Special Report

Report of the Joint ISFC/WHO* Task Force on Coronary Angioplasty

Martial G. Bourassa, MD, Chairman; Edwin L. Alderman, MD; Michel Bertrand, MD; Luis de la Fuente, MD; A. Gratsianski, MD; Martin Kaltenbach, MD; Spencer B. King, MD; Masakiyo Nobuyoshi, MD; Paul Romaniuk, MD; Thomas J. Ryan, MD; Patrick W. Serruys, MD; Hugh C. Smith, MD; Jose Eduardo Sousa, MD, Members; Siegfried Böthig, MD, Ex-officio; Elliot Rapaport, MD, Ex-officio

Introduction

The Council on Clinical Cardiology of the International Society and Federation of Cardiology has formed several task forces with the World Health Organization in recent years to provide guidelines and recommendations where confusion exists but there is sufficient experience for conclusions to be generalized by international experts. In November 1984, the council recommended that a task force be formed for coronary angioplasty. This task force has described current indications and interpretation of results, and made recommendations regarding training, equipment, and preangioplasty and postangioplasty management. The council has also generated guidelines for coronary angioplasty that appear to be internationally acceptable. The task force recognizes that these optimal requirements may not always be applicable at an institutional or local level. The task force also recognizes that indications and techniques of coronary angioplasty continue to evolve and that these recommendations should be reassessed periodically. Finally, coronary angioplasty represents only one of several alternatives in management of patients with coronary artery disease.

Frequency of Coronary Angioplasty

Procedures in Recent Years

Since its introduction by Andreas R. Gruentzig in 1977,1,2 percutaneous transluminal coronary angioplasty (PTCA) has gained wide acceptance as a form of nonsurgical treatment for selected patients with coronary artery disease. Long-term results have been encouraging.3

In the United States alone, according to the Commission on Professional and Hospital Activities, which maintains a data base of in-patient care information, approximately 175,000 patients received PTCA for treatment of coronary artery disease in 1987. According to the same source, 280,000 patients underwent coronary artery bypass surgery in the United States during the same period. These estimates are based on admissions to nonfederal, short-term, general hospitals. The progressive increase in PTCA procedures performed in the United States during the last five years is striking:

32,306 63,315 106,752 159,643 175,680

Table 1 shows the results of surveys of PTCA procedures performed in several countries represented by members of the task force in 1984–1987. Although they are necessarily incomplete, these figures show a marked progression in the number of cases between 1984 and 1987.

Current Indications for Coronary Angioplasty

On the basis of clinical and angiographic descriptors of coronary artery disease, the task force identified areas where indications for coronary angioplasty are clear-cut at present, where results are encouraging and statements about indications can be made based on scientific data, and, finally, areas where it is advisable, in light of present knowledge, not to intervene with coronary angioplasty.4–7 Candidates for coronary angioplasty are classified into three groups: Class I patients have accepted indications, Class II patients have evolving indications, and Class III patients have relative contraindications. These classes are summarized in Table 2.

Class I: Accepted Indications

Usually, the following clinical, functional, and angiographic characteristics must be present: 1) chronic stable angina unresponsive to medical therapy, or unstable angina, 2) objective evidence of
myocardial ischemia, 3) good left ventricular function, and 4) significant coronary stenosis suitable for coronary angioplasty.

Chronic stable angina typically occurs on exercise, interferes with the patient's lifestyle, and persists in spite of adequate medical therapy with nitrates, \( \beta \)-blockers, and calcium antagonists. In addition, a large cohort of candidates for coronary angioplasty has typical unstable angina characterized by prolonged episodes of chest pain at rest with persistent or transient ST-segment changes on the electrocardiogram (ECG) and without a rise in serum cardiac enzymes.

Before intervention, myocardial ischemia must be confirmed whenever possible. In patients experiencing exertional angina, this is generally achieved by exercise testing. As a rule, the stress ECG shows typical ST-segment depression. In a few patients, the presence of myocardial ischemia can only be proven by thallium-201 scintigraphy and/or equilibrium radionuclide angiography. In patients with unstable angina or chest pain at rest, objective evidence of myocardial ischemia requires demonstration of ST-segment changes on the ECG during episodes of pain at rest.

The left ventricular cineangiogram must show contracting myocardium in the poststenotic area of the culprit lesion.

Finally, the coronary angiogram must demonstrate a single, severe, discrete (less than 1 cm in length), coronary lesion that is also suitable for coronary artery bypass grafting.

**Class II: Evolving Indications**

Initially coronary angioplasty was restricted to patients with single, discrete coronary lesions that were easily accessible to the dilating catheter and located in a relatively straight portion of the artery. Following the introduction of steerable guide wires, low profile balloon catheters, and increased experience of angiographers, patients with more complex lesions are frequently selected for coronary angioplasty. Multiple stenoses and long, calcified stenoses with irregular contours in tortuous segments can now be dilated, but the complication rate in these cases is higher. Lesions in the distal right and circumflex coronary arteries are accessible for dilatation. Also most side-branch (diagonal, marginal, or posterior descending artery) lesions of major arteries can be dilated. Lesions involving major bifurcations (i.e., anterior descending artery and diagonal branch) carry an increased risk of total occlusion of the side branch. Use of multiple balloons or special guide wires can reduce risk of this complication.

Table 2 lists areas that the panel considered evolving indications for coronary angioplasty. The rationale for this classification is discussed below.

**Angina and Multivessel Disease**

The use of coronary angioplasty in symptomatic patients with multivessel disease has grown rapidly.

**TABLE 1. Coronary Angioplasties Between 1984 and 1987: A Survey by the Members of the Task Force**

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<tbody>
<tr>
<td>Argentina</td>
<td>235</td>
<td>248</td>
<td>581</td>
<td>637</td>
<td>1</td>
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<td>2</td>
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<tr>
<td>Belgium</td>
<td>500</td>
<td>994</td>
<td>1,706</td>
<td>2,599</td>
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<td>1,132</td>
<td>1,681</td>
<td>2,115</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>9</td>
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<tr>
<td>Canada</td>
<td>2,249</td>
<td>3,992</td>
<td>5,535</td>
<td>7,349</td>
<td>25</td>
<td>30</td>
<td>31</td>
<td>31</td>
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<tr>
<td>Federal Republic of Germany</td>
<td>2,362</td>
<td>4,589</td>
<td>8,000</td>
<td>12,000</td>
<td>35</td>
<td>47</td>
<td>55</td>
<td>60</td>
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<tr>
<td>France</td>
<td>2,208</td>
<td>4,098</td>
<td>6,880</td>
<td>—</td>
<td>16</td>
<td>16</td>
<td>44</td>
<td>—</td>
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<tr>
<td>Japan</td>
<td>1,934</td>
<td>4,795</td>
<td>6,233</td>
<td>10,048</td>
<td>112</td>
<td>112</td>
<td>112</td>
<td>176</td>
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<tr>
<td>The Netherlands</td>
<td>1,673</td>
<td>2,565</td>
<td>3,508</td>
<td>4,656</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>United States</td>
<td>63,315</td>
<td>106,752</td>
<td>159,643</td>
<td>175,680*</td>
<td>618</td>
<td>620</td>
<td>620</td>
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*Data available for first nine months of 1987; extrapolated for the last three months.

**TABLE 2. Current Indications for Coronary Angioplasty**

<table>
<thead>
<tr>
<th>Class I: Accepted indications</th>
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<tbody>
<tr>
<td>Chronic stable angina unresponsive to medical therapy or unstable angina:</td>
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<tr>
<td>1. Preferably with objective evidence of myocardial ischemia</td>
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<td>2. With good left ventricular function</td>
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<td>3. With a single significant coronary stenosis suitable for PTCA</td>
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<table>
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<th>Class II: Evolving indications</th>
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<tr>
<td>1. Chronic stable angina or unstable angina in patients with multivessel disease</td>
<td></td>
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<tr>
<td>2. Angina in patients with recent coronary occlusion (less than three months)</td>
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<tr>
<td>3. No angina or mild angina following medical therapy with a strongly positive exercise stress test</td>
<td></td>
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<tr>
<td>4. Documented variant angina with significant fixed lesions</td>
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<tr>
<td>5. Acute myocardial infarction</td>
<td></td>
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<tr>
<td>6. Angina after coronary bypass surgery</td>
<td></td>
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<tr>
<td>7. Angina in inoperable/high-risk patients</td>
<td></td>
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<tr>
<td>8. Angina in elderly patients (( \geq )75 years)</td>
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<tr>
<th>Class III: Relative contraindications</th>
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<tbody>
<tr>
<td>1. No angina or mild angina without evidence of myocardial ischemia</td>
<td></td>
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<tr>
<td>2. Severe left ventricular dysfunction (ejection fraction &lt;25%)</td>
<td></td>
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<tr>
<td>3. Significant left main coronary artery stenosis</td>
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<tr>
<td>4. Patients in whom the only lesions are chronic coronary occlusions (older than three months)</td>
<td></td>
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</table>
There are several subsets of multivessel disease patients in whom coronary angioplasty is evolving as a frequent therapy. In addition to unstable angina or chronic stable angina unresponsive to medical therapy, these patients must have adequate left ventricular function and combinations of multivessel disease that can be dilated with a high chance of angiographic success. Each stenosis in multivessel disease should meet the selection criteria accepted for single vessel angioplasty. These criteria should be stricter than for single vessel disease.

Other patients who are suitable candidates for coronary angioplasty are those who have had small coronary artery occlusion with limited myocardial damage but one or more discrete lesions in another artery.

If dilatation of multiple lesions is required in selected cases, the most severe lesion should be dilated first. If dilatation is unsuccessful, the procedure should be terminated. Usually, multivessel angioplasty can be performed as a single procedure. However, if the procedure is prolonged or there is concern about the first dilatation, it is recommended that the remaining dilatation be staged as a second procedure.

If an acute occlusion occurs in a patient with multivessel disease and emergency bypass surgery is required, preservation of left ventricular function is an overriding consideration. Multiple vessel angioplasty should not be undertaken where a single dilatation could result in cardiogenic shock. These patients characteristically have large areas of myocardial dysfunction as a result of previous myocardial infarction and contralateral arteries with high grade lesions that, if acutely occluded, would result in cumulative damage equal to approximately 40–50% of the total myocardium. In certain instances, the area of total occlusion may be dilated first and, if successful, the second stenosis can be dilated with greater safety.

Finally, the rate of restenosis may be higher in patients with multivessel disease. This has not been adequately documented.

Angina With Recent Coronary Occlusion

Patients with either single or multivessel disease who have totally occluded coronary arteries are sometimes candidates for coronary angioplasty. Arteries that have been totally occluded for less than three months, which have anatomic characteristics that allow some estimate of the location of the distal vessel, can be dilated with a primary success rate of 60–70%. In multivessel disease, totally occluded arteries are commonly dilated first since failure to achieve an opening in a totally occluded vessel seldom produces an adverse consequence and should improve safety for attempts at other vessels.

No Angina or Mild Angina With Positive Exercise Test

In asymptomatic patients, all benefit to the patient must accrue from a presumed reduction in complications of coronary disease. Individuals with objective evidence of ischemia but no angina may have faulty warning systems or silent ischemia and an adverse prognosis.

Asymptomatic patients are identified through exercise stress testing or following myocardial infarction. Those with high grade lesions of single vessels supplying large areas of left ventricular myocardium are frequently treated with angioplasty.

Patients with significant obstruction in two or more vessels and significant myocardial ischemia can be considered for angioplasty if the probability of success is high, and if angioplasty can be strategically performed so that large amounts of myocardium are not placed in sudden jeopardy.

Documented Variant Angina

In patients with variant angina and spasm in the affected stenotic artery, angioplasty can improve the patient's condition if the fixed obstruction is significant. If the obstruction is less severe, symptoms frequently persist after angioplasty and are often accompanied by restenosis. Therefore, angioplasty is not recommended for patients with mild stenoses.

Acute Myocardial Infarction

Patients with acute myocardial infarction whose symptoms have been present for less than three to four hours are sometimes treated with immediate coronary angioplasty. The use of angioplasty as the first mode of therapy is controversial, but there is evidence that immediate angioplasty provides reperfusion, improved left ventricular function, and survival.

Angina After Coronary Bypass Surgery

Angina recurs in approximately 50% of patients during the first seven to eight years after coronary bypass surgery. Several mechanisms may be responsible for these new symptoms. New significant lesions are frequently observed in native vessels that may be suitable for coronary angioplasty. In some instances, the bypass graft is totally occluded but the proximal coronary lesion is still technically suitable for coronary angioplasty. In other cases, the graft is patent, and stenoses in the distal coronary artery can be dilated through the graft. Finally, narrowings of the graft itself that are discrete and single can be dilated. The distal artery anastomosis is the ideal location for coronary angioplasty in both the saphenous vein and internal mammary artery grafts. Dilatation of the graft to the aortic anastomotic site and obstructions in the body of the graft are followed by a high rate of restenosis. Lesions in the body of older grafts can be friable and can cause distal embolization.

Angina in High-Risk Patients

Some patients at high risk for bypass surgery are candidates for coronary angioplasty. Those who have had previous coronary bypass operations and
high grade lesions that place them at significant jeopardy if the vessels occlude can still, in some cases, be considered for angioplasty if the alternative to repeat surgery is impossible or performed only at a risk that exceeds the risk of coronary angioplasty. This category would also include patients who suffer from noncardiac conditions that place them at undue high risk for surgical intervention.

Angina in Elderly Patients (≥75 Years)

Old age does not contraindicate coronary angioplasty, which can be performed successfully in patients with severe symptoms.

Class III: Relative Contraindications

Asymptomatic Patients

Controversy persists concerning myocardial revascularization in patients with mild symptoms, equivocal noninvasive studies, and angiographic evidence of significant coronary artery obstructions. The final decision is often an individual one and must take into consideration the severity of ischemia, the amount of myocardium in jeopardy, the patient’s age, and the experience of the cardiology and surgical team.

Symptomatic Patients

Patients with left main coronary disease should not undergo angioplasty unless the left main artery is protected by bypass grafts to either the anterior descending or circumflex system. Angioplasty is not recommended for patients with multivessel disease who have large areas of myocardial dysfunction as a result of previous myocardial infarction or contralateral arteries with high-grade lesions that, if acutely occluded, would result in cardiogenic shock. Patients with multivessel disease who have chronic total occlusions of large vessels that are either anatomically unlikely to be successfully treated with angioplasty or exceed three months in duration should not be considered for angioplasty.

Any combination of multivessel disease in which an alternative form of revascularization would be unequivocally more efficacious should not be treated with angioplasty. Significant obstructions serving large areas of myocardium should not be left unrevascularized, although small arteries, mild stenoses, and arteries supplying nonviable myocardium are appropriately left unrevascularized by PTCA.

Mild lesions (less than 50% stenosis) in patients undergoing multivessel angioplasty should not be dilated as abrupt reclosure may follow even in lesions of mild severity. In addition, late restenosis may occur to a more severe degree than the initial lesion.

Patients in the acute phase of myocardial infarction, who on catheterization are discovered to have severe disease in multiple vessels, should not undergo angioplasty of vessels that are not involved in the acute myocardial infarction.

Criteria for Primary Success and Restenosis

Primary success and restenosis after PTCA may be defined angiographically, hemodynamically, functionally, and symptomatically.4-7

Functional Criteria

Although improvement of symptoms after PTCA is probably the most desirable end point, it is also the least objective evaluation. The frequency of symptomatic improvement appears to be lower than that of angiographic success. Improvement in symptoms and luminal diameter should be confirmed by improvement of myocardial function, that is, less ST depression in the exercise ECG, improved thallium scans, and improved left ventricular function in radionuclide angiocardiography.

Absence of in-hospital complications, that is, absence of death, nonfatal myocardial infarction, or coronary artery bypass grafting during initial hospitalization is a prerequisite to PTCA success.

Hemodynamic Criteria

To some extent, reduction or disappearance of the trans-stenotic pressure gradient provides a direct nonangiographic evaluation of results. However, the presence of both balloon and guide wire within the stenotic cross-section reduces the remaining luminal area. Thus, the trans-stenotic gradient may be overestimating the “true” pressure drop in a manner dependent on the ratio of the catheter diameter over that of the stenosis. Conventional gradient determination with balloon catheters therefore does not accurately reflect the hemodynamic significance of coronary lesions. Nevertheless, trans-stenotic pressure measurements are still clinically useful given the strong relationship between a post-PTCA (final) pressure gradient of 15 mm Hg or less and consequent restenosis rates.

Angiographic Criteria

Angiographic evaluation has emerged as the most reliable method of judging immediate and late results of a dilatation. Despite the possible problem of accuracy of luminal diameter measurements after PTCA, especially in the presence of irregular angiographic vascular wall outlines such as those due to dissection, the mean of stenosis measurements in at least two perpendicular projections in which the involved segment is exposed in full length represents the best widely available technique for assessing anatomic severity of coronary artery stenosis in most patients.

However, visual evaluation of the severity of coronary obstructions from 35 mm cineangiograms has several serious shortcomings. Reproducibility, interobserver variability, and lack of correlation with pathologic and intraoperative findings of the arteriogram are well recognized. Furthermore, reproducibility of visual lesion assessment is influenced by severity of stenosis. In general, there is a wider
range of interobserver and intraobserver variability for moderate lesions than very mild or severe stenoses. Caliper lesion determination from coronary cineangiograms is not sufficiently accurate for measuring small luminal changes in moderate lesions, which is compounded by the fact that these “minor” changes have major hemodynamic consequences. While resting coronary flow is not altered until at least 85% of the diameter is constricted, maximal coronary flow is already diminished by constriction as small as 30%, and marked impairment of coronary flow reserve occurs with progressive stenosis of 65–95% as determined by caliper measurement. Finally, accurate determination of the degree of stenosis can be made only after radiographic processing of cineangiograms, preventing use of this performance in the catheterization laboratory during the procedure.

Other systems have been introduced in recent years to enhance objectivity and reproducibility in the assessment of coronary arterial dimension, but they are not widely available. Systems for quantitation of coronary angiograms vary from manual procedures that use a Vernier caliper or a comparable device to a computerized manual edge-tracing procedure and methods that use computer edge-detection algorithms to determine arterial dimensions in a two-dimensional projection. Several investigators have applied densitometric procedures in an attempt to derive cross-sectional area measurements from single-view coronary cineangiograms. Finally, methods have been proposed for three-dimensional representation of coronary arterial segments assessed from two orthogonal views.

Definition of Success and Restenosis

The major risk of a lack of standardization in the definition of success and restenosis may be that investigators will prematurely draw important and possibly erroneous conclusions about factors thought to be responsible for low or high rates of these outcomes, such as technique of angioplasty, drug regimen both during and after PTCA, or modification of cardiovascular risk factors.

Definition of Successful PTCA

The task force reviewed the different criteria for primary success frequently reported in current literature.8–21 Until recently, most investigators referred to the degree of percent diameter stenosis before PTCA in evaluating the outcome of the procedure, considering a 20% or greater reduction in diameter stenosis a criterion of success. Some workers used the previous definition in combination with a second angiographic definition in evaluating the short-term efficacy of PTCA, namely, a residual diameter stenosis of less than 50% immediately after dilatation. Recently, several investigators used this latter definition as the sole angiographic criterion for primary success. In addition, most investigators require that no major complication become evident during the procedure itself or the convalescence period.

The task force recommends that the definition of a successful PTCA include the following criteria:

- Absence of major complications, including death, nonfatal myocardial infarction, or coronary bypass surgery during initial hospitalization.
- A 50% or greater pre-PTCA diameter stenosis reduced to less than 50% immediately after PTCA.
- A change of at least 20% from initial to post-PTCA diameter stenosis when angiograms are assessed visually, and a change of at least 10% when angiograms are assessed by computer. This criterion will account for borderline situations and interobserver and intraobserver variability in analysis of coronary angiograms.

Definition of Anatomic Restenosis

Previously proposed criteria for recurrent stenosis relied almost exclusively on angiographic reevaluation in contrast to primary success criteria.8–21 Until recently, the two most frequently used restenosis criteria were an increase of at least 30% in diameter stenosis from immediate post-PTCA to follow-up angiogram, or a loss of at least 50% of total gain in percent diameter stenosis achieved at PTCA.

More recently, several investigators have used a third definition of restenosis, an immediate post-PTCA diameter stenosis of less than 50% that increases to 50% or greater at follow-up.

Whenever a specific threshold is used to identify restenosis, the task force recommends this definition. In general, angiographic change is detectable when there is at least 20% visual increase in percent stenosis from early post-PTCA to follow-up angiogram (or at least 10% by quantitative assessment). In the future, it would be preferable to present quantitative measurements (caliper or computer-assisted) of the extent to which the lesion residual lumen diameter changed from post-PTCA measurement back to pre-PTCA measurement.22 Moreover, the status of blood pressure and vasodilator medication at the time of angiography is also relevant to the evaluation of changes in coronary lesion dimension over time.

Finally, in a given patient, clinical significance of a lesion that meets these angiographic criteria for restenosis must be judged on severity of symptoms, exercise tolerance, and extent of jeopardized myocardium, among other factors.

Multilesion Versus Multivessel PTCA

There is still some confusion about what should distinguish multivessel angioplasty from multilesion angioplasty in a single coronary artery. To standardize these definitions, the task force suggests that the widely accepted coronary anatomy nomenclature described by the Coronary Artery Surgery Study (CASS) group be followed.23 Multilesion PTCA refers to attempted dilatation of lesions in more than one segment of a major coronary artery, using
the CASS nomenclature. Examples of multileesion PTCA in a single major coronary artery include 1) attempted dilatation of lesions in segments 13 (mid left anterior descending artery) and 15 (first diagonal artery), and 2) attempted dilatation of lesions in segments 19 (distal circumflex artery) and 20 (first obtuse marginal artery). Multivessel PTCA refers to attempted dilatation of one or more lesions in segments located in separate major coronary arteries, using the CASS definition.

Training Requirements for Professional Personnel

It is generally acknowledged that specialized skills are required for coronary interventional techniques.4-7,24,25 Training in these procedures requires skills in diagnostic and therapeutic cardiology, particularly cardiac catheterization and angiography. While 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 dictates that formal training programs in angioplasty become the required means of learning. The following recommendations are made:

Training Program

The director of the catheterization laboratory should be board-certified in cardiovascular diseases or have equivalent credentials and should have primary responsibility for administration and teaching in the laboratory. More than one competent faculty cardiologist should participate in cardiac catheterization training of fellows. These cardiologists should be certified by the Board of Cardiovascular Diseases and recognized as experts in cardiac catheterization. For training in coronary angioplasty, there must be at least one cardiologist on the faculty recognized by his peers as an expert in this technique.

Levels of Training

Level 1: Training in Clinical Cardiology

All trainees in clinical cardiology should have a clear understanding of indications, limitations, complications, and medical and surgical implications of findings at cardiac catheterization and angiography. All trainees should have some experience performing right and left heart catheterization (including ventriculography) and coronary angiography. All trainees should receive at least four to six months’ training in the cardiac catheterization laboratory, during which time they must participate in catheterization of at least 100 patients with whom they are involved from precatheterization clinical evaluation to final disposition.

Level 2: Training in Cardiac Catheterization and Angiography

Trainees who plan to perform independent catheterization and angiography require additional training in both percutaneous arterial entry and arterial incision and repair. They must receive additional education in theoretical and practical aspects of radiation physics. A working knowledge of catheterization laboratory equipment, including physiologic recorders, pressure transducers, blood gas analyzers, image intensifiers, and other x-ray equipment, cine processing and quality control of films is required.

For the trainee who plans to perform diagnostic cardiac catheterization and angiography, a minimum of 12 months’ training in the catheterization laboratory is required, during which time a minimum of 300 procedures must be performed, including 200 as primary operator.

Level 3: Training in Coronary Angioplasty

Trainees planning to do coronary angioplasty must also have knowledge of indications, limitations, and complications of angioplasty as well as an understanding of the specialized equipment needs. They must obtain adequate experience in performing the procedure.

For the trainee who plans to perform coronary angioplasty, an additional year of training is required and a minimum of 125 coronary angioplasty procedures must be performed, including 75 as primary operator.

Trainee Evaluation

Judgment, as well as interpretive and technical skills, must be evaluated in every trainee. This is particularly important in the individual who eventually will work full-time in a diagnostic catheterization laboratory or perform angioplasty.

Competency of all cardiology trainees in cardiac catheterization should be documented by both the program director and the director of the cardiac catheterization laboratory. The program director is responsible for confirming or denying the technical competency and catheterization laboratory exposure of trainees. Granting of hospital privileges remains within the purview of the individual institution.

Evaluation of the individual who desires special training in diagnostic cardiac catheterization and angiography shall include documented performance (in the form of a logbook) of a minimum of 300 procedures, 200 as primary operator (Level 2).

Evaluation of the individual training in angioplasty shall, in addition, include documented performance (in the form of a logbook) of a minimum of 125 procedures in angioplasty, 75 as primary operator (Level 3).

In some countries, or in circumstances in which training resources or volume of procedures is limited, or in situations in which the angioplasty trainee has had substantial independent experience in cardiac catheterization and angiography, a one-third reduction in the recommended minimum number of training procedures may be considered. Thus, for the experienced operator with a constrained PTCA training opportunity, a requirement of 35 cases as
assistant and 50 cases as primary operator under supervision of an experienced senior individual, for a total of 85 cases, may be considered acceptable.

The characteristic learning curve associated with coronary angioplasty has been well-documented in reports from the NHLBI PTCA Registry. Introduction of a greater variety of angioplasty instrumentation has facilitated performance of the procedure such that relatively uncomplicated angioplasty procedures can be expertly performed by individuals with the levels of training described above. For patients with multivessel disease, complex lesions, or situations requiring multiple guide wires and other specialized techniques, the additional presence of a senior operator experienced in angioplasty is strongly recommended.

Continued Experience
On completion of formal training, a physician performing PTCA should carry out an adequate number of procedures to maximize patient safety and laboratory efficiency. A minimum caseload for a single physician is estimated to be about one case a week. Continued performance of PTCA should depend on demonstrated success and complication rates that meet international standards. Annual attendance at a major angioplasty course is required to continue education in newer techniques and equipment.

PTCA Equipment and Techniques

Radiographic Equipment
PTCA can be performed either with single plane or biplane angiographic equipment. Cranial and caudal angulations are best achieved with the patient stationary and the x-ray equipment rotating around the patient's body. High-quality fluoroscopy is essential, as is an adequate video replay system, with both real time reproduction and freeze-frame capability. At present, most coronary angioplasty procedures are performed in laboratories with radiographic equipment designed prior to angioplasty that are configured for conventional diagnostic coronary angiography. Modifications to accommodate the imaging needs of interventional procedures are underway. In the near future, methods of quantitative angiographic analysis of video images during an angioplasty procedure will likely become more widely available.

Angioplasty Procedural Equipment
Equipment from a variety of manufacturers is suitable for performance of PTCA. All laboratories performing the procedure should have a selection of equipment that includes a complete range of guiding catheters, balloon catheters from 2-4 mm in diameter, and a range of steerable guide wire systems.

Several variations on the technique of coronary angioplasty are available and the experienced operator should be familiar with as many as possible. It is prudent for the operator and the laboratory staff to be completely familiar with the method that works best for them. At the present time, some form of steerable guide wire or a soft-tipped fixed balloon catheter system is used by all operators. All of these systems are steerable.

Angioplasty results should be assessed by each operator with the technique that serves his or her needs best. Both angiographic and hemodynamic measures of angioplasty success are helpful in guiding performance of the procedure. Some systems do not allow for pressure measurement and in those cases, techniques for excellent angiographic assessment must be available on-line.

If pressures are measured, then equisensitive pressure-monitoring systems must be in place, be maintained properly, and used correctly.

Adequate performance of angioplasty is largely a result of extensive operator experience and is inseparable from training requirements for professional personnel.

Radiation Sources
Protection of personnel from exposure to radiation is critically important. Currently, methods of reducing x-ray radiation are available on standard equipment such as an optimal TV chain and image intensifier, an x-ray beam with automatic collimation, a correct field size on the image intensifier, a carbon fiber scattered radiation grid, a carbon fiber table top, and a correct tube filter. These measures may result in a dosage reduction of up to 50%, a lower x-ray tube loading with a smaller focal spot, and improved picture quality. Whenever possible, lower level radiation video imaging should be substituted for higher radiation cine filming.

Further radiation reduction may be achieved by using extra equipment such as a video image processor. Fluoroscopy filtering, pulsed fluoroscopy, and image hold techniques will considerably reduce the duration of fluoroscopy examination. During cinematography, gap filling and selection of a reference image will improve the operator's visual perception and make frequent cinefilming unnecessary. Pathfinding using a reference monitor, automated video replay after cinematography using a video disc or digital techniques, and automatic and instant storage of the image with a video recorder will all result in a further reduction in x-ray exposure. All personnel should be protected against radiation by special aprons, eyeglasses, thyroid protection, and extra shielding of the x-ray tube.

Surgical Back-Up and Coverage
Specific emergency situations may occur during coronary angioplasty in which coronary surgery is the most expeditious, if not the only, method to maintain myocardial perfusion of severely ischemic myocardium. These situations include failed angioplasty with development of active ischemia, obstructive arterial dissection, thrombosis, or less commonly, cardiac vessel perforation, cardiac tamponade, and peripheral artery complications. Although multi-
ple techniques have been developed, including repeat angioplasty and catheters for distal perfusion, these measures may only be temporizing.

The incidence of complications necessitating emergency surgery is increased for lesions located in tortuous vessels, at bifurcation points or sharp bends, and for lesions that are long (>1 cm), deeply ulcerated, or have associated intraluminal thrombus. The increased risk that accompanies acute closure of a major artery, jeopardizing large amounts of myocardium, should be recognized and particularly close surgical back-up arrangements should be made in these instances. Although there is a tendency to categorize angioplasty procedures as having low, moderate, or high risk, situations do occur in low-risk procedures that lead to catastrophic complications. For instance, angioplasty of totally occluded vessels may be less likely to provoke a greater degree of myocardial ischemia or damage than that already present, but acute reclosure, left main coronary artery dissection, and vessel perforation can occur. It should be assumed that any coronary interventional procedure has the potential for a catastrophic complication that can jeopardize the patient’s life. Consultation with a cardiovascular surgeon or arrangements for appropriate surgical coverage prior to performance of any angioplasty procedure is mandatory. The cardiologist and surgeon performing the angioplasty should agree on the relative risk to a particular patient for a complication that would necessitate emergency surgery. Depending on this determination, a level of standby should be decided, along with a potential management plan in the event of failed PTCA without complications. The cardiologist performing angioplasty is ultimately responsible for the patient’s management, as well as the consequences of inadequate surgical back-up arrangements.

Surgical standby should consider not only the availability of the cardiovascular surgeon, but also an anesthesiologist, pump technician, operating room, and nursing team. In various regional and national settings, operating room availability may be based on a scheduled slot, a continuously ready standby operating room, or close coordination between angioplasty procedures and the operating room schedule. In general, these arrangements should be established prior to angioplasty. Unacceptable arrangements include the absence of formal communication between the surgeons and cardiologists performing angioplasty, and the performance of angioplasty in catheterization laboratories not physically connected with a hospital containing cardiac surgery availability. Arrangements in which coronary angioplasty is performed with all operating rooms occupied and complications handled on a “next room available” basis, must be critically examined to ensure that emergency cardiac surgical backup can be provided with minimal delay.

Preangioplasty and Postangioplasty Management

Before a patient is considered a candidate for coronary angioplasty, risk factors should be corrected to the greatest possible extent. The patient and family should be fully informed of the goals and risks of coronary angioplasty, including the possible need for emergency cardiac surgery.4-7

Medication is given with the aim of reducing the potential for arterial reclosure and restenosis. Coronary angioplasty can stimulate coronary spasm or increase a preexisting tendency toward spasm. The underlying mechanism probably relates to the traumatization of the endothelium and platelet deposition with release of vasoactive substances. Therefore, medications that decrease sympathetic coronary tone and reduce platelet deposition are recommended during and after the procedure. Long-acting nitrates or calcium antagonists plus antiplatelet agents are usually prescribed. Since β-blocking drugs increase the α-adrenergic tone of coronary arteries, they may increase the potential for coronary artery spasm. Whenever possible, these drugs should be reduced or withdrawn prior to angioplasty, or long-acting nitrates or calcium channel blockers should also be prescribed. Similarly, for the first several weeks after a successful procedure, β-blocker drugs should be prescribed only in conjunction with long-acting nitrates or calcium channel blocking drugs.

Coronary thrombosis is one of the major causes of complications during angioplasty. In addition, platelet aggregation probably plays a major role in the genesis of restenosis after successful angioplasty. In general, anticoagulation with warfarin has not been more effective than drugs that inhibit platelet aggregation and deposition. Following successful angioplasty, acetylsalicylic acid is usually given in doses ranging from 100–1,500 mg a day in current practice. Variable doses of dipyridamole (75–400 mg a day) are also prescribed. Neither a clear-cut benefit nor optimum dose for these agents has been defined, but randomized placebo-controlled trials of the effectiveness of these agents in angioplasty are nearing completion.

Similarly the use of heparin during and immediately after the procedure is presumed to be beneficial, but no randomized study demonstrating its benefits exists. Because of the use of multiple catheters for extended periods during coronary angioplasty, there is general agreement about the use of heparin anticoagulation during the procedure. Due to increased rates of abrupt reocclusion in patients in whom protamine was employed to reverse heparin anticoagulation, its routine use is not recommended at the completion of a procedure.

There is much greater variability in the prescription of heparin following successful angioplasty. Current treatment protocols range from no additional heparin at completion to infusions of heparin for 24–48 hours. There is general agreement that the presence of intraluminal thrombus before or
during angioplasty requires more aggressive antithrombotic therapy, and in these circumstances, both antiplatelet agents plus longer infusions of heparin (24–48 hours) are usually employed. In these circumstances, thrombolytic agents have also been employed, but their clinical merits have not been conclusively demonstrated.

Following successful angioplasty, most patients remain in the hospital for 24–48 hours. With recurrence of ischemic pain that is not responsive to medical therapy, the patient should have either angiographic reassessment and/or surgical therapy with minimum delay. Closer observation in a coronary care unit may be necessary for those patients in whom difficulties were encountered during angioplasty (protracted or frequent coronary occlusions, chest pain, ECG changes, hemodynamic instability, presence of significant coronary spasm or thrombus, or a suboptimal result with significant residual stenosis, or extensive intimal dissections).

Because restenosis will occur in approximately one third to one fifth of patients by the sixth month, a clinical reassessment approximately three to six months after angioplasty is recommended. This should include a noninvasive stress test and angiography, if clinically indicated.

Future Developments

Angioplasty is now an accepted method of coronary reperfusion with a 90–95% primary success rate in experienced centers, but limitations exist: 1) a 20–49% restenosis rate; 2) a lower rate of success in totally occluded vessels; 3) lack of reliable techniques to maintain distal perfusion following abrupt arterial occlusion; and 4) inability to reach, cross, and dilate distal lesions in tortuous vessels. These are important limitations. Restenosis is the major complication of current angioplasty practice, and the inability to successfully dilate the totally occluded artery is a major limitation in the angioplasty approach to the patient with multivessel disease.

There is currently an explosion in new devices and approaches designed to overcome the current limitations of angioplasty practice.28–34

Balloon Technology

Advances in balloon catheter design include high-pressure balloons for displacing noncompliant lesions and extremely low-profile balloons that allow crossing very tight lesions, particularly those located distally in vessels where mechanical support from the guide catheter system is difficult. Guide wires are being evaluated that have balloon catheters and are so small that theoretically any severely stenosed arterial segment with a residual lumen can be crossed and dilated.

Other balloon devices will allow special applications. Balloon systems are being designed for introduction over guide wires in such a way that the balloon can be removed for angiographic assessment while the wire remains in place in the artery.

A “monorail” system using short guide wires and standard angioplasty balloons with long guide wire systems are currently being evaluated. Some currently available catheters allow distal perfusion of arterialized blood or oxygenated blood substitutes. Balloons are also being developed that allow blood to enter the lumen of the balloon proximal to the lesion and exit distally while the balloon is still inflated, enabling longer inflations.

Laser Technology

It is hypothesized that by removing atherosclerotic obstructions through vaporization of plaque, laser angioplasty may be more effective than balloon angioplasty. However, to date, the technique has been limited by inadequate delivery systems resulting in an unacceptably high perforation rate and the creation of small recanalized channels that have a poor long-term patency. Attempts to solve the problems of vessel perforation and thrombosis after laser angioplasty have been directed along several lines of investigation. One approach has been to preferentially increase absorption by atherosclerotic tissue of laser radiation by using various compounds such as hematoporphyrin or tetracycline. Whether this will be clinically effective in removing atherosclerotic obstructions remains to be determined. Atherosclerotic lesions can also be distinguished from normal tissue by laser-conducted spectrographic analysis. This technique may represent an alternative means of guiding the selective ablation of atheroma without damaging normal arterial wall. This concept also requires confirmation of safety and efficacy. Other approaches to diminishing vessel perforation with laser energy include the use of lasers with a shorter pulse duration, such as the excimer laser, direct visualization using an angioscope, and the use of specially designed balloon catheters and heated metal tips to allow more circumferential diffusion of the laser energy. Other forms of energy that can be delivered through a catheter system to remove or displace atherosclerotic material in the coronary arteries are also being developed.

Other Mechanical Developments

Other mechanical means of removing atherosclerotic plaque are under active investigation, including a biotome device that “shaves away” the obstructing lesion, resulting in an atherectomy. Intracoronary stents or devices that are placed in a dilated segment of a coronary artery to mechanically maintain lumen size have been developed and are now available for clinical trials. It is likely that the capabilities of modern technology will introduce as yet unknown devices that will restore coronary blood flow by eliminating obstructing lesions without major surgical intervention. Each of these techniques will require thoughtful evaluation by controlled trials and will ultimately be evaluated against the current gold standards for revascularization, that is, coronary bypass surgery or PTCA.
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