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Long Balloons in Practice: Improving Our Treatment Options

By Samuel N. Steerman, MD, FACS, RPVI

As a vascular surgeon in a busy clinical practice, I encounter a wide variety of cases that challenge the tools we have available. In this article, I discuss a complex case that highlights the benefits of a new tool in our endovascular armamentarium: long drug-coated balloons (DCBs).

CASE REPORT

A 61-year-old man presented for evaluation of right leg claudication and new-onset rest pain. His vascular history included a stent in the right superficial femoral artery (SFA), which was implanted in 2010. He also had diabetes and hypertension and smoked a pack of cigarettes a day. He reported experiencing pain in his right leg with ambulation for 6 months, and he was only able to walk for a few minutes before he needed to stop and rest. Upon presentation, he had been experiencing rest pain in his right leg for about 1 week.

After speaking with the patient about blood pressure and diabetes control, ensuring he was on antiplatelets, and recommending smoking cessation, the decision was made to proceed with right lower extremity angiography. The left femoral artery was cannulated with an 18-gauge needle, and a wire was advanced. A 5-F sheath was advanced over the wire, and the wire was removed. A Bentson™* wire (Cook Medical) was advanced past the renal arteries, and angiography was performed using a universal flush catheter. The angiogram showed widely patent renal arteries and aorta. The iliac arteries were bilaterally patent, with mild stenosis of the right external iliac artery. The right common femoral artery was mildly stenotic, the origin of the profunda was stenotic, and there was an occlusion of the SFA from the origin through the previously placed stent in the distal SFA and proximal popliteal (Figure 1). The popliteal artery reconstituted at the knee joint and the tibial arteries

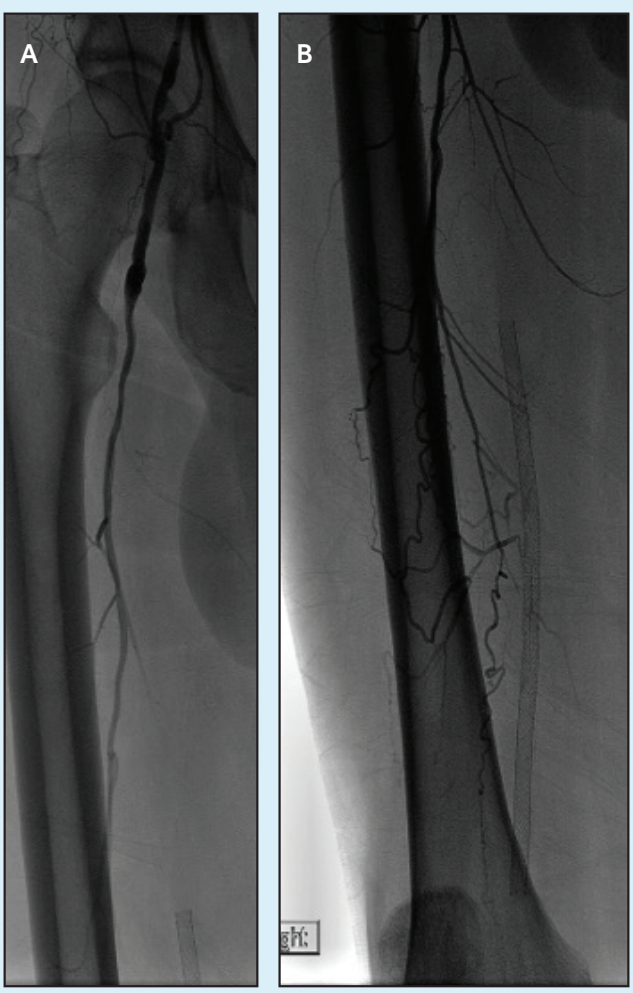

Figure 1. Preintervention angiograms: common femoral artery, profunda, and SFA (A); SFA and occluded popliteal stent (B).

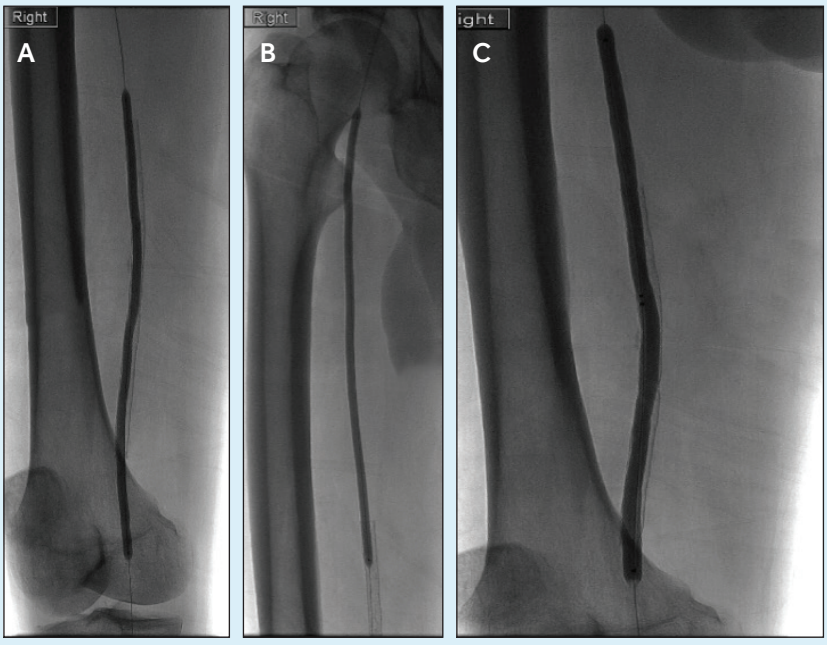

Figure 2. Procedural angiograms: predilation PTA within the stent (A); PTA of the SFA (B); in-stent restenosis treated with the IN.PACT™ Admiral™ DCB (C).

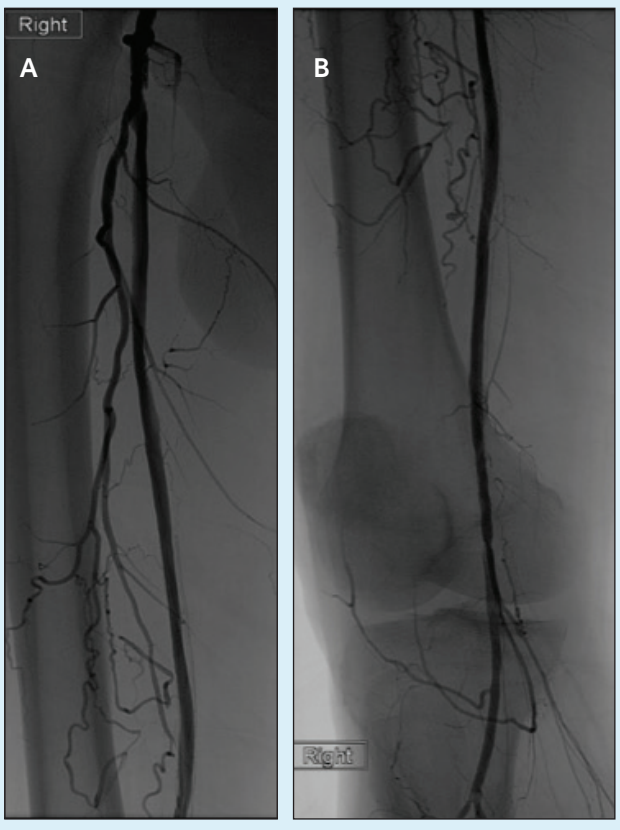

Figure 3. Postprocedure angiograms: patent SFA (A) and patent stent after treatment with the IN.PACT™ Admiral™ DCB (B).

were widely patent. Long lesions, such as this one, that are also chronic total occlusions and have in-stent restenosis are an especially challenging clinical presentation to treat.

A 7-F sheath was exchanged over a stiff wire into the right iliofemoral vessels, and the patient was heparinized. The lesion was crossed subintimally with a Glidewire Advantage™* guidewire (Terumo Interventional Systems) and a Trailblazer™ support catheter (Medtronic); selective injection at the level of the popliteal artery confirmed reentry into the true lumen. Standard percutaneous transluminal angioplasty (PTA) was performed inside the stent with a 5-mm balloon to prepare the vessel for optimal DCB use (Figure 2A). Visual inspection of the inflated balloon in two planes showed no outcroppings or plaque resistant to the inflation process. However, during PTA, plaque shifted and occluded the profunda. In a buddy wire configuration, a Glidewire and Berenstein catheter (AngioDynamics) were used to select the profunda. PTA was performed on the origin with a 5-mm balloon, resolving the occlusion (Figure 2B).

The stented femoropopliteal segment was treated with a 6- X 250-mm IN.PACT™ Admiral™ drug-coated balloon (Medtronic) (Figure 2C). Trackability, even inside a stent, was fluid due to the predilatation, and placement was easily guided by the proximal, mid, and distal markers. The completion angiogram showed an excellent result with preserved runoff to the foot and no dissection; stenting was not required (Figure 3).

DISCUSSION

Since the advent of antirestenotic therapy, cases often have a two-staged approach composed of plaque debulking and DCB angioplasty. After crossing the lesion, the first stage of directional atherectomy is used to debulk the plaque and to open the vessel in the acute setting. Once successful atherectomy is performed to achieve < 30% stenosis, then the second stage of delivering DCB angioplasty is performed. The IN.PACT™ Admiral™ DCB is an excellent choice due to the ease of use and excellent clinical outcomes.

The long lesion indication up to 360 mm was approved based on a subset of imaging data from the IN.PACT Global study that included patients with chronic total occlusions, long lesions, and in-stent restenosis.[1] This cohort of 227 patients treated with DCBs had lesions longer than 18 cm, with a mean lesion length of 28.74 ± 7.11 cm; 70.1% of patients had occlusions. Patients had high rates

of comorbidities: 86.7% had hypertension and 40.6% had coronary heart disease. In addition, rates of previously treated disease of the SFA were 48.1%. Patency through 12 months using Kaplan-Meier analysis was 89.1%, and the rate of clinically driven target lesion revascularization was 7.1%. The complex patients and lesions included in this post hoc analysis are similar to the ones I see in everyday practice, and the outcomes are remarkably good despite these challenges.

Before approval of long DCBs, I still would have used the shorter-length IN.PACT™ Admiral™ DCB to treat these lesions. Now, the 200- and 250-mm lengths allow me to complete cases quicker and keep my endovascular procedures efficient and effective for my patients. ■

1. IN.PACT Admiral DCB [instructions for use, Revision 1H]. Minneapolis, MN: Medtronic; 2018.

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IN.PACT™ Admiral™ Paclitaxel-coated PTA balloon catheter Brief Statement

Indications for Use:
The IN.PACT™ Admiral™ Paclitaxel-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/cerebrovascular 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
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients**.
- 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 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.

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

Trailblazer™ support catheter Reference Statement

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.

TrailBlazer™ Angled Support Catheter

Indications for Use:
- TrailBlazer™ Angled Support Catheters 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.