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Research article

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Two-year outcomes in patients undergoing rotational atherectomy and drug coated balloon therapy for chronic total occluded peripheral arterial diseases: A retrospective cohort study

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Ethics Committee Approval
Ethics committee approval was given by Istanbul Medipol University Non-Invasive Clinical Research Ethics Committee with a decision number of 361 at the date of 03.18.2021.
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Atherectomy is a minimally invasive endovascular surgery technique for removing atherosclerotic plaques in stenosed arteries. It seems to increase the success of angioplasty in the treatment of peripheral artery disease. We aimed to evaluate the outcomes of patients who underwent rotational atherectomy and drug-coated balloon therapy.

Methods: In this retrospective cohort study, thirty-four patients who underwent rotational atherectomy and drug-coated balloon angioplasty between August 2016 and January 2019 were evaluated. The Rotablator System (Boston Scientific Corporation; Scimed, Plymouth, MN, USA) was used in all cases. Drug-coated balloons were used in the femoropopliteal section in all patients.

Results: The mean age of patients was 65.55 (8.36) years. Seventeen had diabetes mellitus, for which 12 were using oral antidiabetic drugs and 5 were using insulin. At the 3rd postprocedural month, 94.1% of patients (n=32) had no clinical symptoms ($P<0.01$), two patients needed additional procedures such as balloon angioplasty and stenting due to decreased blood flow and severe stenosis of the superficial femoral artery. At the 1-year follow-up, while 2 patients needed surgery, one needed stenting to the superficial femoral artery. Within 2 years, 27 patients (79.4%) were clinically stable without any symptoms and 2 patients had undergone surgery.

Conclusion: Atherectomy devices have become a major tool in the management of peripheral vascular disease. Opening the natural lumen of the arteries gives the patient more time before open vascular surgery.

Keywords: Rotational atherectomy, Balloon angioplasty, Peripheral arterial diseases

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Introduction

Peripheral arterial disease (PAD) is one of the most common diseases which increases with age. More than 20% of the >70-year-old population has a PAD. It also aggravates the risk of cardiovascular morbidity and mortality about 5 to 6 times [1].

Atherectomy is considered a minimally invasive endovascular surgery technique for removing atherosclerotic plaques in stenosed arteries. It seems to increase the success of angioplasty in the treatment of a PAD [2, 3].

When blood cannot pass through the arteries to nourish the peripheral tissues due to atheroma plaques, various symptoms, such as ischemia, pain, pulseless, claudication, coldness, loss of sensation, and motor dysfunction occur. The refinement and use of endovascular procedures in the treatment of PAD continue to grow at a rate of about 4.8% per year, hence, the rate of surgical procedures decreases at a rate of 6.6% [4, 5]. This study aimed to evaluate the 2-year follow-up results of 34 patients who underwent rotational atherectomy and drug-coated balloon therapy.

Materials and methods

Study design

Ethics committee approval was granted by the Ethics Committee of Istanbul Medipol University on 03.18.2021, with the decision number 361. All patients or their legal representatives signed informed consent forms before hospitalization.

The data of consecutive patients who underwent rotational atherectomy or drug-coated balloon angioplasty between August 2016-January 2019 were evaluated retrospectively. The findings of the patients were recorded from the hospital records and patients' files. All patients had symptoms of PAD and total occlusion was determined by CT angiography.

Our first choice in the treatment of patients with moderate renal insufficiency not on dialysis and previously occluded, stenotic arteries was open surgical repair for atherectomy. In three patients, the superficial femoral artery was occluded proximally, and the guidewire could not be passed antegrade or retrograde from the popliteal artery. In these patients, femora-popliteal bypass was the treatment of choice, and they were excluded from the study.

Procedures

Patients' lesions were preoperatively determined by CT angiography. All patients received acetylsalicylic acid, statin, and cilostazol if they had severe distal lesions [6]. Local anesthetics and midazolam were administered. The artery was punctured with the aid of ultrasonography. The femoral sheath was inserted, and 5000U of intra-arterial heparin was given for anticoagulation. In proximal lesions, the arterial puncture was performed contralaterally with the crossover technique or brachial access was achieved first, and after dilatation of common iliac arteries, the crossover technique was performed from other extremities, as in the case shown in Figure 1. We also used the ipsilateral antegrade approach in cases of mid and distal SFA lesions. Hydrophilic guidewires were preferred to pass through the arteries, but in totally occluded lesions, naviCross 0.018" support catheter (Terumo) was used. The Rotablator System (Boston Scientific Corporation; Scimed, Plymouth, MN, USA) was used in all cases, after which drug-coated balloons were used in the femoropopliteal section of arteries. In the infrapopliteal target vessels, lesser-sized guidewires of 0.014 were utilized.

Figure 1 shows the pre-procedural CT angiography of a patient and Figure 2 depicts the preoperative DSA angiography of the occluded SFA. The post procedural rotational atherectomy and recanalization of the SFA is shown in Figure 3. The distal pulses of this patient were palpable both after the procedure and during the follow-up period of 2 years. The patients were heparinized for 24 hours to ensure an aPTT level between 50-70. Then they were discharged with acetylsalicylic acid (100 mg/day) and clopidogrel (75 mg/day) [6]. In bilateral cases, the other side was intervened one week later.

Figure 1: Diagnostic CT Angiography of a patient with distal aorta, bilateral iliac and femoral arterial occlusion and multiple stenosis

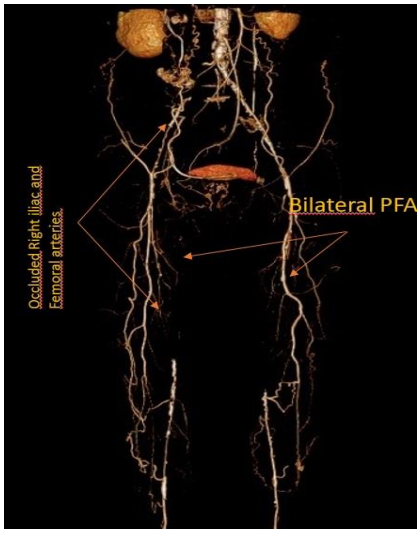


Figure 2: Preprocedural DSA angiography of an occluded right superficial femoral artery

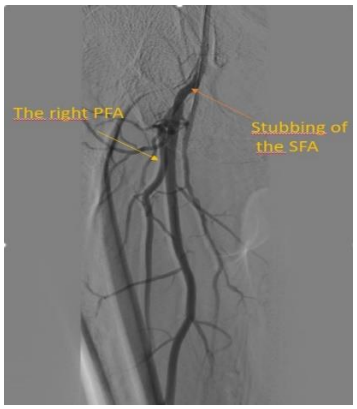
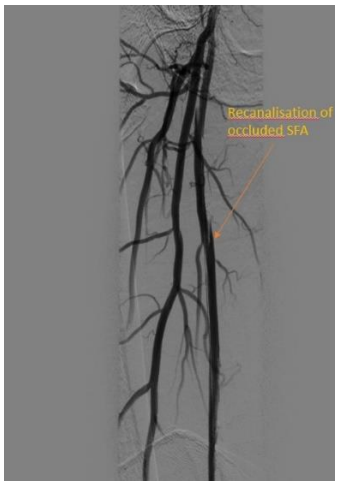


Figure 3: Postprocedural DSA angiography of the right superficial femoral artery



Statistical analysis

The analyses were performed with the Statistical Package for Social Sciences (SPSS) software. The variables were presented as percentages for categorical variables and mean and standard deviation. The Pearson correlation coefficients were used for correlation analysis. A *P* value of<0.05 was considered statistically significant.

Results

A total of 34 patients were enrolled in the study. There were 23 males (67.64%) and 11 females (32.35%). The mean age of patients was 65.55 (8.36) years. Seventeen patients had diabetes mellitus, 12 were using oral antidiabetic drugs and 5 were using insulin for diabetes mellitus. Ten of 17 diabetic patients were male (58.82%). Ten patients smoked one packet of cigarettes per day. Ten had hyperlipidemia, for which they were using antihyperlipidemia medications (Table 1).

Table 1: Patients' demographic findings

		Male	Female	Total (n)
Gender		23 (67.64%)	11 (32.35%)	34
Diabetes Mellitus	Oral Drugs use	7 (20.58%)	5 (14.70%)	
	Insulin	3 (8.82%)	2 (5.88)	17 (50%)
Smoking		8 (23.52%)	1 (2.94%)	9 (26.47%)
Hyperlipidemia		6 (26.47%)	4 (20.58%)	10 (29.41%)

The symptoms of patients included claudication in less than 50 meters, resting pain (n=15) and ischemic lesions or necrosis (n=7). The mean ABI was 0.57 (0.17). All patients' CT angiographies was investigated, based on which the atherectomy procedure was performed (Figure 1). In terms of Rutherford classification, 14 patients (41.17%) were grade 1, category 2 with moderate claudication, 6 (17.64%) were grade I, category 3 with severe claudication, 8 (23.52%) were grade II, category 4, 6 (14.70%) were grade III category 5 with non-healing ulcer (Table 2.). Regarding TASC (Trans-Atlantic Inter-Society Consensus classification, the Number of Type A, Type B, Type C, Type D patients were 3, 5, 11, and 15, respectively. Six cases had bilateral SFA lesions. While ten patients had iliac artery lesions, 4 had bilateral lesions. In the anatomical evaluation of lesions regarding the GLASS classification, the number of patients with SFA grade 1, grade 2, grade 3, and grade 4 were 3, 5, 11, and 15, respectively.

Urea and creatinine levels were evaluated before atherectomy. Moderate renal insufficiency of patients not on dialysis was treated by open surgery to prevent the risk of dialysis. All patients except one were discharged in 24 hours regarding clinical findings. In physical examination, 16 patients' (47.05%) ATP pulses and 6 patients' (17.64%) both ATP and ADP pulses were palpable. While 8 patients' (23.52%) both ATP and ADP pulses were bi-phasic positive by hand Doppler (Huntleigh Mini Dopplex Handheld Doppler System), 4 patients' only ATP pulses were positive by hand Doppler examination. The primary outcomes were mortality and amputation rates, while the secondary outcomes were perioperative complications, such as hematoma, infections, cost-effectivity, and duration of hospitalization. There was no mortality, and 2 patients' amputations were performed at the metatarsal necrotic region in a month due to previous necrotic lesions, saving their heels. In clinical findings, while only two patients had hematoma at the insertion site, there was swelling and hematoma in a patient's thigh region. He needed 600 ml of erythrocyte transfusion. Once his control CT angiography revealed no extravasation, he was discharged on the 3rd postprocedural day uneventfully. The other 33 patients were discharged in 24 hours without any complications.

The clinical and angiographic findings of patients improved. In outpatient follow-ups, Doppler USG was performed. In the 3rd postprocedural month, 94.1% of patients (n=32) had no clinical symptoms (P<0.01), 2 needed additional balloon angioplasty and stenting due to decreased blood flow and severe stenosis of the superficial femoral artery. At 1 year follow-up examinations, 2 patients needed a femora-popliteal 8 mm polypropylene synthetic graft bypass, and one needed stenting to the superficial femoral artery. In 2 years, 27 patients (79.4%) were clinically stable without any symptoms and 2 patients had undergone femora-popliteal 8 mm polypropylene synthetic graft bypass (Table 3). The ankle-brachial index increased significantly from 0.57 (0.17) at baseline to 0.85 (0.24), 0.82 (0.18), 0.80 (0.21) (P=0.02) at 3 months, 12 months, and 24 months respectively.

In follow-up, patients who had the re-interventional procedures or surgical bypass operation were clinically and radiologically (Doppler Ultrasonography) stable, without any complications.

Table 2: Rutherford classification of PAD

Grade	Category	Clinical Description	n (%)
I	2	Moderate claudication	14 (41.17)
I	3	Severe claudication	6 (17.64)
II	4	Ischemic rest pain	8 (23.52)
III	5	Minor tissue loss – non-healing ulcer, focal gangrene with diffuse pedal ischemia	6 (17.64)

Table 3: Reinterventions of patients in follow up of 3 months, 1 year and 2 years

	3 months	1 year	2 years
No symptoms	32 (91.1%)	29 (88.2%)	27 (79.4%)
PTA-Stenting	2 (5.88%)	1(2.94%)	0
Surgery	0	2 (5.88%)	2 (5.88%)

Discussion

Various atherectomy devices were developed by the manufacturers with the main aim of preserving the arterial structure and decreasing restenosis rate, as well as other complications such as dissection and distal embolization. The technology is developing mainly not to disturb or block the blood flow by the destruction of the smooth luminal wall or causing subintimal dissections [7]. In our study, we used the Rotablator System of Boston Scientific Corporation; Scimed, Plymouth, MN, USA). The leading edge has the capability to shave the plaque in 360 degrees [8, 9]. The principle of these devices is to cut the atheroma plaques by layers without destruction of the intimal layer of arteries.

The debris of atheroma plaques is small and can be digested by resident cells without causing embolization [10]. Rotational atherectomy devices significantly increase the luminal area and volume so the patients' comfort increases without using stents. Very short hospitalization duration and lack of general anesthesia administration also decrease mortality and morbidity in PAD patients, which increases the cost-effectivity. The advent of atherectomy devices also increases the effectiveness of drug-coated balloons by increasing the release of paclitaxel through the arterial wall to the media layer, so the compliance and volume of arteries increase. The need for metallic stents decreases more after atherectomy procedures compared to traditional angioplasty procedures [11]. The patients are saved from long-term stent-related complications like intimal hyperplasia, broken stent, occlusion by thrombus, and access difficulties in the branching point of arteries [12, 13].

The primary patency rates with directional atherectomy were 88% and 79% in one- and two-years of follow-up, respectively, in our study. The primary patency rate approaches 60% at 12 months with directional atherectomy as a stent-alone technique, whereas orbital atherectomy in conjunction with

balloon angioplasty and stenting achieved primary patency rates of 90% [14], as in our study. Some studies indicate that about 20% of patients have restenosis and need additional interventional procedures or may lose their extremities [15]. In our study, 32 patients (91%) had no symptoms in 3-month follow-ups. This ratio decreased to 79% in two years. While 7 patients required reintervention, only 4 of the patients needed a surgical approach (11.7%). The patients' limbs were salvaged from major amputation by invasive interventions. Only the previous necrotic sections were amputated in 2 patients.

Atherectomy offers the advantages of surgical endarterectomy by removing atherosclerotic plaques while remaining a minimally invasive and percutaneous method [16]. These devices are major treatment options for peripheral vascular disease. Peripheral arterial disease patients are generally diabetics and demonstrate a gradual, age-related impairment in vascular function, which causes multiple additional pathologies requiring surgery [17]. Additional lesions in the aorta or iliac artery increase the mortality and morbidity of the surgery. Lesion morphology is an important determinant of success and long-term patency. Balloon angioplasty is the procedure of choice for iliac artery occlusive lesions. Stent placement should be reserved for angioplasty failures [18] but in our cases, all iliac arterial lesions were severe and included long segments. The desired opening of the arterial lumen could not be achieved following balloon angioplasty without stent implantation. So, we preferred to implant stents in the narrowed or occluded long-segment iliac arteries. Postoperative antiaggregant treatment also should be aggressive in longer grafts, which increases postoperative drug-related risk for bleeding complications [19].

In our study, about 50% of patients were diabetic, and the mean age was 65 years. In this age group, widespread disease also increases the risk of surgery and general anesthesia. Interventional procedures pose lower risks regarding general anesthesia, the opening of the abdomen, and results in low hospitalization duration, and decreased wound infection and bleeding. Major complications of open vascular procedures are wound complications, graft infections, and poor runoff. Occlusion and anesthesia-related complications occur at a rate of 30%. Patients with PAD are generally elderly, and patient-related risks include increased age, cardiac and renal disease, high American Society of Anesthesiologists score, and those relating to the administration of general anesthesia. The mortality within the first month was about 5% (1% for claudication and 8% for acute ischemia) and the amputation rate was 7% [20]. In our study, there were no major complications, but one patient had thigh swelling. The other patients were discharged within 24 hours with cure. Amputation was performed in 2 patients in the previously necrotic metatarsal region. In two years of follow-up, only 3 patients required open surgery. In this study, the primary outcomes were mortality and amputation rates, while the secondary outcomes were perioperative complications, such as hematoma, infections, cost-effectivity, and duration of hospitalization. Rotational atherectomy provides decreased hospitalization duration and low complication risk, especially for high-risk patients. Also, the risk of redo interventions or need for primary open vascular surgery decrease.

Limitations

The limitation of the study is the relatively low number of patients.

Conclusion

Atherectomy devices have become the treatment of choice in the management of peripheral vascular disease. Opening the natural lumen of the arteries gives the patients time before open vascular surgery.

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