When Is Surgery Still the Best Option?

Given the variety of endovascular treatment modalities for lower-leg interventions, when should physicians consider surgical treatment in their patient management?

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ower-extremity arterial occlusive disease is one of the most common manifestations of atherosclerosis. Patients with this condition may present with a wide variety of symptoms ranging from mild claudication to limb-threatening gangrene. As the population ages, the prevalence of chronic occlusive disease of the lower extremity increases, significantly influencing lifestyle, morbidity, and mortality. In addition, multiple comorbid conditions increase risks of surgical procedures. Recent advances in endovascular interventions have made this minimally invasive approach an important alternative in the treatment of lower-extremity occlusive disease. However, despite rapidly evolving endovascular technology, lower-extremity endovascular intervention continues to be one of the most controversial and challenging areas of therapeutic strategy.

DIAGNOSTIC CONSIDERATION

Lower-extremity occlusive disease is often diagnosed based on a focused history and physical examination, and is confirmed by the imaging studies. A well-performed physical examination often reveals the site of lesions by detecting changes in pulses, temperature, and appearances. The bedside assessment of the ankle-brachial index (ABI) using a blood pressure cuff also aids in diagnosis. Ultrasound doppler measuring the ABI and segmental pressures are routinely utilized in clinical practice, with a relatively good sensitivity and specificity. A normal ABI is greater than 1.0. Segmental pressures are helpful in identifying the level of involvement. A decrease in segmental pressure between two segments indicates significant disease. Additionally, ultrasound duplex scans are used to identify the site of a

lesion by revealing flow disturbance and velocity changes.¹ Other noninvasive imaging technologies, such as MRI and CTA, are rapidly evolving and gaining popularity for diagnosing lower-extremity occlusive disease. Contrast angiography remains the gold standard. Using contrast angiography, interventionists can locate and size the anatomically significant lesions and measure the pressure gradient across the lesion, as well as plan for potential intervention. Angiography is, however, semi-invasive and should be confined to patients for whom surgical or percutaneous intervention is contemplated. Patients with borderline renal function may need to have alternate contrast agents, such as gadolinium or carbon dioxide, to avoid contrast-induced nephrotoxicity.

LOWER-EXTREMITY ARTERIAL LESION CLASSIFICATION

Lower-extremity arterial disease encompasses a wide range of clinical presentations, captured by two classification systems. According to the Fontaine classification, stage I implies asymptomatic disease. Stage II describes the patient with claudication—Ila for mild and IIb for severe claudication. Stage III denotes a patient with rest pain, whereas stage IV is reserved for the cases of tissue loss, such as ulceration or gangrene.² The Rutherford classification includes four grades (0-III) and seven categories (0-6). Asymptomatic patients are classified into category 0; claudicants are stratified into grade I and divided into three categories based on the severity of the symptoms; patients with rest pain belong to grade II and category 4; patients with tissue loss are classified into grade III and categories 5 and 6 based on the significance of the tissue loss.³ These

clinical classifications help to establish uniform standards in evaluating and reporting the results of diagnostic measurements and therapeutic interventions. The realization, however, that not only clinical, but also morphologic characteristics of occlusive disease dictate management options and determine treatment outcomes, led to the development of the newest classification system by a multispecialty group that included representatives from the major societies of vascular surgery, cardiology, and interventional radiology from North America and Europe. This group formed the TransAtlantic inter-Society Consensus (TASC) task force, which published classification guidelines for iliac, femoropopliteal, and infrapopliteal atherosclerotic disease.

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Based on these guidelines, femoropopliteal lesions are divided into four types: A, B, C, and D. Type A lesions are single focal lesions less than 3 cm in length not involving the origins of the superficial femoral artery (SFA) or the distal popliteal artery; type B lesions are single lesions 3 cm to 5 cm in length not involving the distal popliteal artery or multiple or heavily calcified lesions less than 3 cm in length; type C lesions are single and more than 5 cm in length, or multiple lesions between 3 cm and 5 cm in length with or without calcification; and type D lesions are those with complete occlusion of the common femoral artery (CFA), SFA, or popliteal artery.

Similarly, infrapopliteal arterial diseases are classified into four types based on the TASC guidelines. Type A includes single lesions less than 1 cm in length not involving the trifurcation; type B describes multiple lesions less than 1 cm in length or single lesions shorter than 1 cm involving the trifurcation; type C lesions are those that extensively involve the trifurcation (those that are 1-cm to 4-cm stenotic, or 1-cm to 2-cm occlusive lesions); and type D lesions are occlusions longer than 2 cm or diffuse disease.

TREATMENT INDICATIONS

Patients with vascular diseases frequently have complicated medical comorbidities. Careful patient evaluation and selection should be performed for any peripheral arterial vascular procedure. The fundamental principle is to assess not only the surgical risk from the peripheral arterial system, but also the global nature of the atherosclerotic process. Full

cardiac evaluations are often necessary due to the high incidence of concomitant atherosclerotic coronary artery disease, resulting in a high risk for ischemic events. Hertzer et al reviewed coronary angiograms of 1,000 patients undergoing elective vascular procedures and identified 25% of concomitant correctable coronary artery disease, including 21% in patients undergoing elective peripheral vascular intervention.⁴ As the population ages, an increasing number of vascular patients present with increasingly complex medical and surgical challenges.⁵ Therefore, it is imperative to understand the indications for interventions and to balance the risks and benefits of the interventional procedures.

The clinical indications for endovascular and open surgical interventions of lower-extremity peripheral arterial diseases include lifestyle-limiting claudication, ischemic rest pain, and tissue loss or gangrene. Importantly, endovascular procedures should be performed by a competent vascular interventionist who understands the vascular disease process and is familiar with a variety of endovascular techniques. In addition, certain lesions may not be amendable to endovascular treatment or may be associated with poor outcomes, such as long-segment occlusions, heavily calcified lesions, orifice lesions, or lesions that cannot be traversed by a guidewire. A proper selection of patients and techniques is critical in achieving a good long-term outcome.

WHEN IS SURGERY THE BEST OPTION?

Although endovascular intervention has been reported to be a viable treatment modality in lower-extremity arterial occlusive disease, its clinical utility and treatment durability remain a subject of debate under certain clinical circumstances. The clinical outcome of surgical revascularization, in contrast, has undergone significantly greater scrutiny in clinical trials with documented long-term durability. Under certain conditions, surgical revascularization remains a superior treatment option compared to endovascular interventions, due in part to its proven long-term clinical success. Clinical scenarios in which surgical revascularization should be considered a primary treatment include (1) multilevel disease with tissue loss or gangrene, (2) common femoral artery atherosclerosis, (3) long-segment SFA occlusion, (4) popliteal artery disease, and (5) diffuse tibial vessel occlusive disease.

Multilevel Disease With Tissue Loss or Gangrene

Patients who have critical limb ischemia with tissue loss or gangrene frequently present with a multilevel atherosclerotic occlusive pattern in which the disease process may involve aortoiliac, femoropopliteal, and tibial arterial segments. In those patients with focal or short-segment iliac stenosis, such as TASC A or B lesions, along with long-segment infrainguinal occlusive disease, a combined treatment

approach of iliac stenting and infrainguinal surgical revascularization may provide an optimal therapeutic strategy to improve critical limb ischemia. In contrast, endovascular interventions of multilevel aortoiliac and infrainguinal disease may not be sufficient to provide adequate flow to heal lower-extremity gangrene or tissue loss. With a combined treatment approach, balloon angioplasty with stenting of the iliac lesion may be performed initially, then followed by a staged lower-leg revascularization using saphenous vein grafts. Alternatively, the combined procedures may be performed concomitantly in the operating room under the same session of anesthesia.6 One advantage of such a combined treatment strategy includes potentially reduced patient anxiety given that one anesthetic session would enable the treatment of multilevel occlusive disease. In addition, surgical debridement of a foot ulcer or gangrene may be performed at the same time, if warranted.

Another pattern of critical limb ischemia, which is commonly encountered in diabetic patients, is diffusely diseased or calcified femoropopliteal and tibial vessels. Endovascular intervention of multilevel calcified infrainguinal arteries has met with limited clinical success with poor long-term durability. In this circumstance, diffusely diseased infrainguinal and tibial vessels are best treated by surgical bypass, typically from the CFA to a tibial artery or pedal artery. Vein bypass grafts to tibial arteries have a 5-year primary patency rate of approximately 67%, which is equivalent to vein bypass to the popliteal level for patients with critical limb ischemia.⁷ Limb salvage after femoral-tibial bypass is at least 80% at 5 years. Similarly, bypass graft patency rate after pedal bypass is comparable to tibial artery revascularization. In a series of more than 1,000 pedal bypasses, primary patency at 5 years was 57%, with 78% limb salvage and 49% patient survival.

For patients without a suitable venous conduit in whom endovascular therapy is not appropriate or fails, bypass with a prosthetic graft can be performed, but the primary patency rate at 5 years averages only 14%. Use of a vein cuff at the distal anastomosis may improve patency, as it does with below-knee popliteal bypass. One center recently reported a 4-year primary patency rate of 63% for tibial bypass using prosthetic grafts with a distal vein cuff.⁹

These results are superior to those obtained with endovascular treatment. Surowiec et al studied a large group of patients with various stages of SFA disease who presented with symptoms ranging from claudication to tissue loss. ¹⁰ One of the unique features of this series is that concomitant procedures to improve the inflow or outflow were only performed in 2% of patients. Thus, it provides an accurate estimate of failure patterns related to disease located only to the SFA territory. For patients with TASC C and D lesions, the patency rates at 12 and 24 months were 16% versus 3%, and 2% versus 0%, respectively. ¹⁰ Similarly,

Parsons et al analyzed their experience with PTA performed for stenotic or occlusive lesions in patients with limb-threatening ischemia. The 1-year patency rate for SFA, popliteal, and tibial lesions was less than 15%. The investigators concluded that PTA should not be considered a routine primary treatment modality for patients with infrainguinal arterial occlusive disease who also have limb-threatening ischemia, except in unusual circumstances of high-risk individuals. The fact that patients with critical limb ischemia usually have a long-segment SFA occlusion poses special therapeutic challenges and will be discussed separately. Overall, it is now accepted that the presence of TASC C and D lesions in this patient population makes surgical reconstruction a better choice.

Several studies have attempted to address the issue of the most appropriate conduit, since the first femoropopliteal bypass grafting with autologous saphenous vein was performed by Kunlin¹² in 1949. Despite significant variation among different series, 5-year patency rates for infragenicular femoropopliteal and femorotibial bypass performed for critical limb ischemia using autologous conduit averages 67%.6 An early randomized study comparing the autologous vein with PTFE showed that, in the above-the-knee position, there was no significant difference in the 4-year cumulative patency rate, ¹³ encouraging interventionists to advocate use of PTFE for primary femoropopliteal bypass grafting, preserving the saphenous vein for later use. 14 More recently, however, in a randomized, multicenter, controlled trial that included 752 veterans at 20 Virginia medical centers, the long-term efficacy of the autologous saphenous vein as a conduit for bypass to the above-the-knee position was compared to that of PTFE and human umbilical vein (HUV). In the 2-year follow-up, patency rates were only slightly different among the groups (82%, 69%, and 70% for the saphenous vein, HUV, and PTFE groups, respectively). In the 5year follow-up, however, the saphenous vein was found to be superior to HUV, and PTFE with patency rates of 73%, 53%, and 39%, respectively. 15

Conversely, it is widely accepted that at the below-the-knee position, the saphenous vein represents a better choice than PTFE (49% vs 12% patency rate at 4 years). 13 Consequently, PTFE has been regarded as a poor alternative at the more distal site. 16.17 In the absence of veins, the use of an interposition vein cuff has been advocated to improve the patency of below-the-knee popliteal PTFE grafts. 18 Raptis and Miller 19 reported the results of primary femoropopliteal PTFE grafting with or without an interposition vein cuff. They found no difference in the patency rates between cuffed and direct suture for above-the-knee popliteal bypass grafts (85% vs 82% at 12 months, and 69% vs 68% at 36 months, respectively). There was, however, an appreciable difference for the below-the-knee bypass grafts

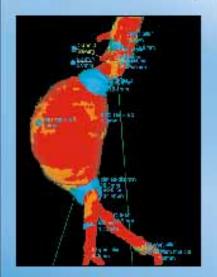
(83% vs 66% at 12 months, and 57% vs 29% at 36 months, respectively). Stonebridge²⁰ reported similar results: in a multicenter, randomized study that included 261 patients, the 12-month patency rates for anastomoses with and without a vein cuff for above-the-knee bypass grafts were 80% and 84%, respectively, as opposed to 80% and 65% for below-knee bypass grafts. At 2 years, the patency rates for the below-the-knee cuffed and uncuffed bypasses were 52% and 29%, respectively.²⁰ Interestingly, despite the improved patency rates after the performance of a vein cuff for infragenicular bypass, the overall limb salvage rate did not improve.²¹

CFA Atherosclerosis

Isolated atherosclerotic lesions of the CFA are uncommon but can be associated with disabling peripheral ischemic symptoms when compared to similar lesions in the SFA because claudication involves both the thigh and calf, and usually limits walking distance substantially. Bending at the hip joint puts the stent at great risk for fracture and recurrent stenosis. One must be cognizant that technical failure

or procedural complications, such as arterial dissection, may occur after endovascular interventions, including balloon angioplasty or catheter-directed atherectomy. In the event that these endovascular complications occur, arterial stent placement may be necessary to salvage the procedural failure. When stent placement is necessary to correct a CFA dissection after endovascular intervention, the result may be further complications such as stent fracture or migration due to the constant flexion of the hip joint. For this reason, endovascular CFA intervention should be discouraged because procedure-related complications cannot be salvaged with intraluminal stent placement. CFA endarterectomy with patch angioplasty, however, is an operation of proven value in cases of CFA atherosclerosis or procedural complications.²² In one study, in 22 of 29 patients who underwent CFA endarterectomy with vein patch angioplasty, the 5-year patency rate was 94% and was associated with significant relief from symptoms and limb salvage rates. Only one immediate postoperative failure as a result of residual disease in the profunda artery and SFA was noted in this series. The durability of the procedure was attested by

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the presence of only one late complication in the form of aneurysmal dilatation at the endarterectomy site.

CFA endarterectomy can be combined with endovascular strategies to address concomitant disease of the ipsilateral iliac artery during the same procedure. Nelson et al²³ reported 100% technical and 97% clinical success rate with a combined CFA endarterectomy and external iliac artery stenting that did not cross the inguinal ligament. For both the stent and the endarterectomy sites, the 1-year primary and primary assisted patency rates were 84% and 97%, respectively.

Long-Segment SFA Occlusion

Depending on coexisting inflow or outflow disease, long-segment occlusion of the SFA can result in symptoms including claudication, rest pain, or tissue loss. The SFA is exposed to special mechanical influences. The superficial course of the artery with relation to flexion points and interaction with the surrounding musculature exposes the vessel to relevant external forces of compression, torsion, and elongation that have a negative impact on vessel patency after both angioplasty and stenting. In fact, stent compression was identified early as one of the principal causes of restenosis, particularly after implantation of balloon-expandable stents.²⁴

As a result, endovascular treatment of a long-segment occlusion is largely disappointing. Smith et al reviewed their experience of 43 patients who underwent subintimal angioplasty for SFA occlusion. Patency at 12 and 36 months on an intention-to-treat basis was 69% and 58% for patients who presented with claudication. Moreover, the 12-month patency rate for patients with critical limb ischemia was only 25%. Length of the occlusion greater than 10 cm was found to be a predictor of reocclusion. The investigators concluded that subintimal angioplasty, especially in the treatment of critical limb ischemia, should be reserved for patients who cannot tolerate surgical reconstruction.²⁵ Scheinert²⁶ performed systematic radiographic screening to detect stent fractures in patients who underwent selfexpanding nitinol stent placement in the SFA to treat longsegment occlusions. The mean length of the stented segment in this series was 15.7 cm. After a mean follow-up time of 10.7 months, 24.5% of stents developed fractures. Interestingly, the fracture rate correlated with the length of the stented segment and was 52% for treatment length greater than 16 cm. The patency rate at 12 months was 84.3% for the subgroup of patients without stent fractures versus 41.1% for the group that had stent damage. Direct lumen occlusion by the fragmented stent, as well as arterial mechanical injury²⁷ from the chronic vessel-stent interaction, are thought to be among the main mechanisms that account for high reocclusion rates after stent fracture. The results after placement of the stent graft in the SFA appear

to be similar. In a series of 35 patients with a median occlusion length of 22 cm, Bauermeister et al reported cumulative primary and secondary patency rates of 73.2% and 82.6%, respectively, at 1 year.²⁸

In sharp contrast to these numbers, as previously discussed, the open surgical bypass with saphenous vein at the above-the-knee position averages a 5-year patency rate of 73% and constitutes the treatment of choice in good-risk patients with long-segment symptomatic SFA occlusions.¹⁵

Popliteal Artery Disease

Isolated popliteal artery occlusive disease requiring either surgical or endovascular intervention is relatively uncommon. In contrast, popliteal artery aneurysms represent the most common indication for isolated popliteal artery interventions. Treatment is indicated for symptomatic or complicated aneurysms of the popliteal artery, whereas the management of asymptomatic aneurysms is more controversial. The presence of thrombus, aneurysm diameter greater than 2 cm, and poor runoff are all postulated as risk factors for the development of complications, ²⁹ and therefore several investigators recommend repair of even an asymptomatic popliteal aneurysm. ³⁰⁻³²

The goals of surgical treatment of popliteal artery aneurysms are isolation of the aneurysm, preventing distal embolization, and effective revascularization. Five-year patency rates after surgical repair are approximately 90% for asymptomatic aneurysms and 75% in patients with symptoms, 31 whereas the surgical mortality rate ranges from 0% to 1% in asymptomatic patients and 2.1% in patients presenting with acute symptoms. 32

Attempts for endovascular treatment of popliteal disease have been made. Unique anatomic and mechanical characteristics of the popliteal artery, however, limit the range of these interventions under the current stent technology. The popliteal artery bends, shortens, rotates, and compresses during normal-range knee movement. The stents available today are not designed to withstand this combination of forces.³³ Although reports of covered stent placement to treat popliteal aneurysms have been published, the patency rates appear to be inferior to those of open reconstruction. Early experience emphasized that this technology should be reserved for patients unfit for open surgery because of concern of inferior patency rates.³⁴ More recently, Tielliu et al reported their experience with 21 patients who underwent Viabahn (Gore & Associates, Flagstaff, AZ) stent graft placement for popliteal aneurysms and noted that, despite their initial 100% success rate, 22% of the grafts occluded within an average follow-up of 15 months.35 In the most encouraging series to date, Antonello et al presented a prospective randomized trial comparing open and endovascular intervention for the management of popliteal aneurysms using

the Viabahn endoprosthesis.³⁶ They reported a primary patency rate at 48 months of 81% and 80% for the open and the endovascular arm, respectively. Given the small population size and the limited power, the results of this study must be viewed cautiously; in addition, the patency rates reported for the open procedure appear to be inferior to historical data.³⁶

Diffuse Tibial Vessel Occlusive Disease

Isolated tibial disease is relatively uncommon except in diabetics, who often present with tissue loss on the foot and have a palpable popliteal pulse but absent pedal pulses. Arteriography typically demonstrates diffuse disease of all tibial arteries, with sparing of the pedal arteries. Tibial PTA is not recommended for claudication and is very rarely indicated for critical limb ischemia that is associated with diffuse multisegment disease and is treated with surgical bypass. No large studies of isolated tibial angioplasty are available because the procedure is usually performed in conjunction with more proximal revascularization, and the role of endovascular intervention for patients who present

with limb-threatening ischemia and localized infrapopliteal disease remains controversial. Low technical success rates. especially when treating occlusions, vessel thrombosis, distal embolization, and recurrent stenosis are some of the issues associated with infrapopliteal angioplasty. Soder et al. reported a 61% technical success rate in treating occlusions and a 52% restenosis rate for tibial stenoses or occlusions at 10 months. However, in this series, an 80% cumulative limb salvage rate was noted at 18 months.³⁷ Clinical success in cases of infrapopliteal PTA is usually superior to angiographic patency because once healing has occurred, even if the artery restenoses or occludes, collateral flow can be sufficient to preserve tissue integrity if there is no further injury.³⁸ The use of stents in the infragenicular territory has not yet been widely adopted and, despite some initial encouraging results,³⁹ additional trials are necessary to establish its role in the management of patients with severe limb ischemia.

This group of patients is best managed with a vein bypass graft from the popliteal artery to either the dorsal pedal or posterior tibial artery below the malleolus. Occasionally, the



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bypass is placed to a branch of one of these arteries (either a tarsal or plantar artery, respectively). The greater saphenous vein, usually from the same extremity, is the conduit of choice for these operations. If saphenous vein is not available, or if it needs to be saved for imminent coronary or contralateral leg operation, then harvesting arm veins, lesser saphenous vein, or the vein of Giacomini is an acceptable alternative.⁶ Diabetes, ABI < 0.7, age younger than 70 years, and coronary artery disease are independent predictors of the need for revascularization in the contralateral extremity. Contralateral intervention is required in 8% of patients with none of these risk factors, and in 67% of patients with all four risk factors. 40 Finally, for those patients who do not have an adequate vein conduit and those at very high operative risk, tibial angioplasty is an acceptable alternative.

SUMMARY

Despite advances in technology and the promising outcomes from a broad range of endovascular interventions, there are still patterns of atherosclerotic occlusive disease in which intraluminal treatment produces less than optimal results. Surgical revascularization, as supported by long-term follow-up clinical studies, remains an effective and durable treatment option in selective circumstances. Careful evaluation of the disease distribution, analysis of each individual patient's risk profile, and versatility in choosing the most appropriate open or endovascular strategy are crucial for successful long-term clinical outcomes.

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