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Original Article

Endovascular revascularization of challenging anatomical lesions: Revascularization in TASC-II C and D classes: A single-centre retrospective report

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Abstract

Aim: Peripheral arterial disease (PAD) is a prevalent condition that significantly impacts quality of life and that can lead to limb amputation and thromboembolic events. Treatment options for PAD include endovascular and open surgical interventions, with the choice depending on the Trans-Atlantic inter-society consensus II (TASC II) classification. Recent evidence suggests that endovascular therapy may be feasible for complex PAD lesions, but further research is needed.

Material and Methods: This retrospective cohort study included 50 patients with TASC II class C and D lesions. The procedures were conducted using a state-of-the-art angiography system, and patients received appropriate antiplatelet therapy and heparin during the intervention. Data collection was performed following ethical considerations and standardization protocols.

Results: This study involved 50 patients with peripheral arterial disease, characterized by an average age of 65.0 years and a prevalence of comorbidities such as coronary artery disease, hypertension, type 2 diabetes mellitus, and tobacco use. The majority of patients presented with claudication and had lesions primarily in the femoropopliteal region. The procedures performed, primarily using drug-coated balloons, resulted in high technical success rates and favorable outcomes at 30 days, with a slight decline in primary patency rates at 6 months. Some patients required readmission due to cardiac reasons, and a small portion necessitated open surgical revascularization.

Conclusion: Our findings support the use of endovascular revascularization as a safe and effective option for patients with complex lesions. Further research is needed to address challenges related to dissection and optimize outcomes in this patient population. This study contributes to the growing understanding of treatment approaches for peripheral artery disease and highlights the potential benefits of endovascular therapy.

Keywords: Peripheral arterial disease, advanced lesions, endovascular interventions, atherosclerosis

INTRODUCTION

Peripheral arterial disease (PAD) represents a prevalent atherosclerotic condition, affecting approximately 20% of individuals above the age of 60 and encompassing 200 million individuals globally [1]. This disease stands as a leading cause of non-traumatic limb amputation in Westernized countries and frequently coexists with risk factors such as tobacco use, type 2 diabetes mellitus, and hypertension. PAD contributes to significant

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morbidity, including limb amputation, thromboembolic events, and diminished quality of life. Therefore, the management of PAD necessitates a lifelong approach to combat the disease [2]. Treatment options for PAD, including endovascular and open surgical interventions, should be meticulously planned and executed by cardiovascular practitioners. Accordingly, the classification of PAD patients assists in determining the appropriate treatment modality for individual cases [2]. The internationally recognized Trans-Atlantic inter-society consensus II (TASC II) classification system aids in classifying lower extremity arterial disease (LEAD) based on the anatomical distribution and nature of the lesions [3].

Based on the TASC II classification, A and B class lesions are generally amenable to primary endovascular interventions, whereas open surgery is considered for C-level lesions and recommended for D-level lesions (3). In recent years, mounting evidence and reports have emerged regarding the feasibility of endovascular therapy in complex scenarios, including chronic total occlusions, multiple lesions, long lesions, and TASC II class C and D lesions [4-6]. However, further evidence is required to establish the feasibility and efficacy of endovascular treatment as a standardized approach for this specific patient population [5,6].

The primary objective of this study was to examine the safety, feasibility, and efficacy of utilizing endovascular therapy as the primary revascularization strategy in patients presenting with TASC II classes C and D. By focusing on this specific subset of patients, the study aimed to generate valuable insights into the outcomes and potential advantages associated with endovascular treatment. The findings from this investigation contribute to the ongoing endeavors aimed at standardizing treatment approaches for individuals affected by complex peripheral arterial disease (PAD) lesions.

MATERIAL AND METHODS

Study Design and Ethical Considerations

This retrospective cohort study aimed to explore the feasibility and efficacy of endovascular revascularization in patients with advanced peripheral artery disease (PAD). The study received ethical approval from the Clinical Trials and Ethics Committee of the university hospital, ensuring compliance with the principles of the Declaration of Helsinki. The approval number for this study is "ESH/GOEK 2022/9," affirming that the research was conducted with due consideration to the rights, safety, and well-being of the participants.

Patients and Procedure

From January 2021 to November 2022, a total of 50 patients with TASC-II class C and D atherosclerotic lesions were included in this study. The patients were selected from among the patients with intermittent claudication who applied to the cardiovascular surgery outpatient clinic within the specified date range. Lower extremity CT angiography was performed in patients whose physical examination findings supported the diagnosis. Endovascular revascularization was planned for TASCD C and D patients according to CT angiography. The position to be given to the patient during the procedure and the arterial puncture point were also determined according to the CT angiogram. The procedures were conducted by a skilled interventionist in a specialized angiography laboratory equipped with a state-of-the-art Canon Infinix-I INFX 8000-V single-plane Toshiba angiography system. This system was enhanced by a movable interventional table to optimize patient positioning and imaging angles, ensuring precise and accurate visualization during the procedures.

Prior to the intervention, all patients received a standard oral dose of 300 mg of clopidogrel to ensure appropriate antiplatelet therapy. Intra-arterial injections of unfractionated heparin were administered to maintain an activated clotting time exceeding 200 seconds, minimizing the risk of thrombotic events during the procedure.

Patient positioning was adjusted according to the arterial access site, either in a supine or prone position, and fine-tuned using a sliding table to achieve the desired field of view. Angiography primarily employed a standard posterior-anterior projection, with occasional implementation of an oblique projection to confirm stenosis presence or evaluate angioplasty outcomes. Magnification was used selectively, particularly for below-the-knee interventions, under the interventionist's discretion, to enhance visualization of smaller vessels.

Therapeutic interventions involved the use of a 7F sheath, and all lesions underwent pre-dilation using an uncoated balloon as a standard procedure. Selection of paclitaxel drug-eluting balloons (DEBs) was meticulously based on precise measurements obtained by using a ruler placed behind the patient's leg. The diameter of the DEB was chosen to match the reference vessel's diameter in a 1:1 ratio, ensuring accurate deployment. The DEB inflation duration was at least 120 seconds, encompassing 10 mm proximal and distal to the target lesion. In cases where multiple balloons were required, a 5-mm overlap was allowed to ensure uniform drug elution in the treated vessel.

Paclitaxel coated PTA balloon (Medtronic, U.S, 6-8 atm, 3 min) was used for balloon anghioplasty and EverflexTM peripheral self-expanding stent system (Medtronic U.S) was used for stent implantation. LifetechR stent grafts were preferred for aortailiac

lesions.

Self-expandable stent implantation was performed when resistant stenosis or a dissection flap that prevents flow to the distal extremity and has the possibility of enlargement was observed during the control phase after balloon dilation. For therapeutic interventions using a retrograde approach, digital subtraction angiography (DSA) was conducted through a pigtail catheter, and manual injection of the Iohexol contrast medium (Omnipaque 350, GE HealthCare, Ireland) was performed to enhance visualization. The average volume of contrast medium used for aortoiliac therapeutic interventions was 100 mm^3 (175 mg/mL).

Data Collection and Standardization

Stringent measures were implemented throughout the study to ensure the utmost confidentiality and anonymity of patient data. The data collection process involved two stages. Initially, all relevant documents were carefully screened for each patient, and preprocedural and periprocedural data were determined and collected. Subsequently, postprocedural data were obtained from the national electronic health database.

To maintain consistency and comparability, the collected data, including patient characteristics, lesion specifics, procedural details, and outcomes, underwent a rigorous anonymization process before being transferred to an electronic database for analysis. The reporting of lesion characteristics, complications, and outcomes adhered strictly to the reporting standards set forth by the Society for Vascular Surgery (SVS) [7]. These standards ensured uniformity.

Statistical Analysis

Descriptive statistics were employed to summarize the demographic and clinical characteristics of the study population. Continuous variables were presented as means, accompanied by their corresponding standard deviations, based on the distribution of the data. Categorical variables were reported as percentages to provide a comprehensive overview of the cohort.

RESULTS

Patient Characteristics

Table 1 summarizes the characteristics of the patient cohort (n=50). The mean age of the patients was 65.0±9.8 years. Among the cohort, 20.0% (n=10) were female. The prevalence of comorbidities and risk factors in the cohort were as follows: coronary artery disease (CAD) - 56.0% (n=28), hypertension (HT) - 50.0% (n=25), type 2 diabetes mellitus (T2DM) - 46.0% (n=23), and tobacco use - 58.0% (n=29).

Table 1. Patient characteristics

Cohort (n=50)	mean±SD	% (n)
Gender (female)		20.0 (10)
Age	65.0±9.8	
CAD		56.0 (28)
HT		50.0 (25)
T2DM		46.0 (23)
Tobacco use		58.0 (29)
Clinical symptoms		
Claudication (m)	271.4±114.8	
Rutherford		
Stage I category II		30.0 (15)
Stage I category III		10.0 (5)
Stage II		18.0 (9)
Stage III		20.0 (10)
Stage IV		4.0 (2)
Stage V		2.0 (1)
Rutherford- chronic limb ischemia		
Stage I		38.0 (19)
Stage II		4.0 (2)
Stage III		2.0 (1)
Medications		
ASA		88.0 (44)
Clodiprogel		88.0 (44)
ACE inhibitors		34.0 (17)
Cilostazol		30.0 (15)
Statin		34.0 (17)
Insulin		32.0 (16)
Oral antidiabetics		14.0 (7)
Laboratory results		
HGB	13.8±2.3	
HCT	42.1±6.5	
Mon	1.8±2.2	
LDL	112±35	
HDL	38±9	
TC	196±63	
TG	201±105	

CAD: Coronary Artery Disease, HT: Hypertension, T2DM: Type 2 Diabetes Mellitus, ASA: Acetylsalicylic Acid, HGB: Hemoglobin, HCT: Hematocrit, Monocyte: MON, LDL: Low-Density Lipoprotein, HDL: High-Density Lipoprotein, Total Cholesterol: TC, Triglyceride: TG

Clinical Symptoms

In terms of clinical symptoms, the majority of patients presented with claudication (m) with a mean distance of 271.4±114.8 meters. The Rutherford classification was used to assess the severity of the disease. The distribution of patients across the

Rutherford stages was as follows: Stage I category II - 30.0% (n=15), Stage I category III - 10.0% (n=5), Stage II - 18.0% (n=9), Stage III - 20.0% (n=10), Stage IV - 4.0% (n=2), and Stage V - 2.0% (n=1). Additionally, the Rutherford classification for chronic limb ischemia showed that 38.0% (n=19) were classified as Stage I, 4.0% (n=2) as Stage II, and 2.0% (n=1) as Stage III.

Medications

The use of medications among the patient cohort is presented in Table 1. Acetylsalicylic acid (ASA) and clopidogrel were used by 88.0% (n=44) of the patients. Other medications included ACE inhibitors - 34.0% (n=17), cilostazol - 30.0% (n=15), statins - 34.0% (n=17), insulin -32.0% (n=16), and oral antidiabetic drugs - 14.0% (n=7).

Laboratory Results

Table 1 provides the laboratory results of the patients. The mean values±standard deviation (SD) were as follows: hemoglobin (HGB) - 13.8±2.3 g/dL, hematocrit (HCT) - 42.1±6.5%, monocyte count - 1.8±2.2×10^9/L, low-density lipoprotein (LDL) - 112±35 mg/dL, high-density lipoprotein (HDL) - 38±9 mg/dL, total cholesterol (TC) - 196±63 mg/dL, and triglycerides (TG) - 201±105 mg/dL.

Lesion Characteristics

Table 2 presents the characteristics of the lesions in the patient cohort (n=50). The mean lesion length was 104±35 mm, and the mean lesion diameter was 5.7±1.1 mm. The stenosis rate distribution was as follows: 50-74% - 21.7% (n=10), 75-99% - 30.4% (n=14), and 100% - 47.8% (n=22). Femoropopliteal disease was present in 80.0% (n=40) of the patients, while aorta-iliac disease was observed in 64.0% (n=32) of the cohort. Multivessel involvement was found in 64.0% (n=32) of the cases. Based on the Trans-Atlantic Inter-Society Consensus (TASC-II) classification, 30.0% (n=15) of the lesions were classified as Class C and 70.0% (n=35) as Class D.

Table 2. Lesion characteristics

Cohort (n=50)	mean±SD	% (n)
Lesion Length (mm)	104±35	
Lesion Diameter (mm)	5.7±1.1	
Stenosis Rate		
50-74 %		21.7 (10)
75-99 %		30.4 (14)
100%		47.8 (22)
Femoropopliteal disease		80.0 (40)
Aorta-iliac disease		64.0 (32)
Multivessel Involvement		64.0 (32)
TASCD-II		
Class C		30.0 (15)
Class D		70.0 (35)

Procedure

Table 3 provides information on the procedures performed on the patient cohort. The majority of the procedures involved the use of drug-coated balloons (DCB) - 78.0% (n=39), while bare metal stents (BMS) were used in 22.0% (n=11) of the cases. The mean intervened length was 119±34 mm. Complications during the procedure included dissection in 18.0% (n=9) of the cases, device malfunction in 2.0% (n=1), and no instances of bleeding, rupture, micro embolization, macro embolization, arteriovenous fistula, or infection were reported.

Table 3. Procedure

Cohort (n=50)	mean±SD	% (n)
DCB		78.0 (39)
BMS		22 (11)
Intervened length (mm)	119±34	
Complications		
Dissection		18 (9)
Bleeding		0.0
Device malfunction		2.0 (1)
Rupture		0.0
Micro embolization		0.0
Macro embolization		0.0
Arteriovenous fistula		0.0
Infection (device)		0.0

Outcomes

Table 4 presents the outcomes of the interventions. The technical success rate at 30 days was 98.0 (49). Hemodynamically successful outcomes were achieved in 98.0% (n=49) of the cases at 30 days. The primary patency rate at 30 days was 98.0% (n=49). Readmission to the hospital due to cardiac reasons within 30 days was observed in 6.0% (n=3) of the patients. At 6 months, the primary patency rate was 80.0% (n=40). Additionally, 38.0% (n=19) of the patients required readmission to the hospital due to cardiac reasons within 6 months, and 4.0% (n=2) of the cases necessitated open surgical revascularization.

Table 4. Outcomes

Cohort (n=50)	% (n)
Technical success 30-Day	98.0 (49)
Hemodynamically success 30-Day	98.0 (49)
Primary patency 30-Day	98.0 (49)
Readmission to hospital due to cardiac reason 30-day	6.0 (3)
Limb amputation 30-day	0.0 (0)
Primary patency 6-month	80.0 (40)
Readmission to hospital due to cardiac reason 6-month	38.0 (19)
Limb amputation 6-month	0.0 (0)
Need of open surgical revascularization 6-month	4.0 (2)

DISCUSSION

The Trans-Atlantic Inter-Society Consensus (TASC-II) classification system provides an anatomical framework that aids in selecting the most suitable revascularization method based on the specific anatomical characteristics of the lesions [3]. Class A and B lesions generally lend themselves to primary endovascular treatment, while Class C lesions may be managed with either open or endovascular approaches, depending on patient factors and comorbidities. Class D lesions typically necessitate open surgical revascularization as the recommended course of action [8].

According to the 2017 ESC guideline, extraanatomical bypass is the last choice in aortailiac diseases. For this reason, we implanted stent when necessary after balloon angioplasty in resistant stenoses, depending on the lesion suitability [9].

There are limited studies comparing surgical and endovascular outcomes in TASC C/D aortailiac lesions. Squizzato et al. compared 63 endovascular and 55 open repair patients and showed that endovascular revascularization can be performed with fewer complications and similar patency rates [10]. Our results suggest that endovascular revascularization is a strong option, similar to our results, considering our technical and hemodynamic success rates, and our 30-day and 6-month patency rates.

The endovascular revascularization of complex lesions poses significant challenges, particularly in terms of technical feasibility. Accurate placement of stents and balloon expansion can be difficult due to the intricate nature of these lesions, often resulting in complications. A comprehensive meta-analysis of 21 studies involving 3029 patients revealed a high technical success rate of 96% (ranging from 92% to 99%) for endovascular revascularization in patients with TASC-II C and D lesions [11].

It should be mentioned that the more frequent use of drug-eluting balloons in the recent period is a strong factor in the success of endovascular revascularization results. Recently, there have been successful studies in this direction in the literature. For this reason, we used drug-eluting balloons in our practice [12].

Our study achieved a comparable technical success rate of 98%, in line with current literature [13]. Importantly, we did not observe any instances of bleeding, rupture, infection, or embolization. However, dissection was encountered in 20% of patients, necessitating prompt intervention through stent angioplasty during the procedure. Although the dissection rate in our study was higher than that reported in the current literature, we attribute this finding to the specific characteristics of the lesions. Notably, the mean lesion length exceeded 10 cm, and nearly half of the lesions were chronic total occlusions (CTOs). Additionally, only one patient experienced thrombotic device failure, and was successfully treated with thrombectomy and safely discharged. Our study also demonstrated a 30-day primary patency rate of 98%, which is consistent with existing literature. Despite a significant proportion of patients presenting with chronic limb ischemia, no amputations were observed during the 6-month follow-up period.

In the existing literature, the 6-month primary patency rates for this specific patient group vary, with an average of approximately 70% and within a range of 53% to 90% [9,10]. In our study, we observed a 6-month primary patency rate of 80%, even considering the challenges posed by extensive tobacco use and type 2 diabetes mellitus (T2DM). This finding highlights the positive outcomes achieved in our study and suggests the potential efficacy of the endovascular revascularization approach in this patient population.

CONCLUSION

In conclusion, our study investigated the feasibility and outcomes of endovascular revascularization in patients with complex peripheral artery disease lesions. We achieved a high technical success rate of 98% and observed no instances of bleeding, rupture, infection, or embolization. Dissection was encountered in 20% of patients but was promptly addressed during the procedure. Despite a higher dissection rate compared to the literature, we attribute this to the specific characteristics of the lesions. Our study demonstrated favorable primary patency rates, with 98% at 30 days and 80% at 6 months, surpassing average rates reported in the literature. These positive outcomes were achieved despite the presence of comorbidities such as extensive tobacco use and type 2 diabetes mellitus.

Of course, there are some limitations in our study. These are the presence of aortailiac and femoropopliteal patients in our patient group, the small number of patients and the single-center study.

Overall, our findings support the use of endovascular revascularization as a safe and effective option for patients with complex lesions. Further research is needed to address challenges related to dissection and optimize outcomes in this patient population. This study contributes to the growing understanding of treatment approaches for peripheral artery disease and highlights the potential benefits of endovascular therapy.

Ethics Committee Approval: The study received ethical approval from the Clinical Trials and Ethics Committee of the university hospital, ensuring compliance with the principles of the Declaration of Helsinki. The approval number for this study is "ESH/GOEK 2022/9," affirming that the research was conducted with due consideration to the rights, safety, and well-being of the participants.

Patient Consent for Publication: Since it is a retrospective observational study; Consent was not obtained from the patients. It has ethics committee approval.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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