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Original Article

Rotational atherectomy for below the knee lesions in critical limb threatening ischemia: Is it a wild goose chase?

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Abstract

Aim: Treatment of infrapopliteal peripheral arterial disease is still challenging. Rotational atherectomy (RA) is a novel option that aims removal of calcium from the lumen and improvement in outcomes.

Material and Methods: Data of 27 patients (19 males, 8 females; mean age: 59.8±13.7 years; range, 25 to 79 years) with infrapopliteal occlusions treated by RA between January 2017 and December 2019 was retrospectively collected. The Global Limb Anatomic Staging System (GLASS) and the Rutherford classification (RC) were used for evaluation. The objective performance goals of Conte et al. (major adverse limb event [MALE] and major adverse cardiovascular event [MACE]) were used for assessing outcome performance. Visits were scheduled at 1, 6, 12, 18, and 24 months after treatment. In each visit, symptoms, RC, wound status, smoking status, lifestyle modifications, and medications were questioned, laboratory tests and Doppler ultrasonography were carried out, and the next visit was planned.

Results: Device success was 88.89%, whereas procedural success was 100%. Unanticipated amputation rate was 11.1% in the 12-month follow-up. Over half of the patients (66.67%) showed RC improvement with a mean change of 3±1.17. Thirty-day safety endpoints were as follows: MALE, MACE, and amputation rates were 12.5%, 0%, and 8.33%, respectively. One-year efficacy endpoints were as follows: freedom from MALE+perioperative death was 71.42%, amputation-free survival was 76.19%, freedom from reintervention (amputation was 75%, limb salvage was 80%, and survival was 90.47%. Associations between RC (5-6) and calcification, chronic renal insufficiency and amputation, being a nonsmoker and failure to improve RC, and smoking and high infrapopliteal GLASS were found. Smoking cessation came with RC improvement in every case. Nonquitters experienced worsening more often compared to quitters (0% vs. 25%).

Conclusion: Rotational atherectomy is feasible and effective in infrapopliteal chronic total occlusions. Closer follow-up is suggested for nonsmokers and patients with chronic renal insufficiency or advanced GLASS stages as they are prone to unfavorable clinical results. Quitting smoking should be underlined with its potential positive clinical effect even after the procedure.

Keywords: Atherectomy, critical limb threatening ischemia, peripheral arterial disease, smoking cessation, tibial arteries

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INTRODUCTION

Peripheral arterial disease is increasing in parallel to life expectancy. For this life-limiting disease, technology offers new choices every day. In the last two decades, miscellaneous options with their advantages and target lesions have been discovered to overcome difficulties [1-3]. Infrapopliteal procedures are challenging due to the smaller caliber of arterial structures. Infrapopliteal involvement is also a sign of severity and poor outcomes [4].

In the management of below the knee lesions, although balloon angioplasty (BA) is still the standard treatment method, with technological developments, atherectomy devices are also being used as a combined treatment that can be used with BA [5-7]. They are developed with the aim to decrease atheromatous burden. Many different atherectomy devices have been developed. There are three types of atherectomy devices according to the working principles: directional (excisional), rotational, and laser atherectomy. Rotational atherectomy devices are proposed for removal of the calcification, particularly in chronic total occlusions and prevention of dissection when applied prior to BA [8,9], but there is still debate over its usefulness [10,11]. This trial aimed to add information to the literature by reporting the results of patients with infrapopliteal lesions treated by rotational atherectomy (RA) (JetstreamTM Boston Scientific Corporation, Marlborough, MA, USA) in a single center.

MATERIAL AND METHODS

The data of 27 patients (19 males, 8 females; mean age: 59.8±13.7 years; range, 25 to 79 years) with infrapopliteal chronic total occlusions (CTOs) treated with RA at Health Sciences University, Izmir Tepecik Training and Research Hospital, Department of Cardiovascular Surgery between January 2017 and December 2019 was retrospectively scanned. Data of all consecutive patients were enrolled.

Patients with symptoms of critical limb-threatening ischemia (CLTI) were questioned in terms of demographics, comorbidities, and risk factors in their first visit and referred for percutaneous treatment. Cilostazol and antiplatelet treatment were prescribed for risk factors. Training for foot care and unsupervised exercise therapy was provided for all. All patients were prescribed 20 min of daily exercise therapy daily for the first three weeks with an aim to reach 40 min per day. Patients were also educated to choose a particular track for daily comparison of pain-free walking distance and maximum walking distance and continue walking until the point of intense pain. After physical examination, Doppler ultrasonography (DUSG) and computed tomography angiography (CTA) were performed. Patients with Rutherford categories (RC) 4-6 due to calcified CTOs of tibial vessels were accepted as candidates for RA. In case of unsalvageable tissue defects, patients were referred to the foot ulcer council before the procedure for scheduling amputation.

From CTA images, lesions were evaluated for their length, calcification, extension, run-off vessels, and accompanying lesions. Patients were evaluated according to the Global Limb Anatomic Staging System (GLASS) [12]. The calcifications with involvements of more than 50% of the total length and 180° of the circumference were defined as moderate. The lesions were divided into two groups according to the existence of at least moderate calcification in the target lesion as defined previously [13,14].

Accompanying suprainguinal lesions were treated separately. Stenoses over 50% or occlusions of the superficial femoral artery were treated simultaneously. An antegrade approach through the ipsilateral femoral artery was used whenever possible.

A loading dose of clopidogrel (300 mg) was administered before the procedure. Heparin with a dosage of 100 IU/kg was administered through the access catheter that was inserted by ultrasonography guidance.

For superficial femoral artery lesions, either plain old balloon angioplasty (Mustang®; Boston Scientific, Marlborough, MA, USA) or drug-coated balloon angioplasty (IN.PACT AdmiralTM; Medtronic, Minneapolis, MN, USA) was performed at the physician's discretion. Stenting in the infrainguinal position was avoided and reserved for flow-limiting lesions.

Predilatation was performed with plain old balloon angioplasty at nominal pressure. Residual stenosis (>50%) was an indication for performing RA. Rotational atherectomy (2.1 mm-popliteal artery, 1.8 mm-tibial vessels, and 1.6 mm-pedal arch) was performed, and subsequently, BA was done. After every step, arteriography was performed to view in-line flow, details of distal runoff, and pedal arch. In the case of flow-limiting lesions, overrated prolonged BA was implemented.

Visits were scheduled at 1, 6, 12, 18, and 24 months after treatment. In each visit, symptoms, RC, wound status, smoking status, lifestyle modifications, and medications were questioned, laboratory tests and DUSG were carried out, and the next visit was planned. Worsening in RC or wound, new wound, or positive DUSG findings were indications for control CTA. When reintervention was unfavorable, a nonhealing wound was present, or systemic findings of infection were observed, the patient was referred for amputation.

The primary outcome was primary patency at 12 months. Secondary outcomes were device success, procedure success, complications, secondary patency at 12 months, primary patency

and secondary patency at 24 months, reintervention, freedom from major unanticipated amputation, RC improvement, and 30-day and overall mortality rates.

Device success was defined as the in-line flow of the target vessel after RA without additional therapies. Procedure success was the in-line flow of the target vessel after the additional therapies subsequent to RA. Primary patency was a peak systolic velocity ratio <2.4 at the target vessel at follow-up without any history of reintervention. Secondary patency was the same DUSG finding after a reintervention. Reintervention included vascular treatments performed during follow-up due to symptoms and loss of primary patency. Major unanticipated amputation was any amputation that was not anticipated before the index procedure.

We also followed the definitions of events and composite endpoints suggested for safety and efficacy measures by Conte et al [4]. in 2009 for standardization and ease in data collection for further meta-analyses. They suggested 30-day major adverse cardiovascular event (MACE), major adverse limb event (MALE), and amputation rates for key safety endpoints and defined safety cut-off rates. A MACE was defined as myocardial infarction, stroke, or death from any cause in the first 30 days after the procedure. Amputation was defined as above-ankle amputation. Reintervention was defined as any repeat vascular procedure and subdivided into major (procedures for lost primary-assisted patency) and minor (endovascular procedures without thrombectomy/thrombolysis) categories. A MALE included amputation or major reintervention.

For key efficacy endpoints, one-year freedom from MALE+perioperative death (primary) and amputation-free survival rates (secondary) were suggested for optimal performance goals (OPGs) with cut-off values of noninferiority. It was recommended to report the one-year freedom from reintervention or amputation, limb salvage, and survival rates. It was suggested to stay below the OPGs of noninferiority for these parameters.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Numeric variables were expressed as mean±standard deviation. Missing data of a specific variable was excluded, and analysis was done over existing data. Categorical variables were analyzed by the chi-square test and Fisher exact test. Student's t-test was used for normally distributed data measured on a continuous/interval scale, while the Mann-Whitney U test was used for nonnormally distributed data. Pearson's correlation test was used to measure the statistical relationship between continuous variables. Kaplan-Meier curves were used to compare the outcomes of the subgroups in terms of the primary and secondary patency. Cox regression (or proportional hazards regression) analysis was used as a method for investigating the effect of variables on the time a specified event takes to happen. The trend of change in RC was shown by a spaghetti plot. A p value <0.05 was considered statistically significant.

RESULTS

Three of the 27 patients were lost to 30-day follow-up, and six patients did not complete the one-year follow-up. Patient demographics and preprocedural characteristics are given in Table 1. The mean treated lesion length was 213.8±144.6 mm, and all lesions had a segment of CTO due to reimbursement criteria. Lesion characteristics are shown in Table 2.

Table 1. Patient demographics (n=27)

	n	%	Median	Min-Max	Q1-Q3
Age (year)			62	25-79	50.5-70.5
Male	19	70.4			
Smoker	16	59.3			
Diabetes mellitus					
Oral antidiabetics	8	29.6			
Insulin	13	48.1			
Coronary artery disease	12	44.44			
Chronic renal disease	8	29.6			
Hypertension	14	51.9			
Hyperlipidemia	11	40.7			
Rutherford category					
4	5	18.5			
5	16	59.3			
6	6	22.2			

Table 2. Lesion characteristics (n=27)

	n	%	Mean±SD	Median	Min-Max	Q1-Q3
Treated lesion length			213.8± 144.5	195	569-30	95-311.5
Lesion type						
Mixed	9	33.3				
Pure chronic total occlusion	18	66.7				
Calcification						
Mild	10	37.0				
Moderate-Severe	17	63.0				
Runoff vessels						
No vessel	5	18.5				
One vessel	12	44.4				
Two vessels	10	37.0				

SD: Standard deviation.

Procedural success was 100%, with a device success rate of 88.9%. One third of the lesions was treated adjunctive drug-eluting balloon. Although stenting was avoided, two nitinol stents were used in two (7.4%) cases. Treated lesion localizations and treatment characteristics are detailed in Table 3.

Table 3. Procedural characteristics (n=27)

	n	%	Treatment approach
Access - common femoral artery	27	100	
Antegrade	27	100	
Support catheters	19	70.4	
Atherectomy localizations			
Anterior tibial artery	16	59.3	
Posterior tibial artery	8	29.6	
Peroneal	3	11.1	
Additional balloon angioplasty , levels (other than atherectomy sites)			
Proximal of atherectomy	3	11.1	
Infrapopliteal vessels	7	25.9	
Both	2	7.4	
Adjunctive balloon angioplasty type			
Drug eluted balloon	9	33.3	
Plain old balloon angioplasty	18	66.7	
Complications			
Dissection	2	7.4	Nitinol (SFA)
Emboli	1	3.7	
Device success	24	88.9	
Procedure success	27	100	

The mean follow-up duration was 566.4±239.4 (range, 110 to 946) days. Attendance rates at follow-up visits were 88.88%, 66.66%, and 48.14% at 6, 12, and 18 months, respectively. The overall amputation rate was 25.92%; however, the unanticipated amputation rate was only 11.11% at 12 months, and the rest was planned before the index procedure. There were two mortalities during the follow-up period. In the outpatient files, Rutherford categories were recorded in 77.78% of patients, and 51.9% of these patients showed improvement in RC (mean change: 2.85±1.35) compared to 66.67% of all patients. Overall RC change was 2.05±2.16. Four (19.04%) patients showed no change, and three (14.28%) patients showed worsening of RC (Figure 1). Among these patients who could not show improvements, five patients experienced major or minor amputations. One of the remaining two patients had a nonhealing wound, and another one had a newly formed wound.

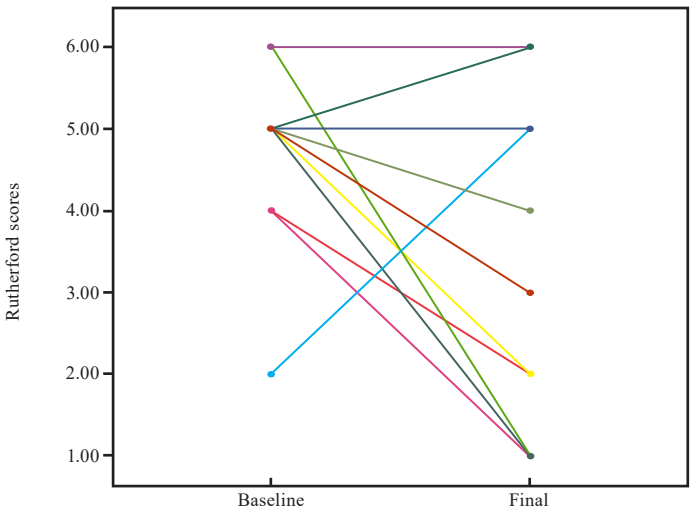

Figure 1. *Trend in Rutherford classification.*

The 30-day MACE rate was 0%, the 30-day MALE rate was 12.5% (n=3), and the 30-day amputation rate was 8.33% (n=2). Another patient died without amputation before the end of the first year. The one-year freedom from MALE+perioperative death rate was 71.42% (n=15 of 21). The one-year amputation-free survival rate was 76.19% (n=16 of 21). The one-year freedom from reintervention or amputation rate was 75%. The rate of limb salvage was 80% in the one-year follow-up, and the survival rate for one year was 90.47% (one cardiac, one sepsis, for a total of two of 21).

Comparison of different Rutherford categories has only shown that tissue loss was with increased rates of severe calcification (p=0.035). However, this did not reflect the clinical outcomes (i.e., primary patency, amputation rates, and RC trends).

Age was not found related to clinical outcomes. Among comorbidities, only chronic renal insufficiency (CRI) correlated with increased amputation rates (p=0.001). In nonsmokers, failure to show improvement in RC was more common than in smokers. In addition, smokers who quit after the procedure showed improvement in RC while nonquitters experienced worsening more often (0% vs. 25%). Those who never smoked had the highest rate of lack in improvement of RC compared to those who smoked at any point (62.5% vs. 15.38%, p=0.017).

Table 4. Unanticipated amputation of GLASS stages

GLASS infrapopliteal	1	2	3	4	Total
Unanticipated amputation					
No	1	5	4	14	24
Yes	0	0	0	3	3
Total	1	5	4	17	27
GLASS pedal		1	2	3	Total
Unanticipated amputation					
No		10	8	6	24
Yes		0	2	1	3
Total		10	10	7	27
GLASS Stage		1	2	3	Total
Unanticipated amputation					
No		2	4	18	24
Yes		0	0	3	3
Total		2	4	21	27

GLASS: Global Limb Anatomic Staging System.

Table 5. Safety and efficacy endpoints

Safety endpoints (30 day)	n/N	%	OPG (%)	AHR (%)	CHR (%)
Mortality	0/24	0			
Amputation	2/24	8.33	3	4	7
MACE	0/24	0	8	10	18
MALE	3/24	12.5	8	9	10
Efficacy endpoints (1-year)	n/N	%	OPG (%)	AHR (%)	CHR (%)
MALE+POD	6/21	71.42	71	67	61
AFS	5/21	76.19	71	68	53
RAO	5/20	75	55	51	54
Limb salvage	4/20	80	84	81	80
Survival	2/21	90.47	80	63	80

OPG: Objective Performance Goals; AHR: Anatomic high-risk group; CHR: Clinical high-risk group; MACE: Major adverse cardiovascular event; MALE: Major adverse limb event; POD: Perioperative death; AFS: Amputation free survival; RAO: Reintervention or amputation.

Neither degree of calcification nor lesion length had any effect on clinical outcomes. Smokers had a higher rate of increased infrapopliteal GLASS scores than nonsmokers (81.25% vs. 36.36%, p=0.048). Run-off score and GLASS stages did not show any significant relationship with clinical outcomes; however, the patients that experienced an unanticipated amputation were in the most advanced classes (infrapopliteal GLASS Stages 3 and 4). The absence of run-off (no run-off vs. at least one vessel) was not related to outcomes.

DISCUSSION

Our procedural success was 100%, with a device success rate of 88.9%, showing that RA is a feasible procedure even in the most difficult lesions. Undoubtedly, the main target is to gain efficacy with safety. Suggested OPGs of Conte et al.[4] for safety were 8% for MACE and MALE and 3% for amputation. Adjusted OPGs were defined for anatomical high-risk (infrapopliteal) and clinical high-risk groups (advanced age and tissue loss). The results of this cohort failed to achieve the OPGs when compared to high-risk subgroups (Table 5). However, they did not define any OPGs for the patients with infrapopliteal lesions and tissue loss. The best explanation is that the safety outcomes were kept down due to the combined effect of extension and severity of the disease. In addition, the center where this trial took place serves people with extremely low socioeconomical status. The majority of the patients had tissue loss at their first attendance. Two amputations performed within the first 30 days were planned before the atherectomy procedure, and the procedure was done with an aim to keep the amputation at the most distal level and prevent stump wound infection. This may explain the failure to fulfill safety endpoints. Nevertheless, OPGs for efficacy were achieved by this cohort when compared to the highest OPGs (Table 5). However, we should remark that our population did not have any octogenarians, and this comparison cannot be a head-to-head one.

Although atherosclerosis and calcified long lesions are found to be related to advanced age in prior trials [4,14], the current one has failed to show any relationship of age with neither lesion characteristics nor clinical outcome. Although without statistical significance, patients who did not experience amputation had a lower mean age compared to those with unanticipated amputation (56.9±13.5 vs. 69.6±6.7 years).

It is known that the vessel structure is affected and calcification is common in CRI [15]. In the current trial, CRI had higher amputation rates irrespective of the lesion characteristics (length, calcification, run-off, and GLASS scores), showing that beyond the lesion characteristics, wound healing and tissue perfusion seems to be impaired by the systemic effects of CRI.

The patients that experienced unanticipated amputations were in infrapopliteal GLASS Stages 3 and 4. It was similar for pedal GLASS; the ones with target arteries crossing the ankle and continuing with an intact pedal arch never experienced an unanticipated amputation. Nonetheless, the event rate was too small for precise implications, and GLASS solely was in line with clinical outcomes and most advanced classes may have an increased risk of amputation. Although the Threatened Limb Classification System, based on grading of wounds, ischemia, and foot Infection, was available for the prediction of limb loss and GLASS was available for the prediction of one-year patency after endovascular procedures [10], only GLASS was used due to inability to perform objective hemodynamic testing, and we found that GLASS is practical for a rough prediction of amputation for centers with limited resources (Table 4).

While smoking history was expected to have a negative effect on the RC trend [16], an inverse relationship was determined. In addition, quitting smoking in the follow-up period was with improvement in RC trend in line with a previous trial, which found that quitting smoking even on the procedure day was with better 12-month primary patency than nonquitters [13]. The effect of quitting was shown despite worse infrapopliteal GLASS scores of the smokers compared to nonsmokers in the current trial. Taking these into consideration, smoking was interpreted as an important reversible predisposing factor and maybe a hint for better prognosis, as shown before [17]. When a patient has CLI without smoking, this suggests that the disease is in an advanced or irreversible stage due to extreme involvement of microvasculature with an inability to provide enough flow for healing.

Although RA has acceptable results in the treatment of advanced clinical stages of surgically difficult lesions regardless of preoperative patient and lesion characteristics, the effect of patient education and follow-up cannot be denied. Patients should be informed about their disease, treatment options, the importance of follow-up, and foot care before the operation. Another suggestion of this trial may be that despite developments in technology, outcomes are always limited by the level of development in patient-doctor relationships and follow-up organization. We suggest using the latest staging systems while evaluating patients, and instead of hesitating, the goal should be optimizing outcomes. For this purpose, postprocedural care and follow-up in the most vulnerable group of patients that are expected to experience the worst clinical outcomes should be idealized. Our experience is that RA is a feasible and valuable option with promising results; however, the amputation is shown to be affected by wound size and coexistence of focal infection, which are evaluated in the Threatened Limb Classification System [10]. This should remind us that in limb salvage, the relationship between the patient and the healthcare professional, quality of follow-up,

patient care, and wound care are in equal weight to performing the endovascular procedure. Thus, education of the patient about the disease during the treatment and follow-up period is critical.

The study is limited with its retrospective design, small number of patients, and lack of comparison. In addition, it lacks objective hemodynamic testing. The rate of patient lost to follow-up was high. In conclusion, the importance and the effects of follow-up must be explained in detail to the patient. It should be told to the patient that quitting smoking even after the procedure has a positive effect on outcomes, and the thought of it being too late should be dismantled. Rotational atherectomy is a reliable option for difficult lesions in infrapopliteal levels. Chronic renal insufficiency patients or nonsmoker patients with advanced peripheral arterial disease should be carefully followed-up as they have worse clinical outcomes than others. Advanced age, GLASS stages, and smoking after the procedure have the potential to be related to worse results.

In conclusion, the results of this trial may seem to state the obvious; nevertheless, one should always see things from a fresh angle in parallel to the developing technology.

Ethics Committee Approval: The study protocol was approved by the Health Sciences University, Izmir Tepecik Training and Research Hospital Ethics Committee (date/no: 2020/9-9, 23.07.2020). 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: Contributed in concept, design, data collection, processing analysis, literature review, writing, review: A.Y.E., D.Ş.

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