JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 7, 2017

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2017.01.028

2-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease

Evidence From the SFA-Long Study

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ABSTRACT

OBJECTIVES The aim of this study was to appraise 2-year outcomes after percutaneous transluminal angioplasty of long femoropopliteal artery disease using paclitaxel-coated balloons (PCBs).

BACKGROUND Percutaneous transluminal angioplasty with PCBs for TransAtlantic Inter-Society Consensus types C and D femoropopliteal artery disease has provided favorable results ≤12 months but no prospective studies performed longer term follow-up assessment.

METHODS Consecutive patients with Rutherford class 2 to 4 disease due to femoropopliteal lesions >15 cm long were prospectively enrolled in a multicenter study. The primary study endpoint was primary patency (i.e., freedom from the combined endpoint of clinically driven target lesion revascularization and >50% restenosis in the treated lesion as appraised by a duplex ultrasound peak systolic velocity ratio of >2.4) at 24 months. Secondary endpoints included major adverse events (the composite of death, target limb amputation, thrombosis at the target lesion, or clinically driven nontarget lesion revascularization), changes in Rutherford class, and quality of life ≤24 months post-procedure.

RESULTS A total of 105 patients (age 68 ± 9 years; 81.9% men) successfully treated with PCBs were included (treated lesion length was 251 ± 71 mm; 49.5% total occlusions). The 24-month follow-up data were available in 98 patients; they showed a primary patency rate of 70.4%, with major adverse events occurred in 10 patients (10.2%, 5 non-procedure-related deaths) and persistently significant clinical benefits in Rutherford class (51% of asymptomatic patients at 24 months).

CONCLUSIONS PCBs benefits on primary patency and target vessel revascularization satisfactorily extend over 24 months in patients undergoing percutaneous transluminal angioplasty for symptomatic femoropopliteal disease. (J Am Coll Cardiol Intv 2017;10:728–34) © 2017 by the American College of Cardiology Foundation.

Percutaneous transluminal angioplasty (PTA) is an effective and well-recognized therapeutic strategy in patients with femoropopliteal artery disease requiring revascularization. Actually, more complex patients and more complex lesions (i.e., longer atherosclerotic disease) are often turned down for surgery and become elective PTA candidates (1–3). In this setting, paclitaxel-coated balloons

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Manuscript received October 17, 2016; revised manuscript received December 20, 2016, accepted January 27, 2017.

(PCBs) were proven to be superior to plain balloons in preventing restenosis and in achieving good clinical outcomes (4-6). PCBs efficacy has been first documented in short (TransAtlantic Inter-Society Consensus [TASC] types A and B) lesions, with favorable outcomes reported by our group over a follow-up period of 24 months (7). The effective clinical usefulness of these devices, by the way, needs to be tested in long and challenging lesions, which are the most commonly encountered ones in clinical practice.

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We previously showed that PCBs are associated with favorable clinical and patency outcomes over a follow-up of 12 months in patients with severe TASC types C and D femoropopliteal artery disease requiring percutaneous revascularization (8). Although clinical evaluation is ongoing, there is currently poor evidence about the duration of clinical and angiographic benefit of PCBs, especially for time periods >12 months. The aim of this study is to report 24-month data from the SFA-Long (Drug Eluting Balloon [DEB] and Long Lesions of Superficial Femoral Artery [SFA] Ischemic Vascular Disease) study, including femoropopliteal lesions >15 cm long.

METHODS

DESIGN. The SFA-Long study was an independent, prospective, multicenter, single-arm study whose aim was to appraise in detail outcomes after femoropopliteal PTA with the IN.PACT Admiral PCB (Medtronic, Frauenfeld, Switzerland) (7). The study was approved by local ethics committees, and all patients provided written informed consent. Angiographic and duplex ultrasound parameters were validated by an independent core laboratory (Euroimaging, Rome, Italy). An independent clinical events committee was responsible for the adjudication of all reported adverse events. One hundred percent external monitoring was provided by the contract research organization MCR (Milan, Italy). The study was registered at (NCT01658540). The study was partially (30%) funded by an unrestricted grant from Medtronic.

PATIENTS. Adult patients diagnosed with peripheral artery disease for claudication or rest pain (Rutherford class 2 to 4) were included in the study in presence of atherosclerotic disease of the superficial femoral and popliteal artery, with reference vessel diameter between 4 and 7 mm, with stenotic lesions or occlusions for a total length of >150 mm. Multiple adjacent lesions without angiographic evidence of healthy segments ≥3 cm were considered cumulatively and treated as single lesions. Angiographic inclusion and exclusion criteria have been described elsewhere previously (8). The presence of a moderate-to-severe calcification was defined as the presence of a calcification >5 cm in length in 2 sides of a single projection or in 1 side each of 2 orthogonal projections (moderate) or in 2 sides of a single projection and in ≥1 side of its orthogonal projections (severe).

PROCEDURES AND DEVICES. Procedure description and patients' management during index revascularization have been previously described (8). Briefly, all lesions were predilated (2 min) with an undersized uncoated balloon (0.5 to 1.0 mm smaller than the reference vessel diameter) and then dilated with a PCB of adequate size and length (vessel/balloon ratio of 1:1 on the basis of visual estimate) for an inflation time of ≥3 min at 6 to 12 atm. Study balloons were inflated only once. An additional long inflation (≥3 min) with an adequate uncoated balloon (same size or 1 mm larger than the PCB) was performed in the tract where angiography revealed persistent stenosis >50% or dissection or at the operator's discretion. If suboptimal results (residual stenosis >50%) persisted after such repeat dilation, self-expanding nitinol stents were implanted as bailout therapy.

DEFINITIONS AND ENDPOINTS. Device success was defined as successful vascular access and exact

ABBREVIATIONS AND ACRONYMS

CI = confidence interval

PCB = paclitaxel-coated balloon

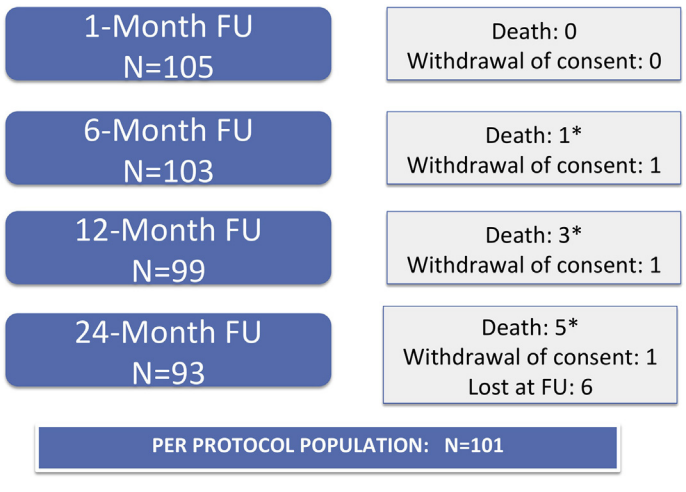
PTA = percutaneous transluminal angioplasty

SFA = superficial femoral artery

TASC = TransAtlantic Inter-Society Consensus

TLR = target lesion revascularization

FIGURE 1 Timeline of the DEB-SFA Long Study



Rate of follow-up data completeness at each time-point. *Deaths were not device related or procedure related. Causes of death were acute myocardial infarction, lung cancer, pulmonary embolism, stroke, and respiratory arrest (n = 1 each). DEB-SFA = Drug Eluting Balloon [DEB] and Long Lesions of Superficial Femoral Artery [SFA] Ischemic Vascular Disease; FU = follow-up.