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Single center experience with percutaneous peripheral atherectomy with the use of C-arm scopy for the treatment of lower extremity peripheral artery disease

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ABSTRACT

Objectives: This study aimed to present our results of endovascular procedures including balloon angioplasty combined with or without atherectomy for the treatment of iliofemoral and distal lesions with the use of a C-arm scopy.

Patients and methods: The retrospective study was conducted on 153 patients (100 males, 53 females; mean age: 60.2±2.1 years; range, 53 to 82 years) with the diagnosis of peripheral artery disease between January 2017 and January 2020. The symptoms of the patients were claudication, rest pain, or tissue loss. The operations were performed at the operation theatre with local or spinal anesthesia in a supine or prone position according to the lesion status. Lesions were classified as superficial femoral, popliteal, and distal lesions below the knee.

Results: Interventional treatment was applied in all patients, and 272 lesions in 204 extremities were intervened. In 78 patients, 160 right leg lesions were treated, and in 75 patients, a total of 112 lesions were treated. Fifty-one patients had bilateral leg lesions. The number of iliac, superficial femoral, and popliteal and distal segment lesions was 30 (11.1%), 213 (78.3%), and 29 (10.6%), respectively. Most of the lesions were confined to the SFA. We performed percutaneous transluminal angioplasty procedures in all 153 patients; however, 143 of them also received atherectomy with two different reliable devices (Avinger in 45 patients, Invamed in 114 patients). All interventions were done on a standard operating theatre bed with a C-arm scope. Doppler ultrasonography was used for popliteal imaging during the insertion. We did not encounter any problems in 125 patients. In 28 patients, progress was observed in the leg or ischemic wound between 30 and 65 postoperative days. A total of 23 patients required amputation; amputations were minor (finger amputation) in five patients and major (below the knee) in 18 patients.

Conclusion: The perioperative and mid-term follow-up results of our study indicate that atherectomy and drug-coated balloon angioplasty may safely be performed by C-arm scopy with favorable outcomes.

Keywords: Atherectomy, C-arm scope, percutaneous, peripheral artery disease.

Atherosclerotic peripheric arterial disease may present with claudication, rest pain, critical leg ischemia, or gangrene. It is known that over 200 million people worldwide are affected by peripheral artery disease (PAD), and the prevalence significantly increases with age.[1-4] The prevalence of PAD is approximately 20% in the age group above 70 years,[5] and approximately 30% of men and 40% of women above the age of 80 are affected by the disease.[4] The burden of PAD-related treatment on the healthcare system is $4.37 billion in the USA.[6] The most advanced form of PAD is critical leg ischemia, which accounts for 1 to 3% of all patients with PAD.[7]

Treatment options for lower extremity ischemia include conservative treatment, bypass surgery, endovascular options, and primary amputation. Bypass grafting has been the main treatment strategy so far for the treatment of symptomatic PAD.[8,9] However, bypass surgery requires prolonged recovery time and has high complication rates.[10] These complications can be classified as graft infection, thrombosis of the graft, distal embolization, edema in the lower extremity, and complications of the incision site, such as dehiscence and infections.[10] Consequently, endovascular treatment modalities have increased in popularity in the last few years.

In this study, we aimed to present the preoperative and postoperative follow-up results of the patients

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with lower extremity PAD who underwent balloon angioplasty in combination with atherectomy by C-arm scopy.

PATIENTS AND METHODS

The retrospective study was conducted on 153 patients (100 males, 53 females; mean age: 60.2±2.1 years; range, 53 to 82 years) with the diagnosis of PAD at the Department of Cardiovascular Surgery, Bozyaka Training and Research Hospital between January 2017 and January 2020. The pathology was diagnosed by computed tomography angiography or digital subtraction angiography in all patients. The symptoms of the patients were claudication, rest pain, or tissue loss. Exclusion criteria were having a contrast allergy, an allergy to paclitaxel, and a life expectancy of less than six months. In patients with multiple lesions, the treatment was started from the proximal lesion, followed by the management of the distal lesions. Lesions were classified as superficial femoral, popliteal, and distal lesions below the knee.

Percutaneous transluminal angioplasty (PTA) in combination with atherectomy was applied in 143 (93.4%) patients, and sole PTA was applied to 10 (6.6%) patients. Sole PTA was performed in patients with less calcified lesions that could be easily passed through and successful revascularization. However, patients with advanced stenosis or occlusion initially underwent atherectomy to reduce the calcification load and ease the balloon's passage through the lesion. Following atherectomy, PTA was performed for residual stenosis. Percutaneous transluminal angioplasty applications were executed with an Extender drug-eluting balloon (INVAMED, Ankara, Türkiye) in all patients. The atherectomy procedures were performed with Avinger (Avinger Inc., Redwood City, CA, USA) in 45 patients, and Invamed (INVAMED, Ankara, Türkiye) was used in 98 of the patients.

The procedure was performed with a retrograde or antegrade approach. A popliteal retrograde approach was used with spinal anesthesia for patients with superficial femoral artery (SFA) lesions in the prone position only, and the antegrade procedure was performed from the femoral area for patients with SFA and distal lesions under general anesthesia. Doppler ultrasonography (USG) was used to minimalize vascular trauma.

Since the plaque load was heavy in some lesions, it was necessary to increase the duration of the scope acquisition during the procedure when it was difficult to advance the support catheter or wire. In addition, long-term use of the C-arm scope was required in the patient group with iliofemoropopliteal and long-lasting mixed lesions. In such cases, the device was turned off by following the warming warnings to prevent the device from overheating, allowing it to cool for approximately 5 min, and the process was continued when it was noticed that the scope had cooled down. Apart from this heating problem, no technical difficulties were encountered during the C-arm scopy. Angioplasty procedures with the C-arm scope, which can also be found in centers that do not have an angiography unit, were successful. A technician who is present in the operating room is usually required to use the device. In the use of the device, as the primary surgeon, we control the image quality and the opaque amount given by foot control. No complications or technical injuries involving the vascular and surgical team were encountered during the procedure. In the operation room, the graft-covered stents, which are prepared according to the sizes of the iliac arteries of the patients, were ready in case of need during the operation of the patients with iliac lesions.

We aimed to complete revascularization in one session for the patients with multiple lesions. Patients were followed after the first week, twice a week in the first three months, and once a month for the next three months. In the six-month follow-up, the symptoms of the patients, including claudication, were assessed.

Endovascular interventions

The operations were performed at the operation theatre with local or spinal anesthesia in the supine or prone position according to the lesion status. In general, for the patients who only had an iliac lesion, local anesthesia was preferred by the physician and the patients. In patients with only iliofemoral lesions or SFA lesions, spinal anesthesia with the prone position was the chosen modality for the proximal vasculature imaging by popliteal arterial intervention. In patients with SFA lesions beyond the popliteal artery, the antegrade route was preferred from the SFA to its distal with spinal or local anesthesia in the supine position.

All of the interventions were done on a standard operating theatre bed and with a C-arm scope

(Ziehm Imaging GmbH, Nuremberg, Germany). At the beginning of the procedures, the introducer (Invaducer; INVAMED, Ankara, Türkiye) was inserted percutaneously into the vessel to facilitate the insertion of the angiographic balloon and other necessary catheters. Afterward, a 0.035-inch guidewire (InWIRE; INVAMED, Ankara, Türkiye) was inserted through the introducer. Doppler USG was used for popliteal imaging during the insertion. After the insertion of the introducer, a sheath (Jaguar Catheter Long Sheat; INVAMED, Ankara, Türkiye) has been placed by pushing the sheath through the introduer. Either atherectomy or PTA with Extender was decided for the patients according to the status of the lesions, which were assessed by injecting contrast material for the imaging followed by a 1 mL heparin injection. After atherectomy operations, secondary PTA was applied by inserting the balloon through the introducer in cases with residual stenosis. The size of the paclitaxel-covered balloon was adjusted according to the size of the vessel in PTA. The time of the inflation of the balloon was 60-100 secin all patients. In patients with 30 to 40% residual stenosis after primary PTA, additional PTA with an inflation duration of 120-180 sec was applied to the residual stenotic segment. The sequence of the operations is explained in Figures 1 through 6.

In the postoperative period, the patients received 1000 IU/h systemic heparin infusion for the first 24 h and were prescribed 75 mg/day clopidogrel and 100 mg/day acetylsalicylic acid for three months and 40 mg/day atorvastatin at hospital discharge. In patients preoperatively receiving anticoagulants, a single antiplatelet drug, preferably clopidogrel, was preferred. During the follow-up, the result was accepted as a failure if the patient developed vascular stenosis, occlusion, or underwent major amputation.

Statistical analysis

Statistical analysis was carried out using the SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA). The demographic data were expressed in mean ± standard deviation.

RESULTS

Interventional treatment was applied in all patients, and 272 lesions in 204 extremities were intervened. In 78 patients, 160 right leg lesions were treated, and in 75 patients, a total of 112 lesions were treated. Fifty-one patients had bilateral leg lesions.

The demographic features, including age, sex, smoking history, diabetes mellitus, hypertension, hyperlipidemia, coronary artery disease, and chronic renal disease, are presented in Table 1. The clinical status of the patients, such as claudication, resting pain, or tissue loss, were also presented in Table 1. The patients with ischemic wounds were compared with the patients with intact extremities, and no statistically significant difference was observed (Table 1).

Usage of at least one antihyperlipidemic, antihypertensive, or antidiabetic agent was accepted as having comorbidity (hyperlipidemia, hypertension, or diabetes mellitus). The patients who previously received hemodialysis and had a history of operation due to coronary artery disease were accepted as coronary artery disease patients in our study. Indications for intervention in the symptom scale were claudication in 110 (71.8%) extremities and rest pain and tissue loss (necrosis) in 43 (28.2%) extremities.

Seven patients with preoperative renal failure or receiving hemodialysis were pre-and postoperatively consulted with the nephrology department. According to suggestions, hemodialysis was scheduled for the morning before the operation or 12 h before the operation and the first postoperative 12 h. The existence of renal damage was controlled

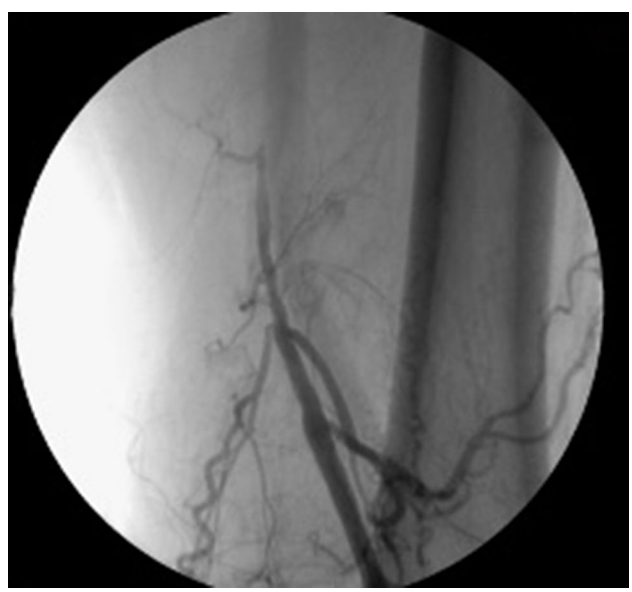

Figure 1. The contrast media image shows the distal lesion in the right SFA, and it is observed that the popliteal artery is open in prone position.

Table 1
Demographic characteristics of the patients according to the presence of ischemic wounds

	Ischemic wound is present	Ischemic wound is not present	
	n	n	Total
Sex			
Male	48	52	
Female	25	28	
History of intervention or operation	24	8	
Diabetes mellitus	40	24	64
Hipertension	43	40	83
Hyperlipidemia	42	39	81
Coronary artery disease	33	38	71
Chronic kidney disease	4	3	7
Cerebrovascular event	6	8	14
Smoking	55	49	104

Mixed lesions: The presence of 60-70% and above lesions in the iliofemoral popliteal and distal below-knee beds.

with biochemical examinations. The postoperative period was uneventful. In addition, we limited the use of opaque to describing the lesion at the beginning of the procedure and observing the result at the end of the operation. We used approximately 40 to 50 mL of opaque in these patients and approximately 70 to 100 mL in other patients.

The length of the patients' extremities and the location of the lesions were recorded. Accordingly, the number of the patients who had iliac lesions was 30 (19.6%), the number of patients with SFA lesions was 94 (61.4%), and the number of patients with popliteal and distal lesions was 29 (18.9%) (Table 2).

The number of iliac, SFA, and popliteal and distal segment lesions was 30 (11.1%), 213 (78.3%), and 29 (10.6%), respectively. Most of the lesions were confined to the SFA. We performed PTA in all 153 patients; however, 143 of them also received atherectomy with two different reliable devices (Avinger in 45 patients, Invamed in 114 patients).

In 23 patients with iliac lesions who had lesions with >70% stenosis, only balloon angioplasty was

Table 2
The locations and the numbers of the lesions treated

	Ischemic lesion is present	Ischemic lesions is not present	
Number of the lesions	n	n	Total
External iliac artery	9	11	20
Common femoral artery	14	17	31
Superficial femoral artery	26	24	50
Popliteal artery	14	18	32
Below the knee	10	10	20
Mixed lesions	140	132	272
Side			
Right	45	59	114
Left	28	21	49

Mixed lesions: The presence of 60-70% and above lesions in the iliofemoropopliteal and distal below-knee beds.

Table 3
Postoperative data

	Ischemic wound is present	Ischemic wound is not present
	n	n
Mortality (independent from the operation)	4	1
Amputation		
Minor	4	1
Major	17	1
Revision	2	1
Infection	12	0

applied. In this group of patients, residual stenosis was not detected, and atherectomy was not required. For the rest of the cases (seven patients), which had approximately ≥90% stenosis, atherectomy in combination with PTA was the chosen modality for the residual stenosis management and stabilization of the plaque in the vessel. In one case, minimal intra-abdominal extravasation of the contrast media was detected, and the stent was implanted, uneventfully finalizing the operation. The patient was followed with abdominal USG and a complete blood count. No complications were observed after three days of hospital stay, and the patient was discharged on the third postoperative day. The mean follow-up period was 596±102 days, ranging from six months to two years. Five (3.2%) patients died due to complications of diabetes mellitus and coronary artery disease, and 23 (15%) patients underwent amputation in the two-year follow-up period. The mean hospital stay of the patients was 2.3 (range, 1-4) days.

No vascular aneurysm, dissection, rupture, pseudoaneurysm, arterial perforation, arterial tear, arterial spasm, arteriovenous fistula, bleeding, emboli, arterial thrombosis, urgent or nonurgent need for arterial bypass surgery, and hematoma were encountered during all procedures. Table 2 demonstrates the lesions and treatment applications in patients with PAD in the cohort.

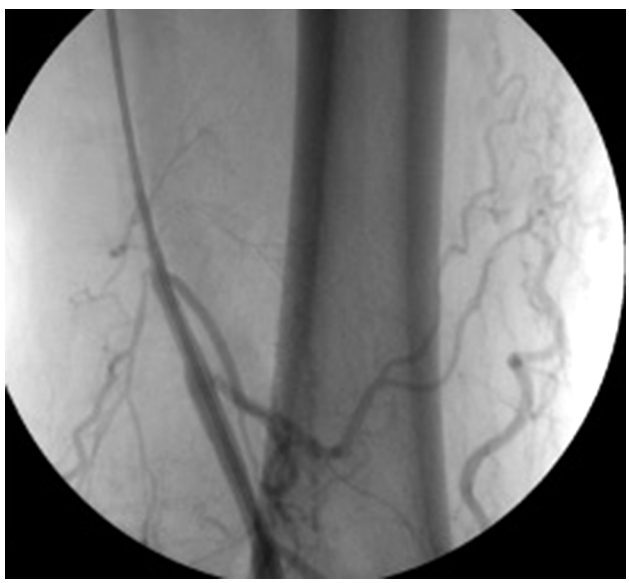

Figure 2. The image shows the movement of the wire inside the support catheter proximal to the popliteal artery.

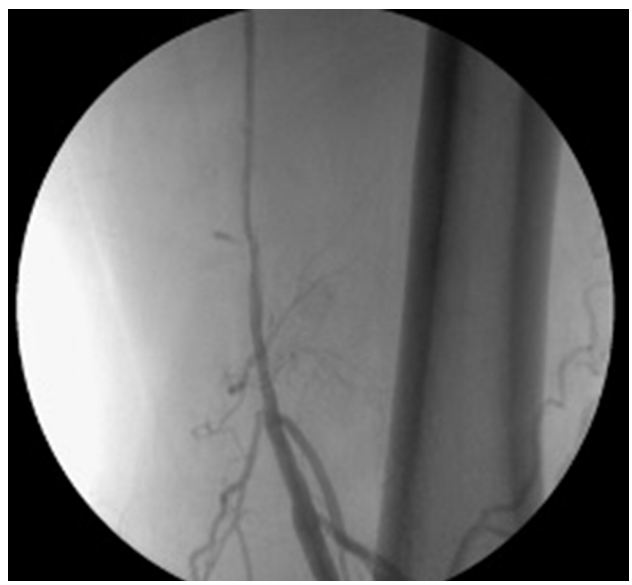

Figure 3. This image shows the wire inside the lesion after retracting the support catheter.

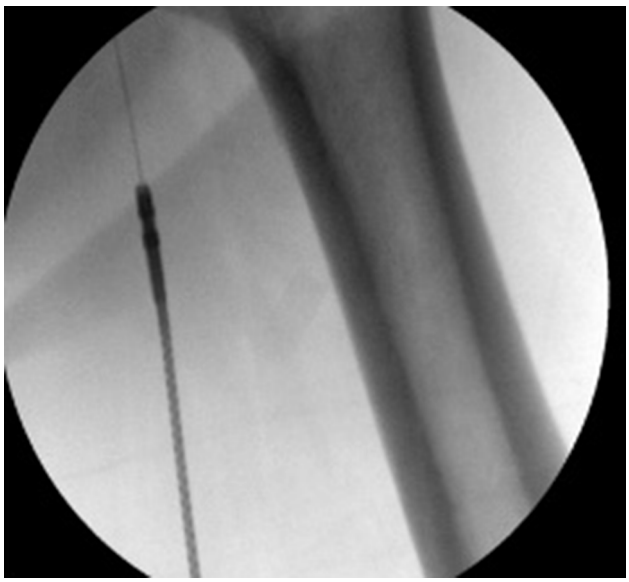

Figure 4. In this image, atherectomy device is pushed forward over the wire inside the SFA through the stenotic lesion.

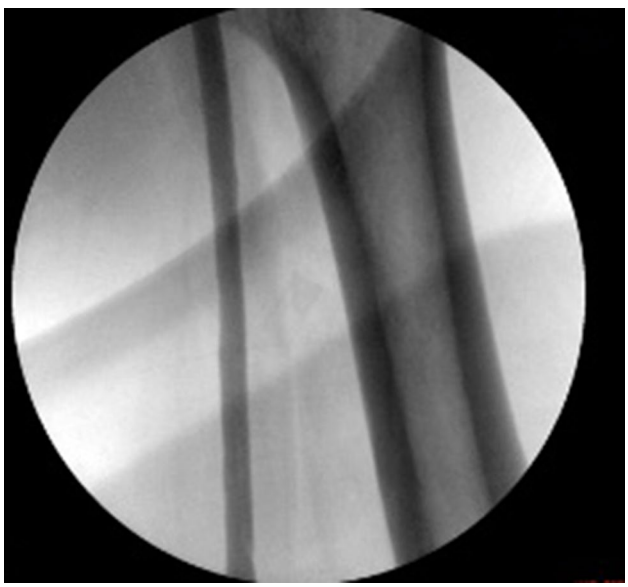

Figure 5. This image shows how PTA is applied to the lesion after the atherectomy.

DISCUSSION

Atherectomy devices and other instruments, such as balloons and stents, have been developed for the treatment of PADs. Balloons and stents are sometimes insufficient when used alone due to the variations in anatomical structures and status of the plaques and

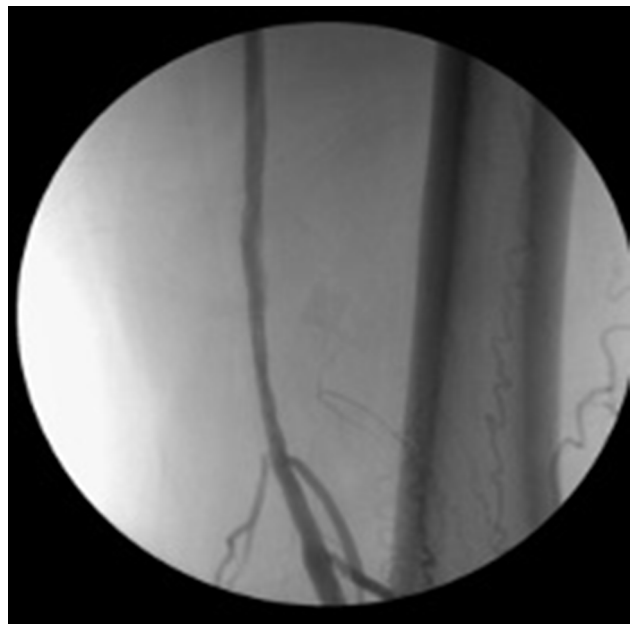

Figure 6. In the image, the SFA can be observed after the lesion is resolved by the procedure.

calcifications in the vascular structures. In general, atherectomy devices are used in circumstances such as high rates of occlusions in the vasculatures caused by the stenosis and hard calcific plaques. Nonetheless, balloons or stents can be used in cases with low levels of stenosis or soft lesions.[11]

In the last 20 years, endovascular treatment options have been the primary modality against claudication and even in critical ischemia of the extremities in several clinics.[12] It has been shown that endovascular treatment has some advantages, such as fast return of the patients to daily activities, decreased time of hospital stay, minimal morbidity, lower hospital charges, and decreased rate of complications to the lower extremity.[13]

It was stated in the DEFINITIVE-LE study that directional atherectomy, which mechanically removes the plaque burden and opens the lumen of the vessel without leaving a stent inside the vessel, is safe and effective in the treatment of the patients, including both the those with claudication and critical leg ischemia.[14] In addition, drug-coated balloons and plain old balloon angioplasty (POBA) were compared in several clinical trials, such as LEVANT 1 and 2, IN.PACT SFA, and ILLIMENATE.[15-18] Thus, it is now known that drug-coated balloons are superior

to POBA in treating short to intermediate lesions. Additionally, drug-coated balloons are superior in anatomical outcomes, such as primary patency, binary stenosis, late lumen loss, and target lesion revascularization, compared to POBA.[19-22]

Minimally invasive endovascular treatments include PTA, PTA with additional stent placement, cold-balloon PTA or cryoplasty, and atherectomy with directional, laser, or orbital volume removal methods.[23]

The principal action of atherectomy devices is reducing the plaque burden by shaving or pulverizing the plaque by piercing or sanding it. In the meantime, this procedure causes minimal barotrauma in the vessel. We can classify the acute complications as dissection or acute occlusion. Potential complications of the atherectomy devices are hematoma, pseudoaneurysm, distal embolization, and tearing of the vessel.[23,24]

In our study, 130 patients with SFA and distal lesions underwent atherectomy with PTA, and 23 patients with iliac lesions had pure PTA without atherectomy. Percutaneous transluminal angioplasty was used for residual stenosis or plaque stabilization after the plaque load was reduced by atherectomy in SFA and complicated lesions. In the group with 29 popliteal and distal lesions, the lesion in the distal popliteal artery was approached as an SFA lesion in 11 patients, and an atherectomy was performed on the distal part of the popliteal lesion up to the distal bifurcation, and PTA or only PTA was performed on the area up to the distal bifurcation not to cause injury to the vessel wall.

It is important to know that complicated lesions may cause unfavorable outcomes, particularly in long-term management. In cases with critical leg ischemia, endovascular revascularization increases the rate of survival of the extremity.[24]

Our study mostly contains patients with SFA and distal popliteal lesions. Percutaneous endovascular treatment is more suitable for these patients as it decreases the time of hospital stay and reduces the rate of mortality and morbidity. However, chronic long segment occlusions in arterial vasculature, widespread calcifications, and involvement of more than one segment cause a decrease in the success of percutaneous endovascular interventions.[25]

In the BASIL study done in the United Kingdom, a comparison between the efficacy of bypass surgery and angioplasty in the treatment of patients with severe leg ischemia was evaluated.[13] They determined that there was no difference between the six-month survival and amputation rates between the two groups; however, cost of the treatment was higher in the surgery group. The immediate primary success rate of endovascular therapies was 75%.[26]

In our clinic, we use surgical therapy as an option in appropriate patients. The patients who underwent surgical therapy were not included in this study. The patients who could not tolerate graft insertion due to severely infected ulcers, had unregulated diabetes mellitus, preferred endovascular treatment, and had suitable lesions underwent endovascular therapies. Medical treatment is another option in these patients, particularly in diabetic patients with foot ulcers and PAD, and adjuvant therapies, such as platelet rich plasma (PRP), have been found to be beneficial.[27] We used medical treatment, including antiaggregant drugs, antithrombotic drugs, and cilostazol in the management of some patients.

The cost of the treatment was not evaluated in our study; however, the mean hospital stay of the patients in our study was 2.3 (range, 1-4) days, which is less than the 5.7 days of hospital stay needed after the bypass.

Due to the low rate of long-term patency rates of standard balloon angioplasty and stents, several studies have used drug-eluting stents and drug-coated balloons to search for an effective endovascular treatment modality. Dake et al.[28] suggested in their study that the patency rates of paclitaxel-coated stents used in SFA stenosis were significantly greater than the ones that only PTA was used, and the patency rates were 83.1% and 32.8% respectively. In the last few years, drug-coated balloons have been thought to be effective in percutaneous interventions; however, no significant difference between drug-coated balloons and conventional balloons has been found.[29,30] Rosenfield et al.[20] found that 12-month patency rates of drug-coated balloon angioplasty and standard balloon angioplasty methods are 65.2% and 52.6%, respectively. In our study, we used drug-coated balloons only to eliminate future complications and increase the patency rates.

Unlike the angioplasty and stenting, which push the plaque to the vessel wall, atherectomy, which uses directional and rotational movements in combination

with physical or ablative technics, takes out the plaque burden out of the vessel. Atherectomy can be used alone or in combination with stenting or angioplasty. Restenosis after the atherectomy operation has not been fully understood; however, there are some links between few mechanisms.[33] Plasma proteins, C-reactive protein, serum amyloid A and fibrinogen are sensitive, specific and sensitive reaction markers of the acute phase,[31] cytokine-dependent indirectly they indicate the inflammatory process of the arterial wall.[32] Restenosis is mainly due to excessive neointima formation.[33] In our study, no restenosis cases occurred in the early period (first 24 h after the operation). The usage of intraoperative and postoperative antiaggregant and antithrombotic agents was considered to have prevented early restenosis.

Percutaneous intervention causes mechanical trauma to the vessel. Vascular stimulants induce vascular inflammation. The proliferation of smooth muscle cells and extracellular matrix cause neointimal thickening and restenosis.[34] Besides the antithrombotic prescription for the postoperative mechanical trauma, diet, and hyperlipidemic agents, aiming to control LDL to below 100 and triglyceride to below 200, were preoperatively prescribed to the patients with hyperlipidemia.

Risks associated with superficial atherectomy femoral, popliteal, anterior tibial, posterior tibial, and peroneal arteries include arterial dissection, arterial perforation, arterial tear, arterial spasm, arteriovenous fistula, bleeding, emboli, arterial thrombosis, urgent or nonurgent need for arterial bypass surgery, complications of the incision site, restenosis of the treated segment, occlusion in the peripheric vessels, and vascular complications.[35,36] The most common vascular complication is distal embolization; however, the prevalence of the distal embolization can be reduced with the postoperative usage of acetil salisilic acid (ASA) and clopidogrel.[37,38]

Doppler USG-guided popliteal intervention in the prone position was shown to be an alternative to the femoral intervention in patients with iliac and SFA lesions but not in popliteal or distal lesions. For this operation, USG was used to examine the popliteal arterial calcification before the operation. In our study, distal embolic protection devices were not used.

Some recommendations to optimize the outcome of peripheral atherectomy and minimize the risk of procedural complications are as follows: using the contralateral access in cases other than distal lesions, preferring the antegrade approach for better management, making slow and methodical cuts, advancing the cutting blade slowly, and ensuring adequate anticoagulation (aiming for an activated clotting time between 275 and 300 sec) to avoid thrombotic complications during the procedure.[39,40]

The success of endovascular treatments depends on the localization, length, and degree of stenosis. Literature includes many studies that demonstrate the high patency rates of iliac artery stents in the long term, but it is still controversial in the distal region.[41] Drug-coated balloons were related to distal embolism in some studies. However, Fukai et al.[42] revealed that drug-coated balloon-induced distal embolisms were not common in femoropopliteal lesions. We mostly used drug-coated balloons in upper knee lesions and avoided their use in patients with distal gangrenous lesions.

In our cases with an antegrade or retrograde approach, thrombotic complications were tried to be avoided by administering 1 mL of intravenous heparin after sheath placement to the patient without activated clotting time follow-up. All patients were checked for the presence of a thrombus on the sheath tip while the postoperative sheath was withdrawn. Furthermore, the patients' postprocedure foot color and fingers were checked for distal microembolism.

We did not encounter any problems in 125 patients. In 28 patients, progression of the disease was observed in the leg or ischemic wound between 30 and 65 postoperative days. Twenty-three (%15) patients required amputation; 20 of the 40 patients with necrotic wounds showed progression of necrosis leading to amputation after approximately 30 days. Amputations were minor (finger amputation) in five patients and major (below the knee) amputation in 18 patients. These patients with progressive disease had femoropopliteal, distal, and multiple lesions. Most of these patients had advanced calcified lesions with a poor distal vascular bed. More than half of these patients were diabetic.

When it is necessary to share the scope with other departments in the operating room, it can be challenging to determine the surgery day and schedule the patients into one day.

In conclusion, certain interventional endovascular procedures can be performed with the C-arm fluoroscopy. We evaluated the success of our

procedures as the satisfaction of the physician and the patient, the short postoperative stay, and, most importantly, the absence of major complications. Moreover, the ergonomics of all the materials used during the procedures, including the use of the C-arm scopy, and their of use facilitated the procedures. In the era of modern hybrid operating rooms, we recommend its use for arterial lesion treatment C-arm for surgeons in centers lacking experienced hybrid theaters I wanted to show that arterial intervention can be done with fluoroscopy.

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Ethics Committee Approval: The study protocol was approved by the Bozyaka Training and Research Hospital Ethics Committee (Date/no: 13.10.2021/ 2021/176). 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.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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