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A pilot study of a novel paclitaxel-coated angioplasty catheter for lower extremity peripheral artery disease: a pilot study

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Abstract

Aim: The aim of the study was to report our preliminary results and real-world experiences regarding the use of a novel paclitaxel-coated balloon catheter in a cohort of patients with lower extremity peripheral artery disease at different stages.

Material and methods: A prospective cohort pilot study was conducted and the study group was made up of a total of 20 patients with peripheral artery disease who underwent endovascular balloon angioplasty with BioPath 014 or 035, a novel paclitaxel-coated, shellac containing balloon catheter. Eleven patients had a total of 13 TASC II-A lesions, 6 patients had a total of 7 TASC II-B lesions, 2 patients had TASC II-C lesions, 2 patients had TASC II-D lesions.

Results: In 13 patients, a single attempt with a BioPath catheter was adequate to treat a total of 20 target lesions, whereas in 7 patients more than one attempt with a different sized BioPath catheter was necessary. In 5 patients, total or near-total occlusion in the target vessel was initially treated with an appropriate sized chronic total occlusion catheter. Thirteen (65%) patients had at least one categorical improvement in Fontaine classification and none had symptomatic worsening.

Conclusions: The BioPath paclitaxel-coated balloon catheter seems to offer a useful alternative to the similar devices for treatment of femoral-popliteal artery disease. These preliminary results warrant confirmation with further research to reveal the safety and efficacy of the device.

Key words: peripheral artery disease, percutaneous transluminal angioplasty, drug-coated balloon, drug-eluting balloon, paclitaxel-coated balloon.

Introduction

Lower extremity peripheral artery disease is an important cause of cardiovascular morbidity and mortality among aged persons with an estimated prevalence of 5.28% to 18.83% in different age/sex groups. Affecting over 200 million people worldwide, the disease has become increasingly prevalent in both low- and high-income countries as the number of individuals with peripheral artery disease increased by 13.1% to 28.7% worldwide within the preceding decade [1]. Patients with intermittent claudication have progressive quality-of-life impairment and most suffer psychological, behavioral and social problems [2]. Moreover, 10% to 15% of patients with intermittent claudication eventually progress to the state of critical limb ischemia that is characterized with persistent pain, ischemic changes and a great risk of mortality and limb loss [3].

Recently, endovascular therapy options have evolved from bare metal stents and plain balloons to interwoven nitinol stents and drug-coated balloons. Results were encouraging regarding early and 5-year patency rates of novel endovascular therapies leading to endovascular therapy replacing surgical revascularization in unifocal, short-segment femoropopliteal and infrapopliteal lesions [4, 5]. Drug-coated balloons have more recently drawn attention by eliminating the potential disadvantages of peripheral artery stenting that result from the highly dynamic mechanical environment of the lower limb [6].

The rationale to use drug delivery across the vessel wall is to suppress negative remodeling of the target segment of the vessel that is proposed to be responsible for restenosis after percutaneous transluminal angioplasty. Paclitaxel is an antimitotic agent acting by disrupting the microtubule assembly during the cell cycle and it has been the drug of choice in various balloon-coating designs. There have been various drug-coated balloon devices differing from each other mainly in the mechanism of drug delivery

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from the balloon surface. The prevention of re-stenosis is mainly dependent on the excipient substance, which carries the paclitaxel coating into the arterial wall. The success of the device depends on the rapid elution of the drug with a single dose of paclitaxel to achieve a durable biological effect without entering the blood stream [7, 8].

BioPath balloon catheter is a novel device featuring a unique shellac coating to facilitate the pressure-induced delivery of paclitaxel across the vessel wall. Shellac is a natural resin, which was approved as a food additive in Europe and US, and it remains over the balloon surface following withdrawal of the catheter.

Aim

We herein report our preliminary results regarding the use of BioPath 035 and BioPath 014 paclitaxel-coated balloon catheters in a cohort of patients with peripheral artery disease at different stages.

Material and methods

The local ethics committee approved the study. All patients were given detailed information about the planned intervention and signed informed consent was obtained. This was a prospective cohort study and it was conducted in a tertiary care hospital between March and September 2018. The study group was made up of patients with peripheral artery disease who underwent endovascular balloon angioplasty with BioPath 014 or 035, a novel paclitaxel and shellac coated balloon catheter. Patients with aorto-iliac, femoral-popliteal or infrapopliteal lesions at any stages who presented with symptoms of intermittent claudication, ischemic rest pain or critical limb ischemia (Fontaine class I to IV) were considered eligible for the study. Lesion characteristics were classified according to the latest update of the TASC II guideline that was expanded to include below the knee lesions [3]. Patients were excluded if they had a clear indication for combined or staged vascular surgery, such as diffuse arterial involvement, several failed attempts with endovascular techniques, lack of distal collateral flow or there was a clear contraindication for use of endovascular technique. Patients were also not included in the present study if they had unstable coronary symptoms or decompensated heart failure.

A total of 20 consecutive patients were included in the study. Distribution of target lesions by TASC-II classification was as follows: 11 patients had a total of 13 TASC II-A lesions (6 had SFA stenosis of ≤ 10 cm in length, 3 had focal PTA stenosis of ≤ 5 cm in length, 2 had both SFA stenosis of 6 cm in length and PTA stenosis of 4 cm in length), 6 patients had a total of 7 TASC II-B lesions (1 patient had multiple ATA stenoses of a total of 6 cm in length, 2 had a single stenosis in the popliteal artery (both 6 cm in length), 1 had a single EIA stenosis of 6 cm in length, 1 patient had multiple stenoses each ≤ 5 cm in length in the tibial vessels, one patient had both multiple SFA stenoses each ≤ 5 cm in length and chronic total occlusion ≤ 3 cm in length in the tibial vessels, 2 patients had TASC II-C lesions (1 had bilateral distal external iliac artery stenosis of 8 cm in length, one had unilateral external iliac artery in-stent stenosis extending into the common femoral artery) and 2 patients had TASC II-D lesions (both had chronic total occlusion of the popliteal artery). Patient counseling charts, laboratory tests and angiography views (computed tomography or conventional angiography) were reviewed and recorded. Patients with diabetes were consulted with an endocrinologist to control blood sugar levels. Smoking patients were referred for smoking cessation department before the operation. Patients with uncontrolled hypertension and dyslipidemia were initiated on appropriate medications before the procedure. Patients were also initiated on aspirin 100 mg daily and clopidogrel 75 mg daily on the same day of the procedure.

Procedure

All interventions were performed according to our institutional standards for angiography and angioplasty. The same operating team performed all interventions in an adequately equipped catheter laboratory for hybrid peripheral vascular interventions. The procedures were performed under local anesthesia with the aid of C-arm fluoroscopy guidance. Vascular access was tailored to the anatomical location and characteristics of the lesion. All patients received an intravenous bolus of unfractionated heparin (70 to 100 U/kg) immediately after the placement of an introducer sheath (4 to 6-F). Diagnostic angiography was performed and target lesions were determined using digital subtraction views, as necessary. Multiple short adjacent lesions were considered in cumulative length and treated as a single target.

A 3 to 4 mm-diameter BioPath 014 balloon catheter was used for below the knee tibial vessels whereas a 4 to 7 mm-diameter BioPath 035 balloon catheter was used for above the knee level including the popliteal artery, superficial femoral artery, common femoral artery and distal portion of the external iliac artery. An ipsilateral vascular access, either antegrade or retrograde fashion, was used in all patients. Bilateral common femoral artery access was used in 1 patient receiving bilateral distal external iliac artery intervention. The target lesion was crossed with a conventional 0.01" or 0.035" guidewire. In 5 patients, total or near-total occlusion in the target vessel (2 patients had total popliteal artery occlusion, 1 patient had subtotal popliteal artery occlusion, 1 patient had subtotal SFA occlusion, 1 patient had total PTA occlusion) was initially treated with an appropriate sized chronic total occlusion catheter. In 1 patient, a near-total occlusion in the superficial femoral artery was initially treated using a rotational atherectomy catheter (Jetstream XC Atherectomy Catheter 2.4 mm/3.4 mm, Boston Scientific). Then, the lesion was first pre-dilated with an uncoated balloon undersized to the target vessel. The BioPath catheter was advanced through the target lesion and fixed 10 mm proximally and distal to the stenosis segment. The balloon was inflated at 6 bars for at least 120 s, according to the instructions of the manufacturer to ensure adequate delivery of paclitaxel through the cracked

Table I. Baseline characteristics of patients

Variable	Mean ± SD or *n* (%)
Age	63.10 ±10.26
Male gender	18 (90)
BMI	25.83 ±4.44
Diabetes	6 (30)
Hypertension	17 (85)
Coronary artery disease	15 (75)
Dyslipidemia	8 (40)
Ankle-brachial index	0.55 ±0.16
TASC classification:	
TASC A	9 (45)
TASC B	6 (30)
TASC C	3 (15)
TASC D	2 (10)

plaque and onto the vessel wall. The catheter was withdrawn and the procedure was finished if a residual stenosis of < 20% by visual estimation was achieved. The effect of heparin was not reversed and Angio-Seal was used to seal the puncture site. Cilostazol 100 mg/day was started after the procedure and continued for 6 months. Aspirin 100 mg daily was continued indefinitely whereas clopidogrel was continued for 3 months after the operation.

The follow-up plan included assessment of the physical symptoms and evaluation of the patency with Doppler ultrasonography at 1 week, 1 to 2 months and 6 months after the intervention. Repeat angiography was scheduled at 12 months unless Doppler examination reveals diminished flow across the target lesion.

Statistical analysis

Statistical analyses were performed using SPSS statistical software version 19.0. Normal distribution of the parameter was assessed using visual histograms and the Shapiro-Wilk test. Continuous parameters were expressed as mean ± standard deviation, and categorical parameters as numbers and percentages within brackets.

Results

Baseline characteristics of the patients are given in Table I. Mean age was 63.10 ±10.26 years and male : female ratio was 18 : 2. There were 6 patients with a history of diabetes but glycated hemoglobin (HbA_{1c}) levels were found higher than 6.5% in 14 (70%) patients; of these 4 patients had HbA_{1c} levels > 10%. History of coronary artery disease was present in 15 (75%) patients; 4 patients had previous coronary bypass surgery, 8 patients had previous percutaneous transluminal angioplasty and 3 patients were receiving medical treatment alone for mild coronary atherosclerosis.

In 13 patients, a single attempt with a BioPath catheter was adequate to treat a total of 20 target lesions; 6 out of these were in the superficial femoral artery, 10 were in the tibial vessels, 3 were in the distal portion of the external iliac artery and 1 was in the popliteal artery whereas in 7 patients more than one attempt with a different sized BioPath catheter was necessary; 3 were in the superficial femoral artery, 3 were in the popliteal artery and 1 was in distal portion of the external iliac artery (in-stent restenosis). In 5 patients, total or near-total occlusion in the target vessel was initially treated with an appropriately sized chronic total occlusion catheter (2 patients had total popliteal artery occlusion, 1 patient had subtotal popliteal artery occlusion, 1 patient had subtotal SFA occlusion, 1 patient had total PTA occlusion). In 1 patient, a near-total occlusion in the superficial femoral artery was initially treated using a rotational atherectomy catheter (Jetstream XC Atherectomy Catheter 2.4 mm/3.4 mm, Boston Scientific) (Table II). The procedure was well tolerated in all patients and none of the patients had procedure-related complications.

Table III demonstrates the follow-up data of the patients. Thirteen (65%) patients had at least one categorical improvement in Fontaine classification and none had symptomatic worsening.

Discussion

Our study presents our real-life experience regarding the use of the BioPath paclitaxel-coated balloon catheter in patients with peripheral artery disease. We used the device both in simple stenoses and complex, calcified and long lesions and we achieved 100% angiographic success in all of the procedures without any need for further intervention.

In our study, the majority of the lesions (20 out of 24 lesions) were TASC II category A and B; we used both above the knee and below the knee versions of the device almost in equal numbers. None of the interventions resulted in potential complications such as distal embolization or plaque dissection. We also used balloon dilatation with BioPath as a complementary procedure following the chronic total occlusion catheter or rotational atherectomy device and these procedures also achieved success. The low number of patients in TASC class C and D is due to the small number of patients in the short enrollment period of our preliminary study.

In the last decade, there have been a number of randomized controlled trials evaluating the potential role of drug-coated balloons as single treatment in patients with femoral-popliteal artery disease. In the FemPac (Femoral Paclitaxel) pilot trial where about two-thirds of the lesions were de-novo TASC IIa and IIb lesions and the mean lesion length was about 5 cm, the paclitaxel-coated balloon group had significantly less late lumen loss and significantly lower target lesion revascularization at 6 months [9]. In the Local Taxane with Short Exposure for Reduction of Restenosis in Distal Arteries (THUNDER) trial, the balloon catheter used was coated with paclitaxel and a nonionic contrast agent, which was referred to as Paccocath coating. Five-year outcomes revealed that paclitaxel-coated balloon angioplasty provided significantly lower rates of target lesion revascularization (21% vs. 56%, p = 0.0005) and restenosis (17% vs. 54%, p = 0.04) [10]. Use of these proto-

Table II. Demonstration of disease severity of patients according to the TASC II classification

Patient no.	TASC II class	Description of the lesion (in length)	Catheter
1	A	SFA stenosis (8 cm)	5 × 150 mm, 4 × 80 mm*
2	A	SFA stenosis (5 cm)	**6 × 100 mm**
3	A	SFA stenosis (8 cm)	**6 × 120 mm**
4	A	SFA stenosis (10 cm)	**Jetstream atherectomy, 6 × 100 mm**
5	B	Multiple ATA stenosis (total 6 cm) with stenosis of the PTA	**4 × 120 mm, 3 × 120 mm**
6	C	Bilateral external iliac artery stenosis (each 8 cm)	**5 × 120 mm, 6 × 60 mm**
7	B	Popliteal artery stenosis (6 cm)	5 × 120 mm, 6 × 60 mm*
8	B	Popliteal artery stenosis (sub-total occlusion) (6 cm)	**CTO catheter, 5 × 120 mm**
9	A – A	SFA stenosis (6 cm) with stenosis in the PTA (4 cm)	**5 × 60 mm, 2 × 80 mm**
10	A	SFA stenosis (10 cm)	CTO catheter, 3 × 80 mm, 3.5 × 120 mm, 4 × 120 mm*
11	B	Right external iliac artery stenosis (6 cm)	**7 × 40 mm**
12	A	Single focal stenosis (4 cm) in the PTA	**3 × 100 mm**
13	A	Focal PTA stenosis (4 cm), stenosis of the peroneal artery	**3 × 120 mm, 3.5 × 120 mm**
14	C	Recurrent stenosis (in-stent) in the EIA extending into the CFA	7 × 80 mm, 7 × 100 mm*
15	A – B	SFA stenosis (6 cm) with multiple stenoses in tibial vessels	**5 × 150 mm, 3 × 120 mm**
16	A – A	SFA, ATA and PTA stenosis (8, 6 and 3 cm, respectively)	**5 × 120 mm, 3.5 × 120 mm, 3 × 100 mm**
17	B – B	Multiple SFA stenosis, CTO < 3 cm in tibial vessels	CTO catheter, 7 × 100 mm, 2 × 100 mm, 3 × 100 mm*
18	D	CTO in the popliteal artery (6 cm) with collateral flow	CTO catheter, 5 × 60 mm, 3.5 × 120 mm*
19	D	CTO in the popliteal artery (5 cm) without collateral flow	CTO catheter, 5 × 60 mm, 5 × 100 mm*
20	A	Focal PTA stenosis (4 cm) with stenosis of the ATA	**3 × 120 mm**

type catheters in these two trials has revealed the efficacy of drug-coated balloons when used as single treatment in patients with TASC IIA and B lesions, thus paving the way for future studies [11].

The catheter used in the PACIFIER trial was the IN.PACT Admiral system that used urea as a hydrophilic natural spacer to facilitate the delivery of paclitaxel. Procedural outcomes including reference vessel diameter, minimum lumen diameter and post-procedural diameter stenosis were similar between groups but the IN.PACT balloon catheter provided a significantly lower rate of late lumen loss and restenosis at 1 year, suggesting the safety and efficacy of paclitaxel coating and delivery during balloon angioplasty [12]. In our study, all of the focal SFA stenoses < 10 cm long could be treated with a maximum of two attempts with BioPath catheters with 100% success.

The Lutonix drug-coated balloon catheter is a newer device coated with a lower dose of paclitaxel (2 mg/mm^2) and polysorbate/sorbitol carrier, which was designed to dispense less of the paclitaxel into the systemic circulation. The LEVANT I study was the first in-human randomized study on the Lutonix catheter and about 90% of participants had superficial femoral artery lesions with a mean length of about 80.8 ±37.0 mm. Moreover, about 40% of the lesions in this study were total occlusions. The device demonstrated 100% angiographic success and patients in the Lutonix group had significantly lower late lumen loss at the 6th month compared to those in the control group

Table III. Fontaine classification of the patients before and after treatment

Patient no.	Time of follow-up [weeks]	Fontaine class	
		Before treatment	After treatment
1	5.34	IIb	IIa
2	7.22	IIb	IIa
3	8.96	IIb	IIa
4	8.96	IIa	I
5	4.33	IIa	IIa
6	4.33	IIb	IIb
7	9.97	IIb	IIa
8	7.66	IIb	IIa
9	7.80	IIb	IIa
10	7.80	III	I
11	8.96	I	I
12	1.88	IIa	IIa
13	1.88	IIb	IIb
14	5.78	III	IIa
15	10.11	IV	IIb
16	18.78	IIb	I
17	11.99	III	IIa
18	28.17	IIb	IIb
19	10.11	III	IIb
20	1.16	IIa	IIa

(0.45 ±1.18 mm vs. 1.19 ±1.15 mm, p = 0.024) [13]. The LEVANT 2 study was a multicenter randomized study made up of a total of 476 patients assigned to the Lutonix catheter or standard angioplasty in a 2 : 1 ratio. The study revealed that 12-month primary patency was significantly higher when percutaneous angioplasty for femoropopliteal lesions was performed with Lutonix as compared to the standard balloon catheter. In addition, patients in the Lutonix group had higher rates of freedom from safety events [14].

The Passeo-18 Lux drug coated balloon is also coated with 3 mg/mm^2 and the paclitaxel over the surface of the balloon is incorporated in butyryl-tri-n-hexyl citrate (BTHC) as an inert excipient. The clinical safety and efficacy of the device was tested in three consecutive trials (BIOLUX PI, PII and PIII) with the latest one being a real-world prospective international all-comers registry to confirm the safety and effectiveness of the device in a large population of patients including those with TASC C and D lesions and infrapopliteal lesions. According to this registry, the rate of freedom from target vessel revascularization was 93.2% at 12 months [15, 16].

The IN.PACT SFA (Randomized Trial of IN.PACT Admiral Drug Eluting Balloon vs. Standard PTA for the Treatment of SFA and Proximal Popliteal Arterial Disease) trial was a large study where a total of 331 patients with Rutherford class 2-4 symptoms with a mean lesion length of about 9 cm were assigned to receive percutaneous balloon angioplasty using either the IN.PACT Admiral system or standard balloon angioplasty [17]. Micari *et al.* [18] recently published the 2-year outcomes of the IN.PACT GLOBAL study, which enrolled a total of 1535 subjects treated with the same drug-coated balloon used in the IN.PACT SFA trial. Although the subjects treated in the IN.PACT GLOBAL study had more challenging lesions than those in the IN:PACT SFA study, the Kaplan-Meier estimate for rates of target vessel revascularization was comparable (83% vs. 91%) between these two studies. More recently, a multicenter study published global 24-month outcomes regarding the use of the Lutonix paclitaxel-coated catheter in a total of 691 patients from 38 centers of 10 countries [19]. The study reported that clinically assessed primary patency was 85.4%/75.6% at 12/24 months. The study also reported that about 90% of patients achieved freedom from target lesion restenosis both for de-novo lesions and in-stent stenosis. Data from the above-mentioned studies on complex lesions led to the role of the drug-coated balloon evolving to be used in complex lesions including long-segmented, heavily calcified lesions and total occlusions. Supporting this was the SFA-LONG study, which revealed a 24-month patency rate of 70.4% in a total of 105 patients with long superficial femoral artery lesions (mean diameter of 251 ±71 mm) treated with the IN.PACT admiral paclitaxel-coated balloon catheter [20].

We used the BioPath system in 5 lesions of 4 patients with TASC C-D lesions. The device was useful to us to treat bilateral distal external iliac artery stenosis, each 8 cm in length. In another patient with in-stent restenosis in the external iliac artery extending into the common femoral artery, 2 attempts with 7 × 80 mm and 7 × 100 mm BioPatch balloons provided satisfactory angiographic success. We also used the device for post-dilatation following use of the CTO catheter for total occlusions in the popliteal artery in 2 patients. Our preliminary experiences warrant further investigation regarding the use of the BioPath catheter in complex de-novo and recurrent lesions.

The small sample size, lack of a control group and non-randomized design limit the generalizability of our results and the follow-up period was too short to draw a conclusion regarding patency attributable to use of this catheter. In conclusion, based on good procedural outcomes of the present study, the shellac-containing BioPath paclitaxel-coated balloon catheter seems to offer a useful alternative to the similar devices for treatment of femoral-popliteal artery disease.

Disclosure

The authors report no conflict of interest.

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