AHA Medical/Scientific Statement

Special Report

Guidelines for Percutaneous Transluminal Coronary Angioplasty

A Report of the American Heart Association/American College of Cardiology 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 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 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

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 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 Percutaneous Transluminal Coronary Angioplasty" was approved by the American Heart Association Steering Committee on June 16, 1993, and by the American College of Cardiology Board of Trustees on June 30, 1993.

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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.[5-12] This improvement in survival 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 revascu-

larization. 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 prolonged 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.

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

*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.

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

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