Novel Therapeutic Options in Critical Limb Ischemia and Infrapopliteal Disease Using Hybrid Atherectomy and Caged-Balloon Angioplasty

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ABSTRACT: Therapeutic options for below-the-knee arterial interventions are currently wide and varied, with limited data. Long-term vessel patency remains a challenge, particularly in critical limb ischemia where the goal is wound healing. The development of novel treatment devices, including hybrid atherectomy and caged-balloon angioplasty, may offer better procedural success and wound-healing outcomes. Herein, we present a case of critical limb ischemia with nonhealing ulceration that was successfully treated with hybrid atherectomy and constrained-balloon angioplasty with excellent angiographic result and short-term follow-up.

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Key words: critical limb ischemia, below-the-knee intervention, hybrid atherectomy, caged-balloon atherectomy, nonhealing wound

An 81-year-old male with a prior history of diabetes mellitus, hypertension, hyperlipidemia, and coronary artery disease was seen and evaluated for a nonhealing ulcer of the left foot localized to the plantar aspect of the first and second toes. The patient noted onset of the ulcer 3 months prior with no improvement despite conservative wound management therapies. On subsequent evaluation, the wound consisted of a central eschar and surrounding erythema. The left dorsalis pedis and posterior tibial (PT) pulses were detectable by Doppler only. Ankle-brachial index (ABI) measurement revealed an ABI of 1.07 in the right lower extremity and 0.48 in the left lower extremity.

Given the clinical presentation of critical limb ischemia (CLI) and nonhealing ulceration of the left foot, the decision was made to pursue invasive revascularization. Right common femoral access was achieved with insertion of a 6 Fr sheath and a crossover technique for engagement of the left external iliac artery. Selective left external iliac artery angiogram with run-off demonstrated mild common, superficial femoral, and popliteal artery disease. The proximal anterior tibial (AT) artery had 90% severe stenosis, with 80% to 90% diffuse tibioperoneal trunk (TPT) disease, and 90% ostial PT artery stenosis (Figure 1).

An 0.014” workhorse wire with a support catheter was advanced across the AT lesion into the distal dorsalis pedis artery. The workhorse wire was then exchanged for an 0.014” Viper wire (Cardiovascular Systems Inc.),
and a Phoenix hybrid atherectomy device (Volcano Corporation) which was positioned in the proximal AT (Figure 2). Two passes of rotational atherectomy were performed with good result, followed by caged balloon angioplasty using a Chocolate 4 mm x 40 mm balloon (Trireme Medical) (Figure 3). Next, the wire was redirected across the TPT lesion into the distal left PT and Phoenix rotational atherectomy performed within the TPT and proximal PT segments (Figure 4), followed by caged balloon angioplasty (Figure 5). Postintervention angiography demonstrated excellent result with less than 10% residual stenosis (Figure 6) and preserved run-off to the foot. Three-month clinical follow-up showed good wound healing of the first and second toes, without further extension or need for additional intervention.
DISCUSSION

Therapeutic options for below-the-knee (BTK) arterial interventions are currently wide and varied, with limited supporting data. Long-term vessel patency remains a challenge, particularly in CLI where the goal is wound healing. Attempts at improving patency have been studied using drug eluting stents (DES) as well as drug-eluting balloons (DEB). In the ACHILLES trial, primary patency of sirolimus-eluting stents (SES) was studied in comparison to balloon angioplasty (BA) in patients with symptomatic claudication and infrapopliteal atherosclerosis. Results of the study demonstrated that SES resulted in reduced angiographic restenosis rates (22.4% vs 41.9%, \( P=.019 \)), and greater vessel patency (75% vs 57.1%, \( P=.025 \)) in comparison to BA.²

Data for DEB for BTK disease have been mixed. In the IN.PACT DEEP randomized clinical trial, paclitaxel DEB was compared to BA in patients with critical
limb ischemia. At 12-month follow-up, there was no significant difference in target lesion revascularization (9.2% vs 13.1%, \( P=.291 \)) in DEB compared to traditional BA, respectively. Although the primary safety endpoint was met, there was a trend toward increased major amputation in the DEB arm.\(^5\) In the DEBATE-BTK trial, diabetic patients with CLI were treated with either DEB or BA. At 12 months, DEB treated patients had significantly less binary restenosis (27% vs 74%, \( P<.001 \)) in comparison to BA as well as less target lesion revascularization (18% vs 43%, \( P=.002 \)).\(^4\) Further clinical trial data is ongoing in the LUTONIX BTK study, also investigating DEB vs BA in CLI patients.

Another recent trial studied the use of paclitaxel DEB vs DES for CLI patients. At 6-month follow-up, the DES patients had less binary restenosis compared to DEB (28% vs 57.9%, \( P=.0457 \)), without a significant difference in target lesion revascularization.\(^5\)

Atherectomy can be a useful adjunctive tool for BTK interventions. Several options exist, including excimer laser atherectomy, rotational or orbital atherectomy, and directional atherectomy. The Phoenix atherectomy device employs a concentrically spinning cutting blade with plaque extraction through an internal Archimedes’ screw. The smaller 1.8 mm device iteration offers BTK atherectomy options.

The Chocolate balloon, a nitinol-constrained balloon catheter, can offer an alternative to traditional BA in BTK disease. Recently presented at the 5th Annual Amputation Prevention Symposium, registry data suggest a lower incidence of bail-out stenting, target lesion revascularization, and amputation at 6 months with Chocolate balloon use compared to BA.\(^6\)

Herein, we present a case of CLI with nonhealing ulceration, successfully treated with Phoenix hybrid atherectomy and constrained balloon angioplasty with excellent angiographic result and short-term follow-up.

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