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PERIPHERAL

Paclitaxel-Eluting Balloon Versus Standard Balloon Angioplasty in In-Stent Restenosis of the Superficial Femoral and Proximal Popliteal Artery

1-Year Results of the PACUBA Trial

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ABSTRACT

OBJECTIVES The hypothesis that paclitaxel-eluting balloon angioplasty provides higher 1-year patency rates in femoropopliteal artery in-stent restenosis compared with standard percutaneous transluminal angioplasty (PTA) was tested.

BACKGROUND Several trials have demonstrated that paclitaxel-eluting balloon angioplasty reduces late luminal loss in comparison with PTA.

METHOD In a prospective, randomized, single-blind, dual-center study, 74 patients with symptomatic peripheral artery disease due to in-stent restenosis were treated with either paclitaxel-based drug-eluting balloon (DEB) angioplasty ($n = 35$) or standard PTA ($n = 39$). Clinical outcomes and patency rates were assessed at 1, 6, and 12 months.

RESULTS The mean lesion length was 17.3 ± 11.3 cm in the DEB group and 18.4 ± 8.8 cm in the PTA group. A single major complication (bleeding) was observed once (1.4%). The mean ankle-brachial index before endovascular treatment was 0.65 ± 0.16 in both groups and 0.79 ± 0.2 versus 0.84 ± 0.3 ($p = 0.70$, Student *t* test) in the DEB versus PTA group at 12 months. The 12-month primary patency rates were 40.7% (95% confidence interval [CI]: 0.26 to 0.64) versus 13.4% (95% CI: 0.05 to 0.36) (log-rank $p = 0.02$) in the DEB versus PTA group. The odds ratio for PTA over DEB angioplasty for experiencing an event was estimated at 2.8 (95% CI: 1.2 to 6.6). Freedom from clinically driven target lesion revascularization was 49.0% (95% CI: 0.32 to 0.75) versus 22.1% (95% CI: 0.10 to 0.48) (log-rank $p = 0.11$) in the DEB versus PTA group. Clinical improvement by ≥1 Rutherford-Becker category was 68.8% versus 54.5% ($p = 0.87$) in the DEB versus PTA group at 12 months.

CONCLUSIONS When treating peripheral artery disease in patients with in-stent restenosis in the femoropopliteal artery, paclitaxel-eluting balloon angioplasty provides significantly higher patency rates than standard PTA. (Paclitaxel Balloon Versus Standard Balloon in In-Stent Restenoses of the Superficial Femoral Artery [PACUBA I Trial] [PACUBA 1]; NCT01247402) (J Am Coll Cardiol Intv 2016;9:1386–92) © 2016 by the American College of Cardiology Foundation.

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Endovascular treatment of peripheral artery disease (PAD) of the superficial femoral artery (SFA) with bare-metal stents has limitations when it comes to intermediate- and long-term patency. Restenosis after treatment with nitinol stents occurs in up to 30% of patients at 12 months and up to 50% at 24 months (1–3). In long lesions, the restenosis rate may be even higher (4,5). The rate of recurrent restenosis after percutaneous transluminal angioplasty (PTA) of an in-stent restenosis (ISR) within the SFA ranges up to 70% at 6 months (5). Paclitaxel-eluting balloons have been shown to reduce late luminal loss after angioplasty of the SFA within the first 6 to 12 months (6–10).

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Initially it was demonstrated in coronary arteries that drug-eluting balloons (DEBs) can reduce the recurrence of ISR (11–14). A recent clinical trial suggested significant inhibition of restenosis after treatment of ISR in peripheral arteries by paclitaxel-coated balloons (15).

We initiated a prospective, dual-center, randomized trial comparing paclitaxel-eluting balloon angioplasty with standard PTA of femoropopliteal artery ISR in patients with symptomatic PAD. The purpose was to test the hypothesis that DEB angioplasty yields superior results compared with standard PTA.

METHODS

STUDY DESIGN. This study was a prospective, dual-center, single-blind, randomized (1:1), investigator-sponsored clinical trial. Consecutive patients with symptomatic ISR of the SFA and P1 segment of the popliteal artery were assigned to either paclitaxel-based DEB angioplasty or standard PTA. The protocol was developed and conducted in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practices, the Declaration of Helsinki, and International Organization for Standardization standards 14155-1 and 14155-2; approved by the local ethics committee; and registered at the ISRCTN Registry (NCT01247402). All patients were required to give written informed consent.

STUDY OBJECTIVE. The purpose of the study was to test the hypothesis that DEB angioplasty yields superior results compared with standard PTA when treating ISR of femoropopliteal arteries.

ENDPOINTS. The primary endpoint was primary patency at 12-month follow-up, defined as <50% diameter stenosis as demonstrated by color duplex ultrasonography (CDUS) and computed tomographic angiography (CTA) in the absence of clinically driven target lesion revascularization (TLR) during follow-up. Secondary endpoints were technical success (achievement of <30% residual diameter stenosis by visual estimate), complication rate through 30 days post-index procedure, clinical success (improvement in clinical Rutherford-Becker category after the index procedure), change in ankle-brachial index (ABI), and clinically driven TLR at 6 and 12 months post-index procedure.

FOLLOW-UP SCHEDULE. Clinical evaluation and ABI were assessed pre-study and at 1 month, 6 months, and 12 months after the index procedure. CDUS was performed at 24 h, 6 months, and 12 months and CTA at 12 months after the index procedure.

ABBREVIATIONS AND ACRONYMS

ABI = ankle-brachial index

CDUS = color duplex ultrasonography

CI = confidence interval

CTA = computed tomographic angiography

DEB = drug-eluting balloon

ISR = in-stent restenosis

PAD = peripheral artery disease

PTA = percutaneous transluminal angioplasty

SFA = superficial femoral artery

TASC = TransAtlantic InterSociety Consensus

TLR = target lesion revascularization

INCLUSION AND EXCLUSION CRITERIA. Key inclusion criteria were age >50 years, symptomatic PAD (Rutherford-Becker category 2 or 3), ISR >50% in the SFA and P1 segment of the popliteal artery, and a distal runoff of at least 1 artery, which, however, may be stenotic but amenable to PTA. Key exclusion criteria were inability to give written informed consent; known allergy, hypersensitivity, or intolerance to radiologic contrast media, aspirin, clopidogrel or ticlopidine, and paclitaxel; and creatinine >2.5 mg/dl.

TREATMENT. All interventions were performed percutaneously from an antegrade or a contralateral approach using a 6-F sheath. Digital subtraction angiography including a ruler fixed at the patient's thigh was performed using 2 views at least 30° apart to evaluate lesion morphology, inflow disease, and runoff. After successful wire passage through the target lesion, patients were randomly assigned to either paclitaxel-based DEB angioplasty or standard PTA using computer-generated random digits and sealed envelopes. In the DEB arm, pre-dilation with a standard balloon for 1 min was followed by paclitaxel-eluting balloon angioplasty for 2 min. The study device was the FREEWAY balloon 0.035 (Eurocor, Bonn, Germany; Opto Eurocor Healthcare, Bangalore, India) with a shellac coating as a spacer and paclitaxel in a concentration of 3 $\mu g/mm^2$. In the PTA arm, balloon angioplasty was performed for 2 min with a standard balloon.

ADJUVANT MEDICAL THERAPY. Aspirin and clopidogrel were given at least 1 day prior to the intervention; otherwise a loading dose of clopidogrel 300 mg was given during the intervention. All patients

received aspirin 100 mg/day indefinitely and clopidogrel 75 mg/day for 3 months post-intervention.

CONTROL IMAGING. On CDUS, the waveform, peak systolic velocity and peak systolic velocity ratio were measured pre-study and 24 h, 6 months, and 12 months post-index procedure. Findings on CDUS were consistent with significant restenosis (>50%), as evidenced by peak systolic velocity ratio ≥2.5 within the treated arterial segment or occlusion of the treated arterial segment. Angiographic evaluation of restenosis at 12 months was performed using contrast-enhanced CTA on a Somatom Flash 128-row, multislice computed tomographic scanner (Siemens Medical Systems, Erlangen, Germany). The accuracy and specificity of multislice computed tomography with automated reconstruction has been shown to be comparable with that of intra-arterial digital subtraction angiography (16-19). Evaluation of the angiograms was performed in the CTA core laboratory at the Medical University Vienna, which was blinded with regard to the treatment arm.

STATISTICAL ANALYSIS. Calculation of the number of patients required for the study was based on an alpha error of 5%, power of 80%, and an average attrition rate of 10% to 15% at 6 to 12 months (death, loss to follow-up, patient withdrawal).

Assuming a 30% difference of the patency rate between the study arm and the control arm, the sample size required for the superiority hypothesis on the 12-month primary patency endpoint was 33 subjects in each arm and 75 patients to compensate for loss to follow-up. This endpoint was evaluated using the Kaplan-Meier method of time-to-event analysis, using the log-rank test to evaluate statistically significant differences between treatment groups. A 1-sided test was chosen because previous studies have shown superiority of DEBs. Data analysis for primary and secondary study endpoints was performed according to the intention-to-treat principle. Descriptive data are expressed as mean ± SD or, for non-normal distributions or censored datasets, as medians with interquartile ranges and were analyzed using Mann-Whitney *U* tests. Proportions were compared using chi-square statistics. Calculations were performed using Stata release 8.0 (StataCorp LP, College Station, Texas).

RESULTS

A total of 74 patients (43 male, 31 female) were enrolled (DEB arm, n = 35; PTA arm, n = 39); the mean age was 68.2 ± 9.8 years. The mean lesion length was 17.9 ± 10.0 cm; 22 patients (30%) had chronic total occlusions. According to the Tosaka classification of ISR, 9 patients were in class I (focal, ≤5 cm), 43 patients were in class II (diffuse, >5 cm), and 22 patients were in class III (chronic total occlusion) (20). Eleven patients were in Rutherford-Becker clinical category 2 and 63 patients in category 3. The mean ABI was 0.65 ± 0.16 before treatment. Patient demographics, cardiovascular risk factors, and baseline lesion characteristics are summarized in Table 1 and clinical stages and outcomes in Table 2.

TABLE 1 Patient Demographics, Cardiovascular Risk Factors, and Baseline Lesion Characteristics

	DEB Angioplasty (n = 35)	PTA (n = 39)
Age (yrs)	68.1 ± 9.2	68.3 ± 0.4
Gender (male)	20 (57)	23 (59)
Smoker	17 (52)	18 (53)
CHD	12 (36)	14 (41)
Hypertension	26 (79)	27 (79)
Diabetes	17 (52)	13 (38)
Hyperlipidemia	18 (55)	25 (74)
Renal failure	6 (19)	6 (16)
Creatinine (mg/dl)	1.03 ± 0.28	0.98 ± 0.25
Obesity	7 (22)	7 (21)
Family history of PAD	7 (29)	8 (28)
Lesions		
Length (cm)	17.3 ± 11.3	18.4 ± 8.8
Occlusions	11 (31)	11 (28)
Reference vessel diameter	5.7 ± 1.0	5.4 ± 0.9
TASC classification		
A	8 (23)	2 (5)
B	8 (23)	14 (36)
C	5 (14)	10 (26)
D	14 (40)	13 (33)
Tosaka classification		
Class I	8 (23)	2 (5)
Class II	16 (46)	26 (67)
Class III	11 (31)	11 (28)
2-vessel runoff	26 (74)	33 (85)

Values are mean ± SD or n (%).

CHD = coronary heart disease; DEB = drug-eluting balloon; PAD = peripheral artery disease; PTA = percutaneous transluminal angioplasty; TASC = TransAtlantic InterSociety Consensus.

Initial technical success of balloon dilation with <30% residual diameter stenosis was achieved in 67 of 74 patients (90.5%). Seven patients (9.5%) required additional stenting. Two patients were in the PTA group, 1 because of dissection, and 5 patients were in the DEB group, 4 because of dissections. Only 1 patient had restenosis with TLR after 6 months (PTA group, 0 of 2; DEB group, 1 of 5). In 1 patient in the PTA group, sufficient reopening of the lumen could not be achieved because of severe calcification compressing the stent. Thus, the technical success rate after bailout stenting was 98.6%. Complications were

observed in 5 of 74 patients (6.8%): 1 severe complication with bleeding required fasciotomy; in 2 patients, embolization into tibial arteries was treated by aspiration embolectomy during the index procedure; and in another 2 patients, groin hematomas required no additional treatment.

FOLLOW-UP. After the index procedure, 1 patient in the PTA group was excluded because of lack of technical success because of severe vessel calcification; 3 patients withdrew their consent. At 1 month, 70 patients (35 per group) were followed. One patient in the DEB group had a thrombosis, which was treated by fibrinolysis. One patient in the PTA group had an occlusion, which remained untreated. At 6 months in the DEB group, 13 patients had recurrent stenoses or occlusions, 3 of whom were treated by TLR. In the PTA group, 21 patients had stenoses, 5 of whom were treated by TLR. At 12 months in the DEB group, 4 additional patients had stenoses, 8 of whom underwent TLR. In the PTA group, another 4 patients had stenoses, 14 of whom underwent TLR (Figure 1).

The primary patency rates were 97.1% (95% confidence interval [CI]: 0.91 to 1.00), 58.8% (95% CI: 0.44 to 0.78), and 40.7% (95% CI: 0.25 to 0.64) in the DEB group and 97.1% (95% CI: 0.91 to 1.00), 31.3% (95% CI: 0.18 to 0.52), and 13.4% (95% CI: 0.05 to 0.36) (log-rank p = 0.02) in the PTA group at 1, 6, and 12 months, respectively (Table 3). The odds ratio for PTA over DEB angioplasty for experiencing an event was estimated at 2.8 (95% CI: 1.2 to 6.6). Freedom from clinically driven TLR was 97.1% (95% CI: 0.91 to 1.00), 88.2% (95% CI: 0.78 to 0.99), and 49.0% (95% CI: 0.32 to 0.75) in the DEB group and 97.1% (95% CI: 0.91 to 1.00), 83.8% (95% CI: 0.72 to 0.97), and 22.1% (95% CI: 0.10 to 0.47) (log-rank p = 0.11) in the PTA group at 1, 6, and 12 months, respectively (Table 3).

In a post hoc analysis, outcomes in TransAtlantic InterSociety Consensus (TASC) A and B lesions and TASC C and D lesions, and in Tosaka class I and II lesions and class III lesions, were analyzed. In TASC A and B lesions, the primary patency rates in the DEB group were 73.3% and 55.0% and in the PTA group were 28.6% and 9.5% at 6 and 12 months, respectively (Table 3). In TASC C and D lesions, the primary patency rates in the DEB group were 47.3% and 28.4% and in the PTA group were 33.4% and 16.7% at 6 and 12 months, respectively (Table 3). In Tosaka class I and II lesions, the primary patency rates in the DEB group were 60.9% and 42.6% and in the PTA group were 39.1% and 13.0% at 6 and 12 months, respectively (Table 3). In Tosaka class III lesions, the primary patency rates in the DEB group were 54.5% and 36.4% and in the PTA group were 11.1% and 11.1% at 6 and 12 months, respectively (Table 3). In a multivariate conditional logistic regression model, diabetes had a significant impact on the primary patency rate of long TASC C and D lesions, and lesion length had an impact on freedom from TLR.

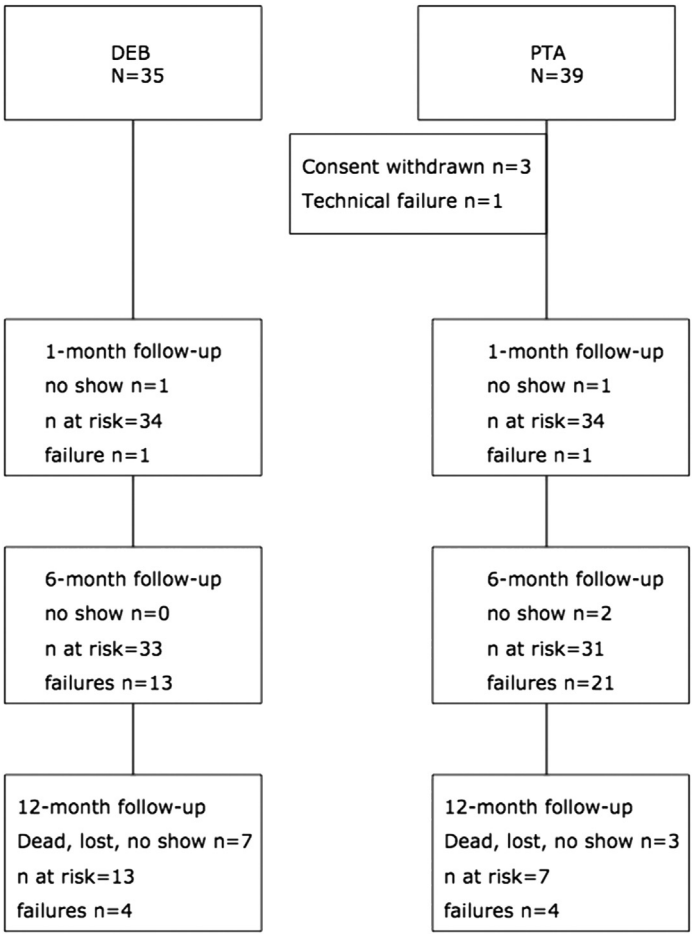
The mean ABI was 0.65 ± 0.16 in both treatment groups before intervention, 0.88 ± 0.14 versus 0.90 ± 0.13 at 1 month, 0.79 ± 0.15 versus 0.78 ± 0.18 at 6 months, and 0.79 ± 0.2 versus 0.84 ± 0.3 at 12 months (p = 0.70, Student *t* test) in the DEB versus PTA group, respectively. At 1 month, clinical improvement of at least 1 Rutherford-Becker category was observed in 32 of 35 (91.4%) versus 32 of 38 (84.2%) patients (p = 0.46, Fisher exact test), at 6 months in 20 of 26 (76.9%) versus 14 of 25 (56.0%) patients (p = 0.23), and at 12 months in 11 of 16 (68.8%) versus 6 of 11 (54.5%) patients (p = 0.87) in the DEB versus PTA group, respectively (Figure 2).

TABLE 2 Clinical Stage and Outcome

	DEB Angioplasty	PTA	p Value
Rutherford-Becker clinical category			
2	3 (9)	8 (21)	
3	32 (91)	30 (79)	0.36
ABI			
Before	0.65 ± 0.16	0.65 ± 0.16	0.99
1 months	0.88 ± 0.14	0.90 ± 0.13	0.58
6 months	0.79 ± 0.13	0.78 ± 0.18	0.96
12 months	0.79 ± 0.20	0.84 ± 0.30	0.70
Rutherford-Becker clinical improvement			
1 mo			
0	3 (9)	6 (16)	
+1	1 (3)	1 (3)	
+2	15 (43)	10 (26)	
+3	16 (46)	21 (55)	0.46
6 mo			
−1	3 (12)	2 (8)	
0	3 (12)	9 (36)	
+1	5 (19)	2 (8)	
+2	9 (35)	5 (20)	
+3	6 (23)	7 (28)	0.23
12 mo			
−2	1 (6)	0 (0)	
−1	1 (6)	1 (9)	
0	3 (19)	4 (36)	
+1	2 (12)	1 (9)	
+2	2 (12)	2 (18)	
+3	7 (44)	3 (27)	0.87
Technical success	31 (89)	37 (98)	
Stenting	4 (11)	1 (2.5)	
Target lesion restenosis/occlusion	18 (51)	26 (67)	0.03

Values are n (%) or mean ± SD.
ABI = ankle-brachial index; other abbreviations as in Table 1.

FIGURE 1 Consolidated Standards of Reporting Trials Diagram of the Trial



Numbers in the figure represent absolute numbers of patients either lost to follow-up or at risk representing treatment failure. DEB = drug-eluting balloon; PTA = percutaneous transluminal angioplasty.

DISCUSSION

The key findings of the single-blind randomized study of DEB angioplasty versus standard PTA treatment of SFA and P1 ISR were as follows: 1) patients treated with paclitaxel-based DEB angioplasty had a significantly higher primary patency rate of 40.7% compared with standard PTA (13.4%) (log-rank $p = 0.02$) at 12 months; 2) this finding was more evident in TASC A and B lesions; and 3) there was no difference in clinical parameters such as ABI, improvement in Rutherford-Becker category, and clinically driven TLR.

Treatment of ISR with DEB angioplasty has proved to be successful in coronary arteries. Scheller et al. (11) showed that after 5-year follow-up, the TLR rate was significantly reduced in patients treated with DEB angioplasty (from 38.9% to 9.3%; $p = 0.004$). In the DEBATE-ISR (Drug Eluting Balloon in Peripheral Intervention for In-Stent Restenosis) study, 44 patients with diabetes with superficial femoral artery ISR were treated with paclitaxel-based DEB angioplasty. In this single-arm observational study, the rate of recurrent ISR was 19.5% and the TLR rate was 13.6% at 1 year (21). This was compared with a historical control group of patients treated with PTA for ISR. The change in the 1-year TLR rate between DEB angioplasty and PTA in favor of DEB treatment was 17.4% (13.6% vs. 31.0%) in that study and 26.9% (22.1% vs. 49.0%) in our study. Stabile et al. (15) reported a single-arm observational study of 39 patients with ISR (mean length 8.3 cm) in short lesions of the SFA. They reported primary patency rates of 92.1% at 1-year and 70.3% at 2-year follow-up and no difference whether lesions were Tosaka class II or class III (15,22). We observed that lesion length had an impact on primary patency and freedom from TLR in both the DEB and PTA groups, but stenosis (Tosaka class I or II) versus occlusion (Tosaka class III) had no impact (20). Another treatment option is to use drug-eluting stents to treat ISR. Zeller et al. (23) reported 108 patients who were enrolled in the ZILVER-PTX (Zilver PTX Global Registry) single-arm study. The mean lesion length was 13.3 cm. Primary patency was 95.7% at 6 months and 78.8% at 1 year. Freedom from TLR was 81.0% at 1-year and 60.8% at 2-year follow-up. Covered stents can prevent ingrowth of neointimal tissue, resulting in good patency rates in long SFA lesions (3,4). In a randomized study (RELINE [GORE VIABAHN® Versus Plain Old Balloon Angioplasty (POBA) for Superficial Femoral Artery (SFA) In-Stent Restenosis]), 83 patients with ISR of the SFA were treated with either a Viabahn endoprosthesis or PTA. Lesion length range from 17.3 to 19.0 cm. The primary patency rate at 1 year was 74.8% versus 28.0% ($p < 0.001$), and freedom from TLR was 79.9% versus 42.2% ($p < 0.001$) in the Viabahn versus PTA group, respectively (24). In the EXCITE-ISR (Excimer Laser Randomized Controlled Study for Treatment of Femoropopliteal In-Stent Restenosis) randomized study, 250 patients with ISR in the SFA (mean length 19.6 cm) were treated with either excimer laser debulking followed by PTA or standard PTA. Freedom from TLR at 6 months was 73.5% versus 51.8% ($p < 0.005$) (25). In the SALVAGE study, 27 patients with ISR of the SFA were enrolled. ISR lesions (mean length 20.7 cm) were treated with excimer laser ablation followed by Viabahn

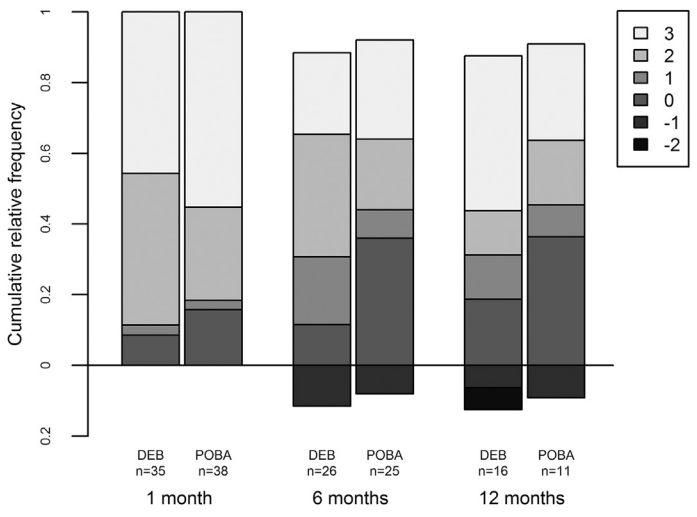
TABLE 3 Primary Patency Rates of Lesions by Category and Freedom From Clinically Driven Target Lesion Revascularization at 6- and 12-Month Follow-Up

	DEB Angioplasty (95% CI)	PTA (95% CI)
Primary patency rate		
6 months	58.8% (0.44–0.78)	31.3% (0.18–0.52)
12 months	40.7% (0.25–0.64)	13.4% (0.05–0.36)*
TASC A and B		
6 months	73.3% (0.54–0.99)	28.6% (0.12–0.65)
12 months	55.0% (0.33–0.91)	9.5% (0.01–0.58)
TASC C and D		
6 months	47.3% (0.29–0.76)	33.4% (0.17–0.64)
12 months	28.4% (0.12–0.67)	16.7% (0.05–0.54)
Tosaka class I/II		
6 months	60.9% (0.44–0.84)	39.1% (0.24–0.65)
12 months	42.6% (0.26–0.72)	13.0% (0.04–0.45)
Tosaka class III		
6 months	54.5% (0.32–0.94)	11.1% (0.02–0.71)
12 months	36.4% (0.14–0.95)	11.1% (0.02–0.71)
Freedom from clinically driven TLR		
6 months	88.2% (0.78–0.99)	83.8% (0.72–0.97)
12 months	49.0% (0.32–0.75)	22.1% (0.10–0.47)

*Log-rank p = 0.02.

CI = confidence interval; TLR = target lesion revascularization; other abbreviations as in Table 1.

FIGURE 2 Distribution of Rutherford-Becker Score in the Drug-Eluting Balloon and PTA Groups at 1, 6, and 12 Months



Number (n) indicates the respective number of patients for which the score was observed. Rutherford-Becker symptom grading: −2 = moderate worsening, −1 = minor worsening, 0 = no change, +1 = minor improvement, +2 = moderate improvement, and +3 = major improvement. DEB = drug-eluting balloon; POBA = plain old balloon angioplasty.

implantation. Primary patency at 12 months was 48.0%, and the TLR rate was 17.4% (26).

When all these studies are put into perspective, it is evident that ISR is a difficult problem that requires new treatment concepts. Standard PTA results in a 1-year primary patency rate of 13% to 28% and freedom from TLR in 22% to 42%. This should not be offered to our patients. The results of DEB treatment are quite different, with 1-year primary patency rates of 40.7% in our study and up to 92.1% in the single-arm trial of Stabile et al. (15). However, lesions in this single-center trial were much shorter (mean length 8 cm vs. 18 cm), and there was no blinded independent core laboratory adjudication, which was performed in our trial. Powerful strategies to treat ISR of the SFA are obviously the use of drug-eluting stents such as the Zilver stent, with a 1-year primary patency rate of 78.8%, and the use of covered stents such as the Viabahn, with a 1-year primary patency rate of 74.8%.

STUDY LIMITATIONS. We enrolled a limited number of patients, and follow-up was only 1 year in length. However, this was the first randomized trial of DEB angioplasty versus PTA in ISR of femoropopliteal arteries with blinded core laboratory adjudication. The study had clinical and imaging endpoints, and long lesions and total occlusions were included. The primary endpoint, 1-year primary patency rate, was met with a significance level of p = 0.02 (log-rank), but this did not translate into a significant improvement of clinical benefit.

CONCLUSIONS

The clinical implication of the present study is that it demonstrates that when treating PAD in patients with ISR of the femoropopliteal artery segment, paclitaxel-eluting balloon angioplasty provides significantly higher patency rates than standard PTA.

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PERSPECTIVES

WHAT IS KNOWN? DEBs have demonstrated superiority over standard PTA in the treatment of ISR of coronary artery disease. Encouraging results have been reported in single-arm observational studies in patients with PAD.

WHAT IS NEW? This is the first randomized study of paclitaxel-based DEB angioplasty versus standard PTA for treatment of symptomatic PAD due to long femoropopliteal artery lesions. The study demonstrated a significantly higher 1-year primary patency rate when treated with DEB angioplasty.

WHAT IS NEXT? The DEB should be compared with drug-eluting stents and covered stents in patients with ISR in PAD.

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