MEDTRONIC
MEDICAL AFFAIRS
CORNER

SPONSORED BY
Medtronic

It Takes Two to Tango: Leveraging Open and Endovascular Options for Treatment of Critical Limb Ischemia

By Nicolas J. Mouawad, MD, MPH, MBA, FSVS, FACS, FRCS, RPVI

Peripheral artery disease (PAD) affects more than 200 million people worldwide, and it continues to burden the health care system due to an increasing and aging population, fortifying its contemporary prevalence.[1,2] To compound these concerns, 10% of patients with PAD are estimated to have critical limb ischemia (CLI), and 10% to 20% of patients with intermittent claudication will progress to CLI over a 5-year period.[3,4]

The implications of CLI are not limited only to clinical pathways but also have significant strain on society, with increased rates of reduced employment due to amputations and the increasing cost of health care. In fact, annual health care costs in the United States obtained from Medicare data were estimated to be greater than $4 billion at the turn of the century.[5]

CLI is a challenging and growing problem because treatment options are limited and complex. In my opinion, it requires an aggressive multidisciplinary approach. The ultimate goal in CLI treatment is revascularization to prevent limb loss. This requires rapid tissue reperfusion in addition to medical optimization of significant comorbid conditions, glycemic control, tissue offloading, podiatric involvement, aggressive wound care, and infection source control. However, the optimal treatment algorithm and strategy remains uncertain.

The lack of comparative effectiveness data between multiple modalities has led to the conception of the BEST-CLI trial, the results of which are anxiously awaited.[6] The BEST-CLI trial is a multicenter, randomized trial that compares approved endovascular therapies with open surgical treatment in patients eligible for both treatments. It aims to provide a better understanding of how to treat which patient with what type of lesion. Multiple options are available, ranging from percutaneous endovascular procedures to open peripheral bypass. However, the combination of both in a "hybrid" procedure may also be effective.

Traditionally, lower extremity open bypass with an autogenous vein conduit was the gold standard for lower extremity revascularization, particularly in patients with CLI. However, recent innovations resulting in lower-profile options mean that percutaneous endovascular devices are now being used quite frequently. In particular, the use of debulking atherectomy devices allows for excellent luminal gain. The DEFINITIVE LE study demonstrated that directional atherectomy is a safe and effective endovascular option for treating patients with PAD, ranging from claudication to CLI. Importantly, the rate of freedom from major unplanned amputation of the target limb at 12 months was 95%.[7] The primary patency rate of tibiopedal vessels in the infragenicular position was 90% in the claudicant group and 78% in the CLI group.[7]

In my practice, most patients are at high risk for restenosis, and we treat them with adjunctive balloon angioplasty. For femoropopliteal lesions, this means using drug-coated balloons. For lesions at a higher risk for dissection, we use specialty balloons such as the Chocolate™* percutaneous transluminal angioplasty (PTA) balloon catheter (Medtronic) after satisfactory luminal gain. The Chocolate BAR registry reported no postprocedural flow-limiting dissections (as adjudicated by angiographic core laboratory) in all 262 patients treated with the device.[8]

CASE EXAMPLE 1

A construction worker in his early 50s presented with lifestyle-limiting claudication of the right lower extremity (Rutherford class 3). He was forced to stop working because he was unable to continue with activities necessary for employment due to his pain. His medical history included coronary artery disease status after coronary

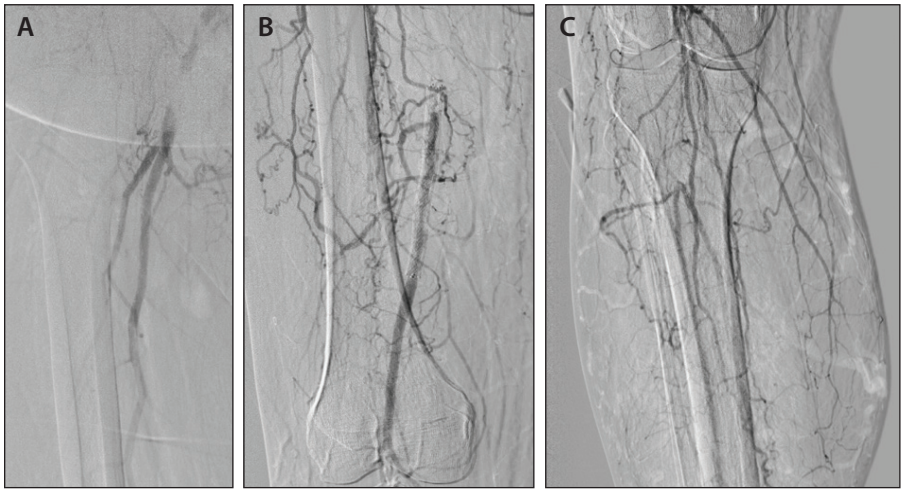

Figure 1. Preprocedural angiography. An occluded right SFA with reconstitution in the mid-thigh (A). Stents present in the distal SFA (B). P3 occlusion and reconstitution of the posterior tibial artery (C).

Figure 2. Final angiographic result.

artery bypass grafting, hypertension, hyperlipidemia, and diabetes mellitus. He had absent right femoral and popliteal pulses. His noninvasive testing noted a right ankle-brachial index of 0.51 at rest. Peripheral angiography and CTA were performed. Fluoroscopy of the right lower extremity identified an occluded right common femoral artery with calcification as well as an occluded right superficial femoral artery (SFA) with reconstitution in the mid-thigh; no proximal stump was present (Figure 1A). Distal SFA stents were noted (Figure 1B). The popliteal artery was patent down to the P2 segment; however, the P3 segment was occluded with reconstitution of the posterior tibial artery as the dominant runoff to the foot (Figure 1C).

Antegrade crossing was not possible given the occluded common femoral artery, and the surgical option was a common femoral artery endarterectomy with a prosthetic bypass to the posterior tibial target. A hybrid concept was elected. First, in-line flow to the foot was established for acute treatment from the planned distal bypass target; second, an adequate above-the-knee target had to be ensured to enable better long-term bypass patency. Retrograde right posterior tibial artery access was performed with ultrasound guidance and micropuncture technique. A 6-F sheath was then placed, and a standard wire and catheter technique with a Glidewire Advantage™* (Terumo Interventional Systems) and Trailblazer™ support catheter (Medtronic) was used to cross the lesion into the mid-SFA. Re-entry was confirmed with contrast injection. The P3 segment chronic total occlusion (CTO) was predilated with a 3-mm NanoCross™ Elite 0.014-inch over-the-wire PTA balloon catheter (Medtronic), enabling satisfactory retrograde passage of a HawkOne™ directional atherectomy system (Medtronic). Four passes were performed, one in each quadrant, and luminal gain was achieved with less than 20% residual stenosis. The lesion was then treated with a 4-mm IN.PACT™ Admiral™ drug-coated balloon (DCB) (Medtronic), which was inflated for 3 minutes per the instructions for use.[9] An excellent angiographic result was achieved, with no evidence of vessel injury or abnormality (Figure 2).

When the endovascular portion was completed, the patient was discharged home on dual antiplatelet agents and a high-dose statin. We generally perform our diagnostic angiography and intervention simultaneously in the same session. Therefore, when we identify that it will become a hybrid procedure, the endovascular portion is completed at the index angiogram and the open revascularization is staged 2 weeks later, after cardiac risk stratification is completed. This patient underwent a right common femoral endarterectomy with a femoral–to–above-the-knee popliteal artery bypass using an expanded polytetrafluoroethylene prosthetic conduit. The patient fared well and has returned to work on clopidogrel, high-dose statin, and a PAD dose of rivaroxaban.

CASE EXAMPLE 2

We have now employed hybrid revascularization techniques in multiple other scenarios. To minimize bypass length, particularly when using prosthetics, performing the bypass to a more proximal target is considered. Then, through the open exposure of the bypass, the prosthetic is accessed with an appropriately sized sheath, and standard wire and catheter techniques are used to cross distal lesions (rather than needing to identify more conduit length for a more distal bypass).

A man in his late 60s presented to the clinic with distal forefoot dry gangrene. The femoropopliteal segment

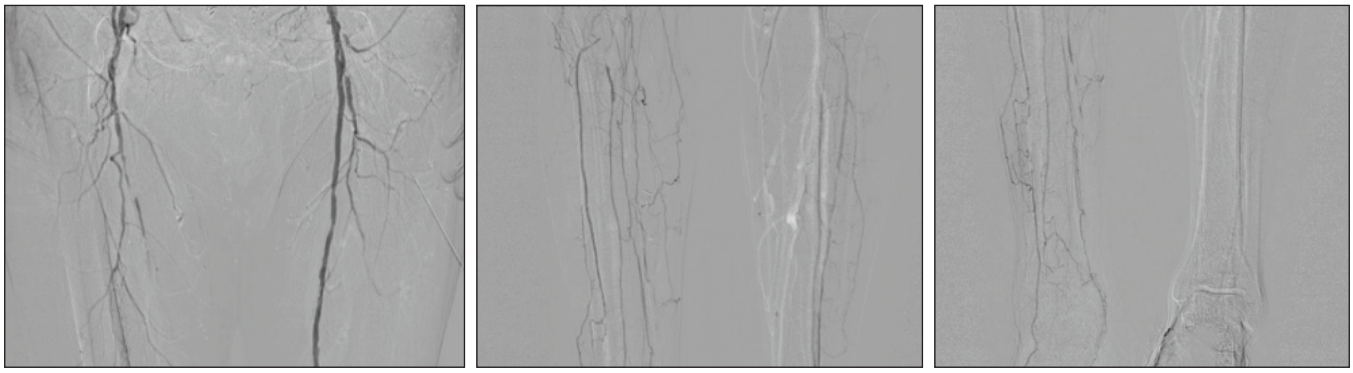

Figure 3. Baseline angiography.

was chronically occluded, with no proximal stump and only a dominant anterior tibial artery runoff into the foot (Figure 3). However, the distal anterior tibial artery had a distal CTO with distal reconstitution. The patient did not have an autogenous conduit of satisfactory size in the upper or lower extremities, even in consideration of spliced vein segments.

A femoral–to–proximal anterior tibial artery bypass was performed with prosthetic conduit, and the prosthetic bypass was accessed with a 6-F sheath. Using a combination of a 0.014-inch wire and a 0.014-inch Trailblazer support catheter, we crossed the distal anterior tibial CTO and exchanged for a 3-mm SpiderFX™ embolic protection device (Medtronic). Directional atherectomy was then performed in two passes with a HawkOne S directional atherectomy system (Figure 4A) followed by completion imaging (Figure 4B).

The patient's wounds have now healed, and the bypass remains patent with satisfactory outflow.

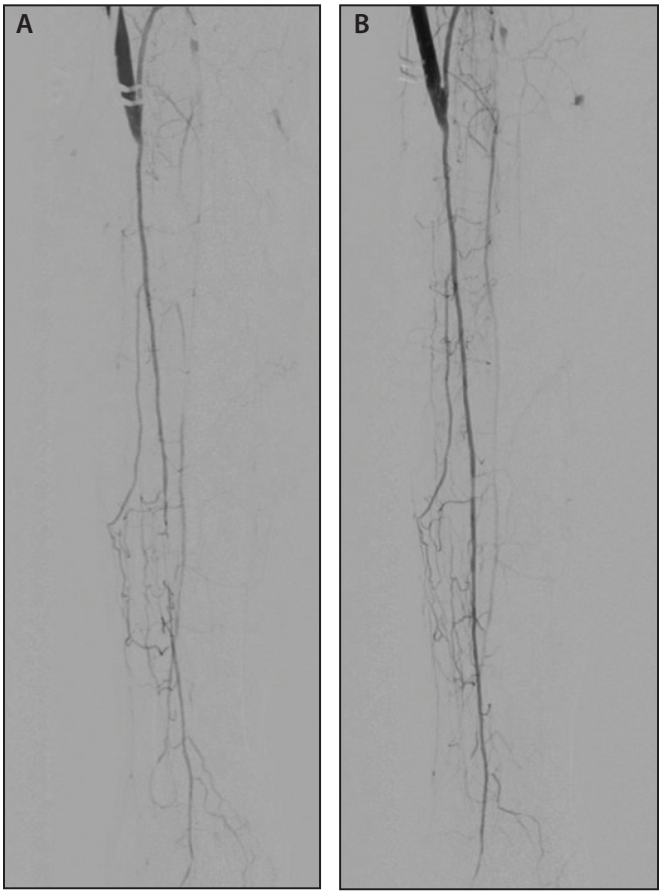

Figure 4. Angiography before directional atherectomy (A). Completion angiography (B).

CASE EXAMPLE 3

Another example is hybrid revascularization with a below-the-knee popliteal target followed by antegrade atherectomy of the distal posterior tibial artery into the tarsal vessels. After completion of the distal anastomosis, the graft is accessed with a micropuncture technique and up-sized to a 6-F sheath. The distal posterior tibial CTO is crossed using a combination of a 0.014-inch wire and a 0.014-inch Trailblazer catheter, which is then exchanged

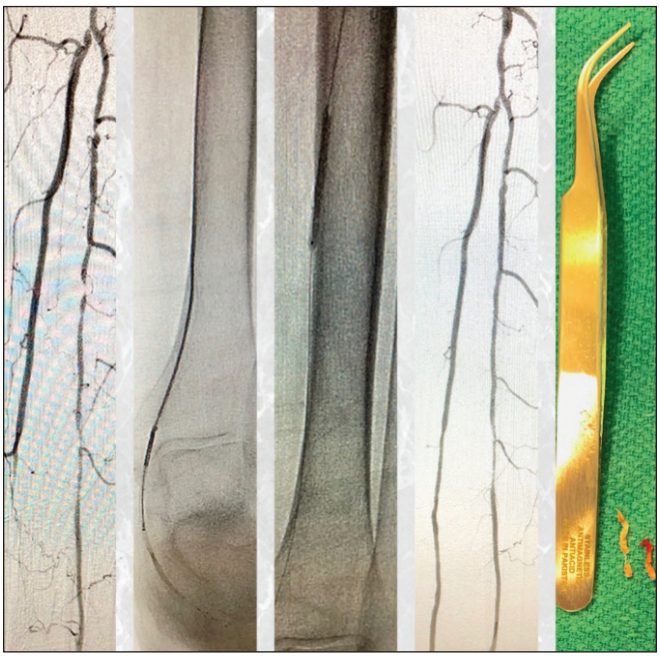

Figure 5. Completion angiography and atheroma extraction.

for a 3-mm SpiderFX embolic protection device. Directional atherectomy was performed in two passes with a HawkOne S directional atherectomy system. A 2.5-mm Chocolate PTA balloon with slow inflation was selected to minimize dissection. Completion angiography with atheroma extraction is shown in Figure 5.

CONCLUSION

The management of PAD and CLI remains complex and challenging because multiple options exist to successfully revascularize and restore blood flow. The BEST-CLI trial is evaluating the effectiveness of endovascular versus open treatment strategies, but there is growing evidence to rethink the proverbial "silo" philosophy. Treatment plans should be based on anatomic- and patient-related factors. As demonstrated in these case studies, a hybrid approach can, at times, be the best of both worlds. Continuing our multidisciplinary evaluation of patients with PAD and CLI is imperative so that we can tailor an effective and long-lasting solution. ■

1. Fowkes FGR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet. 2013;382:1329-1340.
2. Criqui MH, Aboyans V. Epidemiology of peripheral artery disease. Circ Res. 2015;116:1509-1526.
3. Nehler MR, Duval S, Diao L, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. J Vasc Surg. 2014;60:686-69.e2.
4. Sigvant B, Lundin F, Wahlberg E. The risk of disease progression in peripheral arterial disease is higher than expected: a meta-analysis of mortality and disease progression in peripheral arterial disease. Eur J Vasc Endovasc Surg. 2016;51:395-403.
5. Hirsch AT, Hartman L, Town RJ, Virnig BA. National health care costs of peripheral arterial disease in the Medicare population. Vasc Med. 2008;13:209-215.
6. Mills JL Sr. BEST-CLI trial on the homestretch. J Vasc Surg. 2019;69:313-314.
7. McKinsey JF, Zeller T, Rocha-Singh KJ, et al. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv. 2014;7:923-933.
8. Mustapha JA, Lansky A, Shishehbor M, et al. A prospective, multi-center study of the Chocolate balloon in femoropopliteal peripheral artery disease: the Chocolate BAR registry. Catheter Cardiovasc Interv. 2018;91:1144-1148.
9. IN.PACT Admiral [instructions for use]-revision 1H. Minneapolis (MN): Medtronic, Inc.;2018.

Nicolas J. Mouawad, MD, MPH, MBA, FSVS, FACS, FRCS, RPVI
Chief, Vascular and Endovascular Surgery
Vice Chair, Department of Surgery
Medical Director, Noninvasive Vascular Laboratory
McLaren Bay Region
Bay City, Michigan
nmouawad@gmail.com
Disclosures: Consultant for Medtronic, Endologix, WL Gore & Associates, Philips, Silk Road Medical.

- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP 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 µg of paclitaxel in a patient has not been clinically evaluated.

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 resterilize this product. Reuse, reprocessing, or resterilization 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 (IFU) 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 pre-dilatation 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; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia 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 spasms or recoil; vessel trauma which requires surgical repair.

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 leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; 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(opens new window).

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

NanoCross™ Elite 0.014" OTW PTA balloon catheter

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.

The Chocolate™* PTA balloon catheter

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.