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Original Article

Persistent smoking and adverse long-term outcomes after endovascular treatment for lower extremity peripheral artery disease

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Abstract

Aim: Long-term assessment after endovascular treatment for lower extremity peripheral artery disease (PAD) is clinically important because favorable immediate technical results may coexist with later limb and cardiovascular events. This study describes procedural and 5-year clinical outcomes in a single-center cohort.

Material and Methods: This retrospective, single-center, descriptive cohort included 150 patients treated for symptomatic lower extremity PAD between August 2016 and December 2018. Balloon angioplasty was the primary strategy; stenting was used as a bail-out treatment for suboptimal angiographic results, and directional atherectomy was used in 18 patients (12.0%). Clinical severity was summarized using the Rutherford category and the Wound, Ischemia, and Foot Infection (WIfI) stage. Follow-up consisted of clinical assessment and ankle-brachial index (ABI) measurement; median follow-up was 5 years. Fifteen patients were lost to follow-up, and five died. Because only aggregate data were available, analyses were descriptive; no patient-level smoking comparison, paired ABI test, regression model, or time-to-event analysis was performed.

Results: Most patients were Rutherford category 3 (104 [69.3%]), 4 (33 [22.0%]), or 5 (13 [8.7%]); WIfI stages 1-4 were represented. Technical success was 90.7% (136/150), and peri-procedural complications were recorded in 4.0% (6/150). Mean ABI increased descriptively from 0.4 ± 0.1 before treatment to 0.8 ± 0.2 after treatment. During follow-up, 5 patients (3.3%) died, 12 (8.0%) had myocardial infarction, 2 (1.3%) had stroke, 24 (16.0%) underwent repeat revascularization, and 8 (5.3%) underwent major amputation. Event categories were not mutually exclusive.

Conclusion: In this descriptive cohort, favorable procedural results and a higher post-procedure mean ABI coexisted with clinically important long-term limb and cardiovascular events. The study does not establish independent predictors or quantify the effect of smoking because comparative and adjusted analyses were not available. Prospective patient-level studies with standardized lesion characterization, medical-therapy documentation, imaging surveillance, and time-to-event analysis are needed.

Keywords: Peripheral arterial disease; tobacco smoking; angioplasty, balloon; ankle brachial index; follow-up studies

INTRODUCTION

Lower extremity peripheral artery disease (PAD) is a common manifestation of systemic atherosclerosis and encompasses a clinical spectrum ranging from exertional claudication to rest pain, tissue loss, and limb-threatening ischemia. Its consequences extend beyond the affected extremity: reduced walking capacity, impaired quality of life, recurrent hospitalization, major amputation, myocardial infarction, stroke, and premature death are all part of the disease burden. Long-term prognosis worsens as clinical severity increases, supporting the view that PAD is simultaneously a limb disorder and a marker of diffuse cardiovascular risk [1-4].

Accordingly, contemporary PAD care is not limited to revascularization. Major guidelines and consensus documents recommend a longitudinal strategy that combines antiplatelet and lipid-lowering therapy, control of hypertension and diabetes,

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smoking cessation, structured exercise, foot and wound care when indicated, and revascularization selected according to symptoms, limb threat, anatomy, procedural risk, and patient goals [5-8]. Endovascular therapy is frequently favored because it can restore perfusion with a relatively low immediate physiologic burden in appropriately selected patients; nevertheless, the durability and clinical value of an intervention must be judged within this broader secondary-prevention framework.

Accurate baseline assessment and follow-up are central to this longitudinal approach. The ankle-brachial index (ABI) provides a practical hemodynamic measure, whereas duplex ultrasonography, computed tomography angiography, magnetic resonance angiography, and catheter angiography can define lesion distribution and treatment anatomy when clinically required [6,7,9]. Clinical staging systems, including the Rutherford classification and the Wound, Ischemia, and Foot Infection (WIfI) framework, help describe symptom severity and limb-threat burden. At the same time, outcome assessment should extend beyond an angiographic endpoint: technical success, hemodynamic improvement, repeat revascularization, major amputation, functional status, and major cardiovascular and cerebrovascular events capture complementary dimensions of benefit and failure [10].

Endovascular technology for infrainguinal disease has evolved from conventional balloon angioplasty to selective nitinol stenting, drug-coated balloons, atherectomy, and other adjunctive strategies. Randomized comparisons of balloon angioplasty and primary nitinol stenting demonstrated that device selection and lesion characteristics influence early and intermediate outcomes [11,12]. Subsequent drug-coated balloon studies reported sustained effectiveness in femoropopliteal disease over extended follow-up [13-17]. These advances have also highlighted the importance of long-term safety surveillance; a previous meta-analysis raised concern regarding a possible late mortality signal after paclitaxel-coated balloon or stent treatment, illustrating why late clinical outcomes should not be inferred solely from initial patency or technical success [18].

Patient-level risk and disease burden remain equally important. Smoking and other cardiovascular risk factors have been associated with the distribution and severity of lower-limb atherosclerosis, while diabetes is associated with more severe PAD and poorer limb outcomes [19,20]. Coexisting coronary and peripheral arterial disease further identifies a population with substantial systemic atherosclerotic burden [21]. In patients with intermittent claudication, randomized evidence comparing endovascular revascularization with supervised exercise also emphasizes that treatment success should be interpreted in terms of symptoms and function rather than anatomy alone [22]. However, determining whether smoking, diabetes, lesion severity, medication use, or another factor independently predicts long-term MALE or MACCE requires longitudinal patient-level exposure data and appropriately adjusted analyses.

Against this background, real-world studies with extended follow-up can complement device trials by describing how favorable procedural results coexist with later limb and cardiovascular events in routine practice. The objective of the present study was to describe technical results, peri-procedural complications, change in ABI, and 5-year limb and cardiovascular outcomes after endovascular treatment for symptomatic lower extremity PAD at a tertiary referral center. Because the available dataset was aggregate and did not include longitudinal smoking exposure, detailed lesion anatomy, or patient-level time-to-event information, the study was designed as a descriptive analysis and did not test whether smoking or other baseline factors independently predicted major adverse limb events (MALE) or major adverse cardiovascular and cerebrovascular events (MACCE).

MATERIAL AND METHODS

Study design and cohort: This retrospective, single-center, descriptive cohort study was conducted at the Department of Cardiovascular Surgery, Ankara Bilkent City Hospital. Ethics approval was obtained from the Ankara Bilkent City Hospital No. 1 Clinical Research Ethics Committee (Approval No. E1-23-3766; approval date: 12/07/2023). The study included 150 patients with symptomatic lower extremity PAD who underwent endovascular treatment between August 2016 and December 2018. Eligibility in the available records was based on symptomatic lower extremity PAD, treatment at the study center during the defined period, and inclusion in the institutional follow-up dataset. The aggregate source available for this analysis did not preserve a screened-patient denominator or a detailed exclusion log; additional inclusion and exclusion criteria therefore could not be reconstructed.

Data availability and baseline variables: Age, sex, diabetes mellitus, hypertension, hyperlipidemia, chronic obstructive pulmonary disease, chronic kidney disease, coronary artery disease, previous coronary artery bypass grafting, baseline smoking status, ABI, Rutherford category, WIfI stage, and procedural details were summarized. The WIfI system denotes Wound, Ischemia, and Foot Infection. As stated in the source material, some baseline comorbidity distributions and hemodynamic values in the 150-patient summary were carried forward proportionally from an earlier aggregate manuscript rather than re-derived from individual patient records. These values are presented only as descriptive cohort-level estimates and were not used for patient-level hypothesis testing. Detailed lesion-level variables, including Trans-Atlantic Inter-Society Consensus (TASC) classification, lesion length, and anatomic distribution, were not available in analyzable form. Smoking was recorded at baseline only; persistence, cessation, pack-years, and structured cessation treatment were not available.

Endovascular procedure: Balloon angioplasty was the principal strategy. Stenting was used as bail-out treatment for significant residual stenosis or flow-limiting dissection judged to produce a suboptimal angiographic result. Directional atherectomy with the HawkOne system (Medtronic) was performed in 18 patients at operator discretion. Technical success was defined from the procedural record as restoration of antegrade flow with an operator-documented acceptable final angiographic result. A uniform numeric residual-stenosis threshold was not retained in the aggregate dataset.

Follow-up and outcomes: Follow-up consisted of clinical assessment and ABI measurement; median duration was 5 years. Uniform duplex ultrasound, computed tomography angiography, magnetic resonance angiography, or catheter angiography surveillance was not performed. Peri-procedural complications were those recorded during the index hospitalization. The principal long-term outcomes were MALE and MACCE. MALE comprised major amputation and repeat lower-extremity revascularization. MACCE comprised all-cause death, myocardial infarction, stroke, and repeat revascularization. Long-term events were counted from the index intervention through the last available clinical follow-up.

Event ascertainment and follow-up completeness: Outcomes were identified from available clinical records; the source material does not document an independent event-adjudication committee. The aggregate dataset did not retain sufficient event-level detail to report uniform troponin, electrocardiographic, or imaging criteria for each myocardial infarction or stroke, or the anatomical level of each major amputation. Event percentages were calculated using the original cohort denominator (n = 150), and categories were not mutually exclusive. The 15 patients lost to follow-up were not imputed; five deaths were retained as outcome events. Long-term clinical assessment was available for 130 surviving, traceable patients (86.7%).

Statistical analysis: Continuous variables were summarized as mean ± standard deviation or median, as appropriate; categorical variables as number and percentage. Because the available source was aggregate rather than patient-level, the analysis was descriptive. A comparison of persistent smokers with quitters or nonsmokers, a baseline comparison of patients with versus without complete follow-up, a paired statistical test for ABI, multivariable regression, and Kaplan-Meier or Cox analyses could not be performed. No missing-outcome imputation was applied. Accordingly, the results should not be interpreted as establishing causal or independent associations.

RESULTS

The cohort included 150 patients with symptomatic lower extremity PAD. The mean age was 63.0 ± 10.0 years, 131 (87.3%) were male, 81 (54.0%) had diabetes mellitus, 86 (57.3%) hypertension, 85 (56.7%) hyperlipidemia, 33 (22.0%) chronic obstructive pulmonary disease, 11 (7.3%) chronic kidney disease, 63 (42.0%) coronary artery disease, and 20 (13.3%) previous coronary artery bypass grafting. Current smoking was recorded in 110 patients (73.3%) at baseline; longitudinal smoking status was unavailable. Clinical presentation comprised Rutherford category 3 in 104 patients (69.3%), category 4 in 33 (22.0%), and category 5 in 13 (8.7%). WIfI stages 1-4 were represented (Table 1; Figure 1).

Table 1. Baseline demographic and procedural characteristics

Characteristic	Value
Age, years	63.0 ± 10.0
Male sex	131 (87.3%)
Diabetes mellitus	81 (54.0%)
Hypertension	86 (57.3%)
Hyperlipidemia	85 (56.7%)
COPD	33 (22.0%)
Chronic kidney disease	11 (7.3%)
Coronary artery disease	63 (42.0%)
Previous CABG	20 (13.3%)
Current smoking at baseline	110 (73.3%)
Pre-procedure ABI	0.4 ± 0.1
Post-procedure ABI	0.8 ± 0.2
Rutherford	
3	104 (69.3%)
4	33 (22.0%)
5	13 (8.7%)
WIfI stage	
1	18 (12.0%)
2	42 (28.0%)
3	56 (37.3%)
4	34 (22.7%)
Primary treatment strategy	Balloon angioplasty in 150 (100%)
Bail-out stenting	49 (32.7%)
Directional atherectomy	18 (12.0%)
Technical success	136 (90.7%)
Peri-procedural complications	6 (4.0%)
Follow-up duration	Median 5 years
Lost to follow-up	15 (10.0%)
Death during follow-up	5 (3.3%)

Values are n (%) unless otherwise stated. Abbreviations: ABI, ankle-brachial index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; WIfI, Wound, Ischemia, and foot Infection. Smoking status was recorded at baseline only.

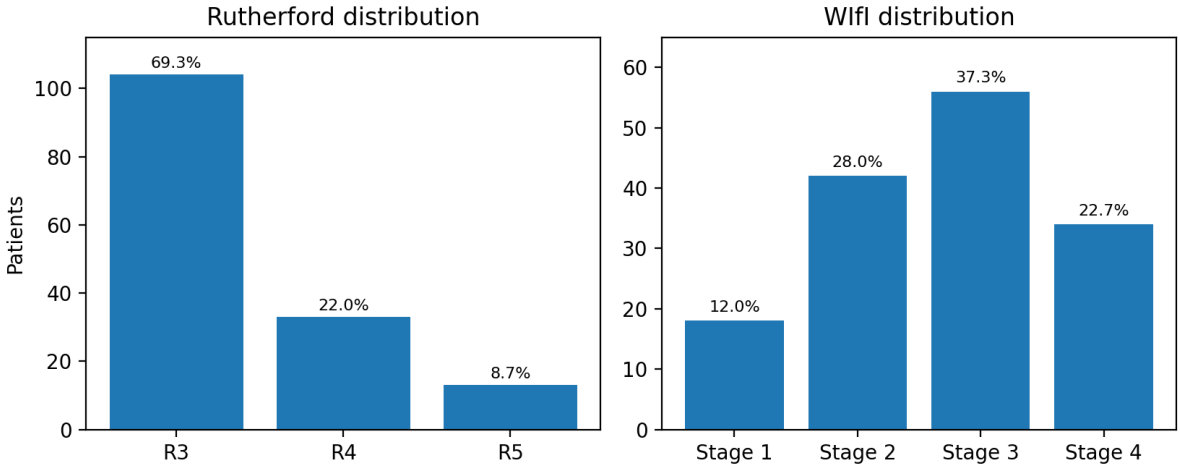


Figure 1. Baseline Rutherford category and Wound, Ischemia, and foot Infection (WIfI) stage distributions.

Endovascular treatment was technically successful in 136 patients (90.7%), and 6 patients (4.0%) had an aggregate-recorded peri-procedural complication. Balloon angioplasty was used in all cases; bail-out stenting was performed in 49 (32.7%), and directional atherectomy in 18 (12.0%). Mean ABI increased from 0.4 ± 0.1 before treatment to 0.8 ± 0.2 after treatment (Figure 2). This change is descriptive because paired patient-level values were not available for hypothesis testing or confidence-interval estimation.

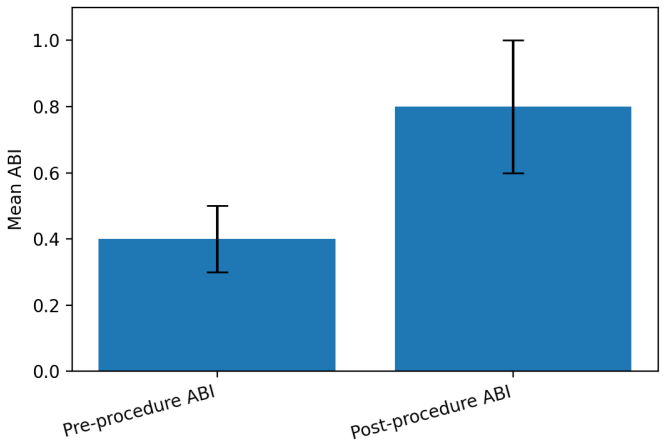


Figure 2. Mean ankle-brachial index before and after intervention. Error bars show standard deviation. The change is descriptive because paired patient-level data were unavailable for hypothesis testing.

Median follow-up was 5 years. Fifteen patients (10.0%) were lost to follow-up, five (3.3%) died, and long-term clinical assessment was available for 130 surviving, traceable patients (86.7%). Using the original cohort denominator, myocardial infarction occurred in 12 patients (8.0%), stroke in 2 (1.3%), repeat revascularization in 24 (16.0%), and major amputation in 8 (5.3%) (Figure 3; Table 2). Event categories were not mutually exclusive. No comparison of patients with and without complete follow-up and no time-to-event estimates were available.

Because uniform imaging surveillance was not performed, primary patency, restenosis, and asymptomatic loss of patency could not be assessed. Repeat revascularization therefore reflects clinically recognized events and may have been triggered by recurrent symptoms or limb findings rather than systematic detection of asymptomatic restenosis.

Baseline smoking was common, but the study did not record longitudinal smoking status or compare outcomes among persistent smokers, quitters, and nonsmokers. Smoking therefore cannot be identified from these data as a determinant of MALE, MACCE, or treatment durability.

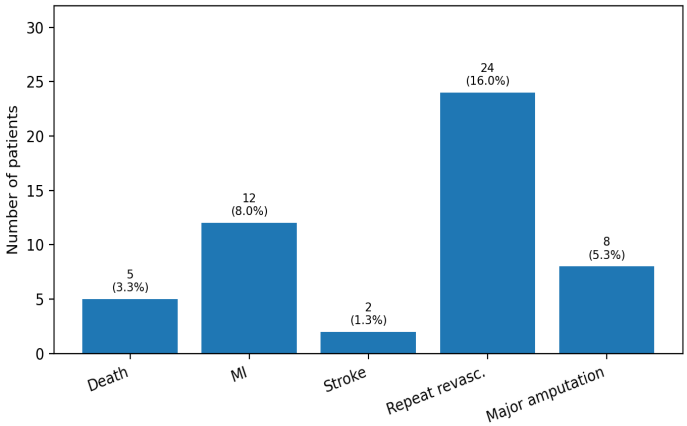


Figure 3. Long-term adverse outcomes during follow-up. Percentages use the original cohort denominator (n = 150); outcome categories are not mutually exclusive and therefore do not sum to 100%.

Table 2. Main long-term outcomes

Outcome	Value
Death	5 (3.3%)
Myocardial infarction	12 (8.0%)
Stroke	2 (1.3%)
Repeat revascularization	24 (16.0%)
Major amputation	8 (5.3%)
Long-term clinical assessment available	130 (86.7%)
MALE definition	Major amputation + repeat lower-extremity revascularization
MACCE definition	All-cause death + myocardial infarction + stroke + repeat revascularization

Percentages use the original cohort denominator (n = 150). Outcome categories are not mutually exclusive. Abbreviations: MACCE, major adverse cardiovascular and cerebrovascular events; MALE, major adverse limb events.

DISCUSSION

This descriptive single-center cohort shows that favorable immediate procedural outcomes can coexist with clinically important long-term limb and cardiovascular events after lower-extremity endovascular treatment. Technical success was 90.7%, peri-procedural complications were recorded in 4.0%, and mean ABI was higher after intervention. Over a median of 5 years, repeat revascularization, major amputation, myocardial infarction, stroke, and death were observed. These findings describe event burden; they do not identify independent predictors.

The emphasis on MALE and MACCE is clinically relevant because PAD is both a limb-threatening and systemic atherosclerotic disorder [1-4,10,21]. The cohort predominantly comprised Rutherford categories 3-5 and intermediate-to-advanced WIfI stages, indicating substantial baseline ischemic burden. The observed late events are therefore consistent with the need to evaluate patient-centered outcomes beyond angiographic success. However, the absence of patient-level comparative and risk-adjusted analyses prevents attribution of these events to any single baseline factor.

The treatment strategy was pragmatic: balloon angioplasty was the primary platform, permanent stenting was reserved for suboptimal results, and directional atherectomy was used selectively. For patients with intermittent claudication, the role of revascularization should also be considered alongside supervised exercise, which has been directly compared with endovascular treatment in randomized clinical research [22]. The mean ABI increase is clinically compatible with improved limb perfusion, but the aggregate dataset did not permit a paired test or confidence interval. Accordingly, the ABI finding should be interpreted as a descriptive hemodynamic observation rather than a formal efficacy estimate.

Long-term vessel durability could not be directly evaluated. Without uniform imaging surveillance, asymptomatic restenosis or occlusion may have been missed, and repeat revascularization may reflect symptom-driven clinical practice rather than a standardized patency endpoint. The reported reintervention rate therefore cannot be interpreted as equivalent to primary patency failure. Future studies should use prespecified duplex or cross-sectional imaging intervals and report patency, target-lesion revascularization, and clinically driven reintervention separately.

Current smoking was recorded in 73.3% of patients at baseline, but the dataset did not distinguish persistent smokers, quitters, former smokers, or changes in exposure during follow-up. No cohort-specific association between smoking and MALE, MACCE, amputation, reintervention, or ABI change can therefore be inferred. Independently of this study's findings, contemporary PAD guidelines support structured tobacco-cessation care, including repeated counseling, referral to a cessation program, and pharmacotherapy when clinically appropriate [5-7]. These measures should be understood as guideline-based management rather than as interventions tested by this cohort.

Other important modifiers of outcome were also unavailable. Detailed TASC classification, lesion length and distribution, antiplatelet and statin treatment, medication adherence, and standardized wound-care or surveillance protocols were not captured in sufficient detail for analysis. Their absence limits interpretation of the observed event frequencies and precludes assessment of guideline-directed medical therapy.

This study has substantial limitations. It is retrospective, single-center, and modest in size. The source available for the present report was aggregate rather than patient-level, and some baseline values were carried forward proportionally from an earlier aggregate manuscript; consequently, robust data verification, subgroup analysis, and modeling were not possible. A complete screening log and detailed exclusion criteria were unavailable. Fifteen patients were lost to follow-up, and baseline differences

between patients with and without complete follow-up could not be assessed. Events were identified from routine clinical records without documented independent adjudication or uniform objective definitions. No paired ABI test, multivariable analysis, survival analysis, or sensitivity analysis for missing follow-up was possible. The absence of standardized lesion characteristics, medical-therapy data, and imaging-based patency surveillance further limits causal and prognostic interpretation.

Within these constraints, the study provides a 5-year descriptive account of procedural performance and clinically important limb and cardiovascular events in a real-world PAD cohort. Its main contribution is the long follow-up horizon and the simultaneous reporting of hemodynamic, limb, and systemic outcomes. Confirmation requires a prospectively assembled patient-level cohort with verified baseline data, explicit eligibility criteria, standardized event adjudication, and complete time-to-event follow-up.

CONCLUSION

In this retrospective descriptive cohort, lower-extremity endovascular treatment was associated with high technical success and a higher mean post-procedure ABI, while repeat revascularization, major amputation, myocardial infarction, stroke, and death occurred during 5-year follow-up. Because patient-level comparative, adjusted, and time-to-event analyses were unavailable, the study does not establish independent predictors or quantify the effects of smoking, medical therapy, or surveillance. Larger prospective studies with standardized lesion characterization, treatment documentation, imaging follow-up, and risk-adjusted time-to-event analyses are required.

Ethics Committee Approval: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ankara Bilkent City Hospital No. 1 Clinical Research Ethics Committee (Approval No. E1-23-3766; approval date: 12/07/2023).

Patient Consent for Publication: Not applicable. The manuscript contains no identifiable individual patient information, images, or case-specific material requiring consent for publication.

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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