Case Study: Complex Long Lesion Intervention With the Lutonix® 035 Drug-Coated Balloon

Choosing the right DCB is paramount to avoiding complications when patients present with nonhealing wounds and single-vessel runoff.

BY ROBERT E. BEASLEY, MD

The opinions and clinical experiences presented herein are for informational purposes only. The results from this case study may not be predictive for all patients. Individual results may vary depending on a variety of patient-specific attributes.

An 87-year-old woman with a history of critical limb ischemia (CLI) presented with rest pain in her left lower extremity and a deep nonhealing ulcer on her left heel from a fall 2 months earlier. Duplex ultrasound revealed an occlusion in the left superficial femoral artery (SFA). An angiogram showed a 200-mm complex lesion from the mid-SFA to the proximal popliteal artery with tandem stenoses and a 5-cm total occlusion (Figure 1). One-vessel runoff was observed via the peroneal artery to the ankle with reconstitution of the anterior tibial and plantar branches.

TREATMENT OPTIONS

Stenting the entire segment restricts surgical options, which is why I see drug-coated balloons (DCBs) as the superior minimally invasive approach, leaving spot stents as a bailout option. Because of this patient's single-vessel runoff, deep tissue ulcers, and history of CLI, choosing a DCB with data supporting safety and a proven record of zero downstream effects is paramount. The primary goal of this case is wound healing; therefore, it is critical to choose a DCB that does not embolize paclitaxel to the ulcer downstream and cause more fibrinoid necrosis.[1] This case cements my strategy of using the Lutonix® DCB (Bard Peripheral Vascular, Inc.) with its low dose of paclitaxel and indisputable safety evidence relating to nontarget tissues and wound healing.[1]

COURSE OF TREATMENT

After crossing the total occlusion with the Crosser® CTO device (Bard Peripheral Vascular, Inc.), a 0.035-inch stiff wire was used to deliver a 4- X 150-mm Ultraverse® 035 balloon (Bard Peripheral Vascular, Inc.) to prep the vessel. After inflation for 1 minute, the balloon was moved distally, and inflation was repeated to prepare the entire lesion (Figure 2). I believe slow inflation and deflation of predilatation balloons reduces the chance of dissections.

On the final Ultraverse® inflation, I utilized Bard's GeoAlign® markers to note that the catheter was showing 69 cm at the marker where it entered the sheath hub (Figure 3). I then ran my first Lutonix® DCB (5 X 100 mm) to read 70 cm where entering the sheath hub, attaining 1 cm of drug overlap from the plain balloon inflation. The GeoAlign® markers enable me to briefly use fluoroscopy to confirm the location of the balloon, because the ruler on the shaft indicates how far the catheter has advanced. As a result, both patient and operator are exposed to less fluoroscopy.

The Lutonix® DCB was inflated for a full 2 minutes after wall apposition. The process was repeated with another 5- X 100-mm Lutonix® DCB followed by a 5- X 40-mm Lutonix® DCB, ensuring proper overlap with each balloon (Figure 4).

RESULTS

Immediately after using the Lutonix® DCBs, angiography revealed excellent blood flow with < 5% residual stenosis

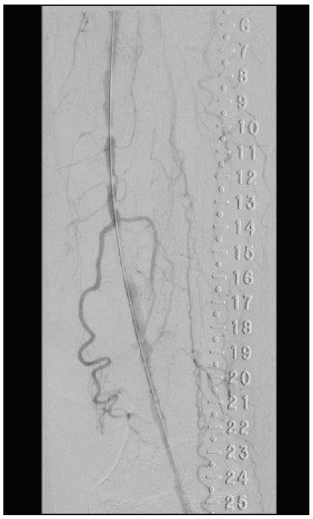

Figure 1. A 200-mm complex lesion extending from the mid-SFA to the proximal popliteal artery. The image was taken after successful crossing.

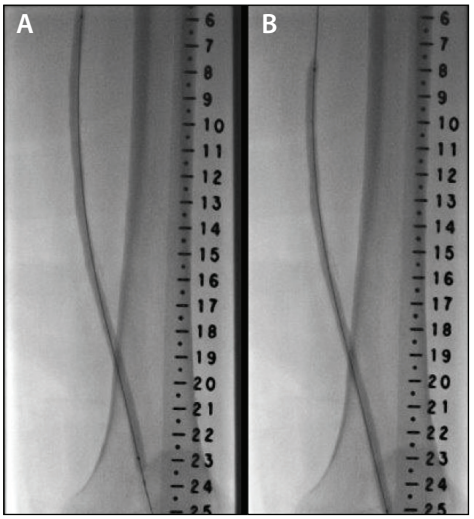

Figure 2. First inflation of a 4- X 150-mm Ultraverse® 035 (A). Second inflation of 4- X 150-mm Ultraverse® 035 (B).

Courtesy of Bard Peripheral Vascular, Inc.

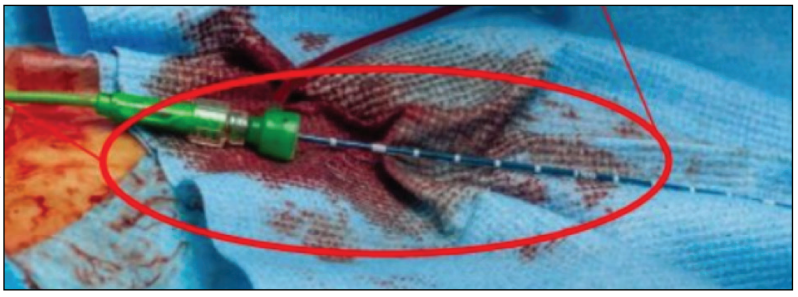

Figure 3. The GeoAlign® markers provide a simple way to reduce fluoroscopy time and ensure fast DCB delivery to the lesion.

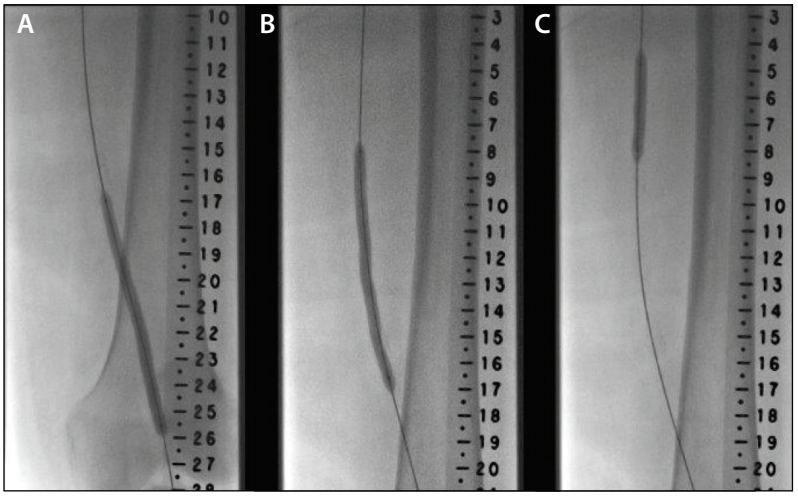

Figure 4. First inflation of a 5- X 100-mm Lutonix® DCB (A). Second 5- X 100-mm Lutonix® DCB inflation (B). Third Lutonix® DCB inflation (5 X 40 mm) (C).

(Figures 5 and 6), and the patient's foot felt warm. One week after the intervention, the podiatry department reported a distinct improvement, with a decrease in wound size and depth. The wound was reduced from deep tissue to a superficial eschar, which was removed to expose healthy tissue recovery (Figure 7).

DISCUSSION

If I were to treat this patient before the approval of DCBs, I would have performed balloon angioplasty and stented this entire segment. Aside from patency advantages over angioplasty alone, DCBs afford the option of spot stenting only when needed for recoil or dissection. I advocate using DCBs over stenting, especially in long lesions, due to the limited surgical options that stents alone create. If in-stent restenosis occurs, the presence of a stent at the popliteal could advance an above-the-knee bypass to a below-the-knee bypass. Additionally, implantation of a foreign body metallic stent can trigger an inflammatory reaction from the immune system, elevating the argument for practicing a no-metal-left-behind approach. DCBs only leave behind therapeutic drug; in avoiding the escalation of treatment, I believe this is the best option, and it is in that mindset that I am driven to choose the safest DCB possible.

With single-vessel runoff and a foot wound, patients like this raise the issue of using a DCB with a strong safety profile. I recommend Lutonix® due to preclinical evidence from Dr. Virmani and the CVPath Institute regarding particulate embolization.[1] This study clearly finds fibrinoid necrosis in tissues treated with the In.Pact™ DCB (Medtronic) in addition to paclitaxel-induced loss of smooth medial muscle cells, whereas no negative effect was observed in the Lutonix® DCB group. Safety also comes to mind when I consider that Lutonix® is the only DCB that the US Food and Drug Administration has approved for lesions as long as the one in this case (up to 300 mm).

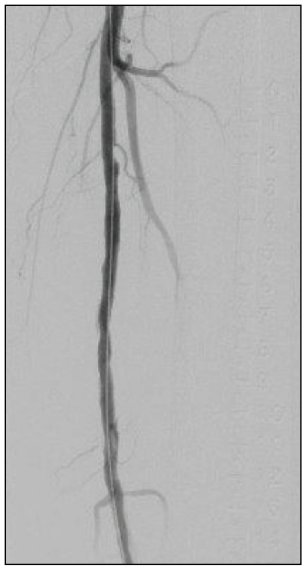

Figure 5. Proximal SFA DCB results showing < 5% residual stenosis.

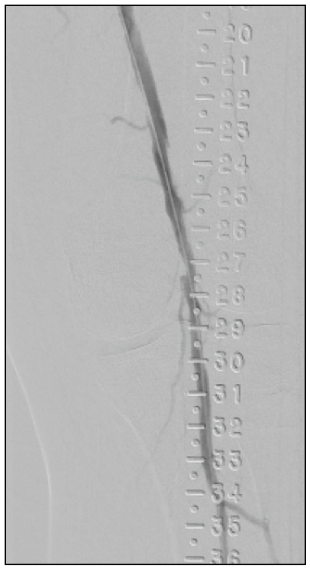

Figure 6. After use of a Lutonix® DCB, the popliteal artery showed < 5% residual stenosis.

In addition to choosing the right DCB for the patient, it is important to employ the best practices possible to achieve optimal results from its inflation. I often treat calcified lesions with the Lutonix® 035, and a 0.035-inch balloon over a 0.018-inch or 0.014-inch wire does not always track well through calcium. To ensure the DCB reaches the lesion quickly, I recommend using a 0.035-inch wire for the 0.035-inch–compatible balloon.

I believe that the GeoAlign® markers provide an elegantly simple way to limit unnecessary fluoroscopy and decrease transit time of the Lutonix® DCB. Although GeoAlign® may save only seconds on each run, those seconds add up to unnecessary exposure time to patients and staff. I believe this will become an increasingly significant topic, and we should call strict attention to any unnecessary fluoroscopy, no matter the duration.

Achieving a residual stenosis of < 20% helps ensure DCB efficacy.[2] I achieve this using long, slow inflations of my vessel prep balloon, as well as keeping my DCB inflated for a full 2 minutes. The sizing of the balloon helps as well; I typically size the DCB diameter to at least 1:1 to the vessel wall. I believe these practices increase introduction of drug to smooth muscle cells as well as tack up dissections without needing stents.

I determined that using the Crosser® was appropriate for this case because the device has increased my intraluminal crossing rate, which I believe yields a better result and decreases the need for spot stenting. As an additional benefit, the Crosser® traversed the occlusion in this patient in < 10 seconds.

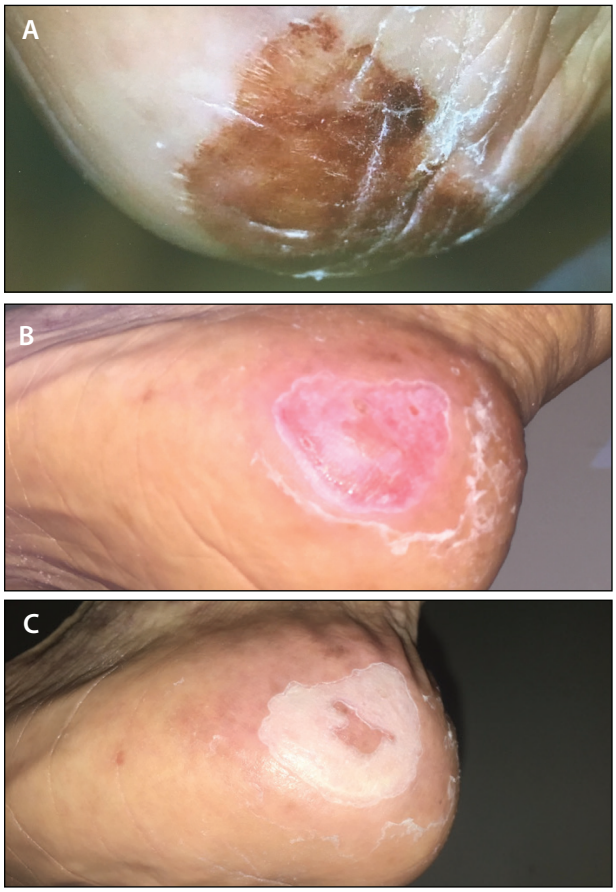

Figure 7. Deep tissue ulcer on the left heel before intervention (A). Dry eschar was removed 1 week after the intervention (B). Just over 2 weeks after the intervention, the wound showed significant improvement (C).

In summary, feedback from podiatry shows immediate wound healing on an 87-year-old woman, reducing her disease from Rutherford class 5 after treating a long lesion with three Lutonix® DCBs. Revascularization was completed from the SFA and pedal work was avoided. At this point, there is no reason to believe this wound will not heal completely. ■

1. Kolodgie FD, Pacheco E, Kazuyuki Y, et al. Comparison of particulate embolization after femoral artery treatment with IN.PACT Admiral versus Lutonix 035 paclitaxel-coated balloons in healthy swine. J Vasc Interv Radiol. 2016;11:1676-1685.
2. Scheinert D. Latest insights from the LEVANT II study and sub-group analysis. Presented at Leipzig Interventional Course (LINC); January 2016; Leipzig, Germany.

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