Impact of angiosomal concept in tibial angioplasty on diabetic foot management and limb survival

Original Article

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ABSTRACT

Introduction: The concept of angiosomes plays a crucial role in revascularization strategies for critical limb-threatening ischemia. Angiosomes are three-dimensional blocks of tissue supplied by specific arteries. Angiosome-directed revascularization aims to restore blood flow to the ischemic tissue by targeting the specific angiosome affected by the arterial occlusion.

Aim: This study aims to determine whether to predict better diabetic foot wound healing angiosome or nonangiosome tibial angioplasty revascularization strategy or the overall wound, ischemia, and foot infection (WIFI) grade of the diabetic foot.

Patients and Methods: A prospective nonrandomized comparative clinical study was conducted between December 2018 and June 2021 in a single tertiary referral center. The patients signed an institutional approved informed consent, and the university institutional review board approved the present study.

Results: We performed a total of 100 infrapopliteal endovascular procedures in 110 limbs from 100 consecutive patients. Patients were divided into two groups according to angiosomal concept, direct group and indirect group. Each group included 50 patients. There was no significant difference between the two groups, 63.7±6.7 and 64.57±7.2, respectively, in the direct and indirect groups. There was no significant difference between the two groups regarding the site of the lesion, the WIFI stage, and the lesion severity scoring system (global limb anatomic staging system) for infrapopliteal disease analysis. However, there was a significant difference between the two groups regarding the treatment of the artery with angioplasty. The healing rate in foot lesions among the nonangiosome group and patients with WIFI (II) were statistically significantly higher than among angiosome group and patients with WIFI (III); 84.6 and 78.2% versus 15.38 and 21.79%, respectively; there was statistical significance difference in the healing rate of foot lesions in the group WIFI (II) more than WIFI (III) 142 days versus 256 days. There was no statistically significant difference ($P>0.05$) between both groups with major amputation, minor amputation, persistent wound, and death. However, there was a significance difference concerning limb salvage ($P=0.045$).

Conclusion: Our results coincide with what was published that the limb scoring severity system (WIFI) is more important than angiosome revascularization in wound healing rate, limb survival rate, and amputation-free survival.

Key Words: Angioplasty, angiosomal, survival, tibial.

Received: 29 May 2024, **Accepted:** 15 July 2024, **Published:** 4 October 2024

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ISSN: 1110-1121, October 2024, Vol. 43, No. 4: 1455-1462, © The Egyptian Journal of Surgery

INTRODUCTION

Critical limb-threatening ischemia (CLTI) is a severe condition characterized by inadequate blood flow to the extremities, leading to significant tissue damage and the potential risk of limb loss. It is a limb-threatening manifestation of peripheral arterial disease and requires prompt diagnosis and management[1].

CLTI typically arises from the progression of underlying peripheral arterial disease. The primary cause of CLTI is atherosclerosis, a condition characterized by the buildup of plaque within the arteries, leading to narrowing and obstruction of blood flow. Other etiological factors can include thromboembolism, arterial dissection, vasculitis, and trauma[1].

In addition, several risk factors contribute to the development and progression of CLTI, including diabetes mellitus, smoking, hypertension, hyperlipidemia, and impaired renal function[2].

Furthermore, the management of CLTI aims to relieve symptoms, promote wound healing, restore blood flow, and prevent limb loss. The Global Vascular Guidelines provide evidence-based recommendations for the management of CLTI. Revascularization is the cornerstone of CLTI management as it involves restoring blood flow to

DOI: 10.21608/EJSUR.2024.293566.1089

the affected limb through either endovascular or surgical interventions. Also, the choice of revascularization modality depends on various factors, including anatomical considerations, comorbidities, and patient preferences[3].

The concept of angiosomes plays a crucial role in revascularization strategies for CLTI. Angiosomes are three-dimensional blocks of tissue supplied by specific arteries. Angiosome-directed revascularization aims to restore blood flow to the ischemic tissue by targeting the specific angiosome affected by the arterial occlusion[4].

On the other hand, in cases where angiosome-directed revascularization is not feasible, a nonangiosome-based approach may be employed. This approach focuses on restoring blood flow to the affected limb through revascularization of any patent artery, regardless of its angiosomal territory[5].

Not only that, but optimal wound care is essential for managing CLTI, which involves regular debridement, infection control, and appropriate dressings. The goal is to create an optimal wound-healing environment[6].

Moreover, to aid in the management and communication of CLTI cases, the global limb anatomic staging system (GLASS) provides a standardized method for describing the anatomic extent of arterial disease in CLTI. It categorizes the disease into four stages based on the involvement of specific arterial segments[3].

Additionally, the inframalleolar GLASS modification of the inframalleolar run-off does not affect the overall (GLASS) and its recommended revascularization strategy in spite of it may affect the outcome of overall patency rate of target artery pathway (TAP) and wound healing[7].

Also, wound, ischemia, and foot infection (WIFI) classification helps assess the severity of CLTI by considering three key parameters: wound, ischemia, and foot infection. Each parameter is graded, and the cumulative score determines the severity of the condition, guiding treatment decisions and prognostication[8].

PATIENTS AND METHODS:

This is a prospective nonrandomized comparative clinical study conducted between December 2018 and June 2021 in a single tertiary referral center. The patients signed an institutional approved informed consent, and the university institutional review board approved the present study.

Patient selection

Patients included in this study had isolated infrapopliteal arterial occlusive disease associated with ankle systolic pressure less than or equal to 50 mmHg or had nonhealing foot wounds or ulcers for more than 2 weeks. In addition, patients who had multilevel occlusive arterial disease, impaired renal function (GFR≤60 ml/min), or a history of contrast allergy were excluded from the study.

Procedure

After a clinical assessment of the patient's status, the foot clinical severity score of tissue loss (WIFI) was calculated for each limb. Moreover, a duplex study by a skillful operator was performed to assess the anatomic pattern of each limb, arterial calcification, ankle/brachial index (highest), and distal waveforms analysis to each tibial vessel obtained.

All patients underwent a computed tomography angiography for better lesion assessment and distal runoff. The best target runoff vessel in order to identify the best low resistance outflow was determined based on the diameter of the artery, the presence of heavy calcification, the integrity of the pedal arch, and the number of collaterals.

The access was ipsilateral ante-grade CFA in all patients. And all procedures were performed in an angio-suite and under local anesthesia. Additionally, sedatives were prescribed to patients who suffered from rest pain.

Patients were divided into two groups based on whether direct blood flow to the foot lesion-bearing area (angiosome – direct group) or (nonangiosome – indirect group) where the foot lesion-bearing area was fed by collaterals from other angiosome. Not only that but if the foot lesion extends to more than one angiosome it is considered to belong to the angiosome group.

Postprocedural care

Patients received double antiplatelet: aspocid 75 mg+clopidogrel 75 mg for 1 month, then continued aspocid 75 mg as a single anti-platelet for life, small dose of antithrombotic (anticoagulant) were prescribed to those who had poor runoff. In addition, patients receiving wound care were seen weekly in the outpatient clinic until healing was complete.

WIFI staging was repeated in case of clinical deterioration or failure to improve in clinical status by 4–6 weeks after revascularization. Surveillance included clinical assessment of wound healing, signs of ischemia and presence of foot infection, and physiologic studies (ankle pressures or ankle waveforms analysis). It was typically performed at 1, 3, and 6 months, then every 6 months thereafter.

Statistical analysis

Statistical Package for the Social Science IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp, was used for data management and analysis. Mean, SD, median, range, numbers, and percentages described quantitive data. The χ^2 test was used for comparing independent categorical variables; the Fisher exact test was used for the comparison of groups. The main outcome variables were shown not to follow a normal distribution. The Mann–Whinty test was performed for numerical variables not displaying normal distribution. An independent t test was used to compare the means of more than 2 independent groups when numerical variables were displaying normal distribution.

Kaplan–Meier univariable analysis was used to estimating cumulative leg salvage, survival, and amputation-free survival. Survival rates are reported as the proportion (SE). Cox regression analysis provides a risk ratio of clinically relevant factors for ulcer healing. *P value* was two-tailed and considered significant at 0.05 level.

RESULTS:

We performed a total of 100 infrapopliteal endovascular procedures in 110 limbs from 100 consecutive patients. Patients were divided into two groups according to the angiosomal concept, direct group and indirect group. Each group included 50 patients.

Demographics

Regarding the age of patients included in our study, there was no significant difference between the two groups, 63.7±6.7 and 64.57±7.2, respectively, in the direct and indirect groups (Table 1 and Fig. 1). Also, sex of patients did not show significant difference with male frequency of 66 and 70%, respectively, in the two groups, as shown in (Table 1).

In addition, there were no significant differences between the two groups regarding comorbidities. Furthermore, as regards to the duration of diabetes, there was no significant difference between the two groups, 14.98±2.6 and 14.32±3.4, respectively, as shown in (Table 1).

Lesion characteristics

There was no significant difference between the two groups regarding the site of the lesion, WIFI stage, and the lesion severity scoring system (GLASS) for infrapopliteal disease analysis. However, there was a significant difference between the two groups regarding the treated artery with angioplasty. Lesion characteristics are shown in (Table 2).

Regarding the GLASS inframalleolar modifier, 65.7% of the patients were P1 (target artery crosses the ankle into the foot, with absent or severely diseased pedal arch) with no significant difference between the two groups; angiosome (direct group) and nonangiosome (indirect group).

Healing rate

The healing rate in foot lesions among the nonangiosome group and patients with WIFI (II) were statistically significantly higher than among angiosome group and patients with WIFI (III); 84.6 and 78.2% versus 15.38 and 21.79%, respectively; as shown in (Table 3).

In addition, there was a statistically significant difference in the healing rate of foot lesions in the group WIFI (II) more than WIFI (III) 142 versus 256 days.

Study outcomes

There was no statistically significant difference (*P>0.05*) between both groups with major amputation, minor amputation, persistent wound, and death. However, there was a significance difference concerning limb salvage (*P=0.045*), as shown in (Table 4).

Rate of freedom from major amputation in the studied groups

The estimated mean time until major amputation is 17.6 months for the direct group and 16.3 months for the indirect group, as shown in (Table 5). In addition, the survival plot. (Figure 2) shows that the survival probability is lower for the indirect group at all-time points, so they are more likely to major amputation.

Survival analysis

Kaplan–Meier curves are shown for the rate of freedom from major amputation in the direct and indirect groups after propensity matching analysis. The estimated number of freedom from major amputation in the direct group and the indirect group at 6 months was 43 versus 38, at 12 months, 30 versus 11, and at 18 months, 4 versus 3, respectively, in the two groups. In addition, there was a higher limb salvage rate in the direct group at all times. These are shown in (Fig. 2 and Table 5).

Case presentation is shown in (Figs 3 and 4) as an example of angiosomal revascularization of anterior and posterior tibial arteries and their impact on wound healing.

Table 1: Patient demographics

Items	Direct group (*N*=50)	Indirect group (*N*=50)	*P* value
Age (years)	6.7±63.7	64.57±7.2	0.989
	n (%)	*n* (%)	
Sex			
Male	33 (66.0)	35 (70.0)	0.668
Female	17 (34.0)	15 (30.0)	
Comorbidities			
Diabetes mellitus	41 (82.0)	39 (78.0)	0.617
Hypertension	40 (80.0)	41 (82.0)	0.799
Hyperlipidemia	34 (68.0)	29 (58.0)	0.300
Coronary artery disease	27 (54.0)	21 (42.0)	0.230
Cerebrovascular disease	17 (34.0)	22 (44.0)	0.305
Current smoking	22 (44.0)	21 (42.0)	0.840
Duration of diabetes in years	2.6±14.98	3.4±14.32	0.276

Table 2: Lesion characteristics

	Angiosome group (50)		Nonangiosome group (50)	*P* value
Site of lesion				
Toes	14	28%	15	27.8%
Planter foot	24	48%	23	46%
Dorsum of the foot	12	24%	16	29.6%
WIFI stage				
II	16	28.6%	21	38.9%
III	40	71.4%	33	61.1
IP GLASS				
I	3	6%	4	8%
II	17	34%	19	38%
III	13	26%	11	22%
IV	7	14%	6	12%
Diseased artery				
ATA	24	42.8%	17	31.2%
PTA	29	51.7%	32	59.3%
Peroneal	3	5.4%	5	9.3%

GLASS, global limb anatomic staging system; IP, infrapopliteal; WIFI, wound, ischemia, and foot infection.

Table 3: Healing rate of the study patients

	Healed (78) [*n* (%)]	Nonhealed (22) [*n* (%)]
Angiosome group	12 (15.38)	17 (77.2)
Nonangiosome group	66 (84.6)	5 (22.7)
WIFI (II)	61 (78.2)	6 (27.7)
WIFI (III)	17 (21.79)	16 (72.7)

Table 4: Study outcomes

	Groups		
Items	Direct group) *N*(56= [*n* (%)]	Indirect group) *N*(54= [*n* (%)]	*P* value
Major amputation	3(5.4)	7(13.0)	0.165
Minor amputation	12(21.4)	15(27.8)	0.438
Limb salvage	49(87.5)	39(72.2)	0.045
Persistent wound	1(1.8)	1(1.9)	0.979
Death	5(8.9)	7(13.0)	0.553

Table 5: Survival analysis using Kaplan–Meier curve showing the rate of freedom from major amputation in studied groups

	Mean				
			95% confidence interval		
Groups	Estimate	SE	Lower bound	Upper bound	*P value*
Direct	17.667	0.276	17.127	18.208	0.045
Indirect	16.371	0.656	15.085	17.657	

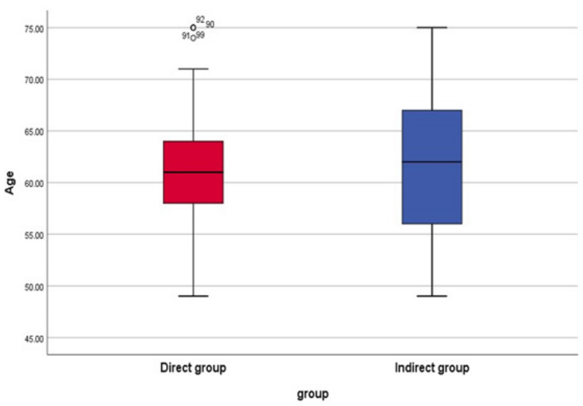

Fig. 1: Patients age.

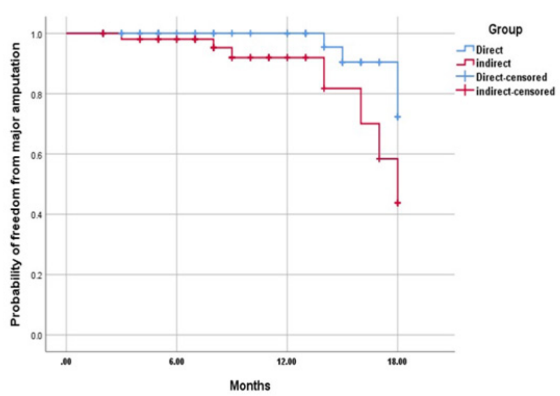

Fig. 2: Survival plot showing the rate of freedom from major amputation in studiedgroups.

Case presentation

Case (1)

(1) Male patient, 63 years old, smoker, diabetic, and hypertensive, presented with the gangrenous infected big toe of the right lower limb of 3 weeks duration.

(2) On physical examination, there was a gangrenous big toe with severe infection extending on the forefoot.

(3) Pedal pulse was absent with preserved popliteal pulse.

(4) Using a handheld Doppler, the patient had an ABI of 0.3.

(5) Additional duplex ultrasonography was done and revealed severely stenosed tibioperoneal trunk, multiple stenoses of PTA, totally occluded mid-PTA, and multiple significant stenoses of ATA. Insignificant stenosis of PEA.

(6) PTA was done according to our protocol, and full revascularization of ATA was successfully achieved (Figure 3).

Case (2)

(1) A female patient, 55 years old, diabetic and hypertensive, presented with a gangrenous infected heel of the left lower limb of 5 weeks duration.

(2) On physical examination, there was a gangrenous heel with severe infections.

(3) Pedal pulse was absent with preserved popliteal pulse.

(4) Using a handheld Doppler, the patient had ABI of 0.4.

(5) Additional duplex ultrasonography was done and revealed severely stenosed tibioperoneal trunk.

(6) Total occlusion proximal PTA, stenosed mid-PTA, multiple significant stenoses of ATA. Insignificant stenosis of PEA.

(7) PTA was done according to our protocol, and full revascularization of PTA was successfully achieved (Figure 4).

Fig. 3: (a) Photo of forefoot showing gangrenous big toe. (b) The foot 1 month after revascularization. (c) Complete healing after 4 months.

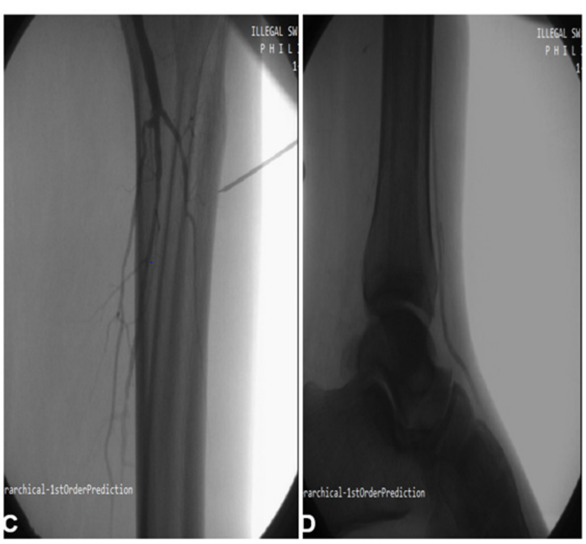

Fig. 3: (d-1) Preprocedure foot angiogram with poor foot vasculatures. (d-2) Postprocedure foot angiogram with good foot vasculatures with accepted recanalization of the previously stenosed arterial segment

Fig. 4: (a) A 55-year-old female patient presented with an unhealed heel ulcer. (b) Postprocedure follow-up with evident healing of the ulcer in 6 months.

Fig. 4: (c-1) Preprocedure angiogram view. (c-2) Postprocedure angiogram showed recanalized posterior tibial artery.

DISCUSSION

Despite recent advances in endovascular tools, the managenent of CLTI is still challenging. The limb severity scoring system, WIFI, is important in recognizing and quantifying factors for clinical assessment of foot and limb survival. It is an analog to TNM system of cancer staging and should be repeated throughout life for monitoring of management strategy and the need for re-intervention[1].

WIFI II, III, or IV needs a perfect revascularization strategy to achieve limb salvage. Global vascular guidelines through its recent GLASS and the concept of TAP; inline flow to the foot and inframalleolar modifier system which classify the completeness of pedal arch into PO; target artery crosses the ankle into foot, with intact pedal arch, P1; target artery crosses the ankle into foot, with absent or severely diseased pedal arch and P2; no target artery crossing the ankle into foot. This system plans the management strategy for CLTI foot lesions[9].

Global vascular guidelines recommend TAP to be an angiosome-based infrapopliteal artery or the least diseased infrapopliteal artery[1].

TAP is an ambiguous pathway depends on the operator's experience after revision of the CTA and the arterial supply to the foot. The correlation between TAP angiosome revascularization and limb salvage rate versus TAP nonangiosome (indirect blood supply to the lesion-bearing area) and limb salvage has been reported in many studies with heterogeneous outcome[10].

In this study, it was found that there was no correlation between angiosome revascularization and healing of foot lesions, but there was a strong correlation between the healing of foot lesions and the WIFI stage. This coincides with many published papers. It may be explained by the angiosome group, the TAP selected is the infrapopliteal artery, which had direct continuation to the wound or ulcer-bearing area irrespective of being the least diseased infrapopliteal vessel or not. This sometimes adds complexity to the procedure and may be challenging[9].

Regarding the completeness of the pedal arch, most of this study population had P1. Many studies reported that PO, and P1 pedal arch had nearly similar results and were better than the P2 arch[11].

It was found that the healing rate correlates to the clinical severity of the wound, either according to the Wagner classification[12] or the WIFI classification system[10].

In the healing group, WIFI (II) was more prevalent, and the rate of wound healing was significantly rapid in the WIFI (II) group.

We compared the result of demographic data between the two groups. It was found that there were no significant differences in age (years), sex, comorbidities, and duration of diabetes mellitus (years).

From this study, a comparison was made between the direct and indirect groups in outcomes. Limb salvage was significantly higher among the direct group when compared with the other group ($P=0.045$). In contrast, it was found that there was no statistically significant difference concerning major amputation, minor amputation, persistent wound, and death.

Iida and colleagues based on a 4-year follow-up of 203 limbs in 177 consecutive patients treated with endovascular methods for CLTI. The results indicated that patients with direct revascularization had a considerably higher rate of limb salvage than those with indirectly revascularized lesions. Additionally, they hypothesized that it is less significant how much blood can be supplied to the foot than whether it can reach the ischemic area[13].

The limb salvage rate between direct and indirect groups at the end of follow-up was 89.1 and 74.3%, respectively[14]. In another study that was done by Farag *et al*.[15] and involved 66 limbs, it was found that CR, DR, and IR had a significant ulcer healing rate at 12-month follow-up (94.7, 66.7, and 57.17%, respectively) with a significant amputation-free survival rate of 94.7, 75.6, and 72.7%, respectively. The improved outcomes seen in some studies based on the use of the angiosome model compared with nonangiosome targeted angioplasty could be explained by the inadequate collateral vessels. When adequate collateral vessels were present, the outcomes of nonangiosome procedures were comparable to those consistent with the angiosome concept[16].

From the result of outcome, we can see that major amputation was 5.4 versus 13.0%, minor amputation was 21.4 versus 27.8%, limb salvage was 87.5 versus 72.2%, persistent wound 1.8 versus 1.9%, and death 8.9 versus 13.0% in comparing direct group versus indirect group. These results reflect those of Alexandrescu *et al*.[17]. The amputation rate was 33.3% (20/60) in patients with complete success and success, while it was 54.5% (12/22) in patients with partial success and failure.

Additionally, Kaplan–Meier curves are shown for the rate of freedom from major amputation in the direct and indirect groups after propensity matching analysis. The estimated mean free time until major amputation is 17.6 months for the direct and 16.31 months for the indirect group.

Iida *et al*.[12] showed that freedom from major amputation (82±5 vs. 68±5%, $P=0.01$) was significantly higher in the direct group than in the indirect group for up to 4 years after the index procedure.

After 1 year of follow-up, amputation-free survival was 75% in the direct group and 67% in the indirect group. According to Iida *et al*.[13], this rate was 71±4% in the direct group versus 50±5% in the indirect group at 1 year and 49±8 versus 29±6% at 4 years, respectively ($P=0.002$).

CONCLUSION

It coincides with what was published that the limb scoring severity system (WIFI) is more important than angiosome revascularization in wound healing rate, limb survival rate, and amputation-free survival.

CONFLICT OF INTEREST

There are no conflicts of interest.

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