Direct versus indirect revascularization in the treatment of ischemic heel: a prospective comparative study

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Objective

Ischemic heel ulcers are widely considered to be extremely difficult to treat and often end up with major amputation. Direct revascularization (DR) of the heel through dilatation of the posterior tibial artery (PTA) is presumed to be superior to indirect revascularization.

Patients and methods

This prospective study included 42 limbs in 42 patients having ischemic heel ulcers or heel gangrene due to isolated below-the-knee arterial lesions. Patients with ischemia due to above-the-knee occlusive disease were excluded from the study.
Non-reconstructable vascular lesions with no distal run-off and cases with failed revascularization during endovascular intervention were early excluded from the study.
The patients were divided, according to whether the PTA was successfully revascularized or not, into group I (direct heel revascularization) and group II (indirect heel revascularization).

Results

A total of 22 (52.38%) patients were included in group I compared with 20 (47.62%) patients in group II. Overall, 32 (76.19%) limbs were salvaged during the study period: 17 in group I and 15 in group II. There was no statistically significant difference in overall limb salvage between both groups (*P*=0.826). The ulcer healing time was shorter in group I, which was statistically significant (*P*=0.002). Complete ulcer healing was observed in 16 patients in group I and 10 patients in group II (*P*=0.039).

Conclusion

DR of heel ulcers through PTA revascularization is associated with higher wound healing rates. In case where DR is not technically feasible, indirect revascularization is an alternative with nearly equivalent rates of limb salvage.

Keywords:
angiosome, critical limb ischemia, gangrene, heel ulcer, revascularization

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Introduction

The heel plays an important role in weight transmission and in the dynamics of walking [1]. Heel ulcers are a significant health care problem, requiring prolonged hospital stays, long periods of disability, and often leads to lower limb amputation, which carries a significant psychological and socioeconomic burden on the individual and community. Several factors including neuropathy, inadequate blood supply, infection, and abnormal pressure on the heel bones are involved in the development of heel ulcers [2].

The management of heel ulcers is complex and needs multidisciplinary management for control of associated comorbidities, management of ischemia, control of infection, coverage, and off-loading. Heel ulcers are difficult to heal owing to many factors such as the frequent development of osteomyelitis, difficulty in keeping pressure off the wound, and differences in regional pedal perfusion [3]. This has led some authors to recommend the consideration of primary amputation for selected individuals with heel necrosis without any attempt for limb salvage [4,5].

The angiosome concept was first described by Taylor and Palmer in 1987. The angiosome concept of the foot describes a three-dimensional anatomical territory, which is derived from a 'source' artery, termed 'angiosome.' The heel has a unique single angiosomal blood supply from the posterior tibial artery (PTA), the occlusion of which results in failure of healing and a major amputation is likely to occur. This is in contrast to the forefoot which has multi-angiosomes that overlap from the anterior tibial artery (ATA) and peroneal artery (PA), allowing for collateral blood supply [6].

In isolated below-the-knee (BTK) arterial lesions, one or more of the infragenicular vessels are affected. Revascularization of PTA gives direct blood flow to the heel, whereas revascularization of ATA gives indirect flow. Direct revascularization (DR) via angiosome-targeted approach is expected to improve wound healing and limb salvage compared with indirect revascularization (IR), which provides blood flow only through collateral vessels originating from a nonaffected angiosome [7].

Aim

The aim of this study was to evaluate and compare the clinical outcomes and ulcer healing rates between DR and IR in patients with ischemic heel ulcers owing to isolated BTK lesions.

Patients and methods

Study design and population

This is a prospective comparative nonrandomized study that included 42 limbs in 42 patients having ischemic heel ulcers or heel gangrene. All patients were admitted to Tanta University Hospital during the period from October 2017 to December 2021. The study was approved by the University Research Ethics Committee. A written informed consent was obtained from all patients before enrollment in the study.

Selection criteria

The patients were included in the study if they had ischemic heel ulcer or heel gangrene owing to isolated BTK arterial lesion(s).

Patients with ischemia due to above-the-knee arterial occlusive disease were excluded from the study. Moreover, patients with extensive soft tissue infection and non-reconstructable calcaneal osteomyelitis were excluded from the study.

Non-reconstructable vascular lesions with no distal run-off and cases with failed revascularization during endovascular intervention were early excluded from the study.

The patients were divided, according to whether the PTA was successfully revascularized or not, into group I, in which patients had direct heel revascularization through dilatation of the PTA, and group II, in which patients had indirect heel revascularization through dilatation of ATA and/or PA.

Preoperative assessment

All patients underwent full history taking for associated comorbidities and clinical examination of the heel ulcer regarding its site, size, shape, edge, margin, base, floor (granulation tissue), and discharge.

Duration of the heel ulcer was registered for each patient. The surface area of the ulcer was calculated in cm^2 using a graph paper counting method through tracing the outline of the wound (wound circumference) onto the graph paper.

Staging of the ulcer was done according to WIFi score for determination of extension of ulcer and its depth, time needed for complete healing, and rate of ulcer healing along the follow-up period.

Ankle–brachial index assessment, duplex scanning, and plain radiograph of the foot were done preoperative routinely for all patients (Fig. 1). Computed tomography angiography was done only in selected cases with suspected infrainguinal lesions.

Operative procedure

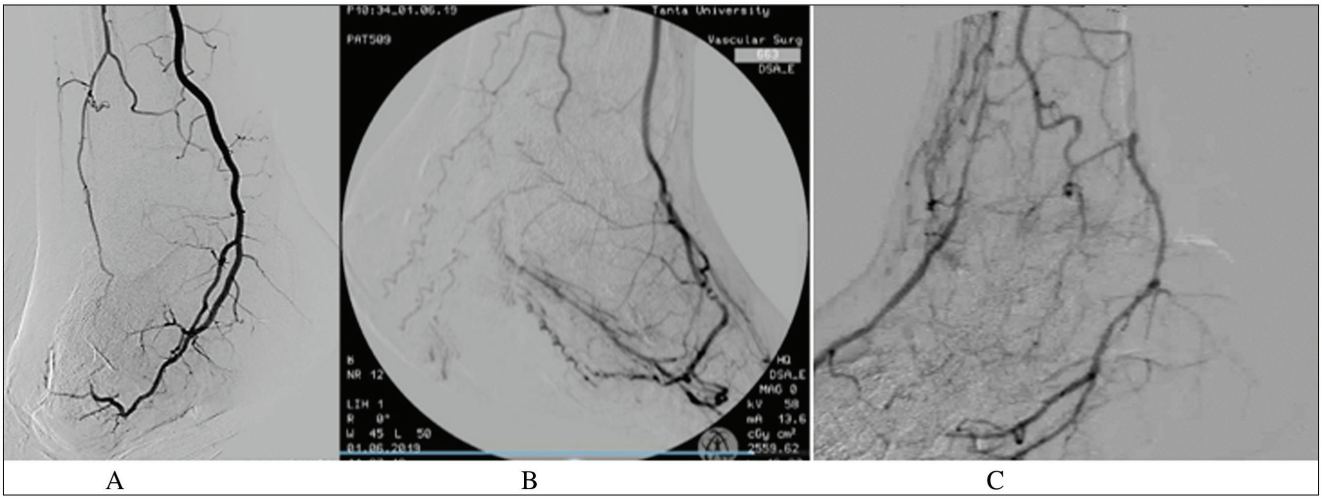
Clopidogrel loading dose 300 mg was given routinely 6 h before the procedure. All of our procedures were performed under radiographic guidance under (Zhiem Vision 2) mobile C-arm using nonionic low-osmolar contrast material. All cases were performed under local infiltration anesthesia with ipsilateral antegrade approach, and additional retrograde access through distal puncture if failed antegrade approach was performed.

Diagnostic angiography was done as an initial part of the procedure to detect exactly which vessel affected and state of distal run-off.

Figure 1

Radiograph showing erosions of the calcaneus overlying heel ulcer.

Figure 2



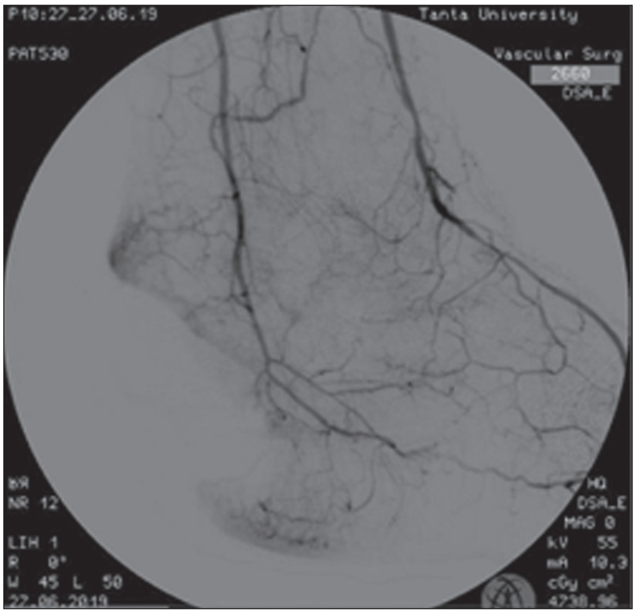
(a) DR through PTA, (b) IR through ATA, and (c) IR through PA. ATA, anterior tibial artery; IR, indirect revascularization; PA, peroneal artery; PTA, posterior tibial artery.

V-18 control wires 0.18 in×300 cm (Boston Scientific, Marlborough, Massachusetts, USA) supported by a 4 F Bern catheter (Boston Scientific) was used in all cases to cross the infragenicular lesions. Additional Hi-Torque Pilot 200 guidewire 0.014 in×300 cm (Abbott, Abbott Park, Illinois, United States, USA) and Rubicon supporting catheter 4 F×150 cm (Boston Scientific) were used in selected cases.

The endovascular treatment modalities were either transluminal or subintimal angioplasty depending on the intraprocedural situation. The recanalized segment was ballooned using appropriately sized noncompliant balloons with inflation time of 120 s and ballooning pressure from 6 to 14 atm. Our first target was to dilate all infragenicular lesions, and if not possible, PTA revascularization was adopted; in case of inability to dilate, the PTA trials to dilate the ATA were performed (Fig. 2).

Postprocedure angiography was then performed to assess the technical success, pedal arch, and wound blush of the ulcer bed (Fig. 3). Dual antiplatelet therapy was prescribed for all patients.

Figure 3



Positive wound blush.

Wound care

Local wound care was individualized for each case. Debridement was performed to remove all devitalized tissue. Infected ulcers underwent surgical revision and microbial therapy according to bacterial culture results. Negative-pressure wound therapy was considered in some cases. If primary or secondary closure was not possible, skin grafting or flaps were considered.

All patients were advised to keep the heel off the bed when sleeping using a soft pillow beneath the leg. All patients were referred for off-loading after debridement.

Follow-up

Postoperative follow-up was done on 1, 3, 6, and 12 months postoperatively. Clinical follow-up was in the form of assessment of ulcer complete healing (complete re-epithelization of the ulcer) and ulcer area reduction, evaluation of distal pulses, ABPI evaluation, and limb salvage or amputation occurrence. Duplex imaging was done to detect the presence of restenosis (and its degree) or re-occlusion, the type of the blood flow pattern, and the velocity of the blood flow.

Definitions

Technical success was defined as crossing the lesion with the guidewire and dilatation with less than 30% residual stenosis.

Ulcer healing was defined as complete epithelialization of the tissue defect by secondary intention or after any additional local ulcer surgery. The foot ulcer was considered unhealed if it did not heal during follow-up period.

Major amputation was defined as amputation performed either above or below knee.

Statistical analysis

The collected data were organized, tabulated, and statistically analyzed using SPSS statistical package for social studies, version 25 manufactured by SPSS, an IBM Company, Chicago, Illinois, USA. For categorical data, the number and percentage were calculated for each observation. Observed differences of different categories were tested using Fisher exact test or Monte-Carlo exact test as appropriate. For numerical data, the range, mean, and SD were calculated. Differences in mean values were tested using Mann–Whitney test (*Z*) as the small sample size did not allow the use of parametric tests of significance. The correlation between variables was calculated by Pearson's correlation coefficient (*r*). The level of significance was considered at probability value of *P* value less than 0.05.

Results

During the period from October 2017 to December 2021, 42 limbs in 42 patients with ischemic heel due to isolated BTK lesions were included in the study. All patients were suffering from nonhealing heel ulceration or heel gangrene (Rutherford 5 or 6).

Of the 42 limbs included in the study, successful PTA revascularization with direct flow to the heel based on the angiosome principle was achieved in 22 (52.38%) patients (group I) compared with 20 (47.62%) patients in which ATA and/or PA was revascularized with collaterals to the heel (indirect heel revascularization) (group II).

Patients' demographics and wound characteristics in both groups are summarized in Tables 1 and 2.

Duplex scan and initial diagnostic angiography showed PTA lesions present in all cases. ATA lesions were detected in 29 cases, whereas PA lesions were detected in 17 patients.

After revascularization, in group I, a single patent outflow vessel was obtained in 14/22 patients and 8/22 patients had multiple outflow vessels, whereas in group II, a single patent outflow vessel was obtained in 9/20 patients and 11/20 patients had multiple outflow vessels (PTA and PA). Therefore, totally 23 (54.7%) patients had a single patent outflow vessel and 19 (45.3%) patients had multiple patent outflow vessels.

After revascularization, 19 (45.23%) patients (nine in group I and 10 in group II) showed type 1 arch (complete pedal arch), six (14.28%) patients had type 2a arch (incomplete pedal arch with predominant dorsalis pedis artery), nine (21.42%) patients had type 2b arch (incomplete pedal arch with predominant plantar artery), and eight (19.04%) patients had type 3 arch (four in group I and four in group II) (absent arch). Wound blush was positive in 23 (54.8%) ulcers (12/22 in group I and 11/20 in group II) and negative for 19 (45.2%) ulcers (10/22 in group I and 9/20 in group II).

A total of 32 (76.19%) limbs were salvaged during the study period: 17 (40.47%) in group I and 15 (35.72%) in group II. There was no statistically significant difference in overall limb salvage between both groups (*P*=0.826). All limb losses (*n*=10) occurred in the first follow-up month, seven of them (four in group I and three in

Table 1 Patients' demographics in both groups

Variables	*N*=42 patients [*n* (%)]
Age (mean±SD)	62±11.5
Male sex	27 (64.3)
Diabetic	35 (83.33)
Smokers	20 (47.6)
Hypertensive	18 (42.8)
Hyperlipidemia	23 (54.7)
CVDs	29 (69.04)
End-stage renal disease	7 (16.66)

CVD, cardiovascular disease.

Table 2 Wound characteristics in both groups

Calcaneal probing [*n* (%)]	
Positive	15 (35.72)
Negative	27 (64.28)
WIFi score [*n* (%)]	
W2	27 (64.28)
W3	15 (35.72)
I1	14 (33.33)
I2	17 (40.47)
I3	11 (26.2)
Fi 0	15 (35.7)
Fi 1	14 (33.3)
Fi2	13 (31) Fi2
Moderate risk for amputation	24 (57.14)
High risk for amputation	18 (42.86)

W2 (deep ulcer), W3 (extensive ulcer with bone involvement), I1 (ABPI 0.6–0.79), I2 (ABPI 0.4–0.59), I3 (ABPI <0.4). Fi0 (no infection), Fi1 (infection limited to skin and subcutaneous tissue), Fi2 (infection deeper to subcutaneous tissue).

group II) were due to inability to control infection even after revascularization, in spite of extensive repeated debridement. The other three cases (one in group I and two in group II) had ongoing ischemia and gangrene even after successful revascularization; the three cases had type 3 pedal arch. All amputated patients were diabetic, even patients were heavy smokers, eight patients were at high risk for amputation according to WIFi score, and two cases were at moderate risk for amputation according to WIFi score.

The mean ulcer healing time for both groups was 17.07 ± 4.79 weeks and the median was 18 weeks. The mean ulcer healing time for group I was 15.9 ± 4.6 weeks and the median was 15 weeks, whereas for group II, the mean ulcer healing time was 21.7 ± 1.66 weeks and the median was 22 weeks. There was a statistically significant difference between both groups' healing time, with a *P* value of 0.002. The mean ulcer area reduction at third and sixth months was 43.96 and 30% versus 95.23 and 92.9% in group I and group II, respectively (Table 3). There was a significant reduction in ulcer size in both groups at all follow-up visits. When compared between groups, this difference was statistically significant at the third follow-up month only (P=0.034). Complete ulcer healing was observed in 16 patients in group I, whereas healing was complete in 10 patients in group II, with *P* value for complete healing between groups of 0.039 (Figs 4–6).

Outcomes analysis

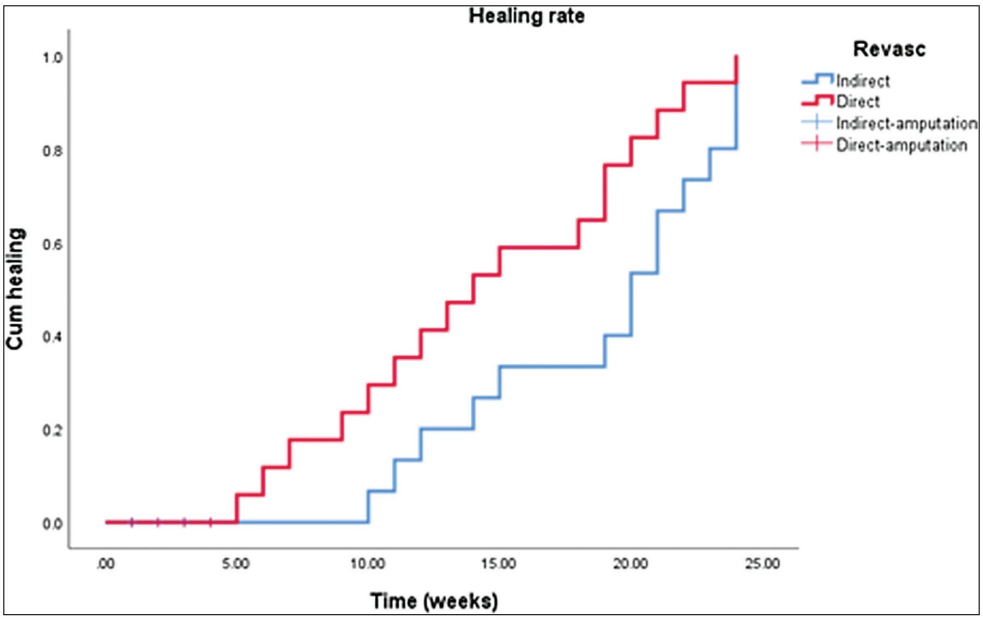
Using multivariate analysis, we found that diabetes mellitus (P=0.012), presence of cardiovascular disease (P=0.036), ulcer stage on admission (P=0.025), W 'WIFi score' (P=0.38) and Fi 'WIFi score' (P=0.032) were positively correlated with healing time, that is, prolonged healing time. However, PTA PSV (postoperatively, at 3 months, and at 6 months) and wound blush

Table 3 Ulcer size changes along the follow-up period

	Admission	1 month	3 months	6 months	*P* value
Group I					
Mean±SD (cm^2)	18 ± 5	11.6 ± 4.1	6.5 ± 3.1	0.3 ± 0.1	*P*1<0.001* *P*2<0.001* *P*3<0.001*
Median (cm^2)	14	10	3	0	
Mean change %	–	35	43.96	95.23	
Group II					
Mean±SD (cm^2)	17.4 ± 8.4	12.5 ± 5.4	8.8 ± 2.4	0.6 ± 0.3	*P*1=0.002* *P*2<0.001* *P*3<0.001*
Median (cm^2)	17	14	8.5	0	
Mean change %	–	28.04	30	92.9	
Z	0.153	0.783	3.551	0.804	
P	0.879	0.439	0.034*	0.426	

Z, Mann–Whitney test coefficient. *P*: *P* value comparing both groups. *P*1, *P*2, *P*3: *P* value (by analysis of variance and post-hoc Dunn's test for pairwise comparison) comparing mean ulcer size in the same group on successive follow up visits. *P*, *P*1, *P*2, and *P*3 are statistically significant at *P* value less than 0.05.

Figure 4

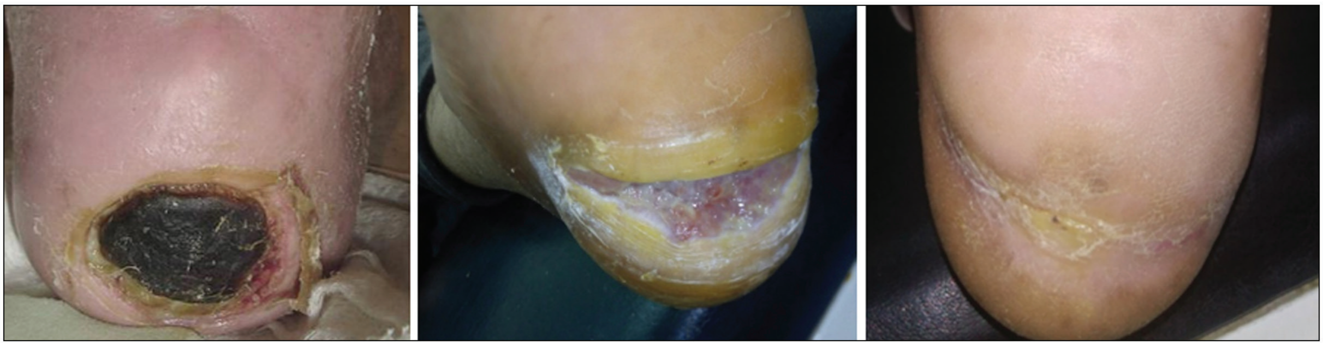


Kaplan–Meier curve of healing rate along follow-up period.

Figure 5

Heel ulcer on admission (a), after debridement (b), after 1 month of VAC (c), and after complete healing (d).

Figure 6



Heel gangrene on admission (a), after 1 month (b), and after complete healing (c).

were negatively correlated with healing time, that is, shortened healing time. However, on correlating the studied variables to limb salvage, we found that smoking (P=0.002), diabetes mellitus (P<0.001), W 'WIFi score' (P=0.002), I 'WIFi score' (P=0.018), Fi 'WIFi score' (P=0.005), and end-stage renal disease (P<0.001) were negatively correlated with limb salvage, whereas number of patent vessels, completeness of pedal arch, and wound blush were positively correlated with limb salvage (P=0.028, 0.005, and 0.041, respectively) (Table 4).

Discussion

The heel is the greatest weight-bearing part of the foot, and all studies show that heel ulcers in diabetic patients are usually difficult to treat [1].

Patients with heel ulcers have a higher risk of major amputation than patients with lesions of the midfoot and forefoot. Severe infections of the midfoot or forefoot can be managed with partial foot amputation, up to the Chopart level. However, severe infections at the heel may end with below-knee amputation [8].

The peculiar anatomic distribution of arterial supply to the heel can impair wound healing. In contrast to other areas, such as the plantar and dorsal foot areas, where an efficient collateral network can be obtained thanks to other foot or ankle arteries, the arterial perfusion of the heel is mainly (or quite exclusively) supplied by the branches of the PTA [9].

Therefore, early management of PTA lesions is of basic importance for healing of ischemic heel ulcer [10]. However, IR of the heel can also be obtained through the management of lesions in the ATA [11].

There is some debate about the importance of the angiosome concept when undertaking isolated BTK vessel revascularization. Initial small observational studies suggested that DR was superior to IR. More recent studies have tended to highlight the importance of DR over IR but have also focused on the importance of adequate collaterals, with some suggesting IR in the presence of adequate collaterals has equivalent outcomes to DR [12].

This study aimed to evaluate the clinical outcome of ischemic heel ulcers after DR and IR in a prospective manner as only some few studies [13] have focused on the endovascular management of heel lesions leading to limb salvage.

Table 4 Correlating the studied variables to healing time and limb salvage

	Healing time		Limb salvage	
	OR	*P*	OR	*P*
Age	1.031	0.827	0.715	0.125
Smoking	1.032	0.822	0.226*	0.002
DM	2.345*	0.012	0.125*	<0.001
HTN	1.007	0.963	0.625	0.108
ESRD	1.273	0.070	0.199*	<0.001
CVS	1.891*	0.036	0.618*	0.022
W	2.288*	0.038	0.126*	0.002
I	1.263	0.060	0.227*	0.018
Fi	2.298*	0.032	0.086*	0.005
Direct revascularization	0.511*	0.034	1.030	0.830
Wound blush	0.099*	0.049	2.065*	0.041
ABPI ATA immediate postoperative	0.050	0.727	1.013	0.927
ABPI PTA immediate postoperative	0.350*	0.027	1.259	0.064
PSV ATA immediate postoperative	0.176	0.211	1.193	0.171
PSV PTA immediate postoperative	0.401*	0.015	1.120	0.395
ABPI ATA 6 m postoperative	0.362*	0.035	1.134	0.410
ABPI PTA 6 m postoperative	0.331*	0.037	1.264	0.100
PSV ATA 6 m postoperative	0.170	0.293	1.016	0.182
PSV PTA 6 m postoperative	0.372*	0.018	1.087	0.594
Number of patent vessels postoperative	0.389	0.065	1.304*	0.028
Dominant side	1.248	0.077	0.077*	0.006
Pedal arch completeness	0.623	0.065	2.0417*	0.005

ABPI, ankle–brachial pressure index; ATA, anterior tibial artery; CVS, cardiovascular system disease; DM, diabetes mellitus; ESRD, end-stage renal disease; Fi, foot infection in WIFi score; HTN, hypertension; I, Ischemia in WIFi score; PSV, peak systolic velocity; PTA, posterior tibial artery; W, wound in WIFi score. OR: odds ratio using multivariate logistic regression analysis. **P* value significant less than or equal to 0.05.

Regarding the technical success in crossing the lesions, it was achieved in all cases of the study because any case with inability to cross the lesion was early excluded.

The results of this study showed that obtaining direct blood flow to the heel ulcer had significantly shortened the ulcer healing time but not significantly differs from obtaining indirect flow regarding the limb salvage rate.

The ulcer healing rate was better in group I, with statistically significant difference between both groups at the third follow-up month (P=0.034). On comparing both groups regarding the limb salvage rate, it was not statistically significant between both groups (P=0.862).

These study results agreed with Kabra *et al.* [11], who studied the effect of DR and IR on heel and nonheel ulcers and reported better ulcer healing rate with DR, with statistically significant difference (P=0.021), whereas the difference in limb salvage rate between both groups was nonsignificant.

These results were inconsistent with Acin *et al.* [14], Alexandrescu *et al.* [15], and Biancari and Juvonen [16], as they found a higher limb salvage rate in case of DR. This inconsistence may be owing to nonspecification of the foot lesions in these studies. Moreover, the presence of more cases having complete pedal arch in the group of IR may have a positive effect on limb salvage rate in our study.

Marston *et al.* [17] in their retrospective study followed patients with foot ulcers treated without revascularization owing to being unfit for revascularization. They found that 25 and 52% of the ulcers were completely healed in 6 and 12 months, respectively, and found that 19 and 23% of the limbs were amputated at 6 and 12 months, respectively. Although this study did not study heel ulcers specifically, its results open the field for adding a third group for studying ischemic heel ulcers outcome without revascularization in patients excluded for non-reconstructable vascular lesions.

In our study, we noticed that revascularization of the ATA led to statistically significant improvement of both ATA and PTA hemodynamic parameters postoperatively but more on ATA parameters ($P \le 0.001$ and P=0.04, respectively). On the same ground, revascularization of PTA led to statistically significant improvement of both PTA and ATA hemodynamic parameters postoperatively but more on PTA parameters ($P \le 0.001$ and P=0.05, respectively). This is mostly due to completeness of the pedal arch in many (45.23%) of our cases. Kawarada *et al.* [18]

studied effect of single tibial artery revascularization on microcirculation in critical limb ischemia and found that skin perfusion pressure increases significantly in dorsal and plantar skin in case of ATA revascularization or PTA revascularization. Nakama *et al.* [19] in their study recommended that pedal plantar arch angioplasty should be considered for patients who do not show adequate wound blushing during angioplasty. Manzi *et al*. [20] reported that pedal artery revascularization has a positive clinical effect at short-term follow-up; both studies support our results.

Multiple vessel revascularization was associated with higher limb salvage rates (P=0.028) but not significantly correlated with the healing time. This finding suggests that although it is recommended to treat all reconstructable infragenicular vascular lesions for better prognosis, this appears necessary for limb salvage only. In other words, multiple revascularizations should be attempted in limbs having moderate to high amputation risk rather than to legs with low amputation risk. The results of this study are consistent with Acin *et al.* [14] who reported nonsignificant difference between single and multiple revascularized vessels regarding healing time. Treiman *et al.* [21] studied the factors affecting successful heel ulcers healing in 91 patients and reported significant difference in limb salvage rate between single revascularization and multiple revascularization (P=0.004). We also agreed with the study by Iida *et al.* [22], in which the estimated limb salvage rate was correlated with the number of patent runoff vessels.

In spite of several published studies about endovascular therapy, the optimal angiographic end point of endovascular therapy remains unclear. Recently, wound blush is considered an important end point for revascularization by some authors [23]. In our study, wound blush was positive for 23 (54.8%) ulcers and negative for 19 (45.2%) ulcers. Wound blush was found on statistical analysis to have a positive correlation with limb salvage and negative correlation with healing time. Utsunomiya *et al*. [23,24] in two different studies had similar results to ours.

All limb losses (n=10) occurred in the first follow-up month with still the patency of revascularization in its peak. This suggests that other factors negatively affect the prognosis of the limb. In this study, these factors were represented by marked soft tissue infection, calcaneal osteomyelitis, profound ischemia at presentation, and associated comorbidities like diabetes mellitus and end-stage renal disease. Although there was apparently low limb salvage rate among our patients, this rate is comparable to the amputation rate in many studies dealing with heel ulcers, for instance, Dosluoglu *et al*. [25], who reported 72% limb salvage rate in patients with heel ulcers treated with endovascular therapy without concern to DR or IR. Kabra *et al.* [11] had limb salvage of 84 and 75% for DR and IR, respectively (P=0.06). Iida *et al.* [22] reported limb salvage of 86 and 69% for DR and IR, respectively (P=0.015). The higher limb salvage in some of these studies may be due to the involvement of all types of foot ulcers, not only heel ulcers, which carries a higher risk of major amputation.

One of the limitations of this study is the small number of patients. This may be owing to the strict inclusion criteria with inclusion only of BTK lesions and exclusion of any case with infrainguinal arterial disease.

Despite the small sample size along with the relatively short follow-up period, this study may be an addition to the currently limited reports regarding the management of heel ulcers.

Conclusion

Endovascular management of BTK arterial disease in patients with ischemic heel is safe and effective with good results for limb salvage and wound healing rates. DR technique should be attempted first for infragenicular angioplasty as it is associated with higher wound healing rates. If DR treatment is not feasible, then the IR technique is an alternative with nearly equivalent rates of limb salvage, especially with good quality of pedal arch.

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Nil.

Conflicts of interest

No conflict of interest.

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