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ORIGINAL ARTICLE

Medicine Science International Medical Journal

Medicine Science 2026;15(2):740-3

Limb salvage and quality-of-life after tibial and pedal endovascular revascularization

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Received 30 October 2025; Accepted 23 December 2025
Available online 30 April 2026 with doi: 10.5455/medscience.2025.10.303

Abstract

Chronic limb-threatening ischemia (CLTI) frequently demands infrapopliteal endovascular treatment to avert the loss of a limb and to improve functional results. The current study assessed the six-month limb salvage and quality of life following tibial and pedal endovascular procedures. Fifty patients with Rutherford classification 4 to 6 CLTI underwent tibial/pedal angioplasty. The primary outcome measure was six-month freedom from major amputation. Secondary outcomes measured the rates of intervention, minor amputation, and rates of complications, along with change in ankle brachial index and quality-of-life scores according to Stark QoL assessment at 1, 3, and 6 months. The standardized post-procedure antiplatelet regimen was followed. Overall success rate was 88%. Pedal access was employed in 35% of patients. Reinterventions were done in 10%, 12%, and 15% at the end of 1, 3, and 6 months, respectively. Amputations, both major and minor, were low (3% to 6% and 8% to 12%, respectively), but six-month survival rates reached 95%. ABIs significantly rose from 0.45 ± 0.12 to 0.72 ± 0.14 ($p<0.0001$), and the Stark QoL score rose from 45 ± 12 to 63 ± 11 ($p<0.001$). Tibial and pedal endovascular revascularization offers excellent limb salvage rates and significant clinical improvement for patients with CLTI. The substantial increase in perfusion and quality-of-life improvement attests to the therapeutic efficacy of infrapopliteal endovascular interventions.

Keywords: Chronic limb-threatening ischemia, tibial angioplasty, pedal access, limb salvage, ankle–brachial index, quality of life

Introduction

Chronic limb-threatening ischemia (CLTI) is the most severe manifestation of peripheral arterial disease and accompanies rest pain, ischemic ulcerations, a high rate of limb loss, and a severely reduced quality-of-life index [1-3]. Modern treatment protocols focus on the re-establishment of the flow in the distal arterial tree in order to inhibit the resultant loss of the limb and to facilitate healing processes in the affected area [4]. For the last decade, the work in the area has shifted in favor of endovascular methods in a large number of cases because of their minimally invasive and fast and complete reversible properties [5,6].

Though the results of femoropopliteal procedures are well known, the efficacy of infrapopliteal and pedal artery revascularization has been shown to be more variable [7,8]. Diabetic and renal patients, along with those who show diffuse calcifications, commonly have complex tibial and pedal disease, making below-knee procedures technically difficult [9]. Nonetheless, the importance of providing direct antegrade perfusion to at least one pedal artery has come to be appreciated in limb salvage [10,11]. Apart from anatomical success, the achievement of functional and patient-driven outcomes, such as changes in the index of perfusion and quality of life, has assumed importance in the assessment of treatment efficacy [12,13]. Taking into account the above issues, there is a need for studies focusing on short-term clinical and functional results in patients undergoing tibial and pedal endovascular revascularization procedures. The purpose of our investigation is to evaluate the results of tibial and pedal procedures in patients with CLTI regarding limb salvage rates, hemodynamic success, and quality of life.

CITATION
Khalil E. Limb salvage and quality-of-life after tibial and pedal endovascular revascularization. Med Science. 2026;15(2):740-3.

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DOI: 10.5455/medscience.2025.10.304

Material and Methods

Research Design and Participants

The current observational study enrolled fifty patients with Rutherford class 4 to 6 chronic limb-threatening ischemia undergoing tibial/pedal endovascular revascularization from September 2020 to June 2022 in a single center. The patients with acute limb ischemia, non-atherosclerotic disease, and incomplete follow-up data were excluded from the study. All patients gave their informed consent, and the study was approved by the institutional ethics committee.

The procedures were conducted under the treatment of local anesthetics through antegrade femoral, retrograde tibial, and pedal approaches according to the lesion anatomy. Crossing the lesion was facilitated with the assistance of hydrophilic wires and supportive catheters, followed by balloon angioplasty according to the diameter and size of the lesion. Additional procedures:

- Atherectomy in 4 patients - 8%
- Stent placements in 3 patients (6%)

Successful procedure was noted if there was <30% residual stenosis and restoration of the flow to at least one pedal artery.

Follow-up Protocol

The patients underwent evaluation at the end of 1, 3, and 6 months. The assessment consisted of ankle brachial index (ABİ), toe brachial index, duplex ultrasound scan for restenosis, assessment of wound and limb, documentation of reintervention, and survival assessment. The quality of life assessment (QoL) was performed by the validated Stark QoL assessment in the patients.

Post-Procedural Medical Therapy Dual anti-platelet therapy (aspirin 100 mg and clopidogrel 75 mg daily) was administered to each patient for a period ranging from 1 to 3 months, followed by a life-long regimen of mono-anti-platelet therapy. The use of anticoagulation was deferred in the presence of clear indications. Vasodilators (such as cilostazol) were given if clinically indicated

A The primary endpoint was the six-month rate of freedom from major amputation. Secondary endpoints consisted of minor amputation, reintervention, changes from baseline in ABI/TBI and Stark QoL scoring, success rates, and complications.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR) as appropriate; categorical variables were presented as counts and percentages. Differences across follow-up visits were assessed using repeated-measures ANOVA or Friedman tests. Statistical significance was defined as a two-tailed $p<0.05$. Data analysis was performed using IBM SPSS Statistics version 27.0 (IBM Corp.,Armonk,NY,USA).

Results

Baseline Characteristics

Fifty patients with Rutherford category 4 to 6 CLTI participated in total. The mean age was 68 years ±10 years, and 70% were male. The incidence of diabetes, hypertension, dyslipidemia, and chronic renal disease was high at 60%, 85%, 55%, and 20% of the population, respectively. The mean baseline values of both ABI and TBI were substantially low at 0.45 ± 0.12 and 0.25 ± 0.10, respectively (Table 1).

Table 1. Baseline characteristics of the study population (n=50)

Variable	Value
Age (years), mean ± SD	68 ± 10
Male sex	70%
Hypertension	85%
Diabetes mellitus	60%
Dyslipidemia	55%
Coronary artery disease	35%
Chronic kidney disease	20%
Smoking (current/former)	70%
Baseline ABI	0.45 ± 0.12
Baseline TBI	0.25 ± 0.10

Procedural Outcomes

The most frequent access was antegrade femoral (60%) followed by retrograde tibial access (25%) and pedal access (15%). The number of atherectomies performed was 4 (8%), and the number requiring stent placement was 3 (6%). The technical success rate was 88%. Pedal-directed therapy was applied in 35% procedures. The periprocedural complications rate was 12%, and the most frequent was hematoma and dissection (Table 2).

Table 2. Procedural and angiographic details

Parameter	Value
Access site: Antegrade / Retrograde / Pedal	60% / 25% / 15%
Procedure duration (min), mean ± SD	95 ± 25
Technical success	88%
Pedal intervention performed	35%
Any complication	12%
Common complications	Hematoma, dissection

Clinical Outcomes

Extensive amputations: 3%, 4%, & 6% at 1, 3, & 6 months, respectively. Minor: 8%, 10%, & 12% at the respective periods. Need for re-intervention: in 10%, 12%, & 15% at the respective periods. Six-month survival rate: 95%.

Hemodynamic Improvement

ABI values significantly increased from 0.45 ± 0.12 at baseline to 0.72 ± 0.14 at six months ($p<0.001$) (Figure 1).

DOI: 10.5455/medscience.2025.10.304

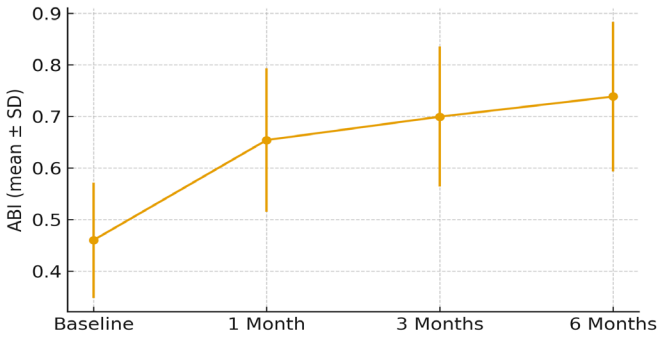

Figure 1. Mean ABI over time (Baseline,1,3,6 months). High-resolution updated figure showing changes in mean ankle–brachial index (ABI) from baseline to 6 months

Quality-of-Life Outcomes

Stark QoL scores rose from 45 ± 12 at baseline to 63 ± 11 at six months ($p<0.001$) (Figure 2) (All outcome measures are listed in Table 3).

However, the ischemic ulcers demonstrated gradual healing. Most of the minor amputations occurred following a success in the revascularization process. The functional mobility began to improve with the increase in perfusion and QoL changes.

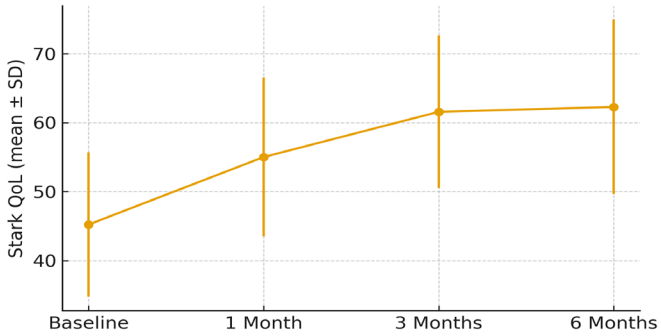

Figure 2. Quality-of-Life Improvement (Stark QoL). High-resolution updated figure showing improvement in Stark Quality-of-Life (QoL) scores across follow-up visits

Table 3. Clinical and functional outcomes at follow-up

Outcome	1 Month	3 Months	6 Months
Reintervention	10%	12%	15%
Major amputation	3%	4%	6%
Minor amputation	8%	10%	12%
Survival	98%	96%	95%
ABI (mean ± SD)	0.65 ± 0.11	0.70 ± 0.13	0.72 ± 0.14
Stark QoL (mean ± SD)	55 ± 10	60 ± 11	63 ± 11

Discussion

The endovascular revascularization of the tibial and pedal arteries has emerged as an important treatment tool in the management of chronic limb-threatening ischemia (CLTI), especially in the presence of coexisting diseases in a nonsurgical candidate. The results of our study confirmed a high success rate and favorable limb-salvage outcomes at six months, in accordance with current literature confirming the efficacy and safety of infrapopliteal endovascular procedures [14,15].

Restoration of direct flow to at least one distal artery is a key factor in the success of the treatment. The hemodynamic changes in the values of ABI and TBI in our population demonstrate the important effect of the restoration of inline flow in limb function, in accordance with the published literature [16,17]. At the same time, the significant changes in the functional status and quality-of-life assessment results underscore the important and evolving role of functional assessment in the success of treatment for CLTI patients [18,19]. Our results for the need for intervention and the number of amputations are in the expected ranges in such a high-risk population. The number of major amputations was low, and the majority of the minor procedures occurred following a successful revascularization and in the process of healing a wound, in accordance with the strategic approach to undertake a minor amputations following restoration of the perfusion [20]. Though long-term patency was not assessed in this trial, available literature has shown a gradual loss of tibial artery patency with the progression of time, especially in diabetic, renal, and severely calcified patients. Notably, available studies have demonstrated the clinical efficacy of a procedure, represented by the steady limb salvage and improvement in symptoms, to persist even in the absence of long-term patency, attributing this factor to the improvements in the microvascular flow in the targeted limb [21,22]. This underscores the fact that the durability of a procedure in chronic limb threat ischemia need not be directly represented by long-term patency and that urgent intervention in the disease process continues to be an important component in the long-term management of the disease.

The safety found in our population finds a supporting rationale in the low incidence of complications reported in the literature for the angioplasty performed in the infrapopliteal region [23]. The judicious utilization of atherectomy procedures in our population (8%) and the utilization of the stenting procedure (6%) finds a supportive rationale in the fact that atherectomy and stenting in the tibial region should be viewed as supplementary tools

DOI: 10.5455/medscience.2025.10.304

to the prevailing treatment strategies in the form of the balloon inflation in the treatment of tibial artery disease, a fact supported by present literature [24].

Several limitations appear in this study. The number of patients studied was relatively low, and the postoperative follow-up period was six months, making it impossible to assess the long-term patency rates and functional success of the procedure. Another point to consider is that QoL assessment tools offer important information but might be supplemented by functional analyses to improve the results of studies concerning this issue in the future.

Conclusion

Tibial and pedal endovascular revascularization brought marked hemodynamic and functional success, and improved quality-of-life scores and rates of favorable limb salvage at six months. The results encourage the ongoing use of endovascular therapy in the first-line treatment of appropriately selected patients with CLTI, especially those in whom bypass surgery is contraindicated.

Ethical Approval
Approved by the Ordu University Research and Education Hospital (No: 62, Date: 26 March 2020).

Patient Consent
Written informed consent was obtained from all participants prior to inclusion in the study.

Conflict of Interest
The authors declare no conflict of interest.

Funding
The authors received no financial support for this study.

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