Original Article

Retrospective Analysis to Compare Prognostic Outcomes of Endovascular vs Open Bypass in Critically Limb Threatening Ischemia (CLTI); A Single Centre Cohort

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ABSTRACT

Objective: This study aims to compare the outcomes of open vs. endovascular revascularization.
Study Design: A retrospective observational study
Place and Duration of Study: This study was conducted at the Department of Vascular and Endovascular Surgery, Shaheed Mohtarma Benazir Bhutto Institute of trauma, Karachi from January 2021 to November 2023.
Methods: A retrospective observational study conducted during 4 years period in all patients of CLTI underwent revascularization. primary patency at 1 year, survival for 6 months, amputation free survival for 1 year, and ambulatory status and limb salvage rates were examined.
Results: We analyzed a final sample size of 247 patients with 80.5% (n=207) males and a mean age of 55.85 years. 64.2% (n=165) of our patients were diabetic, 27.9% (n=123) had known hypertension, 28% (n=72) had ischemic heart disease and 6.6% (n=17) had had strokes. The salvage rate post-intervention varied for open bypass at 80.45% (n=107), endovascular approach at 76.92% (n=90) and hybrid procedures at 71.42% (n=5). The rate of major amputations was found to be 21.8%(n=56). At 6 months, 76.6% of the patients were still alive 68.48% did not undergo any major amputations.
Conclusion: Our study demonstrates that both endovascular and open bypass approaches achieve satisfactory and equivalent limb salvage and patency rates in patients with CLTI. Further high-quality research is needed to establish evidence-based guidelines, ultimately improving outcomes in this high-risk population.
Key Words: Critical Limb threatening Ischemia, peripheral arterial disease, open vs. endovascular, outcomes, amputation free survival.

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INTRODUCTION

Peripheral arterial disease (PAD) or Lower Extremity Arterial Disease (LEAD) when talking specifically about the lower limbs, is commonly used to refer a spectrum of lower limb arterial insufficiency ranging from asymptomatic limb to critical limb threatening ischemia (CLTI).[1] CLTI is a severe manifestation of PAD and clinically presents as rest pain or tissue loss or both.

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The presence of either rest pain or tissue accompanied by appropriate hemodynamic evidence is enough to qualify the disease as CLTI.[2]
Ischemic rest pain is described as any pain in the leg or foot, worsened by resting the affected limb flat on a surface and relieved by hanging the foot off, accompanied by evidence of impaired blood flow.[2] whereas non-healing ulceration or gangrene of any part of the foot and accompanied by evidence of arterial insufficiency is termed tissue loss.[3]
The prevalence of PAD is approximately 6%[4] of the worldwide adult population and advanced symptomatic PAD affects 500 to 1000 people per million every year and is overall present in 0.4% of the world population. Between 120 to 500 per million people are at risk of major limb loss every year attributable to CLTI.[5]
Established risk factors for PAD include smoking, diabetes, old age, dyslipidemia, hypertension, obesity and chronic kidney disease.[4] Senility appears itself to be a significant risk factor for LEAD as the disease manifests after the age of 50 years.[5] Gender and socioeconomic status also influence PAD progression as more common in male while in the developing

world, more women than men are affected.[5] Smoking is particularly strongly associated with PAD and the risk proportionally rises with smoking intensity.[6]

Hypertension is also a known risk factor for PAD.[6,7] In Emdin et al., reports 44,329 incident LEAD events, a 20 mmHg increase of Systolic BP was associated with 63% increased risk for LEAD.[8]

Diabetes is strongly associated with PAD and usually has worse outcomes including a higher amputation risk; roughly five times higher than in non-diabetics.[5,9]

METHODS

We conducted a retrospective observational study at the Department of Vascular and Endovascular Surgery, Shaheed Mohtarma Benazir Bhutto Institute of trauma, Karachi with Non-probability consecutive sampling. All patients included from January 2021 to November 2023 with CLTI who underwent revascularization either via open bypass surgery or endovascular approach of all ages and both genders for CLTI affecting the lower limb. Patient with revascularization procedure done in the upper limbs, procedure abandoned midway for any patient-related or technical factors and incomplete data in patient record.

Data Collection and analysis: Patient were identified by review of patient's medical record and operative logs. Patients' basic demographic profile, stage and severity of the disease, revascularization procedure undertaken, outcomes, and complications was recorded. Follow-ups up to 1 year were extracted to get information on amputation free survival, major and minor amputations, survival, graft patency and ambulatory status. All patients lost to follow-up were contacted by a team of researchers. Data was registered in a pre-designed questionnaire and analyzed by statistical package for social science (SPSS inc, Chicago, IL) version 26. Mean and standard deviation was calculated for quantitative variables with normal distribution while median (IQR) was reported for non-normally distributed quantitative variables. Frequency and percentages calculated for qualitative variables like gender and comorbidities. For the analysis of qualitative variables, the chi-squared test was used to compare the outcomes and demographic as well as comorbids. P value less than 0.05 was considered statistically significant.

RESULTS

Among 247 patients, 80.5% (n=207) were male and 19.5% (n=50) were female, with a mean age of 55.85 years (males: 56.5 years, females: 53.02 years). Diabetes was present in 64.2% (n=165), hypertension in 47.9% (n=123), ischemic heart disease in 28% (n=72), and cerebrovascular accident history in 6.6% (n=17). Dialysis-dependent chronic kidney disease was seen in 0.008% (n=2). Smoking history was recorded in 44% (n=114), significantly correlating with male gender (p=0.000).

Presentation included concomitant rest pain and tissue loss in 67.7% (n=174), tissue loss only in 22.2% (n=57), and rest pain only in 10.1% (n=26). Tissue loss was significantly higher in men (74.3%, n=191) vs. women (15.6%, n=40; p=0.005). Rest pain and tissue loss combined was more common in men (58%, n=149) than women (9.7%, n=25).

Diagnostic imaging included Digital Subtraction Angiography (DSA) in 61.5% (n=158) and CTA in 37.7% (n=97). DSA was used in 46.7% (n=120) of diabetic patients. Fem-popliteal disease was the most common (54.8%, n=141), followed by Aorto-Iliac disease (23.7%, n=61).

Among 257 patients, 51.8% (n=133) underwent open surgery, 45.5% (n=117) had endovascular procedures, and 2.7% (n=7) had hybrid procedures. Stenting was performed in 9.3% (n=24) and was significantly associated with supra-inguinal and femoral disease (p<0.000). Open revascularization included Fem-distal bypasses (50%, n=69) and Fem-pop bypasses (24.6%, n=34).

The overall limb salvage rate post-intervention was 78.6% (n=202), with a 1-year patency rate of 71.2% (n=183). Patency varied by procedure: open bypass (80.45%, n=107), endovascular (76.92%, n=90), and hybrid (71.42%, n=5), with no significant difference (p=0.712). Salvage rates for synthetic grafts (80.77%, n=21) and native grafts (80.91%, n=89) were comparable, with no significant correlation to primary patency (p=0.517) or limb salvage (p=0.987). Re-intervention rates were 9.9% (n=11) for native grafts vs. 19.23% (n=5) for synthetic grafts (p=0.183).

Minor amputations occurred in 42.41% (n=108), including single toes (57.8%, n=63), multiple toes (18.34%, n=20), and tarso-metatarsal amputations (23.14%, n=25). Major amputations were recorded in 21.8% (n=56), comprising below-knee (58.93%, n=33) and above-knee amputations (41.07%, n=23).

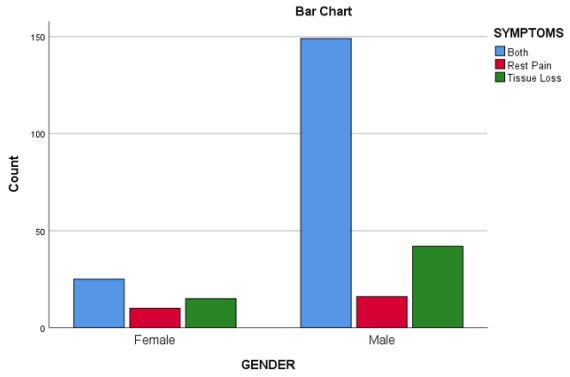

Figure No.1: Bar Chart with gender

Survival tracking showed 12.8% (n=33) mortality within 6 months, 45.5% (n=117) survival up to 6 months, and 31.1% (n=80) survival beyond 1 year. Follow-up was lost for 10.5% (n=27). Major

amputations were performed in 21.78% (n=56) within 6 months of intervention. Amputation-free survival was >6 months in 43.58% (n=112) and >1 year in 24.9% (n=64), with 9.73% (n=25) having unknown AFS due to loss of follow-up.

At 6 months, 10.1% (n=26) were bedbound, 28% (n=72) ambulated with support, and 50.2% (n=129) walked independently.

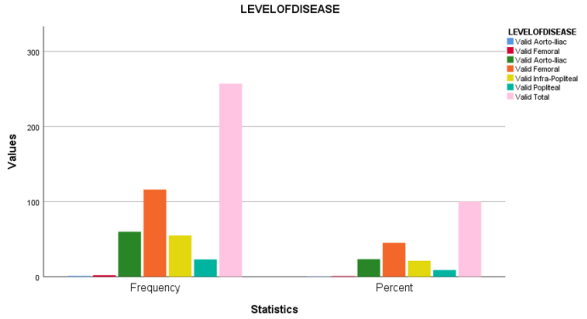

Figure No.2: Level of Disease with statistics

Table No.1: Parameters with percentage

Parameter	Percentage	Total
Gender	Males	80.5%(n=207)
Risk factors	Females	19.5(n=50)
	Diabetes	64.2%(n=165)
	Hypertension	47.9(n=123)
	Ischemic Heart Disease CKD CVA Smoking	28%(n=72) 0.008%(n=2) 6.6%(n=17) 44%(114)
Presentation	Rest pain Tissue loss Both	10.1%(n=26) 22.2%(n=57) 67.7%(n=174)
Imaging	CTA DSA	37.7%(n=97) 61.5%(n=158)
Level of Disease	Fem-Popliteal Aorto-Iliac Infra-Popliteal	54.9%(n=141) 23.7%(n=61) 21.4%(n=55)
Type of Principal Intervention	Open Fem-Fem crossover Aorto-Iliac Aorto-Fem Axillo-Fem Fem-Popliteal Fem-Distal Pop-Distal	51.8% (n=133) 3.6% (n=5) 1.4% (n=2) 8.0% (n=11) 5.1% (n=7) 24.6% (n=34) 50%(n=69) 24.6%(n=34)
	Endovascular Stenting	45.5%(n=117) 9.3%(n=24)
	Hybrid	2.7%(n=7)
Conduit	Native graft Synthetic graft	43.2%(n=111) 10.1%(n=26)
Post-procedure	ICU Stay Re-admission Re-intervention	14.4%(n=37) 45.9%(n=118) 13.6%(n=35)
Salvage		78.6%(n=202)
Amputations	Minor Major	42.41%(n=108) 21.8%(n=56)

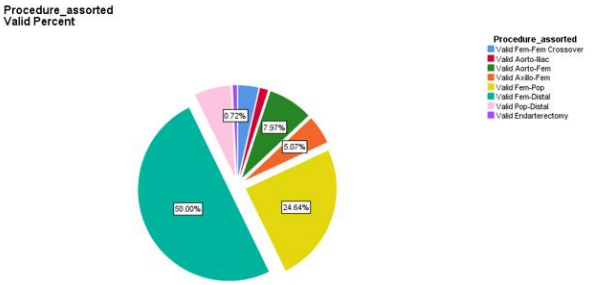

Figure No.3: Procedure assorted valid percentage

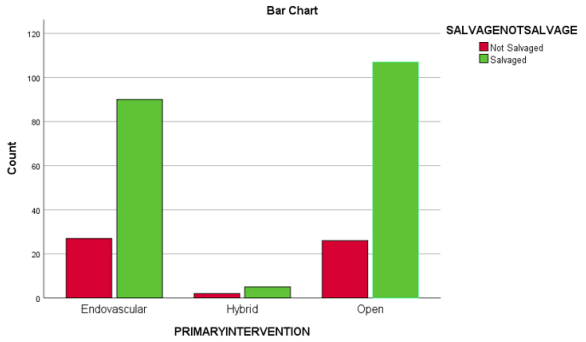

Figure No.4: Primary Intervention with Salvagenotsalvage

DISCUSSION

Our retrospective analysis evaluates the prognostic outcomes of endovascular versus open bypass interventions in patients presenting with chronic limb-threatening ischemia (CLTI). This study provides valuable insights into patient demographics, comorbidities, disease patterns, and procedural outcomes.

Our sample predominantly consisted of male patients (80.5%) with a mean age of 55.89 years. This is consistent with prior studies which have indicated a higher prevalence of peripheral arterial disease (PAD) among men in Pakistan[10]. Diabetes mellitus (64.2%) and hypertension (27.9%) were the most common comorbidities, consistent with previous studies which have shown the association of these conditions with PAD.[5] Additionally, the significant association of smoking with male gender (p=0.000) reinforces the established link between smoking and PAD progression. With many previous studies highlighting smoking as a modifiable risk factor that confers a three-to-four-fold increase in risk of developing PAD.[11-13]

The higher rate of tissue loss in men compared to women (p=0.005) may reflect gender-related differences in healthcare seeking behaviour[5] vascular anatomy, hormonal influences, and smoking prevalence. Further investigation into gender-specific factors contributing to disease severity is warranted.

In our setup, Digital Subtraction Angiography (DSA) was the most commonly used diagnostic modality (61.5%). This was likely due to its superior resolution and its ability to be concurrently diagnostic and

therapeutic.[14] The increased use of DSA may also be correlated with the high prevalence of diabetes in our cohort. While CTA (31.7%) serves as a non-invasive alternative, its role has been shown to be limited in diabetic patients with significant calcification or renal dysfunction.[15-18]

Fem-popliteal disease (54.8%) was the most common anatomical site, aligning with prior studies that identify this segment as a frequent site of atherosclerotic occlusion in CLTI. This pattern may be attributed to the vessel's length, anatomical bends, and exposure to mechanical stress, predisposing it to atherosclerosis and occlusion.

The overall limb salvage rate of 78.6% and similar rates across open bypass (80.45%), endovascular (76.92%), and hybrid approaches (71.42%) suggest that all techniques are viable options for limb preservation. This finding is consistent with a recent meta-analysis conducted by Richard et al in 2024 which found no significant difference in vessel patency rates between the two procedures. Richard et al, also reported no significant difference in the amputation free survival and All-Cause mortality rates between the two populations.[19] This lack of statistically significant difference in outcomes (p=0.712) underscores the importance of individualized treatment plans; where the choice of procedure is guided by lesion characteristics, patient comorbidities, and operator expertise.[20]

With regard to the different graft media; for synthetic conduits, including PTFE and Dacron, the salvage rate was calculated to be 80.7% compared to native grafts which had a salvage rate of 80.91%. Similarly, primary patency was found to be 71.82% in native grafts and 65.38% in synthetic conduits. The type of conduit used did not significantly correlate with primary patency (p=0.517) and limb salvage (p=0.987). These findings are contrary to previous results where a previously conducted systematic review and meta-analysis by Ambler et al in 2018 revealed that natural grafts had better primary patency when compared to synthetic grafts.[21] When analyzing various synthetic grafts however, the scientific literature has reached a consensus. Two recently conducted meta-analyses by Roll et al[22] and Takagi et al[23], revealed no clear superior between the two conduits when it comes to primary patency.

Minor amputations were performed in 42.41% of patients, with single-toe amputations being the most common. Major amputations occurred in 21.8%; these were predominantly below the knee (58.93%). Notably, all major amputations occurred within 6 months of the primary intervention, emphasizing the need for vigilant post-operative monitoring and timely secondary interventions. Functional recovery varied, with just around 50% of patients regaining independent ambulation. This emphasizes the importance of rehabilitation in optimizing post-procedural outcomes

CONCLUSION

Our study demonstrates that both endovascular and open bypass approaches achieve satisfactory and equivalent limb salvage and patency rates in patients with CLTI. This absence of significant differences supports a patient-centered approach, emphasizing individualized treatment plans based on various factors. Moreover, Taking the existing literature into account it is evident that further high-quality research is needed to establish evidence-based guidelines, ultimately improving outcomes in this high-risk population.

Limitations: Despite its many strengths, our study has some limitations that need to be taken into account when analyzing its findings. These include its single-center design, which may affect generalizability. Furthermore, the retrospective nature limits control over confounding variables. Moreover the follow-up durations may not fully capture long-term outcomes of patients, particularly mortality rates and functional recovery.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Farhina Salahuddin, Syed Zain Ali Shah, Muhammad Fahad Tariq Berlas
Drafting or Revising Critically:	Waryam Saleh, Irfan Tariq Keen, Muhammad Muqeem
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

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