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 (Subcommittee 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 on the practice and cost of medical care. Such analysis, carefully conducted, could potentially impact on the cost of medical care without diminishing the effectiveness of that care.

To this end, the American College of Cardiology and the American Heart Association in 1980 established a 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 define the role 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 specific procedures.

The Task Force shall include a Chairman and four members, two representatives from the American Heart Association and two representatives from the American College of Cardiology. 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: Roman W. DeSanctis, MD; Harold T. Dodge, MD; T. Joseph Reeves, MD; Sylvan Lee Weinberg, MD; and Charles Fisch, MD; Chairman.

The Subcommittee on Percutaneous Transluminal Coronary Angioplasty was chaired by Thomas J. Ryan, MD; and the members included the following: David P. Faxon, MD; Rolf M. Gunnar, MD; J. Ward Kennedy, MD; Spencer B. King III, MD; Floyd D. Loop, MD; Kirk L. Peterson, MD; T. Joseph Reeves, MD; David O. Williams, MD; and William L. Winters Jr., MD.

This document was reviewed by the officers and other responsible individuals of the two organizations and received final approval in March 1988. It is being published simultaneously in Circulation and Journal of the American College of Cardiology. The potential impact of this document on the practice of cardiology and some of its unavoidable shortcomings are clearly set out in the introduction.

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Request for reprints should be directed to the Office of Scientific Affairs, American Heart Association, 7320 Greenville Ave., Dallas, TX 75231.

I. Introduction

The American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures was formed to make recommendations regarding appropriate utilization 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 133,000 angioplasty procedures were performed in the United States in 1986, up from 32,300 in 1983.1 Such growth is attributable not only to demonstrated clinical benefit but also to recent technical advances that have led to improved techniques and higher success rates. In turn, this has led to some broadening of the indications for coronary angiography and, in some settings, overuse of both coronary angiography and angioplasty has been suggested. Accordingly, it was recommended that this Subcommittee review current indications and developments for the use of coronary angioplasty. In doing so, we have proceeded on the premise that, because diagnostic coronary angiography is essential for undertaking coronary angioplasty, all of the indications and guidelines for prudent coronary angiography, promulgated in an earlier ACC/AHA Task Force report, have been met.2

Because the technique of angioplasty is in evolution and the intermediate-term results are not yet fully elucidated, these recommendations are likely to change over the years. This report is not intended to provide strict indications or contraindications for the procedure because multiple variables must be weighed in selecting the individual for balloon angioplasty treatment. These relevant considerations include occupational needs, the family setting, associated illnesses, and individual preferences concerning life style. Rather, the report is intended to provide general guidelines that may be helpful to the practitioner as well as to health care administrators and other professionals interested in the delivery of today’s medical care. The American College of Cardiology and the American Heart Association recognize the fact that the ultimate judgment regarding the propriety 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 Subcommittee will not offer detailed recommendations concerning the specific resources required to perform coronary angioplasty or to train individuals performing the procedure. It is essential that physicians performing angioplasty and other 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. Some current thoughts related to training, credentialing, and facilities required to engage in present day angioplasty are presented in Appendixes A and B.

The format of this report includes some general considerations that provide a brief historical review of the growth and development of the procedure, identification of contraindications to its use, and a statement acknowledging general risks associated with angioplasty. This is followed by a brief discussion of considerations unique to angioplasty and include an enumeration of those factors currently recognized as influencing a successful outcome, the requirement for surgical backup, angioplasty performed at the time of initial catheterization, management of the patient after angioplasty, the problems of restenosis and incomplete revascularization, and the need for institutional mortality/morbidity review committees. Lastly, specific guidelines for the application of coronary angioplasty are presented; these have been developed according to anatomic (single versus multivessel disease), clinical (asymptomatic versus symptomatic patients), and physiologic (presence or absence of inducible ischemia) considerations. Most importantly, the indications for angioplasty are judged categorically to be either class I, II, or III*, based primarily on a multifactorial risk assessment weighed against expected outcome. Also included are judgments of feasibility, appropriateness to the clinical setting and overall efficacy viewed in the light of present day knowledge and technology.

II. General Considerations

A. Background

Symptomatic coronary artery disease is present in >6 million individuals 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 284,000 coronary artery bypass operations were performed in 1986, up from 188,000 in 1983; similarly, coronary angioplasty procedures have increased from 32,300 in 1983 to 133,000 in 1986.1 Until recently, angioplasty has been performed most often on patients with single vessel coronary disease whereas coronary bypass surgery now is used more often to treat multivessel coronary disease, with the majority of patients currently receiving three or more bypass grafts. The use of internal mammary artery grafting has risen dramatically in recent years, from an estimated 6,000 procedures in 1983 to 67,000 in 1986.1 The leading indication for surgery continues to be the relief of angina, an approach supported by findings of recent randomized trials that have shown that, compared with medi-

*Classes I, II, and III are defined on page 496 in section IV of this report.
technical therapy, surgical revascularization significantly reduces symptoms and improves the quality of life. At the same time there has been an expansion of the subsets of patients in whom it is recognized that bypass surgery improves survival. This improvement in survival has been established for patients with left main coronary artery disease (>50% stenosis) and certain patients with three vessel coronary disease. Additional information from the Coronary Artery Surgery Study Registry would also suggest that coronary bypass surgery improves survival in patients with three vessel disease and normal ventricular function if either severe symptoms exist or an exercise test is positive for ischemia or chest pain.

B. Immediate and Long-Term Results

Coronary angioplasty was first introduced by Andreas Gruentzig in September 1977 as an alternative form of revascularization; it thus constitutes a relatively new form of therapy. During the early years of its application, Gruentzig and others used coronary angioplasty predominantly to treat patients with discrete, proximal, noncalcified subtotal occlusive lesions in a single coronary artery. In subsequent years the technique has been applied successfully to patients with multivessel disease, multiple subtotal stenoses in the same vessel, accessible complete occlusions of recent vintage, partial occlusion of saphenous vein or internal mammary artery grafts, and recent total thrombotic occlusions in acute myocardial infarction, as well as to isolated high risk patients with congestive heart failure and cardiogenic shock.

By 1980, Gruentzig had performed the procedure on 169 symptomatic patients, 40% of whom had multivessel disease. The follow-up of these patients now extends to as long as 10 years and documents persistent long-term benefit with only 5 cardiac deaths; 90 patients remain asymptomatic. However, repeat angioplasty was required in 27 patients and coronary bypass surgery in 19.

NHLBI Registry. Because of the promising early clinical experience, the National Heart, Lung, and Blood Institute (NHLBI) established a Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry in 1979 to help evaluate the technique. Through 1982, a total of 3,079 patients were entered into the voluntary Registry and numerous analyses from this data bank have substantiated the effectiveness and safety of angioplasty. As with any new procedure, technical advances have resulted in improved success and wider applicability of the procedure. Prompted by these changes, the National Heart, Lung, and Blood Institute reopened the Registry in 1985 to evaluate more recent trends in angioplasty. Sixteen centers agreed to voluntarily collect data on an additional 2,500 patients. These recent additions to the Registry indicate that the immediate success rate (defined as >20% change in luminal diameter narrowing without the occurrence of death, myocardial infarction or bypass operation during hospitalization) increased to 78% compared with 61% in the initial patient cohort. Despite a recognized change in the case mix to more complex cases, the rate of nonfatal myocardial infarction decreased from 4.9 to 4.3% and emergency coronary artery bypass graft surgery from 5.8 to 3.4%; the mortality rate remained unchanged (1.2 versus 1.0%). Whereas only 25% of patients in the initial Registry had multivessel disease, 53% were so categorized in the most recent Registry. This subgroup of patients in the new Registry (that is, patients with multivessel coronary artery disease) had an overall success rate of 73%. However, when the data are analyzed for completeness of revascularization, defined in the conventional manner as no residual lesions of >50% narrowing, only one-third of the patients qualified. Such data must be viewed in the context that balloon angioplasty is not currently undertaken when lesions have 50 to 60% luminal diameter narrowing or when chronic total occlusions are present.

The long-term benefit of angioplasty has been examined in the first PTCA Registry group for which >5 years of follow-up are available. After hospital discharge the annual mortality rate is low, approximately 1% per year, and the rate of nonfatal myocardial infarction is also low at 2% per year. Symptomatic improvement in the successful cases was high with 70% of the patients pain-free at 4 years. Freedom from major cardiac events (death, myocardial infarction, need for bypass surgery) over a 5 year period of follow-up of a large series from one major center was reported to be 79%. These data, although they do not address the problem of restenosis and are derived from a population in which 75% of the patients had single vessel disease, do indicate that long-term clinical benefit without increased risk of death or myocardial infarction can be expected after angioplasty. Follow-up information on patients exclusively with multivessel disease is less complete. Cowley et al reported initial success in 92% of patients with multivessel coronary artery disease, with 48% of the patients asymptomatic and 82% symptomatically improved at a mean follow-up time of 24 months. A follow-up study of 605 patients undergoing angioplasty for multivessel disease at Emory University demonstrated a 3 year freedom from cardiac event rate of 83%. Preliminary findings in the National Heart, Lung, and Blood Institute Registry indicate a freedom from death, myocardial infarction, or surgery after 1 year of follow-up in 75%
of 402 patients with multivessel disease. In these studies restenosis with subsequent hospitalization for radiation was not considered a cardiac event but viewed as an integral part of the strategy of angioplasty.

Comparison with bypass surgery. Whereas angioplasty now is applied successfully to patients with multivessel coronary artery disease, it must be viewed in comparison with coronary bypass surgery. The operative mortality rate for patients undergoing elective bypass surgery has steadily fallen and now approximates 2% in most centers. Although it is recognized that >50% of bypass grafts will occlude after 10 years, internal mammary artery bypass grafts may provide a superior conduit with improved long-term patency. Indeed, recent studies suggest that a patency rate of >90% at 10 years can be achieved. The long-term clinical benefit of bypass surgery is well defined, with a survival rate of 82% at 8 years for double vessel disease and 79% for triple vessel disease as reported from the Coronary Artery Surgery Study. Symptomatic improvement can be expected in 70% and asymptomatic status in 50% after 5 years. For patients who have received an internal mammary artery graft to the left anterior descending coronary artery, with or without associated vein grafts, there is evidence of both improved survival and a reduction in major cardiac events after 10 years of follow-up compared with findings in patients who received vein grafts only.

Inherent differences exist between angioplasty and bypass surgery. When successful, the former is less traumatic, less costly, and requires a shorter hospital stay than the latter. However, bypass surgery is applicable to a wider group of patients because dilation of longstanding total occlusions and diffuse disease is often not possible with angioplasty. Angioplasty, in certain instances, leaves patients with incomplete revascularization, which understandably is a more common phenomenon with increasing severity of disease. There are those who advocate a strategy of “intentional” incomplete revascularization in some patients with multivessel disease, and they report follow-up data suggesting that these patients are no more symptomatic than are individuals who have complete revascularization. Other reports on the long-term follow-up of patients with multivessel disease indicate that those who have incomplete revascularization after angioplasty are more symptomatic than are those who have complete revascularization.

Restenosis. Angioplasty outcome is also complicated by restenosis, the phenomenon of renarrowing of the dilated arterial segment within 8 months of the procedure. Symptomatic restenosis occurs in 20 to 25% of patients, whereas angiographic studies suggest that the rate of restenosis is as frequent as 30 to 35% and may be as high as 45% for lesions at the origin of the left anterior descending artery. Preliminary studies in patients with multivessel disease suggest that restenosis may also be more frequent as more lesions are dilated. Experience indicates that restenosis can be managed very successfully by repeat angioplasty; however, the procedure exposes the patient to additional morbidity, mortality, and cost. Nevertheless, angioplasty is initially less expensive and inherently less invasive than is bypass surgery and is a more attractive alternative to many patients because a rapid return to normal functional status is possible.

C. 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. Before undertaking angioplasty it is imperative that the patient clearly understand the procedure, its potential complications, and the alternatives of medical therapy or bypass surgery. Additionally, 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. With this caveat the following are enumerated as generally accepted contraindications to the performance of angioplasty:

1. Absolute contraindications:
   a) There is no significant obstructing lesion.
   b) Multivessel disease with severe diffuse atherosclerosis is present for which an alternative form of revascularization would be unequivocally more efficacious.
   c) There is a significant obstruction (>50%) in the left main coronary artery and this main segment is not protected by at least one completely patent bypass graft to the left anterior descending or left circumflex artery.
   d) There is no formal cardiac surgical program within the institution.

2. Relative contraindications:
   a) A coagulopathy is present: Conditions associated with bleeding abnormalities or hypercoaguable states may be associated, respectively, with unacceptable risks of serious bleeding or thrombotic occlusion of a recently dilated vessel.
   b) There is no clinical evidence for spontaneous or inducible myocardial ischemia.
   c) In multivessel angioplasty, the patient’s
condition is such that coronary occlusion resulting from any one dilation could result in cardiogenic shock. This group of patients is characterized, for example, by patients who have large areas of myocardial dysfunction as a result of previous myocardial infarction and who have arteries with high grade lesions whose acute occlusion would result in cumulative damage equal to approximately 40 to 50% of the total myocardium.

d) The anticipated success rate of dilation is low (for example, chronic total occlusions >3 months old or subtotal lesions exceeding 20 mm in length).

e) The lesion under consideration is a borderline stenotic lesion (usually <60% stenosis). Such lesions should not be dilated because of the demonstrated risk of a restenotic lesion at the same site of even greater severity. In some instances, objective evidence of myocardial ischemia related to the lesion can change the designation from a "borderline" to a "significant" lesion that would be appropriate for dilation.

f) Variant or vasospastic angina is present in patients with <60% stenoses.

g) The lesion under consideration is in a noninfarct-related artery in patients with multivessel disease who are undergoing cardiac catheterization during the acute phase of myocardial infarction.

In addition to these generally accepted relative contraindications, there are other conditions in which clinicians have considerable reservation about the risk/benefit ratio of angioplasty. Over and above a fundamental risk of mortality and morbidity there is the added dimension of risk of failure of the procedure as a result of early closure as well as a substantial risk of restenosis. These risks are viewed as a continuum and it is their aggregate weight that should ultimately determine whether a specific procedure should or should not be undertaken (see section III.F).

D. 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 potential complications that are known to be associated with diagnostic cardiac catheterization. Included are arterial or venous obstructions, vessel perforations, bleeding, hypersensitivity reactions, and infection. Myocardial infarction, stroke, and death can also occur as a result of cardiac catheterization but are infrequent.

Specific complications can occur that are directly related to the coronary angioplasty procedure. Balloon inflation results in localized trauma to the coronary artery wall; the net result is usually atheroma fracture and arterial expansion that produce an increase in the luminal area available for blood transport. At times, balloon inflation or guide wire or catheter manipulation can cause more extensive arterial wall damage with medial dissection and the creation of an occlusive intimal flap. Thrombus formation also may occur at the dilation site. Either of these two latter consequences can exacerbate coronary narrowing and result in progression to abrupt total coronary artery occlusion. In the absence of a well-developed collateral circulation, acute coronary occlusion usually results in severe myocardial ischemia and myocardial infarction that, if extensive or in the setting of preexisting impaired left ventricular systolic function, may cause hemodynamic collapse and death. The most recent data in the National Heart, Lung, and Blood Institute Registry (derived from very experienced centers) indicate that the procedure is still associated with a 1% in-hospital mortality rate and an incidence rate of nonfatal myocardial infarction of approximately 4%, although the need for emergency bypass surgery has decreased to about 3.5%. In a recent study, investigators reported a death rate of 0.2% for patients undergoing elective angioplasty at two experienced centers.

If coronary occlusion should occur, recrossing the occluded segment and repeating balloon inflation, inserting a perfusion catheter or using thrombolytic or vasodilator agents can, on occasion, reestablish coronary artery patency and relieve ischemia. Prolonged maneuvers to this end are discouraged because emergency surgical revascularization may be delayed. The use of intraaortic balloon counterpulsation in the setting of acute coronary occlusion may reduce the magnitude of ischemia and augment systemic perfusion. When needed, surgical revascularization should be undertaken immediately because of known time limitations on preserving ischemic myocardium. The probability of myocardial infarction is high and mortality is increased when coronary artery surgery is undertaken on an emergency basis; reports indicate a 25 to 40% incidence rate of nonfatal new Q wave infarctions among patients undergoing emergency surgery after failed angioplasty.

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.

E. Need for Surgical Backup

An experienced cardiovascular surgical team should be available within the institution* for emergency surgery for all angioplasty procedures. The Subcommittee feels strongly that
there should be no exception to this requirement and holds the position that all arrangements requiring the transportation of patients to off-site surgical facilities for such emergency surgery fail to meet the necessary standards of care exercised by prudent physicians and cannot be condoned.

A formal surgical consultation for elective angioplasty provides a means for a second opinion to the cardiologist, the patient, and the family, and represents the ideal approach because it underscores the reality of potential, serious complications and the need for a team approach. However, this is often impractical, may introduce delay in the procedure, and lengthen the hospital stay. It is appropriate, however, to obtain prior surgical and anesthesiology consultations on all patients identified as being at high risk for abrupt vessel closure as well as those patients judged to be high risk surgical candidates because of age, markedly impaired ventricular function, or associated medical disorders such as chronic pulmonary disease, cerebrovascular disease and the like. The exact arrangement for surgical standby will vary from institution to institution 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. The primary and essential requirement is the capacity to provide rapid surgical support when angioplasty fails; otherwise, optimal patient care becomes seriously compromised.

On-going experience in large multicenter trials underscores the need for urgent revascularization by emergency bypass surgery in the setting of both elective and emergency angioplasty. Thus it is reaffirmed that all angioplasty procedures should be undertaken only in institutions that have formally approved cardiac surgical programs.

F. Need for Institutional Review
A rigorous mechanism of valid peer review must be established and on-going within 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 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. In this latter circumstance it is imperative that the responsible physician arrange for a consulting opinion from an appropriate specialist.

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 some basic requirements for such review to be meaningful. At a minimum, the opportunity must exist for cardiologists and cardiac surgeons knowledgeable about the procedure to review the overall results of the program on a regular basis. Specific attention should be directed to success and failure rates and complications leading to morbidity, including emergency surgical procedures, and mortality. The review should also examine the quality and accuracy of cinearteriographic studies and the appropriateness of indications and it should discuss contraindications.

The surgical profession has long since provided a workable model for addressing these and similar issues with regularly scheduled mortality and morbidity conferences that include appropriate committee (for example, tissue) reports and impose attendance requirements that are designed to assure impartial peer review. Institutions with medical or surgical groups, or both, that cannot adequately meet this obligation should undertake regional review with cooperating institutions or abandon their program in angioplasty.

III. Specific Considerations
A. Successful Angioplasty and Its Determinants
A successful angioplasty procedure is defined as one in which a ≥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. Atherosclerotic coronary stenoses are considered significant if they have the potential of impairing coronary blood flow under physiologic circumstances. Experimental data indicate that coronary flow reserve declines as coronary diameter is reduced beyond 50%. It is acknowledged that the visual assessment of coronary narrowing on cineangiograms is associated with substantial interobserver and intraobserver variability. Determination of coronary narrowing by caliper techniques is a readily available methodology that correlates closely with sophisticated computer quantitative methods. 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.

After a decade of experience it is now reasonable to expect an overall success rate of ≥85% for single lesion dilations within any angioplasty

“Within the institution” is generally intended to mean within the same hospital. In those instances in which two adjacent 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 viewed as “off site.”
program. This same experience further indicates that, 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 age (<65 years) and gender (male), but clinical variables such as a history of hypertension, diabetes, prior myocardial infarction, prior bypass surgery, and impairment of left ventricular function are known to be associated with procedural mortality.

Angiographic patterns outlining the morphologic characteristics of vessels and defining lesion-specific characteristics have now been identified that greatly 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 Subcommittee proposes the following lesion-specific classification as a guide for estimating the likelihood of a successful procedure as well as the likelihood of developing abrupt vessel closure (see also Table 1, section IV):

Type A lesions
These are lesions in which the anticipated success rate should be ≥85% and the risk of abrupt vessel closure is low because they demonstrate all of the following characteristics: discreteness, concentricity, ready accessibility, location in a nonangulated segment (<45°), smoothness of contour, little or no calcification, absence of total occlusion, nonostial location, absence of major branch involvement, absence of thrombus.

Type B lesions
These are lesions in which the anticipated success rate ranges from 60 to 85% or the risk of abrupt vessel closure is moderate, or both. They include all lesions that are neither type A nor type C (see later) and they are usually identified by such characteristics as, but not limited to, the following: tubular shape, eccentricity, accessibility influenced by moderate tortuosity of proximal segment, location in a moderately angulated segment (>45°, <90°), irregularity of contour, moderate or severe calcification, presence of thrombus, ostial location, bifurcation lesions requiring double guide wires, total occlusions <3 months old. It is recognized that lesions with these characteristics, although associated with some increase in abrupt vessel closure, may in certain instances be associated with a comparatively low likelihood of a major complication. This is often the case, for example, in unsuccessful attempts to dilate total occlusions that are <3 months old or in the dilation of some type B lesions in which the distal vessel is supplied by abundant collaterals.

Type C lesions
These are lesions in which the anticipated success rate is <60% or the risk of abrupt vessel closure is high, or both, because they demonstrate any of the following characteristics: diffuseness (>2 cm in length), excessive tortuosity of proximal segments, location in an extremely angulated segment (>90°), total occlusion >3 months old, inability to protect major side branches, degeneration of older vein grafts with friable lesions. Attempts to dilate such lesions should not be undertaken when they are present in vessels supplying large or moderate areas of viable myocardium.

B. 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 when unhurried review of the cineangiograms can take place (in consultation with colleagues when necessary) to determine the appropriateness of the case and plan a dilation strategy. In addition, the patient, family, and referring physician can be consulted, the therapeutic options reviewed and the risks and benefits of the procedure discussed before obtaining informed consent. This process obviously subjects the patient to a repeat catheterization with its inherent risks and recognized morbidity, adds additional days of hospitalization, introduces delay in the patient's return to work and normal physical activities, and clearly adds to the total direct and indirect costs involved. These disadvantages are counterbalanced by the overriding benefits of a careful preangioplasty evaluation, improved patient preparedness and, in many instances, more timely arrangement for surgical backup and scheduling. In particular, the evaluation of the coronary anatomy is often the most difficult aspect in the selection of patients for angioplasty; decisions made on the basis of video images can be inaccurate and can lead to increased risk for the patient. For these reasons, it is recommended that angioplasty not be performed routinely as an extension of an initial diagnostic catheterization.

There are, however, well defined subsets of patients for whom it is appropriate to contemplate performing angioplasty at the time of the initial diagnostic cardiac catheterization. This group would include patients with unstable angina who cannot be discharged from the hospital without a revascularization procedure and who are suspected of having single vessel coronary disease on the basis of age, absence of prior myocardial infarction or known coronary disease, and recent onset of symptoms. Because a high proportion of these patients have single vessel disease amenable to angioplasty, it is
reasonable to prepare the patient for this possibility before diagnostic cardiac catheterization by obtaining informed consent and a complete preangioplasty evaluation. Similarly, individuals who have had prior angioplasty and are undergoing catheterization to evaluate the possibility of restenosis represent a group of patients whose coronary anatomy is generally known in advance and whose clinical management is facilitated by performing angioplasty immediately after the diagnostic study when indicated. In selected patients with acute myocardial infarction in whom adequate reperfusion is not obtained by thrombolytic therapy, angioplasty may be of benefit. In such patients, when multivessel disease is present, only the vessel related to the area of infarction should be dilated. If angioplasty is to be considered in lieu of thrombolytic therapy, it is recommended that the procedure be applied to patients who present within 4 hours of the onset of symptoms unless there is strong evidence for ongoing ischemia. Whatever the clinical circumstances, it is imperative that high quality fluoroscopic and video replay images or promptly developed cine films be available before undertaking angioplasty at the time of initial diagnostic catheterization.

C. Postangioplasty Management

Immediately after coronary angioplasty, attention is directed to monitoring for evidence of recurrent ischemia and to assure appropriate hemostasis at the site of catheter insertion. Specific protocols for sheath removal, continuation of anticoagulation, and antiplatelet therapy will vary from institution to institution. Ordinarily, heparin anticoagulation used during the procedure is not reversed with protamine for fear of inducing thrombosis at sites of balloon inflation. When angioplasty is performed percutaneously, the indwelling vascular sheaths usually can be removed within 3 to 4 hours after the last bolus injection of heparin. In certain instances, such as the setting of extensive intimal disruption, thrombus formation or embolization, a constant infusion of heparin may be desirable. Sheaths are then removed after the termination of the heparin infusion or after temporary cessation of therapy.

A small proportion of patients in whom angioplasty was judged angiographically successful will experience symptoms of myocardial ischemia during this observation period after the procedure. If electrocardiographic (ECG) abnormalities suggesting ischemia are detected, there is a substantial risk of abrupt vessel closure, which has been associated with a comparatively high mortality rate (10 to 12%). An individualized 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, need to be available 24 hours a day in institutions that undertake a program in angioplasty.

Patients should be instructed about risk factor modification before hospital discharge. Depending on the individual case, this advice would include hypertension control, diabetes management, serum lipid reduction, abstinence from tobacco, weight control, and timing of the return to full activity. Patients should be informed of the importance of contacting their physicians if symptoms recur.

D. Restenosis

Although the initial outcome for coronary angioplasty procedures has improved progressively over the last 10 years (reaching primary success rates in native coronary arteries as high as 90 to 95% in well chosen patients), the incidence of restenosis over the first 6 to 8 months after dilation has remained unchanged at approximately 30%. The rate of restenosis in native arteries depends partly on its definition; in the National Heart, Lung, and Blood Institute Registry, restenosis was defined as a loss of 50% of the gain achieved in luminal diameter at the time of the successful angioplasty, or a 30% increase in narrowing at the site of stenosis. Follow-up of 557 patients undergoing repeat coronary angiography indicated that restenosis was associated with the recurrence of symptoms in the majority of patients; likewise, relatively few patients with single vessel disease harbor a clinically silent restenosis. The rate of silent restenosis was 14% in the National Heart, Lung, and Blood Institute Registry, and a 4% rate was reported in a combined study from the Cardiology Branch of the National Heart, Lung, and Blood Institute and Georgetown University. On the basis of multivariate analysis, independent factors that predispose to restenosis include angioplasty in the left anterior descending coronary artery, absence of intimal dissection immediately after angioplasty, residual gradient after dilation >15 mm Hg, a large residual stenosis after angioplasty, and unstable angina. Univariate analysis has pointed to several other risk factors for restenosis, including male gender, diabetes mellitus, patients with chronic total occlusions, thrombus, an initial transstenotic gradient >40 mm Hg, and recent, as opposed to long-standing, occurrence of angina. In addition, several centers have reported that lesions that involve the origin of a vessel or its branch points are more prone to restenosis. Factors that have not been correlated with risk of restenosis include age, functional class, history of previous myocardial infarction, hypertension, history of smoking,
serum cholesterol, presence of calcification at the site of dilation, morphologic features of the lesion, lesion length, inflation pressure, and medications on discharge.

Patients who develop clinical or angiographic evidence, or both, of restenosis in native coronary arteries are readily treated with a second dilation procedure. For repeat angioplasty, the primary success rate is higher than for the initial procedure (85 versus 63% in the National Heart, Lung, and Blood Institute Registry), a relatively low myocardial infarction rate of 1.5%, and a reduced incidence of complete occlusion with need for emergent coronary artery bypass graft surgery (2 versus 3.5%).

A significantly higher restenosis rate of 50% is noted when coronary angioplasty is performed in the proximal anastomosis or body of a saphenous vein bypass graft. By contrast, dilations performed in the distal graft/artery anastomotic site exhibit restenosis rates comparable with those of native vessel sites.

E. Incomplete Revascularization

As coronary angioplasty is being utilized in ever more complex clinical and pathoanatomic situations, concern is now expressed that patients are being subjected to "incomplete revascularization" or less than optimal correction of their pathophysiological state. In patients with multivessel disease, some operators attempt to dilate all accessible, significant lesions whereas others approach only the lesion deemed most likely to cause myocardial ischemia (the so-called culprit lesion). The surgical experience is relatively convincing that "complete revascularization," that is, graft insertion around all moderate to severe coronary stenoses, leads to a superior therapeutic result. Follow-up studies of patients with surgical revascularization suggest that complete revascularization not only relieves signs and symptoms of myocardial ischemia, but also it is more effective than incomplete revascularization in protecting the patient against future coronary events.

During surgery, partial or incomplete revascularization usually results from the extent or distribution of a patient's coronary artery disease and less often is a reflection of the skills and diligence of the surgical team. In patients undergoing angioplasty, partial revascularization is likely to occur for several reasons in addition to the extent and distribution of coronary disease and the extent of myocardial fibrosis. Quite clearly it also relates to the specific anatomy that determines the accessibility of lesions for angioplasty. The occurrence of restenosis in one or more of the dilated lesions also may result in the development of partial revascularization. Although early graft closure after bypass surgery also converts complete to partial revascularization, this is a less common phenomenon than restenosis after arterial dilation.

At present, partial revascularization after coronary angioplasty is an inherent limitation of the procedure and can be expected to occur frequently in patients undergoing multivessel angioplasty. Notwithstanding, the advocates of angioplasty in patients with multivessel disease point to the successful relief of symptoms and the elimination of objective signs of ischemia after stress tests in a high percentage of such patients in whom all lesions cannot be successfully dilated. Moreover, the claim is made that angioplasty palliates the disease process and often allows a period of clinical temporizing before surgical revascularization is required. Angioplasty also allows for a strategy of performing the dilation procedure on successive days or weeks. Multiple successive interventions are feasible and, although there is some degree of cumulative risk, angioplasty differs in this regard from aortocoronary bypass graft surgery, in which the opportunity for serial repeat thoracotomies is understandably more limited.

There has not been sufficient accumulation of clinical experience, either retrospectively or prospectively, to judge the relative advantage of angioplasty versus aortocoronary bypass graft surgery for relief of signs and symptoms of myocardial ischemia and infarction in multivessel disease. The adequacy of myocardial revascularization by angioplasty, particularly in comparison with that provided by surgery, will require randomized prospective studies in which coronary pathoanatomic subsets are closely matched. The National Heart, Lung, and Blood Institute has funded two such studies to date: one at Emory University that began in July 1987, and the multicenter BARI Trial (Bypass Angioplasty Revascularization Investigation) that began in the fall of 1987. Also of importance will be the long-term follow-up of large numbers of patients treated by these two competing interventions with matched cohorts compared by multivariate analysis.

F. Cumulative Consequences of Failed Angioplasty

Inherent to the strategy of coronary angioplasty is the "price of failure." This is more than the risk of a serious complication and embraces the consideration that 5 to 15% of these procedures will be initially unsuccessful and that 3 to 6% of patients will require urgent or emergent surgery to bypass a coronary artery occluded during the procedure. Furthermore, approximately 30% of the patients who have an initially successful procedure will develop restenosis of the dilated segment within 8 months and will require a second angioplasty or bypass surgery. Thus, there are a number of patients in
TABLE 1. Characteristics of Type A, B, and C Lesions

<table>
<thead>
<tr>
<th>Lesion-Specific Characteristics</th>
<th>Type A lesions (high success, &gt;85%; low risk)</th>
<th>Type B lesions (moderate success, 60 to 85%; moderate risk*)</th>
<th>Type C lesions (low success, &lt;60%; high risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Discrete (&lt;10 mm length)</td>
<td>• Little or no calcification</td>
<td>• Tubular (10 to 20 mm length)</td>
<td>• Diffuse (&gt;2 cm length)</td>
</tr>
<tr>
<td>• Concentric</td>
<td>• Less than totally occlusive</td>
<td>• Eccentric</td>
<td>• Excessive tortuosity of proximal segment</td>
</tr>
<tr>
<td>• Readily accessible</td>
<td>• Not ostial in location</td>
<td>• Moderate tortuosity of proximal segment</td>
<td>• Extremely angulated segments &gt;90°</td>
</tr>
<tr>
<td>• Nonangulated segment, &lt;45°</td>
<td>• No major branch involvement</td>
<td>• Moderately angulated segment, &gt;45°, &lt;90°</td>
<td>•</td>
</tr>
<tr>
<td>• Smooth contour</td>
<td>• Absence of thrombus</td>
<td>• Irregular contour</td>
<td>•</td>
</tr>
</tbody>
</table>

*Although the risk of abrupt vessel closure is moderate, in certain instances the likelihood of a major complication may be low as in dilation of total occlusions <3 months old or when abundant collateral channels supply the distal vessel.

whom the risk relative to the cost and morbidity associated with angioplasty as a primary therapy may be considerably higher than that of some patients who are treated from the outset with revascularization surgery. These consequences of early failure must be considered in clinical decision making and in evaluating the relative merits of bypass surgery versus coronary angioplasty in a given patient. Although there is little specific information on the price of failure in patients with multivessel angioplasty, it is likely that it is higher than for single vessel angioplasty and indeed there will be categories of patients in whom multivessel angioplasty is not prudent.

IV. Indications for Angioplasty

Preamble

The approach to every angioplasty procedure requires a knowledgeable judgment that weighs the likelihood of a successful procedure* against the likelihood of failure and the risk of complications (abrupt vessel closure, morbidity, mortality, and restenosis). In attempting to prioritize indications for angioplasty, the Subcommittee was greatly influenced by the specific considerations discussed in section III: 1) factors favoring a successful dilation; 2) factors associated with abrupt vessel closure; 3) restenosis; 4) incomplete revascularization; and 5) the consequences of failure of the procedure.

Experience to date suggests that the factors favoring a successful procedure are age <65 years, male gender, single vessel disease, single lesion, angioplasty, subtotal occlusions, absence of calcification, accessibility of the lesion, and normal ventricular function. Counterbalancing these variables that support the likelihood of successful angioplasty are the preprocedural factors that favor abrupt vessel closure during or shortly after angioplasty. These are viewed as being female gender, length of lesion, eccentric lesions, bifurcation/side branch lesions, angulation of the segment being dilated, other stenoses in the same vessel, and the presence of thrombus.

The clinical variables that have been associated with increased procedural mortality are currently identified as age >65 years, female gender, a history of hypertension, diabetes, prior myocardial infarction, prior bypass surgery, multivessel disease, left main coronary disease, a large area of myocardium at risk, impairment of left ventricular function, and collateral vessels that supply significant areas of myocardium and originate distal to the segment to be dilated.

The factors associated with restenosis are currently recognized as recent onset of angina (<3 months), unstable angina, variant angina, diabetes mellitus, multivessel disease, right ostial lesions, lesions located at the origin of the left anterior descending coronary artery, lesions in the proximal anastomoses or body of a vein graft, chronic total occlusions, presence of thrombus, severity of residual lesion (>30%), and a significant residual gradient (>15 to 20 mm Hg).

Both clinical judgment and statistical estimates permit appropriate weighting and integration of these variables to formulate likelihood estimates (high, moderate, or low) for any given procedure according to

1. the likelihood of a successful dilation,
2. the likelihood of abrupt vessel closure with subsequent morbidity and mortality, and
3. the likelihood of restenosis.

Although operator experience and individual patient characteristics are important factors relating to outcome, both procedural success and the development of abrupt vessel closure are largely determined by specific characteristics of the vessels and lesions involved. Recognizing the unique technical aspects of angioplasty and with the objective of fostering knowledgeable judgments about risk stratification, the Subcommittee has summarized three types of lesion-specific characteristics based on the current state of knowledge in Table 1 (see also section III-A).

Type A lesions have those characteristics that allow an anticipated success rate of ≥85% and have a low risk of abrupt vessel closure.

Type B lesions have those characteristics that result in a lower than optimal success rate ranging from 60 to 85% or have a moderate risk of abrupt vessel closure, or both.

Type C lesions have those characteristics that result in an unacceptably low success rate (<60%) or have a high risk of abrupt closure, or both.

It is recognized that we are dealing with a discipline of cardiovascular care that is undergoing considerable growth and development; as new insights are gained, we can anticipate further refinement of the guidelines for coronary angioplasty that are set forth in this document using the following classification:

Class I: Conditions for which there is general agreement that coronary angioplasty is justified. A class I indication should not be taken to mean that coronary angioplasty is the only acceptable therapy.

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

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

I. Single Vessel Coronary Artery Disease

A. 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 C)

Class I

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

1. show evidence of severe myocardial ischemia while on medical therapy during laboratory testing, i.e., ischemia induced by low level exercise and manifested by
   a) ≥1 mm of ischemic ST segment depression in multiple leads, or
   b) reversible thallium perfusion defects in more than one vascular region, or
   c) 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. 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, or
4. have a history of myocardial infarction together with a history of hypertension and ischemic ST segment depression on the baseline ECG.

All of these patients should

* have one or more type A lesions in the same vessel or its branches and
* be in the low risk group for morbidity (abrupt vessel closure <4%) and mortality (<0.5%).

II. Moderate or No Symptoms, Single Vessel Coronary Disease

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

1. show objective evidence of myocardial ischemia† while on medical therapy 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 in the low risk group 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 of <50% diameter reduction, or
4. have type C lesions, or

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

† Evidence of myocardial ischemia during laboratory testing is taken to mean exercise-induced ischemia (with or without exercise-induced angina pectoris) manifestated by ≥1 mm of ischemic ST segment depression or one or more exercise-induced reversible thallium perfusion defects and/or exercise-induced reduction in the ejection fraction and/or wall motion abnormalities on radionuclide ventriculographic studies.
5. are in the moderate or high risk group for morbidity and mortality.

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

B. 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 during laboratory testing (including ECG monitoring at rest), or
2. have angina pectoris that has proved inadequately responsive to medical treatment. "Inadequately responsive" is taken to mean that patient and physician agree that angina significantly interferes with the patient's occupation or ability to perform his or her usual activities, or
3. are intolerant of medical therapy because of uncontrollable side effects.

All of these patients should
• have at least a moderate likelihood of successful dilation and
• be in the low risk group 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 while on medical therapy during laboratory testing (including ECG monitoring at rest) and
   a) have one or more type B lesions in the same vessel or its branches, or
   b) are in the moderate risk group for morbidity (abrupt vessel closure <8%) and mortality (<1%), 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 in the low risk group for morbidity and mortality, or
3. despite significant angina do not have objective evidence of myocardial ischemia while on medical therapy during laboratory testing, and
   a) have at least a moderate likelihood of successful dilation, and
   b) are in the low risk group 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 only a small area of viable myocardium at risk in the absence of disabling symptoms, or
2. have clinical symptoms not likely indicative of ischemia, or
3. have Type C lesions, or
4. are in the high risk group for morbidity and mortality.

Comments. 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 undertaking an interventional procedure 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.

II. Multivessel Coronary Artery Disease

A. 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 ischemia, or
5. have a history of myocardial infarction together with a history of hypertension and ST segment depression on the baseline ECG.
All of these patients should
- have one or more type A lesions whose successful dilation would provide relief to all major regions of ischemia, and
- be in the low risk group for morbidity and mortality.

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

This category applies to patients who
1. 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 while on medical therapy, or
2. have significant lesions in two or more major epicardial arteries, each of which subtends at least a *moderate-sized* area of viable myocardium.

All of these patients should
- show evidence of myocardial ischemia while on medical therapy during laboratory testing, and
- have one or more type A or B lesions whose successful dilation would provide relief to all major regions of ischemia, and
- be in the low risk group 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 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, or
3. have more than two major arteries with type B lesions, or
4. have type C lesions in major epicardial vessels serving moderate or large areas of viable myocardium, or
5. are in the moderate or high risk group for morbidity or mortality (for example, advanced left ventricular dysfunction [ejection fraction <20%] in the absence of angina or evidence of ischemia).

**B. 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 each of two 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 (including ECG monitoring at rest), or
2. have 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 type A and B lesions whose successful dilation would provide relief of all major regions of ischemia, and
- be in the low risk group 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 in the moderate risk group for morbidity and mortality, or
2. have angina pectoris but do not necessarily have objective evidence of myocardial ischemia while on medical therapy during laboratory testing.

All of these patients should
- have type A and B lesions whose successful dilation would provide relief of all major regions of ischemia, and
- be in the moderate risk group for morbidity and mortality.

3. have disabling angina that has proved inadequately responsive to medical therapy, and
   a) be considered a poor candidate for surgery because of advanced physiologic age or coexisting medical disorders, and
   b) have one or more type A and B lesions that cannot be successfully dilated, and
   c) be in the moderate risk group for morbidity and mortality.

**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 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, or
3. have type C lesions in major epicardial vessels serving moderate or large areas of viable myocardium, or
4. are in the high risk group for morbidity or mortality, or both.

**Comments.** It is to be stressed that risk assessment is different in patients with multivessel as compared...
with single vessel disease. In the former there ideally should be the opportunity for anatomically complete revascularization, although it is recognized that 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 consequences likely to ensue should any one of the attempted dilations fail and result in abrupt vessel closure. For example, it would be judged inappropriate to attempt dilation of a proximal high grade left anterior descending artery lesion if that vessel was supplying many collateral vessels to a large area of viable myocardium in the distribution of a totally occluded dominant right coronary artery.

III. Acute Myocardial Infarction (Angioplasty During Initial Hospitalization)

Class I

This category applies to the dilation of a significant lesion, in the infarct-related artery only, in patients who
1. have recurrent episodes of ischemic chest pain particularly if accompanied by ECG changes (postinfarction angina), or
2. show evidence of severe myocardial ischemia while on medical therapy during laboratory testing performed before hospital discharge, or
3. have recurrent ventricular tachycardia or ventricular fibrillation, or both, while on intensive antiarrhythmic therapy.

All of these patients should:
- have one or more type A lesions and
- be in the low risk group 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 who
   a) have type B lesions, or
   b) undergo multivessel angioplasty, or
   c) are in the moderate risk group for morbidity or mortality, or both, or
2. are within the very early hours of an evolving myocardial infarction, with or without thrombolytic therapy, or
3. are within 12 hours of the onset of cardiogenic shock or, in those who have survived cardiogenic shock, in the period before discharge, or
4. are asymptomatic and have a significant residual lesion in the infarct-related artery after thrombolytic therapy, or
5. show objective evidence of myocardial ischemia during laboratory testing performed before discharge, or
6. have had a non-Q wave myocardial infarction, and
   a) have single vessel disease with
   b) type A lesions, and
   c) are in the low risk group 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. For example:
1. undertaking dilation of additional lesions in a vessel other than the infarct related artery within the early hours of infarction (0 to 6 hours), or
2. dilation of residual lesions that are borderline (50 to 60% diameter reduction), or
3. dilation of type C lesions, or
4. undertaking angioplasty in patients in the high risk group for morbidity and mortality.

Comments. The role of angioplasty in the management of patients during the course of an acute myocardial infarction is currently the subject of intense investigation. Although there is evidence that the procedure can be used effectively as a primary means of establishing reperfusion in the very early hours of an evolving infarction, many important questions remain unresolved, such as the impact of procedural delay required to undertake angioplasty, the influence of thrombus on abrupt vessel closure and subsequent restenosis.

The use of angioplasty in conjunction with thrombolytic therapy is of particular interest and is thought by many to hold great promise. A note of caution is warranted, however, in light of the findings of three separate large randomized trials that have recently reported adverse effects when angioplasty was performed immediately, rather than later, after the administration of tissue plasminogen activator. The optimal timing and long-term benefit of angioplasty in the management of patients with acute infarction are questions that must await further data.

Appendix A

Training and Credentialing

It is generally acknowledged that specialized skills are required for coronary interventional techniques. Training in these procedures necessitates thorough skills in diagnostic and therapeutic cardiology and particularly cardiac catheterization and angiography. Whereas the majority of individuals currently performing angioplasty learned the technique by observing experts and attending "how-to" seminars, the complexity of the procedure and the recognized need for hands-on experience dictate that formal training programs in angioplasty become the required means of learning. Entrance requirements to such programs should follow the completion of a structured cardiology fellowship training

There is a growing consensus within the cardiology community that, for the individual who plans to perform coronary angioplasty, an additional year of training beyond 3 years of fellowship training that includes extensive experience with angiography is required. A suggested minimum of 125 coronary angioplasty procedures, including 75 performed as the primary operator, has been recommended as the experience required to develop the appropriate skill and judgment. Equally important is the demonstration of continued experience on the completion of a formal training program. A minimal case load for a single physician is estimated to be about one case per week. Continued performance of angioplasty should be dependent on the demonstration of success and complication rates that meet expected standards. Regular attendance at major angioplasty postgraduate courses would provide continuing education in newer angioplasty techniques and equipment.

Alternate routes of training for established angiographers should be developed. Individualized training programs that provide an extensive, primary operator experience can equip such an angiographer to perform angioplasty expertly. In this setting, the quality and manner of the direct supervision are of greater importance than the absolute number of cases to be performed in this "tutorial" setting. In general, it is believed that such a training experience should include involvement in no less than 50 cases.

The physicians with appropriate training and demonstrated competence in the performance of angioplasty are those who should receive proper credentialed to perform angioplasty in hospitals. It is recognized that hospitals are currently under intense pressure to grant privileges to cardiologists who have not had adequate training so as to protect the hospitals’ referral base. This practice should not be condoned; rather, the responsible leadership of institutions offering coronary angioplasty as part of their health care program should insist on the documentation of accredited training and the maintenance of skills of its approved operators by some reasonable standard of practice.

In the present climate it should be clear that not every cardiologist desiring to perform angioplasty should perform the procedure. Similarly, not every institution anxious to offer the procedure as part of its health care program can be allowed to do so. A significant volume of cases per institution and per operator is essential for the maintenance of assured quality and safe care. It is the strong sense of this Subcommittee that these issues should not be resolved in the marketplace but within the structure of organized medicine. Formal credentialing should quickly be put into place and the oversight of the operational aspects and maintenance of skills should fall within the province of organized cardiology. It would seem that existing national organizations have both the resources and the manpower to meet this major obligation in a prompt and effective manner. The hospital industry must likewise alter its current practices regarding this specific form of high technology care. Success, failure, death, and morbidity mandate some form of regionalization and centralization of resources. To accomplish this mission in a responsible fashion, a deregulated industry must, in short order, demonstrate that it can accomplish this stated mission by its own sense of community responsibility, or it should give way to state and federal regulation.

Appendix B
Requisite Facilities for Coronary Angioplasty

The rate of growth for coronary angioplasty within the United States over the past decade has clearly had an impact on the need for well equipped, well staffed cardiac catheterization laboratories.

The minimal requirements for facilities in any hospital where coronary angioplasty is to be performed are:

1. A cardiac laboratory that is well equipped with a physiologic recording system, a high resolution fluoroscopic and cineangiographic x-ray unit, full emergency resuscitation equipment including circulatory assist devices and a full complement of drugs for treatment of myocardial ischemia or infarction, or both;

2. A surgical operating suite that is equipped to provide general anesthesia and extracorporeal circulation and has a full complement of instruments for thoracic and cardiac surgery and a full complement of drugs used for management of the cardiac patient.

The optimal resources for a cardiac catheterization and radiographic facility have been carefully and exhaustively detailed in "Optimal Resources For Examination Of The Heart And Lungs: Cardiac Catheterization And Radiographic Facilities" (Circulation 1983;68:893A–930A). This report sets guidelines for administration, space, equipment, personnel, and working arrangements for diagnostic cardiovascular laboratories. Basically all of the recommendations set forth in that document apply to any laboratory planning to perform angioplasty procedures.

In addition, however, it is recommended that a laboratory performing coronary angioplasty have available the following:

1. An ample inventory of balloon dilation catheters ranging from 2.0 to 4.0 mm, a complete range of existing guide wires of variable flexibility and steerability, and two or more calibrated balloon inflation devices.

2. A high resolution fluoroscopic system and an optimal TV chain that allows ready visualization of a 0.014 inch guide wire and where still frames or "road map images" can be dis-
played simultaneously with the real time fluoroscopic image.

3. Either biplane fluoroscopic capability or preferably an angulating x-ray tube image intensifier arm that allows ready three-dimensional determination of the anatomic position of a guide wire or balloon catheter.

4. Radiation exposure control systems that would include such items as an x-ray beam with automatic collimation, a carbon fiber scattered radiation grid, carbon fiber table top, and a correct tube filter. Further reduction of radiation exposure to personnel can be achieved by gap filling during cinematography, using a reference monitor for path finding and video discs for automatic storage and replay. All personnel should be further protected from radiation exposure by the use of appropriate lead aprons, eyeglasses, thyroid protection, and additional shielding of the x-ray tube.

5. The specific requisite space, equipment, personnel, and administration of a cardiac surgery operating suite have been outlined previously in detail by the Inter-society Commission for Heart Disease Resources (Circulation 1975;52:A23–A41).

Appendix C
Grading of Angina of Effort by the Canadian Cardiovascular Society

I. "Ordinary physical activity does not cause . . . angina," such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.

II. "Slight limitation of ordinary activity." Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than 2 blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.

III. "Marked limitation of ordinary physical activity." Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.

IV. "Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest."

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