Managing Complex Femoropopliteal Lesions

The latest data demonstrating the benefit of including drug-coated balloons in the interventionist's toolbox.

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Peripheral arterial disease is a common manifestation of atherosclerosis, and the majority of patients suffer from lifestyle-limiting or disabling claudication. The main goal of treating patients with claudication is a sustained relief from their lifestyle-limiting claudication, as opposed to preventing amputations, as in critical limb ischemia. Thus, the treatment applied must be safe, durable, and cost effective.

BACKGROUND ON COMPLEX LESION TREATMENTS

Anatomically, approximately 50% of these arterial lesions are located in the femoropopliteal tract. Using dedicated crossing and reentry devices, the technical success rate increased to > 95% for percutaneous transluminal angioplasty to recanalize the femoropopliteal artery.[1,2] Recanalization procedures had been limited by restenosis rates of 40% to 80% after 12 months, depending on lesion complexity.[3,4] The benefits seen with first- and second-generation nitinol stents in femoropopliteal vessels were only fair, with 1-year restenosis rates remaining in the range of 20% to 50%, increasing with lesion length.[4-6] Long stent chains are at significant risk for diffuse in-stent restenosis (ISR), which represents its own class of complex femoropopliteal lesions.

Bypass surgery is still considered as a gold standard for the treatment of complex femoropopliteal lesions such as long TASC II C and D lesions, severely calcified occlusions, and in-stent reocclusions.[1,7,8] Those lesion entities are associated with high restenosis rates for established endovascular treatment modalities. However, recent advances in stent design (interwoven nitinol stents, helical stents), drug device combination technologies such as drug-coated balloons (DCBs) and drug-eluting stents (DES), and endografts (ie, Viabahn, Gore & Associates) have resulted in a significant improvement of longer-term technical success in revascularization of complex femoropopliteal lesions.[9-17] The attractiveness of a stent-less strategy using DCBs lies in the opportunity to easily reintervene in the future when longer-term patency failure occurs. Moreover, stent-based treatment solutions have their limitations in vessel segments exposed to high mechanical forces such as the femoropopliteal transition zone (kink and bending forces) and the distal popliteal segment (compression forces).

The common characteristic of complex femoropopliteal lesions is the limited durability of current therapies in terms of a high restenosis rate. The longer the lesion, the more likely it is that local severe dissection, elastic recoil, and plaque shift will occur. The major limitation in treating calcified lesions is their eccentricity and acute and subacute recoil due to reduced vessel compliance. Finally, ISR is characterized by an overwhelming hyperproliferative vessel wall reaction to injury from neointimal proliferation.

AVAILABLE DCB DATA TO DATE

To address these challenges, DCBs are designed to specifically target the main reason for midterm failure of endovascular treatment, which is neointimal hyperproliferation. Recently published pilot studies and two larger-scale pivotal trials investigating DCBs have shown a substantial improvement in the durability of endovascular treatment for TASC II A and B lesions.[9,10] The randomized IN.PACT SFA Trial[17] is supplemented by the single-arm IN.PACT Global Study, which represents the largest study in peripheral vascular interventions today, with more than 1,500 patients with femoropopliteal artery disease enrolled at 67 sites in Europe, the Middle East, Asia, Canada, Australia, and South America. The objective of this prospective study is to characterize the IN.PACT™ Admiral™ DCB (Medtronic plc) clinical outcomes in a real-world patient population. The large sample size allows for ample subset analyses and offers the ability to detect low event rates, which might be missed in smaller-scale randomized controlled trials. The specific predefined subgroups (each with at least 150 patients) include de novo ISR, long lesions (≥ 15 cm), and chronic total occlusions (≥ 5 cm) are assessed by a core lab. More

than 100 patients who underwent treatment with the 150-mm-length IN.PACT Admiral DCB were also enrolled.*

For IN.PACT Global, the primary efficacy endpoint in the clinical cohort was freedom from clinically driven target lesion revascularization (CD-TLR) within 12 months. In the imaging cohort of the IN.PACT Global Study, the primary efficacy endpoint is primary patency within 12 months, defined as freedom from CD-TLR and freedom from restenosis as determined by DUS PSVR ≤ 2.4. The primary safety endpoint is a composite of the 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and CD-TVR.

The 1-year interim data from the first 655 IN.PACT Global patients confirm the safety and efficacy of the IN.PACT Admiral DCB for the treatment of femoropopliteal disease. IN.PACT Global patients were inclined to have higher Rutherford classification, longer lesions, involvement of the popliteal artery, and included ISR, which is an approved CE indication.* This confirms the positive results seen in other superficial femoral artery lesion studies and supports the IN.PACT Admiral DCB as a front-line therapy, even in complex femoropopliteal lesions. Furthermore, the IN.PACT Global Study sets a new standard in the real-world assessment of femoropopliteal arterial revascularization.

A recent single-center study has reported 1-year patency outcomes for femoropopliteal lesion treatment with DCBs in a range of 75% to 84% for mean lesion lengths of 19.5 and 24 cm, respectively.[18]

In this retrospective study, 228 patients presenting with femoropopliteal lesions longer than 10 cm who were suffering from peripheral arterial disease Rutherford stages 1 through 5 were treated with either DCB (n = 131) or DES (n = 97). Propensity score stratification analysis was employed to minimize the biases in baseline demographics, as well as clinical, anatomical, and procedural characteristics between the two study arms. The mean lesion length was 194.4 ± 86.3 mm (range, 100–450 mm) and 195 ± 64.5 mm (range, 100–350 mm) in the DCB and DES cohorts, respectively. Restenotic lesions were treated in 51.9% and 44.3%, and total occlusions were treated in 52.7% and 62.9%, respectively. Provisional stent placement was performed in 18.3% of the lesions in the DCB cohort. At 1 year, the binary restenosis rate was 23.9% in the DCB cohort and 30.4% in the DES cohort (P = .319), and the CD-TLR rate was 15.6% versus 19% (P = .543), respectively. The combination of a DCB with (provisionally implanted) bare-metal stents did not affect the primary patency in the DCB arm and eventually showed a tendency to slightly improve freedom from death and TLR. Clinical outcomes throughout 1 year did not significantly differ.[18]

In the Leipzig DCB registry,[19] 260 patients with femoropopliteal lesions, including ISR and those with a mean lesion length of 24 cm, were analyzed.* The provisional stent rate was 23.3%. The duplex ultrasound–based 1-year primary patency rate was 77.6% for the entire population, 82.4% for strictly superficial femoral artery lesions, and 85.2% for ISR. Thus, DCBs are an attractive option for treating complex femoropopliteal lesions with a low provisional stent rate. ■

*In-stent restenosis and lesions > 18 cm are not approved indications in the United States, and the 150-mm device is not approved or available in the United States.

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