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Effectiveness of directional atherectomy with the drug-coated balloon method for long and heavily calcified superficial femoral artery lesions

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ABSTRACT

Objectives: This study aimed to examine the mid-term results of patients who underwent directional atherectomy (DA) for vascular preparation before drug-coated balloon (DCB) angioplasty with superficial femoral artery lesions longer than 150 mm and severe calcification and compare these patients with those treated with DCB angioplasty alone.

Patients and methods: This prospective study enrolled 76 patients (66 males, 10 females; mean age: 63.3+9.8 years; range 44 to 105 years) with calcific superficial femoral artery lesions longer than 150 mm treated with DA before DCB angioplasty or DCB angioplasty alone between May 2019 and November 2020. The patients were evaluated in two groups according to DA use: the DA+DCB group with 46 patients and the DCB group consisting of 30 patients. The results of these two methods were compared, and the outcomes were followed up for one year after the treatment. Primary outcomes were patency, freedom from target lesion revascularization, and unplanned amputation.

Results: There was no statistically significant difference between the two groups in demographic features, risk factors, comorbidity, and functional capacity assessment tests. At the 12th month, the primary patency of the DCB and DA+DCB group was 66.6% and 82.6%, respectively ($p<0.05$). Although the bail-out stent requirement rate for the treatment of the flow-limiting dissection (type C-F) was lower in the DA+DCB group (8.6% *vs.* 10.0%), there was no statistically significant difference ($p=0.46$).

Conclusion: The DA prior to DCB in long segment severe calcific superficial femoral artery lesions may provide better patency and may decrease rate of flow-limiting and non-flow limiting dissections.

Keywords: Atherectomy, balloon angioplasty, paclitaxel, peripheral artery disease, vascular calcification.

Nowadays, the role of endovascular interventional methods increases in the treatment of superficial femoral artery (SFA) stenosis or occlusion. The choice of endovascular method may vary depending on the calcification burden, the length of the lesion, concomitant vascular involvement in other segments, and the preference of the endovascular surgeon. Balloon angioplasty technologies form the basis of endovascular procedures. Restenosis, which may develop in the target lesion, is one of the main hindrances of endovascular treatments. However, drug-coated balloon (DCB) technologies provide good results in resolving the restenosis problem. In the literature, there are many trials to prove that DCB is more effective than standard balloon angioplasty in solving the restenosis problem.[1,2] It is known that severe calcification is a significant barrier to administering the antiproliferative drug with the DCB into the media layer of the artery.[3] Atherectomy devices reduce the calcium burden in the artery and provide redistribution, thus providing the vascular preparation to deliver the antiproliferative drug from the DCB to the targeted area. In this study, we aimed to examine the mid-term results of patients who underwent directional atherectomy (DA) for vascular preparation before DCB angioplasty in patients with SFA lesions longer than 150 mm and severe calcification and compare these patients with those treated with DCB alone.

PATIENTS AND METHODS

A total of 76 patients (66 males, 10 females; mean age: 63.3+9.8 years; range, 44 to 105 years) treated

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with DA before DCB angioplasty or DCB angioplasty alone at the Prof. Dr. Cemil Tasçıoğlu City Hospital Cardiovascular Surgery Clinic between May 2019 and November 2020 were enrolled in the prospective, single-center study. Inclusion criteria were the presence of a 150 mm or longer SFA lesion with Rutherford clinical category (RCC) 3-6, a ≥70% occlusion of the SFA in computed tomography angiography (CTA) or digital subtraction angiography, and the presence of at least one distal vessel runoff. Exclusion criteria were patients with SFA lesions less than 150 mm in length, acute SFA thrombosis, previous vascular intervention to the target limb less than three months ago, and inability to quit smoking. The patients were evaluated in two groups according to DA use: the DA+DCB group with 46 patients and the DCB group consisting of 30 patients. Study assessment was done at baseline, procedure, first outpatient polyclinic control, and six and 12 months after the procedure.

Preoperative assessments included the evaluation of the patients at the baseline, determination of the physical capacity with RCC and ankle-brachial index (ABI), flow pattern measurements of the distal arteries in duplex ultrasonography (USG), and topographic determination of the SFA and concomitant arterial lesions in CTA. The flow pattern of the target lesion distal artery was measured by duplex USG and classified as monophasic, biphasic, and triphasic. In addition, the calcium burden of the SFA lesion was longitudinally and circumferentially measured as described by Fanelli et al.[3] (numbers ranging from 1 to 4 determined by the quantification of circumferential grading of calcium plaque in four quarters from 0 to 360 degrees and as letters A and B depending on the length of the calcification, longer or shorter than 3 cm, on the longitudinal axis). Calcium gradings of 3A and above were categorized as severe, whereas 2B and below were nonsevere.

Access site was made from the common femoral artery with the retrograde or antegrade approach during the endovascular procedure. The arterial lesion was passed with appropriate guidewires and catheters (support or total occlusion). After passing the target lesion, vascular preparation before DCB application was made with plain balloon angioplasty in the DCB group and with DA in the DA+DCB group. Additional procedures, dissections with or without flow limiting, and complications (arteriovenous fistula, perforation, distal artery thrombus, or debris migration) were recorded separately for both groups during the procedure. The dissections were grouped according to the classification system of the coronary artery dissection patterns described by the National Heart, Lung, and Blood Institute.[4] Letters from A to F in this classification show the severity of the dissection: (A) minor radiolucent areas, (B) linear dissection, (C) contrast outside the lumen, (D) spiral dissection, (E) persistent filling defects, and (F) total occlusion without distal antegrade flow. Types C to F are described as severe dissections. Firstly, the plain balloon angioplasty was used for the treatment of flow-limiting dissections after DCB angioplasty. Drug-coated balloon inflation time was at least 180 sec. The plain balloon inflation time for the treatment of flow-limiting dissections was at least 300 sec, and if the plain balloon inflation did not solve the issue, a bare-metal stent was used.

In the study, HawkOne™ (Covidien, Dublin, Ireland) DA catheters were used. The IN.PACT Admiral (Medtronic Inc., Dublin, Ireland) DCBs were preferred, and the length of the lesion determined how many balloons were required. The numbers of the balloons varied from one to three.

Outpatient control was made in the first week, six months, and 12 months after discharge from the hospital. The physical assessment of the patients was evaluated with the ABI, peripheric pulse examination, and RCC grade. Detailed medical records after the endovascular intervention, such as amputation or surgical debridement, wound healing, and any target lesion reintervention, were also interrogated. The duplex USG was performed at the six- and 12-month controls. The target lesion flow pattern and patency were assessed by sonographic methods. A monophasic flow pattern at the target lesion was considered a severe restenosis of the target lesion. If there was any suspicion of stenosis or patency, they were also assessed with CTA. Severe restenosis was regarded as the need for reintervention if there was restenosis greater than 30% of the lumen diameter in addition to symptoms. Both sonographic and radiologic methods were used to assess primary patency. Adverse events, such as acute thrombosis or embolism of the distal arterial bed, arteriovenous fistula, perforation, and flow-limiting dissection, were diagnosed and recorded during intervention for both groups.

Statistical analysis

The data were evaluated using the IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). The demographic characteristics of the study groups were analyzed with descriptive statistical information, the mean, median, interquartile range, number, percentage, and standard deviation. The suitability of the data to a normal distribution was analyzed with the Shapiro-Wilk test. In the study, chi-square, Mann-Whitney U, Wilcoxon, and Marginal homogeneity tests were used. A *p* value of <0.05 was considered statistically significant.

RESULTS

Demographic characteristics of patients were well matched between two groups, and there was no statistically significant difference among them (p>0.05). The majority of the patients were RCC 3 in both groups (p=0.159); however, the patients with critical limb ischemia (RCC 4 or above) were more common in the DA+DCB group. All demographic features, risk factors, comorbidities, preintervention RCC grading, and ABI measurements were summarized in Table 1.

The mean lesion length of the DA+DCB group was higher than the DCB group (p<0.05). The calcium burden of the groups was evaluated. Approximately one third of the patient in the DCB group had severe calcification (grade 3A and above) while severe calcification was seen in half of the patients in the DA+DCB group; however, there was no statistically significant difference (p>0.05). The lesion length, calcium burden severity, and presence of concomitant lesions in the two groups were summarized in Table 2. In addition, the detailed arterial calcification grading for patients in both groups was demonstrated in Figure 1.

The type A and B (nonflow-limiting) dissection rates were significantly lower in the DA+DCB group (p<0.05). Type C to F dissections were observed in four (13.3%) patients of the DCB group and four (13.3%) patients of the DA+DCB group. The bail-out stent was performed if the balloon angioplasty was not solved by the flow-limiting dissection. A bail-out stent was required in three (10%) of the patients in the DCB group and four (8.6%) in the DA+DCB group to overcome the flow-limiting dissection or residual stenosis. Although the bail-out stent need was lower in the DA+DCB group, the difference was not statistically significant (p=0.461). The detailed dissection grades and bail-out stent needs of the groups were also summarized in Table 2.

Table 1
Baseline characteristics

	DCB (n=30)					DA+DCB (n=46)						All patients				
	n	%	Mean±SD	Median	Range	n	%	Mean±SD	Median	Range	*p*	n	%	Mean±SD	Median	Range
Age (year)			62.1±8.0	62.0	44.0-87.0			64.0±10.9	63.0	50.0-105.0	0.674			63.3±9.8	63	44.0-105.0
Sex																
Male	29	96.6				37	80.4				0.078	66	86.8			
Medical history																
Hypertension	18	60				29	63.0				0.980	47	61.8			
Diabetes mellitus	13	43.3				22	47.8				0.701	35	46.0			
Coronary artery disease	11	36.6				22	47.8				0.470	33	43.4			
Chronic renal failure	4	13.3				7	15.2				1.000	11	14.4			
Hyperlipidemia	13	43.3				29	63.0				0.146	42	55.2			
Smoking	17	56.6				28	60.8				0.900	45	59.2			
Rutherford clinical category											0.159					
<RCC 4	22	73.3				25	54.3					47	61.8			
≥RCC 4	8	26.6				21	45.6					29	38.1			
Foot ulcer	5	16.6				17	36.9					22	28.9			
ABI			0.3±0.1		0.0-0.5			0.2±0.1		0.0-0.4	0.112			0.25±0.1		0.0-0.5

DCB: Drug-coated balloon; DA: Directional atherectomy; SD: Standard deviation; RCC: Rutherford clinical category; ABI: Ankle-brachial index.

Table 2
Angiographic characteristics

	DCB (n=30)					DA+DCB (n=46)						All patients				
	n	%	Mean±SD	Median	Range	n	%	Mean±SD	Median	Range	*p*	n	%	Mean±SD	Median	Range
Lesion length (mm)			181.5±36.5	165.0	150.0-300.0			244.2±75.5	228.5	150.0-550.0				219.5±69.9	210.0	150.0-550.0
Calcium burden											0.106					
Severe	10	33.3				24	52.1					34	44.7			
Mild-moderate	20	66.6				22	47.8					42	55.2			
Concomitant lesion											0.461					
Iliac	10	33.3				6	13.0					16	21.0			
BTK	5	16.6				7	15.2					12	15.7			
Dissection grade (A-F)																
A	3	10				2	4.3					5	6.5			
B	3	10				0	0.0					3	3.9			
C	1	3.3				0	0.0					1	1.3			
D	0	0.0				0	0.0					0	0.0			
E	0	0.0				0	0.0					0	0.0			
F	3	10				2	4.3					5	6.5			
Dissection not need any intervention (Grade A-B)	6	20				2	4.3				<0.05	8	10.5			
Dissection need intervention (Grade C-F)	4	13.3				2	4.3				>0.05	6	7.8			
Bail-out stent use	3	10.0				4	8.6				0.461	7	9.2			

DCB: Drug-coated balloon; DA: Directional atherectomy; SD: Standard deviation; BTK: Below the knee.

In the DCB group, 12 (40%) patients had at least one complication, and there was a statistically significant difference between the groups (p=0.048). The detailed distribution of the complications according to groups was provided in Table 3.

In the follow-up, the ABI values were higher in both groups at the six- and 12-month outpatient controls. However, the ABI increase was higher in the DA+DCB group, which was statistically significant according to preoperative and postoperative ABI measurements (p=0.014). There was no difference between the groups in pre-and postintervention RCC grades (p>0.05 for each). However, the postintervention RCC grades were lower in both procedures when the preoperative and postoperative RCC grades of the groups were compared, which was statistically significant (p <0.05 for each). In duplex USG, the triphasic flow pattern was more frequently detected in the DA+DCB group at the six- and 12-month follow-ups, and the difference was statistically significant (p=0.025). The primary patency of patients evaluated with duplex USG was 80% in the DCB group and 91.3% in the DA+DCB group. However, the flow pattern measurements were inadequate to asses patency of femoral artery because it was affected other region lesions such as below the knee or iliac artery. Therefore, the primary patency was also evaluated with CT angiography. The primary patencies of the DCB and DA+DCB groups at the sixth month were 76.6% and 82.6%, respectively. There was no statistical significance between the groups. However, at the 12th month, the primary patency of the DCB group was decreased to 66.6%,

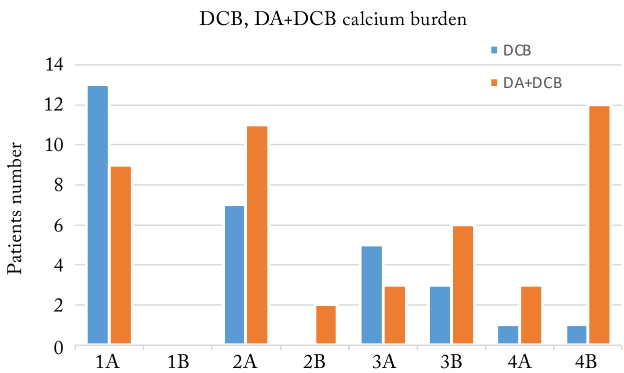

Figure 1. Severity of the calcification according to the grading system (Calcium burden evaluation with CTA (axial) and digital subtraction angiography (longitudinal): "A" <3 cm and "B" >3 cm).

DCB: Drug-coated balloon; DA: Directional atherectomy.

Table 4
Outcomes

	DCB (n=30)					DA+DCB (n=46)					
	n	%	Mean±SD	Median	Range	n	%	Mean±SD	Median	Range	*p*
ABI			0.7±0.2	0.7	0.6-0.8			0.8±0.2	0.8	0.7-0.9	0.014
Rutherford clinical classification			2.6±0.7	3.0	2.0-3.0			2.5±1.3	2.0	2.0-3.0	>0.05
Peripheric pulse examination											0.049
Non-palpable	7	23.33				5	10.86				
One pulse palpable	15	50				16	34.78				
Two pulse palpable	8	26.66				25	54.34				
Duplex USG flow pattern											0.025
Monophasic	6	20				4	8.69				
Biphasic	18	60				19	41.30				
Triphasic	6	20				23	50				
6th month primary patency (CTA)	23	76.66				38	82.60				0.424
12th month primary patency (CTA)	20	66.6				38	82.60				<0.05
Unplanned amputation	2	6.6				2	4.3				>0.05
Mortality (all cause)	0	0.0				0	0.0				

DCB: Drug-coated balloon; DA: Directional atherectomy; SD: Standard deviation; ABI: Ankle-brachial index; USG: Ultrasonography; CTA: Computed tomography angiography.

Table 3
Complications

	DCB (n=30)		DA+DCB (n=46)		
	n	%	n	%	*p*
Distal embolism (need intervention)	2	6.6	1	2.1	
Arteriovenous fistula	0	0.0	1	2.1	
Pseudoaneurysm	0	0.0	1	2.1	
Perforation	0	0.0	1	2.1	0.048
Flow-limiting dissection	4	13.3	2	4.3	
Non-flow limiting dissection	6	20	2	4.3	
All complication	12	40.0	8	17.3	

DA: Directional atherectomy; DCB: Drug-coated balloon.

while that of the DA+DCB group was unchanged ($p<0.05$). The 6- and 12-month outcomes of the groups were presented in Table 4.

DISCUSSION

In this prospective study, we analyzed the impact of a DA device before DCB angiography for the vascular preparation of calcified long-segment femoropopliteal lesions by comparing two groups of patients treated with a DCB with or without DA. Our analysis showed that vascular preparation with DA before DCB enhanced the primary patency and lowered the rates of both perioperative flow-limiting and nonflow-limiting dissections and the necessity of the bail-out stent according to the DCB method alone.

The lesion length and calcification burden are some of the prime factors affecting the success and durability of the endovascular treatment. Increased length of the diseased segment and severe calcification are associated with unsatisfactory outcomes.[5] The current European Society of Cardiology guideline recommends the endovascular strategy first for femoropopliteal lesions ≤25 cm (Class 1C) with primary stenting (Class IIa) and DCBs (Class IIb). Surgical revascularization with an autologous saphenous vein graft is still the best treatment in lesions >25 cm (Class IB). However, endovascular treatment may also be considered in this group, whether the patient is unfit or at high risk for surgery (Class IIb). Therefore, the endovascular methods have become a preferred ‘first’ approach in parallel to increasing experience due to short hospital stays and early recovery in long femoropopliteal lesions. The calcification burden has proven its impact on both procedural success and midterm restenosis occurrence. Fanelli et al.[3] reported that both increased cross-sectional calcification burden in CTA and longitudinal calcification burden in digital subtraction angiography are associated with a progressive decrease in clinical success. Additionally, in their study, a cross-sectional calcification burden was found to be a more powerful indicator of poor outcomes than a longitudinal calcification burden. Similarly, the previous studies have demonstrated that severe calcification burden is an independent factor of restenosis following DCB, and this increases bail-out stent implantation.[6-8] The severity of the calcification burden causes an increase in the probability of perioperative flow-limiting dissection and bail-out stenting.[5] Severe calcification may also cause an inadequate opening of stents. There are various devices decreasing the calcification burden or changing calcification distribution, such as cutting and scoring balloons and atherectomy devices that increase patency.[9-13]

Drug-coated balloons decrease restenosis risk with the antiproliferative properties of the drugs on their surfaces. Previous studies have revealed the superiority of DCBs over standard balloon angioplasty in femoropopliteal lesions.[14-21] However, the antiproliferative effects of DCBs depend on the embedding and up-take of drug particles into the media layer of the arteries with the aid of the balloon inflation pressure.[18] At this point, the advanced calcification burden forms a barrier between the drug and the media layer. Some studies in the literature have reported promising results with DA followed by DCB angioplasty in severely calcified lesions.[10,22]

Lesion length is another important determinant of procedural success and patency. In the majority of previous studies, atherectomy was used for lesions <100 mm. The mean lesion length was 74±53 mm in the DEFINITIVE-LE study and patients with lesions >100 mm were only 28% of the study population.[23] Similarly, the DEFINITIVE-AR study compared DCB alone with DA+DCB in patients with a lesion length between 70-150 mm.[24] In the present study, lesion length was >150 mm for all patients.

In this study, the primary endpoint was defined as <30% of restenosis in target lesion assessed with duplex USG and CTA at the 12-month follow-up. The rate of restenosis at 12 months after the procedure was lesser in patients treated with atherectomy for vascular preparation. Similar studies show similar primary patency rates.[10] Clinical assessment with ABI and physical examination showed improved results in comparison with the preprocedural condition in the radiologic evaluation at the 12-month follow-up. A higher increase of ABI was observed in the DA+DCB group than in the DCB group, consistent with radiologic evaluation.

The nonflow-limiting dissections were usually underestimated in previous studies. However, the effect of nonflow-limiting dissection on restenosis rates is still not well known. We separately evaluated the nonflow-limiting dissections for both groups, and we think that they may affect the mid-term patency. As with similar previous studies, the flow-limiting dissections (types C to F) needing intervention were more common in the DCB group (13.3% *vs.* 4.3%), and the relative risk reduction was 67.6%. Bail-out stenting was required in 10% of the DCB group compared to the 8.6% of the DA+DCB group. The bailout stenting rate in the DA+DCB patients was reported as 3.2% in the DEFINITIVE-LE study. In our study, the stenting rate was notably higher in comparison with previous studies. We consider that our study population was composed of patients with longer lesions and a more severe calcification burden. Therefore, we had to use more stents, unlike similar studies. Although bail-out stenting incidence was lower in the DA+DCB group, we found 2.1% perforation, 2.1% pseudoaneurysm formation, and 2.1% arteriovenous fistula, which did not occur in the DCB group. The distal arterial embolization was more common in the DCB group (6.6% *vs.* 2.1%). We used an antiembolic filter in 86.9% of the DA+DCB group. Therefore, this insignificant difference is secondary to the antiembolic filter use.

The major or minor amputation of the extremity and the healing of the ischemic wound rates did not differ between the members of the groups, although the outcomes of the DA group appear more encouraging depending on the target lesion revascularization and primary patency at the 12-month follow-up. Further studies with more patients are required to evaluate amputation and mortality rates.

In conclusion, vascular preparation with the DA prior to DCB in patients with long-segment and severely-calcific lesions may provide better patency, decrease flow-limiting and nonflow-limiting dissections, and lower the need for bail-out stents.

Ethics Committee Approval: The study protocol was approved by the Prof. Dr. Cemil Taşçıoğlu City Hospital Ethics Committee (Date/no: 14.05.2019/1297). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept, data collection and/or processing: S.K.; Design, analysis and/or interpretation, literature review, writing the article, references and fundings:: S.K., H.G.; Control/supervision, critical review: H.G.

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