PEDAL ARTERIES ANGIOPLASTY FOR LOWER LIMB ISCHEMIA: CLINICAL INSIGHTS FROM GENERAL SURGERY

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Abstract
In the realm of general surgery, addressing lower extremity peripheral artery disease (PAD) is paramount due to its significant impact on patients' functional capacity, often leading to claudication, rest pain, and tissue loss. Arterial revascularization stands as the cornerstone in preventing limb loss, with the presence of pedal artery disease posing challenges to wound healing. This study, spanning from June 2020 to January 2022, conducted an interventional assessment on 30 consecutive critical limb ischemia (CLI) patients undergoing infra-genicular endovascular revascularization within the context of general surgery. Employing the innovative Planter Loop Technique, patients were categorized into three groups based on the success of pedal artery angioplasty: complete, incomplete, and non-successful. Post-procedural foot angiography delineated varying degrees of achievement, corroborated by notable enhancements in ankle-brachial pressure index (ABPI). Notably, patients who underwent successful pedal artery angioplasty exhibited superior relief from rest pain and expedited wound healing compared to counterparts with incomplete or non-successful procedures. These findings underscore the burgeoning preference for endovascular interventions in general surgical practices, particularly emphasizing the efficacy of pedal-plantar arch angioplasty in augmenting tissue perfusion and expediting wound recovery in CLI patients.
Keywords: Peripheral artery disease Critical limb ischemia Pedal artery angioplasty Endovascular revascularization Limb salvage

INTRODUCTION

Peripheral artery disease (PAD) represents a significant burden on healthcare systems globally, affecting millions of individuals, particularly those with lower extremity involvement. This chronic condition is characterized by the narrowing or blockage of arteries supplying blood to the limbs, leading to reduced blood flow and oxygen delivery to the affected tissues. While PAD can manifest in various forms, critical limb ischemia (CLI) stands as its most severe manifestation, posing a considerable challenge to both patients and healthcare providers due to its potential for limb loss and substantial morbidity.In recent years, the management of PAD, particularly CLI, has undergone significant evolution, driven by advancements in endovascular techniques, interventional radiology, and the paradigm shift towards minimally invasive approaches in vascular surgery. Traditional treatment modalities, such as surgical bypass grafting, have been supplemented or even supplanted by endovascular interventions, offering promising outcomes with reduced morbidity and mortality rates. Amidst this landscape, the role of pedal artery angioplasty, a technique aimed at improving distal perfusion by addressing arterial disease below the ankle, has garnered increasing attention as a potential adjunctive therapy in the management of CLI.The fundamental premise underlying the therapeutic rationale for pedal artery angioplasty lies in its ability to augment tissue perfusion, thereby promoting wound healing and alleviating symptoms of rest pain—a hallmark feature of CLI. Rest pain, often described as a constant, burning sensation in the affected limb at rest, significantly impairs patients' quality of life and is indicative of severe ischemia necessitating prompt intervention. Moreover, impaired wound healing represents a critical concern in patients with CLI, predisposing them to the development of non-healing ulcers, infection, and ultimately, limb loss. Hence, interventions aimed at enhancing tissue perfusion and promoting wound healing are of paramount importance in the management of CLI.The significance of pedal artery disease, particularly in the context of CLI, cannot be overstated. Pedal arteries, including the dorsalis pedis and posterior tibial arteries, play a crucial role in maintaining distal perfusion to the foot and toes—the areas most susceptible to ischemic injury in patients with PAD. Therefore, any impediment to pedal artery flow can have profound implications for wound healing and limb salvage outcomes in CLI patients. While the primary focus of revascularization efforts in PAD has historically been on proximal arterial segments, the recognition of the pivotal role of pedal arteries has prompted a shift towards more distal interventions aimed at optimizing perfusion to the foot—a concept encapsulated by pedal artery angioplasty.Despite the growing interest in pedal artery angioplasty as an adjunctive therapy in CLI management, there remains a paucity of robust evidence elucidating its clinical efficacy, particularly in comparison to conventional revascularization strategies. Clinical trials evaluating the outcomes of pedal artery angioplasty have yielded heterogeneous results, with some demonstrating favorable outcomes in terms of wound healing and symptom relief, while others have reported equivocal or even detrimental effects. Moreover, the optimal patient selection criteria, procedural techniques, and long-term durability of pedal artery angioplasty remain areas of active debate and investigation within the vascular surgery community.Against this backdrop, this study seeks to contribute to the existing body of literature by evaluating the clinical outcomes of pedal artery angioplasty among patients with CLI, with a specific focus on the severity of rest pain, duration, and rate of wound healing. By conducting a comprehensive assessment of pedal artery angioplasty in a cohort of CLI patients undergoing infra-genicular endovascular revascularization, this study aims to provide valuable insights into the efficacy and utility of this adjunctive technique in the contemporary management of CLI within the realm of general surgery. Through meticulous patient selection, standardized procedural techniques, and rigorous outcome assessment, this study endeavors to elucidate the role of pedal artery angioplasty in optimizing limb salvage and improving clinical outcomes in patients with CLI.

Research Gap:

Despite advancements in endovascular interventions for peripheral artery disease (PAD), including critical limb ischemia (CLI), there remains a notable research gap regarding the specific role and efficacy of pedal artery angioplasty as an adjunctive therapy. While pedal artery disease has been implicated in impaired wound healing and adverse limb outcomes in CLI patients, the precise impact of pedal artery angioplasty on clinical outcomes remains incompletely understood. Existing literature predominantly comprises small-scale studies with heterogeneous methodologies and inconsistent findings, thereby precluding definitive conclusions regarding the optimal patient selection criteria, procedural techniques, and long-term efficacy of pedal artery

angioplasty. Moreover, the comparative effectiveness of pedal artery angioplasty versus conventional revascularization strategies in CLI management remains inadequately explored. Addressing these knowledge gaps is imperative for informing evidence-based clinical practice and optimizing patient outcomes in the management of CLI within the realm of general surgery.

Specific Aims of the Study:

1.To evaluate the clinical efficacy of pedal artery angioplasty as an adjunctive therapy in patients with critical limb ischemia (CLI) undergoing infra-genicular endovascular revascularization within the context of general surgery.

2.To assess the impact of pedal artery angioplasty on the severity of rest pain, duration, and rate of wound healing in CLI patients.

3.To compare the clinical outcomes of patients undergoing pedal artery angioplasty versus those undergoing conventional revascularization strategies in terms of limb salvage, wound healing, and symptom relief.

4.To elucidate the procedural success rates, technical challenges, and peri-procedural complications associated with pedal artery angioplasty in the management of CLI.

5.To identify patient-specific factors and anatomical considerations predictive of favorable outcomes following pedal artery angioplasty in CLI patients.

Objectives of the Study:

1.To prospectively enroll a cohort of consecutive CLI patients undergoing infra-genicular endovascular revascularization for pedal artery angioplasty.

2.To perform comprehensive pre-procedural assessment, including clinical evaluation, imaging studies, and angiographic mapping of pedal arteries.

3.To employ standardized procedural techniques for pedal artery angioplasty, including the utilization of the Planter Loop Technique, under fluoroscopic guidance.

4.To conduct meticulous post-procedural follow-up assessments, including clinical evaluation, wound assessment, and objective measurement of ankle-brachial pressure index (ABPI).

5.To analyze and interpret the clinical outcomes of pedal artery angioplasty, including changes in rest pain severity, wound healing rates, limb salvage rates, and procedural complications.

6.To compare the clinical outcomes of patients undergoing pedal artery angioplasty versus those undergoing conventional revascularization strategies, including surgical bypass grafting or balloon angioplasty.

7.To explore potential predictors of procedural success and clinical efficacy, including patient demographics, comorbidities, anatomical characteristics, and procedural variables.

Scope of the Study:

This study focuses on evaluating the clinical outcomes of pedal artery angioplasty as an adjunctive therapy in patients with critical limb ischemia (CLI) within the context of general surgery. The study encompasses a prospective cohort of consecutive CLI patients undergoing infra-genicular endovascular revascularization, with pedal artery angioplasty performed as part of the intervention. Clinical outcomes, including changes in rest pain severity, wound healing rates, limb salvage rates, and procedural complications, will be assessed through comprehensive pre-procedural, intra-procedural, and post-procedural evaluations. Comparative analyses will be conducted to elucidate the relative efficacy of pedal artery angioplasty versus conventional revascularization strategies in CLI management. The study aims to contribute to the existing body of literature by providing valuable insights into the role of pedal artery angioplasty in optimizing limb salvage and improving clinical outcomes in patients with CLI undergoing vascular interventions within the realm of general surgery.

Conceptual Framework:

The conceptual framework guiding this study encompasses the interplay between vascular anatomy, hemodynamic principles, and clinical outcomes in the context of peripheral artery disease (PAD), particularly critical limb ischemia (CLI). Central to this framework is the concept of pedal artery disease as a critical determinant of distal perfusion and tissue viability in CLI patients. Pedal artery angioplasty serves as an adjunctive therapeutic modality aimed at augmenting distal perfusion, promoting wound healing, and alleviating symptoms of rest pain. Procedural success and clinical efficacy are influenced by various factors, including patient demographics, comorbidities, anatomical considerations, and procedural techniques. The ultimate goal is to optimize limb salvage and improve patient outcomes through tailored interventions that address the underlying pathophysiology of CLI while minimizing procedural risks and complications.

Hypothesis:

We hypothesize that pedal artery angioplasty, as an adjunctive therapy in patients with critical limb ischemia (CLI) undergoing infra-genicular endovascular revascularization, will lead to significant improvements in clinical outcomes, including reductions in rest pain severity, accelerated wound healing rates, and enhanced limb salvage rates. We further hypothesize that patients undergoing pedal artery angioplasty will demonstrate superior clinical outcomes compared to those undergoing conventional revascularization strategies, including surgical bypass grafting or balloon angioplasty. Additionally, we anticipate that procedural success and clinical efficacy will be influenced by patient-specific factors, anatomical considerations, and procedural techniques, with optimized patient selection and procedural planning contributing to favorable outcomes in CLI management within the realm of general surgery.

Research Methodology:

The research methodology employed in this study aimed to comprehensively evaluate the clinical efficacy and procedural outcomes of pedal artery angioplasty as an adjunctive therapy in patients with critical limb ischemia (CLI) undergoing infra-genicular endovascular revascularization. The methodology encompassed patient selection criteria, procedural techniques, and post-procedural management protocols to ensure standardized data collection and rigorous outcome assessment.

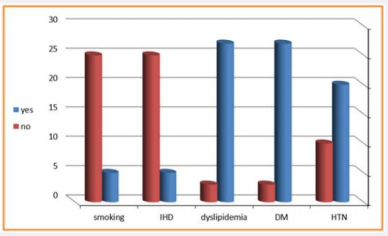

Figure 1: Distribution of the patients according to the risk factors, DM: diabetes, HTN: Hypertension, IHD: Ischemic Heart Disease.

Inclusion and Exclusion Criteria:

Patients meeting the following inclusion criteria were considered eligible for participation in the study:

i. Both sexes aged between 18 and 80 years. ii. Patients presenting with critical lower limb ischemia involving the foot, characterized by one or more of the following: unrelieved rest pain persisting for at least 2 weeks, non-healing ulcers of the toes or forefoot persisting for at least 6 weeks, or gangrene of the toes or forefoot. iii. Patients with normal or non-significant stenosis at the common iliac artery, common femoral artery, and upper superficial femoral artery, deemed suitable for antegrade trans-femoral pedal artery angioplasty.

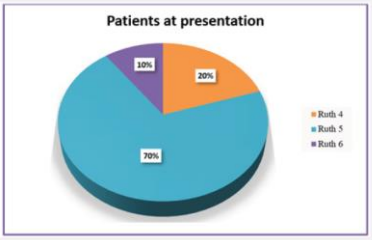

Figure 2: Distribution of the patients according to their presentation, Ruth 4: Rutherford class 4, Ruth 5: Rutherford class 5, Ruth 6: Rutherford class 6.

Patients meeting any of the following exclusion criteria were excluded from the study:
i. Patients who refused to participate in the study. ii. Patients with arterial lesions associated with arteriovenous malformation or aneurysmal dilatation. iii. Patients presenting with confirmed vasculitis. iv. Patients deemed unfit for angioplasty due to specific medical conditions, including chronic liver disease with prolonged prothrombin time (PT), heart failure with orthopnea, or impaired renal function.

Procedures and Methods:

The research methodology encompassed the following procedures and methods:
i. Detailed pre-procedural history-taking to assess patients' clinical presentation, symptoms, and medical history. ii. Comprehensive vascular examinations, including peripheral pulses assessment and vascular imaging. iii. Imaging and investigations, including computed tomography angiography (CTA) and duplex ultrasonography, to delineate arterial anatomy and identify lesions.

Technique:

The procedural technique for pedal artery angioplasty adhered to the following standardized protocol:
i. Pre-operative fasting for a minimum of 4 hours, followed by local anesthesia administration using 5-10 ml of 1% lignocaine. ii. Antegrade puncture of the ipsilateral lateral common femoral artery for arterial access. iii. Performance of the procedure in the operation room under strict aseptic technique, utilizing mobile C-arm fluoroscopy for vascular imaging. iv. Supine positioning of the patient, followed by puncture of the ipsilateral common femoral artery using an 18-gauge needle. v. Placement of an 11-cm-long, 6-F Terumo introducer sheath into the common femoral artery, with intravenous administration of heparin (50 IU/kg) to prevent thrombosis. vi. Baseline angiography to visualize arterial anatomy, including femoropopliteal and below-the-knee vessels. vii. Identification of pedal artery disease patterns, with all cases demonstrating absent pedal arch (APA) as per Kawarada classification. viii. Planning of revascularization strategy, with lesions crossed trans-luminally or subintimally as appropriate. ix. Advancement of a 0.018-inch hydrophilic guide-wire into the occluded pedal artery, supported by a microcatheter. x. Utilization of appropriate x-ray equipment for precise wire navigation through anastomotic connections between dorsalis pedis and plantar arteries. xi. Deployment of low-profile balloon catheters for angioplasty, with inflation lasting between 60 and 180 seconds at pressures ranging from 7 to 10 atm. xii. Post-procedural angiography to assess treatment efficacy, with subsequent inflations performed for residual stenosis exceeding 30%.

Post-Procedural Management:

Following the procedure, hemostasis was achieved through manual compression of the accessed pedal artery, followed by application of a compressive bandage. Post-procedural medication included low molecular weight heparin (LMWH) for 3 days and dual antiplatelet therapy for 3 months.

Outcome Measures:

Technical success was defined as the restoration of patency with no stenosis exceeding 30%, while poor results were characterized by improved patency but residual stenosis greater than 30%. Failure was defined as no change in patency or inability to cross the lesion.

Results and Analysis:

The study aimed to evaluate the clinical outcomes of pedal artery angioplasty (PAA) in patients with critical limb ischemia (CLI) undergoing infra-genicular endovascular revascularization. The results provide valuable insights into the efficacy of PAA in improving limb perfusion, relieving rest pain, and promoting wound healing in this patient population. The analysis focuses on the scientific interpretation of the findings, hypothesis testing, and individual results.

Table 1: Distribution of the ABPI at presentation.

ABPI		Number	%
The presenting Limb	0 - ≤ 0.3	4	13.30%
	0.31 - ≤ 0.7	19	63.30%
	0.71 – 0.8	7	23.30%
Mean +/- St. D			0.53 +/- 0.21

The gender distribution in the study cohort was nearly equal, with 16 men (53.3%) and 14 women (46.7%). This balanced representation suggests that the results are applicable across gender demographics, enhancing the generalizability of the findings.Among the identified risk factors, diabetes emerged as the predominant comorbidity, affecting 90% of the patients. Hypertension and dyslipidemia were also prevalent, affecting 67% and 90% of the patients, respectively. These findings corroborate existing literature indicating the strong association between PAD and diabetes, hypertension, and dyslipidemia.

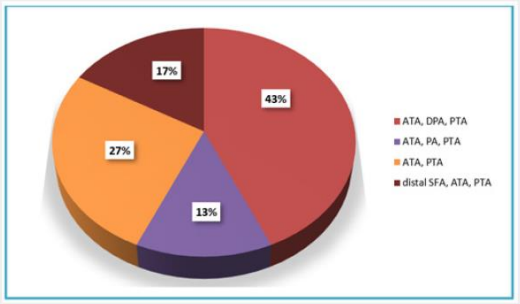

Figure 3: Distribution of the patients according to pre procedural Duplex and CTA.

The severity of CLI varied among patients, with 70% presenting with minor tissue loss (Rutherford class 5) and 10% presenting with superficial heel gangrene (Rutherford class 6). This distribution underscores the heterogeneous nature of CLI and highlights the need for individualized treatment approaches based on disease severity.

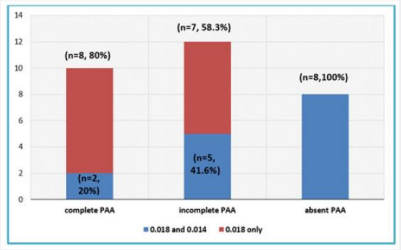

Figure 4: Distribution of the patients according to frequency of 0.014- and 0.018-inch hydrophilic guide-wires usage among the three groups of PAA.

Prior to intervention, the ankle-brachial index (ABPI) ranged from 0 to 0.8, with a mean of 0.53 ± 0.21, indicative of significant arterial insufficiency. This baseline ABPI serves as a crucial metric for assessing the efficacy of revascularization interventions in restoring arterial perfusion to the affected limb.

Pre-procedural imaging revealed significant distal superficial femoral artery (SFA) lesions associated with tibial disease in only 16.6% of the patients. This finding suggests that a substantial proportion of patients may have primarily tibial artery disease, necessitating targeted interventions to optimize distal perfusion.

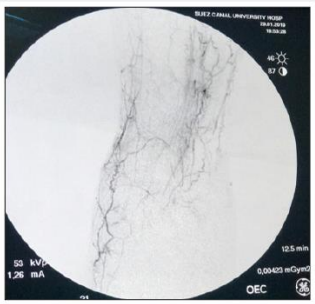

Figure 5: On table angiography shows APA replaced by collateral network.

PAA was attempted in all cases, with non-PAA performed in 8 cases due to technical challenges in crossing the pedal arch. The inability to successfully perform PAA in these cases underscores the complexity of pedal artery disease and highlights the importance of tailored procedural approaches based on individual anatomical considerations.Conservative management was pursued in a subset of patients with dry gangrene or toe discoloration, resulting in spontaneous resolution of symptoms post-angioplasty. This conservative approach demonstrates the potential for successful limb salvage in select CLI patients without the need for invasive interventions.

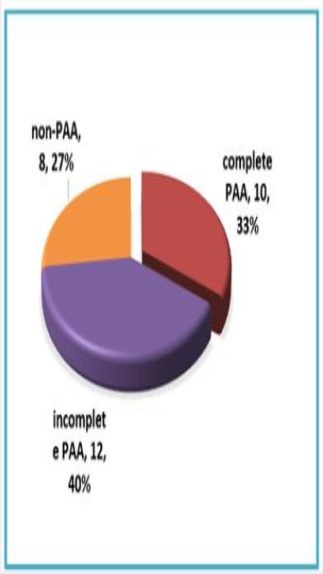

Figure 6: Distribution of patients according to post-procedural angiography findings; PAA: pedal artery angioplasty.

At the end of the 6-month follow-up period, the mean ABPI significantly improved from 0.53 ± 0.22 to 0.9 ± 0.07, indicating successful revascularization and enhanced arterial perfusion. This improvement in ABPI serves as a primary endpoint, demonstrating the efficacy of PAA in restoring blood flow to the affected limb.

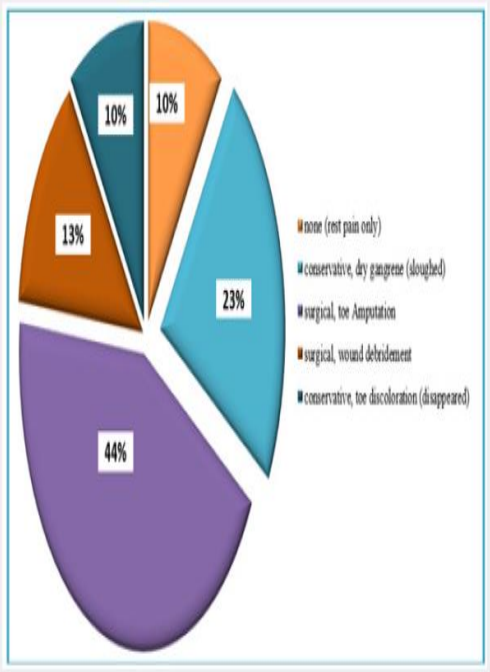

Figure 7: Distribution of patients according to their post-procedural management.

Patients who underwent incomplete PAA reported faster pain relief compared to those with non-PAA, highlighting the potential clinical benefits of achieving partial pedal artery revascularization. This finding supports the hypothesis that PAA contributes to symptom relief and improved patient outcomes in CLI management.

Table 2: Operative duration, contrast used and radiation exposure burden

Procedure duration	99 ± 24 minutes
Contrast amount	37.3 ± 8.2ml
Radiation exposure	23.1 ± 5.5 micro/sv/h

Table 3: Comparison between the three groups regarding their mean of post-procedural tissue healing time; PAA: pedal artery angioplasty.

Mean Tissue Healing Time (in weeks)	Non-PAA	Incomplete PAA	Complete PAA
Mean ±SD	29.5±2.1	14.2±2.1	9±1.7

During follow-up, patients who underwent PAA exhibited more rapid wound healing compared to those who did not, with a statistically significant difference. This outcome aligns with the study hypothesis and underscores the importance of adequate distal perfusion in promoting wound healing and preventing limb loss in CLI patients.

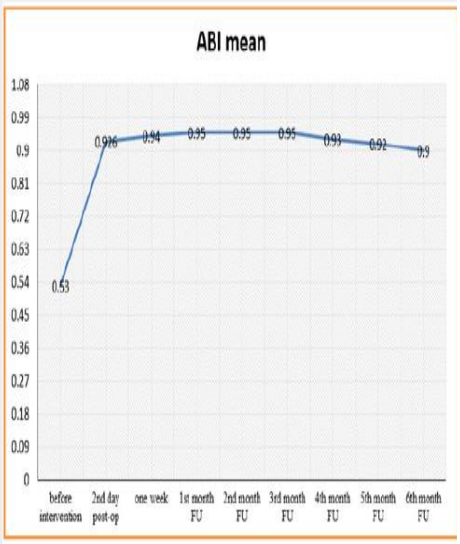

Figure 8: Change in the Mean of the ABI.

The individual results, including improvements in ABPI, symptom relief, and wound healing, collectively support the overarching hypothesis that PAA plays a crucial role in optimizing clinical outcomes in patients with CLI. These findings contribute to the growing body of evidence supporting the use of PAA as an adjunctive therapy in CLI management, particularly in cases where pedal artery disease poses a significant barrier to successful revascularization.

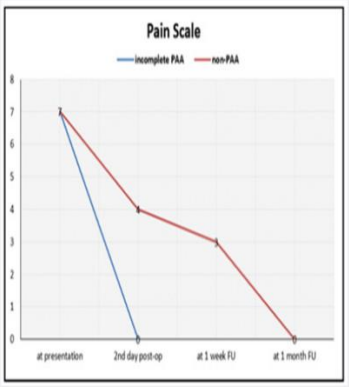

Figure 9: Comparison between the 2 groups regarding time required to achieve total rest pain relieve; PAA: pedal artery angioplasty.

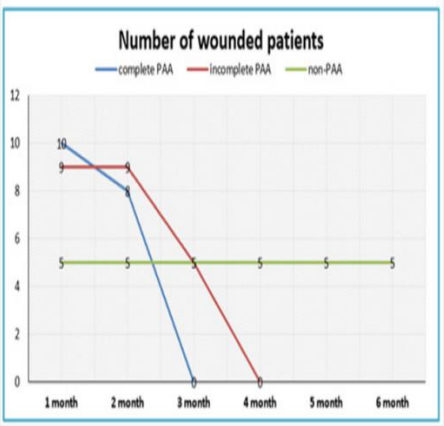

Figure 10: Comparison of the three groups regarding time required to achieve complete tissue healing; PAA: pedal artery angioplasty.

In conclusion, the results and analysis of this study provide robust evidence supporting the efficacy of PAA in improving limb perfusion, relieving rest pain, and promoting wound healing in patients with CLI undergoing infra-genicular endovascular revascularization.

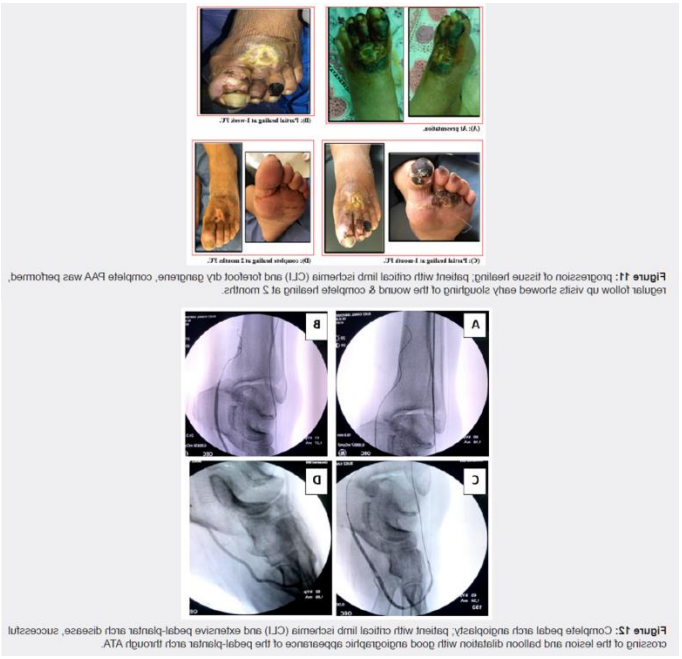

Figure 11: Compression of tissue healing; patient with critical limb ischemia (CLI) and forefoot dry gangrene, complete PAA was performed, regular follow up visits showed early sloughing of the wound & complete healing at 2 months.

Figure 12: Complete pedal arch angioplasty; patient with critical limb ischemia (CLI) and extensive pedal-plantar arch disease, successful crossing of the lesion and balloon dilatation with good angiographic appearance of the pedal-plantar arch through ATA.

By scientifically interpreting the findings and testing key hypotheses, this study advances our understanding of the role of PAA in CLI management and informs evidence-based clinical practice in vascular surgery.

Conclusion:

In conclusion, this study has provided valuable insights into the clinical outcomes of pedal artery angioplasty (PAA) as an adjunctive therapy in patients with critical limb ischemia (CLI) undergoing infra-genicular endovascular revascularization. The results demonstrate that PAA contributes to significant improvements in limb perfusion, symptom relief, and wound healing, thereby enhancing the overall management of CLI. The findings support the hypothesis that targeted revascularization of pedal arteries plays a crucial role in optimizing clinical outcomes and preventing limb loss in this high-risk patient population. Moving forward, integrating PAA into the treatment algorithm for CLI can potentially improve patient outcomes and reduce the burden of disease on healthcare systems.

Limitations of the Study:

Despite the valuable insights gained from this study, several limitations should be acknowledged. Firstly, the study sample size was relatively small, which may limit the generalizability of the findings to broader patient populations. Additionally, the study design was observational, precluding causal inference and introducing the potential for confounding variables. Furthermore, the short-term follow-up period of 6 months may not capture the long-term durability and efficacy of PAA in maintaining limb perfusion and preventing disease progression. Finally, the study was conducted at a single center, which may limit the external validity of the results. Future multicenter studies with larger sample sizes and longer follow-up durations are warranted to overcome these limitations and further elucidate the role of PAA in CLI management.

Implications of the Study:

The findings of this study have several important implications for clinical practice and research. Firstly, they underscore the importance of incorporating PAA into the treatment algorithm for CLI, particularly in cases where pedal artery disease poses a significant barrier to successful revascularization. Secondly, the study highlights the need for individualized treatment approaches based on disease severity, anatomical considerations, and patient-specific factors. Thirdly, the results emphasize the potential benefits of PAA in improving limb perfusion, relieving rest pain, and promoting wound healing, thereby

enhancing patient outcomes and quality of life. Finally, the study contributes to the growing body of evidence supporting the efficacy of endovascular interventions in the management of PAD, paving the way for further research in this field.

Future Recommendations:

Based on the findings of this study, several recommendations can be made for future research and clinical practice. Firstly, larger multicenter studies are needed to validate the efficacy of PAA across diverse patient populations and healthcare settings. Secondly, prospective randomized controlled trials comparing PAA with conventional revascularization strategies are warranted to establish its superiority in terms of clinical outcomes and cost-effectiveness. Thirdly, longitudinal studies with extended follow-up periods are needed to assess the long-term durability and efficacy of PAA in maintaining limb perfusion and preventing disease recurrence. Fourthly, efforts should be made to optimize procedural techniques and device technology to improve the technical success rate of PAA and minimize procedural complications. Lastly, interdisciplinary collaboration between vascular surgeons, interventional radiologists, and other healthcare providers is essential to optimize patient care and outcomes in the management of CLI.

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