CASE REPORT

Vessel Preparation and Drug-Eluting Balloon With Intravascular Lithotripsy (IVL) and SELUTION SLR™ Drug-Eluting Balloon

SFA and popliteal artery occlusions with heavy calcification treated with IVL followed by the SELUTION SLR™ Drug-Eluting Balloon.

By Bruno Migliara, MD, PhD

CASE PRESENTATION

A woman in her late 50s presented with arterial hypertension, dyslipidemia, and diabetes. Two years prior, she had undergone balloon angioplasty of her left leg due to peripheral artery disease with ischemic rest pain (Rutherford class 4) caused by short subocclusions of the superficial femoral artery (SFA) and the popliteal artery, with complete pain resolution.

She presented with recurrence of the ischemic rest pain (Rutherford class 4) on the left side. Clinically, she had hypothermia in the left foot but no wounds. A duplex ultrasound scan showed direct flow in the common femoral artery and proximal SFA; significant stenosis, with heavy calcifications at the level of the distal SFA; and a heavily calcified subocclusion of the popliteal artery in P1 and P2. The duplex scan wave in P3 showed an indirect flow.

TREATMENT

Based on this situation, the idea was to try to better prepare the lesions at the level of the SFA and popliteal artery, trying to avoid stents in this area, and improve long-term patency using sirolimus as a definitive treatment.

As usual, the procedure started with an antegrade ultrasound-guided puncture of the common femoral artery and, after placing a 6-F sheath introducer, the angiographic study of the limb was done. The initial carbon dioxide (CO2) angiogram (Figure 1A) showed a diseased distal SFA and the subocclusion of the popliteal artery. All of these lesions were highly calcified, with a prevalence of medial calcification (Figure 1B). Based on angiography and the high amount of calcium with typical medial artery calcification, we decided to use intravascular lithotripsy (IVL) to obtain adequate vessel preparation. IVL uses acoustic waves to crush not only superficial but also deep calcium, improving lumen gain and the compliance of the artery wall. IVL achieves this result with low pressure (barotrauma), reducing the risk of flow-limiting dissection and early recoil in this "no-stent" zone. IVL was done with a 6.0-mm Shockwave M^{5+} balloon (Shockwave Medical) using half of the pulses in the popliteal artery and half in the SFA (Figure 1C).

The result of IVL was evaluated with angiography and duplex ultrasound. The use of duplex ultrasound scan is very important with IVL because it shows the restoration of the compliance of the treated arteries and a triphasic wave below the lesion.

Based on the results of IVL, which showed complete resolution of the lesions without residual stenosis, plaque recoil, and flow-limiting dissection, treatment was completed using a SELUTION SLR™ Drug-Eluting Balloon (DEB) (5 X 150 mm) (MedAlliance a Cordis company) to cover all of the prepared area (Figure 1D)

SELUTION SLR™ DRUG-ELUTING BALLOON

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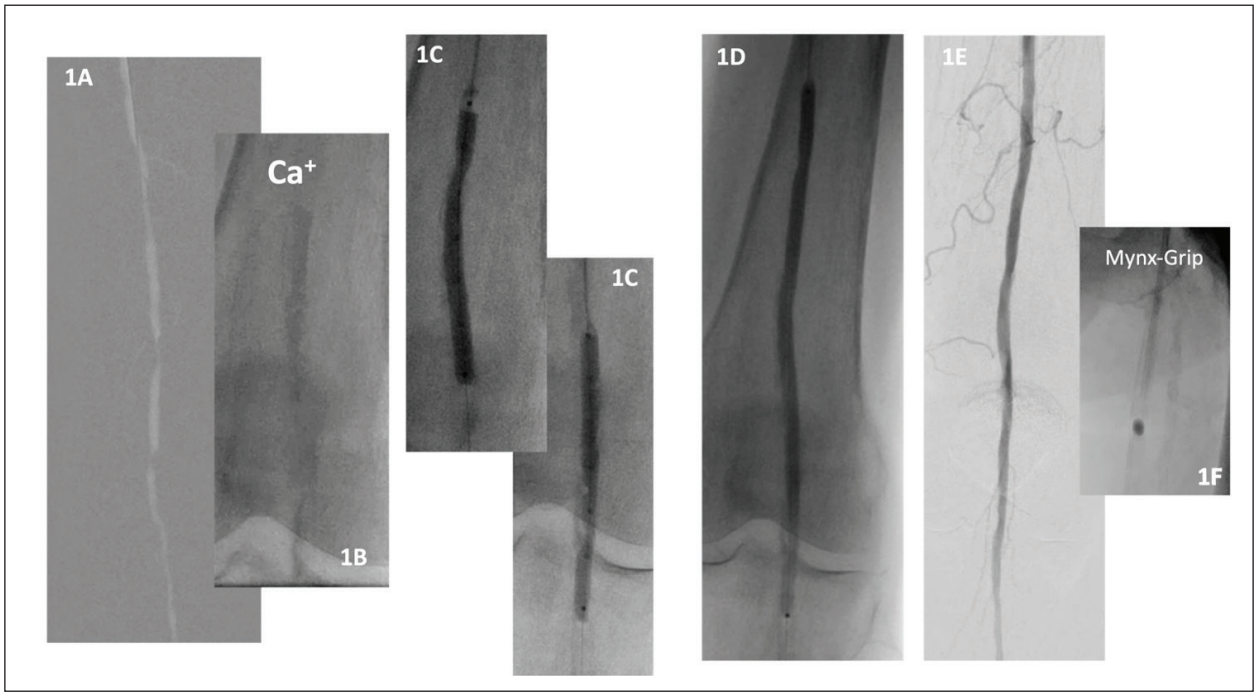

Figure 1. Initial CO2 angiogram (A). Amount of calcium in popliteal artery (B). Use of the 6.0-mm Shockwave M^{5+} device (C). Use of the 5- X 150-mm SELUTION SLR™ DEB (D). Final angiogram (E). Deployment of the MYNX CONTROL™ VCD (F).

and improve long-term patency. The SELUTION SLR™ DEB technology uniqueness is based on two components, which offer sustained sirolimus drug release—the CELL ADHERENT TECHNOLOGY (CAT)™ and MicroReservoirs.

CAT is a mix of phospholipids containing and protecting MicroReservoirs, which facilitates drug uptake and retention in the tissue with a minimal drug loss during the procedure while providing excellent deliverability.

At the end of the procedure, angiography showed complete restoration of flow through the SFA and popliteal artery. The patient had pain resolution, with a normothermic foot on the first postoperative day.

In all such cases, at the end of the procedure, we place a closure device at the femoral access to reduce hemostasis time, bed rest, and access complications. The MYNX CONTROL™ Vascular Closure Device (VCD; Cordis) is our preferred closure device because there are many studies showing the effectiveness in an antegrade approach, with similar results compared with other closure devices. MYNX CONTROL™ VCD also has some advantages, including no intra-arterial material after removal, the possibility to puncture the artery immediately after the deployment, and reabsorbability within 30 days. ■

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