Comparison between direct and indirect revascularization of below-the-knee arterial occlusive diseases based on foot angiosome concept

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Objective
Ischemic wounds of the foot are the most common cause for major amputations in vascular surgical patients. It can be presumed that revascularization of the artery directly supplying the ischemic angiosome may be superior to indirect revascularization (IR) of the concerned ischemic angiosome.
Patients and methods
This prospective study enrolled patients with critical limb ischemia due to isolated infrapopliteal disease (stenosis of ≥70% or complete total occlusions of the crural arteries) presented to our Vascular Department between April 2017 and April 2018. We categorized the treatment groups into two main groups: direct revascularization (DR) and IR. We excluded patients with acute limb ischemia, inflow lesions above the knee, sepsis, myocardial infarction during the previous 14 days, blue toe syndrome (microembolization), and patients who cannot ambulate.
Results
In this study, there were 23 patients with forefoot ischemia, eight patients had ischemic heel, and two patients had mid-foot ischemia. All patients were followed at 1, 6, and 12 months postoperatively for wound healing, major amputation, or death. Wound healing at 1, 6, and 12 months for DR versus IR was 16.6 versus 9.09%, 56.3 versus 33.3%, and 93.75 versus 87.75%, respectively. The limb salvage rate in the DR group was 88.9% and in IR group was 72.7%. The mortality was 10% for DR and 15.4% for IR at 12 months.
Conclusion
To obtain better wound healing rates, DR of the ischemic angiosome should be considered whenever possible. Revascularization should not be denied to patients with indirect perfusion of the ischemic angiosome, as acceptable rates of limb salvage are obtained.

Keywords:
angiosome, critical limb ischemia, gangrene, revascularization, wound

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Introduction

The prevalence of peripheral arterial diseases is increasing and is estimated to affect from 12 up to 20% of elderly people worldwide [1]. The most severe form of peripheral arterial disease is the progression to critical limb ischemia (CLI) characterized by rest pain, ulceration of the leg or foot, or gangrene [2]. In patients who have progressed to CLI, revascularization of the affected limb via surgical bypass surgery or percutaneous transluminal angioplasty (PTA) plays a major role in saving the limb, prolonging overall patient survival, and improving their quality of life [3]. Without revascularization, nearly 40% of patients with CLI will have major limb amputation within 1 year of diagnosis [4,5]. Guidelines from the Transatlantic Inter-Society Consensus II and the American College of Cardiology/American Heart Association recommend multidisciplinary approaches to lower the risk of foot complications in patients with CLI [2,3]. Early intervention via bypass surgery or endovascular intervention is considered to be the gold standard in reducing the possibility of amputation [2,4–6]. Taylor and Palmer [7] recognized the clinical importance of angiosomes as three-dimensional units of tissues supplied by a main source artery. They defined six angiosomes of the foot and ankle originating from the posterior tibial artery (three angiosomes: the medial calcaneal artery angiosome, the medial plantar artery angiosome, and the lateral plantar artery angiosome), the anterior tibial artery (ATA; one angiosome: the ATA and dorsalis

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pedis angiosome), and the peroneal artery (two angiosomes: the lateral calcaneal artery angiosome and anterior perforator artery angiosome). In the zone between adjacent angiosomes [7], they identified smaller caliber (choke) or similar caliber (true) anastomotic arterial channels that provide collateral conduits to allow a given angiosome to receive blood flow from an adjacent angiosome if the source artery is compromised. 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 [6–10].

Patients and methods

Patients with CLI due to isolated infrapopliteal disease who presented to our Vascular Department at Kasr Alaini Hospital between April 2017 and April 2018 were included in this study. All patients with CLI were admitted at our Department of Vascular Surgery for endovascular management of one or more tibial vessels. CLI was defined as rest pain for more than 2 weeks or a nonhealing foot ulcer/gangrene (Rutherford 4–6, Fontaine 3 and 4). The study was approved by the ethical committee anda written consent was taken from all patients declaring the nature of the procedure and the aim of the study with all possible complications. We categorized the treatment groups into two main groups: DR if the affected part was being treated by revascularization of its source artery and IR if the revascularization of the foot was done by correction of arteries other than the source artery of the specific angiosome. All patients with arterial stenosis of more than 70% or more or complete total occlusions of the crural arteries were considered suitable for endovascular therapy. Exclusion criteria were patients with acute limb ischemia, inflow lesions above the knee, sepsis, myocardial infarction during the previous 14 days, blue toe syndrome (microembolization), and patients who cannot ambulate.

Intervention

The foot wounds were examined first to assess the possibility of limb salvage. Cardiac, pulmonary, renal, and blood glucose status was corrected preoperatively with the assistance of the concerned specialist physicians. Percutaneous transluminal balloon angioplasty (PTA) was performed first in most cases, and then debridement and minor amputations (toe/s or transmetatarsal) were performed for patients presenting with wet gangrene/necrotic tissue or slough in the wound bed after 24 h. Dual antiplatelet therapy (aspirin 81 mg/day and clopidogrel 75 mg/day) was started at least 3 days before the intervention with broad-spectrum antibiotic therapy. PTA procedures were carried out in our angiography suite with blood pressure and cardiac monitoring and under local anesthesia (10 ml of lidocaine 2%). In all cases in the study, antegrade puncture of the ipsilateral common femoral artery was performed with insertion of an 11-cm 5- or 6-F sheath that was used to perform an initial diagnostic arteriography using nonionic iodinated contrast media. After systemic heparinization (80 IU/kg; 3000–5000 IU), the navigation of the vessels to be treated was conducted via the roadmap technique and with 0.018- or 0.014-inch guide wire with the support of a suitable curved catheter or low-profile balloon. In cases of failure of endoluminal recanalization, a subintimal approach was used; re-entry to the true lumen distal to the site of the target lesion was done manually using the wire and the catheter, and no special re-entry devices were used. In all cases, a DR was attempted as the first approach, aiming primarily to recanalize the direct source artery supplying the wound territory. In case of failure of DR owing to chronic occlusion or suboptimal PTA, we shifted to IR, which sought to improve the flow in the ulcer territory by collateral vessels. At the end of the procedure, hemostasis was achieved in all cases by manual compression. Technical success was defined as opening of the lesion or residual stenosis of less than 30% and absence of flow-limiting dissections on final angiogram. After the intervention, dual antiplatelet therapy was maintained (aspirin 81 mg/day and clopidogrel 75 mg/day) for 3 months, and then aspirin alone indefinitely.

Follow-up protocol

Patients were examined at each outpatient visit every 1, 6, and 12 months after discharge till the end of study. Duplex scanning was performed every 6 months by an independent experienced operator to exclude bias. The peak systolic velocity was measured by arterial duplex scanning. When the peak systolic velocity was more than 400 cm/s or when the treated artery was reoccluded and the patients showed recurrence of rest pain, cessation of wound healing, or a new ulcer, a new angiography was performed. In most of the patients, ABI measurements were not possible or not reliable owing to calcifications of the vessels. Depending on the wound status, dressings and wound evaluation were performed daily, initially after the arterial intervention, and later at specific time schedule once adequate granulation tissue was noted to cover the wound and wound epithelialization had started. Foot counseling and appropriate offloading footwear were advised to all patients. This treatment protocol was applied in both groups. All wounds were assessed at the time of each review. Limb salvage was considered if the wound segment had healed completely or if at the end of 12 months the wound persisted but with a significant reduction in size of more than 50%. Major amputation was defined as amputation performed either above or below knee. All patients were followed up to the end points of limb salvage at 12 months for major amputation or death.

Results

A total of 33 patients who presented with CLI due to isolated infrapopliteal arterial occlusive diseases between April 2016 and April 2018 were included in our study. There were 21 (63.6%) men, with 81.8% of them having diabetes mellitus. Hypertension was present in 100%, ischemic heart disease in 51.5%, hypercholesterolemia in 57.6%, chronic renal impairment (defined as: creatinine Ë 1.5 mg/dl) in 39.4%, and chronic heavy smoking in 57.6% (Table 1).

All patients were classified as Rutherford classes 5 and 6. There were eight (24.24%) patients who had gangrene located at the heel or Achilles tendon (heel ischemia), two (6.06%) patients had gangrene at the plantar surface or at the lateral margin of the foot (mid-foot ischemia), and 23 (69.70%) patients had gangrene located at toes (forefoot ischemia) (Table 1). More selective analysis showed that forefoot ischemia was evident in 85% in the DR group and in 46.15% of the IR group, whereas heel ischemia was seen in only 15% in the DR group compared with 38.46% in the IR group. ATA was the only runoff vessel to the foot in 48.5% (16/33), posterior tibial artery (PTA) in 33.3% (11/33), and the peroneal artery (PA) in the remaining 18.2% (6/33). The ATA was the only outflow vessel in nine patients with forefoot ischemia, in two patients with a mid-foot ischemia, and in five patients with an ischemic heel. The PTA was the only outflow vessel in eight patients with forefoot ischemia and the only vessel for three patients with ischemic heel. The PA was the only patent outflow artery giving collateral branches to the foot in six patients with forefoot ischemia and none with mid-foot or heel ischemia (Fig. 1).

In the total group, 60.6% (20/33) underwent DR, whereas 39.4% (13/33) underwent IR. Of the 24 patients with limb salvage, 16 had DR and eight had IR. Of the five patients who underwent major amputation, three were in the IR group and two were in the DR group. By the first month, four patients had complete healing of their wounds, two patients underwent major amputation, and two patients had died from cardiac causes. By the end of the 6 months, 12 patients had their wounds fully epithelialized, two more patients had a major amputation, and two more patients died from cardiac causes. At the end of 12 months, a total of 24 patients salvaged their limbs, five patients had a major amputation, and four patients died. By 12 months, 91.6% (22/24) of the wounds healed. The remaining two (8.4%) patients still had granulating wounds which had significantly reduced in size, thus salvaging their limbs (Table 2).

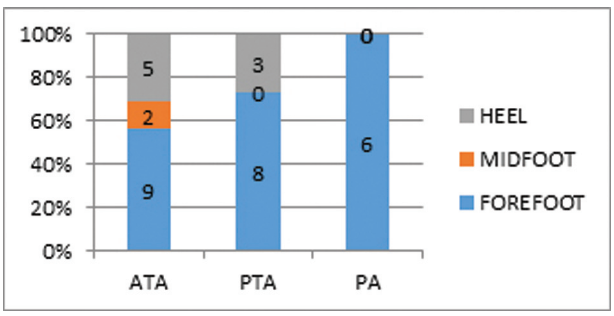
For DR group, by the end of the first month, three patients had their wounds fully epithelialized, one

Table 1 Patients' demographic data and comorbidities

	Total (*N*=33) [*n* (%)]	DR group (*N*=20) [*n* (%)]	IR group (*N*=13) [*n* (%)]
Mean age	63	63	63
Sex ratio (M : F)	21 (63.6)/12 (36.4)	15/5	6/7
Site of ischemia			
Forefoot	23 (69.70)	17 (85)	6 (46.15)
Midfoot	2 (6.06)	–	2 (15.39)
Heel	8 (24.24)	3 (15)	5 (38.46)
Diabetes	27 (81.8)	14 (70)	13 (100)
Renal failure	13 (39.4)	7 (35)	6 (46.2)
Smoking (active or ceased)	19 (57.6)	10 (50)	9 (69.2)
Hypertension	33 (100)	20 (100)	13 (100)
Dyslipidemia	19 (57.6)	11 (55)	8 (61.5)
Previous CABG/PTCA	17 (51.5)	8 (40)	9 (69.2)
Stroke	5 (15.2)	1 (5)	4 (30.7)
Previous major amputation	2 (6.06)	2 (10)	0
Previous minor amputation	10 (30.3)	5 (25)	5 (38.5)

DR, direct revascularization; F, female; M, male.

Figure 1



Angiosome distribution.

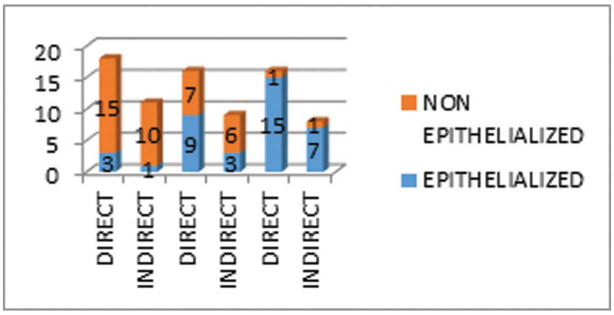
Table 2 Combined results obtained at 1, 6, and 12 months for both groups (direct revascularization and indirect revascularization)

Results	1 month [*n* (%)]	6 months [*n* (%)]	12 months [*n* (%)]
Complete healing	4 (13.8)	12 (48)	22 (91.6)
Major amputation	2 (6.5)	4 (13.8)	5 (17.8)
Minor amputation	8 (27.6)	9 (36)	12 (50)
Persistent wound			2 (8.33)
Limb salvage	29 (93.5)	25 (86.2)	24 (82.75)
Death	2 (6.06)	4 (16.1)	4 (12.1)

Table 3 Results obtained at 1, 6, and 12 months in the direct revascularization group

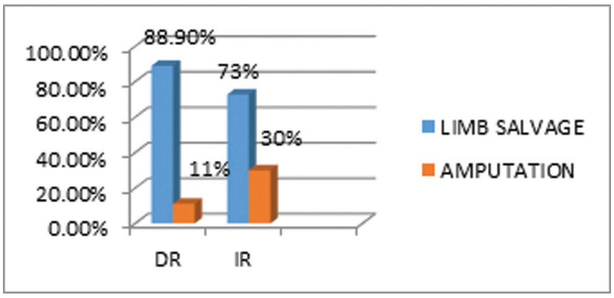
Results	1 month [*n* (%)]	6 months [*n* (%)]	12 months [*n* (%)]
Complete healing	3 (16.6)	9 (56.3)	15 (93.75)
Major amputation	1 (5.3)	2 (11.1)	2 (11.1)
Minor amputation	5 (27.8)	5 (31.25)	8 (50)
Persistent wound			1 (6.25)
Limb salvage	18 (94.7)	16 (88.9)	16 (88.9)
Death	1 (5)	2 (10)	2 (10)

Figure 2



Wound status at follow-up.

Figure 3



Limb status at 12 months.

patient underwent major amputation, and one patient died. By 6 months, nine patients had fully epithelialized their wounds, another one patient had major amputation, and one more patient died. At the completion of 12 months, 15 (93.3%) patients had their wounds completely epithelialized, and one patient had a persistent wound, which had decreased in size by more than 50%, for which regular wound care was being performed. Thus, the overall limb salvage was 88.9%; two (11.1%) patients had a major amputation, and two (10%) patients died, all secondary to a cardiac cause. Limb salvage was 94.7% at 1 month, 88.9% at 6 months, and 88.9% at 12 months. The major amputation rate was 11.1%. The overall mortality was only 10% at 12 months (Table 3, Figs 2 and 3).

For the IR group, by the first-month follow-up visit, one patient had a healed wound, one patient had major amputation, and one patient had died. By the sixth-month follow-up, three patients had fully epithelialized their wounds, two patients died, and two patients had major amputation. By the completion of the 12th-month follow-up, eight (72.7%) patients had limb salvage, three (30%) had major amputation, and two (15.4%) died, all secondary to cardiac causes. Of the eight patients who had limb salvage, seven had completely epithelialized, whereas one patient had more than 50% reduction in the wound area. Limb salvage was 91.6% at 1 month, 81.8% at 6 months, and 72.7% (8/11) at 12 months. The major amputation rate was 30%. The overall mortality was only 15.4% at 12 months (Table 4, Figs 2 and 3).

For both the DR and IR groups, the rates of wound healing were 16.6 versus 9.09% at 1 month, 56.3 versus 33.3% at 6 months, and 93.75 versus 87.5% at the completion of 12 months. This difference in the rates of wound healing between the DR and IR groups was statistically significant. The limb salvage rate in the DR group was 88.9 and 72.7% in IR group. The mortality at 12 months was 10% in the DR compared with 15.4% for IR.

Discussion

The angiosome principle gives a significant importance to the source artery of a specific angiosome. The angiosome anatomy, inter-angiosome connections, and angiosome overlap have been described extensively by Taylor and Palmer [7,11] (e.g. the big toe may be a part of the medial plantar, lateral plantar, or the dorsalis pedis angiosome, or may be perfused by all three). DR is considered the treatment of an artery

Table 4 Results obtained at 1, 6, and 12 months in the indirect revascularization group

Results	1 month [*n* (%)]	6 months [*n* (%)]	12 months [*n* (%)]
Complete healing	1 (9.09)	3 (33.3)	7 (87.5)
Major amputation	1 (8.33)	2 (18.18)	3 (27.2)
Minor amputation	3 (27.3)	4 (44.4)	4 (50)
Persistent wound			1 (12.5)
Limb salvage	11 (91.6)	9 (81.8)	8 (72.7)
Death	1 (7.69)	2 (15.4)	2 (15.4)

that is a direct tributary of the target angiosome, whereas IR is concerned with the treatment of any other artery that is not a direct supply to the involved angiosome [12]. Studies seem to favor the effectiveness of DR according to the angiosome model [13–21]. The angiosome DR as shown in the current study indicates that it is superior to IR in terms of wound healing; although limb salvage seems to be superior but was not statistically significant. At our hospital, the first treatment option is directed to DR, a strategy that is based on data from the literature [13–16]. Only in cases of technical difficulties of DR, we turn to our second choice, the IR strategy. From our analysis, treatment with IR, which was done for only 13 patients, was similarly effective; analysis showed an incidence of major amputation of 27.2% (vs. 11.1% in the DR group) and limb salvage rate of 72.7% (vs. 88.9% the DR group). We believe that the endovascular correction of the distal foot pedal arch could reduce the healing time in patients with foot ulceration, as we observed that the rates of healing and time to healing were directly influenced by the quality of the pedal arch. There are extensive connections between ATA, PTA, and PA all the way along their course in the leg and also in the foot. These inter-angiosome connections by choke vessels [5] 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 [5]. Varela *et al.* [14] further revealed that both the distal peroneal collateral vessels and the patent pedal arch played a significant role in wound healing and limb salvage in patients with CLI who were treated without using the DR strategy. This suggested that the possible cause of IR treatment failure may result from inadequate vascular connections between the angioplastied arteries and the ischemic region. 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 reconstruction of specific source arteries [14]. There are several reports supporting DR using endovascular techniques [15–17]. The ‘pedal-planter loop angioplasty’ technique has also been described to reconstruct the pedal arch in patients with CLI, with an 85% success rate and a significant improvement of transcutaneous oxygen tension after the procedure [22]. Our results regarding the wound healing rate and limb salvage match with the results obtained in a prospective study by Kabra and colleagues, where 64 patients had continuous single crural vessel runoff to the foot presenting with CLI. DR of the ischemic angiosome was performed in 61% (n=39) and IR in 39% (n=25). Open surgery was performed in 60.9% and endovascular interventions in 39.1%. Wound healing rates at 1, 3, and 6 months for DR versus IR were 7.9 versus 5%, 57.6 versus 12.5%, and 96.4 versus 83.3%, respectively. This difference between the DR and IR groups in the rates of wound healing was statistically significant (P=0.021). The limb salvage rate in IR group (75%) and in the DR group (84%) was not statistically significant (P=0.06) [11]. In 203 consecutive patients with CLI treated by endovascular therapy, Iida *et al.* [15] reported 86% limb salvage rate in the DR group compared with 69% in the IR group. Similar results were reported by Varela *et al.* [14] and by Alexandrescu *et al.* [16], documenting how DR strategy in the treatment of diabetic patients with CLI provides better results in terms of limb salvage and wound healing than IR. Three studies were performed with similar investigations in their data analysis [18–20] comparing the outcome of direct (DR) and indirect revascularization (IR) and the time of wound healing had found better results with DR. Söderström and colleagues proved that DR group increased wound healing rate significantly (P<0.001); however Azuma and colleagues showed no difference for wound healing between the two groups (P<0.185). Varela and colleagues showed that DR model treatment significantly increased the wound healing rate 12 months following intervention (92 vs. 73%; P<0.01) and limb salvage rate at 24 months following intervention (93 vs. 72%; P<0.02) for patients with CLI. Traditional bypass surgery and endovascular intervention have been compared in several studies [22–26]. A meta-analysis by Romiti *et al.* [27] compared between the effectiveness of surgical and endovascular interventions and demonstrated no difference in the limb salvage rate (endovascular, 82.4±3.4%; surgery, 82.3±3%). Advantages of endovascular therapy include less operative trauma, less wound complications, fewer operative complications, and shorter hospital stays [23,24]. However, our study focused only on angiosome targeted therapy by utilizing the endovascular intervention and not the surgical bypass for better analysis of the effect of angiosome model on revascularization outside of the morbidity of bypass surgery. In all our patients, the pedal arch quality was assessed before the intervention, and THE patients should have a good pedal arch to focus on only the angiosome effect on the quality of revascularization; in that regard, a study by Rashid and colleagues evaluated the effect of pedal arch quality on the limb salvage and patency rates of distal bypass grafts and its direct effect on the rate of wound healing and time to healing of tissue loss as compared with direct angiosome revascularization in patients with CLI. There was a significant difference in wound healing rate and time to healing according to the pedal arch quality. They concluded that quality of the pedal arch did not influence the patency or the amputation-free survival rates. However, the rates for wound healing and time to healing were directly affected by the quality of the pedal arch rather than the angiosome-targeted revascularization [28]. The results obtained by endovascular intervention were also reported from surgical bypass surgeries in a meta-analysis of nine nonrandomized controlled retrospective cohort studies by Huang *et al*. [5]. They concluded that DR significantly improved the overall survival of limbs. In addition, DR significantly improved time to wound healing. Another study by Lejay and colleagues analyzed outcomes of 58 consecutive CLI limbs of 54 diabetic patients presenting with tissue loss who underwent isolated below-the-knee (BTK) bypasses, and based on angiosome concept for revascularization, bypasses were classified into direct and indirect groups. Analysis showed limb salvage rate was significantly higher in direct group than in indirect group: 91 vs. 66% at 1 year, 65 vs. 24% at 3 years, and 58 vs. 18% at 5 years, respectively (P=0.03). They concluded that achieving a direct arterial flow based on angiosome concept in CLI diabetic patients presenting with tissue loss appears to be an important factor for wound healing and limb salvage [29]. Analysis of our results shows that DR concept leads to significantly better wound healing rates, but the rates of limb salvage did not reach statistical significance, which is in contrast to Neville *et al*. [13], who found statistically significant difference in the limb salvage rates with DR (P=0.03), whereas wound healing did not reach statistical significance (P=0.95). This difference in results may be owing to the high number of patients with CKD (51.8%) in the series by Neville *et al*. [13], which is known to be an adverse risk factor for wound healing and limb salvage. Moreover, the limb salvage rates might not be directly comparable between our study and other similar studies, as the duration of follow-up is different. The limitations of our study include the small number of patients in the IR group compared with the DR group. We believe, however, that it is important to report our experience in the treatment of CLI in a selected population of patients with BTK disease and to evaluate the effectiveness of different treatment options according to the angiosome model.

Conclusion

Our study demonstrated that endovascular therapy in CLI with BTK disease is a safe and effective option, with good results in terms of limb salvage and wound healing. In our opinion, the DR technique should be the first therapeutic choice; however, if DR treatment is not feasible, then the IR technique is a valid and similarly effective, as nearly equivalent limb salvage rates are obtained, especially with good quality pedal arch.

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Conflicts of interest

The authors declare no association with any company having a financial interest in the products used in this paper.

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