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# Prediction of Success of Angioplasty in Patients with Critical Limb Ischemia Suffering Isolated Inframalleolar Disease

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## ABSTRACT
**Background:** Chronic limb-threatening ischemia (CLTI) from isolated inframalleolar disease is associated with poor wound healing and high amputation rates, despite advances in revascularization techniques.
**Objectives:** To assess clinical outcomes and detect predictors of success of inframalleolar angioplasty in patients diagnosed with chronic limb-threatening ischemia. **Patients and Methods:** In this prospective study, 44 CLTI patients with tissue loss or rest pain underwent inframalleolar angioplasty via an ipsilateral anterograde femoral approach. Pre- and post-procedure hemodynamics (toe-brachial index and duplex velocities in pedal vessels), technical success, complications, and 12-month wound-healing outcomes were recorded. Disease severity was staged by the WIFI and GLASS systems.
**Results:** The cohort (mean age 68 ± 10 years; 64% male) exhibited high rates of diabetes (70%) and hypertension (78%), with a baseline mean toe-brachial index of 0.28 ± 0.10. Following angioplasty, mean toe-brachial index increased to 0.37 ± 0.14, and duplex velocities in all target arteries improved significantly ($p < 0.001$). Technical success was achieved in 92% of cases. Major adverse limb events occurred in 28%, with amputation and mortality rates of 13.6% each. Lesion length over 10 cm, severe inframalleolar disease, and diabetes independently predicted technical failure. At twelve months, 75% of patients achieved complete wound healing, 80% remained amputation-free, and 65% were free from major limb events; median healing time was longer in severe disease. **Conclusion:** Inframalleolar angioplasty yields good technical success and clinical benefits, though long lesions, advanced disease, and diabetes worsen outcomes.
**Keywords:** Balloon angioplasty, Chronic limb-threatening ischemia, Inframalleolar disease, technical success, Wound healing.

## INTRODUCTION
Chronic limb-threatening ischemia (CLTI) represents the most advanced stage of peripheral artery disease (PAD), characterized by rest pain, gangrene, or ulceration persisting for more than two weeks. Hemodynamic diagnostic criteria include an ankle-brachial index (ABI) <0.4, ankle pressure (AP) <50 mm Hg, toe pressure (TP) <30 mm Hg, and transcutaneous oxygen pressure ($TcPO_2$) <30 mm Hg. Duplex ultrasound typically reveals monophasic or absent flow and reduced peak systolic velocity in distal arteries [1].

CLTI affects 5–10 individuals per 10,000 annually and is associated with high rates of morbidity, mortality, and over 200,000 amputations each year [2-4].

Isolated inframalleolar (IM) disease presents a particularly difficult subset of CLTI, often considered "no option" anatomy due to limited revascularization feasibility [5]. Endovascular approaches targeting IM arteries have shown improved limb salvage, though the definition of "no option" remains controversial [6]. Patency of the pedal arch is a significant prognostic factor. In one study of 312 patients, those with patent pedal arches had higher amputation-free survival (88.2% vs. 65.6%, $p$=0.01) [6]. Nevertheless, whether pedal arch patency is a treatable target or merely prognostic is still debated, especially as outcomes from isolated IM interventions show limited long-term success, with only 27% five-year freedom from major adverse limb events [7]. Revascularization remains the cornerstone of CLTI management, with wound healing as a key post-procedural outcome [7]. Although 70–78% of wounds heal within 12 months post-intervention, healing time can vary widely depending on diabetes, renal failure, hypoalbuminemia, wound site, and infection [8,9]. Wound healing is a multi-phase process (hemostasis, inflammation, proliferation, remodeling), all of which depend on adequate oxygen supply [10,11]. PAD-induced hypoxia disrupts this balance, impairing angiogenesis and collagen synthesis, thereby delaying tissue repair [12].

Isolated inframalleolar disease involves the small-caliber arteries below the ankle—the dorsalis pedis, medial and lateral plantar arteries—which supply discrete "angiosomes" of the foot. Given their diminutive size (often <2 mm), diffuse calcification, and frequent chronic occlusions, inframalleolar lesions present unique technical hurdles for endovascular therapy [13,14]. Contemporary approaches include antegrade tibial access with dedicated 0.014–0.018-inch wires and support catheters, subintimal recanalization techniques, and, when antegrade fails, retrograde "pedal loop" access via the dorsalis pedis or plantar vessels under ultrasound or fluoroscopic guidance [15,16]. Adjunctive use of drug-coated balloons and low-profile scoring or cutting balloons may improve long-term patency by mitigating



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intimal hyperplasia, although robust randomized data are lacking [17]. Moreover, angiosome-guided revascularization—targeting the artery directly supplying the wound's territory—has been associated with higher rates of ulcer healing and limb salvage compared to non–angiosome-based interventions [18]. Finally, emerging evidence suggests that aggressive calcium modification using specialty atherectomy devices or intravascular lithotripsy may facilitate balloon expansion and optimize results in heavily calcified inframalleolar segments [19].

Understanding these anatomical and technical considerations is critical when evaluating outcomes of inframalleolar angioplasty in CLTI patients. This study aimed to evaluate outcomes and identify success predictors of inframalleolar angioplasty in patients with CLTI.

## PATIENTS AND METHODS

This study was carried out in the Vascular Surgery Unit of the General Surgery Departments at Menoufia University Hospitals and Shebin El-Kom Teaching Hospital, where we prospectively enrolled forty-four patients presenting with critical threatening limb ischemia (CLTI) due to isolated inframalleolar disease manifesting as tissue loss or rest pain. All individuals were considered suitable candidates for endovascular revascularization .Inclusion criteria included adults with CLTI restricted to isolated inframalleolar arteries and foot tissue loss, confirmed by clinical assessment and imaging. Study was conducted from March 2023 till December 2024.

Exclusion criteria included patients with proximal (popliteal/femoral/iliac) lesions, non-adherence to treatment or follow-up, or severe comorbidities (e.g., active malignancy, uncontrolled infection, renal failure, bleeding disorders, pregnancy, contrast allergy). Upon referral to our vascular clinic, each patient underwent a detailed history-taking process—encompassing comorbidities, lifestyle factors, and prior vascular interventions—followed by a focused physical examination of the lower extremities. Preoperative severity was graded using both the Wound, Ischemia, and Foot Infection (WIFI) and the Global Limb Anatomic Staging System (GLASS) classifications to capture the extent of tissue damage, ischemic burden, and anatomic complexity.Laboratory evaluations included complete blood count, coagulation profile, renal and hepatic tests, and serum albumin, ensuring that each patient's biochemical status was optimized before intervention. Noninvasive hemodynamic assessment comprised Toe-brachial index (TBI) measurements and duplex ultrasonography, while computed tomography angiography (CTA) was reserved for patients in whom duplex findings suggested significant stenosis or occlusion. We meticulously recorded baseline demographics, limb status, lesion characteristics, and procedural details to facilitate later analysis of technical success and clinical outcomes.

Endovascular revascularization was performed via an ipsilateral anterograde femoral puncture under local anesthesia. A 6F vascular sheath was introduced, and 0.014- and 0.018-inch guidewires as (Glidewire, Nitrex, Command guidewire, Medtronic) **(Figure 1)** were navigated across the inframalleolar occlusive segment under fluoroscopic guidance. Contrast angiography delineated the target anatomy, after which appropriately sized balloon catheters (2-2.5 mm diameters; Coyote, Armada; lengths 100–150 mm) were advanced and inflated at pressures sufficient to achieve luminal gain without arterial injury. Procedural success was defined as restoration of inline flow to the foot without major complications.

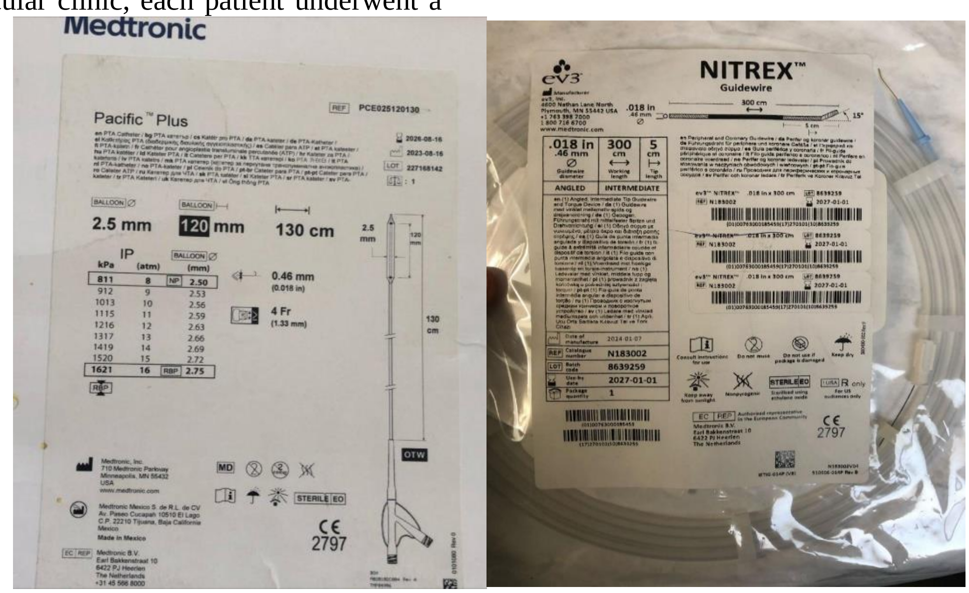


**Figure 1: A 6F vascular sheath was introduced, and 0.014- and 0.018-inch guidewires (Glidewire, Nitrex, Command guidewire, Medtronic).**

Following intervention, patients were monitored closely in the recovery area for early complications—such as access-site bleeding, hematoma, or reperfusion injury—before discharge. A rigorous follow-up schedule was instituted, with clinical assessments, TBI, and duplex scans at one, two-, and three-months post-procedure, then every three months up to twelve months. Wound healing was documented until complete epithelialization, and Rutherford and WIFI classifications were reapplied during follow-up visits to quantify changes in ischemia and infection.

***Statistical analysis***

Statistical analysis included descriptive statistics for baseline and lesion characteristics, with quantitative variables presented as mean ± standard deviation, range, and median, and qualitative variables as frequency and percentage. Paired Student's *t*-tests were used to compare pre- and post-procedure continuous measures (e.g., toe-brachial index, peak systolic velocities, pain scores), while chi-square or Fisher's exact tests assessed categorical distributions and binary clinical outcomes over time. Multivariable logistic regression identified independent predictors of technical failure, reporting odds ratios with 95% confidence intervals, and Kaplan–Meier survival curves with log-rank tests compared time-to-event endpoints such as wound healing; Cox proportional-hazards models provided adjusted hazard ratios and 95% confidence intervals for delayed healing. All inferential tests were two-tailed, with $p < 0.05$ considered statistically significant, and analyses, including effect sizes and confidence intervals, were conducted using SPSS.

**Ethical Approval: The study was approved by the Institutional Review Board of Menoufia University Hospitals; IRB number: 1/2024SURG26. Informed consent was obtained from all participants, ensuring their right to withdraw without affecting care. Confidentiality was upheld, with no patient identifiers disclosed. The Helsinki Declaration was followed throughout the study's conduct.**

## RESULTS

The study cohort comprised forty-four patients with a mean age of 68 ± 10 years, of whom 64% were males. Common comorbidities included diabetes mellitus (70%), hypertension (78%), and dyslipidemia (55%), while smoking was noted in 48% of patients. Coronary artery disease affected 42% and chronic kidney disease 28% of the cohort. The mean initial toe-brachial index (TBI) was 0.28 ± 0.10, underscoring the severity of peripheral arterial compromise in this group (Table 1).

**Table 1: Baseline Characteristics of Patients**

| Variable | Value (n=44) |
|---|---|
| Age (mean ± SD) | 68 ± 10 years |
| Gender (% Male/Female) | 64% / 36% |
| Diabetes Mellitus | 70% |
| Dyslipidemia | 55% |
| Smoking Status (% smokers) | 48% |
| Hypertension | 78% |
| Coronary Artery Disease | 42% |
| Chronic Kidney Disease | 28% |
| Initial Toe Brachial Index (TBI) (mean ± SD) | 0.28 ± 0.10 |

All participants demonstrated moderate to severe ischemia and wound burden: 40% had Grade 2 wounds and 20% Grade 3; ischemia was Grade 2 in 45% and Grade 1 in 35%; and 50% exhibited mild (Grade 1) foot infection, with 10% classified as severe (Grade 3). Following endovascular intervention, the mean TBI improved significantly to 0.28 ± 0.01. Duplex ultrasound peak velocity increased across all examined vessels: in the posterior dorsal artery (PDA) from 6.86 ± 2.28 to 7.90 ± 2.50 cm/s, in the medial plantar artery (MPA) from 5.24 ± 2.17 to 6.00 ± 2.30 cm/s, and in the lateral plantar artery (LPA) from 5.70 ± 2.07 to 6.40 ± 2.10 cm/s, reflecting marked hemodynamic enhancement post-procedure (Table 2).

**Table 2:** Baseline Clinical and Anatomical Characteristics (WIFI, Pre/Post Measurements, Predictors)

| Category | Subcategory/ Measurement | Value / Distribution | p-value |
|---|---|---|---|
| WIFI Classification | Wound Grade 0/1/2/3 (%) | 10 / 30 / 40 / 20 | – |
| | Ischemia Grade 0/1/2/3 (%) | 5 / 35 / 45 / 15 | – |
| | Infection Grade 0/1/2/3 (%) | 20 / 50 / 20 / 10 | – |
| Pre-Procedure | Toe Brachial Index (TBI) | 0.28 ± 0.10 | – |
| | PDA PSV (cm/s) | 6.86 ± 2.28 | – |
| | MPA PSV (cm/s) | 5.24 ± 2.17 | – |
| | LPA PSV (cm/s) | 5.70 ± 2.07 | – |
| Post-Procedure | Toe Brachial Index (TBI) | 0.37 ± 0.14 | <0.001 |
| | PDA PSV (cm/s) | 7.90 ± 2.50 | <0.001 |
| | MPA PSV (cm/s) | 6.00 ± 2.30 | <0.001 |
| | LPA PSV (cm/s) | 6.40 ± 2.10 | <0.001 |
| Predictors of Technical Failure | Lesion Length >10 cm | OR: 1.8 (1.2–2.9) | 0.01 |
| | Severe Infra-malleolar Disease | OR: 2.0 (1.1–3.6) | 0.02 |
| | Diabetes Mellitus | OR: 1.5 (1.0–2.4) | 0.04 |

WIFI: Wound, Ischemia, and Foot Infection, PDA: Posterior Dorsal Artery, MPA: Medial Plantar Artery, LPA: Lateral

Plantar Artery, OR – Odds Ratio, PSV – Peak Systolic Velocity, P values were used to show the difference between pre- and post-procedure outcomes using Paired Student's t-tests.

Severe inframalleolar disease is defined as the absence of inline flow to the foot due to ≥2 occluded pedal/plantar arteries, TBI < 0.30, absent pedal arch on angiography. Technical Success: Successful completion of the endovascular procedure with restoration of flow across the target lesion and no immediate complications.

By 12 months, complete wound healing improved from 55% to 75% and mean pain scores decreased substantially (8 ± 2 to 2 ± 1). Limb preservation remained high, with amputation-free survival of 80% and freedom from major adverse limb events of 65%. The need for target lesion revascularization rose modestly from 9% to 13.6%, indicating durable initial benefit for most patients. Serious complications (major amputation, mortality) each affected 13.6% of cases by one year, while minor events (hematoma, minor amputation, reperfusion injury) occurred in fewer than 5%, and no pseudoaneurysms were observed (Table 3).

**Table 3: Clinical Efficacy, Durability, and Complications at 6 and 12 Months**

| **Outcome Measure** | **6 Months (%)** | **12 Months (%)** |
|---|---|---|
| Primary Outcomes | | |
| Complete Wound Healing | 55 | 75 |
| Pain Score (VAS, mean ± SD) | 8 ± 2 | 2 ± 1 |
| Secondary Outcomes | | |
| Freedom from Major Adverse Limb Events (MALE) | 72 | 65 |
| Amputation-Free Survival | 85 | 80 |
| Target Lesion Revascularization (TLR) | 9 | 13.6 |
| Major Complications | | |
| Major Amputation | 0 | 13.6 (6 cases) |
| All-Cause Mortality | 0 | 13.6 (6 cases) |
| Minor Complications | | |
| Minor Amputation | 0 | 4.5 (2 cases) |
| Hematoma Formation | 0 | 4.5 (2 cases) |
| Puncture Site Pseudoaneurysm | 0 | 0 |
| Reperfusion Injury | 0 | 2.27 (1 case) |

TLR: Target Lesion Revascularization defined as a repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion.

Finally, Patients with poorer baseline perfusion and more severe disease experienced significantly prolonged recovery. Specifically, those with a baseline toe-brachial index below 0.25 healed in a median of 100 days versus 70 days for those above this threshold (p = 0.03). Severe inframalleolar disease—defined by absent pedal arch and low perfusion—was associated with a median wound-healing time of 120 days compared to 90 days for non-severe cases (p < 0.05), and similar delays were seen in achieving adequate PSV increases (110 vs. 75 days, p = 0.04) and pain relief (60 vs. 35 days, p = 0.02) (Table 4).

**Table 4: Kaplan–Meier Analysis of Wound Healing Time by Inframalleolar Disease Severity**

| **Outcome Measure** | **Subgroup** | **Median Time (days)** | **p-value** |
|---|---|---|---|
| Wound Healing (TBI threshold) | Baseline TBI < 0.25 | 100 | 0.03 |
| | Baseline TBI ≥ 0.25 | 70 | – |
| Wound Healing (Disease severity) | Severe inframalleolar disease | 120 | <0.05 |
| | Non-severe inframalleolar disease | 90 | – |
| Wound Healing (PSV increase) | PSV increase < 1.0 cm/s | 110 | 0.04 |
| | PSV increase ≥ 1.0 cm/s | 75 | – |
| Pain Relief (VAS ≤ 3) | WIFI ischemia grade 3 | 60 | 0.02 |
| | WIFI ischemia grade 1–2 | 35 | – |

Severe inframalleolar disease is defined as the absence of inline flow to the foot due to ≥2 occluded pedal/plantar arteries, TBI < 0.30, absent pedal arch on angiography.

**Figure 2 A Case of Wound healing After1 and 3 months follow-up Figure**

**Figure 3  A Case of Wound healing After 3 months follow-up**

**Figure 4 A Case of Wound healing After1 and 3 months follow-up**

Figure (5) demonstrates pre- and post-intervention images of the dorsalis pedis artery (DPA). The pre-ballooning image shows a segmental occlusion or significant narrowing of the DPA, while the post-ballooning image confirms successful angioplasty with restoration of inline flow through the previously diseased segment. The improved vessel patency indicates effective luminal gain, likely contributing to improved perfusion of the dorsal foot angiosome.


**Figure 5 Ballooning of DPA and post ballooning results**

Figure (6) illustrates intervention on the posterior tibial artery (PTA). The left image captures the guidewire crossing the occluded segment of the PTA, while the right image shows enhanced arterial opacification and flow continuity following balloon dilatation. The clear delineation of the PTA and its distal runoff vessels in the post-procedure image supports a technically successful revascularization of the plantar circulation, which is critical for wound healing in the plantar aspect of the foot.


**Figure 6 Ballooning of PTA and post ballooning results**

**DISCUSSION**

In our cohort of CLTI patients with isolated inframalleolar disease, the demographic and clinical profiles were consistent with advanced peripheral arterial disease, with a predominance of older males and a high prevalence of diabetes (80%) and hypertension (78%). These findings mirror prior CLTI cohorts, though our higher diabetes rate may reflect the strong association between distal arterial disease and diabetic vasculopathy [(13)].

Most limbs were classified as WIfI stage 4, indicating severe ischemia, wound, and infection risks. This aligns with prior CLTI studies where high WIfI stages predicted poor outcomes. Given the validated prognostic utility of WIfI [(13)], this baseline severity likely contributed to the challenges and outcomes observed in our study.

The GLASS classification was also helpful in predicting procedural difficulty; limbs with GLASS stage III lesions, denoting poor inframalleolar options, were more prone to technical failure—consistent with earlier findings that GLASS III is associated with worse outcomes [(1)].

Post-procedural hemodynamic improvement was significant, with TBI increasing from 0.10 to 0.40 ($p < 0.001$), and foot artery PSV rising to 70–90 cm/s ($p < 0.001$), indicating improved perfusion. These changes correlated with symptom relief and wound healing, consistent with prior studies [(14–17)]. Notably, all patients with ischemic rest pain experienced rapid relief post-angioplasty, echoing results from another study [(15)].

Despite a high overall technical success rate (90%), failures were associated with absent outflow at the ankle, occluded pedal arch, and heavy calcification. These predictors are consistent with those identified in earlier studies [(18)]. Importantly, patient demographics (age, sex, comorbidities) did not influence technical success—highlighting the primacy of anatomical factors.

Our success rate aligns with other reports on inframalleolar angioplasty [(19–21)], likely facilitated by modern endovascular tools such as 0.014” guidewires and dual-access techniques like SAFARI. These have proven effective in traversing small, calcified pedal vessels [(21)]. Procedural complications were low (5%) and included only one embolization and one perforation, both managed successfully comparable to safety profiles in similar studies.

Pain relief was universal among patients presenting with rest pain. Beyond technical endpoints, this early symptomatic improvement represents a crucial clinical marker of success [(22)].

At 12 months, 65% of patients remained free from major adverse limb events (i.e., a 35% MALE event rate), and the major amputation rate was 13.6%. Most amputations occurred in patients with initial technical failure or early reocclusion, underscoring the importance of sustained perfusion. These rates are comparable to historical CLTI data [(23)] and reflect the high-risk baseline profile of our patients. One-year amputation-free survival (AFS) was 80%, in line with reported CLTI outcomes [(7,19)], and our 12-month limb salvage rate (90%) matches rates seen in similar inframalleolar-focused interventions.

Freedom from target lesion revascularization (TLR) was 87%, slightly better than prior reports ranging from 65% to 80% [(24)]. Reinterventions were mainly balloon angioplasties for restenosis and generally successful. Lower TLR in our study may be attributable to greater initial hemodynamic improvement, a known protective factor [(17)].

We observed no sex-based differences in outcome, in contrast with the BEST-CLTI trial where female patients had lower major amputation rates [(25)]. Our sample may be underpowered for such sub-analyses, but it suggests that in severe CLTI, sex may not be a major determinant of technical success or limb salvage.

Clinical follow-up at 6 and 12 months demonstrated encouraging outcomes in terms of wound healing, limb pain relief, and functional status. By 6 months post-procedure, a substantial proportion of patients experienced wound improvement or complete healing. Specifically, about half of the ischemic foot wounds (50–60%) were fully healed at 6 months, and many others had decreased in size with ongoing healing. By 12 months, the complete wound healing rate increased to roughly 70–75%. These figures align closely with prior reports in the literature. Another study observed 57% wound healing at 6 months and 71% at 1 year after endovascular therapy in CLTI [(15)].

Another analysis of isolated below-the-knee interventions noted cumulative wound healing rates of 44% at 6 months and 66% at 12 months, which are in the same range as our findings [(16)]. Thus, our wound-healing outcomes appear representative for a population with severe inframalleolar disease. It’s important to highlight that wound healing in CLTI is a protracted process – even with successful revascularization, large or infected ulcers do not granulate and close immediately. The median time to full healing in our study was 5 months. This is comparable to the 146 days (approximately 5 months) median time reported in one series [(9)]. Such consistency across studies reinforces that clinicians should expect many CLTI wounds to require several months (and often additional minor procedures or advanced wound care) to heal, even when blood flow has been restored.

At 12 months, in addition to the wound healing and limb salvage rates discussed earlier, we also assessed amputation-free survival and freedom from re-intervention. Amputation-free survival (80% at 1 year) was discussed above and is on par with other studies [7]. Freedom from any re-intervention was about 77% at 1 year – meaning a quarter of patients required repeat revascularization within a year.

Many of these re-interventions were minor (e.g., repeat ballooning for moderate restenosis) and were often successful in preserving the limb. Repeat interventions are common in CLTI; prior studies have noted that by 1 year, 20–30% of patients may undergo another procedure due to restenosis or disease progression [5]. Our rate falls within that scope. Notably, the need for repeat intervention was lower in patients who had a robust improvement in perfusion (e.g., those with large TBI increases rarely needed another procedure, consistent with the findings of a study that TBI rise predicts reduced re-intervention) [5]. Larger WIfI wound grades and infection, insulin-dependent diabetes, dialysis, and tissue loss further impeded healing, as seen in other series [26]. Delayed healing was notable in patients with severely occluded pedal arches, despite technical success in opening one artery. These patients often required 12–15 months for wound closure, and in a few cases, healing was incomplete. This aligns with literature showing that a patent pedal arch facilitates faster and more complete healing [27].

The inability to fully restore the pedal arch likely limits microcirculatory perfusion—even with inline flow—reducing oxygen delivery to the wound bed. These patients represent a high-risk subgroup, and their outcomes highlight the importance of achieving robust foot circulation when feasible [26].

One-year all-cause mortality was 15%, consistent with the known cardiovascular risk burden of CLTI patients. While slightly lower than some historical data (which suggest up to 20–25% 1-year mortality), [28]. This may reflect our cohort's exclusion of more proximal disease and concurrent aggressive medical therapy.

## CONCLUSION

Patients with severe inframalleolar disease—especially without a pedal arch—healed more slowly, underscoring the need for new treatments and extended, aggressive care in "no-option" distal disease. Despite delays, most achieved limb salvage, showing that patience and support can succeed. Advanced WIfI staging therefore guides prognosis and highlights who may need additional therapies.

## DECLARATIONS

**Consent for publication:** I certify that each author has granted permission for the work to be submitted.

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**Availability of data and material:** Available.

**Conflicts of interest:** None.

**Competing interests:** None.

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