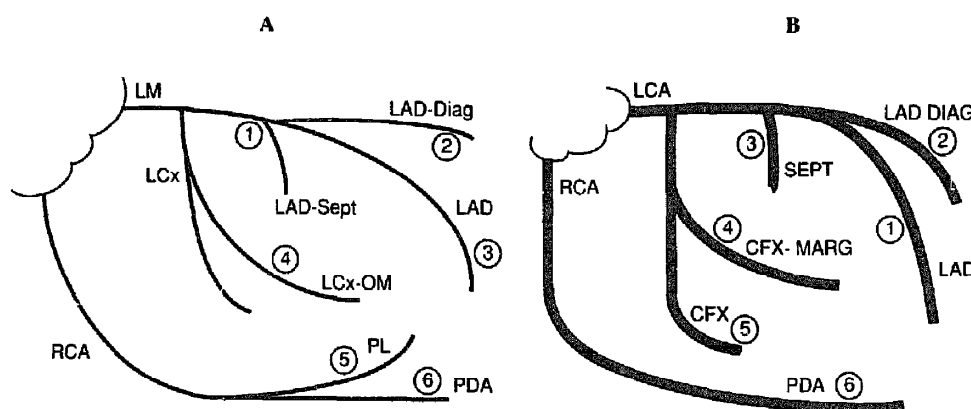
Risk of death. The clinical variables associated with increased mortality are identified as advanced age, female

gender, diabetes, prior myocardial infarction, multivessel disease, left main or equivalent coronary disease, a large area of myocardium at risk, impairment of left ventricular function, and collateral vessels supplying significant areas of myocardium that originate distal to the segment to be dilated (41,82–84,100,101). Recent data have shown that the increased mortality among women undergoing angioplasty, compared with men, is associated with older age, more clinical heart failure, and unstable angina. Despite having more hypertension and diabetes, the extent of coronary artery disease in women undergoing angioplasty is no greater than that among men (102,103). Death is directly related to the occurrence of coronary artery occlusion and is most frequently due to left ventricular failure (84). Left ventricular failure was independently correlated with the coronary artery jeopardy score, female gender, and PTCA of a proximal right coronary artery stenosis. Factors associated with death following angioplasty are listed in Table 4.

These clinical variables can be assessed before the performance of PTCA and should help to determine procedural risk, particularly the risk of abrupt vessel closure and cardiovascular collapse. Patients having a higher-risk profile may be candidates for alternative therapies, particularly coronary bypass surgery, or for more formalized surgical standby or periprocedural hemodynamic support.

Angioplasty at the Time of Initial Cardiac Catheterization

The selection of patients for angioplasty demands careful review of the clinical and anatomic features of each case. This is optimally done after diagnostic cardiac catheterization and review of the cineangiograms. This process, however, obviously subjects the patient to a repeat invasive



Diagrammatic illustration of coronary artery jeopardy score segments for patients with either right coronary (panel A) or left coronary (panel B) dominance. Coronary segments subtended by stenoses of $\geq 75\%$ severity are assigned two points. The occurrence of cardiogenic shock after abrupt vessel closure is more frequently observed with jeopardy scores of ≥ 5.0 in men or ≥ 3.5 in women. Diag or DIAG indicates diagonal branch; LAD, left anterior descending; LCx, left circumflex; LM, left main coronary artery; MARG or OM, obtuse marginal branch; PDA, posterior descending coronary artery; PL, posterolateral branch; RCA, right coronary artery; Sept or SEPT, septal branch. (Adapted from References 84 and 99 with permission.)

Table 4. Factors Associated With Increased Mortality For Angioplasty

Clinical Factors
Female gender
Age >65 years
Unstable angina
Congestive heart failure
Chronic renal failure
Angiographic Factors
Left main coronary disease
Three-vessel disease
Left ventricular ejection fraction < 0.30
Risk index*
Myocardial jeopardy score
Proximal right coronary stenosis
Collaterals originate from dilated vessel

*See reference 96.

procedure with its inherent risk and recognized morbidity, lengthens hospitalization, and adds to the direct and indirect costs involved.

A staged approach to coronary angioplasty after cardiac catheterization has certain advantages: it allows more time to plan the dilation strategy, to have consultation with colleagues, to have more extensive discussion with the patient and family, and to review the therapeutic options. However, in some patients who are informed in anticipation of a combined procedure and who have suitable coronary anatomy, performing combined coronary angiography and angioplasty reduces the hospital stay by 30%, reduces costs by 15%, and reduces radiation exposure without compromising the safety of the procedure (104,105).

Combined angiography and PTCA is particularly suitable for three subsets of patients: 1) patients with unstable angina that cannot be stabilized who require urgent PTCA, 2) patients with signs or symptoms suggesting restenosis following PTCA within the previous 12 months, and 3) patients undergoing PTCA for an acute myocardial infarction with planned PTCA of only the infarct artery. In all instances pretreatment with aspirin is very important (106-108).

In some other elective cases, PTCA can also be performed safely immediately after coronary angiography without additional complications if the lesions are clearly identified at angiography with high-quality image systems and the patient is well informed and prepared before the procedure (109). In all cases, however, any decision regarding PTCA should be delayed if there is any question about the need for, the suitability of, or the preference for PTCA as opposed to medical or surgical treatment.

Postangioplasty Management

Immediately after coronary angioplasty, attention is directed to monitoring for evidence of recurrent ischemia, to ensuring appropriate hemostasis at the site of catheter insertion, and to detecting and preventing contrast-induced renal

injury. Specific protocols for sheath removal, continuation of anticoagulation, and administration of antiplatelet therapy will vary from institution to institution and with the complexity of the procedure. Special skilled nursing units have been developed in some institutions to facilitate post-PTCA management. Most patients can be safely discharged from the hospital within 24 to 48 hours after an uncomplicated angioplasty.

A small portion of patients in whom angioplasty was judged angiographically successful will experience symptoms of myocardial ischemia during the observation period after the procedure. If electrocardiographic abnormalities suggesting ischemia are detected, there is a substantial risk of abrupt vessel closure, which has been associated with a comparatively high mortality rate (33-39). An individual judgment must be made as to whether additional angioplasty, emergency bypass surgery, or continued medical therapy is appropriate. Accordingly, the equipment and services required to perform repeat angiography and, if necessary, repeat angioplasty or CABG need to be available 24 hours per day in any institution that offers an angioplasty program.

Patients must be instructed about appropriate risk-factor modification before their discharge from the hospital. Depending on the patient, advice should include hypertension control, diabetic management, aggressive control of the serum lipids following American Heart Association guidelines, abstinence from tobacco, weight control, regular exercise, and timing of return to full activities. Patients should be informed of the importance of contacting their physician if symptoms recur. To date no pharmacologic therapy has been shown to prevent restenosis (110).

Follow-up studies to detect restenosis and recurrent myocardial ischemia are helpful in the patient management after PTCA. A treadmill test done within days or a few weeks of angioplasty is reassuring if negative (particularly if it was positive preangioplasty) and can be useful in providing advice on exercise and work capacity. A positive exercise test 3 to 6 months after PTCA is suggestive of restenosis, particularly if angina is present (111). Exercise or pharmacologic stress echocardiography and stress perfusion scintigraphy have also been used for the detection of significant restenosis and, in asymptomatic patients, may be somewhat more specific than exercise stress electrocardiography (112-114).

Some 12% to 20% of asymptomatic patients will have significant angiographic restenosis 6 months after PTCA. In many cases, this can be detected by noninvasive stress tests (115,116). However, if a patient has no angina, has a negative stress ECG, or negative results on stress perfusion scintigraphy, the probability of a significant restenosis is approximately 5% (115,116). In the absence of symptoms, a modest reversible defect on stress perfusion scintigraphy may not justify repeat angioplasty. Coronary angiography may be indicated in some patients without evidence of myocardial ischemia because of special employment or

occupational requirements or other factors judged to be important by their physician.

If significant clinical restenosis is identified at any time after PTCA, indications for repeat PTCA should follow the general indications as outlined in "Indications for Angioplasty." If restenosis has not occurred by 6 months after PTCA, it is unusual for it to develop later; subsequent clinical evidence of myocardial ischemia is usually associated with progression of disease elsewhere in the coronary tree (117).

Restenosis

Although the initial outcome for coronary angioplasty procedures has improved over the past 15 years, the incidence of coronary restenosis after dilation has remained unchanged at 30% to 40% and is perhaps higher in certain complex lesions (110,118,119). The rate of restenosis in native arteries depends partly on its definition. Of the different restenosis criteria proposed, a >50% diameter stenosis at follow-up angiography is the most frequently used (120). Investigators using quantitative angiographic techniques have proposed using the change in minimal lumen diameter from that after PTCA to that at follow-up, normalized for the reference vessel diameter (relative loss) (121-123). Ultimately it is the minimal lumen diameter of the residual stenosis after healing related to the vessel's normal size that is important. A dichotomous variable such as >50% stenosis at follow-up may work well in clinical practice, but it is to be noted that all dilated arteries undergo some healing. For this reason, the continuous variables of minimal lumen diameter or percent diameter stenosis at follow-up best describe restenosis in large patient populations. Accordingly, they should be used in clinical trials aimed at altering the restenosis process.

The pathogenesis of the restenotic process subsequent to mechanical injury is incompletely understood but appears multifactorial. The principal factors include elastic recoil, organization of thrombus adherent to the site of arterial injury, and growth factor stimulation of smooth muscle proliferation (124-126).

The value of symptoms for detecting restenosis has varied widely among studies, although on average, 60% to 70% of patients with recurrent angina within 6 months of PTCA have restenosis and 10% to 20% of those without recurrent symptoms have restenosis (110).

Patient-related factors that appear to predispose the patient to restenosis include male gender, continued smoking after angioplasty, diabetes, elevated blood insulin levels, absence of previous myocardial infarction, and unstable angina (119,126,127), although one recent analysis has questioned the relationship of smoking to restenosis (128). Angiographic factors related to restenosis include angioplasty of the proximal left anterior descending coronary, the presence of chronic total coronary occlusion, stenoses at the origin of vessels, branch vessel stenoses, long lesions, the

presence of thrombus, and stenoses involving the proximal and middle regions of saphenous vein bypass grafts (110,118,119,126). Data from one recent report, however, suggest that, at least with respect to the rate of restenosis observed in diverse segments of the coronary tree, restenosis is an ubiquitous phenomenon without predilection for a particular site or segment (123). Procedural variables related to restenosis include postangioplasty residual stenosis of >30% and pressure gradient of >15 mm Hg. Extensive coronary dissection appears to be associated with a high rate of restenosis (110,118-120).

Factors that have not been correlated with an increased incidence of restenosis include age, functional class, history of previous myocardial infarction, hypertension, serum cholesterol, presence of calcification at the site of dilation, morphological features of the lesion, inflation pressure, and medications taken at time of discharge.

Patients who develop clinical or angiographic evidence of restenosis in native coronary arteries usually undergo a second dilation procedure. For repeat angioplasty, the primary success rate appears higher than for the initial procedure with a relatively low incidence of myocardial infarction or need for emergency coronary artery bypass surgery. The rate of recurrent restenosis, however, is somewhat higher than the rate of restenosis after the initial procedure (129).

Incomplete Revascularization

As coronary angioplasty is being used in more complex clinical and pathoanatomic situations, the concern arises that patients are being subjected to incomplete revascularization or less-than-optimal correction of their pathophysiological state. The surgical experience is convincing that complete revascularization leads to superior results in terms of relief of angina, less myocardial ischemia, better hemodynamic performance on postoperative stress testing, and freedom from subsequent coronary events including reoperation, myocardial infarction, and death (130).

Incomplete or partial revascularization is often a pre-planned therapeutic strategy in patients undergoing angioplasty because of morphological factors precluding successful dilation of all lesions (eg, chronic total occlusions, mild lesions) (92,131). Although early graft closure after bypass surgery also converts complete revascularization to partial revascularization, this phenomenon is less common than restenosis after angioplasty. Some studies have suggested that incomplete revascularization in patients undergoing angioplasty may also unfavorably influence long-term survival (23,31,132).

Partial revascularization after coronary angioplasty is an inherent limitation of the procedure and can be expected to occur more frequently in patients undergoing multivessel angioplasty. Frequently, especially in elderly patients, only one targeted lesion thought to be responsible for the patient's symptoms is dilated to reduce the risk of the procedure. Nonetheless, many patients experience relief of symp-

toms despite partial revascularization when one or more significant lesions supplying large areas of viable myocardium have been dilated (133-137). In addition, multiple successive interventions are feasible, unstable patients may be stabilized, and surgical revascularization may be deferred. The cost, in terms of clinical outcome, associated with such a strategy in patients with multivessel disease compared with an initial strategy of surgical revascularization awaits the outcome of ongoing clinical trials.

Those performing CABG and PTCA use different strategies; surgeons bypass all lesions possible, PTCA operators dilate the most significant. Incomplete revascularization after CABG is primarily related to ungraftable severe distal disease or prior infarction and is thus correlated with a higher late mortality. Incomplete revascularization after PTCA is more likely the result of a strategy not to dilate milder stenoses, inaccessible lesions, or chronic total occlusions, and thus does not correlate closely with late mortality (138).

Indications for Angioplasty

The approach to every angioplasty procedure requires careful consideration of the likelihood of a successful procedure* compared with the likelihood of failure and the risk of complications (abrupt vessel closure, morbidity, mortality, or restenosis). In prioritizing indications for angioplasty, the committee was greatly influenced by the items discussed in "Specific Considerations": 1) factors favoring a successful dilation; 2) factors associated with and consequences of abrupt vessel closure; 3) restenosis; 4) incomplete revascularization; and 5) the consequences of failure of the procedure.

Both clinical judgment and statistical estimates permit appropriate weighting and integration of important variables to formulate likelihood estimates (high, moderate, or low) of the success of any given procedure according to the likelihood of a successful dilation (see Tables 2 and 4); the likelihood of abrupt vessel closure, with subsequent morbidity and mortality (Table 3); the likelihood of restenosis; and the long-term prognosis.

Although operator experience and individual patient characteristics are important factors relating to outcome, both procedural success and abrupt vessel closure are in large part determined by specific patient characteristics and lesion morphology (139,140). It must be recognized that this aspect of cardiovascular care is undergoing considerable growth and development and that frequent updates may be required as new insights are gained. Currently, the following classifications are used to indicate the degree of consensus of the committee members and the reviewing bodies for specific applications of angioplasty:

Class I: Conditions for which there is general agreement that coronary angioplasty is justified. A Class I indication does not mean that coronary angioplasty is the only acceptable therapy.

Class II: Conditions for which there is divergence of opinion with respect to the justification for coronary angioplasty in terms of value and appropriateness.

Class III: Conditions for which there is general agreement that coronary angioplasty is not ordinarily indicated.

Single-Vessel Coronary Artery Disease

Asymptomatic or mildly symptomatic (functional Class I) patients with or without medical therapy: symptoms are defined in accordance with the Canadian Cardiovascular Society classification (Appendix A)

Class I

This category applies to patients who have a significant lesion† in a major epicardial artery that subtends a large area of viable myocardium and who

1. show evidence of severe myocardial ischemia during laboratory testing, ie, ischemia induced by low-level exercise (Bruce Stage 1 or less or <4.0 METS, or heart rate <100 beats per minute) and manifested by
 - a. ischemic ST segment depression ≥ 1 mm in multiple leads or lasting ≥ 3 minutes into recovery, or
 - b. systolic hypotension during exercise, or
 - c. evidence of a significant area of ischemia on nuclear, echocardiographic, or radionuclide angiographic stress testing or a moderate area of ischemia with increased lung thallium-201 uptake, or
 - d. exercise-induced reduction in the ejection fraction or wall motion abnormalities on radionuclide ventriculographic studies, or both, or
2. have been resuscitated from cardiac arrest or from sustained ventricular tachycardia in the absence of acute myocardial infarction, or
3. who must undergo high-risk noncardiac surgery, such as repair of an aortic aneurysm, iliofemoral bypass, or carotid artery surgery, if angina is present or there is objective evidence of ischemia as described above.

All of these patients should have a lesion or lesions associated with a high likelihood of successful dilation, and be at low risk for morbidity and mortality.

Class II (mild or no symptoms, single-vessel coronary disease)

This category applies to patients who have a significant lesion in a major epicardial artery that subtends at least a moderate-sized area of viable myocardium and

*A successful procedure is defined as one in which a $\geq 20\%$ change in luminal diameter is achieved with the final diameter stenosis <50%, without the occurrence of death, acute myocardial infarction, or bypass operation during hospitalization.

†For the purpose of this report, a significant stenosis is defined as one that results in a $\geq 50\%$ reduction in coronary diameter as determined by caliper method.

1. show objective evidence of myocardial ischemia* during laboratory testing and
 - a. have at least a moderate likelihood of successful dilation, and
 - b. have a low risk of abrupt vessel closure, and
 - c. are at low risk for morbidity and mortality.

Class III (mild or no symptoms, single-vessel coronary disease)

This category applies to all other patients with single-vessel disease and mild or no symptoms who do not fulfill the preceding criteria for Class I or Class II. It includes, for example, patients who

1. have only a small area of viable myocardium at risk, or
2. do not manifest evidence of myocardial ischemia during laboratory testing, or
3. have borderline lesions (50% to 60% diameter reduction) and no inducible ischemia, or
4. are at moderate or high risk for morbidity and mortality.

In some patients, circumstance of occupation or employment may result in a Class II indication being viewed as a Class I category. Such patients would include those whose occupation involves the safety of others (eg, airline pilots, bus drivers, truck drivers, and air-traffic controllers) and those in certain occupations that frequently require sudden vigorous activity (eg, firefighters, police officers, and athletes). However, Class III indications for asymptomatic or mildly symptomatic individuals with single-vessel disease pertain to a risk profile that precludes the patient's belonging in Class I or Class II.

Symptomatic patients with angina pectoris (functional Classes II to IV, unstable angina) with medical therapy and single-vessel disease

Class I

This category applies to patients who have a significant lesion in a major epicardial artery that subtends at least a *moderate-sized* area of viable myocardium and who

1. show evidence of myocardial ischemia while on medical therapy (including ECG monitoring at rest), or
2. have angina pectoris that is inadequately responsive† to medical treatment, or
3. are intolerant of medical therapy because of uncontrollable side effects.

*Evidence of myocardial ischemia during laboratory testing is taken to mean exercise-induced ischemia (with or without exercise-induced angina pectoris) manifested by ≥ 1 mm of ischemic ST segment depression or one or more stress-induced reversible nuclear perfusion defects and/or exercise-induced reduction in the ejection fraction and/or wall motion abnormalities on radionuclide ventriculographic or stress echocardiographic studies.

†"Inadequately responsive" as used in this report means that patient and physician agree that angina significantly interferes with the patient's occupation or ability to perform usual activities.

All of these patients should have at least a moderate likelihood of successful dilation and be at low or moderate risk for morbidity and mortality.

Class II (symptomatic, single-vessel coronary disease)

This category applies to patients who have a significant lesion in a major epicardial artery that subtends at least a *moderate-sized* area of viable myocardium and who

1. show evidence of myocardial ischemia during laboratory testing and
 - a. have one or more complex (type B or C morphology) lesions in the same vessel or its branches, or
 - b. are at moderate risk for morbidity or
2. have disabling symptoms and a *small* area of viable myocardium at risk, and
 - a. at least a moderate likelihood of successful dilation and
 - b. are at low risk for morbidity and mortality, or
3. have at least moderately severe angina on medical therapy with equivocal or nondiagnostic evidence of myocardial ischemia on laboratory testing and who prefer treatment with coronary angioplasty to medical therapy, and
 - a. have at least a moderate likelihood of successful dilation, and
 - b. are at low risk for morbidity and mortality.

Class III (symptomatic, single-vessel coronary disease)

This category applies to all other symptomatic patients with single-vessel disease who do not fulfill the preceding criteria for Class I or Class II. It includes, for example, patients who

1. have no or only a small area of viable myocardium at risk in the absence of disabling symptoms, or
2. have clinical symptoms not likely to be indicative of ischemia, or
3. have a very low likelihood of successful dilatation, or
4. are at high risk for morbidity and mortality, or
5. have no symptoms or objective evidence of myocardial ischemia during high-level stress testing (≥ 12 METS).

Patients with single-vessel disease who have significant symptoms constitute one of the largest groups of patients undergoing angioplasty. However, the generally excellent prognosis for patients with single-vessel disease should be a paramount consideration before an interventional procedure is undertaken in these patients. It is imperative that there be some assurance that the significant symptoms are indeed due to the coronary lesion proposed for dilation. Although significant symptoms may justify a lower tolerance for the risk of abrupt vessel closure or subsequent restenosis, one cannot compromise on the risk for significant mortality or morbidity. In view of evidence that angina can diminish, or even disappear, in many patients with occlusive coronary disease, especially those with single-vessel disease, patients

should be informed before angioplasty of the possibility that their symptoms may improve spontaneously on medical treatment alone.

Multivessel Coronary Artery Disease

Asymptomatic or mildly symptomatic (functional Class I) patients with or without medical therapy

Class I

This category applies to patients who have one significant lesion in a major epicardial artery that could result in nearly complete revascularization because the additional lesion(s) subtends a small viable or nonviable area of myocardium. Additionally, patients in this category must

1. have a *large* area of viable myocardium at risk, and
2. show evidence of severe myocardial ischemia while on medical therapy during laboratory testing, or
3. have been resuscitated from cardiac arrest or from sustained ventricular tachycardia in the absence of acute myocardial infarction, or
4. be undergoing high-risk noncardiac surgery and demonstrate objective evidence of myocardial ischemia.

All of these patients should have one or more lesions that would have a high success rate, the successful dilation of which would provide relief to all major regions of ischemia, and be at low risk for morbidity and mortality.

Class II (mild to no symptoms, multivessel coronary disease)

This category applies to patients

1. who are similar to patients in Class I but who
 - a. have a *moderate-sized* area of viable myocardium at risk, or
 - b. have objective evidence of myocardial ischemia during laboratory testing, or
2. who have significant lesions in two or more major epicardial arteries, each of which subtends at least a *moderate-sized* area of viable myocardium, or
3. who have a subtotally occluded vessel requiring angioplasty wherein the development of total occlusion of the vessel would result in severe hemodynamic collapse due to left ventricular dysfunction.

All of these patients should show evidence of myocardial ischemia during laboratory testing, have lesions with at least a moderate likelihood of successful dilation, the successful dilation of which would provide relief to all major regions of ischemia, and be at low or moderate risk for morbidity and mortality.

Class III (mild to no symptoms, multivessel disease)

This category applies to all other patients with multivessel disease and mild or no symptoms who do not fulfill the above criteria for Class I or Class II. It includes, for example, patients who

1. have only a small area of viable myocardium at risk, or
2. have chronic total occlusions in major epicardial vessels subtending moderate or large areas of viable myocardium, or
3. are at high risk for morbidity or mortality.

Symptomatic patients with angina pectoris (functional Classes II to IV, unstable angina) with medical therapy and multivessel disease

Class I

This category applies to patients who have significant lesions in two or more major epicardial arteries both subtending at least *moderate-sized* areas of viable myocardium and who

1. show evidence of myocardial ischemia while on medical therapy during laboratory testing, or
2. have unstable angina or angina pectoris that has proved inadequately responsive to medical therapy, or
3. are intolerant of medical therapy because of uncontrollable side effects.

All of these patients should have lesion morphology associated with a high rate of successful dilation, which would provide relief of all major regions of ischemia, and be at low risk for morbidity and mortality.

Class II (symptomatic, multivessel disease)

This category applies to patients who have significant lesions in two or more major epicardial arteries that subtend at least *moderate-sized* areas of viable myocardium and who

1. are similar to patients in Class I but who are at moderate risk for morbidity and mortality, or
2. have angina pectoris but do not necessarily have objective evidence of myocardial ischemia during laboratory testing.

All of these patients should have lesion morphology associated with a high rate of successful dilation, which would provide relief of all major regions of ischemia, and be at moderate risk for morbidity and mortality.

Patients in this category also are those who

3. have disabling angina that has proved inadequately responsive to medical therapy and
 - a. are considered poor candidates for surgery because of advanced physiologic age or coexisting medical disorders, and
 - b. have lesions with at least a moderate likelihood of successful dilation, and
 - c. are at moderate risk for morbidity and mortality, or
4. have a subtotally occluded vessel requiring angioplasty and the total occlusion of the vessel would result in severe hemodynamic collapse due to left ventricular dysfunction.

Class III (symptomatic, multivessel coronary disease)

This category applies to all other symptomatic patients with multivessel disease who do not fulfill the preceding criteria in Class I or Class II. It includes, for example, patients who

1. have only a small area of myocardium at risk in the absence of disabling symptoms, or
2. have lesion morphology with a low likelihood of successful dilation and subtending moderate or large areas of viable myocardium, or
3. are at high risk for morbidity or mortality, or both.

It is to be stressed that risk assessment is different in patients with multivessel disease than in those with single-vessel disease. In the former group there ideally should be the opportunity for anatomically complete revascularization, although adequate functional revascularization can be achieved without necessarily being anatomically complete. In every instance the goal is to achieve relief of ischemia at a risk acceptable for the procedure. In estimating this risk in multivessel disease it is imperative that each lesion be considered in the context of all other lesions present. Some assessment must then be made of the likely consequences should any one of the attempted dilations fail and result in abrupt vessel closure. For example, there is an increased risk in dilating a left coronary artery lesion if it jeopardizes the entire collateral blood supply to a large area of viable myocardium in the distribution of a totally occluded, nondilatable, dominant right coronary artery (141). On occasion exceptions to these guidelines may be made based on operator judgment, experience, and the patient's desires, particularly in some patients at higher risk for a procedural complication.

Direct Immediate Coronary Angioplasty for Evolving Acute Myocardial Infarction**Class I**

This category applies to the dilation of a significant lesion in the infarct-related artery only in patients who can be managed in the *appropriate laboratory setting* and who

1. are within 0 to 6 hours of the onset of a myocardial infarction (the procedure is used as an alternative to thrombolytic therapy),
2. are within 6 to 12 hours of the onset of a myocardial infarction but who have continued symptoms of ongoing myocardial ischemia, or
3. are in cardiogenic shock with or without previous thrombolytic therapy and within 12 hours of the onset of symptoms.

Class II

This category applies to patients who

1. are within 6 to 12 hours of the onset of an acute myocardial infarction and have no symptoms of myo-

cardial ischemia but have a large area of myocardium at jeopardy and/or are in a higher-risk clinical category

2. are within 12 to 24 hours of the onset of an acute myocardial infarction but who have continued symptoms of ongoing myocardial ischemia, or
3. have received thrombolytic therapy and have continuing or recurrent symptoms of active myocardial ischemia.

Class III

This category applies to

1. angioplasty of a non-infarct-related artery at the time of acute myocardial infarction,
2. patients who are more than 12 hours after the onset of acute myocardial infarction at the time of admission and who have no symptoms of myocardial ischemia, or
3. patients who have had successful thrombolytic therapy within the past 24 hours and have no symptoms of myocardial ischemia.

The role of direct angioplasty in the management of patients during the course of acute myocardial infarction is currently the subject of intense investigation (142). Two major factors leading to the current interest in "primary" angioplasty in acute myocardial infarction patients without preceding fibrinolytic therapy are 1) the realization that <25% of acute myocardial infarction patients in the United States receive fibrinolytic therapy and 2) the findings of three large clinical trials that bleeding complications were seen more frequently when PTCA was preceded by intravenous thrombolytic therapy with tissue plasminogen activator (143-145). Not only were transfusion rates after immediate angioplasty two to three times those reported after deferred angioplasty, overall mortality and left ventricular function were not significantly improved by the combination strategy (146). A number of single-center, nonrandomized, noncontrolled studies indicate that the procedure is effective as a primary means of establishing reperfusion in the early hours of an evolving myocardial infarction (147-151). The procedure is associated with the relief of acute symptoms and associated with acceptable mortality rates when dilation has been successful.

In addition, there are observational data from one large registry study (152) and several randomized clinical trials (153-156) comparing direct angioplasty with intravenous thrombolytic therapy in patients with acute myocardial infarction. These data suggest that direct PTCA is at least as efficacious as thrombolytic therapy and, in certain subsets of patients, may even be superior in terms of recurrent ischemic events, cost reduction, and short-term survival. Although these observations have major implications for the large cohort of acute myocardial infarction patients who are ineligible for thrombolytic therapy, there are substantial differences in terms of mortality risk between a population of acute myocardial infarction patients who are eligible and

those who are ineligible for thrombolytic therapy (157). Although it may appear that direct angioplasty may be the desirable therapeutic approach for patients ineligible for thrombolysis, it seems wise to test this hypothesis in well-designed, prospective, randomized clinical trials (142), particularly in light of the unexpected findings of the randomized trials of the potential benefits of following thrombolytic therapy with immediate PTCA (143-145).

One group of patients who appear to achieve significant benefit from direct PTCA, particularly when it is done in conjunction with the use of the intra-aortic balloon pump for hemodynamic support, is that comprising patients with cardiogenic shock complicating acute myocardial infarction (72,73,158,159). Compared with the conventionally high mortality associated with cardiogenic shock (approximately 80%), a relatively low in-hospital mortality (approximately 40%) has been observed in selected patients with cardiogenic shock treated with successful angioplasty (159-163). Angioplasty may, thus, offer some benefit for patients who experience cardiogenic shock complicating acute myocardial infarction, particularly those who are within 12 hours of symptom onset (164).

After Acute Myocardial Infarction (Angioplasty During Initial Hospitalization)

Class I

This category applies to the dilation of any significant lesion(s) in patients who

1. have recurrent episodes of ischemic chest pain, particularly if accompanied by electrocardiographic changes (postinfarction angina), or
2. show objective evidence of myocardial ischemia during laboratory testing performed before discharge from the hospital, or
3. have recurrent sustained ventricular tachycardia or ventricular fibrillation, or both, while receiving intensive medical therapy.

All of these patients should have one or more lesions that predict a high (>90%) success rate and be at low risk for morbidity and mortality.

Class II

This category applies to the dilation of significant lesions in patients who

1. are similar to patients in Class I but
 - a. have more complex lesions with at least a moderate likelihood of successful dilation, or
 - b. undergo multivessel angioplasty, or
 - c. are at moderate risk for morbidity or mortality or both, or
2. have survived cardiogenic shock in the period before discharge or

3. are asymptomatic but have a significant residual lesion in the infarct-related artery supplying a large or moderate area of angiographically functioning myocardium, or
4. have had a non-Q-wave myocardial infarction, and
 - a. have a large area at risk or objective evidence of myocardial ischemia, and
 - b. single-vessel disease with noncomplex lesion morphology, and
 - c. are at low risk for morbidity and mortality.

Class III

This category applies to all other patients in the immediate postinfarction period (during initial hospitalization) who do not fulfill the preceding criteria for Class I and Class II. It includes, for example,

1. dilation of borderline residual lesions (50% to 60% diameter reduction) in the absence of spontaneous or stress-induced ischemia, or
2. dilation of chronic total occlusions subtending nonviable myocardium, or
3. angioplasty in patients at high risk for morbidity and mortality.

The selection of patients for coronary angiography and subsequent revascularization procedures in the recovery phase following acute myocardial infarction continues to be a subject of vital importance for ongoing study. Although the indications for PTCA in a non-infarct-related artery are similar to those outlined in the introduction and "General Consideration" for all patients undergoing coronary angioplasty, controversy continues about the proper approach to the infarct-related artery in this setting.

The use of angioplasty in conjunction with thrombolytic therapy has been one of the most intensely studied issues to date. Data from a number of important randomized clinical trials all suggest that angioplasty should be deferred and performed as clinically indicated following successful thrombolysis (143-146). Studies have also shown that angioplasty can be performed successfully in the majority of patients in whom recanalization fails following thrombolytic therapy alone (165-167). The likelihood of successful dilation in this situation ("salvage PTCA") may also be influenced by the type of fibrinolytic agent previously administered (168,169). Although successful mechanical recanalization of patients who fail thrombolysis appears to be associated with a low hospital mortality rate similar to that observed after successful thrombolysis, it is critical to recognize the high mortality rates reported in patients after failed attempts at either direct or salvage PTCA (169,170). These rates range between 30% and 40% and underscore the importance of caution in the use of angioplasty in acute infarction patients.

Ongoing analyses of patient subgroups in completed trials continue to generate new observations that challenge existing hypotheses and raise questions with far-reaching clinical

implications. An example is the issue and uncertainty surrounding the value of an open infarct-related artery at the time of discharge from the hospital after infarction in the absence of demonstrated myocardial ischemia (171-173). Similarly, data are now emerging to suggest that angioplasty of significant residual lesions in infarct-related arteries in some subsets of patients without symptoms but with objective evidence of ischemia after thrombolytic therapy may be harmful (174). It should be apparent that such subset analyses produce exploratory results that provide clear direction for new lines of investigation but certainly do not establish firm guidelines for clinical practice.

It is in this context that these guidelines are promulgated, with the conviction that the prudent physician will have no difficulty in identifying those areas about which firm clinical opinion is established and those that represent new frontiers of practice that must await confirmation from additional clinical investigation.

Appendix A

This classification is adopted from the grading of angina of effort by the Canadian Cardiovascular Society (175).

- I. Angina is not caused by ordinary physical activity, such as walking and climbing stairs. Angina is experienced with strenuous or rapid or prolonged exertion at work or recreation.
- II. There is slight limitation of ordinary activity, such as walking or climbing stairs rapidly; walking uphill; walking or stair-climbing after meals; or walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions; or angina is experienced in cold, in wind, during emotional stress, or only during the few hours after awakening.
- III. There is marked limitation of ordinary physical activity, such as walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.
- IV. There is an inability to carry on any physical activity without discomfort; anginal syndrome may be present at rest.

Appendix B

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