Endovascular Management of Critical Limb Ischemia

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Abstract
Endovascular management of critical limb ischemia has advanced significantly in the recent past, especially the ability to treat tibial artery lesions with reasonable results. The indications, results, and technical aspects or endovascular management of CLI is reviewed herein. An algorithm for clinical management of CLI in patients with tibial occlusive disease is also presented.

Introduction
Endovascular reconstruction of the tibial arteries is assuming a larger role in limb salvage. The infrageniculate vascular bed has required mostly open surgery in the past, with distal vein bypass being the most common procedure. Disease in the tibial arteries tends to be diffuse and is usually a combination of long segment stenoses or occlusions. The small caliber of the arteries, the remote location, the slow flow of the distal bed, and concerns about preserving runoff capacity have combined to make this a vascular bed that presents challenges to endovascular treatment. Recent advances have enhanced our ability to use endovascular procedures to treat critical limb ischemia (CLI) caused by tibial artery occlusive disease. Improved sheaths have been developed as a result of the routine use of remote access to other vascular beds, such as the carotid system. Low profile platforms are essential in treating small caliber arteries and are being adapted to the infrageniculate vascular bed. Long balloons are used to treat lengthy segments of disease and this has helped to reduce dissection. Better antiplatelet options have been developed for the coronary and carotid beds and are being used for tibial interventions. Small caliber stents are available in both balloon expandable and self-expanding varieties, and there are several studies that will add to our understanding of their potential uses.

Improved devices and techniques have lead to increased aggressiveness in the endovascular treatment of the infrageniculate vascular bed for critical limb ischemia.

Indications
Tibial angioplasty and stenting is appropriate for limb salvage, especially when there is focal tibial disease.
Extensive tibial disease in a nonoperative candidate or a patient with no venous conduit is also reasonable. Whether endovascular tibial reconstruction is appropriate as first line treatment in all patients remains to be proven in randomized trials with long-term follow up. Surgery remains the gold standard by which endovascular interventions are measured and is still favored for appropriate surgical candidate.8

The results of tibial angioplasty and stenting are closely tied to the degree of foot damage with which the patient presents. When foot damage is in an early stage, a small improvement in perfusion may be enough to heal the lesion, even if patency is only short term. The best results are achieved when presenting ischemic foot damage is minimal; risks of intervention are low, the likelihood of damaging the runoff is low, and a leg bypass is often avoided. When there is objective evidence of ischemia and an open ischemic lesion that has caused minimal damage, endovascular is the treatment of choice, rather than waiting to see if the patient needs a distal bypass.

Unfortunately, many patients present with severe foot damage, often with ongoing or partially treated infection. When foot damage is extensive, recanalizing one tibial artery is often not adequate for limb salvage. The goal is to open as many tibial arteries as possible to provide robust in-line flow to a severely damaged foot. If the only target is an isolated segment that does not provide in-line flow to the foot, don’t waste time with endovascular. If there is significant disease at a more proximal level, in the iliac or femoro-popliteal segments, and the foot damage is minor, treat those inflow lesions first and wait to see what the clinical effect will be, especially if tibial disease appears to be high risk.

When revascularization is performed, the mainstay of therapy is balloon angioplasty. Because distal disease is usually diffuse throughout these small caliber flexible arteries, stents are not ideal and are used sparingly. Other options for tibial artery revascularization, such as cryoplasty and laser or mechanical atherectomy, remain to be proven.

Results

A number of articles and studies have been published since 1990 demonstrating the utility of endovascular angioplasty in treatment of critical limb ischemia. The Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial was published in 2005.5 This was a prospective randomized trial of 452 patients comparing patients treated with bypass-surgery-first and balloon angioplasty-first. They found no significant difference between the two arms with respect to amputation-free survival at three years. The majority of the patients in the angioplasty group (80%) had lesions of the SFA treated, and 62% of patients in the surgery group underwent more distal bypass. Long-term follow up and subgroup analysis suggest that surgery is still the best option for fit patients with adequate venous conduit for bypass, though they report a decline in the numbers of operative procedures due to improved medical and endovascular interventions.8

Faglia et al. evaluated angioplasty-first in diabetic patients with CLI.6 In their group of 993 patients, 31.8% had lesions of the infrapopliteal axis alone and 61.4% had lesions in the femoral-popliteal and infrapopliteal segments. The majority of patients underwent balloon angioplasty of multiple vessels, with success rates for PTA of popliteal and proximal vessels being significantly higher than for PTA of infrapopliteal vessels. Regardless, primary patency of the successfully treated vessels at 5 years was 88% and limb salvage was achieved in more than 98% of patients.

A recent meta-analysis of 30 articles by Romiti et al. looked at immediate technical success, primary and secondary patency, limb salvage, and survival for patients treated with infrapopliteal percutaneous transluminal angioplasty (PTA).7 These were compared to similar endpoints for patients treated with vein bypass grafts. The meta-analysis showed tissue loss and diabetes correlated with outcome (P < 0.002). There a significant difference in patency rates between vein bypass and PTA, but limb salvage rates were similar up to three years (Table 1).
Technical tips

Technical tips are provided here about sheath access, lesion crossing and guidewire access, balloon angioplasty, stenting, and managing occlusions.

Sheath access

Patients are pretreated with clopidogrel. As soon as arterial access is achieved, heparin is administered. In treating complex tibial artery occlusive disease, heparin is administered at 100 units per kg and activated clotting time is assessed and maintained at >250 s.

Angiography is performed with an up and over approach. If there is excessive difficulty with passage across the aortic bifurcation, it will become readily apparent during this simple procedure. It is difficult to plan a below the knee intervention in its entirety without an angiogram. Duplex, CT angiograms and MR angiograms are helpful, but a standard catheter-based angiogram is needed prior to intervening. The arteriogram typically influences the final choice of procedure. In general, we plan up front to perform vascular closure, unless some reason becomes apparent why closure should not be done. If an angiogram is performed initially with an antegrade approach and then the operator decides not to intervene, you are stuck with a puncture site that must be managed, and now it is proximal to a segment that may thrombose when pressure is held proximally. After the lesion is assessed and the decision is made to intervene, the distance from the puncture site to the lesion is measured.

In most patients, the sheath can usually be placed in the contralateral femoral artery allowing access to the mid-tibial level. A 90 cm sheath reaches at least to the contralateral popliteal artery in most people who are 5 foot 10 inches or less. In very tall individuals, a 90 cm sheath may reach only the mid-superficial femoral artery. If the plan is to treat the distal tibial, ankle or pedal arteries, an antegrade femoral approach should also be considered when the aortic bifurcation is so unfriendly that it is risky to use as a pathway, such as when it is aneurysmal or very narrow, heavily calcified, or very tortuous.

After measuring the distance to the lesion, the sheath must be selected. If the plan is to go up and over the aortic bifurcation but the aortic bifurcation is tortuous, it is occasionally helpful to place a 7 Fr sheath (45 cm in length) over the aortic bifurcation and then place a smaller caliber sheath (5 Fr) through it. Usual sheath lengths are as follows. Up and over interventions can be performed with a 70 cm sheath, a 90 cm sheath or a 110 cm sheath. Antegrade interventions can be performed with a 55 cm or 70 cm sheath. If there is a lot of distal SFA disease or popliteal disease, place the sheath tip proximal to that level of disease.

Most tibial interventions can be performed with 5 Fr sheaths. This permits balloon angioplasty and stents. If the operator selects cryoplasty or atherectomy, a larger caliber sheath will be required, 6 or 7 Fr. There are no stents approved for tibial interventions but the available appropriately sized self-expanding and balloon expandable stents are possible to place through a 5 Fr sheath. A larger sheath may be used, but if it is intended to place the tip of the sheath into the popliteal artery, the size of the larger caliber sheath may stop flow in this area and that may present other problems.

Place the tip of the sheath as close to the lesion as possible (Fig. 2). When disease is isolated to the tibial arteries, the tip of the sheath can be placed in the below knee popliteal artery. If a 4 Fr sheath is used, the tip can be placed directly into the tibial artery to be treated. If the patient has a more proximal lesion that requires treatment in the same procedure, such as a superficial femoral artery stenosis or occlusion, that is treated first and the sheath is advanced through the treated lesion to get closer to the tibial arteries. All this work of optimal sheath placement pays off: this permits better pushability with 3 Fr monorail catheters, less contrast, faster results, better support, less effort.

Sheaths are available in the range of 50—90 cm in length. In addition, now there is a 110 cm sheath that comes in either 4 or 5 Fr caliber that may be used. Place the diagnostic catheter during the arteriogram and use it to estimate the desired length of the sheath. When passing the
sheath, do not place a stiff guidewire into the tibial artery, it may cause damage. Keep the stiff guidewire in the popliteal artery. Place the sheath as far as possible with the exchange guidewire in the popliteal artery. If there is any excess length outside the patient and the sheath can be advanced an additional length toward the tibial artery origin, place a catheter fitted to the sheath into the tibial over a softer wire (either 0.035 or 0.014). Hold the catheter stable and advance the sheath over the catheter and guidewire combination.

**Crossing Lesion/Guidewire Access**

After the sheath is in place, a 0.014 in diameter guidewire is advanced. I like to use a steerable, soft guidewire. A 300 cm length guidewire is preferred. Even though monorail systems are employed when possible, a longer guidewire is used because the exchange catheters, such as the Quickcross, and some of the stent delivery catheters, such as the Xpert, are coaxial platforms. The guidewire tip should be angled into a hockey stick shape. The tibial artery origin is roadmapped. The guidewire may be supported by a long 4 Fr Glidecath (up to 120 cm length with angled tip). A Tuohy-Borst adapter is placed on the hub. The catheter is angled toward the appropriate tibial artery and the guidewire is advanced. The catheter is advanced into the origin of the tibial artery to support the guidewire. The guidewire is advanced to just above the lesion (Fig. 3). The tibial artery lesion is placed on a magnified field of view. Contrast is administered through the catheter so that the tibial artery will be well delineated, even if flow in it is very slow. Vasodilator may be administered through the catheter into the tibial artery. If there is an occlusion or the suggestion that thrombus is present in the tibial artery, thrombolytic is administered.

Several different oblique projections may be required to see the lesion in its best angle for guidewire passage, and adjust the image so that an important part of the lesion is not superimposed onto a bony cortex that would diminish the quality of the image. The guidewire is advanced deliberately and collaterals are avoided. After the guidewire is across the lesion, it is placed well distal to the lesion. The guidewire may be exchanged for a stiffer one if stability is an issue. The 4 Fr catheter can be advanced. If this will not pass because the lesion is too tight or the catheter is not long enough, a Quickcross catheter (either .014 or .018) may be used to pass over the guidewire and function as an exchange catheter.

**Balloon angioplasty**

Low profile monorail or coaxial balloon angioplasty catheters may be used. Monorail systems are faster and simpler to advance but only work well when the sheath tip can be placed close to the lesion as described above. Balloons are available from 2 to 12 cm in length and from 1.5 to 4 mm in diameter. The shaft length varies from 120 to 150 cm. The length of the balloon catheter should be assessed prior to insertion because there is some limitation to how far it reaches from an up and over approach. The contralateral ankle is out of reach in some patients, even with a 140 or 150 cm catheter. When approaching a lesion from the contralateral side, pushability becomes very poor when reaching toward the distal tibial and ankle. This is worsened by the fact that a long length of guidewire cannot be placed beyond the lesion since the foot is so close. If the long balloon catheter won’t advance, take the time to place a stiffer guidewire, such as an Iron man or a Confianza.

Focal tibial artery lesions of 1.5 cm or less may be treated with cutting balloon angioplasty. Longer lesions or...
multiple sequential subsegmental lesions are treated with long tibial balloons. Do your best to choose a single balloon that just exceeds the length of the lesion. An external marker is good for this and marker guidewires are also available. Compliant balloons come in a variety of sizes and the diameter can be dialed up to match the appropriate size of the normal proximal or distal artery on roadmapping. Oversizing the angioplasty balloon does not seem to be helpful. A single inflation at the desired pressure is performed and then maintained for 3 min. Anticoagulation is maintained while the artery is occluded. If it seems likely that the balloon will require more than one inflation because the lesion is too long, treat the distal lesion first. After the balloon is deflated, it will be easier to withdraw than to advance. A slow, deliberate, extended balloon inflation in only one location offers the lowest chance of dissection. After angioplasty, the balloon is withdrawn into the sheath, but does not need to be removed. If you decide to perform angioplasty again, the balloon will be ready.

A completion arteriogram is performed. If a significant dissection or an occlusion is present, repeat the angioplasty to slightly higher pressure. Make sure anticoagulation is adequate. Consider administering thrombolytic agent if there is an occlusion. An aspiration catheter, such as an Export catheter, may also be passed. Stents are generally avoided when possible but, at some point, if the dissection or the occlusion is not improved, consider placing a stent.

Stenting

Significant dissection that cannot be resolved with balloon angioplasty should be treated with stent placement. Available stents include coronary stents which are short (usually 15 mm or less) and balloon expandable. Self-expanding nitinol stents are available in small sizes (2–5 mm; Abbott Xpert). These are coaxial so a longer guidewire is required and are 4 Fr compatible. For tibial artery origin lesions, balloon expandable stents are desired because of accuracy of placement. Self-expanding stents are longer, more flexible, and are better suited to the tibial arteries distal to the origin. Because of the remote location, the stent deployment process is influenced by a number of forces causing extra play in the system. Therefore the process is performed carefully under magnified fluoroscopic observation. After stent placement, post-stent balloon angioplasty is performed to seed the stents. The patient must be warned to avoid future blood pressure cuff inflation on the leg.

Managing occlusions

Enter the tibial artery as described above. Place a Quickcross .018 catheter (Fig. 4). Through the catheter, place a V18 Control wire (Boston Scientific). Push the V18 guidewire into the occlusion. Push as far as it goes easily. When it stops, push the Quickcross catheter. Sometimes the catheter will go on its own. It has markers on the tip and is relatively stiff. It can be used with the guidewire in a “hopscotch” manner. Don’t try to form a loop with the tip of the wire as is done for subintimal angioplasty in the femoro-popliteal segment. After crossing the occlusion, sometimes it is difficult to get contrast to go into the artery distal to the occlusion to confirm guidewire positioning. Administer nitroglycerine and perform delayed imaging. After crossing the occlusion, perform balloon angioplasty as you would have if it were a stenosis. Be careful with the stiff tip on the V18 wire.

Discussion

Our algorithm for treating infrapopliteal lesions that cause CLI is shown in Fig. 5. If adequate inflow can be established by treating a more proximal lesion and the foot damage is minimal, treat the inflow and follow the patient closely with duplex and clinical exam. If the foot damage is major, treat all

Figure 4 Shown here is an occlusive lesion with distal reconstitution (a) A Quickcross catheter is used to cross the lesion (b) and advance a guidewire into the distal reconstituted artery (c).
levels of disease, including the tibials. If tissue loss appears to be major and the runoff in that limb is poor, consider bypass first in that group: this is approximately 20% of the patients in our practice. When tibial intervention is indicated, determine if the lesion is focal or diffuse. PTA using a short coronary balloon or a cutting balloon is performed for focal lesions. Longer lesions may require either a long, low profile balloon or plaque debulking (we use the excimer laser). If there is severe dissection that cannot be resolved with repeat balloon inflation, consider placement of a bare metal or drug eluting stent.

Conclusion

Endovascular reconstruction of infrapopliteal lesions in critical limb ischemia is a reasonable and effective approach in the appropriately chosen patient. Choosing the best access for below the knee interventions is instrumental in setting the operator up for success and subsequent positioning of an adequate sized sheath with the tip close to the lesion is an essential maneuver. The techniques described here are a guide to approaching distal lesions in patients with critical limb ischemia. This field will continue to evolve as advances are made in stent and instrument technology and may achieve parity with open bypass procedures.

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