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Prognosis of Directional Atherectomy Combined with Drug-Coated Balloon Angioplasty versus Bare Nitinol Stent Angioplasty for Femoropopliteal Arteriosclerosis Obliterans: A Retrospective Cohort Study

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Abstract

Objectives: The present study aimed to evaluate the prognosis value of Directional Atherectomy (DA) +Drug-Coated Balloon (DCB) angioplasty for Femoropopliteal Arteriosclerosis Obliterans (FPAO).

Methods: This retrospective cohort study included FPAO patients who underwent percutaneous endovascular surgery at Xuanwu Hospital of Capital Medical University and the Fourth Affiliated Hospital of Guangxi Medical University between January 2016 and June 2019. The primary outcome was the primary patency rate. The secondary outcomes were technical success and all-cause death.

Results: During the study period, 110 (44%) and 140 (56%) patients underwent DA+DCB and Bare Nitinol Stent (BNS). There were no differences between groups in the 10- and 20-month patency rates (98.2% *vs*. 93.6% and 68.2% *vs*. 60.0%, both P>0.05). The 30-month primary patency rate in the DA+DCB group was significantly higher than the BNS group (27.3% *vs*. 15.7%, P=0.003). Technical success rate and all-cause death were similar between groups. Flow-limiting dissections occurred more frequently in the BNS group than in the DA+DCB group (27.9% *vs*. 10.9%, P=0.033). After adjustment for potential cofounders, such as gender, smoking, hypertension, hyperlipidemia, ABI after surgery, TASC II B, lesion length ≥ 15 cm, vessel runoff 2, and vessel runoff 3, the HR for primary patency rate comparing BNS to DA+DCB was 2.61 (95% CI: 1.61-4.25).

Conclusion: In this retrospective cohort study, DA+DCB was associated with higher 30-month primary patency rate, with a lower incidence of flow-limiting dissection.

Keywords: Directional atherectomy; Drug-coated balloon; Stent; Arteriosclerosis obliterans; Femoral artery; Popliteal artery

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Introduction

Femoropopliteal Arteriosclerosis Obliterans (FPAO) is a common disorder that affects >200 million people worldwide and its incidence is on the rise [1]. FPAO is a progressive disease and is associated with a significant reduction in quality of life. Approximately 10% to 15% of patients with claudication progress to Critical Limb Ischemia (CLI) within 5 years, which increases the risk for amputation [2] and mortality [3].

In recent years, an endovascular technique to treat Peripheral Arterial Disease (PAD) has been widely used in clinical practice because of the advantages of less trauma, fewer complications, and rapid recovery [2]. The first-generation endovascular treatment methods for FPAO include Percutaneous Transluminal Angioplasty (PTA) and provisional Bare Nitinol Stent (BNS) angioplasty placement [2]. Still, the in-stent restenosis and obliterans rates are very high due to the stress of knee joint movement on blood vessels and intimal hyperplasia in femoropopliteal artery disease [4]. In addition, leaving a metal implant in the artery reduces future treatment options [5]. Hence, "leave nothing behind" strategies, such as Directional Atherectomy (DA), Drug-Coated Balloon (DCB) angioplasty, or combination therapy, are supported by many vascular surgeons [6-8].

Compared with standard balloon angioplasty, DCB inhibits neointimal hyperplasia and lowers the restenosis and Target Lesion Revascularization (TLR) rates [9]. Still, DCB alone might be insufficient for calcified or longer lesions [10,11]. Indeed, a significant plaque burden could prevent the drug from reaching the artery wall, which is the main reason for using a DCB [12]. DA is a technique that can safely and effectively remove the atherosclerosis plaque from an artery [13]. DA prior to the use of DCB might have advantages in decreasing the plaque burden, increasing lumen size, preventing dissection, and improving drug delivery efficiency into the vessel wall [6,7,14]. Cai et al. [6] indicated that DCB combined with directional atherectomy was superior to uncoated balloons or DCB alone. Still, few studies examined the combination of DA and DCB *vs.* stent angioplasty. Indeed, a meta-analysis [7] published in 2021 included only six studies [6,15-18] on the subject; although it supports the effectiveness of atherectomy combined with DCB over DCB alone, evidence is lacking.

Therefore, this retrospective cohort study aimed to evaluate the therapeutic effects of DA+DCB angioplasty *vs.* BNS angioplasty in the treatment of FPAO. The results could help improve the management and prognosis of patients with FPAO.

Material and Methods

Study design and subjects

In this retrospective cohort study, FPAO patients who underwent percutaneous endovascular surgery at the Department of Vascular Surgery of Xuanwu Hospital of Capital Medical University and the Department of Vascular Surgery of the Fourth Affiliated Hospital of Guangxi Medical University between January 2016 and June 2019 were included. This study was reviewed and approved by the Ethics Review Committee of Xuanwu Hospital of Capital Medical University and the Fourth Affiliated Hospital of Guangxi Medical University. Being a retrospective study, the requirement for informed consent was waived by the committee.

The patients met the diagnostic criteria of FPAO [3]. The inclusion criteria were 1) Digital Subtraction Angiography (DSA) revealed femoropopliteal artery stenosis ≥ 70% or occlusion, 2) vascular inflow was not obstructed, and 3) lesions of 7 cm to 20 cm in length in the femoropopliteal arteries. The exclusion criteria were 1) cerebrovascular disease for <6 months, 2) contraindications to paclitaxel, antiplatelet, or anticoagulation, or 3) lost to follow-up.

Data collection and definition

Data were collected from the patient's medical record, including patient characteristics (patient origin, age, sex, smoking, hypertension, diabetes, coronary heart disease, hyperlipidemia, chronic kidney disease, and cerebrovascular disease) and lesion location (ABI lesion location, TASC classification, lesion length, reference vessel diameter, and vascular run-off). The patients were routinely followed and evaluated at 30 days and 6, 12, 18, and 24 months after interventions. Follow-up data included clinical manifestations (claudication distance, relief of rest pain, and ulcer healing), physical examination, Rutherford classification, Ankle-Brachial Index (ABI), and vascular ultrasound and/or Computed Tomography Angiography (CTA) and/or DSA. In addition, adverse events were collected, including bleeding, distal embolization, perforation, restrictive dissection, and death.

Outcomes

The primary outcome was the primary patency rate, defined as no significant restenosis (<50%) or occlusion with no clinically driven re-intervention. The secondary outcomes were technical success, limb amputation, and all-cause death. Technical success was defined as residual stenosis of the treated vessel <30%, no perforation of the vessel wall, and no embolism at the distal end. Limb amputation was defined as the amputation of a limb above the ankle.

Statistical analysis

SPSS 22.0 (IBM, Armonk, NY, USA) was used for data analysis. Continuous variables were presented as the mean ± standard deviation and compared using Student's t-test. Categorical variables were presented as n (%) and compared using the chi-square test or Fisher's exact test. Cumulative primary patency rates were estimated and compared between groups using the Kaplan-Meier log-rank method. To adjustment of potential cofounders, multivariable Cox regression analyses were used. P-values <0.05 were considered statistically significant.

Results

Baseline characteristics

From January 2016 to June 2019, 110 patients were treated with DA+DCB, and 140 patients were treated with BNS. There were no significant differences in patient characteristics between the two groups, such as patient origin, age, sex, smoking, hypertension, diabetes, coronary heart disease, hyperlipidemia, chronic kidney disease, and cerebrovascular disease (all P>0.05). Significant differences were observed in lesion location, Rutherford category, TASC classification, and vascular run-off (all P<0.05). The baseline characteristics of the patients and lesions are summarized in Table 1.

Outcomes

The primary patency rate for patients in the DA+DCB group was significantly higher than the BNS group (log-rank P=0.0058). In Figure 1, the 10- and 20-month primary patency rates in the DA+DCB group were similar to the BNS group (98.2% *vs.* 93.6% and 68.2% *vs.* 60.0%, both P>0.05). The 30-month primary patency rate in the DA+DCB group was higher than the BNS group (27.3% *vs.* 15.7%, P=0.003). After adjustment for potential cofounders, such as gender, smoking, hypertension, hyperlipidemia, ABI after surgery, TASC II B, lesion length ≥ 15 cm, vessel runoff 2, and vessel runoff 3, the HR for primary patency rate comparing BNS and DA+DCB was 2.61 (95% CI: 1.61-4.25) (Table 2).

The duration of follow-up was 24.3 ± 8.0 months in the DA+DCB group and 21.1 ± 7.3 months in the stent group (P=0.001). The limb salvage rate and overall mortality rate in the DA+DCB group were similar to the BNS group (both P>0.05). A clinically-driven TLR was performed in nine patients with restenosis in the BNS group. Of the nine patients, three were treated with DCB angioplasty at 7, 9, and 11 months, four were treated with nitinol interwoven stents at 8, 9, 11, and 16 months, and two were treated with artificial blood vessel diversion at 13 and 18 months. Five DA+DCB patients received DA and DCB retreatment after restenosis at 7, 9, 11, 13, and 15 months.

No procedure-related adverse events (hemorrhage, distal embolization, perforation, and death) occurred. In 29 cases (26.4%), debris was collected in the filter basket, and no distal embolization occurred. Flow-limiting dissections occurred more frequently in the BNS group (n=39, 27.9%) than in the DA+DCB group (n=12, 10.9%) (P=0.033). The technical success rate in the DA+DCB group was similar to the BNS group (84.5% *vs.* 95.7%, P=0.667). The mean

Table 1: Baseline characteristics of the patients and lesions.

Clinical characteristics	DA+DCB (n=110)	BNS (n=140)	p
Age (years), mean ± SD	70.2 ± 8.2	71.0±8.1	0.484
Sex (%)	36 (32.7)	59 (42.1)	0.164
Smoking (%)	74 (67.3)	80 (57.1)	0.133
Hypertension (%)	66 (60.0)	88 (62.9)	0.741
Diabetes mellitus (%)	56 (50.9)	67 (47.9)	0.725
Coronary artery disease (%)	51 (46.4)	65 (46.4)	>0.999
Hyperlipidemia (%)	59 (53.6)	75 (53.6)	>0.999
Chronic kidney disease (%)	17 (15.5)	17 (12.1)	0.567
Cerebrovascular disease (%)	29 (26.4)	29 (20.7)	0.368
Rutherford category (%)			**0.031**
Level three	42 (38.2)	32 (22.9)	
Level four	49 (44.5)	79 (56.4)	
Level five	19 (17.3)	29 (20.7)	
Ankle-brachial index, pre-operation, mean ± SD	0.30 ± 0.12	0.32 ± 0.14	0.325
Ankle-brachial index, post-operation, mean ± SD	0.88 ± 0.07	0.82 ± 0.05	**0.003**
Lesion location (%)			**0.025**
Poplitear	14 (12.7)	5 (3.6)	
SFA	29 (26.4)	39 (27.9)	
SFA-Poplitear	67 (60.9)	96 (68.6)	
Lesion type, restenosis (%)	4 (3.6)	9 (6.4)	0.484
TASC II classification (%)			**0.048**
A	10 (9.1)	11 (7.9)	
B	15 (13.6)	7 (5.0)	
C	85 (77.3)	122 (87.1)	
Lesion length ≥ 15 cm (%)	85 (77.3)	121 (86.4)	0.085
Vessel runoff (%)			**0.008**
1	26 (23.6)	35 (25.0)	
2	66 (60.0)	60 (42.9)	
3	18 (16.4)	45 (32.1)	

DA: Directional Atherectomy; DCB: Drug-Coated Balloon; SFA: Superficial Femoral Artery; BNS: Bare Nitinol Stents

Table 2: Hazard ratio for primary patency rate of BNS.

Characteristics	Multivariable analysis		
	HR	95% CI	P
DA+DCB	Reference		
BNS	2.61	1.61-4.25	<0.001

Adjustment for potential cofounders, such as gender, smoking, hypertension, hyperlipidemia, ABI after surgery, TASC II B, lesion length ≥ 15 cm, vessel runoff 2, and vessel runoff 3

ABI: Ankle-Brachial Index; DA: Directional Atherectomy; DCB: Drug-Coated Balloon; BNS: Bare Nitinol Stents

ABI at the time of discharge in the DA+DCB and BNS groups were improved at 0.41 ± 0.27 and 0.38 ± 0.23 (P=0.873), respectively.

Discussion

This retrospective study suggested that compared with BNS angioplasty, DA+DCB angioplasty could achieve a higher 30-month patency rate in patients with FPAO, with a lower incidence of flow-limiting dissections. The use of a BNS was independently associated with restenosis. Although the evidence quality is limited by the retrospective cohort design, these results support the use of DA+DCB in patients with FPAO.

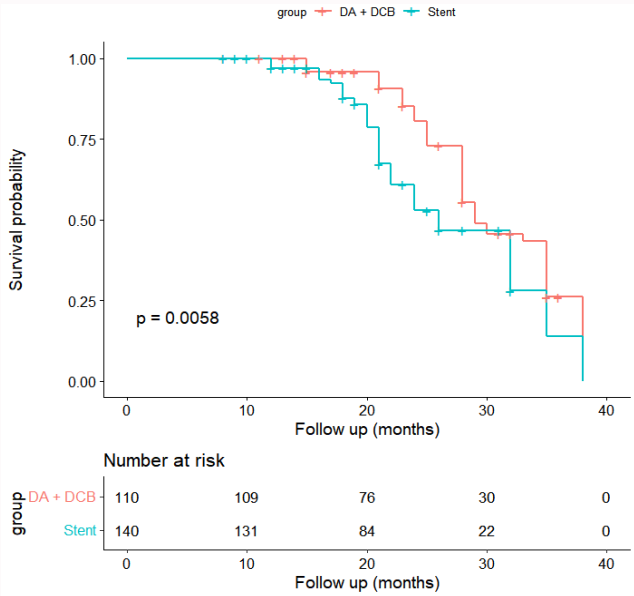

Figure 1: Cumulative primary patency rates of the DA+DCB group and BNS group. (Kaplan-Meier, log-rank test, P=0.0058). The number of people at risk represents the number of evaluable subjects at the beginning of each follow-up interval.
DA+DCB: Directional Atherectomy + Drug-Coated Balloon
Stent: BNS: Bare Nitinol Stents

In this study, the 10-, 20-, and 30-month patency rates were 98.2%, 68.2%, and 27.3% in the DA+DCB group and 93.6%, 60.0%, and 15.7% in the BNS group. A recent meta-analysis indicated no significant differences between DA+DCB and BNS in terms of primary patency rates, but only the 12-month rates were analyzed, which supports the present study since the differences at 10 and 20 months were not statistically significant. All studies included in that meta-analysis examined the patency rate at 12 months [6,15,17,18], except one at 24 months [19]. Iida et al. [20] reported that patients treated with DCBs exhibited superior 12-month primary patency (89%) compared to patients treated with PTA. In the present study, only the 30-month patency rate was better in the DA+DCB group compared with BNS, indicating the need for studies and trials with a long follow-up. Indeed, although immediate and short-term results are satisfactory, stents contribute to vessel wall injury during vessel movement. The extension of the lesion to the popliteal artery puts high demands on the stent's mechanical properties, which also leads to a decrease in patency rates at 1 and 2 years [21-24]. Rastan et al. [25] reported that the 2-year phase patency rate of the popliteal artery lesions treated by a nitinol stent and simple balloon dilation was 64% in the BNS group and 31% in the balloon group.

The "leave nothing behind" strategy has been supported by many vascular surgeons [25]. DA is well-suited to remove plaque and potentially reduce vessel recoil, reduce the rate of severe dissections, and facilitate a more homogenous drug application and diffusion into the vessel wall layers [17,19,26,27]. The mechanism of effect for DCB is to coat the balloon's surface with anti-cell proliferation drugs, such as paclitaxel. When the balloon expands, the drugs contact the intima of the blood vessel and penetrate into the arterial wall to inhibit intima hyperplasia and reduce the possibility of restenosis

or re-occlusion [27,28]. At the same time, a balloon can reduce the rate of stent implantation, leaving the possibility of treatment for the long-term prognosis. DCB can greatly reduce the use rate of emergency rescue stents but has no significant effect on reducing the restenosis rate [29]. It can easily stimulate intimal hyperplasia and secondary thrombosis, resulting in restenosis or occlusion [30]. Still, these advantages of DA and DCB could explain the better long-term patency rates observed in the present study. Still, this better rate will have to be confirmed by clinical trials.

During the 2-year follow-up, the mortality of the DA+DCB angioplasty group was similar to that of the BNS group, suggesting that DA+DCB is safe, which is consistent with the literature [31-33]. The technical success rate of both operations was very high, and there was no significant difference. For severe limb ischemia, including Rutherford grades 4 and 5, the limb salvage rates of the two methods were satisfactory. Therefore, these two treatment methods can effectively restore the blood flow of the ischemic limb and avoid amputation.

Compared with the DA+DCB group, the BNS group had a higher rate of flow-limiting dissections. The average ABI at the discharge of the DA+DCB and BNS groups increased by 0.41 ± 0.27 and 0.38 ± 0.23, respectively. The 30-month main patency rate in the DA+DCB group was higher than that in the BNS group. And there were no device- or procedure-related deaths, major amputations, or thromboses in either group. It is also consistent with the results of this study, proving the safety of DA+DCB.

In order to determine the key factors affecting the cumulative primary patency rate, Cox regression analyses were performed. Male sex, smoking, hypertension, hyperlipidemia, TASC type B, ABI post, vessel run-off (2 or 3 *vs.* 1), lesion length (≥ 15 vs. <15 cm), and stent surgery (BNS) were independently associated with the primary patency rates. These are known risk factors for PAD of the lower extremities and treatment outcomes [2,34,35]. After adjustment for various potential risk factors that may affect vessel patencies, the Hazard ratio of maintaining vessel patencies for BNS was 2.61 times higher than that for DA+DCB. This suggests that DA+DCB is more likely to maintain vascular patency. Still, DA+DCB is a relatively recent method, and further studies are needed to determine whether these risk factors affect the primary patency.

Limitations

First, this study was a double-center, retrospective cohort study. There was some bias for case selection and treatment results. It is necessary to perform a prospective randomized controlled study. Second, the follow-up for some patients did not reach 24 and 36 months. Finally, during the period of this study, some of the newer nitinol and vascular mimetic stents were not available, so the results might not be generalizable to all currently available nitinol stents.

Conclusion

In summary, DA+DCB angioplasty is associated with higher 30-month primary patency rates in patients with FPAO, with a lower incidence of flow-limiting dissection.

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