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Directional atherectomy in femoropopliteal occlusive diseases: Our midterm results

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ABSTRACT

Objectives: This study aims to analyze the midterm results of directional atherectomy (DA) in patients with femoropopliteal occlusive disease.

Patients and methods: Data of a total of 21 patients (20 males, 1 female; mean age 59.7±7.9 years; range, 45 to 77 years) who underwent DA between June 2014 and December 2016 were retrospectively analyzed. The demographic data, symptomatic classifications (pre- and postoperatively), and lesion types were recorded. The pre- and postoperative patency rates were compared using computed tomography angiography and Doppler ultrasonography.

Results: Technical success and clinical improvement were obtained in all patients. One patient (4.8%) required reintervention of the target lesion and another patient (4.8%) required below-the-knee amputation during follow-up. The mean duration of amputation-free survival was 1.6±0.8 (range, 0.4 to 2.8) years. The six- and 12-month major amputation-free survival rates were 100% and 94.1%, respectively. No procedure-related mortality occurred. The mean duration of patency was 1.4±0.9 (range, 0.1-2.7) years. The mean duration of target vessel revascularization-free survival at one, two, and 2.5 years were 93.3±6.4%, 93.3±6.4%, and 62.2±25.8%, respectively. Claudication recurred in seven patients (33.3%). The mean duration of claudication-free survival was 1.4±0.9 years. Tobacco use was the only statistically significant factor for re-claudication (p=0.047).

Conclusion: Based on our midterm results, DA can be used in the first-line treatment of femoropopliteal occlusive diseases in patients with multiple comorbidities and complex lesions with a high technical success rate, a low complication rate, and favorable patency rates.

Keywords: Directional atherectomy; endovascular; femoropopliteal occlusive disease.

Femoropopliteal occlusive disease is an important etiology for significant mortality and morbidity with a significant financial burden.[1] The presence of peripheral arterial disease (PAD) is a poor prognostic factor and survival is worse than many types of malignancies.[2] The incidence of both symptomatic and asymptomatic PAD over the age of 50 years is estimated to be around 13%.[2] Symptomatic PAD is thought to be prevalent in 5% of the patient population at the ages from 55 to 74.[2] Around 200,000 patients are estimated to have PAD by the year of 2010, indicating a 28.7% increase in the incidence of the disease in developing countries.[1-5]

The distribution of occlusive disease in lower extremities is as follows: aortoiliac segment 24%, iliofemoral segment 4%, femoropopliteal segment 50%, popliteal artery 5%, and crural involvement 17%.[6] The superficial femoral artery (SFA) imposes intrinsic difficulties in the treatment of occlusive diseases due to the mechanical forces affecting the aforementioned segment. Everyday movements of leg may cause considerable deformations in SFA. The higher involvement of this artery is postulated to be due to the well-known extrinsic causes.[6] Femoropopliteal artery occlusive disease is, therefore, the most common cause of intermittent claudication.[7]

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It is mostly presented with bilateral involvement and with a progressive course. The tendinous structures in the adductor canal exert a significant force on SFA and, thereby, leading to the highest prevalence of disease involvement in this area.[7] Due to the extrinsic forces and the high mobility of this area, the treatment becomes more difficult.

The main presenting symptoms in SFA disease include intermittent claudication and critical limb ischemia. The main goals of treatment are to increase the exercise capacity and walking distance, to relieve rest pain, and to prevent ulceration and limb loss.[8] Although surgery is favored in the recent European guidelines,[9] endovascular procedures continue to evolve and the results of different clinics are still of interest. According to a national paper in 2012 from Istanbul, one-third of all endovascular procedures were performed for the treatment of PAD.[10] The nationwide-use of atherectomy and reported results of endovascular treatment of femoropopliteal occlusive diseases are scarce either as case reports or small series.[11-14] Therefore, in the present study, we present our midterm results of directional atherectomy (DA) in patients with SFA disease.

PATIENTS AND METHODS

Data of a total of 21 patients (20 males, 1 female; mean age 59.7±7.9 years; range, 45 to 77 years) who underwent DA between June 2014 and December 2016 were retrospectively analyzed. The data were collected prospectively using a separate database. A written informed consent was obtained from each patient. The study protocol was approved by the institutional Ethics Committee (2017/546). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Medical histories of the patients were obtained from hospital records. Diabetes mellitus (DM) was defined as taking an antidiabetic agent or a fasting blood glucose of over 120 mg/dL. Hypertension (HT) was defined as taking a regular antihypertensive therapy prescribed by an internist or cardiologist. Patient who had previous coronary artery disease (CAD) were recorded. Chronic renal dysfunction (CRD) was defined as a serum creatinine level of over 1.5 mg/dL or receiving a routine dialysis program. Patients with a previous cerebrovascular event or with a known diagnosis of an occlusive disease were accepted having a cerebrovascular disease (CVD) (Table 1).

The routine preoperative work-up included computed tomographic angiography (CTA) imaging after SFA disease was confirmed with Doppler ultrasonography (USG). The CTA images were used to classify the lesions according to the TASC-II (The Trans-Atlantic Inter-Society Consensus II) classification (Table 2). The symptomatic statuses of the patients were presented according to the Rutherford and Fontaine classifications to standardize the outcome findings (Table 3). Procedural complications were defined as follows: new-onset ischemia, pain, and bleeding or hematoma formation in the treated limb within one month of the procedure.

Surgical technique

All patients had loading doses of 500 mg acetyl salicylic acid (ASA) and 600 mg clopidogrel at least two hours before the procedure. Intraarterial nitroglycerine was applied intraoperatively, unless the systolic blood pressure was lower than 120 mmHg. After local anesthesia with prilocaine, all patients had a contralateral femoral puncture and long sheaths after cross-over except for a single patient who had antegrade femoral puncture. 7F or 8F sheaths (Destination® Guiding Sheath, Terumo Medical Corporation, Tokyo, Japan) were used in the access site. The skin was incised 1-2 cm distal to the area where the inguinal ligament crosses the femoral artery with a No.11 blade for the 18-gauge needle. After placing the sheath with the Seldinger technique, anticoagulation with 5,000 IU unfractionated heparin was made. Heparin dose was repeated, if the procedure extended over an hour.

Contralateral SFA lesions were confirmed with an arteriography after the sheath was placed into the common femoral artery. A hydrophilic guidewire (Radifocus®, Terumo Co., Ltd., Tokyo, Japan) was placed and the stenotic lesion was crossed with this guidewire using a support catheter (Navicross®,

Table 1. Preoperative patient data

Parameters	n	%
Gender		
Male	20	95.3
Female	1	4.7
Hypertension	17	80.9
Coronary artery disease	15	71.4
Diabetes mellitus	14	66.6
Tobacco use	14	66.6
Hyperlipidemia	11	52.3
Chronic renal dysfunction	3	14.3
Previous cerebrovascular event	1	4.7

Table 2. Lesion types

Parameters	n	%
TASC-II Class		
A	2	9.5
B	5	23.8
C	13	61.9
D	1	4.7
Occlusion type		
Long segment	13	61.9
Short segment	5	23.8
Multisegment	3	14.3
Anatomic location		
Femoral	14	66.6
Aortoiliac+femoral	6	28.5
Popliteal	1	4.7

TASC-II: Trans-Atlantic Consensus Document for Peripheral Artery Disease.

Table 3. Fontaine and Rutherford Symptomatic Classes

Parameters	n	%
Fontaine		
Class 2b	19	90.4
Class 3	1	4.7
Class 4	1	4.7
Rutherford		
Class 3	20	95.3
Class 4	1	4.7

Terumo Co., Ltd., Tokyo, Japan). After the lesion was crossed, the intraluminal position was confirmed with back bleeding from the catheter or arteriography performed via the catheter. A filter (ev3, Dublin, Ireland) was placed at least 10 cm distal to the lesion where atherectomy was planned. The filter was placed mostly in the SFA at or distal to the Hunter canal or at the popliteal artery in all cases. Directional atherectomy was performed with the SilverHawk or TurboHawk catheters (TurboHawk or SilverHawk, ev3, Dublin, Ireland). Directional atherectomy was performed to four quadrants of SFA lesion site. After atherectomy was completed, the catheter was removed and control arteriography was obtained. Sufficient luminal gain and the absence of any complication were confirmed. In cases where an additional procedure was planned (percutaneous transarterial angioplasty [PTA] with drug-coated balloon [DCB] stenting), the previously placed filter was replaced with the hydrophilic guidewire. At the end of the procedure, completion arteriography was performed and sufficient endresults were confirmed.

In one of our patients, the run-off vessels decreased from three to two due to peroneal artery occlusion. A thrombolytic catheter with multi-side holes (Loglysis, Optimed, Ettlingen, Germany) was placed into the peroneal artery. Thrombolytic infusion was continued for 24 h (alteplase; Actilyse®, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany) as 2 mg/hour infusion).

DCB stenting

We used the directional atherectomy with antirestenotic therapy (DAART) protocol in 18 patients. After atherectomy was completed, the catheter and filter were removed and a hydrophilic guidewire was advanced into the SFA. Percutaneous transarterial angioplasty was performed with a DCB (Luminor35, Ivascular, Barcelona, Spain; In.Pact Admiral, Medtronic, Dublin, Ireland; Lutonix, Bard, Georgia, USA) to the atherectomized segments. We preferred subnominal pressure inflations for the PTA procedure to decrease barotraumas to the arterial segment. Inflation durations were five min in all patients. After PTA was completed, control arteriography was obtained. In case of sufficient results, the catheter and guidewire were removed and the sheath was replaced with a shorter one.

Stent and PTA

In case the completion arteriography revealed insufficient results, a dissection involving a segment at 5 cm or more length or a dissection flap causing flow limitation, the related segment was stented as a bail-out procedure. In patients with aortoiliac stenosis or in cases where SFA was highly calcified, provisional stenting was preferred for iliac artery and SFA, respectively. A total of eight patients were stented with the indications given above. Six patients received stents for provisional stenting. Provisional stenting was made for the following indications: four patients for iliac artery lesions and two patients for residual stenosis. We used expandable (BES; Visi-Pro, ev3, Dublin, Ireland) or self-expandable (SES; Protege, ev3, Dublin, Ireland) balloon stents in these patients. After the SES was placed, post-dilatation was performed in all patients with 1-mm smaller size balloon (EverCross, ev3, Dublin, Ireland; Pacific Xtreme, Medtronic, Dublin, Ireland). The remaining two patients had bail-out stents. One of them had extravasation in the external iliac artery and a Fluency Plus stent graft (Bard, Tempe, Arizona, USA) was placed. The other patient had a long segment dissection in a calcified SFA and this patient received self-expandable woven stent (Supera, Abbott Vascular, Santa Clara, CA, USA).

Follow-up

Dual antithrombotic therapy was used in all patients for at least six months (ASA 100 mg/day, clopidogrel

Table 4. Procedures

	n	%
Atherectomy	21	100
PTA with DCB	18	85.7
PTA	8	38.1
Stenting	8	38.1

PTA: Percutaneous transarterial angioplasty; DCB: Drug coated balloon.

75 mg/day). After six months, antithrombotic therapy was continued with ASA 100 mg/day. Routine follow-up was performed at one, three, six, and 12 months in the outpatient setting. Routine follow-up visits included controls for the symptoms, increased walking distance, wound healing (if present), routine physical examination, Doppler USG at six and 12 months and CTA if there was a positive finding in Doppler USG or recurrence of symptoms. After 12-month control visit, routine follow-up was planned annually. The patency rates were calculated based on the hospital records and the most recent imaging modality performed together with the final clinical status.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 (SPSS Inc., Chicago, IL, USA). Descriptive data were expressed in mean±SD or n (%). Data were analyzed using the Wilcoxon/sum rank and chi-square tests. Follow-up duration and claudication-free and amputation-free survivals were calculated using the Kaplan-Meier test. A p value of <0.05 was considered statistically significant.

RESULTS

According to the preoperative data, two patients (9.5%) had necrotic lesions on foot in addition to claudication (Tables 2 and 3). The remaining patients (n=19, 90.5%) were able to walk less than 100 meters without pain. One patient (4.7%) had an isolated popliteal artery lesion, 13 (61.9%) had SFA lesions as long segment total occlusions (between 10 and 25 cm long), five (23.8%) had short segment total occlusions (less than 10 cm), and three (14.3%) had multisegmental lesions. Eighteen patients (85.7%) had lesions in the left limb and three (14.3%) had right-sided lesions.

All procedures were performed with technical success (Table 4). The mean duration of the procedures was 111.0±72.5 (range, 26 to 333) min. Control CTA was obtained for the patient who had thrombolytic therapy one month after the procedure and showed patent three-vessel run-off, and the patient was free of symptoms. Two patients (9.5%) had a hematoma at the puncture site, and one patient (4.7%) had a scrotal hematoma postoperatively. No surgical revisions were needed in these patients, and complete recovery was achieved with the expectant therapy. Three patients with preoperative dialysis-dependent CRD received their dialysis sessions after the procedure, as planned.

The mean duration of hospitalization was 2.5±1.5 (range, 1 to 8) days. All patients had improvements in clinical symptomatic classifications (Rutherford and Fontaine). Symptomatic statuses of the patients are summarized in Table 5. The table shows an early significant symptomatic improvement.

The mean duration of post-discharge follow-up was 1.6±0.8 (range, 0.4 to 2.8) years (31.6 patient-years). Two patients had restenosis of the atherectomized lumen and re-atherectomy was performed in one of them one month after the operation. The rate of target vessel revascularization (TLR) was 4.8%. A popliteal pseudoaneurysm was detected in one patient three months after the procedure and was repaired with a

Table 5. Comparison of preoperative and postoperative Fontaine and Rutherford symptomatic statuses

	Preoperative		Postoperative		
	n	%	n	%	p
Fontaine					
Class 1	None	None	19	90.4	0.007
Class 2a	None	None	2	9.6	
Class 2b	19	90.4	None	None	
Class 3	1	4.7	None	None	
Class 4	1	4.7	None	None	
Rutherford					
Class 1	None	None	18	85.7	0.012
Class 2	None	None	3	14.3	
Class 3	20	95.3	None	None	
Class 4	1	4.7	None	None	

saphenous vein patch. Preoperative lesion involvement was the only statistically significant factor in patients who lost patency (TASC-II Class C or D). All these patients had difficult anatomical characteristics (p=0.047). The mean duration of vessel patency was 1.4±0.9 (range, 0.1 to 2.7) years. The TLR-free survival was analyzed with the Kaplan-Meier analysis and the mean rates at one, two, and 2.5 years were 93.3±6.4%, 93.3±6.4%, and 62.2±25.8%, respectively (Figure 1).

Seven patients (33.3%) had recurrence of claudication during the follow-up period. The mean duration of claudication-free survival was 1.4±0.9 (range, 0.1 to 2.8) years (28.9 patient-years). According to the Kaplan-Meier analysis, the mean claudication-free survival rates at six months, one and two years were 84.2±8.4%, 67.4±11.0%, and 59.9±12.0%, respectively (Figure 2). The patients with recurrent claudication were also analyzed in detail. Six of these patients had DM (42.9% of all diabetic; 85.7% in total). However, no statistical significance was found (p=0.337). Similarly, HT was present in six of these patients (35.3% of all HT patients); however, it did not reach statistical significance (p=1.000). Hyperlipidemia was also present in four patients (36.4% of all patients with hyperlipidemia). However, there was no significant difference in the age of the patients (60.4±8.3 years vs 58.4±7.5 years, respectively for claudicants and non-claudicants; p=0.308). Tobacco use was the only statistically significant factor for re-claudication (p=0.047). All patients with claudication had continued use of tobacco after the procedure, which was 50% of all smokers (p=0.047).

Amputation was needed in three patients during follow-up. Two of these patients had also necrotic wounds preoperatively. Major amputation (below-the-knee) was necessary 7.3 months after the procedure (4.8%). The remaining two cases had minor amputations (toe amputation one and six months after the procedure). The mean duration of major amputation-free survival was 1.6±0.8 (range, 0.4 to 2.8) years (31.6 patient-years). According to the Kaplan-Meier analysis, the six- and 12-month major amputation-free survival rates were 100% and 94.1±5.7%, respectively (Figure 3).

DISCUSSION

In the present study, we report the midterm results of DA for a femoropopliteal occlusive disease. Technical success was 100%, and the postoperative clinical improvement was significant with short

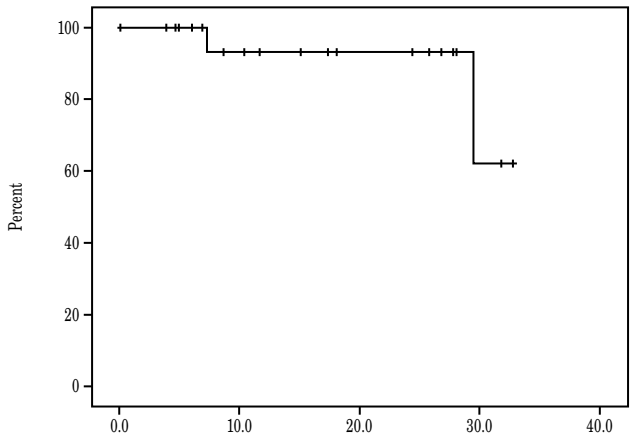

Figure 1. Target vessel revascularization-free survival.

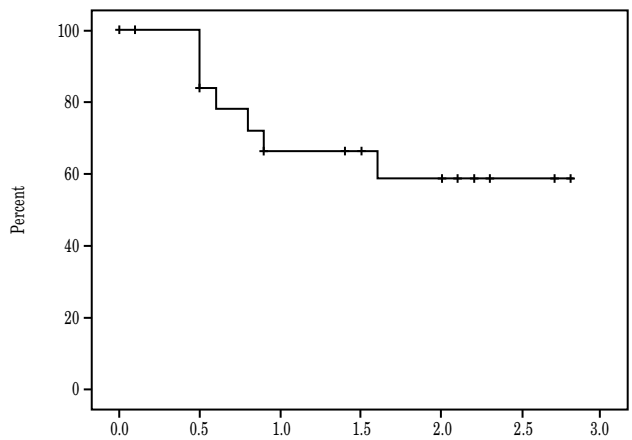

Figure 2. Claudication free survival.

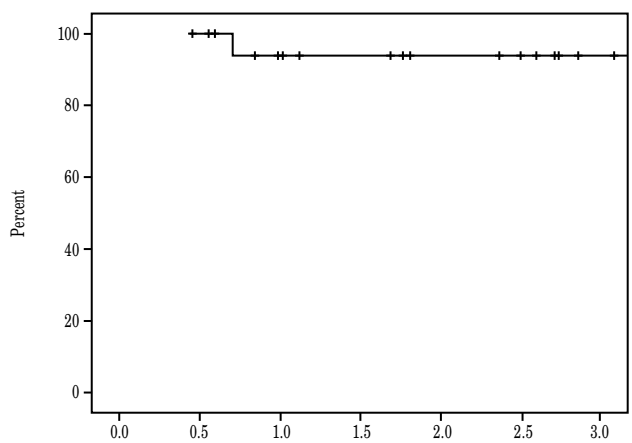

Figure 3. Major amputation free survival.

hospitalization and low complication rates. It should be noted that these successful results were obtained in a patient cohort consisting of multiple comorbidities and complex disease. Although the rates of major amputation and TLR were low, the recurrence rate of claudication was relatively high (33.3%) and most of recurrences were observed within the first postoperative year.

Diabetes, HT, hyperlipidemia, and tobacco use are risk factors for recurrence of claudication.[1] However, none of these factors, except for tobacco use, was found to be associated with recurrent claudication, probably due to the small sample size in our study. In addition, age was not found to be correlated with claudication-free survival in our study. A higher incidence of comorbidities such as additional lesions and atherosclerosis may lead to lower patency rates in elderly population. The Lutonix Paclitaxel-Coated Balloon for the Prevention of Femoropopliteal Restenosis-I (LEVANT-I) trial was also limited with the low number of cases to compare binary outcomes as clinical picture or patency and, therefore, the aforementioned study failed to compare two groups of patients.[15]

Patients with TASC-II Class A and B anatomy are less likely to show claudication or amputation.[4,15] In the univariate analysis, the procedural success was related to SFA lesions, lower stenosis rates, lack of calcification, and short lesion length.[16] Endovascular treatment success rates are more likely related to the anatomically advantageous lesions such as TASC-II class A and B type anatomy. The initial cases operated in our center mostly had similar TASC-II classes. As the experience accumulated, more patients with difficult anatomies were operated with success. Based on our experience, we recommend a clinic planning to start atherectomy procedures in a similar manner beginning with more benign lesions initially and progressing as the experience accumulates. The later patients in our patient cohort were mostly of Class C or worse (Table 2) and, yet, the technical success was 100%. The Determination of Effectiveness of SilverHawk Peripheral Plaque Excision (SilverHawk Device) for the Treatment of Infrainguinal Vessels/Lower Extremities (DEFINITIVE-LE) trial, the major study about atherectomy, reported 5.3% perforation rate and one case with distal embolization requiring an intraoperatively additional intervention with a technical success of 99%.[16] The lesion length, involved arterial segment, advanced calcification, presence of additional multi-level lesions and need for predilatation for the advancement of atherectomy catheter may increase the technical success in difficult cases. The final success is not the success of atherectomy procedure alone, but rather the ability to use endovascular modalities as a whole.

The only significant factor correlated to the patency was found to be tobacco use in our study. Tobacco use was also found to be a significant risk factor for claudication at 12 months in the DEFINITIVE-LE study which was 53.5% ($p<0.001$; n=799).[16] Although our study did not show a significant correlation with patency rates and DM, HT or hyperlipidemia, there are controversial data in the literature. The DEFINITIVE-LE study reported lower primary and secondary patency rates after surgical or endovascular interventions in diabetic patients.[16] The primary patency rate at 12 months was 60% ($p<0.05$). The prevalence of hyperlipidemia (86%; $p=0.001$) and HT (92%; $p=1.000$) were also higher in patients with claudication, but only the rate of hyperlipidemia was significant.[16] The one- and two-year patency rates in DM patients were 71.6% and 45.3%, respectively. These rates were significantly lower than the patients without DM ($p=0.027$).[17] Although six of seven patients with recurrent claudication had DM, the difference was not statistically significant ($p=0.337$). Similarly, the rates of hyperlipidemia and HT did not reach a statistical significance. This lack of differences can be attributed to the small sample size.

The mean duration of the vessel patency preservation was 1.4±0.9 (range, 0.1 to 2.7) years. In the Kaplan Meier analysis, the survival free from TLR was found to be 93.3±6.4% and 62.2±25.8% at one and two years, respectively. Another study reported the outcome results of 83 patients who underwent atherectomy and the one- and two-year patency rates were 85.0±4.3% and 64.0%±6.1%, respectively.[18] However, the patency rates may increase in the near future with recent technological developments and increased experience. Another factor which may be related to the patency may be the presence of CRD. It was shown that, in patients with a glomerular filtration rate (GFR) of >60 mL/h, the one- and two-year patency rates after PTA with DCB in patients with complex femoropopliteal lesions were 81.2±2.8% and 56.8±3.7%, respectively ($p=0.056$).[11] However, these rates were significantly lower in patients with GFR <60 mL/h at one and two years (70.3% and 39.4% vs. 81.2% and 56.8%; $p=0.056$).[17] The lack of a significant difference in the patency rates in CRD patients in our series may be due to the small sample size.

As it is shown in Table 1, most of the patients had several comorbidities; however, no mortality was seen in any case. This is one of the main advantages of endovascular procedures. In a study analyzing the 24-month follow-up results of DCB (n=220) and PTA (n=111), mortality was seen in 17 patients with comorbidities.[19] The mean time from the procedure to mortality was 564.5 days in DCB group and 397 days in PTA group (p=0.008).[19] In addition, we did not observe early (at one month) major amputation in any cases. Many PAD patients with multiple comorbidities are not seen eligible to open surgery due to the high operative mortality. Treatment of such patients requires a guideline-based planning and the use of endovascular therapy to decrease cardiovascular mortality.[18]

Almost two-third of the patients in our study had TASC-II Class D lesions. Similar to the literature, all patients with restenosis had difficult anatomies (60% of cases TASC-II Class C), and the difference was statistically significant (p=0.047). The rate of TLR was 4.8%. Based on these findings, we conclude that difficult anatomy is one of the important predictors of restenosis.

The mean duration of major amputation-free survival was found to be 1.6±0.8 (range, 0.4 to 2.8) months (31.6 patient-years). The Kaplan Meier analysis showed that the rate of major amputation free survival at six and 12 months were 100% and 94.1±5.7%, respectively. In the Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency (DEFINITIVE-AR) study, one-year major amputation free survival rate was 95%, which is consistent with our findings.[16] The patients with TASC-II Class C and D anatomy were likely to have amputations more than Class A and B patients.[16] One patient with TASC-II Class C anatomy required major amputation in our series. To detect restenosis timely, a closer follow-up protocol should be used for patients with difficult anatomies. Our results revealed that most of the restenosis were seen within the first year of the index procedure. Therefore, we amended our follow-up program to every three months after the procedure within the first year. A more frequent office visit follow-up program may be helpful to detect claudication and loss of patency timely and necessary precautions should be taken to increase patency rates.

Limitations of the study

The primary drawback of this study is its small sample size. One of the most important reasons can be explained by the difficulties in using the catheterization laboratories in Turkey. A cardiovascular surgeon is still deemed as a guest in the cath lab, and a hybrid operating theatre is mostly still far from reach. With the increased number of facilities, the number of cases treated by endovascular techniques would surely increase. Another important reason is the ability to make different choices in the treatment of different lesions through different atherectomy techniques.[20] The effect of DM, HT, and hyperlipidemia was unable to be detected due to the low number of cases. The second limitation is the retrospective nature of our study. Despite these limitations, however, we were able to detect the correlation of tobacco use and claudication and the recurrence of claudication within the first year after the procedure. Having practical effects, the study has an important value in this aspect.

In conclusion, DA provides an important endovascular treatment possibility in patients with femoropopliteal occlusive diseases with successful results and low mortality and morbidity rates. This technique can be, thus, performed with high technical success rates even in patients with comorbidities. A high rate of patients shows significant clinical improvement; however, claudication may recur within the first year after the procedure, particularly in patients who are still using tobacco. Irrespective of the difficulty of the lesion in anatomical aspect, DA provides an important therapeutic tool for the endovascular arsenal. Follow-up results may be further improved by enhanced control of tobacco use.

Declaration of conflicting interests

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