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The Benefit of Cryoplasty in the Office-Based Lab

The patient and case dynamics to weigh out when utilizing an interventional approach to PAD.

BY GEORGE NASSER, MD, FACC

The PolarCath Balloon Dilatation System (NuCryo Vascular, LLC) is a versatile specialty balloon that offers the unique mechanism of cryogenic cooling to treat peripheral vascular disease. The PolarCath balloon uses the phase change of liquid nitrous oxide to gas to inflate the balloon and cool the arterial wall to -10° C for a controlled 20 seconds. This controlled cryotherapy can induce apoptosis in smooth muscle cells and other cells that participate in the restenosis process.

The peripheral vascular treatment algorithm in my office-based lab is driven by patient presentation, clinical outcomes supported by clinical data, cost, and overall efficiency of the device. As a result, PolarCath is an integral component of my treatment algorithm for peripheral artery disease for the reasons presented in this article.

INDICATIONS

The intended use of the PolarCath Peripheral Dilatation System is for the dilatation of stenoses in the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal, and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene access grafts or native arteriovenous dialysis fistulas. The PolarCath Peripheral Dilatation System is also indicated for postdeployed stent expansion of self-expanding peripheral vascular stents.

CRYOPLASTY VERSUS DRUG-COATED BALLOONS IN THE OFFICE-BASED LAB

Cryoplasty and drug-coated balloons (DCBs) both tout a mechanism of action that minimizes smooth muscle cell proliferation via apoptosis. DCBs in the United States currently use an excipient and paclitaxel, while cryoplasty uses cryogenic therapy at -10° C to induce apoptosis. With a similar mechanism of action to DCBs, cryoplasty offers several other advantages for my peripheral procedures in the office-based lab.

Cost

Currently, cryoplasty catheters are significantly less expensive than DCBs without any additional reimbursement, and thus cryoplasty offers a significant savings. The cryoplasty balloon also offers savings when multiple treatments are needed in a given case. Because the same PolarCath balloon can be used multiple times as compared to the one-time delivery of the DCB, PolarCath offers incremental savings when treating long, diffuse lesions or stenoses requiring multiple treatments. This cost savings will also now be realized in the hospital setting, as all DCB outpatient pass-through codes were eliminated at the end of 2017.

Procedural Efficiency

Cryoplasty also increases the overall efficiency of my peripheral procedures. Because the PolarCath balloon can provide multiple treatments of long segments with the same balloon, the need for multiple balloons is minimized. Additionally, DCBs require long inflations to ensure that the drug is absorbed into the arterial wall. With cryoplasty, multiple segments can be treated in the time required to treat one segment with a DCB. Balloon exchanges for each treated segment are not needed with PolarCath; however, a fresh balloon is needed for each segment treated with a DCB. PolarCath does not have excipient issues, and there is no need for filter placement to prevent distal embolization of excipient. This means less equipment, less complexity, less expense, and less time. As a result, by using cryoplasty, I can save approximately 15 to 20 minutes per case as compared to DCBs, which allows me to spend more time seeing other patients.

CASE REVIEW #1

An 80-year-old woman presented to our clinic with a 1-month history of resting right lower extremity pain consistent with critical limb ischemia. Her comorbidities included hypertension and end-stage renal disease, and she was on dialysis. On examination, she had

preserved pulses in the common femoral arteries with poor distal pulses, right worse than left, which was suggestive of superficial femoral artery (SFA) disease. This was confirmed with a noninvasive study.

She was then taken to the office-based lab for invasive study. Right lower extremity arteriography was performed utilizing an up-and-over approach after retrograde left common femoral artery sheath placement. This confirmed diffuse, high-grade right SFA occlusive disease extending into the P1 segment of the right popliteal artery. The diseased segments were successfully crossed with an exchange-length 0.014-inch guidewire with the distal tip placed in the distal peroneal artery. The SFA stenoses were first debulked by atherectomy. The SFA and proximal popliteal artery were then treated with a 5- X 150- X 150-mm cryoplasty balloon with sequential overlapping inflations. Blood flow was restored, and distal pulses were easily palpable and 3+ after the procedure. At 6-month follow-up, the patient was free of ischemic rest pain, and she had no intermittent claudication.

CASE REVIEW #2

An 80-year-old man presented to my office with complaints of right leg pain with a wound. His medical history included coronary artery disease, hypertension, hyperlipidemia, and aortobifemoral bypass grafting. On examination, the right foot and the distal half of the right leg were cool to the touch, the right foot was ruddy, and there was a nonhealing wound with skin breakdown at the right heel.

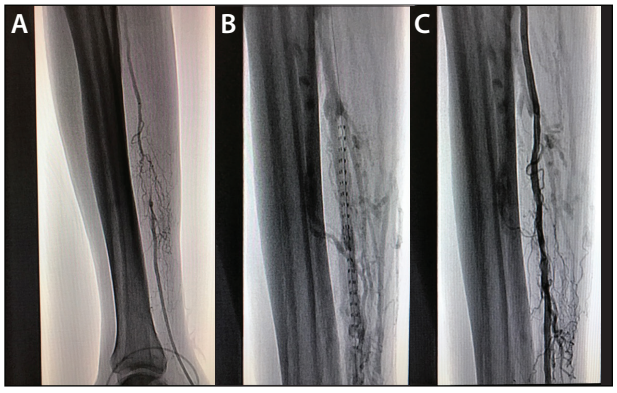

Figure 1. The patient presented with an occluded tibial artery that was treated via pedal intervention (A); cryoplasty was performed with a 2.5- X 150-mm PolarCath balloon (B); and wide patency was achieved (C).

The patient was taken to the office-based lab for invasive evaluation and treatment. After retrograde sheath placement in the left common femoral artery, an up-and-over approach was used for arteriography (Figure 1A). This demonstrated a patent right SFA, occluded anterior tibial artery, patent but diseased peroneal artery, and a total occlusion of the mid-posterior tibial artery. Due to the angulation of the aortobifemoral graft limbs, the patient was sent home and brought back for a pedal intervention.

The posterior tibial artery was accessed utilizing a micropuncture needle under ultrasound guidance. After the total occlusion was crossed, cryoplasty was performed with a 2.5- X 150- X 150-mm balloon (Figure 1B). Wide patency was achieved, and the pedal microsheath was removed with excellent hemostasis (Figure 1C). On follow-up, the wound had completely healed and the ischemic foot changes had resolved.

CASE REVIEW #3

A 68-year-old woman with a prior history of intermittent claudication of the right lower extremity presented to our office. Angiography showed both severe stenoses and aneurysms of the right SFA. She subsequently was treated with placement of a covered stent. After several months, she developed recurrent right lower extremity intermittent claudication; arterial ultrasound showed total occlusion of the stent graft.

She was brought to the office-based lab, placed in the prone position, and a retrograde sheath was placed in the right popliteal artery under ultrasound guidance. The occluded stent was crossed, arteriography was performed proximal to the occlusion, and atherectomy was performed to debulk the stenosis. Cryoplasty was then performed in serial overlapping inflations of the right SFA stent and P1 segment of the popliteal artery utilizing a 6- X 150- X 135-mm cryoplasty balloon. At 3- and 6-month follow-up, she was free of claudication, and 3- and 6- month arterial ultrasounds showed wide patency. ■

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Disclosures: None.