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PERIPHERAL

Drug-Coated Balloons for Complex Femoropopliteal Lesions

2-Year Results of a Real-World Registry

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ABSTRACT

OBJECTIVES The authors sought to investigate the efficacy of a drug-coated balloon (DCB) for treatment of complex femoropopliteal lesions.

BACKGROUND Superiority of DCBs compared with uncoated balloon angioplasty for femoropopliteal interventions has been demonstrated in randomized trials for short lesions. Their performance in complex lesions with higher restenosis rates is unclear.

METHODS Patency, target lesion revascularization (TLR) rate, clinical improvement, and safety endpoints of femoropopliteal lesions in 288 limbs (n = 260) treated with the In.Pact Pacific or Admiral DCB (Medtronic, Minneapolis, Minnesota) were retrospectively analyzed for up to 2 years of follow-up. Predictors of restenosis were identified by logistic regression.

RESULTS Lesions were de novo in 51.7%, restenosis in 11.1%, and in-stent restenosis in 37.2%. Mean lesion length was 24.0 ± 10.2 cm, and 65.3% were occluded. Stent implantation was performed in 23.3%. Kaplan Meier estimates of primary patency were 79.2% and 53.7% for all lesions at 1 and 2 years, respectively, whereas freedom from TLR was 85.4% and 68.6%. Primary patency for in-stent restenosis treatment was 76.6% and 48.6%, and freedom from TLR was 83.0% and 58.7% at 1 and 2 years, respectively. Rutherford category improved from a median 3.3 to 1.2 at 1 year, and to 1.1 at 2 years. Major amputation rate was 2.1% at 2 years. No adverse events were thought to be attributable to the coating of the balloon.

CONCLUSIONS These results suggest that DCB are safe and effective in delaying rather than preventing restenosis in long, complex lesions and restenosis of the femoropopliteal tract. Further studies are recommended to confirm these results. (J Am Coll Cardiol Intv 2016;9:715–24) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

ABI = ankle-brachial index

CLI = critical limb ischemia

CTO = chronic total occlusion

DCB = drug-coated balloon(s)

ISR = in-stent restenosis

PA = popliteal artery

POBA = plain old balloon angioplasty

SFA = superficial femoral artery

TLR = target lesion revascularization

Interventional treatment of patients with complex atherosclerotic disease of the femoral and popliteal arteries has been limited by the high restenosis rate after angioplasty (1,2). Although nitinol stents have contributed to an overall improvement of treatment options in that vascular segment, patency results obtained in long lesions remain poor at 55% to 65% after 1 year (3,4). In addition, there have been significant concerns regarding the durability of long stented segments and the potential association of stent fractures and reocclusion (5).

Drug-coated balloons (DCB) provide a new therapeutic approach, and several randomized trials have shown superior results for DCBs compared with standard noncoated balloons after femoropopliteal artery treatment in terms of reduced late lumen loss, restenosis, and target lesion revascularization (TLR) rate (6–9). However, the mean lesion length in prior studies was comparatively short, between 4.0 and 8.9 cm (6–11), and there is little in the published literature on the performance of DCB in longer lesions (12). Furthermore, follow-up evaluation after DCB treatment is limited, with most studies appraising performance at 6 or 12 months, and only very few reports in smaller patient cohorts with follow-up longer than 1 year (10,11,13).

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The purpose of this study was to investigate whether DCB would improve patency for more complex femoropopliteal lesions and to assess the durability of results over an extended time, beyond 1 year.

METHODS

PATIENT POPULATION. A retrospective analysis was undertaken of patients undergoing treatment of complex femoropopliteal lesions (defined as de novo atherosclerotic lesions ≥10 cm or restenosis after previous endovascular treatment for de novo disease) using DCBs at a single tertiary vascular center between May 2009 and January 2012. No formal inclusion criteria were applied, but patients had to be treated for symptomatic peripheral arterial disease classified as Rutherford stage ≥1. The only exclusion criteria were nonatherosclerotic disease such as aneurysm, vasculitis, entrapment, and treatment of restenosis/reocclusion of surgical bypass. According to our institution's standard protocol, a medical history was obtained at admission, and all patients underwent physical examination with disease classification according to the Rutherford-Becker classification, measurement of ankle-brachial index (ABI), and color duplex ultrasound if not recently performed.

INTERVENTIONAL TECHNIQUE. All treatment decisions including the use of DCB or additional devices were at the operator's discretion. Patients were treated with either the In.Pact Pacific or In.Pact Admiral DCB (Medtronic, Minneapolis, Minnesota). The balloon is coated with FreePac, a proprietary formulation of 3.5-μg paclitaxel per mm^2 and urea, which serves as a hydrophilic spacer to facilitate separation and release of paclitaxel into the vessel wall.

Before the use of each DCB, pre-treatment with either an uncoated balloon or an atherectomy/thrombectomy device was performed, again at the discretion of the interventionist. The devices used were TurboHawk (Covidien/ev3, Plymouth, Minnesota), Rotarex catheter (Straub Medical AG, Wangs, Switzerland), or excimer laser (Spectranetics Corp., Colorado Springs, Colorado). The DCB diameter was chosen 1.0 mm larger than the uncoated balloon to guarantee contact with the arterial wall after predilation. Vessel diameter and lesion characteristics (such as lesion length, degree of stenosis, calcification, and additional inflow and outflow obstructions) were visually estimated. No quantitative angiographic program was utilized. Extent of calcification was also classified by inspection of the angiogram, with severe calcification defined as compromising both sides of the arterial lumen over a length of at least 5 cm. If more than 1 DCB was used per lesion, overlap of the 2 devices was at least 5 mm. Recommended inflation time was 3 min with 1 min at minimum. In case of flow-limiting dissection or residual stenosis >30%, a prolonged dilation up to 5 min was performed. Self-expanding nitinol stents were used as bailout in case of flow-limiting dissection or recoil. Inflow and outflow lesions were often treated during the same intervention as determined by the operator. Procedural success was defined as <30% residual stenosis in the final angiogram.

PHARMACOLOGICAL THERAPY. All patients were taking aspirin 100 mg daily. After sheath insertion, 5,000 IU of heparin were administered. Dual antiplatelet therapy with daily aspirin 100 mg and clopidogrel 75 mg was given for a minimum of 4 weeks and then converted to a single agent thereafter.

FOLLOW-UP PROTOCOL AND STUDY ENDPOINTS. Before discharge, all patients underwent clinical examination, ABI measurement, and duplex ultrasound to determine interventional success. The same information was captured at each follow-up visit, which was routinely performed at 6, 12, and 24 months after the intervention according to our