Redefining the Treatment of Peripheral Artery Disease
Role of Percutaneous Revascularization
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The times, they are a changin’.  
Bob Dylan

The application of a catheter-based approach to the treatment of arterial occlusion of the lower extremities was proposed by Dotter and Judkins nearly 30 years ago; 13 years later, Gruentzig demonstrated that similar techniques could be used to achieve nonoperative revascularization in patients with obstructed coronary arteries. Before even one decade had elapsed following Gruentzig's seminal work, the demonstrated utility of percutaneous transluminal coronary angioplasty (PTCA) altogether redefined the management of patients with coronary artery disease (CAD). In contrast, despite three decades of research and development, the role of percutaneous transluminal angioplasty (PTA) in the management of patients with peripheral artery disease (PAD) has remained uncertain, controversial, and the subject of exhaustive debate.

Such contrary attitudes regarding the respective roles of PTCA and PTA in the management of vascular disease are counterintuitive. The relative risks of attempting to revascularize those arteries supplying the electrical and contractile machinery of the heart pose significantly greater risk than attempts to reestablish patency of the arteries supplying muscles of the hips, buttocks, legs, and feet. The risks of PTCA have in most centers required that an operating room and surgical team be kept free for emergency bypass surgery until revascularization has been completed; in contrast, the lesser risks of PTA have at no time required such a contingency. While restenosis rates as high as 50% have from the outset been regarded as an eminently retreatable complication of PTCA, restenosis following PTA—treatable by repeat PTA—has been implicitly equated with graft failure—typically requiring reoperation.

The reasons for such disparate use of percutaneous revascularization within the chest versus below the belt are complicated and many, and the explanation of same would almost certainly deny any meaningful consensus. Only one thing is clear: the future will be different. Thrombolytic therapy is being used on an increasingly widespread basis to convert total occlusions into subtotal or less lengthy occlusions that may be recanalized with less technical difficulty and greater therapeutic efficacy. Plain old balloon angioplasty (“POBA”) is neither plain nor old: catheter profiles have been reduced considerably, and the use of novel materials for balloon and guide wire construction has permitted routine access to more remote vascular sites with less risk and greater efficacy. New device technology, the most notable being endovascular prostheses or stents, have already been shown to improve both the short-term and long-term outcomes of PTA.

The impact of these advances has unavoidable implications for a population whose demographics are being dramatically altered in rapid fashion. People over 65 years of age now constitute 12.4% of the US population, and by 2030 this figure is expected to reach 22%; it is in this age group that PAD achieves peak prevalence. As pointed out in a recent US Public Health Service Document, “... improving the functional independence, not just the length, of later life is an important element in promoting the health of this age group.” When PAD results in disabling claudication, patients in this age group may be prevented from experiencing the well-documented benefits of exercise and physical activity.

In the days preceding Dotter and Judkins’ bold experiment, available options for restoring the functional capabilities of these patients were limited to surgical reconstruction. Given the plethora of comorbid conditions in these so-called “vasculopathies,” the risk of precipitating extraluminal complications such as acute myocardial infarction or stroke could not be justified, except in severely debilitated patients. The evolution of technology pioneered by Dotter and Judkins, Gruentzig, and others, however, has now greatly altered the risk/benefit equation: even in patients with coexistent coronary and/or cerebrovascular disease, the most serious risks of vascular surgery can be obviated by judicious application of percutaneous techniques. For many individuals, restored ability to walk the full length of the shopping mall with their spouse and/or friends, complete a round of golf, or walk to the senior citizens center when they cannot afford the luxury of a taxi all become relevant issues in the face of low-risk therapy.
These considerations thus dictate that the contemporary approach to the treatment of peripheral artery disease be carefully, thoughtfully, but unequivocally redefined. The purpose of this article is to make explicit the fact that availability of effective alternative therapy, namely percutaneous revascularization, permits a lower threshold for intervention in patients with PAD than has been traditionally practiced. Deferred evaluation of the patient with angina is uncommon, in part due to the physician's anxiety that the patient is at risk for potentially disabling or even fatal consequences of ischemic heart disease. Deferred evaluation of the patient with claudication carries no such penalty—for the physician. The physician can generally rest assured that in the patient with no rest pain, in whom the ability to walk some limited distance is preserved, there is little risk that limb viability will be jeopardized by failure to obtain appropriate noninvasive tests and/or diagnostic angiography. The price that the patient pays for such a decision, however, may be costly in terms of the limitations that are imposed on many of their otherwise routine activities.

The advent of nonsurgical revascularization mandates that our approach to patients with PAD be redefined to identify those patients in whom a low procedural risk and high probability of technical success warrant intervention for unnecessary disability. Accordingly, subsequent sections of this article will attempt to place in appropriate perspective contemporary nonsurgical options for patients with PAD.

**Pharmacologic Therapy**

One critically important issue, directly responsible for lowering the threshold for nonsurgical intervention in patients with PAD, is the fact that pharmacologic therapy is not an option for these patients. Coffman summarized the results of trials designed to evaluate various classes of agents in patients with PAD: "Drug therapy for patients with intermittent claudication has not been successful." Dietary modifications, cessation of smoking, and aerobic conditioning are all requisite therapy in these patients, as they are in patients with coronary heart disease. The absence of a pharmacologic treatment arm, however, clearly distinguishes management options in PAD from those available for patients with symptoms of myocardial ischemia. Excepting certain subgroups, failure of medical therapy conventionally has been regarded as a prerequisite for percutaneous revascularization in patients with ischemic heart disease. In contrast, the absence of effective drug therapy makes nonsurgical revascularization the only effective alternative to surgical therapy for patients with disabling symptoms of PAD. Because medical therapy, however ineffective, nevertheless continues to be prescribed for patients with PAD, certain agents that have been used for this indication merit specific comment.

Pentoxifylline (Trental) is the drug that continues to be most widely prescribed for the treatment of patients with PAD. Selection of this agent is based on the premise that certain of its biochemical properties—viz reduction of red blood cell rigidity—would reduce blood viscosity and thereby facilitate blood flow through obstructed vascular beds. This concept has been investigated in multiple published clinical trials, including two with a placebo-control design. Porter et al observed that pentoxifylline increased so-called "initial claudication distance" by 47% versus 26% in the placebo-treated group (P= .042); "absolute claudication distance," however, was not changed. In a subsequent report, Lindgarde et al were unable to document a statistically significant increase in either initial or absolute claudication distance with pentoxifylline therapy. Posthoc subgroup analysis of patients characterized by a history of claudication of >1 year and an initial ankle-brachial index of ≤0.8 demonstrated that initial and absolute claudication distances increased (P<.05) by 99% and 63%, respectively; percent improvement, however, was calculated relative to mean baseline walking distances of 77 (initial) and 79 (absolute) m, respectively. Accordingly, "... in absolute terms ... improvement [was] equivalent to 1.1-1.3 New York city blocks."

Treatment with L-carnitine, a metabolic agent designed to increase tolerance of ischemic symptoms by increasing availability of substrates required for energy production, has also been reported to produce similar statistically significant but clinically meaningless results. In a double-blind, cross over study of 20 patients, Brevetti et al found that carnitine therapy improved "absolute walking distance" from 174±63 to 306±122 m. No data were reported for time-to-onset of claudication, improvement of symptom-free ambulation, or improvement in functional class.

Trials of other agents have been even more disappointing. At least two placebo-controlled trials of ketanserin disclosed no change in either pain-free and/or maximum walking distance. While a number of vasodilator agents have been investigated as potential therapy for claudication, these, too, have universally failed to show benefit.

**Walking Exercise**

Prior to the availability of nonsurgical revascularization, the absence of effective drug therapy left, by default, exercise therapy as the sole alternative to vascular surgery in patients with claudication. The magnitude of desperation characterizing the search for effective conservative therapy in that era is perhaps best illustrated by a report published in 1966 in which walking exercise was advocated as a means of accomplishing limb salvage in patients with gangrenous feet. The risk/benefit ratio of walking exercise remains beyond dispute among patients in whom symptomatic disability is mild or in whom the risks of operative reconstruction are prohibitive. In patients with disabling symptoms, however, published reports do not support the concept that exercise therapy can achieve the degree of symptomatic benefit typical of successful percutaneous revascularization.

The most concrete evidence of both the benefits and limitations of exercise in treating claudication are to be found in two classic papers published in the late 1960s. The first, by Larsen and Lassen, involved 14 patients with clinical and/or angiographic evidence of PAD randomized to either supervised walking exercise (each patient was instructed to "... exert himself by walking for as long as he could stand the pains in his leg, then rest until the pains had disappeared, and then walk again") or no exercise. Maximum walking time among those who could stand the pain was in fact increased—from 2.9 to 8.2 minutes. Except for three patients who
demonstrated gains of 18.8, 11.1, and 9.4 minutes, however, maximum walking time in the remaining four patients averaged only 4.4 minutes. Moreover, after 6 months of exercise “treatment,” improvement in pain-free walking—1.7 to 3.5 minutes—was, while statistically “highly significant,” clinically virtually meaningless.

Skinner and Strandness reported similar findings among five patients subjected to a similar exercise regimen for 3 to 8 months. While three of the five patients improved their maximum walking time beyond 50 minutes, two of these three were at the outset of training already able to walk 9:31 and 10:50 minutes, respectively. Furthermore, in all five patients, time to onset of claudication remained under 4 minutes.

Two more recent studies place in perspective the gains that may be anticipated from exercise regimens in patients with advanced claudication. Lundgren et al randomized 75 patients with intermittent claudication to reconstructive surgery, surgery with subsequent physical training, or training alone. Compared with physical training alone, revascularization alone or in combination with subsequent training were observed to be superior treatment modalities.

Hiatt et al., using a study design similar to that of Skinner and Strandness, related observed improvements in supervised exercise to improvements in “community-based walking ability.” Although the 10 patients undergoing “exercise therapy” for 12 weeks demonstrated an increase in peak walking time from 6.4±1.7 to 13.9±3.5 minutes, pain-free walking was in all patients still limited to <5 minutes. Furthermore, after 12 weeks, improvement in distance walking reported by treated subjects during nonsupervised exercise amounted to three blocks, compared with two blocks at the onset of training.

Finally, Creasy et al., using simple randomisation, randomized 36 patients with claudication to supervised exercise versus PTA. Of 16 patients randomized to exercise, 7 (44%) were able to double their walking distance after 3 months; because their baseline walking distance, however, was limited to approximately 100 yards, these 7 patients were still limited to walking approximately 200 yards after successfully completing 3 months of therapy. Comparison with the 20 patients treated by PTA was compromised by (1) failure to provide routine angiographic findings including lesion severity before PTA, residual stenosis after PTA, or coexistent, untreated disease in the limb treated by PTA; (2) an unacceptably high incidence of technical failures (4, or 20%), despite the fact that all lesions were stenotic, as opposed to occlusive, and 12 of the 20 involved iliac sites); and (3) the fact that any potential improvement in walking distance as a result of PTA was obviated in 5 of the 20 patients (25%) by persistent claudication in the untreated, contralateral limb.

It remains a fact, as documented by the work of Larsen and Lassen, Skinner and Strandness, and Hiatt et al., that exercise therapy can augment walking distance in patients with PAD. Even if such benefit derives principally from improved conditioning—as suggested by the persistent discrepancy between absolute and pain-free walking distances in these studies—exercise will continue to represent a valuable therapeutic option for many patients with PAD. These include patients with mild or non–lifestyle-altering claudiation; patients in whom the anatomic distribution of vascular occlusive disease is unfavorable for percutaneous revascularization; and patients who represent prohibitive operative risks because of comorbid diseases. In patients with disabling symptoms and anatomic findings favorable for PTA, however, analysis of the published results of exercise therapy and the results of PTA suggest that the latter is typically associated with a greater degree of functional improvement.

**Regions of Interest**

As indicated above, one of the most compelling justifications for redefining the indications for percutaneous revascularization is the evolution in techniques and technology that has occurred over the past two decades. These developments have not only permitted improved procedural results—eg, routine treatment of infrapopliteal arteries—but, in some cases, have also already documented improved long-term patency—eg, iliac stents. Technical features, likelihood of success, and chances for clinical improvement, however, vary in degree according to the region of interest within the lower extremities. Weighted consideration of these individual issues is required to determine, for any given combination of lesions, the appropriateness of nonsurgical revascularization. Accordingly, the purpose of the following section is to briefly review what may be anticipated following percutaneous revascularization applied to specific regions of interest in the lower extremities, in terms of both acute and longer-term clinical results.

**Aortoiliac Disease**

PTA remains the treatment of choice for aortoiliac stenoses (Fig 1). Alternative devices, such as directional atherectomy, have not been widely used for these lesions (except for diagnostic purposes?) for two reasons. First, the relatively large dimensions of devices typically required for all but the smallest iliac arteries create problems for noninflatable devices. Second, the application of endovascular prostheses (stents) to aortoiliac lesions has dramatically changed the short-term (Fig 2) as well as the long-term results. Palmaz et al., Gunther et al., and Rees et al. have each documented the extent to which stents may be used to expertly rescue flow-limiting complications of iliac PTA. Preliminary findings reported by Richter and colleagues have suggested that significant improvements in long-term patency may be achieved in patients randomized to PTA-and-stent versus PTA alone: the angiographic patency (93%) in patients studied at 4-year follow-up rivals the best clinical patency reported at a similar time interval in patients undergoing operative revascularization. These excellent procedural and long-term results of percutaneous revascularization in patients with iliac lesions thus make the physical finding of a diminished femoral pulse a useful sign for identifying patients who are likely to benefit from percutaneous revascularization.

The extent to which lytic therapy may further optimize the treatment of iliac occlusions remains to be defined. There are two specific considerations in this regard. The first is the ability to traverse the segment of occluded artery. This issue has already been addressed by the use of hydrophilic guide wires and novel
technical approaches, the combination of which has yielded an extremely high procedural success rate. The second issue concerns distal embolization: it has been previously suggested that larger mass required to occlude a large-diameter artery, such as the iliac, might increase the likelihood of embolic complications. In patients with an ipsilateral occlusion of the superficial femoral artery (SFA) or one-vessel infrapopliteal runoff, embolic occlusion of the profunda or tibial/peroneal arteries, respectively, may in fact lead to acute limb-threatening ischemia. Prophylactic administration of lytic therapy may therefore be of potential benefit to such patients.

Clearly, the most common indication for iliac angioplasty is claudication. In some patients with claudication, and in rare patients with limb ischemia, the iliac...
lesion typically coexists with more distal disease involving the SFA and/or infrapopliteal vessels; in such cases, initial treatment of the iliac obstruction is based on the premise that improving inflow will secondarily improve outflow, either via the profunda in the case of an occluded SFA or by increasing the head of perfusion pressure to that segment of the infrapopliteal circulation that remains patent (Fig 3). Implicit in this strategy is the lesser degree of technical difficulty, high incidence of procedural success, and low rate of restenosis associated with iliac PTA. Moreover, PTA avoids the complication of iatrogenic postoperative impotence, reported to complicate 10% to 25% of aortoiliac operations.

A similar strategy underlies the preparatory role of iliac angioplasty in patients undergoing surgical revascularization for treatment of distal disease. Percutaneous revascularization of an iliac lesion may be required to facilitate patency of a downstream femoropopliteal conduit designed to bypass an occluded SFA. Alternatively, nonsurgical revascularization of an iliac site may be used in conjunction with surgery to lower the anatomic site and thereby reduce the risk of operative revascularization in patients judged to be at high risk due to coronary heart disease. In the patient, for example, with a lengthy unilateral occlusion of one iliac artery and less extensive obstruction of the contralateral side, higher-risk aortofemoral bypass surgery may be obviated by percutaneous treatment of the less diseased iliac artery, followed by a cross-femoral graft to the contralateral femoral artery (Fig 4).

Two additional issues regarding percutaneous treatment of aortoiliac disease deserve specific comment. The first concerns the role of percutaneous revascularization in modifying the treatment of patients with cardiac disease undergoing vascular surgery. Nowhere is this issue more relevant than in patients with coronary heart disease and aortoiliac occlusive disease, in whom abdominal surgery is associated with a marked increase in cardiac morbidity and mortality. Recent work from several groups has demonstrated the feasibility of intraluminal insertion of a graft-stent prosthesis for the treatment of abdominal aortic aneurysms. Although much less common than aneurysmal dilation, stenoses of the aorta are routinely and effectively treated with PTA (Fig 4). More common is the situation described above, in which percutaneous treatment of the aortoiliac lesion may permit surgical revascularization to be adjusted one level caudal, obviating the risk associated with aortic-level surgery.

The second issue involves angiographic assessment of iliac stenoses. Clinical experience with intravascular ultrasound has documented the extent to which conventional diagnostic angiography may underestimate hemo-dynamically significant luminal narrowing in tortuous common and external iliac arteries. In particular, the ostium of the common iliac as well as the common iliac bifurcation may be problematic in this regard. Intravascular ultrasound permits direct planimetry of luminal cross-sectional narrowing at these sites, obviating the multiple, angulated angiographic views required to unwind and/or eliminate sites of vessel overlap, which may obscure important luminal obstruction. The improved anatomic definition afforded by ultrasound examination may then be used in conjunction with physiologic indexes, including intra-arterial measurement of translesion pressure gradient and/or intra-arterial Doppler measurement flow velocity, to identify those lesions that are appropriate for revascularization.

**Femoral and Popliteal Arteries**

The popliteal artery is the name given to the SFA after it has traversed the adductor canal; previous
experience has failed to document any significant differences in either acute or long-term results for percutaneous revascularization of the SFA versus the popliteal arteries; accordingly, both will be herein considered together under the heading of “SFA.”

The acute procedural success for percutaneous revascularization of nonocclusive, ie, stenotic, lesions in the SFA using conventional guide wires and standard PTA currently approaches 100%. This contrasts with results of earlier reports56-60 describing acute success rates as low as 72%. It must be recognized, however, that the less optimal results described in these earlier reports reflect two issues. First, many of these reports combined analysis of total occlusions together with stenoses. Second, many of the patients described in these reports (including as late as 198557) included patients treated with nonballoon (coaxial 8F/12F/Dotter catheters or tapered Teflon dilating) catheters. Routine use first of the double-lumen, polyvinylchloride-balloon dilating catheter introduced by Gruentzig in 197661 and subsequently of catheters with lower-profile (5F) shafts and polyethylene balloons account in large part for the consistently favorable acute results typical of current practice.

The acute procedural success that may be currently achieved in SFA stenoses is thus similar to that reported for iliac stenoses. Long-term patency in the SFA, however, is clearly inferior to that which may be currently expected in iliac stenoses. Five-year patency rates varying from 47% to 70%57-60,62 have been reported for SFA revascularization; the variability in long-term follow-up results is due in part to the multiple lengths and morphologies of SFA lesions selected for treatment, as well as the aforementioned mixture of stenoses with occlusions, inclusion of earlier patients treated by the non-balloon-catheter Dotter technique. These factors, however, pale by comparison to the variable manner in which vessel patency has been defined and/or evaluated, whether initial failures are or are not excluded from long-term analyses, and the statistical measures used to analyze long-term follow-up.63

A variety of novel technologies have been investigated as potential means of reducing restenosis following SFA revascularization. It must be emphasized that all of these techniques, including directional atherectomy, laser angioplasty, rotational atherectomy, and endovascular stents, have in common the fact that they are wire guided and therefore limited to the treatment of stenoses or otherwise successfully recanalized occlusions.

Among these new devices, directional atherectomy has been used most widely. The fact that atherosclerotic plaque resected by directional atherectomy is preserved intact and in a form that is therefore suitable for a variety of laboratory analyses confers to this modality a unique diagnostic function. Studies of atherectomy specimens performed using conventional light microscopy64,65 as well as more contemporary molecular biological techniques66-69 suggest that it may play a critical role in providing human tissues to develop novel biopharmaceutical agents for the treatment of restenosis. Moreover, recent attempts to exploit the biopsy capabilities unique to directional atherectomy have raised the intriguing possibility that application of molecular techniques to the analysis of atherectomy tissue might prospectively identify those patients likely to develop restenosis.70

The superiority of directional atherectomy from a therapeutic standpoint remains less clear. In patients with short, eccentric lesions, directional atherectomy (with or without adjunctive PTA) appears to offer acute procedural results that are similar to those reported for PTA.65,71-75 The impact of directional atherectomy on subsequent restenosis, however, remains controversial; unlike the recently completed CAVEAT investigation,76 no randomized trial of PTA versus directional atherectomy has been reported. Most nonrandomized studies,65,73,75 however, have thus far been unable to demonstrate, even for selected groups, significant reduction in restenosis among patients treated by directional atherectomy. These preliminary findings may be explained in part by the unpredictable extent to which augmented patency results from the catheter versus balloon versus cutter effects of the atherectomy device (Fig 5).

Rotational atherectomy77,78 has thus far been demonstrated to have no superior advantage for SFA revascularization, save for those rare patients in whom the extent of calcific deposits renders the lesions refractory to alternative techniques. Furthermore, to impact significantly on a vessel the size of the SFA, the disproportionately large introducer sheath required to accommodate appropriately sized devices represents a distinct disadvantage for SFA rotational atherectomy.

The role of laser angioplasty in SFA revascularization remains investigational. A variety of laser sources has been investigated for this application, including thermal (“hot-tip”) systems,79-84 continuous wave (CW) lasers such as Nd:YAG,85 and pulsed laser systems using either visible (flash-lamp–pumped dye),86-88 infrared (holmium),89 or ultraviolet (excimer)90 wavelengths. Thermal systems are now a dead issue: experience with the hot-tip systems demonstrated in dramatic fashion the multiple unfavorable consequences of heat applied to the vasculature.91-94 The lesser degree of heating resulting from pulsed laser systems95 is essential for vascular applications. While all three pulsed wavelengths continue to be investigated for SFA revascularization, our clinical experience with the excimer (Figs 6 and 7) has been more favorable than with the alternative wavelengths. In occasional cases, the excimer laser has clearly facilitated completion of revascularization that was refractory to conventional techniques (Fig 8). While there is preliminary evidence96 to suggest that the thrombolytic properties of excimer laser radiation may be exploited to reduce the need for thrombolytic therapy in selected patients (Fig 9), this application requires further confirmation. Evidence that excimer laser angioplasty can reduce restenosis remains the subject of ongoing study.87,97

In contrast to the documented reduction in restenosis achieved by the use of endovascular stents for iliac PTA, early experience with endovascular stents in the SFA has been less favorable. Preliminary results with a variety of stent designs98,99,100 have failed to demonstrate a significant reduction in restenosis following SFA revascularization. In further contrast to results reported for iliac applications, the use of stents in the SFA has been complicated by an unpredictable incidence of subacute thrombosis and thus uncertainty regarding the
FIG 3. This and facing page. Percutaneous transluminal angioplasty (PTA) and stent used for serial stenoses in left iliac artery (top left) associated with flush total occlusion (T.O.) of left superficial femoral artery (SFA) (top right). Strategy in this case is designed to perform what is technically a more straightforward and durable percutaneous procedure—iliac PTA/stent versus recanalization of SFA T.O.—and use improved inflow from iliac to augment outflow via profunda. Patient, formerly Rutherford class 3, remains asymptomatic 3 years after revascularization.

need for long-term anticoagulation.99 Full analysis of these early results may ultimately identify certain anatomic factors—eg, lesion length, distal runoff—that may discriminate among optimal versus suboptimal candidates for SFA stents. It is likely, however, that the use of stents in the SFA will be governed principally by the size of the artery itself; in the coronary circulation, for example, current data suggest that the larger the dimensions of the native artery, the greater the likelihood of favorable short- and long-term consequences.100

In contrast to the coronary vasculature in which stenotic lesions are the rule and occlusions are the exception, the distribution of lesions in the SFA is the reverse: among patients studied angiographically for consideration of revascularization, occlusions are more prevalent than stenoses. And while the long-term implications for revascularization of SFA and coronary occlusions are similar—both are associated with a high likelihood of recurrence56-59,101,102—the likelihood of achieving short-term patency, ie, acute procedural success, is higher for SFA occlusions. This is the case even for long (>10 cm) SFA occlusions (Figs 6 and 7) and is due largely to two technical modifications.

The first is the use of hydrophilic wires, the prototype of which is the Glidewire® (Tervne, Piscataway, NJ). Among 109 consecutive patients at our institution in whom the Glidewire was used to attempt percutaneous revascularization of SFA total occlusions, the Glidewire was successfully advanced across the occluded segment in 107 (98%); balloon angioplasty alone or in combination with directional atherectomy and/or laser angioplasty was then used to complete percutaneous revas-
culation in all 107 patients in whom Glidewire recanalization was successful. Ankle-brachial index improved from 0.48±0.02 before to 0.82±0.02 after revascularization. Improvement in Rutherford class by one or more grades was observed in 96 of 102 patients (94.1%) seen at 1-month follow-up. This experience was noteworthy because, unlike most previous reports that have excluded occlusions >10 cm long, patients in this series were not excluded on the basis of lesion length. Among the 107 SFA occlusions, 50 measured 5 to 10 cm in length and 21 were >20 cm long; consequently, mean occlusion length (9.8 cm) exceeded that reported in most previous series.

The improved acute procedural success achieved with the Glidewire has two important implications. First, the demonstrated efficacy of the Glidewire in a variety of anatomically complex, including lengthy, arterial occlusions clearly extends the spectrum of patients who may be candidates for percutaneous revascularization. Second, the high success rate achieved with the Glidewire constitutes a new standard against which novel instruments developed for treatment of occluded peripheral arteries and/or grafts should be judged.

The second factor that has contributed to improved procedural success in crossing SFA occlusions is the increasingly aggressive use of thrombolytic therapy. Lytic therapy has in fact been advocated and proven effective even for chronic total occlusions; this is because occlusion of the lower extremity arteries is typically characterized by a lengthy, metastable, submaximally organized, gelatin-like thrombus propagating retrograde from and superimposed on a less lengthy, high-grade atherosclerotic lesion. In such cases, lytic therapy is generally effective in converting a long occlusion to one that is either shorter or no longer occlusive and thereby more amenable to mechanical revascularization. The efficacy of this approach is currently under systematic, multicenter investigation in patients with lower extremity occlusions who are randomized to lytic versus operative therapy (Surgery and Thrombolysis for Ischemia of the Lower Extremity [STILE]).

All attempts to optimize acute procedural results in patients with lengthy total occlusions of the SFA, how-
ever, must be tempered by the high frequency of restenosis following percutaneous revascularization of such lesions. The basis for the higher incidence of restenosis associated with occluded, as opposed to stenotic, peripheral arteries has been clarified in part by recent in vitro and in vivo analyses. Tobis et al performed in vitro studies to determine the mechanism of argon laser-mediated thermal probe recanalization of SFA occlusions 0.5 to 26 cm in length. They observed that regardless of whether the laser was activated, the probe seldom penetrated the central (luminal) portion of a fibrous atheroma; instead, recanalization typically proceeded along an intramural course. We have used catheter-based, intravascular ultrasound to address this same issue in vivo. Three-dimensional reconstruction of ultrasound images from totally occluded peripheral arteries after revascularization confirmed that, in most cases, clinically successful revascularization of totally occluded peripheral arteries does in fact include a significant intramural course.

Accordingly, the extent to which these favorable acute, procedural results in patients with chronic total occlusion will ultimately extend the role of percutaneous revascularization remains to be defined. Certainly for patients with nonhealing lesions and/or threatened limb loss in whom the risks of surgery are considered prohibitive or in whom veins are unavailable for distal bypass procedures, percutaneous revascularization of lengthy, occluded segments may facilitate healing. In similar types of patients with rest pain, PTA may be used to achieve pain relief at a lower risk than conventional surgical reconstruction. For patients with less severe symptoms, improved ability to revascularize a chronically occluded artery does not in and of itself constitute a sufficient basis for routine invasive therapy. Until data have been published to document the cost-benefit of initial and subsequent revascularization procedures necessary to guarantee reasonable long-term patency, the role of percutaneous revascularization for lengthy, chronic total occlusions must be considered investigational.

Three anatomic issues concerning femoral arterial revascularization deserve additional, specific comment. The first issue involves clinical presentation of embolic complications apparently related to ulcerated and/or thrombotic lesions of the SFA, the so-called “blue toe

FIG 4. Preparatory role of iliac percutaneous transluminal angioplasty (PTA) in patient undergoing surgical revascularization for distal disease. Patient was poor candidate for major (aortofemoral) reconstructive surgery. Surgical risk was therefore reduced by PTA/stent therapy of stenotic abdominal aorta and PTA of left external (Ext.) iliac stenosis in preparation for cross-femoral graft from left to right common femoral artery (CFA). Bottom of middle panel shows intravascular ultrasound (IVUS) confirmation of adequate expansion of stent struts in abdominal aorta; asterisk denotes IVUS catheter.
syndrome.” Emboli in such patients were initially inferred to result from friable plaque morphology that posed an unacceptable risk for percutaneous revascularization. It is now clear that such patients can be effectively treated by either PTA or directional atherectomy with both a high degree of procedural success and an acceptably low risk of further embolic complications. The second involves stenotic and/or occlusive lesions of the common femoral artery. Such lesions certainly may be accessed without great difficulty from the contralateral limb (Figs 6 and 7). The acute results of common femoral PTA, however, tend to be less predictable, particularly when PTA-induced plaque fractures propagate into the common femoral bifurca-

FIG 5. Incremental luminal patency resulting from individual components of directional atherectomy (DA). Top left, Angiogram shows high-grade stenosis in superficial femoral artery (SFA) before DA. Top right, Angiogram shows improved luminal patency resulting from “Dotter” effect of advancing DA catheter through lesion (no balloon inflation, no atherectomy). Bottom left, Angiogram shows further improvement in luminal patency resulting from balloon inflation (2 atm) without activating cutter. Bottom right, Angiogram shows final result accomplished by activating cutter.
FIG 6. Recanalization of occluded common femoral artery (CFA) and superficial femoral artery (SFA). Baseline angiogram shows CFA and SFA occlusions. Profunda femoris is seen below CFA. B, Glidewire was advanced through entire length of SFA occlusion, following which occluded segment was treated with excimer laser angioplasty.

FIG 7. Post-percutaneous transluminal angioplasty (PTA) angiography of vessels shown in Fig 6. Common femoral artery (CFA) and native superficial femoral artery (SFA) are widely patent after excimer laser angioplasty and PTA.
FIG 8. Excimer laser–facilitated revascularization of totally occluded left superficial femoral artery (SFA) in 86-year-old woman with nonhealing lesions of the first toe, fifth toe, and heel. Top left, Total occlusion (T.O.) of left SFA. Left middle, Neither a hydrophilic guide wire nor a Wholey wire, shown here, could be advanced beyond a nodular calcific deposit (Ca++) in the distal left SFA. An excimer laser catheter was therefore advanced over the Wholey wire and used to irradiate the proximal portion of the occlusion. Right middle, After excimer laser irradiation of the nodular calcific deposit in the distal SFA, Wholey wire could then be advanced into the distal SFA. Top right, Final angiographic result following adjunctive PTA. Below, Photographs of left foot taken before and after revascularization demonstrate healing of lesions involving the first toe (left), fifth toe (middle), and heel (right).

tion, leading to potential compromise of both the SFA and profunda. PTA of the common femoral artery must therefore be undertaken with considerable caution. The third anatomic consideration is the combination of a stenotic profunda with a proximal occlusion of the SFA. Technically satisfactory results of profunda PTA have been described previously and in this particular situation might well be more easily accomplished than revascularization of a coexisting, proximal, long SFA occlusion. Should revascularization of the profunda—a site not currently favored for stent deployment—be complicated by acute occlusion, however, complete interruption of antegrade flow via both femoral arteries may result in an acutely ischemic limb.

Infrapopliteal (Crural) Arteries
Published clinical experience involving percutaneous revascularization of the anterior tibial, tibioperoneal
trunk, posterior tibial, and peroneal arteries, while
dating to the time of Dotter and Judkins' original work,
has nevertheless been far more limited than that de-
scribed above for aortoiliac and SFA sites. This is
related to several issues, including the fact that clau-
dication is rarely due to isolated disease of the infrap-
opliteal arteries; knee-to-foot patency of one of the three
major branches is generally regarded as sufficient to
prevent critical lower-limb ischemia; restenosis rates in
these vessels have typically been the highest of any of
the lower extremity sites; and obstructive disease in
these arteries is often occlusive, severely diffuse, and
complicated by heavy calcific deposits.

There is little question that application of techniques
used for coronary arterial revascularization, develop-
ment of catheters having design features similar to those
used for coronary interventions, and improvements in
radiographic imaging equipment have all resulted in
more widespread application of percutaneous revascu-
larization for infrapopliteal disease. Prior to the use of
coronary-type dilating equipment, for example, nonbal-
loon, tapered angiographic or even nonangiographic
catheters were often used for infrapopliteal "angi-
plasty." Several reports have now documented
that with application of contemporary angioplasty
equipment, stenotic and even short (<2 cm) occlusions
of one or more infrapopliteal arteries can be revascu-
larized percutaneously with a very high degree of effi-
cacy and at extraordinarily low risk.

Even lengthy total occlusions (Fig 10), previously
resistant to conventional techniques, can often be
satisfactorily revascularized by combined use of hydro-
philic guide wires, excimer laser angioplasty, and/or
rotational atherectomy. Among 20 consecutive patients
with occlusion of one or more infrapopliteal arteries in
whom percutaneous revascularization was performed in
our institution, percutaneous revascularization was suc-
cessfully completed in 19 (95%), including 11 occlusions
1 to 4 cm in length and 9 measuring 5 to 10 cm long. Postprocedural luminal diameter narrowing was at all
sites along the length of original occlusion <30% in 15,
<40% in 17, and <50% in 19. Ankle-brachial index
improved from 0.41±0.06 before to 0.77±0.10 after
revascularization. Improvement in Rutherford class by
short-lived patency of prosthetic materials used as conduits for lower extremity distal bypass surgery.\textsuperscript{120,121} Consequently, use of the native vein—either as a reversed autologous graft or, more frequently, as an in situ graft—has become the standard for surgical treatment in such patients. While the use of native vein and improved surgical techniques have led to improvements in short-term success and long-term patency, certain liabilities of this approach persist. Long-term patency is still inferior to that reported for suprapopliteal disease.\textsuperscript{122} In situ bypass surgery appears to have a higher risk of infectious complications than most other lower extremity vascular procedures.\textsuperscript{123} Finally, and most important, use of the saphenous vein for lower extremity surgery precludes its future use, as a conduit both for coronary bypass surgery in a population of patients with a nearly universal incidence of coronary artery disease and for subsequent lower extremity vascular disease, including graft occlusive disease. If the latter is refractory to percutaneous or operative reconstruction, the patient is often left with limited options, including conservative therapy and/or eventual amputation.

Most vascular surgeons have thus understandably advocated distal lower extremity bypass surgery only for those patients with an advanced (IV through VI) Rutherford classification. For these groups, percutaneous therapy consequently becomes a very useful and appropriate alternative to reconstructive surgery. Even in patients with Rutherford class IV (rest pain) or V (minor tissue loss), a percutaneous approach, if technically feasible, may have several advantages. First, it may defer definitive surgical therapy, thus preserving native veins. Second, it may accelerate healing of an ulcerative lesion and/or obviate superimposed infections. Third, in more advanced cases, it may lower the anatomic level of proposed amputation and thereby preserve patient mobility by helping to heal a more limited (eg, transmetatarsal) amputation site.\textsuperscript{124}

It must be emphasized that the goals of infrapopliteal revascularization often differ from those of above-the-knee therapy. Because claudication is rarely the result of infrapopliteal obstruction alone, percutaneous treatment of these sites is typically performed in conjunction with SFA/popliteal revascularization. Even when present as an associated lesion(s), however, the requirement for angioplasty is not automatic: uninterrupted patency of at least one of the three major infrapopliteal arteries is generally sufficient to obviate claudication and/or heal a distal ischemic lesion. In patients in whom infrapopliteal disease coexists with SFA/popliteal disease and in whom at least one of three vessels has no flow-limiting obstruction, it has thus been our practice to limit associated treatment of the infrapopliteal arteries to short (<2 cm) stenoses and/or occlusions if we choose to treat them at all.

More often, however, consideration of infrapopliteal angioplasty is necessary not for symptoms of lower extremity ischemia but for signs of limb ischemia such as nonhealing, ulcerated lesions with or without superimposed infection. In such patients, uninterrupted patency of at least one of the three infrapopliteal arteries may be anticipated to expedite healing of a distal lesion (Fig 11) and/or a residual stump in patients requiring amputation for nonsalvageable tissue. In this group of patients in whom the benefits of successful revascularization far outweigh the risks of a failed procedure, aggressive

**FIG 10.** Percutaneous transluminal angioplasty (PTA) of occluded anterior tibial artery, tibioperoneal trunk, and peroneal artery in elderly patient with foot ulceration and threatened limb loss. A, Baseline angiogram demonstrates 2-cm occlusion of anterior tibial artery (AT), high-grade stenosis of tibioperoneal trunk (TPT), and lengthy occlusion of peroneal artery (Per.). All three segments were recanalized with Glidewire\textsuperscript{TM}, followed by excimer laser angioplasty and PTA. B, Final angiogram after PTA demonstrates widely patent anterior tibial, tibioperoneal trunk, and peroneal artery.

one or more grades was observed at 1-month follow-up in 18 of 19 patients (94.7%). Among 17 patients classified as Rutherford class 5 or 6, successful limb salvage was achieved in 15 of 17 patients (88.2%).

Given this documented technical success, there are several factors that combine to make nonsurgical revascularization particularly attractive for patients with infrapopliteal disease. The first is the well-documented,
FIG 11. Excimer laser angioplasty of totally occluded (T.O.) anterior tibial (Ant. Tib.) and tibioperoneal (T-P) trunk in a 67-year-old woman with nonhealing lesion of the left heel. Top left, Baseline angiogram. Top right, Final angiogram following sole therapy with wire-guided excimer laser irradiation. Below, Progressive healing of left heel lesion at 2 (left) and 7 (right) months after revascularization. Patient remains asymptomatic 2 years later.

application of percutaneous revascularization may be expected to achieve extremely gratifying results, even in patients with calcified and/or lengthy total occlusions.

Two points concerning percutaneous infrapopliteal revascularization require special emphasis. First, results previously achieved with conventional wires and balloon catheters do not represent what may be currently accomplished using more contemporary techniques. There is little doubt that excimer laser angioplasty (Fig 11) has facilitated percutaneous revascularization of long, total
occlusions. Likewise, rotational atherectomy (Fig 12) may play an important role in the treatment of heavily calcified infrapopliteal arteries. Even in the presence of lengthy, multivessel occlusions, demonstrated reconstitution of one or more arteries suggests that percutaneous revascularization of at least one major artery should be possible. Consequently, recommendations based solely on previous experience with standard angioplasty equipment deserve to be reconsidered.

Second, the incidence of restenosis—which remains high in these patients irrespective of the technique used—should not be a factor in the decision to use a percutaneous approach for what is, in most of these patients, a short-term problem. If uninterrupted patency of even one vessel can be achieved, the improvement in antegrade nutrient flow is typically adequate to facilitate limb salvage. Once healed, most patients will do satisfactorily, even in the face of documented restenosis, if they can avoid subsequent foot trauma. This strategy is further supported by the fact that both the short-term and long-term outcomes of distal surgical reconstruction for infrapopliteal disease are likewise imperfect.

**Bypass Grafts**

Percutaneous revascularization represents an alternative to operative reconstruction for achieving so-called secondary patency of failing or failed native or prosthetic conduits. Nonsurgical revascularization has several obvious advantages: it saves the patient the morbidity and additional hospitalization associated with a repeat surgical procedure; it does not require the availability or use of additional native veins; and in certain cases it may obviate the need to use prosthetic materials for distal reconstruction, an application for which such materials have been shown to confer low patency rates.120,121

The published experience with stenotic (ie, compromised but nonoccluded) lower extremity bypass grafts is extremely limited and therefore not surprisingly variable. Cohen et al125 used PTA to treat 7 of 29 patients with “impending vein graft failure” and reported a
5-year cumulative patency rate of 43% for this group versus a 5-year cumulative patency of 83% in the remaining 22 patients treated by reconstruction with patch angioplasty. Perler et al. described a 7-year experience during which a total of 19 grafts were treated by PTA: primary and secondary patency rates at 36-month follow-up were 22% and 27%, respectively. Again, because a primary 5-year patency rate of 62% was achieved in 9 vein graft stenoses revised surgically during the same time period, the authors concluded that surgical reconstruction was preferable to PTA for vein graft stenosis. Bandyk et al. used PTA to perform 18 of 103 secondary procedures intended to correct primary or recurrent graft stenoses. Their case selection—13 involved an “adjacent artery stenosis,” 3 a venous conduit, and 2 an anastomosis—reflected their bias that “...PTA be reserved for management of atherosclerotic lesions that develop in arteries proximal or distal to graft anastomotic sites.” Recurrent stenosis was observed in 3 cases early (<3 months) and in 5 cases late after PTA.

Whittemore et al. reviewed their institutional experience with balloon angioplasty applied to 54 stenotic lesions in 30 patients. In none of the patients was PTA associated with a serious complication. While the overall 4-year patency rate was only 18%, the case mix demonstrated an important bimodal distribution: vein grafts requiring only a single PTA had a patency rate of 59% at 3 years, as opposed to those requiring repetitive dilation in which 3-year patency was 6%. Neither anatomic nor clinical factors predicted protracted patency. While the authors are no doubt correct in concluding that PTA has “... significant limitations in providing sustained secondary patency,” their data may also be interpreted to argue for at least one PTA in those cases where it is technically feasible, given that up to two thirds of impending graft failure may be obviated by a single percutaneous intervention.

In fact, among two more recently described, larger groups of patients with vein graft stenoses, the long-term outcome associated with PTA of vein graft stenoses appeared substantially improved. Berkowitz et al. used PTA alone to treat 44 of 72 graft stenoses (61%). The 5-year life-table-assisted primary patency after correction of the stenotic lesion was 61%. In contrast to the above-reported experience, lesion location was a principal determinant of graft patency: lesions in the proximal (including anastomosis) and distal graft had significantly better patency than midgraft and distal anastomotic lesions.

Similarly, Sanchez et al. reported encouraging results with PTA in the treatment of 156 of 285 lesions (56%) involving failing or threatened vein and polytetrafluoroethylene bypass grafts. For inflow or outflow lesions <5 cm in length, 5-year secondary patency was 58%. For graft stenoses <1.5 cm in length within vein grafts >3 mm in diameter, the 24-month extended patency rate was 93%.

Our approach to stenotic grafts (Figs 13 and 14), regardless of the dimensions or location of the stenoses, is to make at least one attempt at percutaneous revascularization. This approach is derived from consideration of several issues. First, percutaneous revascularization of stenotic grafts is most often technically straightforward. Second, the risk of serious complications is low. Third,

![Fig 13. Revascularization of occluded in situ vein bypass graft in patient with continuous rest pain. A, Angiogram obtained after Glidewire™ (GW) is advanced through entire length of occluded femoropopliteal tibial in situ vein bypass graft. B, Angiogram following thrombolytic therapy with urokinase and balloon angioplasty demonstrates widely patent graft.](image-url)
feeling that percutaneous revascularization of stenotic bypass conduits will for the near future continue to be expanded.

Limited published data are available regarding comprehensive series of patients in whom occluded bypass conduits have been percutaneously revascularized without preemptive administration of thrombolytic therapy. In most of these previous reports, unspecified numbers of patients were excluded from consideration if the occlusion could not be crossed with a guide wire; lytic therapy was delivered primarily to the origin—as opposed to the "body"—of the thrombus, and/or PTA was performed following lytic therapy only in selected patients. Although not broken down in terms of graft cases versus native arterial sites, McNamara and Fischer observed that the ability to completely traverse the occluded site with the guide wire constituted the best single test for predicting the likelihood of recanalizing a

FIG 14. Recanalization of distal graft and anastomosis in patient from Fig 13. A, Baseline angiogram demonstrates absence of graft but filling of distal runoff vessels (arrow) via collaterals. B, Following thrombolysis and balloon angioplasty, distal graft and anastomosis (anast.) with anterior tibial (ant. tib.) artery now widely patent. Flow was restored to ankle level, with restoration of palpable pulse and resolution of rest pain.
given occlusion and obtaining complete clot lysis: in every case in which the guide wire was advanced completely through the occlusion, the ensuing infusion produced complete clot lysis.

Among 14 consecutive patients from our own institution in whom a bypass graft was successfully crossed with the Glidewire™, revascularization was successfully completed in 12 (85.7%).23 The length of the occluded segment measured 3 cm in one patient and was >10 cm in the remaining 11. Residual luminal diameter narrowing was <30% in all 12 patients. Postprocedural ankle-brachial index values improved from 0.37±0.08 to 0.82±0.08. Rutherford class also increased by one or more grades in all 12 patients, including 4 who were classified as class 5 or 6 before the procedure.

Our current approach to percutaneous revascularization of occluded grafts exploits not only the ability of the Glidewire™ to more readily traverse lengthy graft occlusions, but also profits from the advent of low-profile catheter/wire perfusion systems that permit protracted delivery of lytic therapy directly into the occluding thrombus via side holes in the perfusion instrument. The extent to which these procedural factors were directly responsible for successful revascularization in the above-described cases will require further assessment in a larger patient cohort. It is noteworthy, however, that similar to the experience of McNamara and Fischer,137 the one occluded graft in our series that could not be successfully crossed with the Glidewire™ could not be salvaged with lytic therapy. The capability to nontraumatically salvage these conduits constitutes a potentially valuable treatment strategy in a group of patients who often have no remaining veins available for repeat surgery and in whom use of prosthetic grafts to distal sites may be undesirable.

There are limited published data regarding the application of novel device technology to the treatment of occluded bypass grafts. Consequently, the potential efficacy of novel mechanical approaches, including endovascular stents, cited above for reducing graft restenosis, remains undetermined. It is likely that efforts similar to those that have been proposed in the past to augment graft patency through genetic engineering142 may, in the future, be applied percutaneously144 to prevent restenosis following successful revascularization.

### Current Treatment of PAD

The therapeutic armamentarium for and clinical experience with percutaneous revascularization described above has markedly improved the prospects of patients with PAD. In the bygone era when vascular surgery was the only effective option available to patients with claudication or threatened limb loss, there was little reason to perform diagnostic angiography unless surgery was indicated. And there were justifiable reasons, given the risks of major reconstructive surgery in a population of patients riddled with coronary and cerebrovascular disease, to restrict surgery to patients with altogether disabling claudication or threatened limb loss.

In the current era, intervention at an earlier stage of symptomatic disability is possible due to the lower risks and lower lower costs of nonsurgical revascularization. As has been pointed out by Kumpe and Rutherford,39 "...the advantages to the patient able to undergo angioplasty rather than surgery...are lower initial morbidity and mortality, no need for general anesthesia, shorter hospital stay, [and] less trauma...." This is true, even when one adds to the morbidity of PTA that of diagnostic angiography. In a multicenter trial of 118,591 arteriographic procedures reported by Hessel et al.,145 for example, the incidence of complications with axillary, translumbar, and femoral approaches were 3.29%, 2.89%, and 1.73%, respectively; overall mortality was 0.025%. Complications of PTA are for the most part minor and typically do not require surgical treatment.146 In contrast to PTCA, access-related events account for most complications (2% to 8% in most series39,146–148); these range from the less serious and more common (eg, groin hematoma) to the serious but rare (eg, retroperitoneal hematoma).149 The incidence of complications at the angioplasty site, 1% to 7% in most series,39,146–148 is similar to that of PTCA and consists principally of acute occlusion; as with PTCA, many of these can be managed with lytic or adjunctive mechanical therapy, including stents, so that the need for emergent surgery due to a jeopardized limb is rare. Distal embolization has been reported in up to 5% of cases147; most, however, are clinically silent,148 and even those that might be potentially problematic can often be obviated before PTA or treated successfully after PTA by judicious use of lytic therapy.

The conclusion that PTA is cost efficient is supported by several published analyses150–153: these studies demonstrated that the initial costs of PTA are 18% to 34% those of surgical intervention, principally as a result of reduced length of hospitalization. The classic article by Doubilet and Abrams,150 published in 1984, demonstrated the extent to which the cost of treating PAD would be progressively diminished by increased application of PTA. They estimated that in 1980, PTA was being used in lieu of surgery in approximately 6.7% of patients who required therapeutic intervention; the projected cost savings at that level was estimated to be $16.6 million. According to their analysis, if PTA were to be used as the initial procedure in 40% of patients, the anticipated savings would approach $100 million. A subsequent analysis151 suggested that the original estimates of Doubilet and Abrams might be conservative and that the estimated savings could exceed $180 million per year for femoral lesions and $117 million for iliac lesions.

More recently, Tunis et al154 called into question these projections. To assess the extent to which PTA was used and resulted in changes in surgical management of lower extremity vascular disease, Tunis and colleagues reviewed discharge abstracts from a database maintained by the Maryland Health Services Cost Review Commission. The patient cohort included patients 25 years of age or older who were discharged between January 1979 and December 1989 with a procedure code listed for lower extremity bypass surgery, major lower extremity amputation, or "other vessel repairs," the code used for PTA of lower extremity arteries. The authors estimated that over this 10-year period, the annual rate of PTA rose from 1 to 24 per 100,000 residents; despite this apparent increase in the use of PTA, the annual rate of peripheral bypass surgery was estimated to have increased as well (32 to 65 per 100,000 residents), while the annual rate of lower extremity...
amputation was estimated to remain unchanged. The suggestion that PTA and bypass surgery were being used with increased frequency (and cost) without improved efficacy (as judged from constant estimate in the rate of lower extremity amputations) was widely interpreted as evidence contradicting the utility of peripheral revascularization in general and PTA in particular.

Certain aspects of the design and execution of this analysis have raised questions regarding the validity of these conclusions. First, the procedural code used to identify PTA ("other repair of vessel") was by no means specific for either percutaneous or lower extremity procedures. The same code was also used to code operative profundoplasty; percutaneous central vein, visceral and brachiocephalic PTA; and operative as well as percutaneous revision of dialysis fistulae. The importance of misclassifying the latter group is underscored by 1984 data suggesting that up to 400 patients in Maryland were candidates for dialysis-access PTA compared with 245 patients who underwent PTA that year. Second, the code used to identify amputations did not differentiate the level of lower extremity amputation. Such coding could therefore not identify those patients in whom PTA had been used effectively to lower the level of amputation required, a practice that has been well documented to preserve patients' mobility and psyche, particularly when amputation can be limited to a transmetatarsal procedure.

Apart from limitations inherent in the procedural codes used, the study design obviated any opportunity to examine the likely possibility that PTA was employed with increasing frequency from 1979 through 1989 to treat patients with claudication as opposed to limb-threatening ischemia. As the authors acknowledged, "...the increased number of angioplasty and bypass procedures performed ... may have reduced patients' discomfort and improved their functional status—outcomes that we could not detect with the HSCRC data base." The authors later reiterated this point in defense of their original paper, stating that:

"Concern about the accuracy of the Maryland hospital discharge abstract data is justified. ... [Admittedly] ... our analysis did not provide any direct evidence regarding ... the clinical circumstances in which PTA ... is either most effective or clinically indicated. ... We thus do not think it is appropriate to draw conclusions regarding the circumstances in which PTA ... is indicated from our data."

It is nevertheless true that both the risks and cost of percutaneous revascularization increase with the complexity and extent of anatomic involvement. The decision to revascularize the patient with claudication in 1993 must therefore take into account two principal considerations. The first is the patient's symptoms. Reduction in pulse amplitude or inability to palpate one or more pulses on physical examination altogether supports a vascular basis for the patient's complaints. While noninvasive testing continues to represent an indispensable and necessary initial step in the evaluation of PAD, failure to document an abnormal ankle-brachial index at rest does not exclude the presence of severe obstruction, particularly in diabetic or other patients with calcified, noncompressible arteries. Even in the absence of extensive vascular calcification, exercise or alternative stress testing may be required to elicit hemodynamic evidence of symptomatic vascular obstructions. Duplex, including color flow, examinations may help to clarify such discrepancies. Angiographic examination, however, is still required to define the second consideration, namely, the full extent and complexity of the anatomic basis for symptomatic disability.

Once having clarified the anatomic basis for claudication, the recommendation to advise percutaneous revascularization is then individualized according to the two considerations indicated above. Two patients, for example, may be similarly limited, and in both, the degree of limitation may be inadequate to justify the risks of vascular surgical reconstruction. Diagnostic angiography may suggest that percutaneous revascularization has a high likelihood of technical success in one patient who may thus be a suitable candidate for percutaneous revascularization. In the second patient, certain risks and a complex of anatomic factors suggesting a low likelihood of acute and/or long-term success may dictate that only surgical revascularization would constitute effective therapy, in which case it may be appropriate to defer the risk of surgery until the patient is more critically disabled. Angiography may thus critically raise or lower the threshold for recommending that an intervention be performed. In previous days, when higher-risk and higher-cost surgery represented the sole option to medical and exercise therapy, it could be reasonably argued that the decision to proceed with angiography could come down to consideration of symptomatic disability only. The option of performing lower-risk and lower-cost PTA, however, implies that the threshold for responding to a given level of symptomatic disability may be raised or lowered, depending on the extent and complexity of anatomic findings.

Should the patient treated by percutaneous revascularization return with clinical evidence of restenosis, repeat percutaneous intervention is probably indicated for the same reasons that led to the recommendation for the original procedure. A certain proportion of these patients— as has been clearly documented in certain patients undergoing one or more repeat coronary angioplasty procedures—will achieve a satisfactory long-term result following the second intervention. In those who fail repeated percutaneous attempts to achieve long-term patency, the decision to undergo surgical revascularization may involve a reassessment of the patient's anatomy and clinical status.

To adopt this approach with maximum concern for safety and efficacy clearly requires coordinated input from enlightened experts in cardiology, radiology, and vascular surgery. The cost of underuse of such enlightened and coordinated input will be reflected in both loss of dollars and patient-years that might have been otherwise fulfilling and useful.

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