Original Article

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Navigating Vascular Pipelines: A Comparison of Amputation free Survival and Two-year patency between Open and Endovascular Revascularization in Patients with Peripheral Arterial Disease; A Retrospective analysis

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Author`s Contribution

[1,2]Substantial contributions to the conception or design of the work; or the acquisition, [3,5]Active participation in active methodology, analysis, or interpretation of data for the work, [4]Supervision, [1,6]Drafting the work or revising it critically for important intellectual content

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ABSTRACT

Objective: Chronic limb-threatening ischemia (CLTI) represents the most severe form of peripheral arterial disease and is associated with high risks of limb loss and mortality. Both open surgical bypass and endovascular revascularization are established treatment options; however, comparative long-term outcome data from South Asian populations are limited. This study aimed to compare two-year primary patency and amputation-free survival between open surgical and endovascular revascularization in patients with CLTI.

Methodology: This retrospective observational cohort study was conducted at a tertiary care university hospital in Islamabad. Medical records of patients with CLTI who underwent lower-limb revascularization between January 2020 and January 2022 were reviewed. Patients were grouped according to the type of intervention: open surgical bypass or endovascular revascularization. Baseline demographics, comorbidities, procedural details, and outcomes were collected. The primary outcome was two-year primary patency, while the secondary outcome was two-year amputation-free survival. Kaplan–Meier survival analysis and appropriate statistical tests were used for comparison.

Results: A total of 109 patients were included, of whom 67 (61.5%) underwent surgical bypass and 42 (38.5%) underwent endovascular intervention. Two-year primary patency was 70.1% in the surgical group and 78.7% in the endovascular group (p = 0.091). Two-year amputation-free survival was 77.6% following surgical revascularization and 80.8% following endovascular intervention, with no statistically significant difference between groups (log-rank p = 0.092).

Conclusion: Both open surgical and endovascular revascularization provide comparable and acceptable two-year patency and amputation-free survival in patients with CLTI. Treatment decisions should be individualized through multidisciplinary discussion, considering anatomical factors, comorbidities, and patient-specific risks.

Keywords: Peripheral Vascular disease, lower limb bypass, endovascular revascularization, lower extremity amputation, amputation free survival.

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Introduction

Peripheral artery disease (PAD) is a major global health problem, affecting more than 230 million individuals worldwide, and is associated with significant morbidity and mortality due to its cardiovascular and limb-related complications.[1] Chronic limb-threatening ischemia (CLTI) represents the most severe clinical manifestation of PAD and is characterized by ischemic rest pain, non-healing ulcers, or gangrene, with a high risk of limb loss and death if left untreated.[2]

The development and progression of CLTI are strongly influenced by patient-related comorbidities, particularly

diabetes mellitus, smoking, hypertension, chronic kidney disease, and ischemic heart disease. South Asian population has anatomical variations in vascular structure. Diabetes and chronic kidney disease are associated with diffuse, distal, and heavily calcified arterial disease, impaired collateral formation, endothelial dysfunction, and poor wound healing, all of which negatively affect revascularization durability and limb salvage. Smoking accelerates atherosclerosis and promotes inflammatory and thrombotic pathways, contributing to graft failure and restenosis following both open and endovascular interventions. These pathophysiological factors play a crucial role in determining not only disease severity but also the relative effectiveness, advantages, and limitations of different revascularization strategies.

CLTI has become an increasing public health concern in low- and middle-income countries due to the rising prevalence of diabetes and tobacco use. Pakistan faces a growing burden of PAD and CLTI, with recent estimates reporting a diabetes prevalence in Pakistan of17.1%, while the prevalence of tobacco use was 13.4%.[3, 4] The most common form of diabetic limb disease is infra popliteal disease, which affects the arteries below the knee and leads to CLTI.[5] The management of CLTI involves restoring blood flow to the affected limb by either bypass surgery, using reversed great saphenous vein autograft or prosthetic graft, or endovascular intervention, such as stenting or angioplasty.[6]

Several studies have compared the outcomes of surgical and endovascular interventions on revascularization of chronic limb ischemia.[7-9] Parvar et al concluded that surgical revascularization had some advantages over endovascular approach such as lower long-term mortality.[7] Similarly, another randomized control trial with 1830 patients reported among patients with CLTI with sufficient great saphenous vein autograft for surgical revascularization, surgical group had lower mortality and fewer major adverse limb events than the endovascular group.[10]

More recently, large trials such as BASIL-2 and SPINACH have further highlighted the complexity of revascularization decision-making, reporting differing outcomes based on patient selection, anatomy, and comorbidity burden.[11, 12] However, these studies were largely conducted in Western populations and included limited representation from South Asia.

Despite the high prevalence of diabetes, smoking, and advanced peripheral arterial disease in South Asian populations, there is a paucity of region-specific data comparing long-term outcomes of open versus endovascular revascularization in patients with CLTI. Differences in disease distribution, comorbidity profiles, healthcare resources, and patient selection may limit the generalizability of existing international trials to this setting. The present study was therefore undertaken to compare two-year primary patency and amputation-free survival between open surgical and endovascular revascularization in patients with CLTI in a South Asian cohort, with the aim of providing locally relevant evidence to inform clinical decision-making and optimize limb salvage strategies.

Methodology

This was a retrospective observational cohort study conducted at Shifa International Hospital (SIH), Islamabad. The study was approved by the Institutional Review Board of SIH (IRB reference No. 0249-23). Data were obtained by retrospective review of hospital electronic medical records, operative notes, vascular laboratory (duplex ultrasound) reports, radiology reports, and outpatient follow-up documentation for the study period.

All consecutive patients treated for chronic limb-threatening ischemia (CLTI) who underwent lower-limb revascularization at SIH between January 2020, and January 2022 were eligible for inclusion. CLTI was defined clinically by ischemic rest pain and/or minor tissue loss (non-healing ulceration or limited gangrene) consistent with Rutherford category 4–5 and supported by imaging demonstrating infra-inguinal arterial disease requiring revascularization.

Patients were included if they had a diagnosis of chronic limb-threatening ischemia (CLTI), defined by ischemic rest pain and/or minor tissue loss, and had undergone either open surgical bypass or endovascular revascularization of the lower limb during the study period. Eligible patients were required to have complete baseline clinical and imaging documentation, as well as at least one post-procedure assessment recorded in the medical record.

Patients were excluded if revascularization was performed for acute limb ischemia or traumatic vascular injury, malignancy-related limb ischemia, or gas gangrene or extensive infection necessitating immediate major amputation without an attempt at revascularization.

Additionally, patients with incomplete medical records that prevented accurate assessment of study outcomes were excluded.

Baseline clinical characteristics and comorbidities were extracted from patient records, including age, sex, diabetes mellitus, hypertension, smoking status, chronic kidney disease, and ischemic heart disease. Pre-procedure anatomical assessment was performed using computed tomography angiography (CTA) and/or magnetic resonance angiography (MRA); where performed, diagnostic angiography findings were used to guide endovascular planning.

Limb threat severity was assessed using the Wound, Ischemia, and foot Infection (WIfI) classification system, which stratifies risk of amputation and estimates potential benefit of revascularization[13]. Patients categorized as WIfI stage ≥2 were generally considered for revascularization in the institutional pathway. The primary exposure variable was type of revascularization, categorized into: Open surgical bypass group and Endovascular revascularization group.

Treatment selection was non-randomized. Patients were discussed in a multidisciplinary team (MDT) forum including consultant vascular surgeons and an interventional radiologist. Our study involves various surgeons and interventional radiologists with more than a decade of post fellowship experience Allocation to open or endovascular treatment was based on anatomical suitability (including lesion distribution and complexity), feasibility of bypass conduit (availability of suitable great saphenous vein), comorbidity profile and estimated procedural risk, and MDT consensus. Where applicable, patient preference and anticipated rehabilitation potential were also considered.

Endovascular revascularization: Endovascular procedures included balloon angioplasty with or without primary stenting. Access was typically obtained via percutaneous common femoral artery puncture under ultrasound guidance. Lesion crossing, angioplasty, and stent deployment (when used) were guided by angiographic findings.

Open surgical revascularization: Open procedures consisted of femoropopliteal or femorodistal bypass. Autologous great saphenous vein (ipsilateral or contralateral) was used preferentially. Prosthetic grafts were used only when suitable autologous conduit was unavailable. Standard groin exposure of the common femoral artery was performed for proximal anastomosis; distal target exposure was determined by planned outflow (popliteal artery or tibio-peroneal trunk/infra-popliteal targets).

Follow-up data were obtained retrospectively from outpatient clinic notes, vascular lab reports, and hospital re-admission records for up to 24 months after the index revascularization procedure. Post-procedure surveillance in routine clinical practice commonly included clinical assessment and duplex ultrasound; however, as this was a retrospective study, follow-up intervals were not protocolized and were documented as per standard care.

The primary outcome was two-year primary patency, defined as patency of the treated segment (graft or endovascular target lesion) without the need for repeat surgical or endovascular intervention on the same limb during follow-up. The secondary outcome was two-year amputation-free survival (AFS), defined as survival without major (above-ankle) amputation of the treated limb. Major amputation was defined as any amputation above the ankle joint.

Data were analyzed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were reported as frequencies and percentages, and continuous variables as mean ± standard deviation (or median with interquartile range where appropriate). Baseline characteristics were compared between groups using Chi-square or Fisher's exact tests for categorical variables and independent-samples t-test (or Mann–Whitney U test) for continuous variables.

Amputation-free survival was analyzed using Kaplan–Meier survival curves, with differences between groups assessed using the log-rank test. A p-value <0.05 was considered statistically significant. P-values were reported to three decimal places.

Results

A total of 109 patients meeting the inclusion criteria were identified during the study period. Of these, 67 patients (61.5%) underwent open surgical bypass, and 42 patients (38.5%) underwent endovascular revascularization. The patient selection process and two-year amputation-free survival are summarized in Figure 1.

Baseline demographic and clinical characteristics of the two treatment cohorts are summarized in Table I. Most patients in both groups were male. Patients in the endovascular cohort had a higher prevalence of diabetes

mellitus, hypertension, ischemic heart disease, and prior cerebrovascular or coronary interventions, whereas smoking history and chronic kidney disease were more frequent in the surgical cohort.

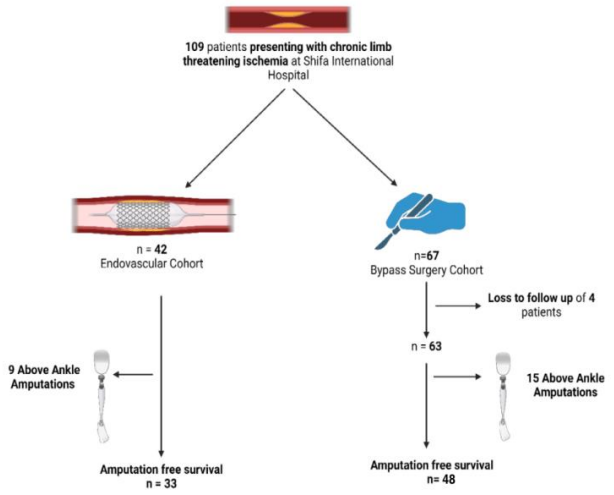

Figure 1. Graphical abstract showing the patient selection process and 2-year follow-up of the 2 cohorts. (Created with biorender.com)

Table I: Baseline demographics of the two treatment cohorts.

	Total	Surgical Arm	Endovascular Arm
Age		57.67±13.86	63.57±11.43
Number of Patients	109	67	42
Males	87	52	25
Females	22	15	07
Smokers	44	34	10
Diabetics	60	30	30
Chronic Kidney Disease	08	06	02
Previous history of stroke	09	03	06
Hypertensive	65	39	26
Ischemic Heart Disease	46	31	15

In the surgical cohort, 41 patients underwent above-knee femoropopliteal bypass and 22 patients underwent below-knee or femorodistal bypass. In the endovascular cohort, 12 patients underwent above-knee intervention, and 30 patients underwent below-knee intervention. Outcome data for two years were unavailable for four patients due to incomplete follow-up records; these patients were excluded from time-to-event analyses but included in baseline descriptions.

Our primary end point in this study was patency of the procedure done at two years. The two-year patency of surgical and endovascular cohort was 70.14% for the surgical cohort and 78.71% for endovascular cohort. The p-value was insignificant between the two. (Table II)

Table II: Two-year patency of surgical and endovascular revascularizations.

Type of Procedure	Frequency	Patency at Two years	p-value
Surgical Cohort	47	70.14%	
Endovascular Cohort	37	78.71%	0.091

At two years, 77.6% of patients in the surgical cohort and 80.8% of patients in the endovascular cohort remained amputation-free. Kaplan–Meier survival analysis demonstrated no significant difference in amputation-free survival between the two treatment strategies (log-rank p = 0.092) (Figure 2, Table III).

Table III: Two-year amputation free survival of surgical and endovascular revascularizations.

Type of Procedure	Amputation free survival at two years	Percentage	p-value
Surgical Cohort	52	77.6%	
Endovascular Cohort	38	80.8%	0.092

Kaplan-Meier survival curves were generated to assess amputation free survival in the two treatment cohorts: Endovascular intervention and open bypass surgery. Figure 2 displays the Kaplan-Meier survival curves for two groups, demonstrating survival rates over period of two years.

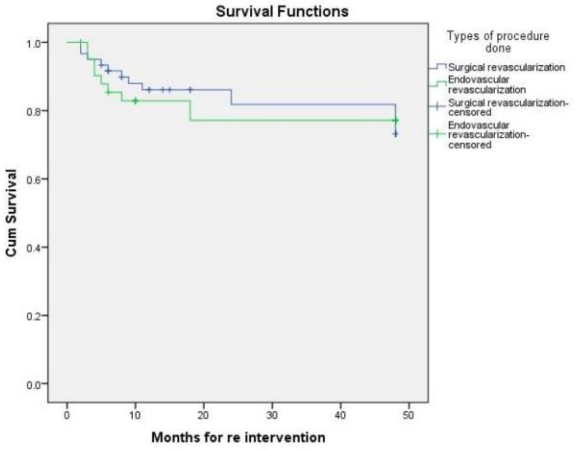

Figure 2. Kaplan-Meier survival curves for two intervention cohorts (y-axis has amputation free survival)

A total of 24 patients underwent major (above-ankle) amputation during follow-up: 15 (22.3%) in the surgical cohort and 9 (21.4%) in the endovascular cohort. The proportion of major amputations did not differ significantly between treatment groups (p = 0.906).

Exploratory univariate analysis showed that loss of primary patency occurred more frequently in patients with diabetes mellitus and active smoking; however, these associations did not reach statistical significance. The study was not powered to perform multivariable or subgroup analyses assessing the independent effect of comorbidities on patency outcomes.

Discussion

The increasing incidence of peripheral arterial disease is attributed to population aging and the rising prevalence of diabetes mellitus and chronic kidney disease.[14, 15] These conditions are associated with diffuse and distal atherosclerotic disease, particularly involving infra-popliteal vessels, which is increasingly encountered in vascular practice.[16,17] In parallel, advances in revascularization techniques over the past decade have led to wider adoption of endovascular approaches.

The SPINACH study compared surgical reconstruction and endovascular treatment in patients with critical limb ischemia and reported no significant difference in amputation-free survival between the two strategies.[12] Subgroup analyses suggested that outcomes may vary based on patient characteristics, highlighting the importance of individualized treatment selection. In contrast to SPINACH, treatment allocation in our study was guided by anatomical considerations and multidisciplinary team discussion based on established guidelines.

A substantial proportion of patients in the SPINACH study had chronic kidney disease, which may have influenced outcomes. However, inclusion of such patients also reflects real-world clinical practice. Our study similarly included patients with a range of comorbidities, allowing assessment of outcomes in a heterogeneous population.

In our cohort, two-year amputation-free survival and primary patency rates were comparable between open surgical bypass and endovascular revascularization. Kaplan–Meier analysis demonstrated no significant difference in amputation-free survival between the two treatment strategies. These findings differ from some previous studies reporting superior patency or limb outcomes with surgical bypass[18,19], while aligning with others showing comparable or favorable outcomes with endovascular intervention.[20,14] Differences in patient selection, disease severity, comorbidity burden, study design, and follow-up duration may account for these variations.

Selection of the optimal revascularization strategy in patients with chronic limb-threatening ischemia is influenced by anatomical complexity, comorbidities, and institutional expertise. These factors complicate direct comparison between treatment modalities, even in studies employing advanced statistical adjustment techniques.

The BASIL trial demonstrated improved survival and amputation-free survival with bypass surgery in patients who survived beyond two years, whereas an angioplasty-first approach appeared suitable for patients with limited life expectancy.[21] BASIL-2 trial concluded that endovascular treatment was better than vein bypass in terms of reducing the risk of death or major amputation.[22] However, both trials predominantly included Western populations, with limited representation from South Asia, which may restrict generalizability of their findings.

This study has limitations inherent to its retrospective, single-center design and relatively small sample size, which precluded detailed multivariable or subgroup analyses. Procedural techniques and available resources may also have influenced outcomes.

Despite these limitations, the study benefits from a relatively long follow-up of 24 months compared with many published series.[23, 24] Importantly, it provides region-specific data from South Asia, where the burden of diabetes and peripheral arterial disease is high but published outcome data remain limited. Our findings support a patient-centered approach to revascularization, guided by individual clinical and anatomical factors rather than a single preferred modality.

Conclusion

Our study concludes that both open and endovascular revascularization are successful in achieving an acceptable amputation free survival. The cases should be tailored to individual needs after being discussed in MDT and the best revascularization options should be offered to the patients.

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