CLINICAL CASE UPDATE

Percutaneous Intervention of Chronic Total Occlusion in Critical Limb Ischemia
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Chronic critical limb ischemia (CLI) represents the extreme spectrum of peripheral arterial disease (PAD), accounting for about 1% to 3% of all PAD patients. CLI manifests as ischemic rest pain, gangrene and/or ulceration. CLI is considered chronic when symptoms persist for more than 2 weeks. It occurs when skin perfusion pressure at the affected site is reduced to a degree such that tissues’ resting metabolic needs are not met. Generally, ischemic rest pain occurs when systolic pressures at the ankle and toe are lower than 50 mm Hg and 30 mm Hg, respectively. Particularly in non-diabetic patients, the loss of perfusion pressure is due to multi-level occlusions between the aorta and pedal vessels.

Some ulcers are caused solely by ischemia; others are caused by a combination of factors such as ischemia, neuropathy, trauma and venous insufficiency. Regardless of the etiology of the ulcer, if ischemia is present, it must be corrected to achieve wound healing.

The majority of the foot ulcers present below the ankle are typically due to arterial insufficiency. Wound healing is an inflammatory response and, therefore, requires greater blood flow than is needed to simply sustain tissues. Perfusion pressure needs to be about 70 mm Hg at the ankle and 50 mm Hg at the toe to achieve wound healing. Collateral flow generally lacks enough pressure-head to achieve wound healing. To heal wounds in chronic CLI, therefore, it becomes necessary to establish straight-line pulsatile flow from the aorta to the vessel supplying the affected area.

Like ischemic ulcers, ischemic gangrene results from spontaneous necrosis of the skin due to severe ischemia, usually precipitated by some local trauma. While the underlying cause of gangrene is ischemia, the treatment often is primary amputation of the affected part. A study that involved a large Medicare database found the rate of primary amputation for gangrene to be 67%. The same study reported surgical revascularization before amputation at 23% and percutaneous revascularization at 10%. The study also reported underutilization of vascular studies, such as ABI and angiography, to diagnose ischemia before amputation.

Failing to correct underlying ischemia before primary amputation often results in amputation revision to higher levels, until the plane of adequate vasculature is reached. Major amputations such as...
below-the-knee or above-the-knee carry 6.3% to 13.3% mortality rates in the perioperative period and 43% and 61% mortality rates within 3 years. Only about 70% of stumps heal by primary intention with a 15% conversion rate to above-the-knee amputation. Furthermore, the contralateral limb is also at risk in an amputee, as about 30% to 53% of amputees undergo contralateral major amputation within 5 years. The goal should be to achieve enough revascularization to establish a straight-line pulsatile flow to the pedal arch, with a view to minimizing the amputation level (so that the patient remains ambulatory) or healing without amputation.

Tibial vessels are involved in the majority of CLI cases. Tibial occlusions are often long-segment occlusions. Revascularization can be achieved with surgical bypass or via percutaneous endovascular means. Surgical revascularization of tibial vessels has good long-term patency when venous conduits are used. However, many CLI patients have had coronary bypass surgery, making venous conduits unavailable. Further, surgical revascularization is associated with prolonged recovery, potential saphenous vein loss, chronic lower-extremity edema, and worsened symptoms if a graft fails. Infraginguinal bypass complications include death (up to 6%), myocardial infarction (up to 3.4%), wound infection and complication (up to 40%), and vein infection (1.4%).

Even with successful bypass, amputation is needed in 5% to 10% of patients. In contrast to surgical revascularization, the endovascular approach offers several advantages. It is minimally invasive with virtually no recovery time. Mortality and morbidity are much lower. Restenosis that occurs after wound healing is easily tolerated, as intact skin has much lower metabolic demands than healing tissue. Revascularization via the endovascular approach can be achieved in up to 94% of patients, with resulting 5-year limb salvage rates up to 91%.

The BASIL trial supported the percutaneous approach, showing equivalent patency and limb-salvage rates compared to bypass surgery at 3 years and superior cost effectiveness. In CLI, revascularization's goal is to heal tissue and complete wound closure. With good wound care and infection control, wounds typically heal within 6 to 12 weeks of achieving straight-line pulsatile flow in the affected area. After wound healing, intact skin can maintain integrity with good foot care, even with occluded vessels. Further, percutaneous intervention can be repeated as needed until wound healing is achieved. While this approach may seem expensive compared to primary amputation, economic analysis has shown that successful revascularization and amputation prevention are more economical from patient and societal standpoints.

Percutaneous revascularization (percutaneous transluminal angioplasty, or PTA) of tibio-pedal vessels poses many challenges. Calcification and long-segment total occlusions are some of them. Calcification is especially problematic in chronic renal failure and dialysis patients. Chronic total occlusions (CTOs) of tibial vessels are the rule rather than the exception in patients with CLI. Ipsilateral femoral antegrade access, popliteal access, and tibial access are essential in many cases.

Tools available to cross these CTOs include 0.014-in. and 0.018-in. stiff wires, 0.018-in. glide wires and, more recently, the CROSSER™ Recanalization Catheter (Bard, Inc., Murray Hill, NJ). The CROSSER™ Catheter uses high-frequency mechanical vibration (delivered at 20,000 cps) and cavitation to penetrate through atherosclerotic plaque. The CROSSER™ Catheter is indicated to facilitate the intraluminal placement of a conventional guidewire beyond the peripheral artery’s chronic total occlusion via atherectomy. A multicenter, non-randomized prospective clinical trial of 85 patients with guidewire refractory CTOs demonstrated 84% success crossing with an average activation time of 2 minutes. A large, single-center, registry experience has shown this device successfully crosses CTOs at a rate of about 95% in tibial arteries.

The following sections examine 3 successful cases.

**Femoral CTO**

A 77-year-old, nonsmoker, nondiabetic African American female presented with a more than 6-month history of severe calf claudication of the left leg. She had a prior history of CLI, with threatened amputation of the left leg, which had been due to an infected, non-healing ulcer of the left great toe in August 2010. At that time, she was noted to have a totally occluded left external iliac artery; severely diffusely diseased common femoral, superficial femoral and popliteal arteries; and an occluded left anterior tibial artery. She had been treated with PTA and stenting of the left external iliac artery, orbital atherectomy, and PTA of the left femoro-popliteal and anterior tibial arteries in a staged manner.

At this visit, the angiogram showed patent left external iliac and common femoral arteries. The superficial femoral artery (SFA) was totally occluded just past the ostium, with a favorable anatomy. It reconstituted in the Hunter’s canal, where there was diffuse stenosis up to the origin of the popliteal artery. Infrapopliteal arteries were patent.
A contralateral approach was used with a 6 Fr, 45 cm Pinnacle sheath. The sheath tip was positioned in the left common femoral artery. The CROSSER™ Catheter 14P (RX) system was used over a Grandslam wire. Using the roadmap technique, the proximal cap was crossed in 15 seconds. Heavy calcification in the middle portion of the occlusion posed some difficulty. The distal cap was crossed luminally. Balloon angioplasty was performed using a 5.0 x 200 mm VASCUTRACK® PTA Dilatation Catheter at 6 atmospheres of pressure for 3 minutes. Due to dissection and residual stenosis in the calcified portion of the artery, the SFA was stented using 6.0 x 150 mm and 6.0 x 80 mm LIFESTENT® Vascular Stent Systems. The stents were post-dilated using a 5.0 x 200 mm balloon.

The completion angiogram showed an excellent result, with no residual stenosis or gradient. Distal runoff was normal. Heparin (50 units/kg of body weight) was used for periprocedural anticoagulation. The arteriotomy was closed with the Perclose device.

**Infrapopliteal CTO**

A 70-year-old male smoker presented with a history of chronic venous stasis edema and a 6-month history of bilateral, lower-leg/foot ulceration and gangrene of the heels. An angiogram performed elsewhere showed stenotic SFA and occluded infrapopliteal vessels. SFA was treated percutaneously. An attempt at tibial vessel intervention was unsuccessful, resulting in a pseudoaneurysm of the right anterior tibial artery. The patient was sent for tibial vessel angioplasty consideration.

Ipsilateral antegrade femoral access was obtained, and a 6 Fr Pinnacle sheath was used. A proximal occlusion cap in the right anterior tibial artery (ATA) was crossed with the CROSSER™ Catheter 14P (RX) system over an Asahi Prowater wire within 9 seconds. However, the CROSSER™ Catheter was caught in the pseudoaneurysm in the mid-vessel (which was unknown to the operator at the time). Therefore, the CROSSER™ Catheter was withdrawn, and the wire was exchanged for an Asahi Astato-30 wire, which was maneuvered into the distal vessel. The wire was then exchanged for a Grand Slam wire, and PTA was performed using a 2.0 x 200 mm balloon at 6 atmospheres for 3 minutes. More proximally, PTA was performed using 3.0 x 100 mm balloon at 8 atm for 2 minutes. The portion of ATA with pseudoaneurysm was stented using a 3.0 x 32 mm stent. The distal ATA terminated at the ankle.

Next, the occluded posterior tibial artery was crossed with the CROSSER™ Catheter 14P (RX) system over the Asahi Prowater wire in 5 seconds. The CROSSER™ Catheter was taken to the pedal arch. The wire was then switched to a Viper wire and orbital atherectomy was performed using a 1.25 mm classic crown at 140,000 rpm for 24 seconds and 180,000 rpm for 16 seconds. Subsequently, balloon angioplasty was performed.
with a 2.0/2.5 x 210 mm balloon at 6 atmospheres for 3 minutes. The more proximal vessel was treated with a 3.0 x 100 mm balloon at 7 atmospheres of pressure for 1 minute.

Heparin was used for periprocedural anticoagulation. The arteriotomy was closed with the Angio-Seal device. Intravenous antibiotics were administered and wound care was performed on a long-term basis; 8 weeks later, the wounds had completely healed.

**Popliteal CTO**

A 66-year-old white male with history of diabetes, hypertension and smoking presented with a 6-month history of a non-healing ulcer on the dorsal shin of the right leg. He had undergone primary transmetatarsal amputation of the right leg 3 years prior. PAD had not been diagnosed previously.

The right leg ABI was 0.37, and the left leg ABI was 0.94. Arterial duplex suggested occlusive dis-
ease in the popliteal segment. Angiography showed diffuse disease in the SFA with focal high-grade stenosis in the distal segment, occlusion of popliteal artery with reconstitution above the popliteal bifurcation, and severe disease in the distal popliteal artery and the origins of ATA and tibioperoneal (TP) trunk with three-vessel runoff. The SFA was treated with PTA using contralateral femoral access at the time of diagnostic angiography.

For popliteal and below-the-knee intervention, ipsilateral antegrade femoral access was used with a 6 Fr system. The CROSSE™ Catheter 14P (RX) system was used over a Grandslam wire, and the lesion crossed in 36 seconds. PTA of the anterior tibial-distal popliteal artery was carried out with a 3.0 x 80
mm VASCUTRAK® PTA Dilatation Catheter at 3 atmospheres of pressure for 3 minutes. PTA of the distal popliteal artery-TP trunk was carried out with a 4.0 x 80 mm VASCUTRAK® PTA Dilatation Catheter at 3 atm pressure for 3 minutes. Proximal popliteal-distal SFA was treated with a 5.0 X 150 mm VASCUTRAK® PTA Dilatation Catheter at 5 atm pressure for 3 minutes. A stent-like result was achieved with PTA alone with no dissection. Heparin was used at 70 units/kg bodyweight for periprocedural anticoagulation and arteriotomy was closed with the Mynx closure device. Dual antiplatelet therapy with acetyl salicylic acid and clopidogrel was prescribed.

References