Surgical Versus Endovascular Revascularization in the Critical Limb Ischemia Patient

Guiding treatment decisions based on lesion characteristics, patient characteristics, and indications for intervention.

BY ERIC C. SCOTT, MD

This year marks the 10-year anniversary of the BASIL trial, the first and, at present, the only randomized, controlled trial comparing outcomes in patients with critical limb ischemia (CLI) treated by balloon angioplasty or surgical bypass.[1] Investigators in the UK randomized patients who were "equally well treated" to either angioplasty alone or bypass surgery, and 5-year amputation-free survival did not differ significantly between groups. The trial brought additional legitimacy to the application of endovascular therapies but did little to guide physicians through the myriad clinical scenarios they encounter in patients with CLI. Subsequently, the Trans-Atlantic Inter-Society Consensus (TASC) guidelines provided well-defined treatment recommendations based upon lesion length, location, and presence of occlusions, but even these are irrespective of presenting symptoms (claudication or CLI).[2,3] In short, there are no data from randomized, controlled trials or current guidelines that outline how to treat every unique patient in need of revascularization. The BEST-CLI trial, a randomized, controlled trial comparing best endovascular therapy to best surgical therapy in patients deemed equally treated by either, has recently begun, but is not anticipated to be completed until 2018.

SURGERY AND ENDOVASCULAR THERAPIES ARE FUNDAMENTALLY DIFFERENT

Nothing accentuates the benefits and limitations of an endovascular device or surgical procedure more than using them frequently. Push each to its limits, and the differences become more apparent. When the BASIL trial was published in 2005, it was standard practice to perform femorotibial bypass with the greater saphenous vein (GSV) for a patient with a nonhealing ischemic foot ulcer and both superficial femoral and tibioperoneal disease. In the PREVENT III trial, a study of 1,404 CLI patients who were treated with vein bypass between 2001 and 2003, the morbidity and mortality of surgical bypass were well documented. Perioperative mortality occurred in 2.7% of patients, and postoperative myocardial infarction occurred in 4.7% of patients. Early graft occlusion was reported in 5.2% of patients.[4]

Today, these same patients are more frequently treated by endovascular techniques alone. General anesthesia and hospital admission can often be avoided. Pulses can be restored to the foot, and multiple tibial arteries can be recanalized if necessary to restore circulation to appropriate angiosomes. Wounds can heal rapidly without creating additional surgical wounds.

From this perspective, it would be hard to justify continued use of surgical bypass if not for two key limitations of endovascular therapies. The first is technical success. Chronic total occlusions are nearly always present in patients with CLI, yet they are successfully crossed in only 85% to 90% of cases. As these lesions increase in length and extend into the tibioperoneal arteries, the difficulty increases. In contrast, surgical technical success rates approach 100%.

The second limitation is restenosis. There are ample 1-year primary patency data that suggest this problem is infrequent, yet these data more frequently derive from patients with claudication or from studies in which TASC D lesions are almost always excluded. So, regardless of whether 5% or 25% of patients with CLI develop early and/or rapid restenosis, select patients will have successful procedural "half-life" measured in weeks to months and at some point may require surgical bypass to end the cycle of reintervention and restenosis.

THREE KEY FACTORS INFLUENCING THE TREATMENT DECISION

Before making treatment decisions, hemodynamic and angiographic information should be obtained for the affected extremity. An arterial duplex examination can reveal the severity and location of arterial stenoses or occlusions, while the ankle-brachial index quantifies the severity of arterial insufficiency. Diagnostic angiography with selective imaging in the setting of the endovascular therapy can be performed as necessary to obtain high-quality images from the aorta to the toes. In patients with CLI, this includes magnified anteroposterior and lateral images of the foot after administration of intra-arterial nitroglycerin.

Due to the minimally invasive nature and proven efficacy of endovascular revascularization, each CLI patient should be approached with a preference for these therapies. Results of every diagnostic angiogram are reviewed, and three questions related to a potential endovascular intervention should be asked: (1) What is the likelihood of technical success? (2) What is the projected patency? and (3) Will any important collateral vessels or bypass targets be jeopardized in the attempt? The answers to these questions support a safe and effective endovascular approach in the majority of cases. However, certain factors or a combination of factors make surgical bypass a necessary and valuable alternative.

Lesion Characteristics

The success or failure of endovascular therapy is determined largely by lesion morphology and length. These two factors introduce significant variability into each procedure, and this heterogeneity is further compounded by multilevel occlusive disease, which many CLI patients have.

Stenoses

Patients with stenoses of the iliac, superficial femoral, popliteal, and tibioperoneal arteries are typically treated with an endovascular approach. These are usually technically simple to perform and have reasonable durability. Patency data for stenoses have consistently been superior to outcomes in occluded arteries, regardless of whether balloon angioplasty, stenting, or atherectomy is used.

Severe, diffuse stenoses of the common femoral artery are the one exception where I choose surgical endarterectomy provided that the patient is a reasonable candidate. The procedure requires a single incision and can be performed even under local anesthesia and sedation. The 5-year primary patency rate has been recently reported as high as 91%, and the procedure remains the gold standard therapy for this artery.[5] Directional atherectomy and 6- to 7-mm balloon angioplasty can be used for simpler, focal common femoral stenoses, with good clinical results.

Chronic Total Occlusions

Chronic total occlusions remain one of the largest obstacles to both technical success and durability of endovascular therapies in patients with CLI. In the BASIL trial, 20% of patients in the endovascular treatment arm could not be treated due to an inability to cross the lesion. However, the abundance of different wires, support catheters, and dedicated crossing devices now available has increased the ability to cross chronic total occlusions to nearly 90%. Use of retrograde popliteal or pedal access can further improve crossing rates, but the severity and/or exceedingly long length of certain occlusions makes 100% crossability a goal at this time, not a reality. In cases in which the occlusion cannot be crossed with an antegrade or retrograde approach or in the case of severe or repeated restenosis or reocclusion, bypass procedures are a valuable alternative.

Calcium

The degree of calcium deposition in atherosclerotic plaque is extremely heterogeneous, ranging from nearly absent on CT angiography to having a density greater than bone on fluoroscopic imaging (Figure 1). Severely calcified lesions, although they remain ambiguously defined, are associated with an increased risk of numer-

Figure 1. Fluoroscopic images of a heavily calcified, occluded distal superficial femoral and popliteal artery in a 74-year-old man with ischemic rest pain of the right foot.

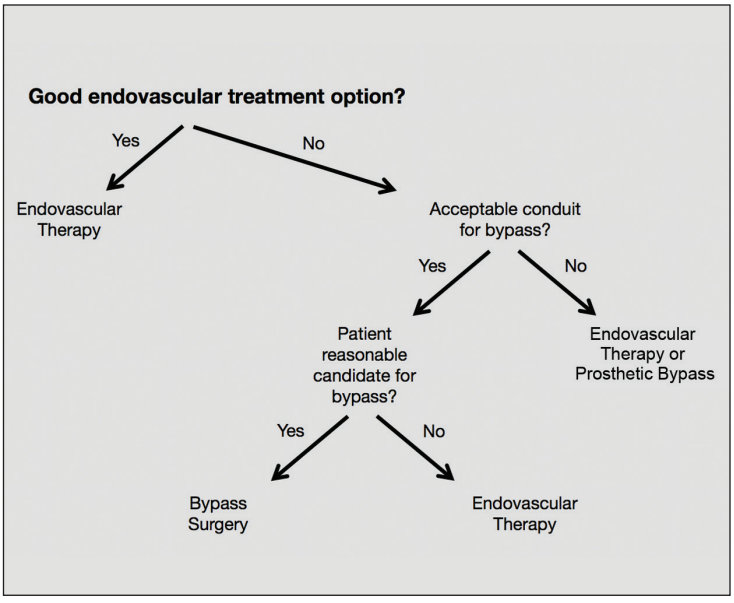

Figure 2. An algorithmic approach to the patient with critical limb ischemia.

ous complications, including distal embolization, dissection, poor response to balloon angioplasty, wire perforation when crossing occlusions or an inability to cross, and reduced primary patency. In these difficult lesions, embolic protection in combination with various forms of mechanical atherectomy can be extremely valuable in increasing technical success. I infrequently use atherectomy, angioplasty, and stenting together to treat a single lesion, but longer, heavily calcified occlusions sometimes require all available resources to achieve a satisfactory result. When this approach fails or when diagnostic imaging reveals calcification to the extent seen in Figure 1, bypass procedures should be considered.

Stent Occlusions

Acutely occluded peripheral arterial stents can be easily managed with pharmacologic and mechanical thrombolytic techniques, but treatment of chronically occluded stents in patients presenting with CLI can be significantly more challenging. Navigating a wire or crossing device through such lesions can be technically difficult or sometimes impossible. If wire traversal is accomplished, data from the recent EXCITE ISR trial show superior 6-month outcomes in patients treated with laser atherectomy and angioplasty over angioplasty alone.[6] However, the 6-month target lesion revascularization rate was 26.5% in the combination therapy arm, and only 30.5% of these patients had stent occlusions. Currently, chronic femoropopliteal stent occlusions are one of the most common indications for femoropopliteal bypass in my practice.

Patient Attributes

Several factors related directly to the CLI patient play an important role in determining appropriate initial therapy.

Medical Comorbidities

During the initial review of diagnostic images of the ischemic lower extremity, there are instances in which either the chance for endovascular technical success or the potential risks makes open surgical revascularization an appropriate consideration. Surgical risk is then calculated. The patient's comorbidities are reviewed with particular attention paid to cardiac, pulmonary, and renal disease. If the patient has severe coronary or pulmonary disease, endovascular therapy should be the preferred option in order to avoid obvious surgical risk. However, in the presence of severe renal insufficiency, surgical therapy can minimize contrast exposure.

Quality of Venous Conduit

Most patients who present with CLI have a suitable GSV for bypass. However, in the PREVENT III trial, 24% of patients did not have a suitable GSV (defined as > 3 mm in diameter throughout its length).[4] These patients, who underwent bypass surgery using spliced vein segments or GSV < 3 mm in diameter, achieved

primary patency of < 50% at 1 year. I now strongly consider endovascular solutions when the GSV is < 3 mm in diameter or has been previously harvested for coronary artery bypass grafting.

Patient Preference

Not all patients are willing to undergo open surgical revascularization. According to Medicare data, more than 40% of patients with CLI are over 80 years of age.[7] In some cases, the patient's body seems fit for open surgery, but the mind is not. In this setting, patients may accept a potentially inferior treatment if they can avoid the risk, pain, and recovery associated with open surgery. In recent years, I have witnessed a 99-year-old patient successfully undergo bypass surgery and recover. I have also witnessed much younger patients choose hospice care over surgical revascularization when endovascular solutions have failed. These types of patients should motivate us to continue advancing the capabilities of endovascular therapies.

Indication for Intervention

The degree of revascularization required will vary in patients with CLI. Patients with ischemic rest pain (Rutherford stage 4) are aided by any form of revascularization that increases perfusion pressure to the foot. This may come in the form of an iliac stent for a common iliac artery occlusion, via a common femoral endarterectomy and profundoplasty even while the superficial femoral artery remains occluded, or by popliteal or tibioperoneal interventions. Whatever the means, it is not angiosome specific, and patients with ischemic rest pain are often the easiest to manage in the short term. If there is a shortcoming of endovascular therapy in patients with Rutherford stage 4 disease, it is that rest pain often returns when the intervention begins to fail and patency is lost. If these patients are fortunate to live several years, they sometimes find themselves in a cycle of reintervention, and in this setting, bypass options should be considered.

In contrast, patients with Rutherford stage 5 and 6 ischemia are optimally treated with revascularization directed toward the area of tissue loss. Numerous publications have demonstrated improvements in wound healing and limb salvage when revascularization is delivered to the appropriate angiosome, regardless of the method (bypass surgery or endovascular therapy). However, wounds do not always correspond to a single discrete angiosome. In a recent review of CLI patients, only one-third of patients had lesions ascribed to a single angiosome.[8] Endovascular revascularization can target multiple angiosomes by treating more than one tibial artery when warranted by the region of tissue loss. This is a key distinction between open and endovascular revascularization, as surgical bypass cannot offer this.

A SIMPLE ALGORITHM

Consideration of each CLI case in terms of the lesion, the patient, and the indication for intervention is a valuable framework to organize the key details of a case. However, these key factors do not necessarily spell out a clear path of optimal intervention. An algorithm outlining an approach to the patient with CLI is shown in Figure 2. In many cases, endovascular intervention can be quickly selected as the intervention of choice, but the first question is a physician-specific question, and the algorithm may appropriately point toward an open surgical therapy. Unlike specific guidelines, this algorithm takes into consideration a physician's clinical judgment and degree of comfort with each of the treatment modalities.

CONCLUSION

Many variables must be considered when determining the optimal therapy for patients with CLI. Endovascular therapies are appropriate for the majority of CLI patients in my practice, but I remain aware of the open surgical options patients have throughout their course. These patients sometimes require the resourceful utilization of all revascularization options in order to maintain a perfused limb. It is our responsibility to choose the right interventions for the right indications in the right patient, every time. ■

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