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Transbrachial Access for Stenting of Femoropopliteal Lesions

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Femoral access is the access site of choice for most cardiovascular interventions, but in some cases, a transbrachial or transradial approach is necessary. For lower extremity revascularizations, wires and balloon angioplasty catheters are available in working lengths sufficient for transbrachial or transradial access. However, the shaft length of most self-expanding stents is too short for bridging the distance from the arm to the distal superficial femoral artery (SFA) or popliteal artery.

Due to the recent meta-analysis investigating increased mortality risk after use of drug-coated devices[1] and the response of regulatory bodies worldwide, bare-metal stenting of femoropopliteal lesions has experienced a renaissance. In some cases, the femoral approach is risky or not feasible, and thus, transbrachial stenting with a 150-cm working length, triaxial Entrust™ delivery system (Medtronic) is a valid alternative.[2]

CASE REPORT

A man in his late 70s presented with claudication of his right leg. He had a documented medical history of multiple interventions and operations in both groins, with postprocedural secondary wound infections. Duplex ultrasound and CT scan revealed a calcified stenosis of the distal SFA and a short occlusion of the popliteal artery (Figure 1).

Endovascular treatment through a left brachial access was deemed to be appropriate to treat the lesion. The puncture site was infiltrated with 10 mL of a 2% lidocaine hydrochloride solution. After catheterization of the artery, a 0.035-inch guidewire was introduced, and a 5-F arterial sheath was inserted using the Seldinger technique. Then, 5,000 IU of heparin were administered and angiography was performed, confirming the preoperative diagnosis. A 5-F, 90-cm arterial sheath was introduced to achieve a stable access and perform selective angiographic controls during the procedure.

After recanalization of the popliteal occlusion and angioplasty of the diseased segment with a 5- X 80-mm percutaneous transluminal angioplasty (PTA) catheter, the angiographic control showed a residual stenosis of 50% (Figure 2A). Because alternative methods such as atherectomy were not feasible, transbrachial stent implantation was performed with a nitinol 6- X 80-mm EverFlex™ self-expanding peripheral stent (Medtronic) pre-mounted on a 5-F, 0.035-inch, over-the-wire, one-handed Entrust delivery system. Stent deployment was followed by postdilation with a 6- X 80-mm plain angioplasty catheter. Completion angiography

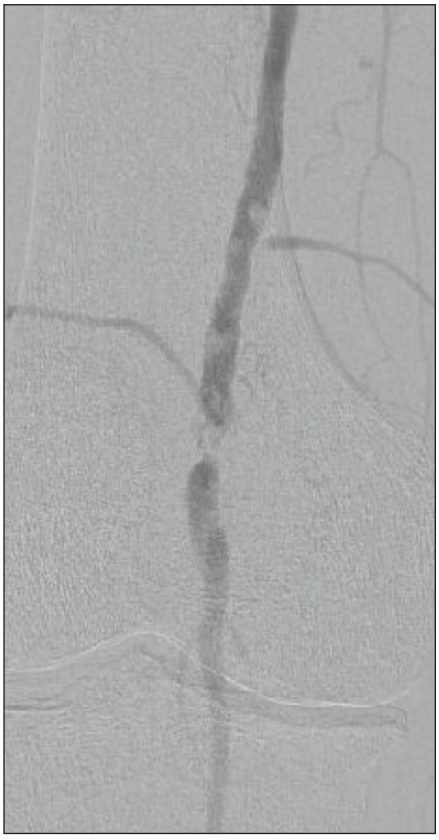

Figure 1. Initial angiography.

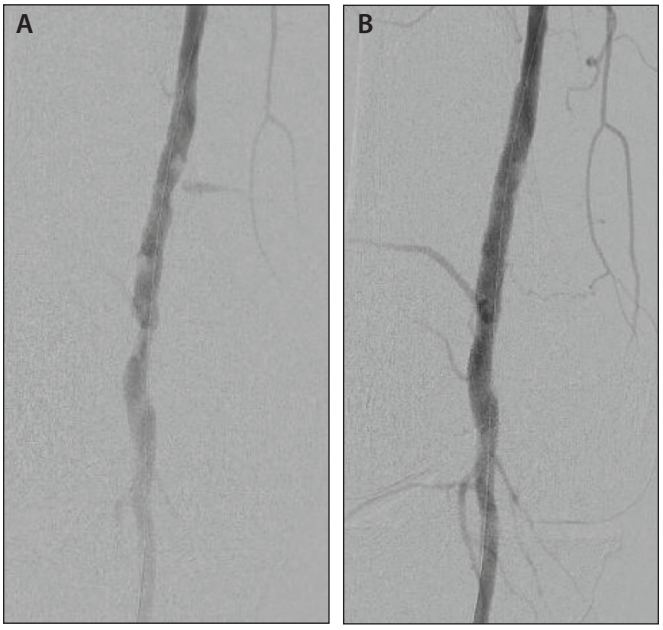

Figure 2. Angiography after PTA (A) with residual stenosis and after implantation of a 6-mm EverFlex self-expanding peripheral stent (B).

showed excellent patency of the femoropopliteal segment (Figure 2B) without any sign of dissection or peripheral thrombosis (Figure 3). Hemostasis was achieved through manual compression of the brachial artery and application of a pressure bandage for 24 hours. Dual antiplatelet therapy with acetylsalicylic acid and clopidogrel was administered for 8 weeks, and the patient will be on lifelong acetylsalicylic acid. Pedal pulses were palpable postoperatively, and the patient completely recovered from his claudication.

DISCUSSION

Transbrachial implantation of a self-expanding stent using the Entrust delivery system enabled the safe and effective treatment of the femoropopliteal lesion in our patient. The Entrust delivery system with a catheter working length of 150 cm was evaluated by Stavroulakis et al.[3] The authors reported a 100% technical success rate, without stent compression or elongation; premature jumping or movement of the nitinol stent was not observed. Early clinical success was achieved in 100% of the patients, with one patient requiring a surgical procedure for a pseudoaneurysm. No stent fractures or occlusions were observed through 1 year.

Several factors can make transfemoral access unsuitable, including extreme obesity, groin infections, severe scars, or hematoma after multiple surgical or catheter interventions.[2] Additionally, endovascular or surgical implantation of bifurcated grafts may challenge the transfemoral crossover approach. Despite the limited availability of appropriate materials, upper extremity access could serve as an accepted alternative in all of these instances.

In most cases, approaching the femoropopliteal lesion through the left brachial artery approach is the access of choice. This access point avoids wire manipulation at the origin of the carotid arteries, reducing the risk of a cerebrovascular event, which suggests that transbrachial access can serve as a safe alternative approach. Unfortunately, only a minority of the market-available devices can be used for transbrachial treatment of infrainguinal lesions. However, the availability of self-expanding stents with long shafts makes stent deployment in the SFA and proximal popliteal artery possible when a transbrachial approach is needed.

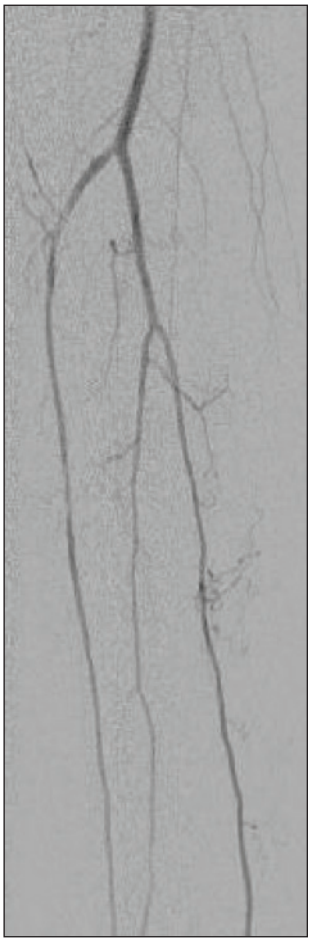

Figure 3. Postinterventional angiography showing no peripheral thrombosis or dissection.

In our experience, primary stenting with the EverFlex stent is associated with acceptable clinical and radiologic long-term outcomes.[4] At 7 years, the primary and secondary patency rates were 33% and 67%, respectively; amputation-free survival (AFS) was 73%; and freedom from target lesion revascularization was 47%.[4] Also at 7 years, Cox regression analysis revealed decreased AFS among patients with diabetes, and popliteal artery disease was identified as an independent risk factor for secondary interventions.

Overall, in patients who cannot be treated by transfemoral access, the Entrust delivery system enables the safe and effective treatment of femoropopliteal lesions. ■

1. Katsanos K, Spiliopoulos S, Kitrou P, et al. Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: a systematic review and meta-analysis of randomized controlled trials. J Am Heart Assoc. 2018;7:e011245.
2. Stavroulakis K, Usai MV, Torsello G, et al. Efficacy and safety of transbrachial access for iliac endovascular interventions. J Endovasc Ther. 2016;23:454-460.
3. Stavroulakis K, Bisdas T, Torsello G, et al. Early experience with the Entrust™ Stent delivery system for stent treatment of the lower extremities' arteries via transbrachial approach. J Cardiovasc Surg (Torino). 2014;55:483-488.
4. Stavroulakis K, Torsello G, Manal A, et al. Results of primary stent therapy for femoropopliteal peripheral arterial disease at 7 years. J Vasc Surg. 2016;64:1696-1702.

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EverFlex™ self-expanding peripheral stent with Entrust™ delivery system Brief Statement

Indication:
Contraindications: Use of the EverFlex self-expanding peripheral stent with Entrust delivery system is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. The EverFlex self-expanding peripheral stent with Entrust delivery system is contraindicated for use in the carotid artery.

Potential Adverse Events:
Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: allergic reaction, amputation, artery perforation or rupture, bleeding requiring transfusion, infection, pseudoaneurysm, restenosis, stent collapse or fracture, stent migration, surgical or endovascular intervention, thrombosis/occlusion of the stent.

See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events and device information.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.