Critical limb ischemia (CLI) is a global epidemic associated with comorbid conditions that add to the complexity of the disease.\(^1\) Patients often have extensive tissue loss due to misdiagnosis or infection from a previous hospital visit.\(^2\) Many patients still have severe tissue loss even after endovascular or surgical treatment, at which point referral for a second opinion typically leads to a limb salvage approach. These cases are complex, pose significant challenges, and require great skill to treat the underlying lesions. In patients with diabetes, obstructive arterial disease related to CLI is characterized by multilevel lesions that can involve arteries below the knee, calcification, and chronic total occlusions (CTOs).\(^3\)\(^-\)\(^5\) These types of complex lesion characteristics, in combination with comorbid conditions that are often present among patients with diabetes, can make revascularization especially challenging, which ultimately increases the risk of amputation, as seen in the following case.

**PATIENT HISTORY**

A 75-year-old woman with peripheral artery disease (PAD) was referred to our service by podiatry for treatment of CLI. Her medical history included insulin-dependent diabetes, hypertension, chronic renal insufficiency, and stable coronary artery disease. At presentation, she had a deep wound to the left great toe, which was being treated by wound care and podiatry. She had a palpable left femoral pulse, but her popliteal and tibial pulses were absent.

This case was unique because the patient was deemed to have no further endovascular or surgical options and was also referred to the orthopedic group for a below-the-knee amputation and subsequent hospice. In the United States, patients are commonly referred directly to an orthopedic surgeon for amputation before a full vascular evaluation can be performed. The additional referral to hospice after amputation showed a lack of hope or empathy for the patient. This case occurred prior to the full initiation of the
CLI program at our institution. Currently, we have a system where referrals for amputations are flagged for review by the vascular interventional team, or the “CLI Team,” which has significantly reduced amputation rates.

**PROCEDURE**

In the cath lab, right common femoral artery (CFA) contralateral access was achieved via a Glidesheath Slender™ sheath (Terumo Interventional Systems). A diagnostic angiogram revealed patent aortic and iliac arteries with moderate levels of plaque. A left lower extremity angiogram confirmed a CTO of the superficial femoral artery (SFA) at the bifurcation of the deep profunda artery and extending into the popliteal artery with reconstitution at the tibioperoneal trunk. Digital subtraction angiography (DSA) revealed a single runoff vessel—the peroneal artery—with CTOs in the anterior and posterior tibial arteries (Figure 1). Adding to the complexity of the situation, a totally occluded self-expanding stent was found in the mid-distal SFA. The presence of the stent showed that another interventionalist had already treated this patient, but the status of this previous care was unknown.

After the diagnostic angiogram, a Glidesheath Slender sheath was exchanged for a 6-F X 45-cm Destination™ sheath (Terumo Interventional Systems) and advanced over the iliac bifurcation into the left CFA using a 6-F Concierge™ Internal Mammary guide catheter (Merit Medical) as a telescope along with a stiff, angled Glidewire™ (Terumo Interventional Systems). DSA images were taken at various angles, which located the remnants of the SFA (Figure 2). The 0.035-inch stiff, angled Glidewire and an angled 0.035-inch NaviCross™ support catheter (Terumo Interventional Systems) were introduced to engage the nub of the occluded SFA. Under fluoroscopic guidance, a consistent strong push broke the proximal cap of the CTO, utilizing only the catheter and paying close attention to the points of entry (Figure 3). The remnant SFA was then navigated via a subintimal technique (Figure 4). A 6-F Glidesheath Slender sheath was then introduced into the SFA (Figure 5).
attention that the Glidewire remained inside of the catheter (Figure 2).

In our experience, engaging the cap of the CTO in this way gives better control and reduces the chance of going subintimal. We closely watched the trajectory of the catheter as it traversed the CTO, constantly manipulating the angled tip in various degrees of motion and with consistent force applied throughout. We placed special attention on staying intraluminal within the stent itself, as occluded stents can create a very hard proximal cap that often deflects the catheter into the subintimal space. Unfortunately, that is exactly what occurred in this case (Figure 3).

We considered approaching the occluded stent in a distal retrograde fashion, but the usual distal retrograde access targets (anterior and posterior tibial arteries) were completely occluded and only the peroneal artery was visible by DSA. We determined the best approach was to do a direct stick to the occluded stent and prolapse an 0.018-inch wire with a solid body so that a Glidesheath Slender sheath could be introduced (Figure 4).

The puncture site was a few centimeters proximal and medial to the knee joint. As this was an anterior approach, with the patient lying in the supine position, there was no need to reposition the patient, reprep, or break sterility, which saved time and kept the procedure moving forward.

Once the Micropuncture™* introducer sheath (Cook Medical) was inserted (Figure 5), a second angled 0.035-inch NaviCross support catheter and stiff angled Glidewire were pushed through the occluded stent and aimed toward the antegrade NaviCross support catheter.

Both catheters were advanced to within a millimeter of each other, on the same plane. The retrograde 0.035-inch wire was exchanged for a 0.014-inch CTO wire with a heavy gram tip weight. Under fluoroscopic guidance, the wire was introduced from the retrograde catheter into the lumen of the antegrade NaviCross support catheter (we call this the “south-meets-north” technique; Figure 6).

The wire was advanced through the catheter and externalized out of the contralateral sheath, and the retrograde NaviCross support catheter was removed. Both ends of
the wire were externalized, giving outstanding control and support. The antegrade NaviCross support catheter was advanced distally toward the retrograde Glidesheath Slender sheath in the stent. The 0.014-inch CTO wire was exchanged back to an 0.035-inch stiff angled Glidewire, which was advanced distally past the sheath in the distal SFA, stopping near the end of the stent.

We removed the antegrade NaviCross support catheter and advanced a 4-mm X 80-mm EverCross™ percutaneous transluminal angioplasty (PTA) balloon (Medtronic) through the occluded SFA and into the lumen of the stent, centering the puncture site between the radiopaque markers. The micropuncture sheath was removed as the balloon was inflated to nominal pressure, creating hemostasis by internal tamponade, and held for a period of 5 minutes (Figure 7).

The balloon was removed and an angled NaviCross support catheter was reinserted to continue traversing through the distal CTO, which involved the distal SFA and popliteal artery. We made several attempts at crossing this part of the occlusion but were unsuccessful. When considering the peroneal artery as an alternative access strategy, the challenge is balancing safe access with avoiding complications that impair wound healing. It can also be difficult to visualize the artery with standard imaging techniques because of how deep the artery is in the interosseous space. Therefore, our approach is generally to access the artery under fluoroscopic guidance.

We created a roadmap with an injection through the antegrade sheath, and the micropuncture needle was advanced toward the opacified peroneal artery approximately 10 cm above the lateral malleolus (Figure 8).

Once accessed, an 0.018-inch X 80-cm Nitrex™ guidewire (Medtronic) was inserted and a Glidesheath Slender sheath was advanced into the peroneal artery, attached to TAMI solution (500 mL heparinized normal saline, 1,600 µg nitroglycerin and 5 mg verapamil) at 100 mL per hour (Figure 9).

We performed a retrograde injection and saw that the peroneal artery was moderately diseased and totally occluded at the level of bifurcation, with an occluded posterior tibial artery and minuscule tibioperoneal trunk (Figure 10).
An angled 0.035-inch NaviCross support catheter was inserted through the retrograde peroneal sheath and approached the distal cap of the occluded peroneal artery, using the same motion previously described. The distal cap was successfully entered, and the catheter was advanced through the lesion into the popliteal artery toward the antegrade NaviCross support catheter that was located just distal to the SFA stent. Using the same south-meets-north crossing technique performed in the SFA, we brought each of the NaviCross support catheter tips to within a millimeter of each other. The wires were exchanged in both antegrade and retrograde catheters for 0.014-inch CTO wires. We introduced the antegrade wire into the lumen of the retrograde catheter, and subsequently externalized through the peroneal sheath. Once the wire was externalized, the rest of the procedure was completed from an antegrade fashion.

Predilation of the occluded SFA, tibioperoneal trunk, and peroneal artery was performed with a 3.5-mm X 150-mm NanoCross™ PTA balloon (Medtronic). Angiography after predilation showed successful recanalization of the entire SFA with multiple dissections (as expected) and persistent plaque burden.

The initial plan was to perform directional atherectomy with the HawkOne™ device (Medtronic) with a SpiderFX™ filter (Medtronic) placed in the distal tibioperoneal trunk to protect the remaining runoff vessel. Atherectomy (Figure 11) was successful in removing plaque from the SFA (outside of the stent) and popliteal artery.

This was followed by angioplasty with the Chocolate™* PTA balloon (Medtronic) to reduce the potential for flow-limiting dissections and, finally, angioplasty with the IN.PACT™ Admiral™ drug-coated balloon (DCB, Medtronic) to reduce the risk of restenosis. A final angiogram after DCB angioplasty showed excellent flow into the SFA and popliteal and peroneal arteries (Figure 12).

When removing the distal retrograde access sheath, manual compression was not an option due to the location of the peroneal artery deep in the interosseous membrane. To achieve hemostasis, we performed a balloon tamponade technique from an antegrade fashion, where a 2.5-mm X 120-mm NanoCross PTA was positioned just proximal to the peroneal entry site. The same 0.018-inch X 80-cm Nitrex guidewire was introduced into the retrograde peroneal sheath, and the sheath was removed. This maneuver was performed to allow the antegrade wire to bypass the puncture site going distally into the tibial artery. The PTA balloon was advanced forward and toward the puncture site, which was marked by the intersection of the retrograde access wire. The intersection was centered on the balloon, and the balloon was inflated to a pressure that occluded the artery while simultaneously removing the peroneal access wire, so that the blood trickle outside was interrupted. We typically hold pressure to 5 minutes at a time, then take a contrast image through the antegrade sheath to visualize any extravasation. In this case, it took two 5-minute rounds of inflation to achieve hemostasis.

The final image showed a cessation of extravasation (Figure 13) and thrombolysis in myocardial infarction grade 3 flow to the foot with excellent collateralization of the dorsalis pedis and plantar arch artery through the anterior and posterior communicating branches of the peroneal artery.

The procedure was concluded with the long sheath being exchanged for a short 6-F sheath, and the patient recovered without any complications. The wound was completely healed at 3-month follow-up (Figure 14).

**CONCLUSION AND LEARNING POINTS**

The current case illustrates multiple strategies that can be used to treat patients with CLI with complex anatomy, including CTOs at multiple levels. These include the quick-thinking “fail fast” approach, a willingness to use the tibial arteries, the balloon tamponade technique to achieve hemostasis, and a multidisciplinary team approach to support the best possible outcomes after treatment.

One of our teaching philosophies when performing complex endovascular intervention is “fail fast,” a strategy that saves time, resources, and patient discomfort when an operator is unsuccessful with a current course of action. This is compared with the “we’ll bring them back” ideology. Many times, patients with CLI may not get another chance before infection or severe tissue loss forces the surgeon to amputate. In our experience, the “fail fast” mentality means we always have plans B, C, and D in mind, ready to
change course as circumstances require, thus increasing the chances of successfully crossing an occlusion, restoring in-line flow, and ultimately delivering a positive outcome for all parties involved.

Utilization of tibial vessels is also vital to the successful treatment of patients with CLI who have complex, multilevel CTOs. We strongly advocate the use of ultrasound-guided access and highly recommend that all operators become more comfortable with its use in retrograde tibial access. Tibials are your friends; use them.

The balloon tamponade technique is a reliable form of achieving hemostasis when handling multiple delicate retrograde access sites. There is a real-time response associated with the deliberate action, and the operator can repeat the tamponade until complete hemostasis is achieved. Although this approach adds time to the procedure, the avoidance of adverse events, such as bleeding, is worth the additional effort.

The mission of our practice is to produce the best possible outcomes for every patient with PAD and CLI. We achieve this with a multidisciplinary team approach that begins with the intervention and leads into a follow-up strategy that integrates the patient, caregiver, and referring and treating physicians. At the center of the circle is a patient liaison who closely monitors the patient for healing, manages coordinated care from all specialists, and ensures regular communication among all parties. The approach requires close and regular follow-up so that if there is a bump in the healing process, the patient can promptly return for evaluation and additional therapy if needed. All working together toward a single unified goal: wound healing and limb preservation.


Laqi Raja, MD, FACC, FSCAI
El Paso Cardiology Associates
El Paso, Texas


Lorie Henderson, APRN, MSN, NP-C
El Paso Cardiology Associates
El Paso, Texas

Disclosures: Consultant for Cardiovascular Systems, Inc., and Terumo Interventional Systems.

The IN.PACT™ Admiral™ drug-coated PTA balloon catheter: Brief Statement

Indications for Use
The IN.PACT Admiral Ptaclast-coated PTA balloon catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications
The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/tetrobvascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP (14 atm [1419 kPa]) is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 mg paclitaxel in a patient has not been clinically evaluated.

Potential Adverse Effects
- The potential adverse effects (e.g. complications) associated with the use of the device are:
  • Abrupt vessel closure, access site pain, allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; anaphylaxis; arterial aneurysm; arterial thrombosis; antithrombotic (A) fronto; death; dissection; embolization; fever; hemotoma, hemorthage; hypotension/hypertension; inflammation; ischemia; infection or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock, stroke; systemic embolization; vessel spasm or recoil; vessel trauma which requires surgical repair.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or reinitialize this product. Reuse reprocessing or reinitialization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient’s exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- Vessel preparation using only predilation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects
- The potential adverse effects (e.g. complications) associated with the use of the device are:
  • Abrupt vessel closure, access site pain, allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; anaphylaxis; arterial aneurysm; arterial thrombosis; antithrombotic (A) fronto; death; dissection; embolization; fever; hemotoma, hemorthage; hypotension/hypertension; inflammation; ischemia; infection or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock, stroke; systemic embolization; vessel spasm or recoil; vessel trauma which requires surgical repair.

References

Laqi Raja, MD, FACC, FSCAI
El Paso Cardiology Associates
El Paso, Texas


Lorie Henderson, APRN, MSN, NP-C
El Paso Cardiology Associates
El Paso, Texas

Disclosures: Consultant for Cardiovascular Systems, Inc., and Terumo Interventional Systems.
MEDTRONIC MEDICAL AFFAIRS CORNER

• Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture, detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.
• Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/myositis; peripheral neuropathy.
• Refer to the Physician’s Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
• Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

HawkOne™ directional atherectomy 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 HawkOne directional atherectomy system is intended for use in atherec- tomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.
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 labeling 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.

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 pro- tection 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.

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

EverCross™ PTA balloon 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 EverCross 0.014” OTW PTA dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

NanoCross™ Elite 0.014” OTW PTA balloon 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 NanoCross Elite 0.014” OTW PTA balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

© 2019 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic TM. Third party brands and trademarks of their respective owner. All other brands are trademarks of a Medtronic company. 500097 A 07/19