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Peripheral Artery Disease Below the Knee: Unique Challenges and Algorithmic Solutions

By Peter P. Monteleone, MD

Peripheral artery disease (PAD) of the lower extremities affects 200 million people globally, and that number continues to rise given the increasing burden of risk factors and an aging population.[1,2] PAD is commonly encountered in the tibiopedal vessels located below the knee (BTK), and in this territory, surgical or endovascular treatments can be particularly challenging. The procedural challenge of BTK anatomy is compounded by the coincident clinical challenge of critical limb ischemia (CLI), with which these patients present. CLI is defined as the presence of rest pain or wounds, and to effectively treat these high-risk patients, multidisciplinary care before, during, and after a revascularization procedure is required. Care begins with meticulous clinical planning, incorporates rapid achievement of tissue reperfusion, and is absolutely dependent on the critically important postprocedure wound care optimization, infectious disease management, tissue offloading, and management of comorbid diseases like diabetes or hypertension.

PREPROCEDURAL PLANNING

Clinical decision-making for PAD patients with CLI and BTK disease begins long before their arrival to the catheterization laboratory. Any revascularization therapy should only be considered if it is appropriate for a patient's clinical presentation, rather than simply appropriate for a patient's anatomy. Prior to invasive angiography, anatomic evaluation should begin with noninvasive testing including, at a minimum, segmental ankle-brachial index and toe-brachial index measurements, though CTA and duplex ultrasound can and often should also be used. Anatomy can thus be defined and procedural planning can be initiated long before a needle ever touches the skin.

Upon initiation of invasive evaluation for BTK PAD, close consideration should be paid to access site decision-making and preparation. Most commonly, contralateral common femoral artery (CFA) access is utilized for an up-and-over approach. An antegrade ipsilateral CFA approach may be used if previous iliac stenting or anatomic tortuosity limits up-and-over accessibility.

To allow for seamless transition to retrograde tibiopedal access if procedurally indicated, our laboratories elevate and sterile-cleanse the foot of CLI patients during initial preparations. The foot is then placed atop a sterile drape. If tolerated by the patient, a large sterile glove is placed over the toes of the foot (particularly if a wound is present) to serve as a further barrier of sterility. The patient is then covered by a total body drape. If retrograde tibiopedal access is needed, the overlying drape can be cut open to expose the tibial access site without compromising the sterility of the operating field.

BTK TREATMENT STRATEGIES

Multilevel anatomic disease demanding treatment is often identified. In our laboratories, we attack such disease first with preliminary treatment of inflow lesions in the aortoiliac or femoropopliteal territories, most commonly with atherectomy or angioplasty alone. BTK disease is then treated through its final destination therapy, usually angioplasty or atherectomy. Final destination therapy to the previously prepared inflow lesions is performed "on the way out," most frequently with drug-coated balloons or stenting. This prevents proximal stent damage/migration or removal of applied drug from the vessel wall while working BTK. The main risk of this algorithmic strategy is that downstream sequela of final inflow therapies (eg, embolization, poor reflow) may compromise the successful results of hard-fought BTK therapies that were previously applied.

When beginning BTK treatment, a long sheath (60 or 90 cm) is first advanced as close as possible to the tibial

trifurcation, usually in the popliteal artery. Angiography can then be performed to clearly define the tibial trifurcation and distal vessels. This includes near-anteroposterior visualization as well as lateral projection to allow for identification of distal tibial reconstitution and delineation of what tibial vessels perfuse which pedal arch vessels in the angiosomes of the foot.

Lesion Crossing

The first step to revascularizing BTK PAD is passing a wire beyond the diseased segment. As is typically the case, anatomy dictates the complexity of wire passage. In the particularly high-risk case of patients with an occluded popliteal artery that reconstitutes beyond the trifurcation (ie, "trifurcation obliteration"), our practice is to briefly attempt soft workhorse wire passage into the trifurcation. Soft plaque will allow passage with low risk of dissection or perforation. If passage in the setting of this anatomy is unsuccessful, we do not escalate to stiff wires, crossing devices, or re-entry devices but rather rapidly transition to retrograde tibiopedal access to ensure wire positioning within the distal target vessel. The usually softer distal occlusive plaque cap allows for effective wire passage into the true lumen, limiting risks of perforation.

In the absence of an obliterated tibial trifurcation, the procedural goal becomes to first establish a "base of operations" as close to the targeted disease as possible, from which to escalate wire passage techniques. To do so, we bring a 0.014-inch workhorse wire like a Nitrex™ guidewire (Medtronic) through a microcatheter (0.018-inch Trailblazer™ support catheter, Medtronic) to the level of the lesion and perform focused angiography at increased magnitude and in multiple projections. If nonocclusive, the Nitrex guidewire can often be navigated across the lesion; if subtotally occluded but with evidence of an antegrade microchannel, a dedicated hydrophilic crossing wire like a Fielder XT™* (Asahi Intecc) can be used to slide antegrade through the microchannel.

CTO crossing. In the setting of a tibial total occlusion, there are different strategies for antegrade wire passage, although they have not been directly compared. In short chronic total occlusions (CTOs), we will often use Asahi Intecc wires: high tip-weight CTO wires like the coronary MiracleBros 12™* or Confianza Pro 12™* wires, or the peripheral-dedicated Astato™* series. In our practice, we commonly begin with a MiracleBros 12 wire with a 0.5-mm, 45° "CTO tip" created by the operator. We also use alternative techniques depending on the lesion type: *drilling* is a fast but controlled 360° rotation with a high tip-load nontapered wire with only gentle advancement; *penetrating* uses smaller 45° to 90° rotations performed with higher pushing force. If such wire escalation fails, we progress to "knuckle wire" techniques and use small-diameter soft wires in this territory to create the smallest possible knuckle loops to limit plane dissection size.

Although many CTO crossing devices exist, most are not optimized for the BTK space. However, the Viance™ crossing catheter (Medtronic) is 0.038 inch in diameter and can be used safely in the tibiopedal vessels. It is composed of a multicoiled wire shaft and an integrated fast-spin torque handle. Rapid rotation of the torque handle is transmitted 1:1 to the low-profile atraumatic catheter tip, enabling the catheter tip to find and select microchannels to surf through a chronic occlusion. The low-profile diameter and compatibility with a 0.014-inch guidewire platform make it useful in both antegrade and retrograde passage of BTK CTOs.

If a wire fails to pass into the distal patent vessel, re-entry must be performed as close to vessel reconstitution as possible. We most commonly achieve re-entry with a high tip-weight 0.014-inch wire (Miracle 12) or with the dedicated Enteer™ re-entry system (Medtronic).

Retrograde crossing. If antegrade wire passage cannot be successfully achieved, transition to a retrograde tibiopedal approach is indicated. Endovascular therapy using retrograde access is safe, although the potential complications in this space demand that an interventionalist proceeds carefully.[3] The first step in retrograde tibiopedal access is selection of a target vessel site for access, and both anatomy and state of the individual vessels must be taken into account. First, if access is attempted more proximally (above ankle level), access site bleeding can cause a profound pressure increase within a fascial compartment of the calf and precipitate malignant pressure-induced tissue injury resulting in the need for emergent fasciotomy or amputation. Second, a diseased vessel should be chosen preferentially to a "last remaining" dominant vessel of the runoff to the foot. Third, it is worth remembering certain anatomic foundations: peroneal vessels exist deep within the tissue and are often a more dangerous target than superficial anterior tibial or posterior tibial arteries; and the tortuosity of the ostial/proximal anterior tibial may make an ostial anterior tibial CTO more complicated to cross retrograde than an ostial peroneal or posterior tibial occlusion that is in line with the proximal patent vessel.

To gain retrograde access, we most often rely on ultrasound-guided retrograde access using the Micropuncture Pedal Access Set™* (Cook Medical). The 4-cm, 21-gauge echogenic needle is used to access the vessel, and the included 0.018-inch nitinol wire is guided into the artery. The dilator is passed over the micropuncture wire into the vessel, and then the wire is replaced with a 0.018-inch V-18™* ControlWire™ (Boston Scientific Corporation). The dilator is removed over this wire and the

7-cm Micropuncture introducer with dilator is advanced over the wire. The dilator is removed and the included Check-Flo™* hemostasis valve (Cook Medical) is attached to the introducer, resulting in an effective 2.9-F inner diameter. Vasodilating agents such as nitroglycerin or verapamil can also be given via the retrograde sheath, which allows passage of 0.014- to 0.035-inch wires as well as particular microcatheters.

The aforementioned wire escalation techniques can then be used in a retrograde fashion through the typically softer distal cap. After wire passage, the retrograde wire is externalized by navigating it into the antegrade sheath. A smaller (often 4 F) sheath is then advanced through the antegrade sheath inlet valve, and the distal tip of the retrograde wire is advanced through the initial antegrade sheath into the smaller sheath. The smaller sheath is then removed, revealing the externalized distal wire. A long microcatheter is advanced antegrade (or retrograde) over the externalized wire. Once the microcatheter is across the target lesion(s), the externalized wire can be removed, flipped, and passed within the microcatheter antegrade across the target lesions. The microcatheter is then removed. At this point, we will then remove the retrograde access sheath and achieve hemostasis of the retrograde access site with manual pressure. This takes approximately 5 minutes of manual pressure as the site is still underperfused.

Revascularization

After antegrade or retrograde techniques are utilized to cross BTK lesions, revascularization therapies are initiated, all with the goal of limiting dissections and returning flow to the foot. If angioplasty is indicated, we preferentially utilize the Chocolate™* PTA balloon catheter (Medtronic) BTK, a choice driven by the low flow-limiting dissection rates reported in the real-world Chocolate BAR study.[4] Although outcome data are limited, another option for BTK PAD is atherectomy. In our labs, we most often use directional atherectomy for tibial vessel debulking with the Turbohawk™ SX-C peripheral plaque excision system (Medtronic) over the SpiderFX™ embolic protection device (Medtronic) to avoid plaque shift and prevent distal embolization of debris into the nonhealing malperfused microcapillary environment of the wound bed. Other atherectomy devices, including Diamondback™* (Cardiovascular Systems, Inc.) and Rotablator™* (Boston Scientific Corporation), can be utilized BTK.

POSTINTERVENTION MANAGEMENT

There is a great deal of variation in utilization of antiplatelet and anticoagulant strategies in patients treated for BTK PAD. Our practice is to treat with dual antiplatelet therapy for at least 3 months postprocedure, and we will sometimes extend this therapy until improved clinical healing is achieved. Recent industry-sponsored data on implementation of the novel oral anticoagulant rivaroxaban in PAD patients demonstrated striking improvements in major adverse cardiovascular and limb events with implementation of this therapy.[5] Although we await confirmatory data and guideline recommendations, we have increasingly implemented these therapies in our high-risk PAD patients.

As interventionalists, we meticulously evaluate every step of a BTK revascularization procedure, yet to achieve high-quality clinical outcomes in BTK PAD with associated CLI, we must bring the same tenacity and detail orientation to each component of our patient's entire clinical course. We must collaborate with podiatry, wound care, and surgical colleagues to follow these patients extremely closely after intervention to ensure that the reperfused tissue bed is optimally prepared for wound healing through debridement, dressing, and offloading. We must follow with our medicine colleagues to ensure that the patient's clinical milieu is optimized for healing through appropriate nutrition, infection treatment, and diabetes management. Only together can a multidisciplinary team allow for translation of an excellent angiographic result to an excellent clinical outcome. Only together can we achieve success in the war against CLI and BTK PAD. ■

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Peter P. Monteleone, MD
The University of Texas at Austin Dell School of Medicine
Seton Heart Institute
Austin, Texas
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TurboHawk™ peripheral plaque excision system Reference Statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- The TurboHawk peripheral plaque excision system is intended for use in the atherectomy of the peripheral vasculature. The TurboHawk catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.
- The TurboHawk catheter is indicated for use in conjunction with the SpiderFX embolic protection device in the treatment of severely calcified lesions (LX-C only).

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

SpiderFX™ embolic protection device Reference Statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
Lower Extremity (LE) Interventions
- The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

Carotid Interventions
- The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

Saphenous Vein Graft (SVG) Interventions
- The SpiderFX embolic protection device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

TrailBlazer™ support catheter reference statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- TrailBlazer support catheter are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer support catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CAUTION:
- Federal (USA) law restricts these devices to sale by or on the order of a physician.

Enteer™ re-entry catheter reference statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- The Enteer re-entry catheter is indicated for directing, steering, controlling and supporting a guidewire in order to access discrete regions of the peripheral vasculature. When used as part of the Peripheral System, the Enteer Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

Nitrex™ Guidewire Reference Statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- The 0.014 in. (0.36 mm) and 0.018 in. (0.46 mm) diameter NITREX nitinol guidewires are intended for use in the peripheral and coronary vasculature.
- The 0.025 in. (0.64 mm) and 0.035 in. (0.89 mm) diameter NITREX nitinol guidewires are indicated for use in the peripheral vasculature.

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

Viance™ catheter Reference Statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:
- The Viance catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the peripheral system, the Viance catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

Chocolate™* PTA balloon catheter Reference Statement
- Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.

Indications for Use:
- The Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.

Caution:
- Federal (USA) law restricts this product for sale by or on the order of a physician.

Note: Safety information provided is for the United States. Please refer to your region's Instructions for Use for specific details.