# Effect of endovascular revascularization of pedal artery on healing of the wound in patients with chronic limb-threatening ischemia

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**Introduction**
Disease of the pedal artery is one of the most significant predictors of wound healing, so endovascular pedal artery revascularization (PAR) may affect the extent and speed of wound healing.
**Patients and methods**
All of the patients in this study had infrapopliteal and pedal artery diseases and chronic limb-threatening ischemia. The patients were divided into two groups: one with endovascular PAR and the other without PAR. Comparisons of the timing and rate of wound healing between the two groups were made.
**Results**
The research involved 42 individuals: 20 patients did not get PAR, whereas the other 22 patients underwent PAR. Results regarding timing of wound healing was shorter in the group with PAR than in the group without PAR (92.0±12.6 vs. 143.0±53.2 days), and the wound healing rate was greater in the group with PAR than in the group without PAR (89 vs. 61%).
**Conclusion**
Endovascular PAR in patients with chronic limb-threatening ischemia has an excellent effect on limb salvage as it improves the rate and timing of wound healing.

**Keywords:**
endovascular, pedal artery, revascularization, wound healing

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## Introduction

Approximately 73–95% of patients with chronic limb-threatening ischemia (CLTI) lose their limbs within a year of receiving conservative therapy [1]. The best way to prevent limb loss is by arterial revascularization, through either surgical bypasses or endovascular procedures [2]. However, owing to their serious comorbid conditions and old age, individuals with CLTI are rarely surgical candidates. Contrarily, owing to its reduction in invasiveness and equivalent limb salvage rate to surgical bypass, percutaneous intervention has gained popularity [3]. Complete wound healing is difficult to achieve even if severe amputation is successfully avoided as delayed or insufficient wound healing negatively affects patients' quality of life and social reintegration [4].

According to several clinical investigations, having pedal artery disease makes it harder for wounds to heal [4]. Therefore, supplementary revascularization procedures for pedal artery dysfunction may speed up the healing of wounds [5]. Patients who had pedal artery angioplasty (PAA) demonstrated a faster rate of wound healing and reduced healing time [6].

## Patients and methods

A prospective research including 42 individuals with critical limb ischemia was conducted.

### Inclusion criteria

Patients with critical limb ischemia who had Rutherford classification 5 with minimal tissue loss were included.

### Exclusion criteria

The following were the exclusion criteria:

(1) Major tissue loss Rutherford 6.
(2) Acute thrombosis.

The evaluation of patients was done as follows:

(1) Clinical presentation:
   (a) Age and sex of patients.
   (b) Comorbid diseases such as diabetes mellitus and hypertension.
   (c) Wound depth and bone involvement: foot radiograph using Wound, Ischemia, and Foot Infection (WIFI) classification.
(2) Diagnostic procedures:
   (a) Duplex scan of arterial system to show site and nature of lesion.

Clinical outcomes were assessed with the calculation of the clinical success and wound healing duration.

Clinical success was considered when wound healing occurs.

Wound healing was defined as full epithelialization of every incision without the need for a major amputation.

Primary patency was defined as the time to wound healing and the rate of wound healing 1 year after initial therapy.

Secondary patency was characterized as independence from reintervention rate, limb salvage rate, amputation-free survival rate, and overall survival rate.

#### Operative procedure

All procedures were held in the Angio suite. Dual antiplatelets (aspirin 81 mg and clopidogrel 75 mg) were administered before the procedure.

Systemic anticoagulation was achieved with unfractionated heparin 70–100 U/kg once intravascular access was confirmed and before wire and catheter manipulation over the occlusive lesion.

Common femoral artery was accessed under ultrasound guidance, then a 6-Fr introducer sheath was inserted, and then contrast injection for diagnostic angiogram.

If there were any femoropopliteal lesions, they were first treated using standard endovascular methods (optimal balloon angioplasty and provisional nitinol stenting). An infrapopliteal artery that had stenosis was treated using a standard balloon angioplasty procedure and a 0.014-inch guide wire. Sometimes tougher penetration guide wires were used in situations of occlusive lesions. A retrograde method, such as distal puncture or the transcollateral approach, is used when the antegrade approach fails. After the guide wire had been passed, balloon dilation was carried out for at least 2 min using an ideal-sized balloon at nominal pressure.

Procedure for pedal artery revascularization (PAR) is as follows: as necessary, adjunctive PAA was performed. With the use of a microcatheter, a 0.014-inch hydrophilic guide wire was inserted into the blocked pedal artery. New retrograde access methods, such as a transcollateral route or a puncture of the metatarsal artery, were employed as necessary. Occluded pedal arteries were dilated with a 2.0-mm balloon for at least 2 min after the guide wire was crossed.

Through fluoroscopic reference to anatomical features, the balloon was successfully positioned correctly across the target lesion. Fluoroscopy for road mapping proved useful for precise placement.

Fluoroscopic balloon inflation monitoring shows that any waist in the balloon profile vanishes as the lesion enlarges as the pressure within the balloon rises. The ideal inflating time was between 60 and 120 s. The angioplasty balloon was removed from the area and out of the guiding catheter or introducer sheath after fluoroscopy confirmed full deflation.

Anatomically, PTA was deemed technically effective if, as judged by a multiplane angiogram, there was less than 30% residual stenosis and no flow-limiting dissection evident after the treatment.

Procedures without considerable residual stenosis or without complications were deemed to be technically successful.

Technical failure was characterized as either severe residual stenosis (>30%) or failure to traverse or dilate the lesion. This is a failure of the used wires to cross the lesions.

A complication was defined as any complication requiring endovascular or surgical intervention that was not expected to occur after the operation.

#### Postoperative care

Patients were monitored for any edema or sheath site leaking for three hours following surgery. Surgical debridement and antibiotic injections were carried out as necessary in wound infection scenarios. The Rutherford classification, UT grade, and Wound, Ischemia, and Foot Infection (WIFI) classification systems were all used to assess all wounds.

#### Follow-up

Regular follow-up of the patients after the dilatation, either clinical or radiological, was advised for better correlation of the study for early detection of recurrence of the problem, and determination of exact time of primary patency along every 3, 6, and 12 months.

#### Clinical signs of improvement

(1) Attempt of granulation at wound depth.
(2) Resolution of hyperemia and signs of infection.
(3) Rate of healing correlation to wound size.

Functional outcome was assessed based on the duration needed to return to regular activities.

#### Radiological

Duplex study of arterial system was done every 3 or 6 months.

#### Statistical analysis

Continuous data were compared using the independent Student *t* test and provided with a mean, SD, or median (range). The $\chi^2$ test was used to compare categorical data, which were presented as frequency (%). A statistically significant *P* value was less than 0.05. The SPSS, version 16, was used for all statistical analyses (SPSS Inc., Chicago, Illinois, USA).

#### Ethical consideration

The local ethics commission gave its approval for the project. The study was explained to all patients or their family members, and each patient gave their written consent.

## Results

This is a prospective study conducted on 42 patients presented with CLTI with 42 limbs, with a mean age of 63.37 years. Male patients were 24 (57.2%), and female cases were 18 (42.8%). A total of 39 cases had diabetes mellitus, 23 were hypertensive, 11 had coronary artery disease, and 24 were smokers. All cases had Rutherford classification 5 with minor tissue loss. Regarding ankle brachial index before intervention, ABPI ranged between 0.1 and 0.8 with a mean of 0.56. Regarding the location of the wound, 31 (73.8%) patients had it in the forefoot and 11 (26.2%) cases in the toes. Nine wounds were infected. Total occlusion of infrapopliteal vessels was present in 67.3%, and the lesion was more than 20 cm (83.5%). During the procedure, diagnostic angiography revealed that 39 cases had diseased infrapopliteal vessels and the remaining three patients had superficial femoral artery disease in addition to infrapopliteal lesions. Diseased pedal vessels and absent pedal arch presented in all patients. Balloon dilatation was done using plantar-loop technique. In 22 patients, complete PAR was done using V-18 and V-14 wires together with infrapopliteal lesions (antegrade access used in 18 cases and retrograde access used in four cases). In the other 20 patients, PAA failed despite both V-14 and V-18 trials owing to heavy calcifications, and retrograde access in these cases not used due to ulcers and infection, and the angioplasty in these cases ended only with tibial angioplasty. Therefore, we divided the patients into two groups: the first group with successful PAR, and the second group with failed PAR. After procedures, nine patients with wound infection in forefoot and toes were managed by either debridement or toe amputation during their hospital stay. In this study, 22 patients had complete PAR (both lateral plantar artery and pedal artery). Regarding complications, there were no PAR-related complications. At 6-month follow-up, overall survival was 89 and 78%, limb salvage rate was 94 and 87%, and amputation-free survival was 81 and 62% in the group with PAR and the group without PAR, respectively; moreover, the wound healing rate was higher in the group with PAR than in the group without PAR (89 vs. 61%, respectively), and the time to wound healing was shorter also in the group with PAR than in the group without PAR (92.0±12.6 vs. 143.0±53.2 days, respectively).

## Discussion

For patients with CLTI who had endovascular intervention, incomplete wound healing continues to be a significant clinical concern. In the most recent clinical studies, 1-year limb salvage rates ranged from 86 to 92%. However, the percentages of wound healing after 1 year have stayed between 63 and 74% [3]. Compared with rates of wound healing and 1-year limb salvage, there is a 20% difference. Even though significant amputation can be successfully avoided in 20% of the instances that had endovascular intervention, the wounds have not yet totally healed in these patients [7]. Reed and colleagues came to the conclusion that full wound healing was crucial to patients' outcomes in a retrospective research. In light of their findings, it is possible to enhance quality of life and cut expenses associated with medical care by implementing measures to speed up wound healing and shorten the time it takes for a wound to heal. Complete wound healing should come after the successful avoidance of major limb amputation, which is the initial stage and aim in the management of CLTI [6]. Nakama and colleagues conducted a research on 275 patients based on clinical presentation, classifying 200 (77.8%) affected limbs as Rutherford class 5 with 128 (49.8%) involved limbs requiring surgical debridement or minor amputation [8]. All of the 42 patients in our research had a Rutherford rating of 5, with minimal tissue damage. Additionally, nine individuals who had gangrene and an infection in a toe or foot incision had severe debridement or minor amputation.

Numerous investigations, including those by Nakama and colleagues and Nicola and colleagues, demonstrated that the treatment was carried out using a 0.014-inch hydrophilic guide wire as their first preference almost often. According to Nakama and colleagues, 140 (54%) patients who underwent PAA had their blocked pedal arteries successfully crossed with V-14, whereas 117 (45.5%) patients did not succeed. However, Nicola and colleagues demonstrated that 42 (30.7%) patients had effective completion of PAA, 60 (43.8%) patients had partial PAA, and 35 (25.5%) patients had no PAA [8,9]. Complete PAR was accomplished in our study's 22 individuals employing V-18 and V-14 wires in conjunction with infrapopliteal lesions (antegrade access used in 18 cases and retrograde access used in four cases). Owing to severe calcifications, both the V-14 and V-18 trials for PAA in the other 20 patients were unsuccessful.

Successful endovascular intervention of the pedal arterial tree is related to longer life without severe amputation and greater rates of wound healing. Successful PAR was an independent feature related with improved wound healing, and the absence of a patent pedal arch before and especially after endovascular revascularization was linked with poor wound healing [10]. Most vascular lesions in individuals with CLTI are seen below the knee. Endovascular treatment has changed significantly over the past 10 years as a consequence of improvements in procedural methods and equipment, and it has shown promising therapeutic results in patients with CLTI. When compared with bypass surgery, endovascular treatment has generally been linked to poorer primary patency but equivalent wound healing and avoidance of severe amputation. Endovascular therapy has evolved into many centers' chosen first-line therapy owing to its decreased morbidity [11].

Given that the pedal arch links the anterior and posterior circulations and serves as the major blood supply for the whole distal forefoot, its quality is thought to be a crucial element in foot revascularization. According to Kawarada *et al.* [12], direct revascularization based on angiosomes had no effect on wound healing, but post-endovascular intervention of the pedal arch revascularization was an independent predictor of wound healing. Similarly, Rashid *et al.* [13] observed that the quality of the pedal arch, rather than the angiosome used for revascularization, directly increased the rates of wound healing and time to healing in patients handled by infrapopliteal bypass. Additionally, Higashimori *et al.* [14] reported that direct flow into a patent pedal arch has been shown to be crucial for improving limb survival rates and amputation-free survival, particularly when only one drainage channel can be constructed to the foot. Nakama *et al.* [8] recently came to the conclusion that pedal arch angioplasty was beneficial for enhancing wound healing in the rendezvous prospective registry. However, this advantage was not shown in patients with low or high risk, only in those with moderate risk. In our study, wound healing rates were greater in the PAR group than in the non-PAR group (89 vs. 61%, respectively), and overall survival (89 vs. 78%, respectively), limb salvage (94 vs. 87%, respectively), and amputation-free survival (81 vs. 62%, respectively) were also higher in the PAR group, and the time to wound healing was shorter also in the group with PAR than in the group without PAR (92.0±12.6 vs. 143.0 ±53.2 days, respectively).

## Conclusion

Successful PAR increases the rate of freedom from severe amputation and enhances wound healing in patients receiving endovascular treatment for CLTI. As the pedal arch is totally missing, efforts should be made to revascularize the pedal arteries.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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