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Original Article

Clinical advantage of drug-coated balloon in treatment of restenosis in superficial femoral artery stents

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Abstract: Background: This investigation probed the clinical effectiveness of drug-coated balloon (DCB) and common balloon (CB) for treating restenosis in superficial femoral artery stents. Methods: We retrospectively analyzed 295 patients with lower extremity arteriosclerosis obliterans with superficial femoral artery stenting restenosis admitted to Shaanxi Provincial People's Hospital from March 2017 to March 2020. Cases were segregated within two cohorts adopting different treatment methods (cohort 1, DCB and cohort 2, CB). The restenosis and clinical outcomes were evaluated by Doppler ultrasound, computed tomography angiography, or digital subtraction angiography at 1 week, 6, and 12 months. Results: Following six months, the restenosis rate on angiography was 4.2% within cohort 1, and 26% within cohort 2 ($P<0.05$); at 12 months the rates on duplex ultrasonography were 18% and 84%, respectively ($P<0.001$). ABI and MDL of cohort 1 ($P<0.05$) were higher than those of cohort 2, 6 and 12 months post-operation; late lumen loss (LLL) and peak systolic velocity ratio (PSVR) of cohort 1 ($P<0.05$) were lower than those of Cohort 2. Cohort 1 cases demonstrated increased mobility upon treadmill at 12 months compared to within cohort 2. Conclusions: Medium-/long-term clinical effectiveness for drug-coated balloon treating restenosis in a superficial femoral artery stent is significantly higher than that of an ordinary balloon.

Keywords: Superficial femoral artery, drug-coated balloon, in-stent restenosis stenosis rate, Salgrexate

Introduction

Lower extremity occlusive arteriosclerosis is due to the development of atherosclerotic plaques of lower extremities, leading to arterial stenosis/occlusion and subsequent chronic limb ischemia. Percutaneous transluminal stent implantation is an established method in treating superficial femoral artery occlusive disease [1]. The revascularization of the superficial femoral artery with a percutaneous transluminal stent implantation can make the initial technical success rate >95% [2]. Increased employment of percutaneous trans-luminal stent implantation within the superficial femoral artery (superficial femoral artery stenting-SFAS) mainly arises following reduced incidences in surgical morbidity/mortality, reduced hospitalization periods, and reduced wound-related adverse events. Notwithstanding, post-12-month in-stent restenosis (ISR) is required for 18-40% of cases selecting SFAS [3].

A drug-coated balloon is a chemical treatment on the surface of diseased blood vessels, so it is a new device in the treatment of stenotic or occlusive vascular diseases. Paclitaxel, a chemical drug, makes the coating penetrate rapidly into the arterial wall after the lesion surface and inferior membrane wall enter completely through the balloon dilatation, thus inhibiting intimal hyperplasia and preventing PTA restenosis [4].

Multicenter randomized controlled clinical trials have confirmed that drug-coated balloon (DCB) has a better medium-and short-term effect than conventional balloon in the treatment of femoral and popliteal artery occlusion. It can significantly reduce delayed cavity loss (LLL) and improve the initial patency rate [6]. However, for patients with intrastenting restenosis or for occlusion in patients with femoral popliteal artery stenting, stenting or common balloon angioplasty is the most commonly used

procedure at present. Drug-coated balloon dilatation has not been studied, so the purpose of this study is to compare the clinical efficacy of drug-coated balloon angioplasty in the treatment of SFAS stenosis with conventional balloon angioplasty for one year.

Methods

We retrospectively analyzed 295 patients with lower extremity arteriosclerosis obliterans with superficial femoral artery stenting restenosis admitted to Shaanxi Provincial People's Hospital from March 2017 to March 2020. The inclusion criteria consisted of: 1. The superficial femoral artery had clinical symptoms again post-stent implantation and needed to be admitted to the hospital for interventional treatment; 2. Computed tomography angiography (CTA) confirmed the diagnosis of stent restenosis (stenosis rate >70%); 3. TASC-II classification for femoral artery [5]: TASC-IIA, TASC-IIB, and TASC-IIC cases; 4. Minimum of one arterial run-off below the knee, although stenosis lesions that were not impairing flow could be included; 5. No proof regarding residual in-flow issues within the aorto-iliac artery, although stenosis lesions that were not impairing flow could be included. Exclusion criteria consisted of: 1. Contraindications to anti-coagulation; 2. Persistent infection, chronic inflammatory disease, tumor and chronic obstructive pulmonary disease; 3. Proof of hematological condition; 4. Severe cardiac insufficiency (New York Heart Association III or IV), liver dysfunction (child B or C) or renal insufficiency (creatinine clearance <30 mL/min); and 5. No arterial run-off below the knee. Cases were segregated into two cohorts according to different treatment methods (cohort 1, DCB and cohort 2, CB). Hypertension was deemed upon blood pressure ≥140/90 mm/Hg or ongoing anti-hypertensive drug therapies. Diabetes mellitus was defined as fasting glucose ≥126 mg/dl or ongoing oral anti-diabetic drugs/insulwithinrapies. Smokers were deemed to be ongoing cigarette users or cases who had quit smoking within 1 month prior to the procedure. Cases were excluded from the study if they deceased within 30 days prior to the procedure. Survival cases were medically supervised for clinical endpoints/angiographic variations. The ankle-brachial index (ABI), minimal lumen diameter (MLD), late lumen loss (LLL) and relative normal diameter (RD) of all cases were recorded before and 7 days as well as 6 months and 12 months. Systolic velocity peak at the narrowest position, relative normal velocity, peak systolic velocity ratio (PSVR).

Endpoints

The primary endpoint was the rate of binary restenosis within the treated segment one week, 6 months, and 12 months post-intervention, as evaluated through computed tomographic angiography (CTA) or Digital subtraction angiography (DSA). Restenosis was deemed to be lumen stenosis rate >50% [6] within the stent. Secondary endpoints were evaluated anatomically, clinically, and hemodynamically. Anatomical endpoints were restenosis >50%, as evaluated by Doppler ultrasonography at one week, 6 months, and 12 months. Restenosis was defined as PSVR >2.4 [7]. The clinical endpoint was the maximum distance the cases walked on the treadmill was less than 100 meters [6], measured at one week, 6 months, and 12 months; amputation by 6 or 12 months; and mortality event by 6 or 12 months. The hemodynamic end point was resting ABI measured at 1 week, 6 months and 12 months. The differences were resolved through consensus with a third investigator, who was also unaware of the case's treatment decision. The study was accepted by the institutional ethics committee.

Interventions

All cases before interventional therapy agreed to accept lower limbs of color doppler ultrasound, CTA examination, ankle-brachial index and the minimum target vessel lumen diameter, platelet (aspirin clopidogrel), anticoagulation (low molecular heparin), the expansion of blood vessels (top injection), lipid-lowering statin (Rui shu logging), such as drug therapy, positive step-down hypoglycemic treatment with high blood pressure, or diabetes cases.

The contralateral crossover strategy was adopted in all procedures. Surgical procedures were conducted using a 5F or 6F sheath (11-45 cm). Selective angiography was carried out for localizing lesions and measuring lesion range through a 4F or 5F catheter. For cases within DCB cohort, the restenosis stent was predilated for 2 min with an ordinary balloon (diameter

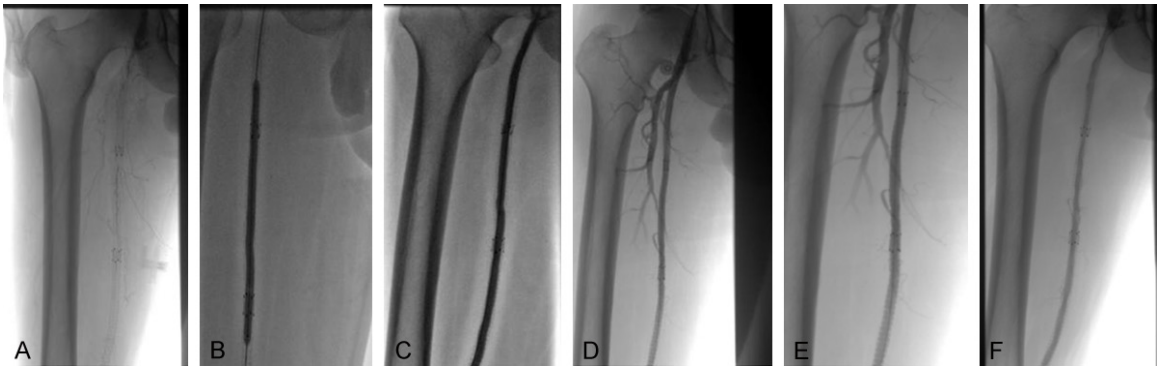

Figure 1. Imaging of long occlusion of superficial femoral artery stent treated with drug-coated balloon. A: DSA suggested long segment occlusion of superficial femoral artery stent. B: Ordinary balloon pre-expansion stent occlusion segment. C: Drug-coated balloon dilatation and restenosis stent. D: Postoperative angiography indicated smooth flow of superficial femoral artery. E: Six months post-operation, DSA indicated that blood flow within superficial femoral artery stent was unobtrusive without obvious stenosis or occlusion. F: Twelve months post-operation, DSA indicated that blood flow within superficial femoral artery stent was unobtrusive without obvious stenosis or occlusion.

<0.5-1 mm of reference vessel), and then continuously dilated for 3 min with a drug-coated balloon of 5 or 5.5 mm diameter (length 10 mm at both proximal and distal ends of > target lesion) at a pressure of 6-8 atmospheres (1 atmosphere = 101.325 kPa). Within the CB cohort, the restenosis stent was expanded with a normal balloon (diameter <0.5-1 mm of reference vessel) for 3 min. The pressure was the same as within the DCB cohort. Biplane angiography was carried out post-intervention across cohorts, adopting identical angles/magnifications employed within baseline angiograms. The angiography showed that the superficial femoral artery blood flow was restored and at least one branch within the superficial femoral artery directly connected with the subgenital artery within the foot. If there were subgenital artery lesions, at least one branch for subgenital artery should be opened. All surgical treatments were carried out under local anesthesia. All cases were treated with heparin (5,000 units) during surgery. All cases were treated with aspirin (100 mg daily) indefinitely and Salgrexate (300 mg daily) for one-year post-surgery. Imaging findings of the drug-coated balloon for treating prolonged SFAS occlusion are shown in (**Figure 1**).

Follow-up

Analyses were carried out at baseline and one week, 6 months, and 12 months post-randomizing, and consisted of staging for peripheral-artery disease depending upon Rutherford classification [8], resting ABI assessment, treadmill-exercise (3.2 Km/h, 12-degree slope), together with Doppler ultrasonography [9].

Angiographic assessment of restenosis using a 320-slice CTA or conventional intra-arterial DSA at 6 months. CTA was carried out through 320-row multislice computed tomographic (CT) scanner (Somatom Sensation® 320, Siemens Medical Systems™). The accuracy/specificity of multi-slice CT + automated reconstruction was nearly equivalent to intraarterial DSA [10]. All cases of CTA-identified restenosis (>50% for vessel diameter) was designated for conventional DSA for confirming diagnoses. Prior to CTA, DSA was performed on patients designated for ipsilateral or contralateral intervention or re-intervention at six-month follow-up.

Statistical analysis

Datasets were evaluated through SPSS version 21.0®. Continuous datasets were presented as mean ± SD. Discrete measures were represented by percentages. The Kolmogorov-Smirnov test was employed to evaluate the normal distribution. Independent-samples t-test was employed to conduct comparative analysis of continuous variables across cohorts. X^2 test was employed for comparative analysis of categorical data. Kaplan-Meier analysis was employed for comparative analysis of cumulative risk for ISR across cohorts. A probability (*P*) value of <0.05 was deemed to confer statistical significance.

Table 1. Baseline profiles for 173 cases

	Total, n = 295 (%)	Cohort 1 (DCB); n = 145 (%)	Cohort 2 (CB); n = 150 (%)	*P* value
Male	223 (75.6)	118 (81.3)	105 (70)	0.20
Age, Y	68.54±10.50	67.2±11.3	68.6±9.6	0.53
Smoking	144 (48.8)	66 (45.8)	78 (52)	0.54
Hypertension	178 (60.3)	88 (60.4)	90 (60)	0.84
Diabetes mellitus	160 (54.2)	82 (56.3)	78 (52)	0.67
CAD	90 (30.5)	39 (27.1)	51 (34)	0.46
Hyperlipidemia	33 (11.2)	15 (10.4)	18 (12)	0.8
TASC II classification				
TASC A		12 (8.3)	9 (6)	0.89
TASC B		69 (47.9)	72 (48)	
TASC C		64 (43.8)	69 (46)	

Key: CAD, Coronary Artery Disease.

Results

Overall, 295 cases participated in this investigation. No serious adverse events (death, serious cardiac and cerebrovascular accidents) were observed in any patients followed up. The average age for enrolled cases was 67.92± 0.46 (57-75) years. There were 223 (75.5%) men and 72 (24.5%) women. In the cohort of DCB and CB, there were 160 with diabetes mellitus (54.1%), 144 smoking (49%), 90 coronary heart disease (30.6%), 33 hyperlipidemia (11.2%) and 178 hypertension (60.2%), but there was no significant difference in comparative analysis. Furthermore, TASC II classification for the femoral artery had no statistically significant variations across DCB and CB cohorts (P = 0.89; **Table 1**).

Comprehensive follow-up datasets were collected across 295 cases at one week, 6 months, and 12 months. Excellent agreements existed across duplex ultrasonography/angiography dataset outcomes (κ = 0.92). At 6 months, the angiographic restenosis rate in the DCB cohort was 4.2% and 26% in the cohort. Depending on the treatment, the restenosis rate in the DCB and CB cohorts were 4.2% and 26% at 12 months (P<0.05). Cases undergoing DCB had a significantly minimized risk of restenosis post-6 and 12 months, in comparison to cases undergoing CB, according to case examination results.

Dataset outcomes concerning remaining secondary endpoints reflecting the cases' anatomical outcomes are depicted in **Table 2**. No major variations existed within MLD, ABI, PSVR and Rutherford grading across cohorts before and 7 days post-surgery (P>0.05). The ABI and MDL were also significantly better at 6 months and 12 months within the stent cohort than the angioplasty cohort (P = 0.03). LLL and PSVR of DCB cohort were reduced in comparison to CB cohort 6- and 12-months post-operation (P<0.05). 6 months post-operation, Rutherford grade 1 and grade 2 in DCB cohort were slightly higher than those in CB cohort, but there was no statistical difference between the two cohorts (P>0.05). Cases within DCB had markedly increased mobility on a treadmill in comparison to CB cohort at 12 months (P<0.05) (**Table 3**).

Figure 2 highlights Kaplan-Meier analyses for cumulative freedom from ISR depending upon different treatment methods. The log-rank test suggested the risk for ISR was markedly increased in cases of Cohort 2 compared to Cohort 1 at baseline (P<0.001).

Discussion

Restenosis is the main problem of endovascular treatment of superficial femoral artery, especially for long lesions [11]. At present, the most commonly used method for the treatment of in-stent restenosis is simple balloon dilation, which is easy to operate and has a high success rate. However, the long-term efficacy is not satisfactory, with a 1-year restenosis rate as high as 49.9%-84.8% [12].

As a new intracavitary therapy, DCB has been used in the treatment of femoral and popliteal

Table 2. Comparison of efficacy evaluation indexes across cohorts before operation and during each follow-up period

Time	Cohort 1 (DCB); n = 145	Cohort 2 (CB); n = 150	t	*P* value
Pre-interventional MLD	0.50±0.14	0.48±0.11	1.40	0.310
Post-interventional MLD	3.29±0.36	3.22±0.34	1.65	0.190
Post-interventional MLD at 6 months	3.05±0.41	2.88±0.41	3.58	0.032
Post-interventional MLD at 12 months	2.90±0.43	1.58±0.36	28.2	<0.001
Post-interventional LLL at 6 months	0.23±0.15	0.34±0.29	-3.74	0.004
Post-interventional LLL at 12 months	0.39±0.23	1.64±0.51	-26.80	<0.001
Pre-interventional ABI	0.32±0.05	0.31±0.07	1.23	0.140
Post-interventional ABI at one week	0.93±0.34	0.90±0.13	1.17	0.330
Post-interventional ABI at 6 months	0.82±0.07	0.82±0.13	0.24	0.027
Post-interventional ABI at 12 months	0.77±0.07	0.47±0.13	23.722	<0.001
Pre-interventional PSVR	3.42±2.17	3.80±2.07	-1.49	0.100
Post-interventional PSVR at one week	1.15±0.11	1.17±0.06	-1.90	0.270
Post-interventional PSVR at 6 months	1.54±0.17	2.28±0.72	-11.84	<0.001
Post-interventional PSVR at 12 months	2.00±0.78	3.57±0.99	-14.99	<0.001

Key: MLD (mm), Minimal Lumen Diameter; LLL (mm), Late Lumen Loss; ABI, Ankle Brachial Index; PSVR, Peak Systolic Velocity Ratio.

Table 3. Rutherford grading, compared across cohorts preoperatively and during each follow-up period

	Classification	0	1	2	3	4	*P* value
Pre-interventional	Cohort 1	-	-	-	102	43	0.92
	Cohort 2	-	-	-	105	45	
Post-interventional at one week	Cohort 1	121	24	-	-	-	0.86
	Cohort 2	123	27		-	-	
Post-interventional at 6 months	Cohort 1	-	106	33	6	-	0.191
	Cohort 2		84	51	15	-	
Post-interventional at 12 months	Cohort 1	-	91	39	15	-	<0.001
	Cohort 2	-	15	12	57	66	

artery diseases in recent years. Its surface is coated with the lipophilic anti-proliferative drug paclitaxel, which has a high permeability and high tissue absorption rate. The drug can rapidly penetrate the vascular wall through balloon expansion and have long-lasting effect [13]. The main advantages of DCB are as follows: (1) It avoids the risk of metal-and polymer-induced restenosis, thrombosis and stent rupture, and does not require continuous dual antiplatelet therapy after operation. (2) The contact area for the tube wall is larger, the drug release is more uniform, and the bioavailability is higher. (3) Better adaptability to twisted vessels, bifurcated vessels and diffuse lesions [14]. (4) High drug concentration can be maintained within the smooth muscle cell layer and fibroblast layer of the arterial vascular wall, which can effectively inhibit the hyperplasia of diseased intima [15]. Heidemann et al. also confirmed by performing an arterial experiment that paclitaxel could continuously inhibit the proliferation of vascular smooth muscle [16].

Krankenberg et al. [17] conducted a multicenter, prospective, randomized controlled clinical trial. A total of 119 cases were included, and 62 cases were randomly assigned to the DCB cohort and 57 cases to the CB cohort. The incidence of in-stent restenosis at 6 months was 15.4% (DCB cohort) and 44.7% (CB cohort), respectively (P = 0.002). The Rutherford grade was improved by at least 1 grade at 12 months. In this study, the Rutherford score improved by at least 2 levels at 12 months. In the PACT Global trial [18], 131

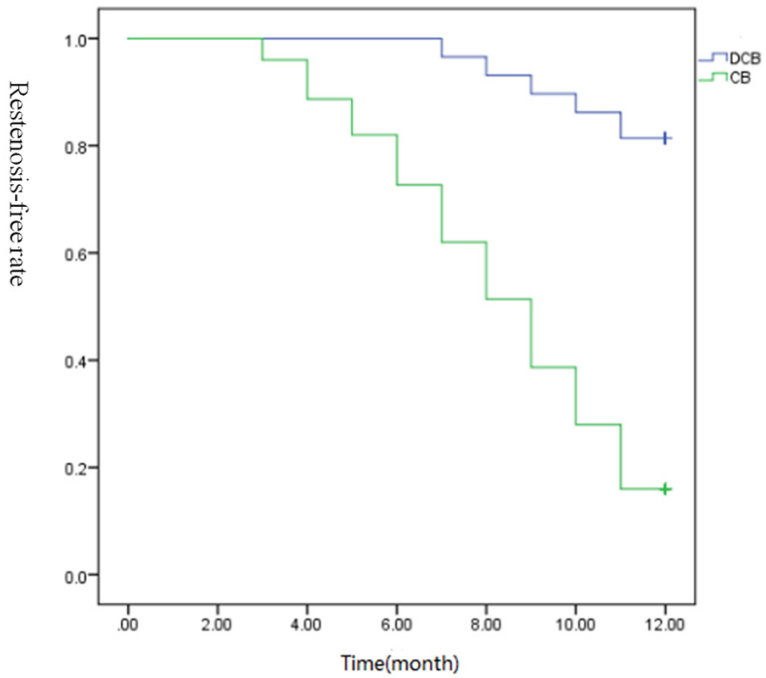

Figure 2. Cumulative freedom from in-stent restenosis with Kaplan-Meier analysis. Cases with CB are in green line; Cases with DCB are in blue line. Cumulative rates of freedom from in-stent restenosis were compared using log-rank test (P<0.001).

cases of in-stent restenosis were included, of which 34% were complete occlusion and 59.1% were calcification. The patency rate was 88.7% 12 months post-drug coated balloon dilation. In China, ACOART1 [19] studied 46 cases of femoral and popliteal artery restenosis in the subcohort, including 26 in the DCB cohort and 20 in the CB cohort. Post-different balloon dilation treatment, the restenosis rate was 23% and 95% within two cohorts 12 months post-the intervention. It was proven that DCB was significantly better than CB for treating femoropopliteal artery ISR within the short and medium term. In this study, the restenosis rates for lesion sites within the DCB cohort and CB cohort were 4.2% and 26% at 6 months post-intervention. Rates of restenosis 12 months post-intervention were 18% and 84% in both cohorts. Compared with the above studies, we found that the restenosis rate was slightly lower within the DCB cohort and the CB cohort post-6 and 12 months of interventional treatment in this study. The mechanism of stent restenosis remains unclear. Intravascular ultrasound studies have shown that the application of vascular stents can completely eliminate the contraction and negative remodeling of the vascular wall, while intrastent restenosis is completely the result of the new intima [20], which is mainly composed of proliferating smooth muscle cells [19] and extracellular matrix [20]. We considered and analyzed the following two possible reasons: 1. Sagrel hydrochloride has a specific antagonistic effect on the 5-hydroxytryptamine (5-HT) 2A receptor of vascular smooth muscle; sagrel hydrochloride plus aspirin can significantly reduce the restenosis incidence after peripheral vascular stenting, and at the same time significantly reduce endostent proliferation; in addition, it can also improve collateral circulation [21]. 2. A drug-coated balloon has a higher drug concentration in smooth muscle cell layer and fibroblast layer of the arterial wall, which can effectively inhibit endometrial hyperplasia. Thus, our restenosis rate is a little bit lower than in other studies.

This investigation has limitations. The primary angiographic endpoint was in-stent restenosis evaluated by combining CTA and DSA. Even though CTA is a high-potential methodology, validated comparative analyses using conventional angiography across large series of measurements within stented arteries remain scarce. Notwithstanding, all restenoses detected by CTA throughout this investigation were confirmed through DSA, with revelations both CTA and DSA demonstrated excellent agreements with dataset outcomes from duplex ultrasonography, being the established clinical method for evaluating in-stent restenosis.

Conclusion

In conclusions, the medium- and long-term clinical effectiveness for drug-coated balloon in the treatment of restenosis in superficial femoral artery stent is significantly higher than that of an ordinary balloon.

Acknowledgements

The study was approved by the local Ethics Committee for Shaanxi Provincial People's Hospital. All cases signed an informed consent.

Disclosure of conflict of interest

None.

Abbreviations

DCB, Drug-Coated Balloon; CB, Common Balloon; SFAS, Superficial Femoral Artery Stenting; CAD, Coronary Artery Disease; MLD, Minimal Lumen Diameter; LLL, Late Lumen Loss; ABI, Ankle Brachial Index; PSVR, Peak Systolic Velocity Ratio; CTA, Computed Tomography Angiography.

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