Treatment of Infrapopliteal Arterial Occlusive Disease in Critical Limb Ischemia

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Infrapopliteal Arterial Occlusive Disease

There is increasing evidence supporting endovascular intervention in patients with critical limb ischemia (CLI) and infrapopliteal artery occlusion where in-line flow to the foot can be reestablished. Patients with CLI due to infrapopliteal arterial occlusive disease are a high-risk group in which the current reported amputation and mortality rates at 1 year are 25% and 20 to 25%, respectively.^{1,2} Treatment of infrapopliteal arterial disease is vital to prevent amputation, relieve ischemic pain, heal lower extremity wounds, and prevent gangrene.

Technical success rates are often high (approaching 90%) in infrapopliteal angioplasty, with associated clinical success of approximately 70% in some larger series of patients with CLI.³ Predictors of a successful outcome include a short occlusion length and minimal vessels or stenoses needing treatment. The updated Trans-Atlantic Inter Society Consensus (TASC)-II guidelines concluded that there is increasing evidence to support the recommendation for angioplasty in patient with CLI and infrapopliteal artery occlusion; lesion length alone is no longer used to determine a recommendation for treatment (as was seen with the TASC-1 guidelines).¹ The following procedure describes our approach to treating infrapopliteal arterial occlusive disease.

Preprocedure

Initial evaluation of the patient begins with a detailed history and physical exam, including specific lower extremity evaluation with pulse exam at all levels. This is followed with a noninvasive workup including ankle-brachial index, segmental pressures, and pulse volume recordings in the lower extremities. Based on the results of these studies, computed tomographic angiography or magnetic resonance angiography (MRA) may be performed of the lower extremities for further evaluation and procedural planning. When using

MRA, we preferentially use dynamic time-resolved MRA of the calf station to better evaluate tibial vasculature and avoid venous contamination, which further aids in treatment planning.

Routine laboratory tests are drawn on the day of the procedure to ensure that the platelet count is > 50,000/dL, and the international normalized ratio is < 1.5. If needed, blood products are administered to correct these parameters. Routine serum creatinine is also drawn on the day of the procedure. Typically for extremity arteriograms, iodixanol [Visipaque] is used as the contrast agent, as it causes less injection-related pain compared with other agents. In patients with renal failure, carbon dioxide (CO₂) can be used as a contrast agent, which is typically adequate for imaging to the knee but is often suboptimal in the infrapopliteal region with multiple occlusions. Almost all of our cases are performed under conscious sedation with the intravenous administration of fentanyl and midazolam.

There is no consensus on a protocol for antiplatelet therapy in patients undergoing infrapopliteal intervention, although the trend is to load patients preprocedurally. Ideally, patients are preloaded with 300 mg of oral clopidogrel before the procedure, or started several days before the intervention. Aspirin (81 mg) is also given for several days preprocedure when possible.

Procedure

The initial decision is made either to make a retrograde puncture into the contralateral common femoral artery and cross up and over the aortic bifurcation or to access the ipsilateral common femoral artery using an antegrade approach. In most patients, we favor a contralateral up and over approach, as it is easier to manage the femoral puncture, particularly in obese patients, and does not preclude the use of antegrade techniques if required. An antegrade puncture

adds some in-line stability for crossing occlusions, and is also the preferred access when patients have had previous aortoiliac endovascular repair where the bifurcation is too steep to cross. It may also be required for distal pedal intervention or in very tall patients when length of the equipment may be of concern. The frequently used contralateral approach is described later (► **Fig. 1**).

Arterial access to the contralateral femoral artery is obtained using a combination of fluoroscopic landmarks and ultrasound with micropuncture technique. Close attention is paid to accessing the common femoral artery at the level of the middle third of the femoral head. Under ultrasound guidance, the femoral artery is accessed at a site where it is > 5 mm in diameter in an area of minimal anterior wall

calcification. Before percutaneous puncture, the soft tissues are anesthetized with 1% lidocaine, a small incision is made in the skin, and blunt dissection is performed to the depth of the common femoral artery.

After a single-wall puncture of the common femoral artery under ultrasound guidance, a 0.018-in wire is advanced under fluoroscopic guidance, and a 5F transitional sheath is placed. The inner dilator and 0.018-in wire are removed, and a 0.035-in wire is advanced into the aorta. The transitional sheath is then exchanged for a 5F vascular sheath. An ipsilateral oblique common femoral arteriogram is then performed to ensure satisfactory access site in the common femoral artery, and to assess the anatomy in planning for closure at the termination of the procedure.

Figure 1 (A) Popliteal arteriogram reveals an occlusion in the distal popliteal artery (arrow). The distal popliteal artery occlusion is crossed with a V18 wire and 0.018-in Quick Cross catheter, and the catheter is advanced into the posterior tibial artery. Contrast injection (B) confirms catheter location across the occlusion within the posterior tibial artery. (C) Angioplasty of the distal popliteal artery and the posterior tibial artery is performed with a low-profile 2.5-mm balloon. Postangioplasty arteriogram (D) reveals improved flow across the infrapopliteal stenosis, with persistent luminal narrowing (arrow). (E) A balloon expandable stent is advanced to the location of the residual infrapopliteal arterial stenosis (arrow). The stent is deployed, and postdeployment arteriogram (F) reveals significantly improved luminal diameter and flow through the distal popliteal and proximal posterior tibial artery with decreased filling of collateral arteries.

A 5F SOS Omni flush catheter (AngioDynamics, Latham, NY) is advanced over the guidewire to just above the iliac bifurcation. If needed, an arteriogram is performed to assess the iliac and femoral arteries. Using the arteriogram as a guide with image overlay, a 0.035-in stiff angled Glidewire (Terumo, Somerset, NJ) is advanced through the SOS Omni catheter up and over the aortic bifurcation, and the catheter is advanced over the Glidewire into the contralateral external iliac artery. Runoff arteriography is performed with orthogonal views obtained in the infrapopliteal segment and foot. The Glidewire is exchanged for a 0.035-in Amplatz wire (Cook, Flagstaff, AZ), and the 5F catheter and sheath are removed over the wire and exchanged for a 6F, 45-cm Destination sheath (Terumo), which is advanced over the aortic bifurcation into the contralateral superficial femoral artery. In practice, we place the sheath as deep into the superficial femoral artery as possible, as long as it is not occlusive, to provide maximal support. The sheath is connected to a heparinized saline drip. Low-dose IV unfractionated heparin is administered to achieve an activated clotting time (ACT) > 250 seconds. The dose given may be weight based (75–100 units/kg), but a bolus of approximately 5,000 units is typically sufficient in most patients.

As a principle, large vessel inflow lesions such as aortoiliac, femoral, and popliteal segments should always be treated first. The goal of infrapopliteal revascularization is to establish in-line flow with at least a single vessel to the foot to relieve rest pain or heal an ulcer. Although wound healing can occur with indirect revascularization with flow through collaterals, direct revascularization of the angiosome of interest likely increases chances of healing and is preferred when possible. It is controversial whether to attempt single or multiple vessel recanalizations; in general, our preference is to attempt to open as many infrapopliteal arteries as possible within reason.

To cross an infrapopliteal arterial occlusion, we initially use a low-profile (0.014 or 0.018 in) system with an attempt to remain intraluminal (→ **Fig. 1A**). We always use exchange length (260 or 300 cm) wires to cross occlusions, as occasionally the support catheter will not track across a particularly tight area. Use of an exchange length wire allows for the use of other devices before giving up the access. Balloon angioplasty of the tract leading up to the stenosis, or use of a 1- to 2-mm low-profile coronary balloon across the lesion may salvage the access. Our most commonly used support catheter is a 0.018-in Quick Cross catheter (Spectranetics, Colorado Springs, CO), which we often use with a V-18 or Grand Slam wire (Boston Scientific, Natick, MA; Abbott, Abbott Park, IL), although a wide variety of chronic total occlusion (CTO) wires are available adapted from coronary technology. The distance of the wire tip from the support catheter determines its stiffness. With the wire tip just protruding from the support catheter, a wire of almost any tip load becomes very rigid. We initially attempt to pass the fibrous cap at the point of occlusion with the V-18 wire at a distance from the support catheter, but if it does not pass, we advance the support catheter to the tip of the wire and push the system as a unit. If this does not cross the occlusion, we may use the back end of a CTO wire to start the arterial dissection, advance the support catheter into the occlusion, and covert

back to the front end of the wire to cross the remaining length of the occlusion. Although an attempt is made to stay intraluminal, the earlier-mentioned technique may result in subintimal dissection, which is typically evidenced by spiraling or loop formation of the wire. Although there are many devices currently available on the market for crossing CTOs, we find that the method described earlier is inexpensive, safe, and typically effective.

If the wire does form a loop, the loop is advanced in the subintimal space toward the distal end of the occlusion. The catheter is then advanced to the distal end of the occlusion, with close attention paid to not making the subintimal tract excessively large near the intended reentry point by extending the loop beyond the distal end of the occlusion. It is critical to reduce the loop near the intended area of reentry. With the wire just out of the tip of the catheter, probing of the wire is performed to advance into the true lumen. Intraluminal passage is often recognized by free rotation of the wire in the unconstrained distal vessel.

Subintimal crossing can be a fast and easy way to cross long length tibial CTOs. The main complication of this technique is compromise of important collateral arteries if reentry is not achieved and the subintimal plane is extended, which could worsen the patient's CLI. A 0.035-in wire system can be used for better support, although there is a greater risk of perforation. When using a 0.035-in wire system, a J-tip Glidewire may be quite useful for starting or crossing the majority of the subintimal tract, although we prefer to reenter with an angled wire without a loop. If crossing with a 0.035-in wire system, after achieving reentry we will convert back to a 0.014- or 0.018-in platform to use long tibial balloons for angioplasty of the tract.

If perforation is encountered in the calf region where compartment syndrome is a concern, prolonged balloon inflation or external manual compression or compression with a blood pressure cuff can be performed for 3 to 5 minutes. Angiography is then repeated to ensure that the perforation has sealed. Crural artery perforation rarely results in compartment syndrome, although management can be performed in a similar fashion.

Once the support catheter is past the occlusion, blood is aspirated before contrast injection to confirm location within the true lumen (→ **Fig. 1B**). If reentry cannot be achieved from an antegrade approach, retrograde crossing from a distal tibial or pedal access or subintimal arterial flossing with antegrade–retrograde intervention can be used.⁴ These techniques greatly add to the success rate of treating tibial CTOs. Retrograde access is obtained in the distal target artery (anterior tibial/dorsalis pedis, posterior tibial, or peroneal artery) with ultrasound or fluoroscopic guidance, and a retrograde true lumen or subintimal channel is created. A guide wire is used to connect the retrograde and antegrade subintimal channels simultaneously to create an externalized guide wire. The objective of retrograde access is to cross the occlusion with a low-profile access, and as early as possible convert to an antegrade intervention. We typically use the inner 3F dilator from a micropuncture kit without a sheath and similar crossing wires to those used during an antegrade approach. After the access has been converted to antegrade

and the lesion has been crossed with the externalized wire, the retrograde access is removed and hemostasis is obtained with light manual pressure. If needed, balloon angioplasty across the access may help seal the access point, although it is rarely required.

With any of these techniques, once guidewire access is obtained across the occlusion with a 300-cm, 0.018-in Grand Slam wire (Abbott), balloon angioplasty is performed from an antegrade approach with a low-profile balloon (►Fig. 1C) such as a Coyote (Boston Scientific). Tibial balloons are generally on the order of 1.5 to 3 mm in diameter, with the length tailored to the length of the occlusion/subintimal tract. Long balloons are used to cover the entire treatment segment with long, slow inflations. Follow-up arteriography is performed, and if there is a focal residual flow-limiting stenosis then the lesion is stented (►Fig. 1D–F). Long segment dissections are treated first with repeat angioplasty. If bailout stenting is required, we will often use drug-eluting coronary stents, given their improved patency and favorable outcomes with early data compared with bare metal stents.⁵ These are used primarily in noncompressible areas such as the upper calf. We typically oversize stents by 10% and deploy them using roadmap or image overlay technique. Completion angiography is performed both at the treated level and at the level of the foot to ensure maintained pedal arterial supply. Self-expanding bare metal stents are used when bailout stenting is required and the treatment area is mobile or compressible, such as at or near the ankle.

With tibial interventions, we routinely use 100 to 200 µg injections of nitroglycerine to treat spasm during the procedure and monitor the ACT at least every 30 minutes to ensure adequate intraprocedural anticoagulation.

When satisfied with the intervention, an ACT level is checked, and if less than 200, the catheter and sheath are removed and hemostasis at the arteriotomy site is achieved with a closure device if the anatomy and arteriotomy site are favorable. If the ACT is elevated, protamine is administered before closure. Hemostasis is ensured after closure with a short period of manual compression.

Postprocedure

Distal pulses are evaluated at the completion of the procedure to ensure there was no procedure-related complication. The patient is transferred to the postanesthesia care unit for monitoring, and is observed for 3 to 6 hours postprocedure with routine monitoring and postangiography care provided. Dual antiplatelet therapies are typically continued for 3 months.

If not already performed, referral to a wound care laboratory is critical to ensure that chances of wound healing are maximized.

Discussion

Advancement in endovascular techniques has resulted in substantial growth in endovascular tibial, peroneal, and pedal arterial revascularization, and it has become a well-accepted

treatment for CLI due to infrapopliteal disease. Balloon angioplasty remains the most appropriate endovascular treatment modality for infrapopliteal disease. Even with severe disease and suboptimal runoff, overall limb salvage is reported to be > 75%, despite a primary patency of only approximately 35% at 1 year.^{6,7} Reestablishing in-line flow, even if only temporary, can allow tissue healing, which is vital in achieving limb salvage. Although balloon angioplasty remains the preferred endovascular treatment in infrapopliteal CLI, there are emerging data on drug-eluting balloons, revealing improved patency in treating infrapopliteal disease.⁸ Multiple randomized trials are currently underway comparing conventional angioplasty with angioplasty with drug-eluting balloons.

There is no evidence that primary stenting improves patency or limb salvage compared with angioplasty alone.^{9–11} We use stenting as a bailout after suboptimal results from balloon angioplasty. Currently, there is no consensus on whether to use balloon-expanding or self-expanding stents, although typically a balloon-expandable stent is favored for lesions near a bifurcation given the greater accuracy of placement. Preliminary data on drug-eluting stents might hold promise for better long-term patency and might be preferable to bare metal stents.¹² The question of whether drug-eluting stents are superior to balloon angioplasty requires additional research and investigation.

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