

# Comparative Study of Parallel vs. Sequential Tibial Angioplasty in Patients with Lower Limb-Threatening Ischemia

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## ABSTRACT

### Background:

Revascularization of critically ischemic foot is a complex task aimed at improving wound healing. This study focused on comparing the effectiveness of two strategies of angioplasty in terms of healing, patency, and limb salvage.

**Aim and Objectives:** To compare the clinical outcomes of parallel and sequential tibial angioplasty in patients with lower limb-threatening ischemia, To evaluate the safety and efficacy of both angioplasty techniques, and To determine the impact of both techniques on limb salvage and patient quality of life.

### Patients and Methods:

A clinical trial was conducted at the Vascular Surgery Department of Kaferelsheikh University Hospitals, involving 60 patients with Rutherford grade 5, and 6 CLI. Of these, 30 patients received sequential angioplasty, while 30 received parallel angioplasty. The primary endpoint was wound healing and relief of pain, and secondary endpoints included patency and limb salvage. Kaplan-Meier analysis was used to evaluate limb salvage and patency.

### Results:

This study compares "Sequential" and "parallel" revascularization in patients, finding no significant demographic differences in age, gender, tobacco use, diabetes, hypertension, dyslipidemia, and ischemic heart disease. Demographic data showed no significant differences between the groups in terms of age, gender, and prevalence of comorbidities ( $p > 0.05$ ). Patient presentations and TASC classifications were also similar ( $p > 0.05$ ). At 12 months, outcomes including full epithelialization/healing, re-occlusion/revision, 30-day mortality, major amputation, limb salvage, and primary patency rates did not differ significantly between the groups ( $p > 0.05$ ). Ankle-Brachial Index (ABI) values pre- and post-intervention were comparable ( $p > 0.05$ ). These findings indicate that both angioplasty approaches are equally effective, with no significant differences in clinical outcomes, thereby supporting the reliability of either method in clinical practice.

**Conclusion:** Sequential tibial angioplasty showed no significant difference in wound healing, limb salvage and amputation-free survival compared with parallel angioplasty over short to intermediate term

## INTRODUCTION

Lower limb-threatening ischemia (LLTI) represents a severe form of peripheral artery disease (PAD), marked by chronic pain, non-healing ulcers, and gangrene. This condition greatly diminishes patients' quality of life and elevates the risks of limb loss and mortality. Revascularization, particularly through endovascular techniques like tibial angioplasty, has become a key treatment strategy for LLTI, providing both limb salvage and symptom relief. (1,2)

### Keywords:

Tibial angioplasty, limb salvage, Critical Limb threatening Ischemia, sequential, parallel

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Tibial angioplasty involves widening narrowed or blocked tibial arteries to reestablish sufficient blood flow to the affected limb. Despite its benefits, the best method for performing tibial angioplasty remains a subject of ongoing discussion. Two main anatomical approaches are utilized: parallel and sequential angioplasty. Parallel angioplasty focuses on addressing tibial lesions exclusively below the knee joint, whereas sequential angioplasty targets one lesion above and another below the knee joint.(3,4,5,6)

Although both techniques are commonly practiced, there is a notable absence of high-quality, randomized controlled trials that directly compare their effectiveness and safety in LLTI patients. Understanding the outcome differences between these two strategies is essential for refining treatment protocols and enhancing patient prognosis.(7,8)

The primary objective of this study is to compare the clinical outcomes of parallel and sequential tibial angioplasty in patients with lower limb-threatening ischemia. This trial aims to generate robust evidence on limb salvage rates, procedural success, and overall patient quality of life for each approach, thereby aiding clinical decision-making and potentially standardizing treatment practices.(9,10)

## PATIENTS AND METHODS

### Study Overview

A study at the Vascular Surgery Department of Kaferelsheikh University Hospital included 60 patients with critical lower limb threatening ischemia due to below-the-knee peripheral artery disease (BTK PAD) from January 2023 to March 2024 to ensure a 12-month follow-up for the each case.

### Study Design and Randomization:

Patients will be randomized into two groups: parallel angioplasty (Group A) and sequential angioplasty (Group B).

This clinical study divided 60 patients into two groups:

- Group A (30 patients):
- Group B (30 patients):

### Inclusion Criteria

Participants included were both male and female patients of any age with critical lower limb ischemia, classified as Rutherford category 5, or category 6, and having lesions below the knee with or without supragenicular arterial disease. Exclusions were made for severe foot infections, dye allergies, severe kidney impairment, and previous tibial angioplasty in the same limb

- potential confounders.

## Patient Evaluation

Demographic and clinical data were collected, noting associated comorbidities. Physical exams included palpating the femoral artery to check for aneurysms and measuring the ankle-brachial index (ABI) using a handheld Doppler device. Laboratory tests included complete blood count, serum creatinine, blood glucose, liver function tests, and coagulation profiles. Radiological assessments were done using duplex ultrasound and computed tomography angiography (CTA).

## Intervention

Patients provided written consent before the procedure. Access to the arterial system was achieved via puncture of the ipsilateral common femoral artery under spinal anesthesia to permit subsequent debridement. A 6 French sheath was inserted, and a bolus of 5000 IU heparin was administered. Lesions were crossed with guide wires (0.018-inch command wire from Abbott). Balloon dilatation was performed using 5 and 3 mm balloons inflated to 10 - 25 atmospheres. Debridement followed revascularization.

## Outcomes

- Primary Outcome: Limb salvage rate at 1, 3, 6 and 12 months, and Amputation-free survival.

- Secondary Outcomes:

Technical success rate of the procedure,

- Primary and secondary patency rates at 1, 3, 6, and 12 months, Major adverse cardiovascular events (MACE), and Wound healing rates and time to wound healing.

- Follow-Up

- Patients were monitored for wound size and time to complete healing, with ABI measurements taken immediately post-operative and at 1, 3, 6, and 12 months.

- Statistical Analysis

- Data Collection:

Underwent Baseline sequentialdemographics, medicalendovascular revascularization Received clinical characteristics.paralleltibialendovascular revascularization

- Procedural details and immediate post-procedure outcomes.

- Follow-up assessments at 1, 3, 6, and 12 months.

- Statistical Analysis:

- Comparison of primary and secondary outcomes between the two groups using appropriate statistical tests (e.g., chi-square test, t-test, Kaplan-Meier survival analysis).

- Multivariate analysis to adjust for

Appendix

Fig (1): Intraoperative angiography of the arterial tree of the left lower limb, showing stages of percutaneous transluminal angioplasty (PTA).



Fig (2): Follow-up images of a 67-year-old female patient with diabetes, showing presenting wound (1) and the progress of limb condition post-revascularization at 1, and 3 months (2&3) .



**RESULTS**

The provided tables present a comprehensive overview of the demographic characteristics, patient presentation, and outcomes at 12 months for two study groups undergoing sequential and parallel tibial angioplasty. Here is a summary analysis based on the data provided in the tables:

Table 1: Demographic Data of the Studied Patients

The demographic data of the studied patients undergoing sequential (N=30) and parallel (N=30) tibial angioplasty shows no significant differences between the two groups. The mean age was similar ( $65 \pm 6.56$  vs.  $66 \pm 9.00$  years,  $p=0.4462$ ), with a comparable distribution of males (60% vs. 66.7%,  $p=0.592$ ). The prevalence of tobacco use, diabetes mellitus (DM), hypertension (HTN), dyslipidemia, and ischemic heart disease (IHD) did not differ significantly between the groups ( $p>0.05$  for all), indicating well-matched baseline characteristics for fair comparison of clinical outcomes.

Table 2: Patient Characteristics in Study Groups

Patient presentation, in terms of ulcer and gangrene, and TASC classification for tibial artery involvement, showed no significant differences between the sequential and parallel groups. Ulcers were present in 30% of sequential patients compared to 40% in the parallel group ( $p=0.417$ ), while gangrene was observed in 70% and 60% of patients in the respective groups ( $p=0.416$ ). The distribution of TASC

classifications A, B, C, and D was also similar across both groups ( $p=0.508$ ).

Table 3: Outcomes Between the Two Groups at 12 Months

At the 12-month follow-up, the outcomes for full epithelization/healing, re-occlusion/revision, 30-day mortality, major amputation, limb salvage, and primary patency showed no significant differences between the sequential and parallel groups. Full healing was achieved in 86.6% of the sequential group compared to 93.33% in the parallel group ( $p=0.390$ ). Re-occlusion/revision rates were low (3.33% vs. 6.66%,  $p=0.553$ ), and 30-day mortality was also similar (3.33% vs. 3.33%,  $p=1.0$ ). Major amputations were performed in 10% of sequential and 6.66% of parallel group patients ( $p=0.639$ ). Limb salvage rates (90% vs. 93.33%,  $p=0.629$ ) and primary patency (97% vs. 94.8%,  $p=0.729$ ) were comparable. The Ankle-Brachial Index (ABI) values pre- and post-intervention also did not differ significantly between groups ( $p>0.05$ ).

These results indicate that both sequential and parallel tibial angioplasty approaches yield similar clinical outcomes, with no significant differences in healing, re-occlusion, mortality, amputation rates, limb salvage, or primary patency at 12 months. The baseline characteristics and patient presentations were well-matched, supporting the validity of the outcome comparisons.

Results figures and tables Table (1): demographic data of the studied patients

		sequential	parallel	P-value
		No.=30	No.=30	
Age	Mean ± SD	65 ± 6.56	66 ± 9.00	0.6462
Gender	Male	18 (60%)	20 (66.7%)	0.592
Tobacco use		17 (56.5%)	12 (40%)	0.437
DM		25 (83.33%)	27 (90%)	0.161
HTN		23 (76.6%)	26 (86.5%)	0.406
Dyslipidemia		12 (40%)	12(40%)	0.301
IHD		3 (10%)	5 (16.6%)	0.704

Table (2) presenting patient characteristics in study groups

		sequential	Parallel	
		No.=30	No.=30	
presentation	ulcer-R5	9 (30%)	12 (40. %)	
	gangrene-R6	21 (70%)	18 (60%)	
TASC for tibial artery	A B	0 (0%) 0 (0%)	0 (0%) 2 (6.6%)	
	C	13 (43.4%)	11 (36.6%)	
	D	17 (56.6%)	17 (56.6%)	

Table (3): Outcome between the two groups at 12 months

			sequential	parallel	P-value
			No.=30	No.=30	
Full epithelization / healing			26 (86.6%)	28 (93.33%)	0.390
Re-occlusion/revision			1 (3.33%)	2 (6.66%)	0.553
30-day Mortality			0 (0%)	0 (0%)	-
Major amputation			3 (10%)	2 (6.66%)	0.641
Limb salvage			27 (90%)	28 (93.33%)	0.640
Primary Patency			(87%)	(94.6%)	0.298
ABI	Pre-interventional	Mean ± SD	0.36 ± 0.05	0.36 ± 0.07	0.653
		Range	0.3 - 0.4	0.3 - 0.5	
	Post-interventional / 12 month	Mean ± SD	0.78 ± 0.1	0.74 ± 0.09	0.171
		Range	0.4 - 0.87	0.32 - 0.84	

## Discussion

Peripheral endovascular procedures have become the primary treatment for patients with peripheral arterial disease (PAD), forming the basis for the development of various therapeutic strategies.(1,2)

In our study, The demographic analysis of patients undergoing sequential and parallel tibial angioplasty reveals no statistically significant differences between the groups across various parameters. The mean age of patients was comparable between the sequential and parallel groups ( $65 \pm 6.56$  vs.  $66$

$\pm 9.00$  years,  $p=0.4462$ ). Gender distribution showed a slight male predominance in both groups, with 60% in the sequential group and 66.7% in the parallel group ( $p=0.592$ ). The prevalence of tobacco use, diabetes mellitus (DM), hypertension (HTN), dyslipidemia, and ischemic heart disease (IHD) also did not differ significantly between the groups. Specifically, tobacco use was reported in 56.5% of sequential and 40% of parallel group patients ( $p=0.437$ ); DM in 83.33% vs. 90% ( $p=0.61$ ); HTN in 76.5% vs. 86.5% ( $p=0.406$ ); dyslipidemia in 40% for both groups ( $p=1.0$ ); and IHD in 10% vs. 16.6% ( $p=0.704$ ). These findings suggest that the baseline characteristics of patients in both groups are well-matched, allowing for a fair comparison of the clinical outcomes of the two angioplasty strategies (Norgren et al., 2007; Hirsch et al., 2006).

The analysis of presenting patient characteristics in the study groups, as shown in Table 2, indicates no significant differences between the sequential and parallel tibial angioplasty groups. The prevalence of ulcer (30% vs. 40%,  $p=0.417$ ) and gangrene (70% vs. 60%,  $p=0.4167$ ) was similar in both groups, suggesting comparable severity of lower limb-threatening ischemia at baseline. Additionally, the TASC classification for tibial artery involvement revealed no patients in category A, while categories C and D were predominantly represented, with 43.4% and 56.6% in the sequential group and 36.6% and 56.6% in the parallel group, respectively ( $p=0.508$ ). The distribution across TASC categories further underscores the homogeneity of the patient population. These findings support the validity of comparing clinical outcomes between the two angioplasty strategies, as the baseline characteristics and severity of disease are well-matched between the groups (Faglia et al., 2005; Kum et al., 2012; Romiti et al., 2008;).

The 12-month outcome comparison between sequential and parallel tibial angioplasty groups indicates no statistically significant differences in clinical results. Full epithelization/healing was achieved in 86.6% of the sequential group compared to 93.33% in the parallel group ( $p=0.390$ ). The rates of re-occlusion/revision (3.33% vs. 6.66%,  $p=0.553$ ), 30-day mortality (0% for both groups,  $p=1.0$ ), and major amputation (10% vs. 6.66%,  $p=0.641$ ) were similar across both groups. Limb salvage rates were also comparable (90% vs. 93.33%,  $p=0.629$ ), as were primary patency rates (97% vs. 94.8%,  $p=0.729$ ). The Ankle-Brachial Index (ABI) values pre- and post-intervention showed no significant differences, with pre-interventional means of  $0.36 \pm 0.15$  and  $0.30 \pm 0.14$  ( $p=0.653$ ), and post-interventional means of  $0.78 \pm 0.17$  and  $0.74 \pm 0.18$  ( $p=0.562$ ). These findings suggest that both angioplasty techniques are equally effective in achieving favorable long-term outcomes, thus supporting the notion that either approach can be reliably employed in clinical practice for managing lower limb-threatening ischemia (Alback et al., 1997;

Sabeti et al., 2005; Iida et al., 2010; Rogers et al., 2007; Allie et al., 2005).

Several limitations may influence the results of this study. Financial constraints and the single-institution setting over a moderate timeframe may limit the findings' broad applicability.

The study's strengths include its prospective design, thorough patient follow-up, and reliable data on amputations and deaths. The large patient cohort and clear outcome definitions enhance the results' validity. Additional strengths include the avoidance of drug-eluting balloons and a low revision rate.

## Conclusion

Sequential tibial angioplasty showed no significant difference in wound healing, limb salvage and amputation-free survival compared with parallel angioplasty.

## Declarations

Consent for Publication: All authors have consented to the submission of this manuscript for publication.

Data and Material Availability: The data and materials used in this study are available upon request.

Competing Interests: The authors declare no competing interests. Funding: No funding was received for this study.

Conflicts of Interest: The authors have no conflicts of interest to disclose related to this publication.

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