Treating BTK CLI With Balloon-Expandable DES After Retrograde Tibial-Popliteal Recanalization

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A 99-year-old independently living patient presented with ulceration over the base of the right metatarsophalangeal joint. The lesion developed after hospitalization for anemia secondary to occult gastrointestinal bleeding. She was evaluated by the wound care division of the Columbia-St. Mary's Vascular Institute. Local wound care measures were recommended because of her advanced age, comorbidities, absence of resting pain, and desire to avoid invasive procedures.

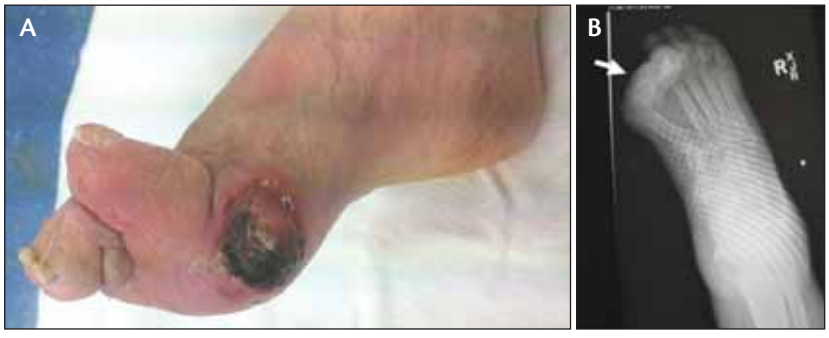

Figure 1. Preintervention. Deep ulceration and gangrene of the first metatarsal head (A). X-ray of the foot showing lytic destruction of the first metatarsal (B).

She had a history of diabetes, atrial fibrillation, episodic occult gastrointestinal bleeding, anemia, renal insufficiency (creatinine = 1.7 mg/dL), hypertension, hyperlipidemia, and a failed left femoropopliteal bypass. One year earlier, she had undergone successful endovascular therapy of an occluded left femoropopliteal graft for Rutherford class 5 critical limb ischemia (CLI) with complete wound healing and resolution of symptoms.

During the next month, the patient developed resting foot pain requiring oral narcotic analgesia, a 4-cm full-thickness circumferential purulent lesion, foot cellulitis, and associated necrotic tissue (Figure 1A). Intravenous antibiotics were started, and endovascular and podiatric consults were obtained. Radiography of the foot revealed lytic destruction of the great toe (Figure 1B). Ankle-brachial indexes were incompressible with monophasic waveforms and a digital right toe pressure of 32 mm Hg. Angiographic evaluation was recommended. On the day before the procedure, clopidogrel, aspirin, and sodium bicarbonate hydration were initiated.

A 5-F sheath was placed in the right femoral artery via an antegrade approach for angiography. The superficial femoral artery (SFA) showed moderate diffuse disease of the mid- and distal SFA and total occlusion of the popliteal artery from the joint space extending to the proximal one-third of all three tibial vessels (Figure 2A and 2B). There were collaterals from the popliteal artery that reconstituted the midportions of the anterior tibial and posterior tibial arteries. The peroneal artery was occluded, there was an intact dorsal-plantar loop, and the peroneal artery was occluded (Figure 2C).

A 45-cm, 5-F Pinnacle Destination sheath (Terumo Interventional Systems, Somerset, NJ) replaced the 11-cm sheath, and unfractionated heparin (40 U/kg) was

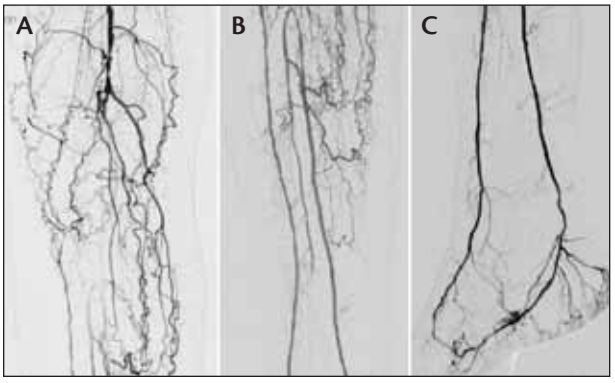

Figure 2. Preintervention angiograms of the distal SFA (A), popliteal, and proximal tibial vessels (B) and pedal runoff (C). There is total occlusion from midpopliteal space to midcalf with well-developed collateral reconstitution of anterior and posterior tibial arteries and distal peroneal artery occlusion. Note intact pedal loop.

administered. Attempts at recanalizing the occluded popliteal segment from the antegrade approach were unsuccessful, resulting in extensive subintimal dissection to the level of the anterior tibial-popliteal bifurcation. Arterial access was then achieved from the retrograde posterior tibial artery, just above the lateral malleolus, using fluoroscopic roadmapping and a 21-gauge micropuncture needle. A 4-F dilator was placed in the tibial artery over a 0.018-inch wire. A number of different 0.014-inch uncoated and hydrophilic wires were used in an attempt to enter the true lumen without success.

Finally, a Winn 200T wire (Abbott Vascular, Santa Clara, CA) with a 70º bend, supported with a 0.018-inch QuickCross catheter (Spectranetics Corporation, Colorado Springs, CO), successfully entered the true lumen in the distal popliteal artery. The wire and catheter were exteriorized through the femoral guiding sheath. From the femoral direction, balloon angioplasty was performed on the proximal and midpopliteal segment using a 4- X 60-mm Amphirion balloon (Medtronic Invatec, Frauenfeld, Switzerland). The subintimal track crossing the joint space was stented with a 5- X 60-mm Xpert self-expanding stent (Abbott Vascular).

The distal popliteal and posterior tibial arteries were then dilated with a 3.5- X 40-mm Savvy balloon catheter (Cordis Corporation, Bridgewater, NJ), ensuring that there was complete balloon expansion. This entire segment was then stented using overlapping drug-eluting stents (DES) as per the PARADISE protocol.[1] These included a 3.5- X 33-mm Cypher stent (Cordis Corporation), a 3.5- X 28-mm Xience stent (Abbott Vascular), and a 3- X 28-mm Cypher stent. The transition between the self-expanding stent and the proximal 3.5-mm DES was tapered using a 4-mm-diameter balloon deployed at high pressure.

Finally, an additional 2.5- X 28-mm Cypher stent was deployed to treat a midportion posterior tibial lesion. Repeat angiography showed that the artery was now smooth and continuously patent with rapid runoff into the foot, complete filling of the pedal artery, and retrograde filling of the anterior tibial artery (Figure 3). Hemostasis of the tibial access site was achieved by inflating a 2.5- X 40-mm balloon at the site of puncture. The patient left the lab with a bounding posterior tibial pulse.

Two days later, under conscious sedation, the patient underwent an elective first ray amputation, incision and drainage, and primary closure (Figure 4A). Four weeks later, the surgical site was healed (Figure 4B), and the patient was pain free. She remains asymptomatic 4 months after the procedure, with palpable posterior and anterior tibial pulses.

DISCUSSION

This case illustrates a number of issues related to contemporary endovascular limb salvage.

First, it is important to foster an integrated approach among endovascular, surgical, and wound care specialties. The importance of restoring hemodynamically stable straight-line blood flow (to the appropriate angiosome if possible) is paramount. Once this has been accomplished, aggressive wound care, surgical debridement, and minor amputation should be instituted as soon as possible to take advantage of maximal blood flow.

Advanced age or comorbidities alone should not constitute an absolute contraindication to aggressive inter-

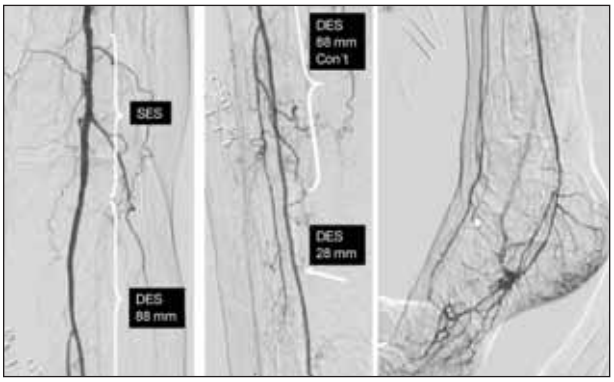

Figure 3. Postintervention angiograms. Note the 6-cm Xpert self-expanding stent proximally transitioning into 89 mm of overlapping DES.

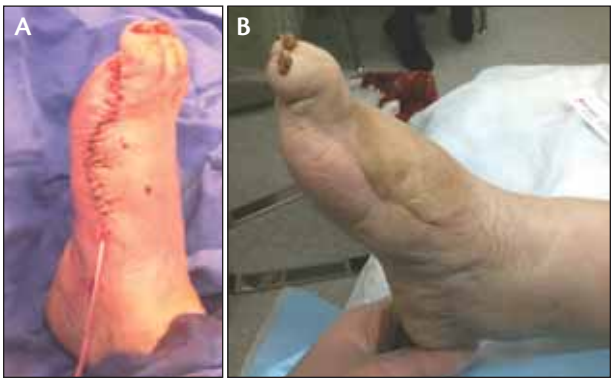

Figure 4. Status immediately after first ray amputation (A). Results 4 weeks after intervention (B). Note complete healing of amputation site.

vention as long as there is a reasonable expectation that the patient's quality of life will improve.

It is important to consider a retrograde tibial artery approach when the antegrade approach fails. Familiarity with this approach is imperative if the interventionist is to successfully develop a limb salvage program. In this case, although retrograde access could have been achieved from either the anterior or posterior tibial arteries, the posterior tibial approach was chosen because of its straighter course, which facilitated popliteal reentry to the true lumen as well as stent deployment. Because the pedal loop was intact, adequate revascularization from either artery was possible with good prospects of providing appropriate angiosome flow.

The hemodynamic goal of CLI intervention is to provide maximum and sustained conduit flow for sufficient time to heal the lesion and relieve symptoms. To attain this goal, we advocate primary stenting of all CLI-related lesions, especially in patients with tissue loss (Rutherford class 5 and 6) and total occlusions. Early percutaneous transluminal angioplasty (PTA) failures are common even when the initial results are cosmetically appealing. Balloon PTA has an average procedural failure rate of at least 20% (BASIL)[2] and a 1-year primary patency rate of ≤ 30% depending on vessel size, lesion length, diabetes, chronic renal insufficiency, and tobacco use.[3] To date, only stents have shown the ability to reliably minimize elastic recoil and prevent abrupt occlusion from secondary intimal flaps and dissection.

In our practice, we advocate the use of DES for many CLI tibial interventions. For the past 7 years, we have been enrolling patients in the institutional review board-approved PARADISE trial,[1] evaluating the use of primary stenting with DES in patients with below-the-knee (BTK) CLI. The rationale for DES use may be stronger than the use of any other approved CLI treatment modalities. There is more than a decade of data regarding the use of DES in coronary vessels between 2 and 4 mm, which is nominally the size of the tibial vessels. Primary coronary intervention with DES is the most effective approach for both preventing early interventional failures and suppressing restenosis in high-risk subgroups (ie, patients with long lesions and diabetes).

There is a rapidly accumulating body of evidence, both randomized and single-center studies, that uniformly draws the same conclusion: DES for BTK CLI not only stabilizes the early intervention but maintains long-term patency.[4] We have found that the use of DES for CLI provides gratifying results with negligible early failure rates, substantially lower target lesion revascularization rates, and higher long-term patency than balloon PTA, bare-metal stents, or any of the multiple atherectomy devices available.

Moreover, there are accumulating data that show that these results are sustained for more than 3 years.[1,4] Finally, treating a vessel with DES requires less time than atherectomy, has a minimal risk of procedural complications (ie, embolization), reduces the amount of contrast used, and can be delivered through 4- or 5-F sheaths. Unfortunately, although BTK DES have CE Mark approval in Europe, there is no US Food and Drug Administration approval for using this coronary-approved device in the unapproved BTK location. ■

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