

Guidelines for Peripheral Percutaneous Transluminal Angioplasty of the Abdominal Aorta and Lower Extremity Vessels

A Statement for Health Professionals From a Special Writing Group of the Councils on Cardiovascular Radiology, Arteriosclerosis, Cardio-Thoracic and Vascular Surgery, Clinical Cardiology, and Epidemiology and Prevention, the American Heart Association

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THE diagnosis and management of peripheral vascular disease has undergone tremendous change during the past two decades. Diagnostic angiography is complemented and, in some cases, even supplanted by digital subtraction techniques, duplex sonography, intravascular ultrasound, and magnetic resonance imaging. Similarly, percutaneous transluminal angioplasty has evolved from a novelty to a vital component in the treatment of peripheral vascular disease. This document discusses the background and current state of peripheral angioplasty, including the prevalence of peripheral atherosclerosis and the history, clinical results, and risks of angioplasty.

As a less invasive treatment, angioplasty has been placed in an awkward position between surgery and nonoperative therapy. To clarify the role of angioplasty, the determinants of success, requisite symptoms for intervention, indications for treatment, and appropriate clinical setting are described. Because the alternative treatment is typically surgery when a patient's con-

dition necessitates intervention, the literature comparing the two treatments is reviewed.

EPIDEMIOLOGY

Prevalence and Incidence of Peripheral Arterial Disease

The prevalence of peripheral arterial disease (PAD) in populations depends on the criteria used for diagnosis. Traditionally investigators have used the criterion of classic intermittent claudication, as determined by the Rose questionnaire (1), which can only detect symptomatic disease. Such investigations have found the rate in people approximately 60 years of age to vary from 1% to 6%, with rates 1-1/2 to 2 times higher in men than in women (2-9). In a population-based study of older adults in southern California, classic claudication rates were negligible in those less than 60 years old, rose to 2.4% at ages 60 to 69, and were 2.7% at age 70 and above (10). Similar gradients with age have been seen in other studies. The southern California study also looked at Rose and "possible" claudication, or all exercise calf pain not present at rest. This category has considerable validity as a marker of PAD (11). The rates in this category were 3.1% at ages 40 to 59,

5.4% at ages 60 to 69, and 7.7% at age 70 and above (10). Noninvasive testing was also used in this study to accurately determine whether subjects were symptomatic, asymptomatic, or atypically symptomatic for PAD. The results were rates of about 2.5% at ages 40 to 60, 5% at ages 60 to 64, 13% at ages 65 to 69, 16% at ages 70 to 74, and 22% at age 75 and above. Therefore, use of classic Rose claudication as a criterion appears to result in a dramatic underestimation of the prevalence of PAD. In addition to the low sensitivity of Rose claudication (9.2%) or Rose and possible claudication (20%) for noninvasively determined PAD, the positive predictive values are also lower than might be expected: 54.5% for Rose claudication and 38.2% for Rose or possible claudication (12). Thus, even in a population of patients with classic claudication, only half may truly have PAD.

Determining the incidence of PAD requires careful repeated investigations in the same cohort over time. Such data are available from the Framingham Study (13). PAD was defined by intermittent claudication. The age-specific annual incidence in men and women per 10 000 population at risk is shown in **Table 1**.

Like prevalence, the incidence rates

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Table 1
Age-Specific Annual Incidence of Peripheral Arterial Disease in Men and Women, Per 10 000 at Risk

Age	Men	Women
30-44	6	3
45-54	19	7
55-64	53	18
65-74	61	54

From Kannel WB, Skinner JJ Jr, Schwartz MJ, Shurtleff D. Intermittent claudication: Incidence in the Framingham Study. *Circulation*. 1970; 41:875-883. Reproduced with permission.

of claudication increase sharply with age, and become quite similar in men and women at the oldest ages, a trend also apparent in the study of PAD prevalence as diagnosed with noninvasive tests (10).

Natural History and Prognosis

Changes over time.—Two thirds to three fourths of PAD patients who survive for several years after diagnosis will have no worse than stable symptoms, while the remaining one third to one fourth will show deterioration or progression. One percent to 5% will eventually require amputation (14).

This natural history of PAD is contingent upon long-term survival. However, cardiovascular mortality in patients with PAD is sharply increased, leading to a significantly higher overall death rate (see below). It seems logical that PAD would progress more rapidly in patients who eventually suffer early cardiovascular death.

Comorbidity from cardiovascular disease.—The prevalence of comorbid coronary disease in patients with PAD may exceed 50%, and there is an excess prevalence of cerebrovascular occlusive disease as well (14). Such comorbidity is to be expected, given the similarity of risk factors for atherosclerosis in various arterial beds (15).

Mortality.—In early studies using intermittent claudication to define PAD, there was a doubling of total mortality in persons with claudication (8,16,17), primarily because of

cardiovascular disease. However, whether this excess risk could be explained by the excess of cardiovascular disease risk factors or existing cardiovascular disease in persons with PAD was controversial. In a prospective study, in which noninvasive tests were used to make a more accurate diagnosis of PAD, the relative risk of all-cause mortality in patients with PAD was 4.5 (18). Thus, a better definition of PAD, with less misclassification, indicated a true excess risk much higher than the doubling reported in earlier studies in which PAD was defined by claudication. In addition, this risk was demonstrated to be independent of cardiovascular risk factors or extant cardiovascular disease at baseline. Further follow-up of this population revealed that the relative risk for cardiovascular mortality was about 6, and in patients with severe or symptomatic disease the relative risk was about 10 (19). These data highlight the sharply elevated risk of cardiovascular mortality in PAD patients.

PAD Hospitalization and Treatment in the United States

Gillum (20) recently published estimates of hospitalization and treatment for PAD in the United States, using data from the National Hospital Discharge Survey conducted by the National Center for Health Statistics. Between 1985 and 1987 the NCHS coded up to seven diagnoses and four procedures, using the ninth revision of the International Classification of Disease, Clinical Modification. These codes were used to distinguish between diagnoses of chronic PAD and acute PAD and procedures related to PAD. Data were averaged over 1985 to 1987.

Chronic PAD.—Every year 55 000 men and 44 000 women had a first-listed diagnosis of chronic PAD, and 229 000 men and 184 000 women had chronic PAD noted at discharge. In the latter group 66.3% of the men and 74.1% of the women were 65 years old or older. Like intermittent claudication and noninvasively diagnosed PAD, the rate increased sharply with age, and the condition was 1½ to 2 times more common in men. Interventional techniques were the most common procedure used to treat chronic PAD, with 88 000 hospital discharges, a sharp increase from 37 000 in 1979. Aorto-iliac

femoral bypass was coded for 31 000 discharges, a sharp increase from 18 000 in 1979. Other shunt or bypass procedures were coded for 74 000 discharges, compared with 46 000 in 1979. Endarterectomy of lower limb arteries was listed for 17 000 discharges, compared with 10 000 in 1979.

A bias toward underestimation of chronic PAD was evident in these data because, on average, only half the patients with arteriography, aorto-iliac-femoral bypass, or other shunt or bypass procedures had chronic PAD discharge diagnoses. This underestimation may reflect, in part, there being only seven discharge and four procedure codes.

Amputations were coded for 21 000 men and 15 000 women with a diagnosis of chronic PAD per year in the period from 1985 to 1987.

Acute PAD.—Each year 60 000 men and 50 000 women had this diagnosis, and 57.6% of the men and 69.8% of the women were aged 65 or older. Ninety-one percent of these diagnoses involved the lower extremity. Like that of chronic PAD, the incidence of acute PAD increased sharply with age and was 1½ to 2 times more common in men than women.

Deaths due to PAD.—Few deaths were attributed to chronic PAD, a finding compatible with previous observations that the excess mortality in people with PAD is attributable to other cardiovascular causes.(19) In 1985 acute PAD (arterial embolism and thrombosis of the extremities) was mentioned 583 times as the underlying cause of death, and 2661 times anywhere on the death certificate.

Trends in PAD Treatment and Economic Implications

A recently published study conducted in Maryland confirms the sharp increase in procedures for PAD noted in the NCHS data (21). Between 1979 and 1989 the rate of percutaneous transluminal angioplasty for PAD rose from 1 to 24 per 100 000 Maryland residents. Despite this dramatic increase, the annual rate of peripheral bypass surgery also increased sharply, from 32 to 65 per 100 000. Despite these two therapeutic interventions, the annual rate of lower extremity amputation was stable at 30 per 100 000. In constant dollars, total hospital charges for stays involving a revascularization procedure increased from \$14.7 million in 1979 to \$30.5 million in 1989. The associated number of

hospital days rose from 20 695 in 1979 to 33 830 in 1989. The aging of the population cannot be blamed for these dramatic increases, because data were adjusted for age (and sex) over the 10-year period. An editorial accompanying the article suggests that angioplasty and bypass may have been performed for mild to moderate disease, which could not save limbs and could lead to complications such as amputation, and may have been performed in too many hospitals, including those with limited expertise (22). Veith et al (23) have described a coordinated effort by an expert vascular surgery team that produced a reduction in amputations.

When considering the economic implications of current therapy for PAD, it is important to remember that the data in the Maryland study were age adjusted. In fact, the US population continues to age, and this factor, combined with the advance in surgical techniques, suggests that medical care costs will mount, particularly given the rather disappointing impact of angioplasty for PAD on bypass and amputation rates in Maryland to date (21).

History of Angioplasty

In 1964 Dotter and Judkins (24) described the first angioplasties performed in the femoropopliteal system with coaxial catheters up to 12F in diameter. These catheters were later modified by Staple (25) and then van Andel (26), who described serial tapered dilators. The concept of vessel-sized dilators was clearly unsuitable, and in 1973 Porstmann (27) described a caged latex balloon for use in the iliac system. However, it was not until Grüntzig and Hopff (28) described a coaxial balloon catheter that inflated to a fixed diameter that angioplasty came to be used with any frequency, particularly in the United States. Nevertheless, Grüntzig's balloons were made of polyvinyl chloride and were relatively compliant: ie, they increased their diameter considerably with pressure. However, over the working pressure of 2 to 6 atmospheres, the change was no more than 1 or 2 ml. Since then, less compliant materials like polyethylene have been used to maintain fixed diameters through a wide range of pressures (29). Advances in technology, particularly in size, trackability, and profile of catheters, have been important, as have the advances in the pharmacologic adjuncts to angioplasty. Combined with the improvement in image intensification and digital subtraction filming, these ad-

vances have contributed to the slowly progressive growth in the number of procedures performed.

Grüntzig's primary interest was in taking his techniques to the coronary circulation, and soon the equipment was miniaturized for use coaxially through a guiding catheter. In 1978 the first renal angioplasty was performed (30) and shortly after that, the first coronary angioplasty (31).

Results of Angioplasty

In 1991 Rutherford (32) produced reporting standards for peripheral interventions that have since been adopted by *Radiology* and the *Journal of Vascular and Interventional Radiology* (33). These standards, modified from standards proposed to the vascular surgical community in 1986 (34), will bring uniformity to a field in which reports are sometimes difficult to evaluate. Previous studies by both Johnston et al (35) and Capek et al (36) meet Rutherford's criteria, but to circumvent these problems Adar et al (37) proposed a meta-analysis technique called confidence profile analysis, deriving patency rates similar to those reported by Becker et al (38) in a literature review. To date, no registry has been reported, and there is only one randomized trial in the literature in which angioplasty is compared with surgery (39). It indicated similar results over 3 years between surgery and angioplasty in both the iliac and femoropopliteal systems.

Angioplasty has been recognized for some time as a valid technique. In 1984 the Council for Scientific Affairs of the American Medical Association concluded that "angioplasty is an acceptable procedure in selected patients as an alternative to bypass grafting" (40). In 1983-1984 the Health and Public Policy Committee of the American College of Physicians concluded that "the morbidity in the periphery is less than for surgery" (41). The success rates approximate those of bypass surgery and are superior to those of prosthetic femoropopliteal artery bypasses. Success is increased in short stenosis and occlusions with good runoff and in disease limited to the site of the angioplasty. It is also more successful in patients with claudication than in those with ischemia (41).

Aortic Angioplasty

Several small series and case reports are in the literature (42-49); the largest series included 32 patients (49). Mean

follow-up in this series was 25 months (1 to 96 months), and 25 of 28 patients maintained postangioplasty improvement in their ankle/brachial indexes (mean improvement 0.24). The condition of only three patients deteriorated. Aortic angioplasty has previously been recommended for short stenoses, but in this series 41% of the stenoses were 2 cm or longer, and half of those were 4 cm or longer. Patients with these stenoses did as well as those with isolated stenoses. Nevertheless, the majority of patients with widespread aortic disease will have surgery because in most it will be associated with widespread iliac disease.

Iliac Angioplasty

The overwhelming majority of series in the literature concern stenosis, and the procedure has been performed for claudication rather than advanced ischemia in about 75% (35,50-63). Becker et al (38) analyzed 2697 procedures from the literature and found a 92% initial success rate, a 2-year patency rate of 81%, and a 5-year patency of 75%. Nevertheless, long-term follow-up was not available for the majority of these patients. Continued improvement in ankle/brachial index is a valid method of reporting, but a decrease in the index may indicate femoral occlusion rather than restenosis of the iliac lesion. Little experience has been reported with a thigh/brachial index, which is a more logical criterion (33).

The most recent series in the literature is that of Tegtmeier et al (63), who reported on 340 procedures in 200 patients. Sixty-eight percent of the angioplasties were for claudication. There was an 80% 4-year patency rate (including initial failures) measured by improvement in clinical grade only, so these data are falsely high. The 60% 4-year patency for common iliac lesions found by Johnston et al (35) is probably falsely low because it includes an unknown number of femoral occlusions occurring at some time after the iliac angioplasty. Nevertheless, results of the only randomized trial of surgery showed no significant difference between the long-term results of iliac angioplasty and surgery, with a 73% 3-year patency rate (39).

Femoropopliteal Angioplasty

Whereas in the iliac system stenoses predominate, in the femoropopliteal system occlusions predominate by a factor of at least three. Furthermore, most oc-

clusions are long, so the majority of lesions are not suitable for angioplasty (64). Nevertheless, considerable data have been accumulated about angioplasty in the femoropopliteal system. Capek et al (36) reported a follow-up of a mean of 7 years on 217 patients having femoropopliteal angioplasty. The majority had the procedure between 1979 and 1980. They were followed up noninvasively, but 78 patients had follow-up angiograms. Because the procedures were done some time ago, failure to cross the lesion occurred in 7% of the stenoses and 18% of the occlusions. More recent series suggest that this rate could be improved, and in 1989 Morgenstern et al (65) reported a 91% primary success rate in complete occlusions. Excluding these initial failures, the 1-, 3- and 5-year patency rates in the series reported by Capek et al were 81%, 61%, and 58%. The statistically significant factors negatively influencing the success rate were diabetes and threatened limb loss. Occlusions were treated as successfully as stenoses, but treatment of short occlusions (less than 2 cm in length) was better than longer occlusions of 10 cm or more. Specific cutoff points were not identified, but lesions of more than 10 cm clearly have unsatisfactory long-term patency. In the femoropopliteal system, Capek et al (36) convincingly showed that after 1 year the patency rates are essentially linear until 10 years, indicating the durability of the procedure. Furthermore, each subsequent angioplasty has the same prognosis as the initial procedure.

The most significant factor negatively affecting stenotic disease is long-segment stenosis (greater than 7 cm). Although these lesions are technically easy to dilate, the 6-month patency rate is only 23% (66).

The data of Capek et al (36) are fairly consistent with an analysis of 984 consecutive angioplasties by Johnston et al (35), who reported that patients with claudication had a 20% greater patency rate at 5 years than patients treated for limb salvage. The patency rate of femoropopliteal disease at 5 years was 40%, with 11% of the procedures being technically unsuccessful. However, the primary failure rate in occlusions was 26%, compared with 8% in stenoses, and the primary failure rate accounts for the 20% difference between stenoses and occlusions. A 20% difference at 5 years was also seen between patients with good runoff and poor runoff.

In a randomized Veterans Administration trial comparing angioplasty with surgery there were 98 patients with fem-

oropopliteal disease (39). At 3 years the patency rate for patients who had undergone angioplasty was 59%, not significantly different from that in patients who had undergone surgery. These data compared with the meta-analysis by Adar et al (37), who found a 5-year patency of 60%, while the literature review by Becker et al (38) of 4304 femoropopliteal artery angioplasties revealed a 67% 2-year patency. The majority of these lesions were stenoses. These studies are in accordance with the majority of series in the literature (50–56,67–73).

Tibial Angioplasty

In 1988 Schwarten and Cutcliff (74) reported on 146 below-knee angioplasties in 98 patients with a primary success rate of 97%. All had distal ischemia. Only 35 patients were followed up, but in this group there was a 2-year limb salvage rate of 83%. Ankle/brachial index rose from a mean of 0.25 to 0.62 as a result of the procedure, and after 2 years was a mean of 0.55.

With the very significant improvement in equipment, in good hands the complications of tibial angioplasty are few. It would appear that results are best when straight-line continuity of the vessel to the foot can be achieved (75); similarly, Capek et al (36) noted that in the femoropopliteal system the best predictor of success is a palpable pulse. There is therefore a tendency to include high tibial angioplasty in conjunction with femoral angioplasty to attempt to provide a palpable pulse in patients with that particular combination of lesions. Five years ago they would have undergone femoral angioplasty alone.

Restenosis

A patency rate of 70% indicates a significant rate of restenosis, even if progression of atherosclerotic disease, which usually occurs more than 1 year after angioplasty and is frequently known as late restenosis, is excluded (76). Acute closure immediately after angioplasty is usually caused by dissection, spasm, or embolism and frequently is complicated by thrombosis. It occurs in 1% to 4% of peripheral angioplasties (52,77). Spasm is now aggressively pretreated and treated, with calcium channel blockers and nitroglycerin, as is the thrombosis itself with heparin and thrombolytic agents like urokinase. Stents may well emerge as the best treatment for dissection, which is the major

cause of immediate postangioplasty closure (78). The other acute problem is elastic recoil, which usually results only in a poor angioplasty result with a significant gradient. It is seldom associated with acute thrombosis. Again, vascular stenting appears to be the treatment of choice.

Early restenosis, the most common type of restenosis (76), most frequently occurs from 1-2 months to 1 year after angioplasty and is an intimal proliferative response. It also occurs after vascular surgery and is not specific to angioplasty (79). Essed et al (80) first suggested that it was caused by exposure of the myocytes of the media to blood, and restenosis treated by atherectomy confirms the intimal fibroproliferation (76). Plaque disruption causes local platelet deposition with release of thromboxane A₂ and platelet-derived growth factor. The vessel endothelium also releases endothelin, which is a potent vasoconstrictor, endothelium growth factor, and fibroblast growth factor. This results in the migration and proliferation of the smooth muscle cells as well as fibrocellular tissue accumulation, which may completely occlude the vessel (81).

A recent study of the coronary circulation showed restenosis to be most frequent in saphenous vein bypass grafts rather than in the native coronary circulation. It was more prevalent in longer than in shorter lesions. Restenosis was lowest in the lesions with the largest postangioplasty diameter (82).

Drug regimens to modify restenosis have so far been unrewarding. Aspirin has no influence on the restenosis rate, and neither does coumadin (83). Omega-3 fatty acids may be of some benefit (84), but no long-term studies have been done. A trial of intracoronary prostacyclin showed no benefit (85).

Requisite Symptoms for Intervention Signs and Symptoms of Peripheral Vascular Disease

Chronic lower extremity ischemia has a broad spectrum of severity. The most widely used classification is that developed by Fontaine, which encompasses four stages of severity based on signs and symptoms (Table 2 [86]). Stages I and II in the Fontaine classification include ischemia only with exercise, while stages III and IV include ischemia at rest. Although not commonly used in the United States, this classification is widely used in other parts of the world and appears frequently in publications.

Table 2
Claudication-Fontaine Classification

Stage	Symptoms
I	Asymptomatic
II.	Intermittent claudication
II-a.	Pain-free, claudication walking >200m
II-b.	Pain-free, claudication walking <200m
III.	Rest/nocturnal pain
IV.	Necrosis/gangrene

Adapted from Reference 86.

Most patients with chronic ischemia of the lower extremity will have pain as the primary symptom. To establish a vascular etiology for this pain, it is essential to confirm the presence of arterial occlusive lesions and quantitate their hemodynamic and physiologic significance. Intermittent claudication is a clinical condition characterized by the appearance of symptoms in the muscles of the lower extremities during exercise, with prompt relief after cessation of exercise. The location of the exercise-induced discomfort, its relation to walking, and its duration and severity are usually constant in each patient. Worsening of symptoms in a patient with stable claudication is usually caused by occlusion of previously stenotic axial vessels or one of the major collaterals that circumvent an obstruction. Advanced ischemia (Fontaine stages III and IV) is characterized by pain at rest. This includes ischemic rest pain, characterized by burning or aching discomfort, or sometimes numbness confined to the toes and forefoot. Its onset is usually within a few hours of assumption of the recumbent position and is relieved by placement of the foot in a dependent position. This symptom must be distinguished from night cramps, which are quite common in elderly patients. Night cramps affect primarily the calf muscles (although they can affect the muscles of the foot as well), are probably not directly caused by circulatory impairment, and do not carry the same prognostic implications as does ischemic rest pain. Ulceration and gangrene are obviously manifestations of far-advanced arterial insufficiency. Whereas the patient who has just intermittent claudication has a generally favorable natural history for which any intervention can be considered elective, patients with ischemic rest

pain, ischemic skin lesions, or both are in a limb-threatening situation unless the circulatory status of the affected limb can be improved.

Almost all patients with intermittent claudication have diminished or absent lower extremity pulses, but occasionally patients may have a normal examination at rest with the diminished perfusion detectable only with exercise, either by physical examination or Doppler-measured ankle/brachial systolic blood pressure ratios. As disease severity progresses, physical findings of ischemia at rest develop before the onset of symptoms at rest. These physical findings include atrophy of the skin and dermal appendages manifested as loss of hair and atrophy of the subcutaneous tissue with shiny, tight, smooth skin stretched over the toes. Ridging of the toenails and slow or poor healing of breaks in the skin are other manifestations of this stage of ischemia. Finally, as noted above, the development of ischemic ulcers or gangrene marks the end stages of circulatory impairment.

In most patients, the diagnosis of intermittent claudication or ischemic rest pain can be established by a thorough clinical history and physical examination. These will usually allow determination of the approximate location and the hemodynamic significance of various obstructive lesions. Modern noninvasive, physiologic testing can then be used to confirm the presence of arterial insufficiency, quantify its severity, document the location and hemodynamic importance of individual arterial lesions, and provide an objective means of follow-up and monitoring of treatment.

Clinical Indications for Revascularization

For patients truly incapacitated by their exercise limitation, be it for recreational, vocational, or personal reasons, invasive intervention is appropriate. This also applies to patients with limb-threatening ischemia. A balance must obviously be maintained between the risks of the various interventions and the risks of the natural history of the disease if left untreated. The recent introduction of percutaneous treatments, including balloon angioplasty, atherectomy, and stents, has expanded the scope of physicians treating patients with peripheral vascular disease. These interventional techniques have been promoted as safe, cost-effective, reliable, and durable alter-

natives to conventional vascular surgical procedures, and they have been offered to many patients with milder degrees of ischemia that would not meet conventional criteria for surgical intervention. Unfortunately, there have been few properly performed prospective, randomized, clinical trials to substantiate these claims.

When the degree of ischemia is limb-threatening (there is ulceration, rest pain, or gangrene), the natural history is one of progressive deterioration, and the only treatment alternatives are revascularization or amputation. Nearly all patients in this situation are candidates for attempted lower extremity revascularization, and in most series account for more than 70% of patients operated on. There is relatively little controversy about the decision to intervene in this group of patients. On the other hand, patients who only have ischemia with exercise, ie, intermittent claudication, have a much more favorable prognosis, and intervention has not been traditionally considered by vascular surgeons until the symptoms become truly incapacitating. This long-standing tradition of interventional conservatism is based on the perceived favorable natural history of this condition as reported in prospective studies more than 30 years old as well as in the Framingham study of 1970. These studies show that only 7% to 10% of patients with intermittent claudication will progress to a degree of ischemia requiring amputation over a 5-year follow-up (87-90). However, more contemporary data suggest that the natural history may not be so favorable. McDaniel and Cronenwett (91) reviewed 6 studies involving 2307 patients with an average follow-up of 4.4 years. The conditions of only 50% improved or became stable and of 14% worsened; 30% of the patients required operations for rest pain or tissue loss, and 6% ultimately underwent amputation.

Percutaneous transluminal angioplasty has been the endovascular procedure most widely used for treating occlusive arterial lesions. For most lesions, the published data on the procedure are not comparable to contemporary results of conventional surgical procedures (exceptions being short, focal lesions affecting the common iliac and superficial femoral arteries). Endovascular treatment of these lesions might be appropriate earlier in the course of a patient's disease than would conventional surgical procedures. The relative risks and benefits of the various treatment modal-

ities are discussed in detail later in this report.

Role of Conservative Treatment and Risk Factor Reduction

Nonoperative treatment is appropriate for most patients with non-limb-threatening chronic lower extremity ischemia (stages I and II). Symptomatic lower extremity atherosclerotic occlusive disease is a marker of a similar disease process affecting other vascular beds, particularly the extracranial carotid and coronary circulations. Therefore, assessment of these areas may be appropriate as an adjunct to cessation of smoking, exercise, and pharmacologic agents (92).

The adverse effects of cigarette smoking are well known, and smoking clearly has been shown to be an important risk factor for both the development and progression of peripheral vascular disease. There is abundant evidence that cessation of smoking leads to improvement of the symptoms of intermittent claudication, which can be expected in 85% of patients, and improvement in walking distance can be as much as 200% to 300% (92-95). There is also evidence that continuation of smoking after reconstructive arterial surgery results in a statistically significant increased incidence of reconstruction failure (96). Most patients experience great difficulty in discontinuing the use of cigarettes. Nicotine-containing chewing gum and transdermal patches are probably helpful, but the importance of the physician's role and the supplemental use of counseling and group therapy must be emphasized. Cessation of tobacco use is the single most important factor in the nonoperative management of patients with intermittent claudication.

The second most important nonoperative treatment factor is exercise. The beneficial effects of exercise in patients with intermittent claudication have long been known. In addition, regular physical training has potentially beneficial effects on other cardiovascular risk factors, neuromuscular function, and joint mobility, particularly in elderly patients. Data from controlled studies strongly suggest that supervised active leg exercise programs are associated with improvement in pain-free and maximum walking distance (97-100). The most successful programs combine regular, supervised group sessions with daily home activities. The prescribed exercises must be safe, simple, and convenient, and are most successful when they are

combined with comprehensive objectives, regular supervision, and outcome evaluation.

Many pharmacologic agents have been used for the treatment of intermittent claudication, including vasodilators, antiplatelet agents, hemorheologic agents, and metabolic enhancers. Although a large number of vasodilators have been used, none have proven to be of benefit in patients with chronic lower limb ischemia, and none are currently approved for this condition by the Food and Drug Administration. Several, in fact, have been withdrawn from the market. Antiplatelet aggregating agents may be helpful in the prevention of atherosclerotic progression and are widely used, particularly for their effects on the coronary and cerebral circulations. Their effects on the progression of lower extremity lesions are not known. Pentoxifylline, a methylxanthine derivative, is the only hemorheologically active agent currently approved by the FDA for treatment of intermittent claudication. Several randomized prospective clinical trials have reported statistically significant improvement in walking distance when this drug is administered, and improvement can be expected in about 25% to 50% of patients with mild to moderate symptoms (101). Unfortunately, there is a poor correlation between response to treatment and improvement in blood rheologic parameters, and 6 to 8 weeks of treatment may be required before beneficial effects are seen.

Drugs that increase the metabolic efficiency of ischemic skeletal muscle are not yet available in the United States but are being extensively tested in Europe. These include naftidrofuryl (Praxilene) and carnitine (102). The early results have been promising, but the results of additional randomized prospective clinical trials in North America will be needed to determine whether these agents will have a role in the management of intermittent claudication.

Modification of other risk factors may be necessary. Diabetes mellitus, hyperlipidemia, and hypertension are the most frequent disorders associated with peripheral vascular occlusive disease. Several reports have shown a strong association between elevated plasma homocystine concentration and peripheral arterial occlusive disease (103). Because this is a genetic disorder, this diagnosis may be worth considering in patients under the age of 50 who have intermittent claudication (104).

Pretreatment Noninvasive Vascular Laboratory Assessment

Although the clinical history and physical examination are key elements in the evaluation of patients with chronic lower extremity ischemia, physiologic testing with modern noninvasive techniques has become an essential component of the pretreatment evaluation and post-treatment follow-up. Several techniques have been used for this purpose, including plethysmography (volume flow, pulse volume recordings) and Doppler ultrasound techniques. The simplest and most widely used is the determination of the ankle/brachial systolic blood pressure index, which serves as an excellent indicator of the overall arterial supply of an extremity. Multiple pneumatic cuffs are used on the extremity to determine arterial pressure in different segments of the limb. The Doppler analog waveform can also be analyzed in a qualitative fashion, and all of these studies can be combined with treadmill exercise testing. These exercise tests are particularly useful in symptomatic patients who have normal or near normal ankle/brachial index values at rest as well as in patients with other conditions associated with chronic, exercise-related, lower extremity discomfort. Duplex ultrasound has recently been used in the evaluation of the aorto-iliofemoral vessels and may become more important for this purpose in the future. Proper interpretation of the results of any of the noninvasive physiologic tests depends on in-depth knowledge of vascular disease in general as well as of the individual patient. Each of the different techniques has its own advantages, disadvantages, and limitations, and the physician using these modalities must be aware of them. Standards for Evaluating and Reporting Peripheral Angioplasty

An arterial stenosis or occlusion is significant when physiologic alterations result in immediate or potentially long-term adverse consequences. Therefore, documentation must be obtained that (1) substantiates the physiologic and clinical abnormality, (2) enables comparison to determine procedural and clinical success, and (3) provides a database that allows assessment of long-term patency, clinical success, or lesion recurrence.

A vascular obstruction (stenosis or occlusion) that diminishes arterial blood flow sufficiently to alter function may be manifested as exercise-induced limb claudication, basilar artery insufficiency (ie, subclavian steal syndrome), renovascular hypertension or renal ischemic at-

Table 3
Clinical Categories of Acute Limb Ischemia

Category	Description	Capillary Return	Muscle Weakness	Sensory Loss	Doppler Signals	
					Arterial	Venous
Viable	Not immediately threatened	Intact	None	None	Audible (AP > 30 mm Hg)	Audible
Threatened	Salvageable if promptly treated	Intact, slow	Mild, partial	Mild, incomplete	Inaudible	Audible
Irreversible	Major tissue loss, amputation regardless of treatment	Absent (marbling)	Profound, paralysis (rigor)	Profound, anesthetic	Inaudible	Inaudible

AP indicates ankle pressure.

rophy, or ischemic tissue injury (eg, ulcers or nonhealing wound).

The documentation of a significant lesion may include visualization and hemodynamic determinations including arteriography, translesion pressure gradients, ankle/brachial index, pulsed volume recordings, and duplex scanning. There may be a physiologic response to ischemia, including claudication or physical signs of tissue damage such as hair loss, skin atrophy, or ulceration. Determination of other parameters such as isotopic muscle imaging and transcutaneous pO₂ may be of value, particularly when compared serially with baseline studies.

Standards for reporting results are particularly important in the evaluation of percutaneous interventions to ensure that results of different therapies (ie, surgical and interventional) can be compared. Such standards have recently been proposed and published (32–34). Although such recommendations may seem arbitrary and be unpopular, compliance is critical for meaningful analysis of utilization data, quality of care, and the scientific literature.

Definitions and Classification Criteria (Table 3)

1. Viable: Limb not immediately threatened; no ischemic pain, no neurologic deficit, skin capillary circulation adequate; clearly audible Doppler flow signal in pedal arteries or ankle pressure greater than 30 mm Hg.
2. Threatened viability: Implies reversible ischemia and a limb salvageable without major amputation if arterial obstruction promptly relieved; ischemic pain

and/or mild and incomplete neurological deficit present (eg, sensory loss involving only vibration, touch position, or weakness of toe/foot dorsiflexion); "pulsatile flow" in pedal arteries not audible with Doppler instrument, but venous patency demonstrable.

3. Major, irreversible ischemic change: Will require major amputation regardless of therapy; profound sensory loss and muscle paralysis, absent capillary skin flow or evidence of more advanced ischemia (eg, muscle rigor or skin marbling); neither arterial nor venous flow signals audible distally.

The Fontaine classification has been further modified and subdivided to permit more accurate classification (32–34). Henceforth, patients with chronic extremity ischemia should be categorized according to **Table 4**.

Modification of certain criteria is necessary to permit comparison of endovascular techniques (33,34,105). For example, whether obstruction of the superficial femoral artery is due to stenosis or a long occlusion may be irrelevant to the vascular surgeon, but such a distinction is very important to the interventionalist. Thus, arterial lesions should be described by location and type (eccentric or concentric, calcified or noncalcified, focal or diffuse). The length of lesions should be quantified (<2 cm, 2 to 5 cm, 5 to 10 cm, >10 cm) and the status of runoff vessels defined (number of adequately patent vessels, minus those with <50% stenosis, minus the number of runoff vessels).

Criteria for improvement after percutaneous interventions are different for

early and late success. Early success should be judged on a combination of clinical, hemodynamic, and angiographic factors, with improvement in all three for the procedure to be considered successful. Clinical improvement should include symptomatic improvement and change of at least one category in **Table 5**.

Hemodynamic improvement should be defined as an increase in ankle/brachial index of 0.10. For diabetic patients with incompressible vessels, pulse volume recording distal to revascularization of 5 mm above preprocedure testing should be documented. Finally, angiographic success should result in less than 30% residual stenosis. Changes in the condition of the affected extremity should be categorized on a scale of +3 to –3 as described in **Table 5**.

OUTCOME CRITERIA

Criteria for Significant Change in Status (Improvement, Deterioration, or Failure)

Patency is the ultimate criterion of success when results of arterial reconstruction are reported, because it is a discrete and comparable end point. However, patency does not necessarily mean success (eg, patient is not relieved of claudication, rest pain, or the need for major amputation, although the graft is clearly patent). This may be termed a "hemodynamic failure." At the other extreme, a bypass graft, performed for limb salvage, may occlude but the limb may no longer be threatened. How often such cases are the result of loosely defined indications and how often they represent true salvage because of time gained for collateral development or suf-

Table 4
Clinical Categories of Chronic Limb Ischemia

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic—not hemodynamically significant	Normal treadmill/stress test
I	1	Mild claudication	Completes treadmill exercise,* AP after exercise <50 mm Hg but >25 mm Hg less than BP.
	2	Moderate claudication	Between categories 1 and 3.
	3	Severe claudication	Cannot complete treadmill exercise and AP after exercise <50 mm Hg.
II	4	Ischemic rest pain	Resting AP <40 mm Hg, flat or barely pulsatile ankle or metatarsal PVR; TP <30 mm Hg.
	5	Minor tissue loss—nonhealing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP <60 mm Hg, ankle metatarsal PVR flat or barely pulsatile; TP <40 mm Hg.
III	6	Major tissue loss—extending above TM level, functional foot no longer salvageable	Same as category 5.

AP indicates ankle pressure; BP, blood pressure; PVR, pulse volume recording; TP, toe pressure; TM, transmetatarsal.

* Five minutes at 2 mph on a 12% incline.

efficient improvement in circulation to allow healing remain grounds for debate. Clear definitions of patency, foot salvage, or significant improvement are needed to serve as ultimate measures of success, and reporting the rates of other criteria in addition to patency will provide greater perspective and better grounds for comparison.

For reporting purposes, the designation “significantly improved” ordinarily requires an improvement by at least one clinical category, but patients with actual tissue loss (those in category 5) must improve by at least two categories and reach a level of claudication to be considered improved. In addition, some objective criteria of improvement should be included (eg, a change in the ankle/brachial index of more than 0.10).

Classification of Peripheral Vascular Disease: Selection Criteria for Percutaneous Therapy

When a patient meets the clinical criteria for therapy, a choice must be made between traditional surgical procedures or percutaneous revascularization. The choice is based primarily on the angiographic findings, but a number of factors must be considered. These include the severity of the symptoms, the durability and risks of each therapeutic alternative, the skills of the various specialists involved, and the patient’s preferences. In addition, when considering the durability of the alternatives it must be remembered that there will usually be an opportunity to repeat angioplasty if restenosis occurs, with prolongation of clinical benefit at moderate additional

Table 5
Clinical Improvement After Percutaneous Interventions

Grade	Clinical Description
+3	Markedly improved: symptoms gone or markedly improved; ankle/brachial index increased to more than 0.90.
+2	Moderately improved: still symptomatic, but at least single category improvement; ankle/brachial index increased by more than 0.10 but not normalized.
+1	Minimally improved: greater than 0.10 increase in ankle/brachial index but no categorical improvement, or vice versa (ie, upward categorical shift without an increase in ankle/brachial index of more than 0.10).
0	No change: no categorical shift and less than 0.10 change in ankle/brachial index
-1	Mildly worse: no categorical shift but ankle/brachial index decreased more than 0.10, or downward categorical shift with ankle/brachial index decreases less than 0.10.
-2	Moderately worse: one category worse or unexpected minor amputation.
-3	Markedly worse: more than one category worse or unexpected major amputation.

cost and morbidity. Furthermore, the morbidity associated with the reocclusion of a percutaneously treated lesion compared with a surgical bypass must be weighed. Therefore, the relative merits of percutaneous and conventional surgical therapies must be evaluated with the total cost, length of hospitalization, lost time, and morbidity considered. All these factors make the development of a rigid classification based on angiographic criteria alone unworkable.

Using the results of published studies is the obvious method for developing guidelines. However, use of the literature as the final arbiter only confounds this process. There has been only one

large randomized prospective trial comparing balloon angioplasty with surgical therapy (39). The results of most trials are not strictly comparable because of the variability in study design, criteria for patient selection, clinical success, patency, and follow-up, so there is a broad range of reported success rates. In addition, most published series come from centers that have special expertise in the procedure reported, and the results may not be achievable in the community at large.

Therefore, to define criteria, data from the literature were used as a guide for the development of a consensus among the committee members as to the

most appropriate therapy. A similar set of previously published guidelines (106) has been modified for this article. For each vascular distribution, the angiographic extent of disease was divided into one of four categories. The categories, defined below, are written to allow leeway for judgment. It is important to remember that this is only a set of guidelines. In any individual patient, alternative management may be valid for sound clinical reasons. In addition, certain surgical or percutaneous procedures require the physician to be highly trained or unusually skilled in the specific technique. Practitioners are cautioned to recognize the level of skill and experience they possess and to weigh the appropriateness of therapy in that light. Finally, these guidelines are intended to define in a general way the current procedures of choice and should not be used to discourage innovation or new developments in properly controlled clinical research protocols. They will be reviewed and updated periodically as knowledge of the therapy of vascular disease advances.

Definition of Categories

Category 1.—Lesions for which percutaneous transluminal angioplasty alone is the procedure of choice. Treatment of these lesions will result in a high technical success rate and will generally result in complete relief of symptoms or normalization of pressure gradients.

Category 2.—Lesions that are well suited for percutaneous transluminal angioplasty. Treatment of these lesions will result in complete relief or significant improvement in symptoms, pulses, or pressure gradients. This category includes lesions that will be treated by procedures to be followed by surgical bypass to treat multilevel vascular disease.

Category 3.—Lesions that may be treated with percutaneous therapy, but because of disease extent, location, or severity have a significantly lower chance of initial technical success or long-term benefit than if treated with surgical bypass. However, percutaneous transluminal angioplasty may be performed, generally because of patient risk factors or because of lack of suitable bypass material.

Category 4.—Extensive vascular disease, for which percutaneous therapy has a very limited role because of low technical success rate or poor long-term benefit. In very-high-risk patients, or in

those for whom no surgical procedure is applicable, percutaneous transluminal angioplasty may have some place.

Aortic Angioplasty

Focal aortic stenosis is an unusual manifestation of atherosclerosis, and as a result the number of reported cases treated with balloon angioplasty is small. Early case reports and small series established the feasibility of percutaneous treatment (42–46,107), and two recent larger series (49,108) support the use of angioplasty in focal stenotic disease of the abdominal aorta. Technical success is greater than 90% and patency rate appears acceptable, although long-term follow-up is still very limited. Patients with focal severe stenosis of the infrarenal aorta with an otherwise minimally diseased vessel have the best clinical results. Treatment of patients with severe diffuse atherosclerotic disease of the aorta is not advocated. The dilation of stenoses more than 4 cm in length has been reported in small numbers of patients (49), and although the initial results have been encouraging, the data supporting the percutaneous treatment of long segment aortic stenosis are insufficient to recommend it categorically. Treatment of patients with atheroembolic symptoms has also been successful, but a reported death associated with this procedure dictates caution in this group of patients (108).

Category 1.—Short segment stenosis of the infrarenal abdominal aorta (less than 2 cm) with minimal atherosclerotic disease of the aorta otherwise.

Category 2.—Medium-length stenosis of the infrarenal abdominal aorta (2 to 4 cm) with mild atherosclerotic disease of the aorta otherwise.

Category 3.—(1) Long segment (>4 cm) stenosis of the infrarenal abdominal aorta; (2) aortic stenosis with atheroembolic disease (blue toe syndrome); or (3) medium-length stenosis of the infrarenal abdominal aorta (2 to 4 cm) with moderate to severe atherosclerosis of the aorta otherwise.

Category 4.—(1) Aortic occlusion or (2) aortic stenosis associated with an abdominal aortic aneurysm.

Iliac Angioplasty

Percutaneous transluminal angioplasty has proved to be an effective technique for treatment of symptomatic atherosclerotic disease in the iliac arteries, with a success rate of 95% and 5-year patency of 80% to 90% reported for short

segment stenosis (35,51,52,57,58,63,109,110).

These results approach those of surgical bypass procedures (111,112). The success of iliac angioplasty is related to many factors, including lesion length, presence of occlusion or stenosis, adequacy of distal runoff, and the presence of diabetes (112–114). In general, the best results are obtained with limited stenotic lesions with patent runoff vessels and in nondiabetic patients. Control of other cardiovascular risk factors has an uncertain effect on iliac patency. An overall technical success of 95% can be anticipated with proper selection for category 1 or 2 stenoses. Five-year patency is 80% to 85% for ideal short segment lesions, with patency decreasing to approximately 65% to 75% for stenoses in category 3 (35,51,57,63,109). Although longer lesions can be successfully dilated, the long-term patency is lower, and surgical treatment would be preferred in patients with low surgical risk.

Total occlusion of an iliac artery has been considered a contraindication to percutaneous transluminal angioplasty because of the risk of distal embolus or contralateral embolization by dislodgment of atheromatous material or clot (115). In addition, angioplasty of occlusions has generally had a much poorer outcome (116). Although recent reports of percutaneous therapy are more optimistic (117,118), they have failed to place sufficient emphasis on the role of thrombolytic therapy prior to balloon angioplasty. Before percutaneous therapy is attempted on total iliac occlusions, a trial of intra-arterial thrombolytic therapy should be done. The conversion of an occlusion to a stenosis by the preliminary use of a thrombolytic agent should improve results while reducing the risk of distal embolization. The lesions discussed below are categorized based on their appearance after thrombolytic therapy. Recent studies have defined a subgroup of patients with unilateral "blue toe syndrome" and hemodynamically significant stenosis, in whom percutaneous therapy has been beneficial (119,120). At present, the experience with percutaneous treatment of such atheroemboli or blue toe syndrome is small and the role of angioplasty not completely defined. Although the presence of dense calcification increases the difficulty of angioplasty, with newer balloon technology these lesions can be successfully dilated. Because of the increased risk of arterial rupture, aneurysms adjacent to stenosis are best treated surgically.

Category 1.—Stenosis is less than 3 cm in length and concentric and non-calcified.

Category 2.—(1) Stenosis is 3 to 5 cm in length or (2) calcified or eccentric and less than 3 cm in length.

Category 3.—(1) Stenosis is 5 to 10 cm in length or (2) occlusion is less than 5 cm in length after thrombolytic therapy with chronic symptoms.

Category 4.—(1) Stenosis is greater than 10 cm in length, (2) occlusion is greater than 5 cm in length, after thrombolytic therapy and with chronic symptoms, (3) there is extensive bilateral aortoiliac atherosclerotic disease, or (4) the lesion is an iliac stenosis in a patient with abdominal aortic aneurysm or another lesion requiring aortic or iliac surgery.

Femoropopliteal Angioplasty

After more than 15 years of experience with angioplasty in the femoropopliteal segment, a number of factors that directly affect the success of the procedure have been identified. Short lesion length, minimal vascular disease elsewhere, claudication as the presenting symptom, stenosis rather than occlusion, and absence of diabetes all correlate with improved patency. Treatment of lesions less than 5 cm in length has better results than that of lesions more than 10 cm long. Significant residual stenosis after angioplasty correlates with a poor long-term outcome (36). The presence of patent runoff vessels correlates with long-term benefit, reflected in the improved outcome in patients with milder symptoms (35,36,113). Surgery is indicated for long segment occlusions (greater than 10 cm) and for patients with severe diffuse disease for which dilation of very long segments of vessel would be required. Angioplasty has a limited but definite role in patients with advanced disease, either in combination with vascular reconstruction or when surgery is not possible (122,123).

During the past decade there have been consistent advances in both the surgical and percutaneous management of femoropopliteal disease. The recent development of devices for the percutaneous treatment of femoropopliteal disease holds promise for improvement in the technical success and patency rates. However, until longer follow-up is available for results of many of the newer devices, therapeutic decisions will continue to rely on the extensive data available on balloon angioplasty and surgical revascularization. Meanwhile, improve-

ments in the technique of femoropopliteal bypass have resulted in a 5-year patency of 80% in the best-reported series (124). However, whether this level of success can be matched in the community seems doubtful (125), and an average patency of vein graft bypasses is probably closer to 60% to 70% at 5 years. In addition, failure of a femoropopliteal graft has graver consequences than restenosis of an angioplasty site (126). Therefore, it appears that surgery and angioplasty have a complementary role, with percutaneous treatment for patients with less severe disease and those who are poor candidates for surgery, and surgery for more advanced disease in patients who are candidates for surgery.

Category 1.—(1) Single stenosis up to 5 cm in length that is not at the superficial femoral origin or distal portion of the popliteal artery, or (2) single occlusion up to 3 cm in length not involving the superficial femoral origin or distal portion of the popliteal artery.

Category 2.—(1) Single stenosis 5 to 10 cm in length, not involving the distal popliteal artery, (2) single occlusion 3 to 10 cm in length, not involving the distal popliteal artery, (3) heavily calcified stenosis up to 5 cm, (4) multiple lesions, each less than 3 cm, either stenoses or occlusions, or (5) single or multiple lesions where there is no continuous tibial runoff to improve inflow for distal surgical bypass.

Category 3.—(1) Single occlusion 3 to 10 cm in length, involving the distal popliteal artery, (2) multiple focal lesions, each 3 to 5 cm (may be heavily calcified), or (3) single lesion, either stenosis or occlusion, with a length of more than 10 cm.

Category 4.—(1) Complete common and/or superficial femoral occlusions, (2) complete popliteal and proximal trifurcation occlusions, or (3) severe diffuse disease with multiple lesions and no intervening normal vascular segments.

Infrapopliteal Angioplasty

Early experience with transluminal angioplasty of the infrapopliteal vessels met with limited success because of limitations in available catheter technology (69,126,127). Recent advances in catheter and guidewire design have allowed safe and efficacious application of angioplasty techniques in the anterior tibial, posterior tibial, and peroneal arteries (74,75,128,129). However, the risks are somewhat greater in these vessels than in the larger, more proximal arteries. The

indications for intervention in these vessels are more limited than those previously discussed, and should be applied judiciously (75). In addition, the greatest benefit occurs when the disease is localized, with restoration of straight-line flow to the foot. Because of the advanced multilevel disease frequently present, the most common symptoms are ischemic rest pain, ischemic ulceration, or gangrene. Generally, infrapopliteal angioplasty is only indicated when these symptoms are severe. However, severe claudication that prevents minimal ambulation may be an acceptable indication, particularly if a vessel at a higher level is to be treated (129). Mild to moderate claudication is not an indication for treatment of these vessels, both because treatment at other levels generally relieves the symptoms and because the risk of occlusion is unacceptably high for treatment of this condition.

Category 1.—Single focal stenosis, 1 cm or less, of tibial or peroneal vessels.

Category 2.—(1) Multiple focal stenoses, each 1 cm or less, of tibial or peroneal vessels, (2) one or two focal stenoses, 1 cm or less, of tibial trifurcation, or (3) tibial or peroneal stenosis dilated in combination with femoral popliteal bypass.

Category 3.—(1) Moderate-length stenosis (1 to 4 cm) or moderate-length (1 to 2 cm) occlusion of tibial or peroneal vessel or (2) extensive stenosis of tibial trifurcation.

Category 4.—(1) Tibial or peroneal occlusions longer than 2 cm or (2) diffusely diseased tibial or peroneal vessels.

Angioplasty of Bypass Grafts

Balloon angioplasty has been advocated as a safe and effective means of treating many stenoses that develop in or near bypass grafts (130–137). Although there is variable long-term patency based on the underlying pathology, dilation can sometimes extend the life of grafts for years. However, two recent studies have cast some doubt on the long-term results of balloon dilation (137,138). Early recurrence has been frequently noted and one recent study reported an 18% 5-year patency rate (138). In this study there were improved results in grafts that required only one dilation. A subset of patients have acute graft occlusion, and after treatment with a thrombolytic agent the underlying stenosis is discovered. Graft patency of lesions treated with balloon angioplasty after thrombolytic therapy has been

poorer than those discovered and treated prior to thrombosis (138). Although surgical revision may have better long-term results, percutaneous therapy may provide a less expensive and durable result in some patients. The pathology of these stenoses may vary to some degree, but myointimal hyperplasia is the most common cause. This may occur within the graft or at the anastomosis. In 77% of cases the stenosis occurs within the first year. Hypertrophy of a venous valve can also cause stenosis and usually occurs in the first year. Graft failure or occlusion within the first week after surgery usually indicates a technical problem and should be treated with reoperation. Graft failure after the first year may be due to either myointimal hyperplasia or progression of atherosclerosis, either above or below the bypassed segment.

Atherosclerotic lesions within native vessels above or below the bypass are not discussed here and the type of therapy should be chosen using the categories from the appropriate vascular distribution. The lesions categorized below are assumed to have developed after the perioperative period.

Category 1.—Focal stenosis of the distal anastomosis of a femoral popliteal or femoral-tibial vein bypass.

Category 2.—(1) Focal stenosis of the proximal anastomosis of a saphenous vein femoral-popliteal or femoral-tibial bypass, (2) short-segment (up to 3 cm) stenosis occurring within vein bypasses, (3) stenosis associated with aortobifemoral or aortobiliac bypasses, or (4) stenosis associated with prosthetic extra-anatomic bypasses.

Category 3.—Moderate-length stenosis (more than 3 cm) of venous bypass grafts.

Category 4.—(1) Long-segment stenosis (more than 10 cm) in vein bypass grafts or (2) stenosis associated with anastomotic aneurysms.

Patient Care Standard During Percutaneous Transluminal Angioplasty

Percutaneous transluminal angioplasty and other methods of percutaneous revascularization have become established as effective therapies for some patients with peripheral occlusive disease. Extensive literature now documents the safety and efficacy of this procedure in the management of atherosclerotic and other vascular diseases.* As with any invasive therapy, the patient will most likely benefit when appropriate selection criteria, preprocedure and

postprocedure care, and monitoring are used. In this section guidelines are presented for the care of patients undergoing angioplasty of the peripheral vessels. In all cases, the type of care provided should be directed by the operating physician, and treatment decisions should be made after individual consideration of each case. Variation from this standard may be necessary and appropriate, depending on the specific clinical circumstances.

Patient Selection Considerations

The indications for angioplasty have been outlined earlier in this article and in previous reports; a patient should meet the appropriate criteria for clinical symptoms and angiographic findings (106). These should be documented as follows:

A written medical history should be available, including a history of the presenting symptoms, indications for the procedure, pertinent medical and surgical history, a list of current medications, allergic history, and vascular risk factors.

Physical examination should have been performed, including a detailed vascular examination and a general examination of sufficient depth to exclude significant concurrent illnesses. For patients with lower extremity vascular disease, ankle/brachial index should be measured prior to arteriography. In some patients, measurement of segmental pressures or pulse volume recordings may help define the level of disease and assist in planning the angiographic approach.

Complete diagnostic arteriography should precede any vascular intervention. This study should be permanently recorded and should be of sufficient detail to fully characterize the extent of vascular disease that might contribute to the symptomatology. This study may immediately precede intervention when appropriate.

Informed consent must be obtained in all cases.

Laboratory evaluation may be indicated: this may include determination of hemoglobin, hematocrit, creatinine, electrolytes, and coagulation parameters.

Alternative therapies, including surgical revascularization, should be discussed with the patient and referring physician. Vascular surgical consultation is often helpful in clarifying alternate approaches. All interventions should be done in a setting that will allow prompt surgical intervention in

emergencies; ideally this setting would be an acute care hospital.

Procedural Care

All patients should have cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.

All patients should have intravenous access for the administration of fluids and medications as needed.

If the patient is to undergo conscious sedation, pulse oximetry should be used and a registered nurse or other appropriately trained person, whose primary responsibility is to monitor the patient, should be present.

In certain circumstances, intra-arterial pressure measurements are very helpful in the preprocedure and postprocedure assessments, and their use is encouraged when indicated.

In all cases, postprocedure arteriography should be performed and permanently recorded to document the anatomic result and to identify potential complications.

Equipment and medications for emergency resuscitation should be immediately available and the personnel present should be trained in their use.

Postprocedure Care

All patients should be observed while in bed rest in the initial postprocedure period. Depending on the size of the arteriotomy and risk factors (see below), bed rest may be required for up to 24 hours.

During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the vascular distribution distal to the puncture and angioplasty sites.

Hemodynamic monitoring is required to detect late rupture and hemorrhage in all patients undergoing angioplasty.

The patient should be monitored for urinary output, cardiac symptoms, pain, and other indicators of systemic complications. This may include laboratory evaluation of renal function at 24 to 48 hours.

The initial ambulation of the patient must be supervised. Vascular perfusion, mobility, puncture site stability, and independent function must be ensured.

When the treatment or vascular access requires manipulation in the thoracic aorta or brachiocephalic vessels,

neurological status should be assessed periodically.

The operating physician or a designate should evaluate the patient after the procedure and be available for continuing care during hospitalization and after discharge.

The patient should be counseled about reduction of risk factors, in particular smoking cessation, blood pressure control, proper diet, weight loss, and exercise. These changes should be integrated into the overall treatment of the patient by the primary care physician.

Selection Criteria for Short-Term Observation

The duration of postprocedure observation must be decided on an individual basis. Many patients may be candidates for short-term observation (less than 12 hours), while others require overnight care in a hospital. Short-term observation should only be considered when all of the following conditions can be met:

Patients should be capable of independent ambulation before the procedure and of stable independent ambulation after the procedure.

Mental status should be intact, with the patient capable of following instructions and of detecting changes in symptoms.

A responsible adult must be present during the first night after discharge.

The patient should be free of concurrent unstable serious medical illness that might contribute to a significantly increased risk of complication.

The patient must have recovered from the effects of the sedation.

Travel time to the hospital or to another acute care facility should be less than 1 hour from where the patient is to spend the first night after the procedure.

Relative Contraindications for Short-Term Observation

Several factors must be considered when determining the length of postprocedure skilled nursing care. Short-term observation is generally contraindicated for the patients listed below. This list is not meant to be comprehensive, and any clinical circumstance that might predispose the patient to significant complications should prompt overnight admission.

Patients with poorly controlled hypertension, in whom there appears to be increased risk of hematoma formation, should be observed overnight.

Azotemic patients with significant

risk of contrast-induced renal injury may benefit from periprocedure intravenous hydration and should be monitored overnight.

Patients with coagulopathies or electrolyte abnormalities that require correction should be hospitalized until stable.

Patients with insulin-dependent diabetes who have labile serum glucose levels in the periprocedure period should be hospitalized until stable.

Complications occurring during or after angioplasty, including large hematoma, anuria, and persistent nausea and vomiting, should prompt observation until symptoms resolve.

The decision for short-term or longer-term postprocedure observation must be made on an individual basis, and a patient's care may vary from the above criteria for sound clinical reasons. The decision in each case must be made by the operating physician after review of all pertinent data.

Quality Improvement

All angioplasty procedures should be monitored as part of the overall quality improvement program of the facility. Incidence of complications and unexpected admissions should be recorded and periodically reviewed for the opportunity to improve care. To protect the confidentiality of the peer review data, this data should be collected in a manner that complies with statutory and regulatory peer review procedures.

Complications of Peripheral Transluminal Angioplasty

Because angioplasty for peripheral vascular disease does not generally have a more durable result than surgical revascularization, its use is justified only by its reduced risk and cost, combined with a reasonable likelihood of success. It is therefore essential for those performing angioplasty to have a thorough understanding of the hazards associated with the procedure, including the incidence and causes of complications and the steps that should be taken to minimize the consequences when a complication occurs. It is important to remember that the literature on angioplasty may not accurately reflect the actual or current incidence of complications (24,35,38,47,77,145-151). Because prospective multicenter trials have only recently begun, the existing literature is derived from either multi-institutional retrospective surveys or the results achieved by individual experts with vast

Table 6
Complications of Angioplasty

Complication	Incidence
Puncture site (total)	4.0%
Bleeding	3.4%
False aneurysm	0.5%
Arteriovenous fistula	0.1%
Angioplasty site (total)	3.5%
Thrombus	3.2%
Rupture	0.3%
Distal vessel (total)	2.7%
Dissection	0.4%
Embolization	2.3%
Systemic (total)	0.4%
Renal failure	0.2%
Myocardial infarction (fatal)	0.2%
Cerebrovascular accident (fatal)	0.55%
Consequences	
Surgical repair	2.0%
Limb loss	0.2%
Mortality	0.2%

experience. Moreover, the techniques of angioplasty have been rapidly improving, so conclusions about current outcomes cannot always be obtained from older literature. Each institution needs to maintain an ongoing quality assurance program for review of not only outcomes and complications of angioplasty procedures but also for all of the therapies used to treat patients with peripheral vascular disease. **Table 6** is a composite of the incidence and consequences of complications reported in multiple series and includes angioplasty procedures performed on 3784 patients.

Protocol for Surgical Support

When angioplasty is performed in peripheral vessels, there are very few complications that would require immediate surgical intervention. Therefore, there is no need for a standby surgical team or operating room. Although a few reports indicate that peripheral angioplasty can be safely done on an outpatient basis, most authors recommend integrating the procedure as part of a team approach in a hospital where surgical support and consultation are readily available.

Comparison of Surgery With Angioplasty

Direct comparison of the results of percutaneous transluminal angioplasty and surgery is not possible because percutaneous transluminal angioplasty is most often performed in the treatment of

patients with localized arterial stenosis or occlusions and for those needing relief from claudication rather than limb salvage. The following sections summarize the data on the results of percutaneous transluminal angioplasty from published series and review a randomized study in which that procedure was compared with surgery. Interpretation of results is often difficult because in many cases the definitions for success or patency were not clearly stated; appropriate statistical methods were not used; only angiography was used as the end point, even though it does not allow for continuous regular follow-up; the series was not a consecutive analysis of all patients having percutaneous transluminal angioplasty (36,152); follow-up was incomplete on all the patients in the series (109); or only cases that were technical successes were considered in the analysis (65). Although patency of a surgical bypass can be determined more accurately and appropriate statistical methods have generally been applied more rigorously, many of the same criticisms apply equally to the published surgical series and make comparison of surgery with percutaneous transluminal angioplasty impossible.

Comparison Between Surgery and Angioplasty

Only one study presents data for a randomized comparison between percutaneous transluminal angioplasty and surgery in the treatment of peripheral arterial occlusive disease (39). One hundred twenty-nine men underwent percutaneous transluminal angioplasty of iliac, femoral, or popliteal arteries, with a technical success rate of 92.2% and a 1-month success rate of 84.5%. Of the 126 patients who had surgical procedures, iliac bypass grafts were carried out in 74 cases and femoral popliteal bypasses in 58. Although the overall long-term success rate was better for surgery (74.9% compared with 64.5% at 3 years), the observed differences in treatment were mainly due to early events rather than late failures. If only those cases in which the procedure was technically successful were analyzed, percutaneous transluminal angioplasty and surgery had similar success rates. In the case of percutaneous transluminal angioplasty, it seems justified to exclude early failures in the analysis because failed angioplasty does not seem to increase the risk of limb loss (153) or subsequent surgical failure (39,154).

Thus, for patients who are candidates

for either percutaneous transluminal angioplasty or surgery, angioplasty, with its lower cost and morbidity, is preferred because the methods have similar results. However, it should be noted that in this study, because of the eligibility criteria, all patients had to be candidates for percutaneous transluminal angioplasty, and as a consequence the incidence of claudication was much higher than in a normal population of patients with arterial occlusive disease (39). Furthermore, in the femoral popliteal group, 23 of 58 bypasses were performed using a prosthesis rather than autogenous vein.

Results of Iliac Angioplasty

University of Toronto.—In the Toronto series, 667 iliac percutaneous transluminal angioplasties were analyzed (35). At 1 month after the angioplasty, 90.2% of the procedures were considered a success (ie, both the clinical grade and the noninvasive vascular laboratory measurements improved). Late success rates were 75.2±1.8% at 1 year, 64.9±2.1% at 2 years, 59.7±2.2% at 3 years, 56.7±2.4% at 4 years, and 53.4±2.7% at 5 years. Upon Cox regression analysis, the following combination of variables was associated with the success of percutaneous transluminal angioplasty: Patients undergoing the procedure because of mild or disabling intermittent claudication had a better success rate than those with limb salvage (53.8% compared with 48.7% at 5 years); common iliac results were better than external iliac or percutaneous transluminal angioplasty of both sites (58.8% compared with 46.1% at 5 years); arterial stenosis were dilated more successfully than occlusions (77.4% compared with 48.3% at 1 year); and patients with good runoff had a higher success rate than those with poor runoff (57.0% compared with 44.7% at 5 years).

Other results.—For iliac angioplasty, Grüntzig and Kumpe (155) reported an 87% success rate at 2 years; O'Mara et al (156), 84% success at 1 year; van Andel (157), 90% success at 1 year; Spence et al (52), 82% cumulative patency at 2 years; Schoop et al (158), 50% patency at 5 years; Schwarten (159), 89% at 2 years; Kadir et al (57), 89% at 3 years; Kumpe and Jones (160), 82% at 3 years; and Gallino et al (161), 87% at 4 years.

Surgical results.—In the hands of very experienced surgeons, the perioperative mortality for aortobifemoral reconstruction is now between 2% and

3% (162–165), and the expected long-term patency rates are excellent. According to reports in the literature, patency rates of 85% at 5 years, 70% at 10 years, 60% at 15 years, and 55% at 20 years can be expected (163–177). Although a patent graft does not necessarily reflect functional improvement, most patients with a patent graft are clinically improved or asymptomatic. Axillofemoral or bifemoral bypass grafts are most often carried out for limb salvage and in patients who have a significant cardiorespiratory risk or multiple previous abdominal operations. The primary patency rate with grafts without external support is 55% to 75% at 3 years; however, secondary patency is approximately 75% at 3 years and 50% to 75% at 5 years (178–184). Patency rates for iliofemoral bypass grafts between 80% and 90% have been reported. (185,186) Femoral-femoral bypass grafts have approximately 75% 5-year patency rates and 50% 10-year patency rates (187–189); however, lower patency rates of 57% at 5 years (190) and 67% at 3 years (191) have been reported.

Results of Femoralpopliteal Angioplasty

University of Toronto.—In the University of Toronto series, 254 percutaneous transluminal angioplasties of the femoral or popliteal arteries were performed in 236 patients (35). The following summary is of a recent reanalysis of this data (192). Procedures were successful in 96% of patients. When evaluated 1 month after the procedure, 88.8% of the procedures were considered successful (ie, both the clinical grade and the noninvasive vascular laboratory measurements improved). Late success rates were 62.5±3.2% at 1 year, 52.6±3.5% at 2 years, 50.7±3.5% at 3 years, 44.1±4.0% at 4 years, 38.1±4.4% at 5 years, and 35.7±4.8% at 6 years. Upon Cox multiple regression analysis, the type of the femoral popliteal lesion (stenosis or occlusion) and the runoff were the variables found to be useful in predicting the late results. For stenosis with good runoff, the success rate was 53% at 5 years; for stenosis with poor runoff it was 31% at 5 years; for occlusions with good runoff it was 36% at 5 years; and for occlusions with poor runoff it was 16% at 5 years. When the early failures were excluded from the analysis, the results were 7.9% higher at 1 year and 4.8% higher at 5 years. According to Cox regression analysis,

the predicted success rates were dependent only on the runoff. If the procedure was initially successful and the runoff was good, the predicted success rate was 76% at 1 year, 64% at 3 years, and 52% at 5 years. For poor runoff, the success rate was 61% at 1 year, 44% at 3 years, and 30% at 5 years. This statistical model that excludes early failures is less realistic because it does not predict the success rate prior to the procedure.

Other results.—It should be noted that our criteria for defining success are more strict than those used by many others, and as a consequence other reported results are higher. Adar et al (37) reviewed several published series and for intermittent claudication reported an early patency rate of 89% and a 3-year rate of 62%. For salvage, the early patency rate was 77% and was 43% at 3 years. Wilson et al (39) reported an immediate overall failure rate of 15.5%. Jørgensen et al noted initial technical success of 98% and 3-year patency of 68% for short stenoses (193) but only 59% early patency after percutaneous transluminal angioplasty for femoral or popliteal occlusion (194). Capek et al (36) noted that the femoral popliteal lesion could not be crossed in 7% of stenoses and 18% of occlusions. Blair et al (195) reported an 18% 2-year patency rate for percutaneous transluminal angioplasty carried out for salvage. Henriksen et al (196) reported a 41% 2-year patency. Hewes et al (71) calculated a 4-year patency of approximately 65%. Gallino et al (51) reported a 5-year patency rate of 58%. Krepel et al (73) reported excellent results: an 84% initial success rate and 5- and 7-year patency rates of 70% and 60% respectively. Capek et al excluded early failures and reported 1-, 3-, and 5-year patency rates of 81%, 61%, and 58% respectively. Jeans et al (121) noted good results for percutaneous transluminal angioplasty of femoral popliteal stenosis with good runoff (78% at 3 years) but worst results in femoropopliteal occlusions with poor runoff (25% at 3 years).

Surgical results.—Comparison between the numerous surgical series is difficult because of the multiple sites of distal anastomosis and alternative conduits. For reversed saphenous vein, the cumulative 5-year patency for femoral popliteal bypass is 60% to 75% (197,198), but in a recent report a 5-year patency of 80% was reported (199). In situ femoral popliteal bypass grafts have secondary patency rates of

89% at 3 years (200) and femoral tibial grafts have an 80% patency rate. Leather et al (201) reported a 5-year patency rate of 76% (201) and Donaldson et al (202) a secondary patency of 83%. For polytetrafluoroethylene grafts, Veith et al (198) reported a patency of 38% at 4 years and Z'graggen et al (203) 48% at 5 years; however, some groups have documented patency rates of 40% to 65% for above-knee grafts or in patients with claudication (204–207).

Conclusion

These guidelines should provide the reader with an understanding of the background and appropriate use of peripheral transluminal angioplasty. Several factors cannot be adequately addressed by such a report. First, the actual application of these recommendations can only be evaluated at the local level, where utilization data and quality of care issues can be judged. Second, guidelines are just guidelines, not rigid rules to be applied without considering the unique situation of every patient. Third, these guidelines represent a compilation of the scientific literature combined with the consensus opinion of leaders in the field. They should serve as a springboard for prospective studies of the influence of risk factor reduction, comparisons of different modalities, anticoagulants, the effect of estrogen replacement on outcomes, and the role of age, ethnicity, and gender on peripheral atherosclerosis. Finally, the recommendations are formulated at a particular moment in time and must constantly be updated as new developments, such as stents, arise.

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Appendix A

Tissue State Class	Sign or Symptom
1	Mild tissue damage*
2	Moderate tissue damage†
3	Severe tissue damage‡

* Discrete sore or tender area(s) with ischemic changes in skin but without break in skin.

† Ischemic changes present; includes uninfected ulcers up to 2 cm in diameter.

‡ Ischemic changes present; includes ulcers larger than 2 cm, multiple ulcers, infected ulcers, and gangrene.

Appendix B

Guide to Rating Permanent Impairment Due to Occlusive Arterial Disease of the Extremities

Class*	Impairment %	Ischemic Pain	Ischemic Ulceration	Amputation Due to Occlusive Arterial Disease
1	0	None	None	None
2	5-20	Claudication walking 100 yards or more	Healed	Healed painless stump of single digit
3	25-45	Claudication walking 25-100 yards	Persistent, superficial	Healed stumps of two or more digits
4	50-75	Claudication walking 25 yards	Persistent, widespread or deep, of one extremity	At or above wrist or ankle of one extremity or two or more digits of two extremities
5	80-95	Severe and constant rest pain	Persistent, widespread or deep, of two or more extremities	At or above wrist or ankle of two extremities or of all digits of two or more extremities

* Patients in class 1 have occlusive arterial disease but none of the symptoms or findings listed in the table. Patients in classes 2, 3, 4 and 5 have occlusive arterial disease and one or more of the symptoms or findings mentioned.

From Juergens JL, Pluth JR: Trauma and peripheral vascular disease. In: Juergens JL, Spittell JA Jr, Fairbalm JF, eds. *Peripheral Vascular Disease*, ed 5, Philadelphia, Pa: WB Saunders Co; 1980; pp 607-627. Reproduced with permission.

Appendix C
Noninvasive Laboratory Assessment of Arterial Insufficiency of the Legs

Degree of Arterial Insufficiency	Standard Exercises		Systolic Blood Pressure Index*	
	Claudication	Duration (min)	Before Exercises	After Exercises
Minimal	0	5	Normal to mildly abnormal	Abnormal
Mild	+	5	>0.8	>0.5
Moderate	+	+	<0.8	<0.5
Severe†	+	<3	<0.15	

* Systolic pressure index is obtained by dividing the systolic ankle blood pressure by the systolic brachial blood pressure, both measured with the patient supine (normal is 0.95 or greater).

† Often the systolic ankle blood pressure is less than 50 mm Hg.

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Appendix D
Grading of Elevation Pallor

Grade of Pallor	Duration of Elevation*
0	No pallor in 60 seconds
1	Definite pallor in 60 seconds
2	Definite pallor in less than 60 seconds
3	Definite pallor in less than 30 seconds
4	Pallor on the level

* Elevation of extremity at angle of 60° above the level.

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Appendix E
Color Return and Venous Filling Time

Condition	Time for Color Return (sec)	Venous Filling Time (sec)
Normal	10	15
Moderate ischemia	15–20	20–30
Severe ischemia	40+	40+

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Appendix F
Clinical Categories of Chronic Limb Ischemia (33–38)

Grade	Category	Clinical Description	Objective Criteria
I	0	Asymptomatic, no hemodynamically significant occlusive disease	Normal results of treadmill*/stress test
	1	Mild claudication	Treadmill exercise completed, postexercise AP is >50 mm Hg but >25 mm Hg below normal
	2 3	Moderate claudication Severe claudication	Symptoms between those of categories 1 and 3 Treadmill exercise cannot be completed; postexercise AP is <50 mm Hg
II	5	Ischemic rest pain	Resting AP of 40 mm Hg or less, flat or barely pulsatile ankle or metatarsal plathysmographic tracing, toe pressure <30 mm Hg
	5	Minor tissue loss, non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP of ≤60 mm Hg, ankle or metatarsal plathysmographic tracing flat or barely pulsatile toe pressure <40 mm Hg
III	6	Major tissue loss, extending above transmetatarsal level, functional foot no longer salvageable	Same as for category 5

AP indicates ankle pressure.

* Five minutes at 2 mph on a 12° incline.