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PERIPHERAL

1-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 1-year outcomes after percutaneous treatment of long femoropopliteal artery disease using paclitaxel-coated balloons.

BACKGROUND Percutaneous transluminal angioplasty with paclitaxel-coated balloons for TransAtlantic Inter-Society Consensus types A and B femoropopliteal artery disease has provided favorable results.

METHODS Consecutive patients with Rutherford class 2 to 4 disease due to femoropopliteal lesions >15 cm long and with 4- to 7-mm reference vessel diameter were prospectively enrolled in a multicenter study. The primary study endpoint was primary patency at 12 months. Secondary endpoints included major adverse events (the composite of death, major target limb amputation, thrombosis at the target lesion site, or clinically driven non-target lesion target vessel revascularization), changes in Rutherford class, ankle-brachial index, and quality of life up to 24 months post-procedure.

RESULTS A total of 105 patients (mean age 68 ± 9 years, 81.9% men) treated with paclitaxel-coated balloons and provisional stenting were enrolled, and final procedural success was obtained in all. The mean treated lesion length was 251 ± 71 mm, including 63.4% moderate to severely calcified lesions and 49.5% total occlusions. The bailout stent rate was 10.9%. Follow-up after 12 months was obtained in 101 patients (96.2%), showing that primary patency was maintained in 84 (83.2%), and major adverse events had occurred in 7 (6.2%), with persistently significant clinical benefits in Rutherford class.

CONCLUSIONS Paclitaxel-coated balloons are associated with favorable functional and clinical outcomes at 1 year in patients with long femoropopliteal artery disease requiring percutaneous revascularization. (Drug Eluting Balloon [DEB] and Long Lesions of Superficial Femoral Artery [SFA] Ischemic Vascular Disease [DEB-SFA-LONG]; NCT01658540)
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Percutaneous transluminal angioplasty (PTA) is a well-established, minimally invasive treatment strategy for the management of patients with femoropopliteal artery disease requiring revascularization, especially when atherosclerotic burden or surgical risk does not favor bypass surgery (1-3). Paclitaxel-coated balloons (PCBs) have been shown to be a safe and effective therapy for atherosclerotic disease in this vascular territory, while limiting stenting, with its potential negative consequences such as stent fracture, to bailout indications (4-6). However, published trials of PCBs thus far have included simple and short (TransAtlantic Inter-Society Consensus [TASC] types A and B) lesions. This holds true for PCBs as well as for new devices in general, as long challenging lesions, occurring routinely in the real world, were not reported, thus limiting effective clinical decision making.

SEE PAGE 957

We previously reported the findings of a prospective multicenter study including 105 patients undergoing femoropopliteal PTA with PCBs in short lesions, showing favorable clinical results up to 24 months (7). With the objective of providing similarly detailed results on this treatment strategy in longer lesions, we herein report 12-month data from an ongoing study that included femoropopliteal lesions longer than 15 cm.

METHODS

DESIGN. The SFA-Long (Drug Eluting Balloon [DEB] and Long Lesions of Superficial Femoral Artery [SFA] Ischemic Vascular Disease) 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. All angiographic and duplex ultrasound parameters were validated by the independent core laboratory (Euroimaging, Rome, Italy). An independent clinical events committee was responsible for the adjudication of all reported adverse events. One hundred percent monitoring was provided by the contract research organization MCR (Milan, Italy). The study was registered at (NCT01658540).

PATIENTS. Adult patients diagnosed with peripheral artery disease for claudication or rest pain (Rutherford class 2 to 4) were screened. Angiographic inclusion criteria included atherosclerotic disease of the superficial femoral and popliteal artery, with reference vessel diameter between 4 and 7 mm, having stenotic lesions or occlusions for a total length ≥150 mm. Multiple adjacent lesions without angiographic evidence of healthy segments 3 cm or greater were cumulatively considered and treated as single lesions. Patients were required to have adequate runoff, with evidence of at least 1 patent crural vessel to the foot either pre-existing or re-established (patients were eligible if an impaired outflow vessel [>50% diameter stenosis] was successfully treated during the index procedure). Unhindered inflow in the aortic-iliac and common femoral districts (either pre-existing or re-established) was also required for patient inclusion. Long (>150 mm) inflow lesions constituted an exclusion criterion, whereas patients presenting with shorter lesions were deemed eligible if these inflow lesions could be successfully treated before the target femoropopliteal lesion. In-stent restenosis, aneurysm in the target vessel, and acute thrombus in the target limb constituted exclusion criteria. Other exclusion criteria included failure to cross the target lesion with a guidewire and concomitant (intentional or accidental) use of alternative therapies in the target vessel, including atherectomy, excimer laser, or cutting balloon during the index procedure.

PROCEDURES AND DEVICES. Patients not taking aspirin and clopidogrel before study enrollment received loading doses of 300 mg aspirin and 300 mg clopidogrel 12 h before the procedure. After PTA, all subjects received 100 mg/day aspirin indefinitely and 75 mg/day clopidogrel for 12 weeks (6 months in case of stenting). Patients received a bolus dose of 5,000 IU heparin after insertion of the sheath in the common femoral artery. Vascular access was accomplished via the contralateral or ipsilateral approach. After crossing the lesion with a guidewire, pre-dilation (2 min) with an undersized uncoated balloon (0.5 to 1 mm smaller than the reference vessel diameter) was followed by insertion of a PCB of appropriate size and length. The target lesion was dilated 10 mm beyond both ends of the lesion using a PCB with a vessel/balloon ratio of 1:1 (on the basis of visual estimate) and an inflation time of 3 min at 6 to 12 atm. Study balloons were inflated only once. An additional long (at least 3 min) inflation with an adequate (same size or 1 mm larger than the PCB) uncoated balloon was performed in the tract where angiography revealed persistent stenosis >50% or dissection. If suboptimal results (residual stenosis

ABBREVIATIONS AND ACRONYMS

CI = confidence interval

PCB = paclitaxel-coated balloon

PTA = percutaneous transluminal angioplasty

TASC = TransAtlantic Inter-Society Consensus

TLR = target lesion revascularization

>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 deployment of the device according to the instructions for use using appropriate imaging modalities, whereas technical success was defined as device success plus completion of the endovascular procedure with <30% residual stenosis of the treated lesion by visual estimate.

The primary study endpoint was primary patency rate at 12 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 drop in ankle-brachial index of ≥20% or >0.15 compared with post-procedure. Secondary endpoints were major adverse events (the composite of death of any cause, major target limb amputation, thrombosis at the target lesion site, or non-target 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 (8). Quality of life was assessed using the EQ-5D questionnaire (9). This tool looks at 5 dimensions of health: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has 3 levels: no problems, some problems, or extreme problems. Finally, during each follow-up visit, patients completed a visual analogue scale (0 to 100) to assess their overall health state. All such endpoints were collected at baseline and 12 months after the index procedure.

STATISTICAL ANALYSIS. The sample size was calculated to estimate at 12 months the primary patency rate of 80% with precision of 0.10 (half width of the 95% confidence interval [CI]). The 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. Descriptive statistics (absolute frequencies and percentages for categorical variables, mean ± SD and medians and interquartile ranges for continuous variables) were used to summarize the values and changes from baseline at follow-up. 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 McNemar test. For the statistical analysis of primary and main secondary endpoints, 95% exact CIs are reported. The Kaplan-Meier estimate was used to estimate the probability of primary patency persistence, together with an approximated 95% CI. The EQ-5D levels were dichotomized into "no problems" and "problems" for graphical presentation, and change in quality of life between baseline and 12-month follow-up was analyzed by means of the McNemar test. In addition, change in quality of life was described in the categories of "no change," "improved" (from "problems" to "no problems"), and "worsened" (from "no problems" to "problems"). A Cox proportional hazards multivariate regression analysis was also performed including the following known and potential prognostic factors related to outcomes: age, sex, diabetes, lesion length (<25 vs. >25 mm), calcification, and impaired versus unimpaired outflow. Statistical significance was set at a 2-tailed level of 0.05, and p values unadjusted for multiplicity are reported throughout.

RESULTS

BASELINE AND PROCEDURAL CHARACTERISTICS. Between September 2012 and May 2014, a total of 105 patients (105 femoropopliteal lesions) were enrolled at 6 sites in Italy (Online Table 1), with 3 sites contributing 86% of cases, and were treated with 273 PCBs (Tables 1, 2, and 3). The mean lesion length was 251 ± 71 mm, had a 5.1 ± 0.5 mm reference vessel

TABLE 1 Baseline Clinical Characteristics (N = 105)

Age (yrs)	68 ± 9
Male	81.9% (86)
Hypertension	88.6% (93)
Hyperlipidemia	78.1% (82)
Diabetes	57.2% (60)
Current smoking	68.6% (72)
Renal failure	16.2% (17)
Coronary artery disease	55.2% (58)
Previous peripheral revascularization	47.6% (50)
Previous SFA revascularization	38.1% (40)
Rutherford class	
0 or 1	0% (0)
2	27.6% (29)
3	61.9% (65)
4	8.6% (9)
5*	1.9% (2)
6	0% (0)

Values are mean ± SD or % (n). *Rutherford class 5 were protocol deviations.
SFA = superficial femoral artery.

TABLE 2 Lesion Characteristics (N = 105)

Lesions	105
Lesion type	
De novo	91.4% (96)
Restenosis	8.6% (9)
Calcification	
None or slight	37.1% (39)
Moderate	37.1% (39)
Severe	13.3% (14)
Lesion length (mm)	251.71 ± 78.9
Reference vessel diameter (mm)	5.1 ± 0.5
Diameter stenosis (%)	93.7 ± 8.4
Total occlusion	49.5% (52)
Inflow disease	13.3% (14)
Outflow disease	40% (42)

Values are % (n) or mean ± SD.

TABLE 4 Key Outcomes Through 12 Months

Outcome	n (%)	95% CI
Primary patency*	84 (83.2)	74.4%–89.8%
Freedom from clinically driven TLR	97 (96)	90.17%–98.9%
Freedom from >50% restenosis	85 (84.2)	75.5%–90.6%
Major adverse events		
At least 1 occurrence	7 (6.9)	2.83%–13.7%
Death of any cause	4 (4)	1.1%–9.83%
Thrombosis	1 (1)	0.03%–5.4%
NTL TVR	2 (2)	0.24%–6.9%

*Freedom from the combined endpoint of clinically driven TLR and >50% restenosis.

NTL TVR = non-target lesion target vessel revascularization; TLR = target lesion revascularization.

diameter, and had 93.7 ± 8.4% diameter stenosis, as evaluated by visual estimation by an independent operator. Occlusions were treated in 49.5% of patients. Device success was obtained in all cases, with bailout stenting in 11 lesions (10.9%) (Table 3).

EFFICACY OUTCOMES. Technical success was achieved in 97.1% of subjects. Key outcomes through 12 months are displayed in Table 4. The actual 12-month follow-up primary patency rate was 83.2%. Patency at 12 months (360 days) by Kaplan-Meier estimate was 89.3% and at 390 days was 86.1% (Figure 1A). Patency was also evaluated in patients with occlusive versus stenotic lesions. The rate at 360 days was 88.4% (95% CI: 78.6% to 98.2%) versus 91.5% (95% CI: 83.5% to 99.5%), respectively, with no statistically significant difference (log-rank p = 0.1649) (Figure 1B). The rate of clinically driven TLR was 4% (95% CI: 0.2% to 7.8%). No statistically significant association with the primary endpoint in the multivariate analysis was revealed in the Cox proportional hazards model for any of the considered covariates. The proportion of asymptomatic (Rutherford class 0) patients increased from 0% at baseline to 58% at 12 months (Figure 2).

TABLE 3 Procedural Details (N = 105)

Lesions	105
Devices	273
Pre-dilation	100%
Post-dilation	49.6% (52/105)
Stenting	10.5% (11/105)
For flow-limiting dissection	6.7% (7/105)
For persistent stenosis	8.6% (9/105)
Paclitaxel-eluting balloon inflation time (s)	181 ± 20
Paclitaxel-eluting balloon/lesion ratio	2.6
Residual diameter stenosis (%)	10.2 ± 8.8
Device success	100%
Technical success	97.1% (102/105)

Values are % (n/N) or mean ± SD.

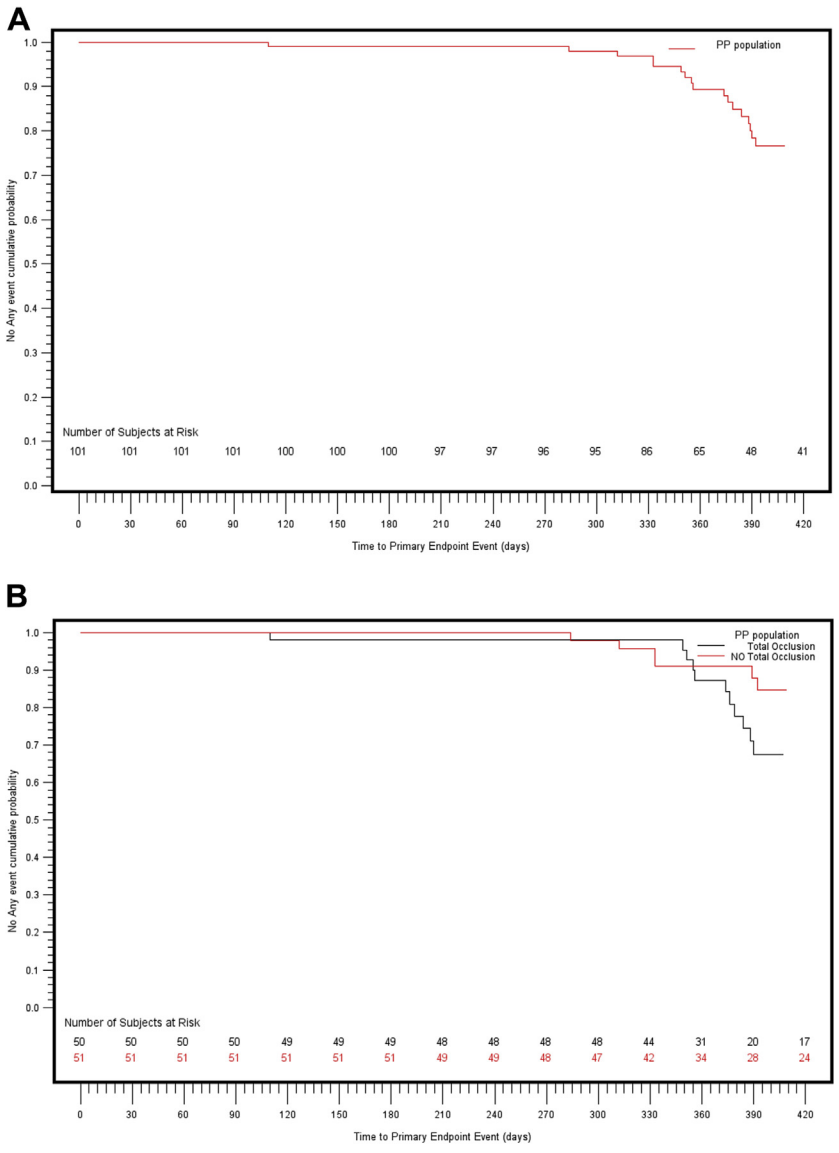
SAFETY OUTCOMES. There were no procedure- or device-related deaths and no major amputations through 12 months. Site-reported and clinical events committee-adjudicated vessel thrombosis occurred in 1 subject. All-cause death through 12 months was 4.0% (n = 4) (Table 4). Causes of death included cerebral infarction, myocardial infarction, pulmonary embolism, and lung cancer. There were no untoward paclitaxel-related adverse effects as determined by the clinical events committee.

FUNCTIONAL OUTCOMES. At 12 months, there was significant improvement in quality of life using the EQ-5D assessment, as well as in walking impairment at 12 months (p = 0.01) (Online Figure 1). The ankle-brachial index was significantly higher at 12 months (0.63 vs. 0.95, p < 0.001) (Online Figure 1).

DISCUSSION

The present report, providing detailed 1-year follow-up on a prospective multicenter study of PCB angioplasty for TASC types C and D femoropopliteal lesions, has the following implications: 1) primary patency was favorably maintained in most patients despite a low bailout stenting rate during the index procedure; 2) accordingly, successful repeat revascularization was required in only a minority of patients (4%); and 3) these benefits were accompanied

FIGURE 1 Survival Free From Target Lesion Revascularization and Restenosis >50% (Primary Patency) at 12 Months

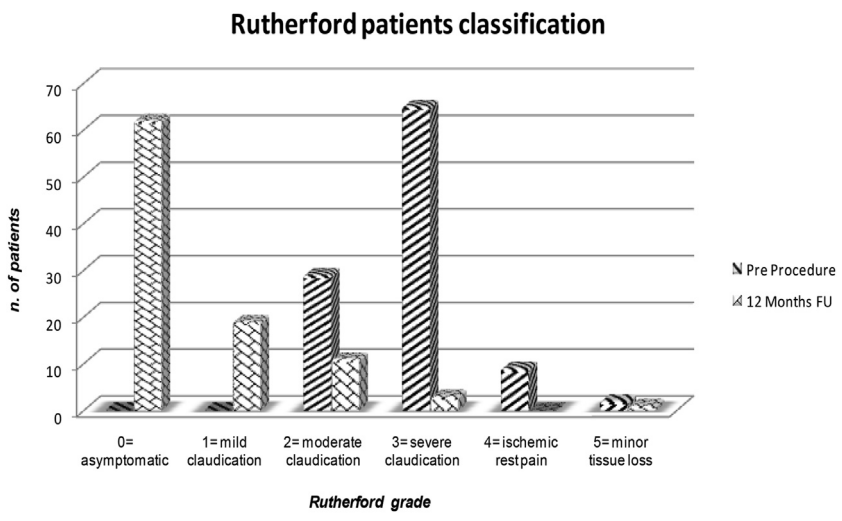


(A) Overall per protocol (PP) population. **(B)** Occlusive versus stenotic lesions.

by similarly favorable results on ankle-brachial index, Rutherford class, and quality-of-life measures.

There is still uncertainty regarding the most appropriate treatment strategy for TASC types C and D femoropopliteal artery disease. Despite its established limitations, PTA with or without stenting is widely used at many centers. Self-expandable bare-metal stents have recently been shown to be beneficial in comparison with standard PTA (10-12), especially when new-generation devices are used (13-15) for relatively simple lesions. However, the inherent benefits of such permanent prostheses over PTA alone have not convinced all operators to use them in a routine fashion, especially for long lesions for which placement of full metal jackets is not considered the standard of care. Restenosis following stenting in long superficial femoral artery lesions has been reported to occur at a frequency of up to 50% (16-18). The pattern of restenosis in full metal jackets is diffuse in-stent restenosis or

FIGURE 2 Rutherford Class During Follow-Up



FU = follow-up.

in-stent occlusion, which poses a challenge to treat (16).

Current studies of paclitaxel-eluting stents in short lesions have produced encouraging data regarding primary patency and TLR (19,20). However, very limited evidence exists on their use in long lesions. Zeller et al. (21) recently reported outcomes from a 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 in a similar population (21). The 12-month loss of patency was 23.9% with PCBs and 30.4% with drug-eluting stents ($p = 0.372$). These findings are similar to the results presented in our study, despite the inclusion of longer lesions that were at higher risk for failure. Moreover, the bailout stenting rate of 10.9% is markedly lower than that reported by Zeller et al. This low bailout stent rate strongly highlights the importance of careful PTA technique and long-duration balloon inflations.

In contrast to an elective stent strategy such as drug-eluting stents, PCBs may present an optimal long-term therapeutic option for patients with claudication. Extensive stenting might affect the biomechanics of the superficial femoral artery, bending, temporarily occluding, and stretching the native artery. Given the unavoidable disease progress, PCBs represent a viable option that is less likely to affect future interventions compared with any first-line stent strategy.

To the best of our knowledge, PCBs have been tested in simple lesions and within the boundaries typical of selective pivotal randomized trials. We designed a multicenter prospective study of PCBs to evaluate primary patency and various functional secondary endpoints for long (≥15 cm) femoropopliteal lesions. We found that PCBs were associated with favorable results 1 year after the index procedure in this long lesion population. The very limited use of bailout stenting (10.9%) was due to the intention of the operators to limit stenting as much as possible and favor spot stenting if needed.

STUDY LIMITATIONS. Limitations of this work include its nonrandomized and noncomparative design, the focus on a single treatment strategy, 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. However, the prevalence of the primary outcome was similar at these sites as at the 3 other centers combined. Further insights on the risk-benefit balance of these devices will necessarily require careful analysis of recent or ongoing randomized clinical trials comparing

them with standard balloon-only PTA and routine stenting.

CONCLUSIONS

PCBs are associated with favorable clinical outcomes in patients with severe TASC types C and D femoropopliteal artery disease requiring percutaneous revascularization. These findings signal that a stentless therapy approach with the IN.PACT Admiral PCB and optimal PTA provides favorable outcomes and is likely to leave more interventional options open for the future.

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PERSPECTIVES

WHAT IS KNOWN? Although surgical intervention remains the recommended standard for treating TASC types C and D lesions of the femoropopliteal segment, endovascular approaches have become an acceptable method.

WHAT IS NEW? The use of PCBs in treating complex long lesions is new and potentially revolutionary. Early results have shown promise in moderate-length lesions. This Italian registry presents valuable information on outcomes in very long and occluded lesions with the use of PCBs. The consistency of the results from this more complex lesion set with those reported in randomized controlled trials provides some reassurance to physicians considering the use of PCBs of good clinical outcomes.

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

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KEY WORDS paclitaxel-coated balloon, percutaneous transluminal angioplasty, peripheral artery disease

APPENDIX For a supplemental table and figure and their legends, please see the online version of this article.