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Research Article

Novel paclitaxel-coated balloon angioplasty via single retrograde popliteal access for challenging superficial femoral artery and iliac artery lesions?

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Summary

Objectives: We report our results regarding the use of BioPath™ paclitaxel-coated balloon catheters for superficial or distal external iliac artery revascularization via single retrograde popliteal access.

Methods: We included 105 prospective consecutive patients. Single retrograde popliteal access was achieved under ultrasound guidance with the patients laid prone. An over-the-wire atherectomy system was used if risk of distal embolization was high due to plaque intensity of the target lesion. A 4 to 7 mm-diameter BioPath™ 035 balloon catheter was used for all lesions. Follow-up at 6th month included doppler ultrasound examination for patency.

Results: Seventy-two patients (68.6%) had total SFA occlusion and 41 patients (39%) had concomitant external iliac artery involvement, out of whom 31 (29.5%) had total occlusion. Procedural success 90.5% for superficial femoral artery and 85.3% for external iliac artery. One-year patency rates in SFA and EIA were 84.8% and 80.4%, respectively

Conclusion: Single retrograde popliteal access and drug-coated balloon angioplasty may offer a useful alternative to known modalities in treatment of challenging superficial femoral artery and concomitant iliac artery lesions.

More Information

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Introduction

Lower extremity peripheral artery disease (PAD) reduces the quality of life and affects social life. Moreover, it is a major cause of cardiovascular mortality and morbidity in the elderly [1,2]. Data suggest that femoral-popliteal segment involvement is present about 70% of patients with symptomatic peripheral artery disease whereas aortoiliac disease is associated with a poorer prognosis [3,4]. There has been a recent trend towards endovascular revascularization of both aortoiliac and femoral-popliteal segment lesions even in the presence of chronic total occlusion. However, use of drug-eluting or self-expanded stents has been troublesome due to the risk of stent fracture.

Stent implantation to the superficial femoral artery (SFA) in its proximal half may become complicated due to the technical difficulty of deployment the proximal crown of the stent into a highly calcified SFA and profunda branch bifurcation, which compromises long term patency of the stent [5]. Drug coated balloons have recently attracted attention by eliminating these drawbacks of stent implantation to the lower extremity [6]. Recently, retrograde route of endovascular intervention to the SFA lesions via popliteal artery has gained attraction [7].

BioPath™ is a novel drug eluted balloon device which contains shellac coating on the surface of its balloon to facilitate the pressure-induced delivery of Paclitaxel, a known antimitotic agent to inhibit vascular restenosis. We herein report our results regarding the use of BioPath™ 035 and

BioPath™ 014 paclitaxel-coated balloon catheters during SFA or distal external iliac artery (EIA) revascularization via single retrograde popliteal access.

Patients and Methods

The study was approved by the institutional review board. This was a prospective cohort study which was conducted in a tertiary hospital between December 2017 – May 2018 and we included Fontaine stage II-IV symptomatic peripheral artery disease patients who underwent endovascular balloon revascularization for above the knee lesions through single retrograde popliteal access. Patients were included if use of the retrograde popliteal access was decided in advance and patients in whom route of access was switched from retrograde to antegrade during procedure were not included. Patients were excluded if retrograde popliteal access was inevitable due to lack of blood flow within popliteal artery. Patients with a history of several failed attempts with endovascular techniques or those having a clear contraindication for use of endovascular techniques were also excluded.

A total of 105 consecutive patients were included in the study. All patients had at least 80% involvement within the SFA whereas 41 patients (39.0%) had concomitant > 80% distal EIA involvement. Patient counseling charts, laboratory tests and angiography views (computed tomography or conventional angiography) were reviewed and recorded. Ankle-brachial index (ABI) measurements were performed and recorded before the operation. Diabetic patients were consulted with endocrinologist and subcutaneous insulin therapy was initiated, as needed. Patients who continue smoking were referred for smoking cessation department before the operation. All patients were started on dual antiplatelet therapy with aspirin 100mg daily and clopidrogel 75mg daily on the same day of the procedure.

All procedures were performed in a fully equipped catheter laboratory and were completed under local anesthesia with the aid of C-arm fluoroscopy guidance. Standard monitoring included 12-lead electrocardiogram, pulse oximetry and non-invasive blood pressure monitoring. The patients were placed in prone position and the procedure was completed without switching to supine position. All patients received an intravenous bolus of unfractioned heparin (70 to 100 U/kg) immediately before initial retrograde popliteal access. A diagnostic angiography was performed to determine target locations using digital subtraction views, as necessary. Multiple short adjacent lesions were considered as a single target and balloon dilatation was performed according to the cumulative length. Retrograde popliteal access was achieved by puncturing the popliteal artery beneath popliteal fossa using a 19-G to 21-G puncture needle under ultrasound guidance. After insertion of a 4F or 6F sheath into the popliteal artery lumen, a translucent shafted support microcatheter (0.015 to 0.036 inch in diameter) was crossed first if SFA was totally occluded, as it was the case in majority of patients. Then a standard guide wire was introduced through its lumen and it was withdrawn. The SFA lesion was first pre-dilated with an uncoated balloon undersized to the target vessel. An over-the-wire atherectomy system which allows clearance of the debulked material from the lumen was used if risk of distal embolization was high due to plaque intensity of the target lesion. The BioPath™ catheter was then introduced through the target SFA lesion and fixed 10mm proximal and distal to the diseased segment. A 4 to 7mm-diameter BioPath™ 035 balloon catheter was used for all lesions. The balloon was inflated at 6 bars for at least 120s and balloon catheter was withdrawn if angiographic result was satisfactory. In patients with concomitant distal EIA involvement, the same procedure was repeated using appropriately sized catheters. Procedural success was defined as at least 20% residual stenosis after completion of the procedure whereas patients with < 20% residual stenosis received stent implantation at the same session. The procedure was completed after closure of the puncture site with an Angio-Seal catheter. Cilostazol 100mg/d was started after the procedure and continued for 6 months. Aspirin 100mg daily was continued indefinitely whereas clopidrogel was continued for 3 months after the operation.

Ankle brachial index measurements were repeated 1 to 2 days after operation. Patients were invited to follow-up visits at 1 week, 1 to 2 months and 6 months after the operation. Follow-up assessments included doppler ultrasound examination for patency. Repeat angiography was not performed unless Doppler examination reveals diminished flow across the target lesion.

Statistical analysis

All analyses were performed using SPSS (Statistical Package for the Social Sciences) version 19.0. Continuous parameters were defined as mean ± standard deviation and categorical parameters were defined as percentages. Normal distribution of the continuous parameters was evaluated using visual histograms and analytical methods (Kolmogorov-Smirnov or Shapiro-Wilk's test). Comparison of ABI values between preoperative and postoperative measurements were made using Wilcoxon Signed Ranks Test. A *p value* of less than 0.05 was statistically significant.

Results

Baseline characteristics of the patients were given in table 1. Mean age was 63.73 ± 9.23 years and 98 (93.3%) of the patients were males. All patients had at least 80% SFA involvement, out of whom 72 (68.6%) had total SFA occlusion. Forty-one patients (39%) had concomitant distal EIA involvement, out of whom 31 (29.5%) had total occlusion. Occluded segment was crossed with a support microcatheter in 93 patients (88.6%) and pre-dilatation with an uncoated balloon catheter was performed in 61 patients (58.1%). Catheter atherectomy was used in 19 patients (18.1%).

Table 1: Baseline characteristics.

Variable	Mean ± SD / n (%)
Age (years)	63.73 ± 9.23
Males	98 (93.3%)
Hypertension	70 (66.7%)
Diabetes	43 (41.0%)
Dyslipidemia	48 (45.7%)
Tobacco use	89 (84.8%)
Family history	73 (69.5%)

Procedural success for SFA lesions was achieved in 95 patients (90.5%) whereas drug coated balloon did not result in adequate expansion of the target arterial segment in the remaining. Four of these failed procedures was due to the extreme stiffness of the arterial wall despite successful removal of excessive plaques with catheter atherectomy whereas SFA was hypoplastic and thin and catheter atherectomy was not attempted in 6 patients.

Procedural success was achieved in 35 of 41 patients (85.3%) with concomitant distal EIA involvement. In four patients, complete distal EIA occlusion could not be treated with atherectomy device due to failed SFA recanalization. In 2 patients, atherectomy was successful but drug coated balloon could not dilate the diseased segment enough because of extreme stiffness.

After the procedure, mean ABI values showed a significant increase from 0.42 ± 0.21 to 0.85 ± 0.27 ($p < 0.001$) and number of patients with an ABI > 80% significantly increased from 5 (4.8%) to 76 (72.4%) ($p < 0.001$). One-year patency rates in SFA and EIA were 84.8% and 80.4%, respectively (Table 2).

Discussion

Our study demonstrated that drug-coated balloon angioplasty with Biopath™ device via single retrograde popliteal access produced acceptable procedural success and satisfactory 1-year patency for treatment of challenging SFA and distal EIA lesions. In our study, about two-third of SFA lesions and one third of EIA lesions were total occlusions and most of the remaining lesions were long segmented near-total occlusions. Concomitant use of assistive devices including supporting micro-catheter, uncoated balloon and atherectomy devices allowed us to cross these lesions and achieve satisfactory angiographic results in about 90% of the patients.

Table 2: Study outcomes.

Variable	Mean ± SD / n (%)
Use of microcatheter	93 (88.6%)
Uncoated balloon angioplasty	61 (58.1%)
Drug-coated balloon angioplasty	89 (84.8%)
Atherectomy catheter	19 (18.1%)
SFA success	95 (90.5%)
Iliac success	35 (85.3%)
Amputation	2 (1.9%)
Surgery	9 (8.6%)
Ankle brachial index (Preoperative *vs.* Postoperative)	0.42 ± 0.21 *vs.* 0.85 ± 0.27[a]
ABI ≥ 80% (Preoperative *vs.* Postoperative)	5 (4.8%) *vs.* 76 (72.4%)
1-year patency in SFA	89 / 105 (84.8%)
1-year patency in iliac artery	33 / 41 (80.4%)

[a]$p < 0.001$ for Wilcoxon Signed Rank Test

Our results revealed that crossing the challenging SFA lesions through a single retrograde popliteal access without any additional antegrade recanalization was possible in about 90% of the patients and this also allowed us crossing the concomitant lesions in distal EIA in 85.3% of our patients. Balloon dilatation with drug-coated Biopath™ device eliminated the need for implantation of a stent and produced a one-year patency rate that is comparable to those reported in previous studies using various stent devices.

Retrograde approach for SFA occlusion has recently gained popularity. Some authors reported the use of retrograde approach as a salvage alternative particularly when the antegrade route was unsuccessful. Pappy, et al. [8], reported in their case series of 4 patients in which retrograde approach achieved successful SFA stent recanalization following their failed attempts with antegrade route. In a larger scale study, Sangiorgi, et al. [9], used the retrograde approach as a bailout strategy in 23 (25 limbs) of a total of 130 patients with SFA occlusions. In this study, 13 of 23 patients received stent implantation and the remaining had adequate patency with balloon dilatation. The authors reported that retrograde approach achieved higher procedural success rates compared to antegrade approach (95.7% *vs.* 86.0% for retrograde and antegrade access, respectively) and they reported similar one-year patency rates (80% *vs.* 86% for standard access and retrograde access, respectively, $p = 0.78$) this effect was not counterbalanced by increased risk of complications.

Ye, et al. [10] used the retrograde access in 19 of 213 patients who had challenging SFA occlusions. The authors performed retrograde subintimal tracking to re-enter to the proximal lumen and they completed the procedure *via* dual-channel intervention (antegrade + retrograde). Fourteen out of these 19 patients achieved adequate patency with balloon dilatation only and the authors reported a 6-month patency rate of 84.2%. Similarly, Shi, et al. [11], used a dual antegrade-retrograde approach in 21 patients and they achieved successful stent implantation in all patients. Although 6-month patency was 80% in this study, the one-year patency rate was as low as 42%.

Tokuda, et al. [12] reported on 68 patients in whom they switched from antegrade access to retrograde access during endovascular balloon + stent angioplasty for long-segment occluded SFA lesions. The procedural outcomes of the study were compared between patients receiving or not receiving sheath insertion during retrograde access. Although the study reported no follow-up patency rate, the procedure was completed with a success rate of 89.8% and with very low complication rates in patients whom a sheath was not needed at all during the procedure.

Although, there have been some reports on use of the retrograde technique almost routinely as a facilitating adjunct to antegrade femoral access [13-16], its use as a sole rather than an alternative or adjunctive to antegrade technique is rare. In one study where primary success of intervention was compared between patients receiving antegrade (n = 55 patients) *vs.* retrograde (n = 36 patients) approach, the decision for performing retrograde access was made in advance in all but three patients in the retrograde group [17]. In this study, after initial retrograde access was performed in the prone position, the patient was placed in the supine position and the procedure was continued. The authors reported that the procedural success rate was significantly higher in the retrograde access group (97.2% *vs.* 78.2%, respectively; $p < 0.01$) with acceptable morbidity rates (5 minor complication and 1 major bleeding). Dumantepe, et al. [18], used the retrograde technique as the primary choice in 28 patients, performed the initial popliteal puncture in the prone position while guided by duplex ultrasound and continued the procedure in the prone position. From a technical point of view, the authors report that they pass total occlusion using an atherectomy catheter through a sheath and insert nitinol vowen stent after balloon dilatation. One-year patency was reported to be 85.7%.

The main limitation of the present study was that there was no control group to test the effect of the technique used on study outcomes. The technique we described here has become our standard of care in recent years and we thought it was inappropriate to use a technique we abandoned for construction of a control group. In conclusion, single retrograde popliteal access and drug-coated balloon angioplasty may offer a useful alternative to known modalities in treatment of challenging SFA and concomitant iliac artery lesions.

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