

Endovascular strategies for critical limb ischemia: A two-year clinical review of peripheral vascular intervention

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ABSTRACT Critical limb ischemia (CLI) is a severe manifestation of peripheral arterial disease characterized by rest pain, non-healing ulcers, and a high risk of limb loss. This study evaluates the efficacy of various endovascular interventions in treating CLI over a two-year period, analyzing limb salvage rates, vascular patency, and the need for reintervention. A total of 150 patients underwent either stenting or balloon angioplasty, with follow-up assessments utilizing contrast-enhanced CT angiography or Doppler ultrasound. Findings indicate a limb salvage rate of 92%, with infragenicular lesions exhibiting the lowest vascular durability (45% patency rate) and the highest requirement for redo percutaneous angiography (31.6%). These results underscore the effectiveness of minimally invasive techniques in CLI management, while emphasizing the need for advancements in restenosis prevention. Future strategies should focus on drug-eluting technologies and regenerative approaches, particularly stem cell therapy, to enhance long-term outcomes.

KEYWORDS Critical limb ischemia, endovascular therapy, stenting, balloon angioplasty, vascular patency, restenosis, limb salvage, atherectomy, laser therapy, stem cell treatment

1. INTRODUCTION

Critical limb ischemia (CLI) is a severe condition caused by arterial obstruction, leading to significantly reduced blood flow to the extremities [1]. This can result in severe pain, non-healing ulcers, tissue necrosis, and even gangrene. Patients with ischemic rest pain often experience a burning sensation in the ball of the foot and toes, worsening at night. The discomfort is aggravated when lying down due to the loss of gravity-assisted circulation, forcing patients to dangle their legs over the bed or sleep in a recliner to relieve the pain. Non-healing ulcers typically appear in areas prone to foot trauma and fail to respond to conservative therapy within several weeks [1], [2].

Peripheral arterial disease is classified using Fontaine and Rutherford schemes. The Fontaine classification categorizes patients from asymptomatic stages to ulceration and gangrene, while the Rutherford classification extends from mild claudication to severe tissue loss. These classifications help determine severity and appropriate intervention strategies [2].

Diagnosis relies on clinical evaluation, ankle-brachial index measurements, Doppler arterial studies, and CT angiography to assess vascular blockages and blood flow patterns [3].

Treatment approaches vary based on disease severity. Conservative management includes smoking cessation, exercise, and medical therapy. Surgical bypass grafting remains an option for advanced cases. However, endovascular therapy has become a preferred strategy due to its minimally invasive nature [4]. Although some cases ended in amputation after vascular intervention, there is a study that proved that the level of amputation improved after performing this therapeutic vascular intervention [5].

Balloon angioplasty is commonly used to restore blood flow, particularly in tibial arteries, where successful limb salvage requires adequate circulation to the pedal arch [6]. Stenting is frequently performed in the iliac and femoral arteries to address hemodynamically significant lesions, particularly in cases of vascular recoil or flow-limiting dissections [7].

Excimer laser therapy utilizes ultraviolet energy to ablate plaque while minimizing thermal injury to surrounding tissues. This technique facilitates recanalization of chronic occlusions and is beneficial when traditional wire passage

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is unsuccessful. Excisional atherectomy employs specialized devices to remove plaque with reduced arterial trauma, potentially improving overall luminal gain [8], [9]. Cryoplasty delivers cold thermal energy to the artery, promoting apoptosis of smooth muscle cells and reducing elastic recoil and neointimal hyperplasia [10].

Stem cell therapy is an emerging approach currently under investigation, offering potential benefits in tissue regeneration and limb salvage [11].

Critical limb ischemia remains a challenging condition requiring timely intervention to prevent limb loss. Endovascular techniques continue to evolve, providing promising solutions for improved patient outcomes [12]. Ongoing research into advanced therapies and long-term efficacy will further shape the future of CLI management. Let me know if you'd like further refinement [13].

1.1 Aims of the study

The study aims to achieve several key objectives:

- 1) Evaluate Clinical Outcomes Assess the effectiveness of endovascular interventions in treating critical limb ischemia over a two-year period.
- Compare Techniques Investigate the performance of balloon angioplasty, stenting, atherectomy, cryotherapy, and laser therapy in improving limb salvage and symptom relief.
- Assess Long-Term Patency Examine how well different endovascular treatments maintain vascular patency and prevent restenosis.
- Determine Patient Benefits Analyze how interventions impact pain reduction, ulcer healing, mobility improvement, and amputation rates.

2. PATIENTS AND METHODS

A total of 150 patients diagnosed with critical limb ischemia (CLI) of the lower extremities underwent endovascular intervention, receiving either stent placement or balloon angioplasty between January, 2020, and January, 2022. The study was conducted at the Peripheral Catheterization Center at Ghazi Al-Hariri Hospital in coordination with Al Razan scientific bureau in Baghdad, Iraq.

Patients were monitored for two years post-procedure to assess vascular patency, limb salvage rates, and overall clinical outcomes. Inclusion was strictly limited to those meeting CLI diagnostic criteria who received an endovascular procedure involving stenting or balloon angioplasty. Patients treated with other catheter-based methods or those undergoing surgical bypass revascularization were excluded from the study.

Follow-up evaluations utilized contrast-enhanced CT angiography or Doppler ultrasound to assess arterial patency, restenosis, and treatment success.

3. RESULTS

3.1 Clinical presentation

Among the patients studied, the presentation of rest pain, foot ulcer, and a combination of both was observed with the

following distribution:

Rest pain: 22%Foot ulcer: 37%

• Rest pain and foot ulcer: 41%

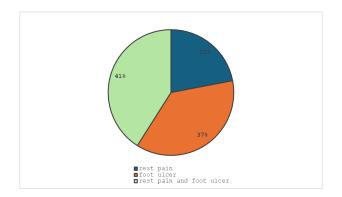


FIGURE 1. Clinical presentation among CLT patients

3.2 Lesion site distribution

The anatomical distribution of arterial lesions among patients was classified as in Table 1. This table outlines the anatomical distribution of arterial lesions among the study population. Many patients presented with infragenicular lesions (40%), followed by femoropopliteal (34%) and iliac (26%) involvement. This distribution underscores the high frequency of distal arterial disease in patients with critical limb ischemia.

TABLE 1. Distribution of site lesion

Site of lesion	Count	N(%)
Iliac	39	26%
Femoropopliteal	51	34%
Infragenicular	60	40%

3.3 Patency rate over two years

Vascular patency was assessed using ultrasonography or CT angiography during follow-up, with the following findings as in Table 2. This table presents the two-year vascular patency rates stratified by lesion site. Iliac lesions demonstrated the highest patency (62%), followed by femoropopliteal (56%), while infragenicular lesions showed the lowest durability (45%). These findings emphasize the relative challenge of maintaining long-term vessel patency in distal arterial segments.

TABLE 2. Patency rate within two years

Site of lesion	N(%)
Iliac	62%
Femoropopliteal	56%
Infragenicular	45%

3.4 Redo percutaneous angiography

A subset of patients required redo percutaneous angiography during follow-up, categorized by lesion site: Table 3 details

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the proportion of patients who underwent repeat angiography by lesion location. Reintervention was most frequently required in infragenicular lesions (31.6%), compared with femoropopliteal (19.6%) and iliac lesions (12.8%). The data indicates a clear trend of higher reintervention rates in more distal vascular territories.

TABLE 3. Patients who underwent redo percutaneous angiography

Site of lesion	Count	N(%)
Iliac	5	12.8%
Femoropopliteal	10	19.6%
Infragenicular	19	31.6%%

Two-Year Limb Salvage and Amputation Rates

The two-year outcomes of percutaneous angiography, including limb salvage and amputation rates, are summarized below. Table 4 summarizes limb salvage and amputation outcomes over the two-year follow-up. Overall, 92% of patients achieved limb salvage, while 8% required amputation. The highest amputation rate was observed in infragenicular disease (11.7%), compared to femoropopliteal (5.9%) and iliac (5.1%) lesions. These outcomes highlight both the efficacy and limitations of endovascular interventions in advanced diseases

TABLE 4. Two-year outcomes following percutaneous angiography

Site of lesion	Limb salvage	Amputation
Iliac	37(94.9%)	2(5.1 %)
Femoropopliteal	48(94.1%)	3(5.9 %)
Infragenicular	53(88.3%)	7(11.7 %)
Total	138(92%)	12(8%)

3.5 Discussion

Endovascular interventions in the management of critical limb ischemia (CLI) demonstrate a high limb salvage rate of 92%, reinforcing their role as a primary therapeutic approach in contemporary vascular practice [4], [14], [15]. This outcome is comparable to the findings of the BEST-CLI trial, which reported superior limb salvage with surgical revascularization overall; however, endovascular therapy performed similarly when a great saphenous vein conduit was unavailable [15], [16].

Despite this efficacy, our study highlights significant challenges in vascular durability, particularly in infragenicular lesions, where the patency rate was notably low at 45% [17]. This finding aligns with the BEST-CLI trial, which also reported increased restenosis risks in distal vascular territories [15], [16]. The need for reintervention was most pronounced in these infragenicular lesions, with 31.6% of patients requiring redo angiography—further supporting the notion that endovascular therapy, while effective, often necessitates more frequent follow-up procedures compared to surgical bypass [15], [16].

Looking ahead, the issue of restenosis remains a critical barrier to long-term success. Future strategies may benefit from incorporating advanced technologies such as drugcoated balloons or regenerative approaches like stem cell therapy, which hold promises for improving vascular longevity and reducing amputation rates. The study did not address cases where amputation was scheduled, nor whether the decision changed after the procedure. However, it did address the fate of the limb after catheterization and the decision to amputate [5]

Comparative analyses suggest that endovascular therapy is particularly advantageous for high-risk patients due to its minimally invasive nature and reduced procedural morbidity, a benefit emphasized in multiple studies [18], [19]. In contrast, surgical bypass remains the preferred option for patients with favorable anatomy and available conduit, offering superior long-term durability. Our reported patency rates, ranging from 45% to 62%, reflect this trade-off between procedural safety and vascular longevity, underscoring the importance of individualized treatment planning in CLI management [13].

4. CONCLUSION

The study confirms that endovascular therapy is an effective modality for achieving limb salvage in patients with critical limb ischemia; however, patency rates remain a significant limitation, particularly in infragenicular lesions. Compared to surgical bypass, endovascular interventions are associated with a higher frequency of reinterventions, underscoring the need for advancements in drug-eluting technologies and regenerative therapies to enhance long-term outcomes.

Future research should prioritize the development and clinical evaluation of biodegradable stents, stem cell-based therapies, and combination treatment strategies aimed at improving vascular durability and reducing the burden of repeat procedures.

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