RESEARCH ARTICLE

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Endovascular Revascularization of Lower Extremity Arteries: A Single-center Retrospective Report on Long Lesions (>100 mm)

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Abstract

Background and Aim: Lower extremity peripheral artery disease (PAD) is a prevalent condition characterized by the accumulation of plaque in the arteries of the lower extremities. Traditionally, open surgery has been the conventional method for managing complex lesions in these patients. However, there is a growing trend toward using endovascular therapy as the preferred approach. This study aimed to assess the feasibility and effectiveness of endovascular revascularization in patients with a lower extremity PAD, specifically those with long lesions exceeding 100 mm. By focusing on this subgroup, the study sought to provide insights into the potential benefits of endovascular treatment for this particular patient population.

Materials and Methods: This retrospective cohort study included 41 patients with long lesions who underwent endovascular revascularization. The study received ethical approval and patient data were collected and analyzed. Statistical analyzes were conducted to summarize the data.

Results: In the analyzed cohort, the study reported that most patients undergoing PAD treatment was males. The average age of the patients was 62.4 years. The prevalence of common comorbidities was as follows: coronary artery disease in 43.9% of patients, hypertension in 43.9%, type 2 diabetes mellitus in 41.5%, and tobacco use in 51.2%. Medication usage included aspirin (97.6% of patients), clopidogrel (82.9%), angiotensin-converting enzyme inhibitors (29.3%), cilostazol (29.3%), statins (36.6%), insulin (24.4%), and oral antidiabetics (17.1%). Lesion characteristics revealed that 41.5% of patients had complete occlusion, while most procedures involved drug-coated balloons (90.2%). Complications were reported in a small percentage of cases (9.8%). Revascularization outcomes showed high rates of technical success (87.8%) and hemodynamic success (97.8%), with favorable primary patency rates at both 30-day (97.8%) and 6-month (87.8%) follow-ups.

Conclusion: This study highlights the effectiveness of endovascular treatment for long lesions in lower extremity arteries, with favorable outcomes in terms of primary patency and hemodynamic success.

Keywords: Peripheral arterial disease, advanced lesions, drug coated balloon angioplasty, stent angioplasty

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INTRODUCTION

Lower extremity-peripheral artery disease (PAD) is a prevalent atherosclerotic condition affecting a significant number of individuals worldwide, with estimated 200 million patients affected.[1] The disease is characterized by the diffuse spread of plaques, often progressing from the iliac bifurcation to the femoral artery and even to the popliteal artery in symptomatic patients.[2]. While open surgery has traditionally been used for complex lesions falling into the anatomically advanced class, endovascular therapy has rapidly become a standardized approach for treating PAD.[3]

In recent years, there have been increasing reports suggesting that even complex lesions can be effectively revascularized through endovascular means.[4-6] Particularly, the focus has been on addressing long lesions, defined as cohesive plaques longer than 100 mm. However, vascularizing these longer segments poses challenges as interventions covering an extended area elevate the risk of complications and treatment failure.[7]

Given the evolving landscape of endovascular treatment for lower extremity PAD, it is crucial to contribute to the existing literature by reporting the outcomes of endovascular interventions in patients with long lesions. This study aims to explore the feasibility and efficacy of endovascular revascularization in this specific patient population, shedding light on the success rates, complications, and overall treatment outcomes (Figure 1).

MATERIALS AND METHODS

Study design

This retrospective cohort study explored the feasibility and efficacy of endovascular revascularization in patients with lower extremity - PAD lesions exceeding 100 mm in length.

Ethical considerations

The study and its methodology, conducted in adherence to the principles of the Declaration of Helsinki, received approval from the Clinical Trials and Ethics Committee of the Eskişehir City Hospital. The ethics committee approval number for this study is "ESH/GOEK 2022/9" (date: 21.12.2022).

Patients

From January 2021 to January 2023, 41 patients with atherosclerotic lesions exceeding 100 mm in length who underwent endovascular revascularization were enrolled in this study.

Procedure

A single interventionist conducted the procedures within a designated angiography laboratory, using a Canon Infinix-I INFX 8000-V single-plane Toshiba angiography system, complemented by a movable interventional table. Before starting the intervention, all patients received a routine oral dose of 300 mg of clopidogrel. To maintain an activated clotting time of more than 200 s, intraarterial injections of 70 to 100 U/kg of unfractionated heparin were administered.

Patients were positioned either supine or prone depending on the puncture site and manually adjusted on a sliding table to achieve the appropriate field of view. A standard posterior anterior projection was consistently used, with occasional implementation of an oblique projection to confirm stenosis presence or evaluate the outcome of angioplasty. Magnification was employed sparingly, primarily at the interventionist's discretion and mostly for below-the-knee interventions.

For all therapeutic interventions, a 7F sheath was utilized, and lesion predilation with an uncoated balloon was performed as

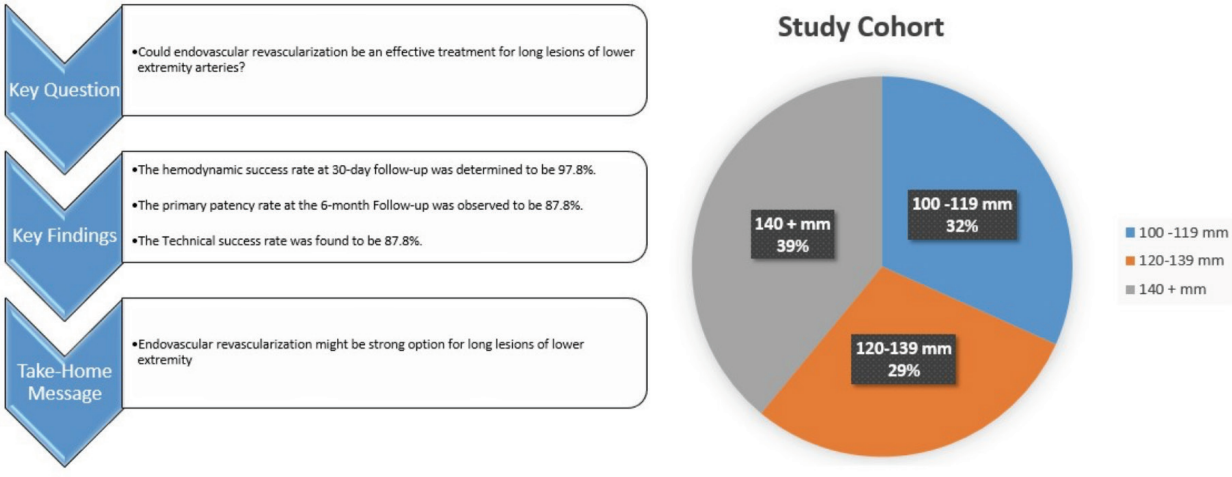

Figure 1: Graphical abstract of the study

a standard procedure. The size and length of paclitaxel drug-eluting balloons (DEBs), crucial for determining the total drug load, were carefully selected based on measurements using a ruler placed behind the patient's leg, with diameter sizing set at a 1:1 ratio to the reference vessel. The inflation of the DEB occurred for a minimum of 120 s, starting 10 mm proximal and extending 10 mm distal to the target lesion. When multiple balloons were necessary, a 5 mm overlap was allowed to ensure uniform drug elution in the treated vessel.

Self-expandable stent implantation was performed in cases of progressive stenosis or when a dissection flap was observed during the control phase after balloon dilation. For therapeutic interventions using a retrograde approach, digital subtraction angiography was conducted through a pigtail catheter. A manual injection of the iohexol contrast medium (Omnipaque 350, GE HealthCare, Ireland) into the arterial system was performed by the interventionist. On average, 100 mm^3 (175 mg/mL) of contrast medium was used for patients undergoing aortoiliac therapeutic interventions.

Report standardization definitions

The terminology used in this report, including lesion characteristics, complications, and outcomes, adheres to the Society for Vascular Surgery reporting standards.[8] The comorbidities of patients during the preprocedural period were obtained by examining the National Health Database. Follow-up data at 1 month and 6 month intervals were assessed during postprocedural follow-up appointments with the patients.

The collected data were anonymized and transferred to an electronic database for analysis. All analyzes were conducted within this anonymous database.

Statistical analysis

Descriptive statistics were employed to summarize the demographic and clinical characteristics of the study population. Continuous variables were presented as means based on the distribution of the data. Categorical variables were reported as percentages.

RESULTS

Patient characteristics

Table 1 presents the patient characteristics of the cohort. The cohort consisted of 17.1% (n = 7) females, with a mean age of 62.4 ± 10.5 years. The prevalence of comorbidities in the cohort was as follows: coronary artery disease was present in 43.9% (n = 18) of patients, hypertension in 43.9% (n = 18), type 2 diabetes mellitus in 41.5% (n = 17), and tobacco use in 51.2% (n = 21). Regarding the clinical symptoms, the patients exhibited varying degrees of claudication, with a mean distance of 250 ± 110 meters. The Rutherford classification system was used to assess the severity of PAD, with the following distribution: 24.4% (n = 10) of patients were categorized as stage I category II, 14.6% (n = 6) as stage I category III, 17.1% (n = 7) as stage II, 31.7% (n = 13) as stage III, and 12.2% (n = 5) as stage IV. For Rutherford-chronic limb ischemia staging, 48.8% (20) of patients were classified as stage I, 12.2% (n = 5) as stage II, and no patients were categorized as stage III. In terms of medication

Table 1: Patient characteristics

Cohort (n=41)	**mean ± SD**	**% (n)**
Gender (female)		17.1 (7)
Age	62.4±10.5	
CAD		43.9 (18)
HT		43.9 (18)
T2DM		41.5 (17)
Tobacco use		51.2 (21)
Clinical symptoms		
Claudication (m)	250±110	
Rutherford		
Stage I category II		24.4 (10)
Stage I category III		14.6 (6)
Stage II		17.1 (7)
Stage III		31.7 (13)
Stage IV		12.2 (5)
Rutherford chronic limb ischemia		
Stage I		48.8 (20)
Stage II		12.2 (5)
Stage III		0.0 (0)
Medications		
ASA		97.6 (39)
Clodiprogel		82.9 (34)
ACE inhibitors		29.3 (12)
Cilostazol		29.3 (12)
Statin		36.6 (15)
Insulin		24.4 (10)
Oral antidiabetics		17.1 (7)
Laboratory results		
HGB	13.7±2.4	
HCT	41.8±5.8	
MON	2.0±2.5	
LDL	116.5±36.2	
HDL	39.6±8.5	
TC	208±66	
TG	227.4±126.0	

SD: Standard deviation, CAD: Coronary artery disease, HT: Hypertension, T2DM: Type 2 diabetes mellitus, ASA: Acetylsalicylic acid, ACE: Angiotensin-converting-enzyme, HGB: Hemoglobin, HCT: Hematocrit, MON: Monocyte, LDL: Low density lipoprotein, HDL: High density lipoprotein, TC: Total cholesterol, TG: Triglyceride

usage, a high percentage of patients were prescribed aspirin (acetylsalicylic acid) (97.6%, *n* = 39) and clopidogrel (82.9%, *n* = 34). Other medications included angiotensin-converting enzyme inhibitors (29.3%, *n* = 12), cilostazol (29.3%, *n* = 12), statins (36.6%, *n* = 15), insulin (24.4%, *n* = 10), and oral antidiabetics (17.1%, *n* = 7). Laboratory results revealed the following mean values: hemoglobin 13.7 ± 2.4 g/dL, hematocrit 41.8 ± 5.8%, monocyte count 2.0 ± 2.5 x 10^9/L, low density lipoprotein cholesterol 116.5 ± 36.2 mg/dL, high density lipoprotein cholesterol 39.6 ± 8.5 mg/dL, total cholesterol 208 ± 66 mg/dL, and triglycerides 227.4 ± 126.0 mg/dL.

Lesion characteristics

Table 2 presents the lesion characteristics. The cohort exhibited a mean lesion length of 126 ± 18 mm and mean lesion diameter of 5.8 ± 1.1 mm. Analysis of the stenosis rate revealed that 26.8% (*n* = 11) of the lesions had a stenosis rate between 50% and 74%, while 31.7% (*n* = 13) exhibited a stenosis rate ranging from 75% to 99%. Notably, a significant proportion of lesions, accounting for 41.5% (*n* = 17) of the cohort, demonstrated complete occlusion with a stenosis rate of 100%. In terms of lesion distribution, the majority of patients (70.7%, *n* = 29) presented with femoropopliteal disease, while a smaller subset (29.3%, *n* = 12) displayed aorta-iliac disease. Multivessel involvement was observed in 17.1% (*n* = 7) of the patients.

Periprocedural outcomes

Table 3 provides insights into the procedural characteristics. The majority of procedures involved the use of drug-coated balloons (DCB), accounting for 90.2% (*n* = 37) of the cases. A smaller proportion of patients, 9.8% (*n* = 4), underwent treatment with bare metal stents.

Analysis of the complications arising from these procedures revealed that 9.8% (*n* = 4) of the patients experienced a dissection. However, no instances of bleeding, rupture, micro embolization, macro embolization, arteriovenous fistula, or infection related to the device were reported in any of the patients. Additionally, device malfunction was observed in only 2.2% (*n* = 1) of the cases.

Revascularization outcomes

Table 4 presents the outcomes. Technical success, defined as the successful completion of the procedure without any immediate complications, was achieved in 87.8% (*n* = 36) of the cases. Hemodynamic success, indicating the restoration of normal blood flow, was achieved in 97.8% (*n* = 40) of the patients at the 30 day follow-up.

Assessing the primary patency rates, defined as the absence of significant restenosis or occlusion, the 30 day primary patency rate was reported as 97.8% (*n* = 40), indicating a high rate of procedural success in maintaining vessel patency. At the 6 month follow-up, the primary patency rate remained favorable at 87.8% (*n* = 36).

DISCUSSION

PAD requires lifelong management to preserve the extremities and prevent complications. In recent years, endovascular treatment has emerged as the primary therapeutic option, with surgical or endovascular interventions reserved for secondary or tertiary approaches depending on the specific

Table 2: Lesion characteristics

Cohort (*n*=41)		mean ± SD	% (*n*)
Lesion length (mm)		126±18	
The lesion diameter (mm)		5.8±1.1	
Stenosis rate	50-74%		26.8 (11)
	75-99%		31.7 (13)
	100%		41.5 (17)
Femoropopliteal disease			70.7 (29)
Aorta-iliac disease			29.3 (12)
Multivessel involvement			17.1 (7)

SD: Standard deviation

Table 3: Procedure

Cohort (*n*=41)	mean ± SD	% (*n*)
DCB		90.2 (37)
BMS		9.8 (4)
Intervened length (mm)	146.3±19.3	
Complications		
Dissection		9.8 (4)
Bleeding		0.0 (0)
Device malfunction		2.2 (1)
Rupture		0.0 (0)
Microembolization		0.0 (0)
Macroembolization		0.0 (0)
Arteriovenous fistula		0.0 (0)
Infection (device)		0.0 (0)

SD: Standard deviation, DCB: Drug-coated balloons, BMS: Bare-metal stents

Table 4: Outcomes

Variable	mean ± SD	% (*n*)
Technical success 30 day	87.8 (36)	
Hemodynamically success 30 day	97.8 (40)	
Primary patency 30 day	97.8 (40)	
Primary patency 6 month	87.8 (36)	
Need for open surgical revascularization 6 month		0.0 (0)

SD: Standard deviation

clinical scenario.[9] However, due to the unique anatomical and histological characteristics of peripheral arteries compared with coronary arteries, several anatomical and structural limitations in the current treatment practices still warrant further investigation and clarification.[10] Long lesions, defined as lesions exceeding a length of 100 mm, pose particular challenges in endovascular management.[8,11] Initially, the 100 mm threshold for endovascular treatment was established in 2007.[12] However, subsequent randomized controlled trials, including FAST, ABSOLUTE, BASIL, and EMINENT, have provided compelling evidence supporting the efficacy and feasibility of endovascular interventions for long lesions.[11,13-15]

Notably, the 2018 report from the American College of Cardiology, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine acknowledged the growing body of evidence supporting endovascular treatment as a viable option for lesions longer than 100 mm.[11] This recognition further solidified the role of endovascular interventions in managing long lesions of the lower extremity arteries. The inclusion of endovascular treatment in the management of long lesions signifies a shift in the treatment paradigm, reflecting a patient-centered approach that aims to maximize therapeutic options while minimizing invasiveness. By considering endovascular treatment as a primary option for long lesions, clinicians can reduce the need for extensive surgical procedures, offering patients a less invasive and more efficient therapeutic pathway.

Our study investigated the outcomes of endovascular treatment for long lesions, and the findings align with existing literature,[11-15] highlighting promising results in terms of primary patency. In addition, our study demonstrated superior hemodynamic success rates compared to both surgical and endovascular cohorts reported in the current-15). Particularly noteworthy is the high rate of primary technical success (88%) achieved in challenging cases involving long, diffuse, and calcific lesions, half of which occurred in diabetic patients and the other half in individuals with chronic ischemia. Additionally, the subsequent secondary endovascular intervention achieved a remarkable 100% technical success rate at the 30 day follow-up, underscoring the feasibility of endovascular therapy in this complex patient population. These encouraging findings pave the way for further exploration of endovascular treatment as a promising option in managing long lesions, particularly in patients with challenging comorbidities and chronic ischemia.

Study limitations

This study has certain limitations that warrant a careful consideration when interpreting the findings. The primary limitation lies in the relatively small sample size which may limit the generalizability of the results to larger populations. Furthermore, the retrospective design of the study introduces inherent selection bias, potentially impacting the validity and reliability of the results. Given these limitations, it is crucial to emphasize the necessity for large-scale randomized controlled trials, accompanied by comprehensive treatment guidelines, to establish the optimal revascularization approach for patients with PAD and long complex lesions. Such studies would not only shed light on the risk factors associated with treatment failure but also provide valuable insights into refining and individualizing the management of patients with PAD.

CONCLUSION

In conclusion, our study reinforces the growing body of evidence supporting the effectiveness of endovascular treatment for long lesions in lower extremity arteries. The findings demonstrate favorable outcomes in terms of primary patency and hemodynamic success, indicating the feasibility of endovascular interventions in this challenging patient population. However, the limitations of our study, including the small sample size and retrospective design, highlight the need for large-scale randomized controlled trials to further validate these results and guide treatment strategies. Future research should identify risk factors for treatment failure and develop comprehensive guidelines for managing patients with long and complex lesions in PAD.

Ethics

Ethics Committee Approval: The study and its methodology, conducted in adherence to the principles of the Declaration of Helsinki, received approval from the Clinical Trials and Ethics Committee of the Eskişehir City Hospital. The ethics committee approval number for this study is "ESH/GOEK 2022/9" (date: 21.12.2022).

Informed Consent: Retrospective cohort study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: İ.Ç.K., M.Ö., A.S.K., Concept: H.B., Design: İ.Ç.K., H.B., Data Collection or Processing: İ.Ç.K., M.Ö., A.S.K., Analysis or Interpretation: İ.Ç.K., H.B., M.Ö., A.S.K., Literature Search: H.B., Writing: İ.Ç.K., H.B.

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