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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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(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

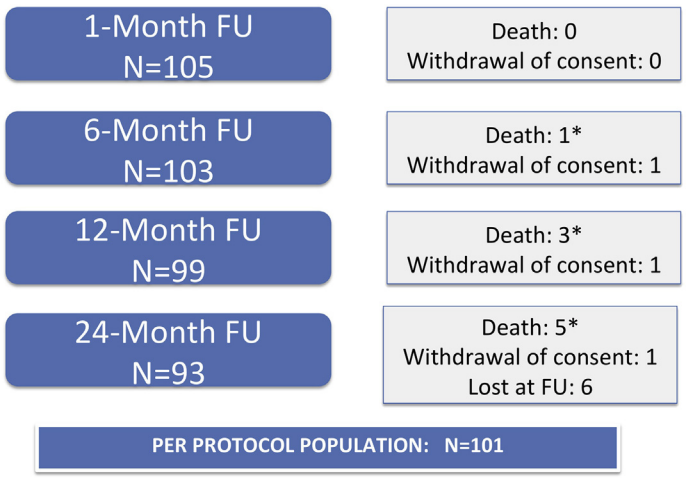
PTA = percutaneous transluminal angioplasty

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.

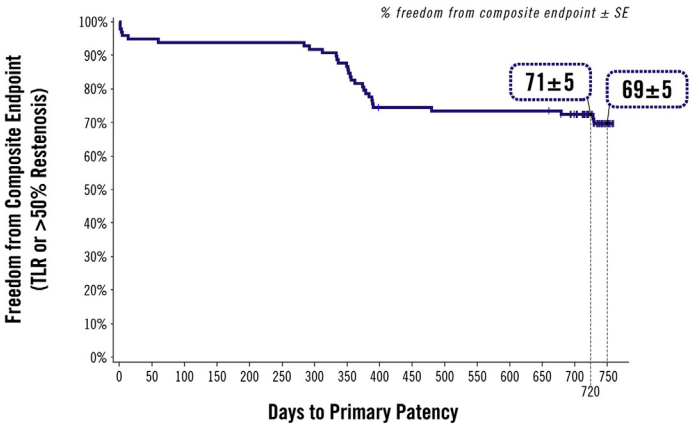
TABLE 1 Key Clinical Outcomes at 24 Months

Primary patency	69/98 (70.4%; 95% CI: 60.2% to 79.6%)
Freedom from clinically driven TLR	83/98 (84.7%; 95% CI: 77.6% to 90.8%)
Secondary patency	78/98 (79.6%; 95% CI: 71.4% to 87.8%)
Major adverse events	
At least 1 occurrence	10/98 (10.2%)
Death of any cause	5/98 (5.1%)
Thrombosis	2/98 (2.0%)
NTL TVR	3/98 (3.1%)

Values are n/N (%; 95% confidence interval).
CI = confidence interval; NTL = nontarget lesion; TLR = target lesion revascularization; TVR = target vessel revascularization.

deployment of the device according to the instructions for use, and technical success was defined as device success plus completion of the endovascular procedure with <30% residual stenosis of the treated lesion (visual estimation). Our primary endpoint was the primary patency rate at 24 months, defined as freedom from the combined endpoints of clinically driven target lesion revascularization (TLR), occlusion, and >50% restenosis in the treated lesion as appraised by duplex ultrasound (peak systolic velocity ratio >2.4); clinically driven TLR was defined as any reintervention within the target lesion due to symptoms or decrease in the ankle-brachial index of >20% or >0.15 compared with the post-procedure one. Secondary endpoints were major adverse events (the composite of death of any cause, major target limb amputation, thrombosis at the target lesion site, or nontarget lesion target vessel revascularization), change in Rutherford class, and quality of life. Notably, walking capacity was measured using a validated 5-point walking impairment questionnaire that assessed walking distance, speed, ability to climb stairs, and symptoms with walking (9). Quality of life was assessed using the EQ-5D questionnaire (10), as previously described (8).

FIGURE 2 Primary Patency Endpoint



Kaplan-Meier curve showing the incidence of the composite endpoint of the study (target lesion revascularization [TLR] or >50% restenosis as assessed at Duplex scan) over a 24-month follow-up period.

STATISTICAL ANALYSIS. Efficacy data were analyzed on the per protocol population, consisting of included patients fulfilling the inclusion and the exclusion criteria, and treated according to protocol specifications. Data are reported with frequencies and percentages for categorical variables, mean ± SE or SD (as specified) for continuous variables. Comparisons for continuous variables were performed by means of the Wilcoxon signed rank sum test applied on the difference between baseline and follow-up data for completers. Qualitative variables were compared using the Fisher exact test. For the statistical analysis of primary and main secondary endpoints, 95% exact confidence intervals (CIs) are reported. The Kaplan-Meier estimate was used to estimate the probability of primary patency persistence, together with an approximated 95% CI. Cox regression univariate hazard analysis was performed to assess predictors of the combined endpoint among clinical and angiographic parameters. Statistical significance was set at a 2-tailed level of 0.05.

RESULTS

Baseline and procedural characteristics have been described previously (8). As a reminder, a total of 105 femoropopliteal lesions were treated with PCB at 6 different Italian sites, with a mean lesion length of 251 ± 71 mm and a 49.5% of total occlusions. The bail-out stenting rate was 10.9%.

During follow-up, there were 5 deaths not related to the procedure and another 7 patients did not complete 24-month follow-up (1 withdrew his consent, 6 were lost to follow-up). Data completeness throughout the entire duration of the study are summarized in Figure 1.

EFFICACY OUTCOMES AT 24 MONTHS. Key clinical outcomes through 24 months are displayed in Table 1. The actual 24-month follow-up primary patency rate was 70.4%. Patency at 24 months (720 days) by Kaplan-Meier estimate was 71 ± 5% (SE) and at 750 days was 69 ± 5% (SE) (Figure 2). The prevalence of the primary outcome was similar in the different study sites (data not shown).

TABLE 2 Univariate Predicators of Primary Patency Endpoint at Cox Regression Analysis

Univariate Predictor	HR (95% CI)	p Value
Male	1.29 (0.53 to 3.18)	0.57
Age, yrs	1.01 (0.97 to 1.05)	0.54
Renal failure	0.47 (0.20 to 1.1)	0.08
Diabetes	0.74 (0.35 to 1.57)	0.43
Lesion length	1.004 (1.00 to 1.008)	0.07
Total occlusion	0.73 (0.35 to 1.55)	0.42
Bail-out stenting	4.00 (0.54 to 29.44)	0.17
Moderate-to-severe calcification	0.69 (0.32 to 1.47)	0.34

CI = confidence interval; HR = hazard ratio.

Cox regression analysis showed no predictors of patency at 24 months for clinical and angiographic variables (Table 2). Consequently, with regard to primary patency, no difference was found between occlusive and nonocclusive lesions (log-rank p = 0.42) (Figure 3) as well as between long (lesions between 15 and 25 cm) and very long lesions (lesions >25 cm; log-rank p = 0.25) (Figure 4).

The rate of clinically driven TLR was 15.3% (95% CI: 9.2% to 22.4%), whereas secondary patency rate was 79.6% (95% CI: 71.4% to 87.8%). No difference was observed, as to primary patency, between patients with diabetes and patients without diabetes (Figure 5).

SAFETY OUTCOMES AT 24 MONTHS. There were no procedure- or device-related deaths and no major amputations. Vessel thrombosis was reported by the clinical event committee in two patients (2.0%). All-cause death through 24 months was 5.1% (n = 5) (Table 1). Causes of death included cerebral infarction, myocardial infarction, pulmonary embolism, lung cancer, and respiratory arrest. There were no untoward paclitaxel-related adverse effects as determined by the clinical events committee.

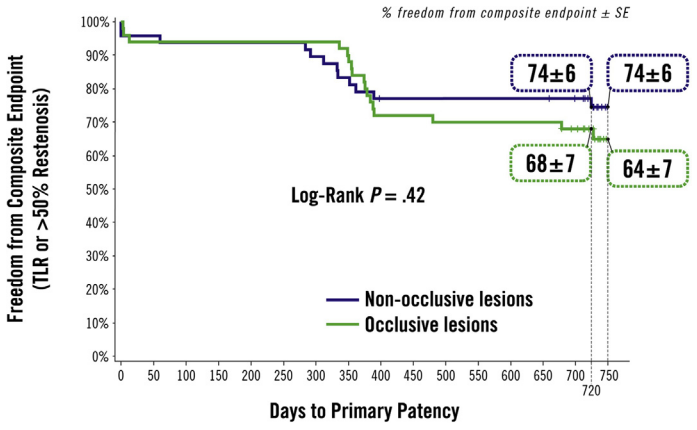
FUNCTIONAL OUTCOMES AT 24 MONTHS. The proportion of asymptomatic (Rutherford class 0) patients increased from 0% at baseline to 51% at 24 months while being 58% at the 12-month follow-up assessment (Figure 6, Table 3). The previously observed improvement in quality of life, as assessed by EQ-5D assessment, was confirmed, compared with preprocedural questionnaires, at the 24-month follow-up (p < 0.01) (Figure 7).

DISCUSSION

Our data describe the 2-year outcomes of PCB angioplasty to treat TASC types C and D femoropopliteal lesions. Poor evidence is present in published data about the results of PCBs at this follow-up timing, with the prevalent evidence coming for the 12-month follow-up (11) and scarce data reporting the rate of TLR at 24 months (12).

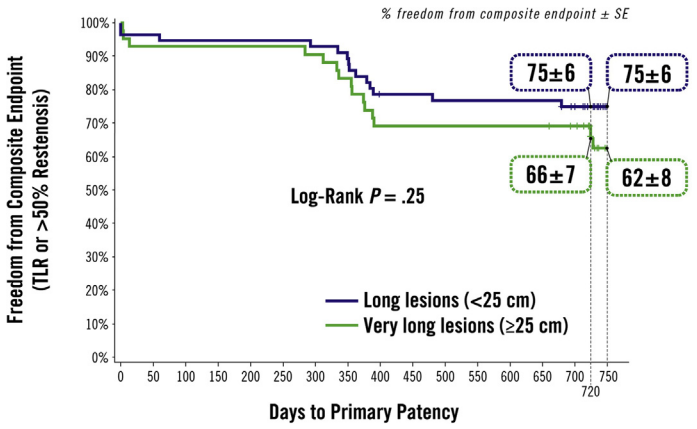
A number of implications about the efficacy of PCB over a long-term period could be derived from the present study.

FIGURE 3 Primary Patency Endpoint (Occlusive Versus Nonocclusive Lesions)



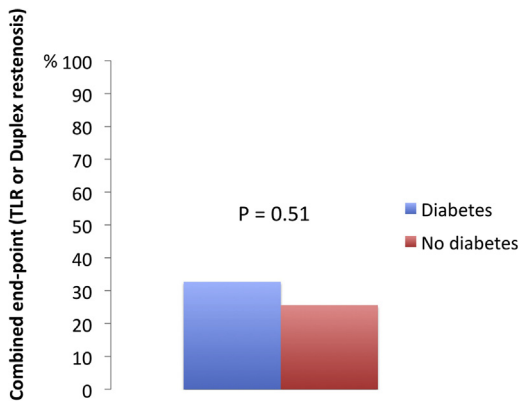
Kaplan-Meier curve showing the incidence of the composite endpoint of the study (target lesion revascularization [TLR] or >50% restenosis as assessed at Duplex scan) over a 24-month follow-up period in patients with occlusive **(green line)** versus nonocclusive **(blue line)** femoropopliteal lesions.

FIGURE 4 Primary Patency Endpoint (Long Versus Very Long Lesions)



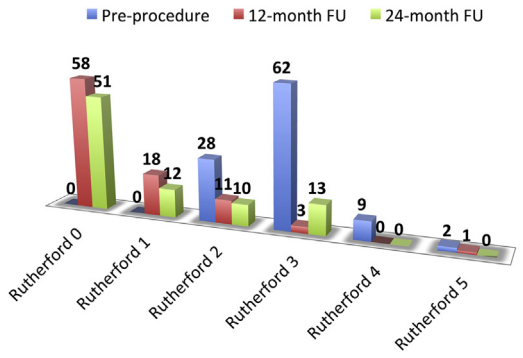
Kaplan-Meier curve showing the incidence of the composite endpoint of the study (target lesion revascularization [TLR] or >50% restenosis as assessed at Duplex scan) over a 24-month follow-up period in patients with very long (i.e., ≥25 cm; **green line**) versus long (i.e., <25 cm; **blue line**) femoropopliteal lesions.

FIGURE 5 Primary Patency Endpoint (Diabetic Versus Nondiabetic Patients)



Incidence of the composite endpoint of the study (target lesion revascularization [TLR] or >50% restenosis as assessed at Duplex scan) over a 24-month follow-up period in patients with diabetes versus patients without diabetes.

FIGURE 6 Functional Results



Rutherford class prevalence of patients at baseline (pre-procedural), at the 12-month and at 24-month follow-ups. FU = follow-up.

1. The primary patency rate showed a satisfactory result even at 24 months from the procedure, with about 3 patients over 10 showing target lesion reocclusion and 2 requiring clinically driven revascularization;
2. The patency results were not related neither to lesion length and complexity or to clinical features (diabetic vs. nondiabetic), thus highlighting, in a complex setting of long and very long lesions, the independent beneficial effect of PCBs, although subgroup analysis might be limited by the small group of patients;
3. Clinical functional status was still good, with an high rate of asymptomatic patients at 2 years from the index procedure.

Long femoropopliteal lesions remain a challenge for PTA procedures. Actually, restenosis after stenting in long superficial femoral artery lesions has been reported to occur at a frequency of ≤50% (13–15), with presenting restenosis patterns as diffuse restenosis or in-stent occlusion that pose a challenge to treat (13).

The DEB-SFA long trial was designed to assess the impact of PCB during femoropopliteal revascularization on primary patency and functional status at the 12-month follow-up. Clinical results ≤12 months have been reported in detail elsewhere (8), but given the lack of carefully collected long-term data on such a clinical topic, clinical follow-up was prolonged to 24 months, including adjudication of adverse events as well as appraisal of key quantitative and objective estimates pertinent to patients with claudication and rest pain, such as primary patency, ankle-brachial index, and quality of life measurements. We continued to focus on primary patency as primary endpoint, because this can best appraise the results after revascularization, as indeed other endpoints (such as TLR rate) might suggest more optimistic results for a given revascularization technique.

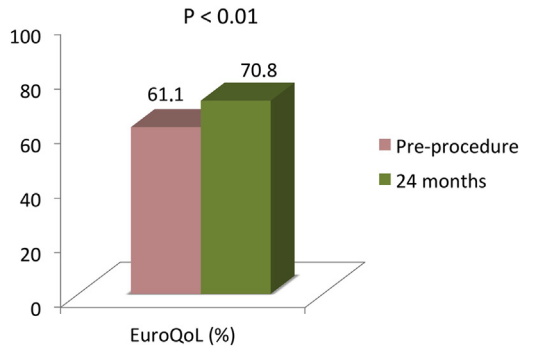
Scientific evidence is growing about the effectiveness of PCB in short lesions (16–18), even over a 5-year follow-up period (19), but scarce data are available about long lesions. Zeller et al. (20) reported outcomes from a retrospective registry comparing paclitaxel-eluting stents with PCBs in long lesions, with a mean lesion length of 19 cm in both groups. Primary paclitaxel-eluting stenting was associated with a similar and high primary patency at 12 months compared with PCBs; of note, there was no difference for the loss of patency at angiographic follow-up. This result was confirmed by the recently published

TABLE 3 PAD Questionnaire Results at the 24-Month Assessment

PAD-specific final score	3.2 ± 1.4
Walking distance final score	15.2 ± 9.2
Walking speed final score	12.9 ± 5.8
Stair climbing final score	7.8 ± 4.5

Values are mean ± SD.
PAD = peripheral artery disease.

FIGURE 7 Quality of Life Outcomes



Mean EuroQol results, as assessed by EuroQoL questionnaire (10) at baseline and the 24-month follow-up.

data of a large registry by Jia et al. (21) with a mean lesion length of 15 cm and a mean late lumen loss at 6 months of 0.05 ± 0.73 mm versus 1.15 ± 0.89 mm of uncoated balloons. Although no direct comparison is possible from these data, PCB results should be read in the context of all currently available therapeutic options for femoropopliteal revascularization. The early 6-month results from the SIROCCO trial (A Clinical Investigation of the SIROlimus Coated Cordis SMART Nitinol Selfexpandable Stent for the Treatment of Obstructive Superficial Femoral Artery Disease) spread enthusiasm by reporting superior patency rates for sirolimus-eluting self-expanding DES in the SFA (22), but results were not confirmed at 2 years (23). The ZILVER-PTX study (Evaluation of the Zilver PTX Drug-Eluting Stent in the Above-the-Knee Femoropopliteal Artery), which was designed to assess a paclitaxel self-expanding DES, showed better results with a primary patency rate of 74.8% for primary DES at 2 years (24). Covered stents have also been applied in the femoropopliteal segment. Polytetrafluoroethylene-covered nitinol stents (VIABAHN stents) were associated with a primary patency rate of 65% at 12 months (25), whereas the recently published VIASTAR study (Viabahn Endoprosthesis with PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease), compared the heparin-bonded VIABAHN covered stent with bare metal stents, showed a primary patency rate of 71.3% at 1 year for TASC D lesions (26).

Our study population is probably the most difficult one in which to test PCB efficacy. Long lesions are the most challenging, even though they are the most usually encountered in daily practice. This difficulty is in contrast with traditional randomized, controlled clinical trials, which are often bound to strict eligibility criteria for the selection of a more consistent, although less representative, subject population. In addition, such a long-term follow-up (with only 7 patients lost) required a strict monitoring of the patients, together with the use of an independent Clinical Events Committee to adjudicate all major adverse events and independent core laboratories to analyze all angiography and duplex ultrasonography. The satisfactory results we observed both in primary patency rate and in clinical status are among the first reports of the efficacy of PCBs in the challenging setting of long lesions over a long-term follow-up.

STUDY LIMITATIONS. Limitations of this work include its nonrandomized and noncomparative design, the focus on a single treatment strategy, which makes it impossible to drive conclusions about the superiority of PCBs compared with other forms of treatment, and the focus on patients with claudication. The imbalance in the number of enrolled patients, with 3 sites contributing the majority of cases, might have influenced the results. In addition, given the small numbers of subgroups, any speculation about the role of PCB in subsets at higher risk of restenosis (e.g., diabetes, calcified lesions, total occlusions.) should be not considered conclusive.

CONCLUSIONS

PCB results on SFA long lesions are still evident at 24 months from the index revascularization procedure both in clinical outcomes and in primary patency. The clinical impact of such a relevant clinical result should suggest a cost-effectiveness analysis to evaluate the usefulness of PCBs for all de novo lesions of the SFA in routine clinical practice.

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PERSPECTIVES

WHAT IS KNOWN? Endovascular treatment of TASC types C and D femoropopliteal is often challenging and poor results have been reported over time.

WHAT IS NEW? The use of PCBs in treating complex femoropopliteal lesions has shown promising results for moderate-length lesions. We previously reported good outcomes for PCBs in long lesions at 12 months. This registry provides data of long lesions at a follow-up duration of >1 year: our clinical and functional results definitely confirm the efficacy of PCBs in a complex lesion set and their cost effectiveness in preventing TLR even at such a long-term follow-up.

WHAT IS NEXT? Larger registries and randomized studies comparing PCBs with PTA or stenting are needed to confirm the long-term outcomes observed here.

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