

Original Article

Comparative study between the effect of direct and indirect revascularization of infrapopliteal occlusive disease on the rate of wound healing in diabetic foot ulcer

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Abstract

Aim: The purpose of this study is to assess the effectiveness of collateral circulation, which is guided by an angiosome model of perfusion, in the healing process of diabetic foot ulcers. It also evaluates the effects of direct and indirect endovascular revascularization of isolated infrapopliteal occlusive disease on wound healing and limb salvage rates.

Material and Methods: In this prospective, non-randomized, comparative clinical investigation, 42 patients who presented with isolated infrapopliteal illness with a patent ilio-femoral arterial segment for endovascular treatment of one or more tibial arteries with a Rutherford classification of 5–6 were included. Revascularization of the limb's source artery was performed on 21 direct group members, and revascularization of the arteries other than the angiosomal artery was performed on 21 indirect group members.

Results: The demographic information, Rutherford classifications, number, site, duration (months), foot ulcer size, diseased artery, and investigations before and after the treatment did not significantly differ across groups; however, the ABI did. The rates of healing at the 1-month and 3-month follow-up, major and minor amputation, chronic wounds, and death did not differ significantly across groups. Nonetheless, limb salvage and healing at the 6-month and 12-month follow-up showed a significant difference $P \leq 0.05$). The direct group had an amputation-free survival rate of 10.2 months, while the indirect group had an amputation-free survival rate of 8.8 months.

Conclusion: Chronic limb-threatening ischemia can be effectively treated with angiosome-oriented primary targeted infrapopliteal percutaneous transluminal angioplasty. To increase the chances of limb salvage in situations where the target artery's angioplastic outcomes are insufficient, infrapopliteal percutaneous transluminal angioplasty of the non-target artery should be tried.

Keywords: Angiosome, targeted ip-pta, non-targeted ip-pta, healing, limb salvage, diabetic foot ulcers

INTRODUCTION

A significant number of amputations and fatalities are linked to chronic limb-threatening ischemia (CLTI). Patients who exhibit leg ulcers, gangrene, or rest pain and have signs of decreased arterial blood supply to the foot are diagnosed [1].

The capacity to restore and sustain straight-line tibial arterial flow to the foot is the foundation for the crucial objective of preventing major amputation (MA) in CLTI [2].

Jan Taylor originally proposed the angiosome concept of vascular architecture in the 1970s as a way to maximize tissue transfer. It describes three-dimensional (3D) vascular regions that are supplied by discrete source arteries. The idea has been used in CLTI during the past few years to improve the chances of limb salvage during distal revascularization planning [3].

The main justification for using an angiosome-based strategy is that the best probability of wound healing and limb salvage will be achieved by providing direct artery flow to an ischemic

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area [4]. For chronic limb-threatening ischemia, infrapopliteal percutaneous transluminal angioplasty (IP-PTA) is a safe and efficient therapeutic option that can replace bypass surgery [5]. Though the clinical importance is still up for debate, Several research investigations have indicated the key to healing infrapopliteal illness is angiosome-based treatment [6].

According to certain research, limb salvage rates are higher, and wound healing is better with direct revascularization (DR) than with indirect revascularization (IR). However, other recent investigations demonstrated that when compared to IR, DR had a similar limb salvage rate, but a much higher rate of wound healing [7].

Therefore, this study intends to assess collateral circulation efficacy guided by an angiosomal concept in the healing process of diabetic foot ulcers, as well as the impact of DR vs. IR of isolated infrapopliteal occlusive disease on wound healing and limb salvage rates.

MATERIAL AND METHODS

Selection/Enrollment

Between October 2022 and October 2023, a prospective, non-randomized, comparative clinical investigation was carried out in a tertiary hospital's Vascular Surgery Unit. Patients with isolated infrapopliteal artery substantial stenosis of $\geq 70\%$ occlusions with a Patent ilio-femoral arterial segment appropriate for endovascular therapy, who had tissue loss in the feet and/or legs in the form of ischemic ulcer and/or gangrene were the subjects of the study (Rutherford classification 5-6).

In the current study, we used a non-randomized technique that was based on the anatomical feasibility of targeted arteries for Percutaneous transluminal angioplasty after the patients signed their written consent.

Critical lower limb ischemia manifested as rest pain alone, acute lower limb ischemia, extensive foot infection, ulceration and/or gangrene beyond salvage, inflow lesions above the knee, patients with supramalleolar ulcers, patients with active cardiac conditions, and patients with impaired renal function were all excluded.

Sample size: The following formula was used to determine the sample size: $n = (Z\alpha/2 + Z\beta)^2 * (p_1(1-p_1) + p_2(1-p_2)) / (p_1 - p_2)^2$, where $Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (at a 95% confidence level, α equals 0.05 and the critical value to be 1.96). $Z\beta$ represents the critical value of the Normal distribution at β , where β is 0.2, and the critical value is 0.84 for a power of 80%. p_1 and p_2 represent the two groups' expected sample proportions. According to a 95% CI and a significance level of 0.05, the wound healing rate for patients who had infrapopliteal endovascular revascularization, contrasted with the standard of care using the angiosome model of perfusion, was 85.71% against 42.85%. The anticipated sample size for each group was $N = 21$ [8].

Ethical consideration: The study protocol was reviewed and approved by the institutional research and ethical committee of the faculty of medicine – Cairo University on 12/1/2023. (Protocol number: MD-367-2022). The goals of the study were fully explained to the participants, and then their informed permission was obtained.

The research was entirely voluntary, and participants may withdraw from it whenever they want. All stages of data entry, gathering, and analysis were conducted in accordance with the Declaration of Helsinki in a very private and confidential way.

Statistical methods

The statistical software for the social sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA) was used to code and enter the data. For quantitative variables, the mean and standard deviation were used to summarize the data; for categorical variables, the frequencies (number of cases) and relative frequencies (percentages) were used. The unpaired t-test was used to compare groups [9]. Using the Chi-square (2) test, categorical data were compared. When the anticipated frequency was less than 5, the exact test was employed [10]. The Kaplan-Meier method was used to plot survival curves, and the log-rank test was used for comparison [11]. Statistical significance was defined as P-values below 0.05.

A full history and physical examination were performed on each patient. For each individual artery, the ankle brachial index (ABI) was measured. The required laboratory tests were performed: serum creatinine, complete blood count, coagulation profile, glycated hemoglobin, C-reactive protein (CRP), lipid profile, serum albumin, and culture and sensitivity from an infected lesion. Duplex ultrasonography, CT angiography, and foot X-rays were among the imaging tests. Patients were split into two groups based on whether the ulcerated angiosome was fed by collaterals from other angiosomes (indirect group, IR) or if direct in-line flow from the aorta to the foot ulcer, based on the angiosome concept, was effectively achieved (direct group, DR). The leg was classified as being in the DR group if the PTA was able to provide direct blood flow to the ulcer from at least one crural artery, even if the foot ulcer covered more than one angiosome region.

Procedure

Under local infiltration analgesia (10 ml of 2% lidocaine), all interventions were carried out. Before the surgery, 300 mg of clopidogrel and 150 mg of aspirin were administered to all patients. It was preferable to use the 6F sheath and the antegrade approach from the ipsilateral CFA. 5000IU of heparin was being given intravenously to the patient following the sheath placement. Using nonionic iodinated contrast media, diagnostic angiography was performed in every instance. Every localized infrapopliteal artery lesion was examined in hindsight. Both the target vessel and the spread of lesions were noted. When antegrade crossing is unsuccessful, the retrograde tibiopedal access is utilized in addition to the antegrade access. We did intraluminal guidewire

passage mostly. When the intraluminal guidewire passage failed; the subintimal guidewire passage approach was employed. Regularly, a hydrophilic 0.018-inch microguidewire (V18®, Boston Scientific or Command 18 ST, Abbott) was used to traverse the infrapopliteal artery lesions.

In heavily calcified vessels that were completely occluded, the failure of hydrophilic 0.018-inch micro guidewires led to the introduction of chronic total occlusion (CTO) wires in heavily calcified, fully blocked arteries. When the diseased vessel was cannulated, a micro support catheter was utilized. They employed balloons that were only a little bit longer than the lesion and had diameters between 2.5 and 3 mm. We performed IP-PTA on the primary target lesion, which was decided by the wound location based on the angiosome concept in all patients. In case where recanalization of the target artery failed, an additional IP-PTA was performed on another artery (i.e., the non-target artery).

The primary target lesion underwent percutaneous transluminal angioplasty, which was determined by the wound location using the angiosome concept in the direct group.

The indirect group's cases involved another infrapopliteal artery that underwent percutaneous transluminal angioplasty.

All infrapopliteal arteries were subjected to percutaneous transluminal angioplasty if the wounds were multifocal or extremely extensive, or if all of the arteries were blocked. This was done by as closely as possible adhering to a sequence from the target artery to the nontarget artery using the angiosome concept.

All antegrade puncture sites were closed right after angioplasty by applying manual compression over the puncture site for 15 to 20 minutes, and movement was postponed for 12 to 24 hours.

Wound care

In order to eliminate devitalized tissue, debridement was done. Depending on the culture results, infected ulcers were surgically revised and treated with microbiological therapy. In cases where primary or secondary closure was not feasible, flaps or skin grafting were taken into consideration. We did not use standard wound dressing methods in all patients, but we started with repeated dressing once daily for every patient, after the repeated dressings of wounds looked healthy and not infected, negative-pressure wound therapy and offloading were applied.

Technical success

The technical success of percutaneous transluminal angioplasty was based on completion angiography as follows:

- Complete re-canalization of the lumen and an increased intraluminal flow, or residual stenosis of < 30%,
- Highly increased contrast staining or tissue blush around the wound,
- Elevated ankle brachial pressure index of >0.6 after percutaneous transluminal angioplasty [12].

Follow-up

All patients were routinely prescribed 75 mg of oral aspirin once daily for life, and 75 mg of oral clopidogrel once daily for at least three months, provided that neither medication was contraindicated. Before being released, each patient received personalized foot care instructions and the proper footwear guidance. The size, appearance, and healing of the ulcers, as well as the duplex scanning of the target versus non-target section to confirm the patency of the targeted and non-targeted vessels were monitored at 1, 3, 6, and 12 months following surgery. Technique, wound healing, and the preservation of the foot's functional ability were assessed for each participant. Amputation-free survival, major adverse limb events (MALE), reintervention rate, and the amount of time required for wound healing between the target and nontarget groups were also examined.

A worsening of the wound was one of the reasons for a second percutaneous transluminal angioplasty during the follow-up. In the absence of wound aggravation, reocclusion of the recanalized infrapopliteal artery during the follow-up does not suggest a need for further percutaneous transluminal angioplasty.

A complete recanalization of the lumen and an increase in intraluminal flow, or residual stenosis of less than 30%, significantly elevated contrast staining or tissue blush surrounding the wound, or an elevated ankle brachial pressure index of greater than 0.6 following percutaneous transluminal angioplasty were considered technical success criteria. A survival rate without significant amputation around the knee joint throughout the follow-up period was known as the limb salvage rate (Figure 1) [12].



Figure 1. Direct revascularization technique results on one of the study participants. a: Photo of the forefoot showing a gangrenous big toe. b: The foot 1 month after revascularization. c: Complete healing after 3 months

Definitions

Diabetic foot ulcer was defined as a full-thickness skin defect distal to the malleolar level present for at least 2 weeks. Ulcer location before PTA was registered. Patients with supramalleolar ulcers were excluded.

Complete healing of the ulcer was defined as complete epithelialization of the tissue defect by Secondary intent or after any additional local ulcer surgery. Partial healing was defined as partial epithelialization of the tissue defect only. The foot ulcer was considered non-healed if it did not heal during follow-up, or the patient underwent infrainguinal bypass surgery or a major

amputation due to a non-healing foot ulcer [13].

Regarding the level of amputation, minor amputation was defined as an amputation distal to the ankle joint; major amputation was defined as an amputation through or above the ankle joint.

Primary outcomes

- Success of technique [Time Frame: Intra-operative completion angiography],
- Wound healing,
- Salvage of the functional capacity of the foot,
- Amputation-free survival.

Secondary outcomes

- Healing time between the target and the nontarget groups [Time Frame: 12-month follow-up],
- Re-intervention rate.

RESULTS

There were 42 patients in total, 21 in the direct group and 21 in the indirect group; the bulk of these patients (71.4%) were male. Participants were in their early sixties on average. Of the study subjects, 18 (85.7%) of the direct group had diabetes, compared to 17 (81%) of the indirect group. But a notable numerical difference in the duration of diabetes was shown (21.22 years in the direct group vs. 16.88 years in the indirect group).

Table 1 indicates that there was no significant difference in the characteristics and comorbidities of the study groups.

Every patient was assigned to one of Rutherford’s classes, five or six. 71.4% of the lesions in the direct group and 61.9% in the indirect group were toes, and the majority (85.7%) of the lesions were DE NOVO ulcers. The features of the lesions did not significantly differ between the groups ($P > 0.05$) (Table 1).

Table 1. Demographic data and lower limb and lesion characteristics in the two studied groups					
Demographics	Direct group N = 21		Indirect group N = 21		P value
Age (years)					0.620
Mean± SD	63.43 ± 4.60		64.24 ± 5.82		
	N	%	N	%	
Sex					
Male	16	76.2%	14	66.7%	0.495
Female	5	23.8%	7	33.3%	
DM	18	85.7%	17	81.0%	1
HTN	20	95.2%	20	95.2%	1
Hyperlipidemia	10	47.6%	13	61.9%	0.352
IHD	15	71.4%	13	61.9%	0.513
Cerebro-vascular disease	7	33.3%	7	33.3%	1
Current smoking	16	76.2%	16	76.2%	1
Duration of DM (years), Mean ± SD	21.22 ± 8.80		16.88 ± 6.96		0.117
DM: Diabetes mellitus, HTN: Hyperternsion, IHD: Ischaemic heart disease					

Prior to the intervention, the direct group's mean ankle-brachial index (ABI) was 0.5 ± 0.08 , whereas the indirect group's was 0.47 ± 0.07 . A statistically significant difference is indicated by these results (P -value = 0.001) (Table 2).

We use multivariate linear regression to adjust for baseline ABI in the comparison of ABI (Follow-up) between the 2 groups. The comparison between the 2 groups regarding 6 and 12 months Follow-up ABI was statistically significant ($P = 0.024$) and ($P = 0.028$) after adjustment for baseline ABI, respectively (Table

3). Nevertheless, there was no statistically significant difference between the two research groups in terms of pre-intervention tests, including serum albumin, Hb, and HbA1c (Table 2).

The study groups' follow-up post-intervention studies at the one, three, six, and twelve-month marks revealed notable alterations. According to Tables 2 and 3, the two study groups' Hb level at one month after the intervention and their ABI at one, three, and six months after the intervention exhibited a P -value < 0.05 (Tables 2 and 3).

Table 2. Baseline and follow-up investigation in the two studied groups

	Direct group N = 21	Indirect group N = 21	P value
Before, Mean ± SD			
ABI	0.55 ± 0.08	0.47 ± 0.07	0.001*
HbA1c	9.84 ± 1.96	9.54 ± 2.27	0.649
Hb	11.8 ± 2.12	11.06 ± 1.53	0.200
Albumin	3.34 ± 0.34	3.37 ± 0.38	0.766
1st month, Mean ± SD			
ABI	0.76 ± 0.06	0.74 ± 0.05	0.229
HbA1c	9.18 ± 2	9.32 ± 2.23	0.853
Hb	11.53 ± 1.43	10.54 ± 1.01	0.027*
Albumin	3.29 ± 0.26	3.27 ± 0.26	0.823
3rd month, Mean ± SD			
ABI	0.76 ± 0.06	0.72 ± 0.04	0.040*
HbA1c	8.37 ± 1.29	8.75 ± 1.91	0.523
Hb	11.1 ± 1.43	10.74 ± 1.09	0.459
Albumin	3.28 ± 0.18	3.22 ± 0.25	0.517
6th month, Mean ± SD			
ABI	0.74 ± 0.05	0.70 ± 0	0.004*
HbA1c	8.21 ± 1.09	8.35 ± 1.88	0.835
Hb	11.06 ± 0.94	11.29 ± 0.75	0.508
Albumin	3.13 ± 0.2	3.28 ± 0.19	0.060

*P value is significant ≤0.05. ABI: Ankle brachial index, Hb: Hemoglobin

Table 3. Multivariate linear regression to adjust for baseline ABI in the comparison of ABI (follow-up) between the 2 groups

Model	Unstandardized coefficients		Standardized coefficients	t	P value
	B	Std. Error	Beta		
ABI (1M follow up)					
Group	0.014	0.023	0.121	0.599	0.553
ABI (before angioplasty)	0.109	0.127	0.175	0.863	0.395
ABI (3M follow up)					
Group	0.041	0.023	0.369	1.749	0.092
ABI (before angioplasty)	0.001	0.126	0.001	0.004	0.997
ABI (6M follow up)					
Group	0.046	0.019	0.518	2.412	0.024*
ABI (before angioplasty)	0.023	0.100	0.049	0.228	0.821
ABI (12M follow up)					
Group	0.044	0.019	0.514	2.342	0.028*
ABI (before angioplasty)	0.037	0.098	0.083	0.376	0.710

The comparison between the 2 groups regarding 6 and 12 months Follow-up ABI was statistically significant (P = 0.024) and (P = 0.028) after adjustment for baseline ABI, respectively

When it came to the outcome and complications between the two study groups, there was a significant difference in complete and partial healing rates ($P < 0.05$) at 6 and 12 months post-intervention, but there was no significant difference in complete and partial healing rates between the two groups for the 1 and 3 months ($P > 0.05$). Regarding limb salvage, there was also a statistically significant difference. In contrast, there was no significant difference ($P > 0.05$) in major or minor amputations, persistent wounds, or death between the two groups throughout the follow-up period (Table 4) (Figure 2).

After 13 patients in the direct group had their wounds followed up on, after exclusion of patients with minor and major amputation and death, over half (53.8%) of them needed 1 to 3 months for their wounds to fully heal, and one patient (7.6%) still had a persistent wound a year after the intervention. However, of the eight patients in the indirect group who were monitored for their wounds, three (37.5%) had chronic wounds, and half (50%) had full healing within three to six months after the intervention. (Table 5).

Table 4. Outcome in the two studied groups

Healing	Direct group	Indirect group	P value
	Count	Count	
Healing (1M follow up)			
Complete	3	0	0.445
Partial	14	13	
Healing (3M follow up)			
Complete	7	1	0.213
Partial	7	9	
Healing (6M follow up)			
Complete	11	5	0.043*
Partial	3	3	
Healing (12M follow up)			
Complete	12	5	0.001*
Partial	1	3	
The other outcomes			
Minor amputation	2	3	0.648
Major amputation	3	5	0.429
Persistent wound	1	3	0.323
Limb salvage	15	11	0.045*
Death	3	5	0.697
*P value is significant ≤ 0.05			

*P value is significant ≤ 0.05

Table 5. Comparison between healing time in the studied groups

Healing time	Direct Group N = 13		Indirect group N = 8	
	Count	%	Count	%
1-3 m	7	53.8	1	12.5
3-6 m	4	30.7	4	50
6-12 m	1	7.6	0	0
Persistent wound	1	7.6	3	37.5

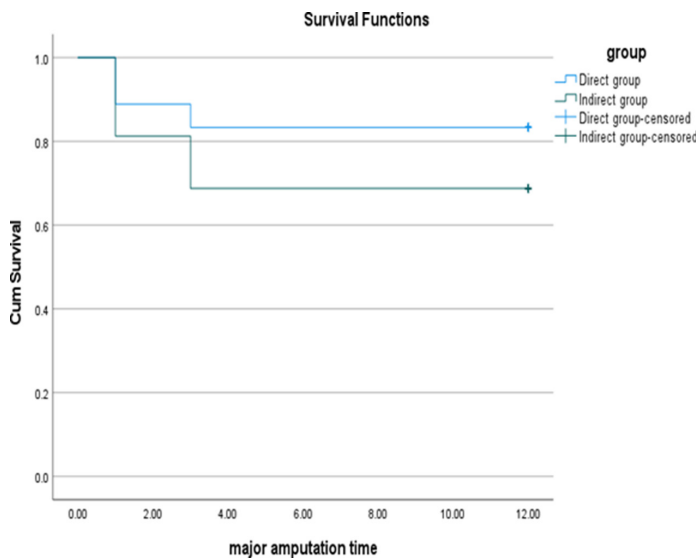


Figure 2. The estimated mean time amputation-free survival rate was 10.2 months for the direct group versus 8.8 months for the indirect group. The survival probability is lower for the indirect group at all time points, so they are more likely to undergo major amputation

DISCUSSION

The progression of peripheral artery disease to CLTI, which is typified by gangrene, leg or foot ulcers, or rest pain, is the most severe kind [14]. When a patient develops CLTI, revascularization of the damaged limb is crucial for preserving the limb, increasing overall survival, and enhancing quality of life [15].

It is anticipated that angiosome-targeted direct revascularization (DR) may enhance limb salvage and wound healing in contrast to indirect revascularization (IR), which only allows blood flow via collateral arteries originating from an unaffected angiosome [16].

Using an angiosome model of perfusion to guide the healing process, the current study evaluated the effectiveness of collateral circulation in diabetic foot ulcers and compared the effects of DR and IR of infrapopliteal occlusive disease on the rate of wound healing and limb salvage.

According to the current study, over 80% of both study groups had diabetes, indicating co-morbidity. It is widely recognized that diabetes raises the risk of both limb ischemia and associated consequences. Diabetes-related CLTI is frequently more widespread and increases the risk of amputation by 5–30 times. In our aging society, the rate of infrapopliteal arterial occlusive disease and the requirement for intervention rise in tandem with the incidence and prevalence of diabetes mellitus [17]. At the first, third, sixth, and twelfth months following intervention, there was a significant difference in the research groups' levels of complete recovery. In contrast to the indirect group, which had three limbs with persistent wounds and one limb with a persistent wound, the direct group demonstrated

higher rates of full healing. Remarkably, half of the direct group participants' wounds took one to three months to heal, but half of the indirect group participants' wounds took three to six months to fully heal. According to Jeon et al., there was a substantial difference in both the healing rate and the healing duration, with the direct group's wound healing rate being 87.3% of 63 limbs and the indirect group's wound healing rate was 47.3% of 19 limbs [18]. In their study of 226 diabetic individuals with CLTI, Söderström et al. found that at 12 months, the total wound healing rates in DR were lower (72%) than in IR (45%) [16]. According to Fossaceca et al., DR seems to be more successful than IR at maximizing wound healing results, and it might provide a greater contribution to the global initiative to lessen the number of unnecessary non-traumatic lower limb amputations among diabetic patients [19]. These results suggest that ischemic ulcerations may continue and/or worsen even after technically successful revascularizations, in part because of the unrecognized link between the target vessel and the ulceration site [20]. In contrast to our findings, a 2016 investigation reported that at 6-month follow-up, 78.3% of ulcers in the indirect group and 57.7% in the direct group had healed; however, this difference was not statistically significant [18]. We can explain the disparity by pointing out that while their indirect group seems to heal better, their direct group may contain a higher percentage of smokers, CKD patients, and grade 3 ulcers—all of which are known risk factors for diabetic foot non-healing [21]. Based on the current study's data, a comparison of the direct and indirect groups' results was conducted. There was no statistically significant difference between the direct and indirect groups in terms of major amputation (16.7% versus 31.3%), minor amputation (11.1% versus 18.8%), persistent wound (5.6 % versus 18.8%), or death (14.3% versus 23.8%). However, limb salvage was significantly higher among the direct group (83.3% versus 68.8% in the indirect group; $p = 0.045$). Furthermore, following propensity matching analysis, Kaplan-Meier curves for the amputation-free survival rate in the direct and indirect groups are displayed. The direct group's estimated mean amputation-free survival rate is 10.2 months, while the indirect groups are 8.8 months. These findings are in line with those of Alexandrescu et al., who found that patients who had total success had an amputation rate of 33.3%, whereas patients who had partial success and failure had an amputation rate of 54.5%. However, there was no statistically significant difference between the two groups [22]. Direct revascularization showed a significantly better rate of limb salvage than indirectly vascularized lesions, according to several earlier investigations [23]. Additionally, they postulated that whether blood can reach the ischemic area is more important than how much can be delivered to the foot [24]. Some studies that used the angiosome model showed better results than non-angiosome focused angioplasty, which may be due to the insufficient collateral arteries. Non-angiosome

treatments produced results similar to those in line with the angiosome idea when sufficient collateral vessels were present [25]. Hendawy et al. believe that the endovascular correction of the distal foot pedal arch could reduce the healing time in patients with foot ulceration, as they observed that the rates of healing and time to healing were directly influenced by the quality of the pedal arch [7]. There are extensive connections between the ATA, PTA, and PA all the way along their course in the leg and also in the foot. Furthermore, the distal peroneal collateral vessels and the patent pedal arch played a significant role in wound healing and limb salvage. These inter-angiosome connections by choke vessels are important for IR. This most frequently happens when the heel is being supplied by the dorsalis pedis artery only, or the forefoot is being perfused by the PA, which depends on its connection channels with the dorsalis pedis and lateral plantar artery for perfusion via its anterior perforating branch or the calcaneal branch [7,26,27]. Therefore, a patent pedal arch and/or peroneal distal collateral vessels might show a similar result in limb salvage and wound healing as that obtained through the reconstruction of specific source arteries. This concept is used in the 'pedal-planter loop angioplasty' technique to reconstruct the pedal arch in patients with CLI, which showed an 85% success rate and a significant improvement of transcutaneous oxygen tension after the procedure [28,29].

Recommendations

DR of the ischemic angiosome should be taken into consideration whenever possible in order to increase the rate of wound healing. Revascularizations should not be refused to patients with indirect perfusion of the ischemic angiosome if the rates of limb salvage are satisfactory.

Limitations

To confirm or disprove the angiosome notion, a bigger study population with long-term follow-up is advised. The current study has a small sample size (21 patients per group) and a short term follow-up time (12 months), additionally, a non-randomized design and secondary outcomes, including amputation-free survival and major and minor amputation rates, added more limitations in our study.

Secondly, wound care was not standardized, which may have affected how long it took for ulcers to heal.

Thirdly, diabetic patients may present with a variety of lesions that are variable in morphology and topography because of several anatomical variances in the foot arteries. As a result, assigning patients to a certain angiosome became challenging.

CONCLUSION

For diabetic foot ulcers, direct revascularization yields better results and promotes wound healing than indirect

revascularization. In diabetic foot, microvascular dysfunction and atherosclerotic artery disease interact in intricate ways, making the results of angioplasty uncertain. To increase the chances of limb salvage in situations where the target artery's angioplastic outcomes are insufficient, infrapopliteal percutaneous transluminal angioplasty of the non-target artery should be tried.

Ethics Committee Approval: The study protocol was reviewed and approved by the institutional research and ethical committee of the faculty of medicine – Cairo University on 12/1/2023 (Protocol number: MD-367-2022). The goals of the study were According to certain research, limb salvage rates are higher, fully explained to the participants, and then their informed permission was obtained.

Patient Consent for Publication: The research was entirely voluntary, and participants may withdraw from it whenever they want. All stages of data entry, gathering, and analysis were conducted in accordance with the Declaration of Helsinki in a very private and confidential way.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

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