Predictive value of angiographic characteristics for endovascular revascularization of the ischemic diabetic foot

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Received 9 November 2017
Accepted 3 December 2018

The Egyptian Journal of Surgery
2018, 37:294–303

Background
Endovascular techniques have undergone major advances with respect to the treatment of infrapopliteal arterial occlusive disease, mainly as a result of development of new devices.
Objective
The aim was to evaluate the agreement between the angiographic characteristics and the clinical outcomes after endoluminal revascularization in diabetic patients with critical limb ischemia (CLI).
Patients and methods
During the study, 64 patients were subjected to angioplasty and followed during an average of 12 months. Clinical and procedural data of diabetic patients with CLI were collected. Preprocedural and postprocedural angiographic images were reviewed to classify lower limb arterial involvement according to the Joint Vascular Society Council calf and foot scores classification. Foot lesions were graded according to the University of Texas classification. Clinical results (healing, nonhealing, or major amputation) were compared with baseline clinical data and angiographic results.
Results
During the study period, 64 percutaneous procedures were performed, with an immediate technical success rate of 89.8%. Preprocedurally, the mean±SD calf and foot scores were 7.8±1.6 and 7.3±2.3, respectively. After the procedure, the mean calf and foot scores were 4.8±2.3 and 5.9±2.6, respectively. The limb salvage rate was 87% and the major amputation rate was 9.4%. Among all the clinical and angiographic variables included in the analysis, only preprocedural and postprocedural foot scores were associated significantly with the clinical outcome ($P<0.05$).
Conclusion
Endoluminal revascularization represents a valuable treatment option in diabetic patients with CLI. Preprocedural and postprocedural foot scores represent the most significant angiographic parameters to evaluate treatment success.

Keywords:
angiographiccharacteristic, diabetic patients, revascularization

Egyptian J Surgery 37:294–303

1110-1121

Introduction

Diabetes mellitus is a disease with a major impact in terms of morbidity and mortality, the incidence of which has increased rapidly [1]. In 2015, it was estimated that 514 million individuals worldwide were affected by diabetes mellitus [2]. Diabetes mellitus can lead to severe complications such as myocardial infarction, stroke, blindness, chronic renal failure, and lower limb lesions [3].

Diabetic patients are four times more likely than the general population to develop peripheral arterial occlusive disease [4]. The vascular changes are more diffuse and distally located, commonly at an infrapopliteal level [5]. The most common manifestation in patients with diabetic vasculopathy is diabetic foot. Its main features are foot ulcers, the etiopathogenesis of which recognizes the triad of ischemia, neuropathy, and infection [1].

Critical limb ischemia (CLI) represents an advanced stage of peripheral arterial occlusive disease where the arterial blood supply to the limb and foot is markedly reduced and the viability of the tissue is jeopardized [6]. The reduced blood supply may lead to tissue ischemia, causing rest pain, nonhealing foot ulcers, tissue necrosis, and gangrene. A total of 5–8% of patients with diabetic foot will undergo major amputation within 1 year and 85% of all amputations are preceded by foot ulcers that subsequently evolve to severe infection and gangrene [7].

CLI and infection are associated strongly with a high risk of amputation and mortality in diabetics, the majority of whom have attendant CLI and infection requiring urgent efforts by several medical specialists for limb salvage. In the presence of severe infection and concomitant severe morbidities, less invasive revascularization is crucial for successful treatment [8].

Several studies have shown that the evaluation of peripheral artery disease is the main prognostic determinant for amputation [9]. The location, length, and severity of stenosis and the patency of runoff vessels must be assessed precisely before planning revascularization procedures [10].

The primary goal of treatment is to restore the patency of at least one below the knee vessel, preferably the tributary of the anatomical region of the ulcer [11]. Less invasive revascularization is crucial for treatment and percutaneous transluminal angioplasty (PTA) has become the first-choice procedure [8].

Several studies have reported good results in terms of patency and limb salvage after endovascular treatment of diabetic foot [12].

Patients and methods

We carried out a prospective study of 64 patients who were subjected to infrapopliteal angioplasty out of 239 patients who presented to Menoufia University Hospitals (Shebin Elkom) with critical lower limb ischemia during the period between October 2014 and December 2015.

Percutaneous revascularizations of the infrapopliteal segment were performed in all patients with critical lower limb ischemia defined by the presence of diabetic foot lesion including nonhealing foot ulcers, tissue necrosis, or gangrene according to the definition of the Trans-Atlantic Inter-Society Consensus [6].

Indication for endovascular treatment was based on clinical evaluation and angiographic assessment. Exclusion criteria were nonsalvageable foot with extensive foot necrosis or gangrene necessitating amputation, and major renal dysfunction (creatinine >2.4 mg/dl) [13]. All preprocedural data were collected, with a specific focus on age, sex, comorbidities, diabetes type and duration in years, serum levels of HbA1c and creatinine, and lesion location and severity according to the classification of the Texas University (Table 1).

All the patients were subjected to a thorough general and local physical examination, with a special focus on the pulse, skin lesions, ulceration, tissue necrosis, infection, ankle–brachial index (ABI), and transcutaneous O_2 pressure ($TcPO_2$) measurement. All patients underwent full laboratory investigations including complete blood count, blood sugar curve, kidney functions, liver functions, coagulation, and lipid profile. Duplex and computed tomography angiography were performed for the diagnosis and characterization of the lesions before the endovascular intervention.

Classification of the infrapopliteal arterial lesion

Preprocedural and immediately postprocedural angiographic images were reviewed to classify lower limb arterial involvement using The Joint Vascular Societies Council classification, which provides a score from 0 to 3 on the basis of the most severe stenosis (score 0 for stenosis less than 20%, score 1 for 20–49% stenosis, score 2 for 50–99% stenosis, score 2.5 for occlusion of less than half the total length of the vessel, and score 3 for longer occlusion). The following arteries were included in the analysis: anterior tibial (AT), posterior tibial (PT), peroneal (Per), dorsalis pedis (DP), lateral plantar (LP), and medial plantar (MP). We evaluated the DP on its entire length from the ankle joint level to the level at which it gives off its arcuate branch. We counted up a 'foot score' (sum of the 3 foot vessels scores plus 1) and a 'calf score' (sum of the 3 calf vessels scores plus 1) [14] (Table 2).

Table 1 University of Texas classification of diabetic foot lesions

	Grade 0	Grade 1	Grade 2	Grade 3
Stage A	Superficial ulceration	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
Stage B	Infection	Infection	Infection	Infection
Stage C	Ischemia	Ischemia	Ischemia	Ischemia
Stage D	Infection and ischemia	Infection and ischemia	Infection and ischemia	Infection and ischemia

Intervention

An endovascular revascularization procedure was performed in all patients.

Technique of endovascular revascularization

Informed written consent was obtained for endovascular treatment and for any procedure required to achieve wound healing. Endovascular revascularization was performed in all cases after the administration of broad-spectrum antibiotic therapy and dual antiplatelet therapy (aspirin: 100 mg/day, clopidogrel: 75 mg/day). PTA procedures were performed in the angiography suite using dedicated digital angiography (Toshiba-Interventional Angiography System, Infinix I, Model DFP8000D), with monitoring of blood pressure and ECG, under local anesthesia (10 ml of lidocaine 2%). In all cases, an antegrade puncture of the common femoral artery with the positioning of a 6F, 12-cm-long introducer (Terumo Corp., Tokyo, Japan) was used to perform a diagnostic arteriography with nonionic iodinated contrast media (20 ml of Telebrix 35). After intra-arterial administration of a bolus of heparin (5000 IU), the navigation of the vessels to be treated was performed using the road map technique and the stenosis was crossed using 0.018–0.035-inch hydrophilic guide wires and treated by transluminal angioplasty using 2.5–3 mm balloon catheters with variable lengths depending on the target vessels.

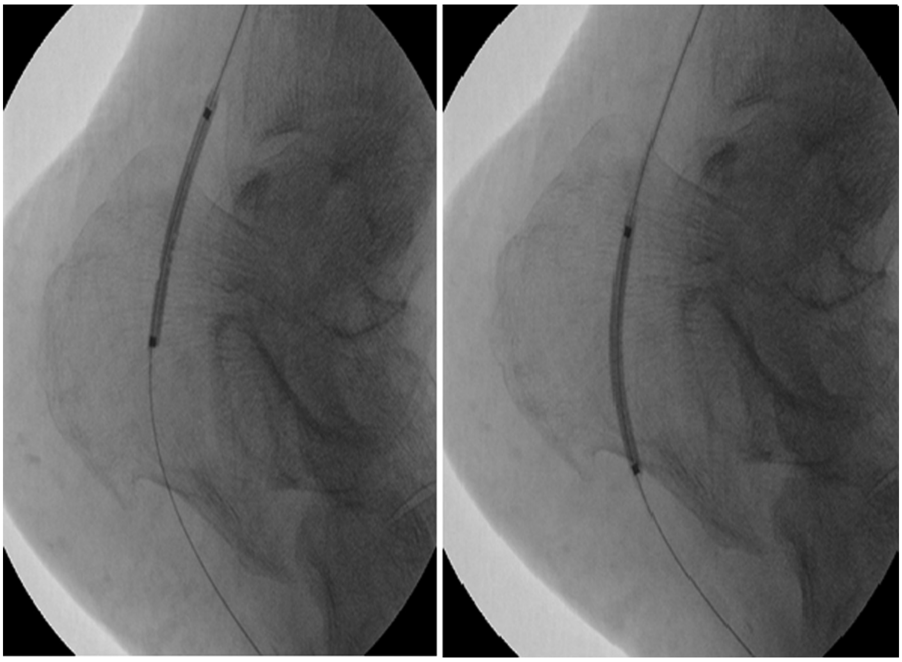
Table 2 Joint vascular societies council classification

Scores	Angiographic finding
0	Stenosis <20%
1	20–49% stenosis
2	50–99% stenosis
2.5	Occlusion of less than one-half the total length of the vessel
3	Occlusion of more than one-half the total length of the vessel

In specific cases, revascularization was performed by subintimal angioplasty according to the indications and technique described by Bolia *et al.* [15]. The target vessel was identified on the basis of the initial angiogram and the treating physician's opinion. At the end of the procedure, hemostasis was achieved in all cases by means of manual compression.

Dual antiplatelet therapy was maintained (aspirin: 100 mg/day and clopidogrel: 75 mg/day) for 6 months and aspirin alone was maintained indefinitely. Immediate technical failure is defined as the inability to perform the PTA procedure correctly or failure to cross the lesion with a guide wire. This will lead to termination of the procedure and will be considered an immediate clinical and anatomic failure [16]. Immediate technical success was defined by the presence of direct blood flow through the treated arteries with residual stenosis less than 30% of the vessels' diameter, Figs 1 and 2, in the absence of immediate complications [17].

Figure 1



Ballon dilatation of posterior tibial artery.

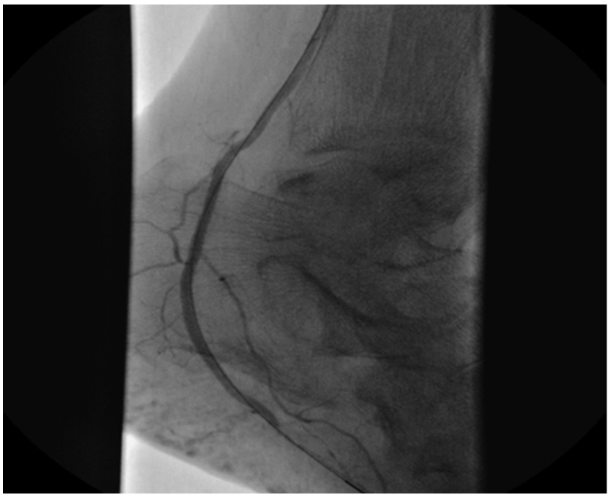
Foot lesions were treated surgically (i.e. surgical debridement or minor amputations, Fig. 3, assisted wound closure with the application of the dermal substitutes) 2–5 days after revascularization; acutely infected lesions were subjected to surgical treatment the day before percutaneous revascularization as an emergency procedure.

Follow-up

The patients underwent follow-up at the vascular surgery outpatient clinic at 1, 6, and 12 months by clinical examination, measurement of ABI, $TcPO_2$, and ultrasound color Doppler examination in terms of the following factors:

(1) Clinical improvement on the basis of Rutherford upward categorical shift, with absence of rest pain and/or progressive tissue healing.
(2) Hemodynamic state (ABI and $TcPO_2$ percutaneous oximetry).
(3) Limb salvage rate (absence of major amputation). Toe and transmetatarsal amputation were classified as minor amputations.
(4) Short-term clinical success of PTA was evaluated on the basis of ulcer size and appearance.
(5) Clinical success of PTA is defined as the disappearance of necrotic and inflammatory symptoms and partial (at least 30%decrease in ulcer size) or total healing of the ulcer without bypass grafting or major amputation.

Figure 2



Posterior tibial artery refilling.

Statistical analysis

The data were evaluated by descriptive statistics (mean, median, and SD) and compared using the χ^2-test or Fisher test for the categorical data and Student's t-test for the continuous variables. Lesion severity and clinical results were evaluated in relation with the clinical and preprocedural and postprocedural angiographic variables. The statistical analysis was carried out using the SAS software (SAS Institute, Cary, North Carolina, USA). A P value of less than 0.05 was considered statistically significant.

Figure 3

Line of demarcation. Amputation good healing.

Results

In our study, 52 (81.3%) patients were men and 12 (18.7%) patients were women; the age of these patients ranged between 42 and 74 years, with a mean age of 64.28±6.35 years. Sixty two (96.9%) of our patients had type 2 diabetes mellitus and two (3.1%) patients had type 1 diabetes. The duration of diabetes since first-time diagnosis ranged from 0 (discovered accidentally on admission) to 32 years, with a mean of 17.9±5.8 years. A total of 28 (43.7%) patients were taking oral hypoglycemic drugs, whereas 36 (56.3%) patients were using insulin. A history of cardiovascular problems, as an indicator of systemic atherosclerosis, was found in 34 (53.1%) patients, manifested as a history of angina or myocardial infarction, 39 (61%) patients had a history of hypertension, 10 (15.6%) patients had a history of neuropathy, seven (10.9%) patients had a history of cerebrovascular disease, and 34 (53%) patients had a history of retinopathy (Table 3).

All patients 64 (100%) had a current wound; it was noninfected in 27 (42.2%) patients and infected in 37 (57.8%) patients. According to The University of Texas wound classification system, five (7.8%) patients were grade I stage C, eight (12.5%) patients were grade II stage C, 14 (21.9%) patients were grade III stage C, 11 (17.2%) patients were grade I stage D, eight (12.5%) patients were grade II stage D, and 18 (28%) patients were grade III stage D (Table 4). Lesion severity according to the University of Texas wound classification system was significantly related to patients' age (P=0.03), with patients with type D lesions (lesions with infection) being older (mean: 64.3 years) compared with patients with type C lesions (without an infectious component) (mean: 60.9 years). Moreover, type D lesions (i.e. with infectious component) were significantly more frequent in patients with diabetic retinopathy (P=0.0007) and those with higher levels of HbA1c (P=0.01).

In terms of ABI and $TcPO_2$ measurements, 24 (37.5%) patients had ischemia grade I, 29 (45.5%) patients had ischemia grade II, and 11 (17.2%) patients had ischemia grade III as shown in Table 5.

Evaluation of the angiographic images

In the preprocedural angiograms, the 64 patients included in this study had 117 infrapopliteal lesions. In all, 66.7% of the below-knee lesions were occlusions (74% of occlusions were longer than 10 cm) and 33.2% were stenosis. Occlusion of all below the knee vessels was present in 29.7% of the patients. The mean calf score was 7.8±1.6 (median: 8), whereas the mean foot score was 7.3±2.3 (median: 8); at least two calf and foot obstructed arteries (score: 2.5 or 3) were observed in 63 and 65% of the limbs, respectively (Table 6).

The preprocedural calf and foot scores were statistically lower in patients with III-D lesions (P=0.002 and 0.03, respectively).

Table 3 Patients' demographic and clinical data

Variables	*n* (%)
Age [mean±SD (range)] (years)	64.28±6.35 (42–74)
Sex (male/female)	52/12
Co-morbidity	
Coronary artery disease	21 (32.8)
Other cardiac disease	13 (20.3)
Cerebrovascular disease	7 (10.9)
Hypertension	39 (61)
Retinopathy	34 (53)
Neuropathy	10 (15.6)
Charcot	3 (4.7)
HbA1c [mean±SD (range)] (%)	7.8±1.8 (0.9–14.5)
Diabetes type 1/2	2/62
Diabetes duration [mean±SD (range)] (years)	17.9±5.8 (0–32)

HbA1c, glycated hemoglobin.

Table 4 Data on the foot lesion

Characteristics	*n* (%)
University of Texas wound classification	
I-C	5 (7.8)
II-C	8 (12.5)
III-C	14 (21.9)
I-D	11 (17.2)
II-D	8 (12.5)
III-D	18 (28.0)
Lesion site (*n*=64)	43 (67.2)
Forefoot	11 (17.2)
Midfoot	6 (9.4)
Hindfoot	4 (6.3)
Leg	
Foot lesion duration (weeks)	
Mean±SD	16±24

Table 5 Ischemia grades

Ischemia	*n* (%)	ABI (mean±SD)	$TcPO_2$ (mean±SD)
Grade I	24 (37.5)	0.716±0.0543	41.5±4.15
Grade II	29 (45.3)	0.563±0.0371	32.5±3
Grade III	11 (17.2)	0.385±0.0168	24±3.95

ABI, ankle–brachial index; $TcPO_2$, transcutaneous O_2 pressure.

Table 6 Preprocedural angiographic classifications according to The Joint Vascular Societies

	Total	AT	PT	PER
Calf score (mean±SD)	7.8±1.7	2.4±0.9	2.6±0.8	1.8±1.0
Foot score (mean±SD)	7.3±2.3	2.0±1.0	2.1±1.1	2.2±1.1

AT, anterior tibial artery; PER, peroneal artery; PT, posterior tibial.

Table 7 Characteristics of successfully treated vessels

Artery	*n* (%)	Stenosis		Occlusions	
		N	Length (mean±SD) (cm)	*N*	Length (mean±SD) (cm)
PTA	40 (34.2)	11	118±102	29	154±97
ATA	26 (22.2)	8	106±98	18	172±76
PA	19 (16.2)	6	102±91	12	123±82
Pedal artery	6 (5.1)	3	50±23	3	43±21
Plantar artery	5 (4.3)	2	48±21	3	39±19
Total	96 (82.2)	31		66	

ATA, anterior tibial artery; PA, peroneal artery; PTA, posterior tibial artery.

Table 8 Preprocedure and postprocedure morphologic evaluation according to the guidelines of The Joint Vascular Societies, compared with clinical outcome

	Total (n=64) (mean±SD)	Healing (n=52) (mean±SD)	Nonhealing (n=12) (mean±SD)	*P*
Pre-PTA				
Calf score	7.8±1.7	7.5±1.8	8.0±1.5	0.37
Foot score	7.3±2.4	7.0±2.5	7.8±2.0	0.047*
Post-PTA				
Calf score	4.8±2.3	4.5±2.2	4.8±2.4	0.421
Foot score	5.9±2.6	5.5±2.7	6.3±2.3	0.049*

PTA, percutaneous transluminal angioplasty. *Significant at level 0.05.

The revascularization procedure was technically successful in 57 (89.1%) patients (revascularization of at least one tibial artery). The posterior tibial artery was the most commonly treated artery (34.2%), the anterior tibial artery (22.2%), while the peroneal artery (16.2%), the stenosis treated in 31 (26.5%) lesions with mean stenotic length 10.9 cm, while the occlusion treated in 66 (56.4%) lesions with mean occlusion length 14.9 cm as shown in Table 7. In seven (10.9%) cases, the procedure was not effective. This was because of the presence of heavily calcified chronic occlusions that could not be overcome with guide wires. There were two minor complications (two groin hematomas that did not require any special treatment), and therefore, the overall complication rate was 3.1%.

At immediate postprocedural angiographic examination, the mean calf score was 4.8±2.3 (median: 4), with a mean reduction of 3±0.6 (range: 0–8), whereas the mean foot score was 5.9±2.6 (median: 6.5), with a mean reduction of 1.4±1.2 (range: −2.5 to 8) (Table 8).

Follow-up was performed in all patients at 1, 6, and 12 months. The results are listed in Table 9. There was a statistical improvement in the hemodynamic markers in the technically successful group. This included a mean improvement in ABI from 0.60 (before angioplasty) to 0.91 (day 1 after angioplasty) and mean $TcPO_2$ from 32.3 mmHg (before angioplasty) to 47.7 (day 1 after angioplasty). Using Student's t-test, the baseline values of $TcPO_2$ were compared with those recorded at 1, 6, and 12 months, and a statistically significant increase was found ($P<0.005$).

Table 9 Results obtained at 1, 6, and 12 months

Results	1 month [*n* (%)]	6 months [*n* (%)]	12 months [*n* (%)]
Major amputation	1 (1.6)	3 (4.7)	2 (3.1)
Minor amputation	6 (9.4)	3 (4.7)	5 (7.8)
Complete healing	4 (6.4)	19 (29.6)	9 (14)
Partial healing	28 (49.1)	9 (15.8)	
PTA retreatment	1 (1.8)	3 (5.3)	1 (1.8)
Limb salvage		16 (28.1)	29 (50.9)
Mean ABI	0.75	0.70	0.68
Mean $TcPO_2$	40.1	41.3	41.4

ABI, ankle–brachial index; PTA, percutaneous transluminal angioplasty; $TcPO_2$, transcutaneous O_2 pressure.

Table 10 Preprocedural wound evaluation according to The University of Texas wound classification compared with clinical outcome

Wound	Total [*n* (%)]	Healed group [*n* (%)]	Nonhealed group [*n* (%)]	*P* value
Noninfected	24 (42.1)	21 (36.8)	3 (5.2)	0.023*
Infected	33 (57.9)	24 (42.1)	5 (15.8)	
Total	57	45	12	

*Significant at level 0.05.

At 1 year, we observed a limb salvage rate of 78.9%, six (10.5%) major amputations, 14 (21.9%) minor amputations, and complete healing in 32 (50%) patients; also, healing was achieved in 21 of 24 patients in the noninfected wound group, with a patency rate of 87.5%, whereas in the infected wound group, healing was achieved in 24 of 37 patients, with a patency rate of 72.7% (Table 10).

At the Duplex evaluation, we found 21 (36.8%) cases of restenosis. Fifteen were symptomatic, with recurrent and worsening ulcer, and the patients underwent further treatment. Six were asymptomatic, with no recurrence or worsening ulcer, and thus were not treated. Treatment was provided in five cases with PTA (40% of treatments), in three cases with major amputation, and in seven cases with minor amputation.

Among the clinical and angiographic variables included in the analysis, the clinical outcome was related significantly to the foot scores, with ulcer healing achieved in patients with lower preprocedural (mean score 6.8 in healed patients and 7.8 in nonhealed patients, $P<0.047$) and postprocedural (mean score 5.5 in healed patients and 6.3 in nonhealed patients, $P<0.049$) foot scores (Fig. 4).

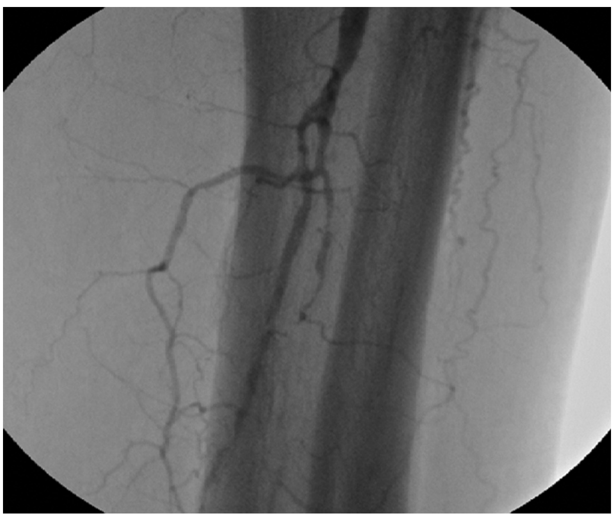
Discussion

Peripheral arterial disease is a relatively common complication of diabetes mellitus that can be underestimated, although it is associated with a higher risk of CLI, major amputation, and death compared with the nondiabetic population [18].

Limb salvage should be the goal in patients with CLI caused by infrapopliteal occlusive diseases as amputation has a major impact on the patient's quality of life; any type of revascularization that can preserve the limb has to be considered.

Bypass surgery, which is still the standard procedure [19], requires the presence of a good venous conduit and at least one patent artery in the region of the leg, and there is a non-negligible rate of perioperative mortality (0.9%), severe cardiac complications (myocardial infarction or acute heart failure rate of about 3%), and retreatment (thrombosis, bleeding, or infection rate of about 6.6%) [19].

Figure 4



Clinical success according to preprocedural and postprocedural calf and foot scores (box plot).

Revascularization by means of PTA has become the first line of treatment for CLI in patients with diabetic foot, with results similar to surgery in terms of limb salvage and patency [20].

The main studies in the literature, Faglia *et al.* [11] and Ferraresi *et al.* [21], reported a technical success rate of about 90%, a negligible mortality rate, and a limb salvage rate at 3–5 years of 72–98% for endovascular treatment. The main finding of our study is that a successful endovascular procedure saves a very high percentage of limbs at follow-up in a highly selected patient population with ischemic diabetic foot and isolated tibial, peroneal, or foot–artery disease. This meant that the studied population consisted of a very homogeneous group of predominantly patients with widespread small infrapopliteal vessels involvement (29.7% had three diseased leg vessels and 42.2% had two diseased leg vessels), a lesion length of greater than 10 cm in most cases, and an extraordinary length of treated vessel per procedure (≤20 cm).

However, despite the severity of the disease, successful endovascular procedures lead to optimal follow-up outcomes. Although this population only represents a minority of the patients referred for CLI treatment, they are technically challenging, and our results support the role of PTA as the therapeutic option for CLI patients with infrapopliteal arterial disease in diabetic patients.

Our study focused on the possible correlation between the severity of arterial involvement and clinical results. Our patients were aged (mean: 64.25), with multiple comorbidities and microvascular as well as macrovascular multiple diseases. Coronary artery disease was present in about one-third of the patients, whereas 11% of the population was affected by cerebrovascular disease and hypertension was found in over 60% of cases. Among microvascular complications, diabetic retinopathy was found in 53% of patients and neuropathy in 15.6% of patients. With respect to the limb lesions, the vast majority (75%) of our patients had either grade II or grad III wound according to the Texas University, which means that the vast majority of the lesions involved the deeper levels. The wound severity was determined in accordance to the degree of arterial involvement. In fact, the median calf and foot scores were 8, which means that there were at least two obstructed arteries for each district in the vast majority of our cases (60%).

In agreement with previously published data of Faglia *et al.* [11], our immediate technical success rate of the percutaneous treatment was 89%. The procedure was unsuccessful in seven patients in whom angiography showed total occlusion of the three tibial arteries with heavy calcification of the limb and foot arteries, a marker that has been identified previously as a strong predictor of a poor prognosis (Ketteler *et al.*, 2006). However, lesion extension was not a determining factor for worse outcome. This is probably because of the fact that most patients in our sample had critical ischemia, certainly with extensive and multisegmental lesions.

Postprocedural angiographic results showed a marked reduction in the postprocedural calf scores, indicating that at this time, it is possible to recanalize most of the infrapopliteal arteries. However, we did not observe a similar reduction in the postprocedural foot scores. At the foot level, the presence of heavy calcifications, long-lasting chronic occlusions, and development of multiple tiny collateral arteries might interfere with our technical chances of achieving complete patency of at least one entire native foot artery. In these conditions, implementing the blood flow at the level of collateral arteries is often the only available option.

Our results are in agreement with those of Ferraresi *et al.* [21]. At 1 year, we observed a limb salvage rate of 78.9%, a major amputation rate of 10.5%, a minor amputations rate of 24.6%, and complete healing rate of 56.1%. The rate of restenosis was 36.8%, with a PTA retreatment incidence of 8.7%. We observed a statistically significant increase in $TcPO_2$ values at 1, 6, and 12 months, indicating the effectiveness of the endovascular treatment in the short and medium term. This result could be influenced by the nature of our study, in which only patients who were candidates for percutaneous treatment were included. Ulcer healing depends on many variables, such as patient age, presence of comorbidities, glycometabolic control, lesion size, and duration [22], as well as patients' compliance to treatment and prevention. In other words, the 'diabetic foot' is a complex multifactorial disease that requires the organization of a dedicated multidisciplinary team for patients' preprocedural evaluation, treatment, and follow-up [23].

The clinical outcome was related significantly to the foot scores, with ulcer healing achieved in patients with lower preprocedural (mean 6.8 in healed patients and 7.8 in nonhealed patients, $P<0.047$) and postprocedural foot scores (mean score 5.5 in healed patients and 6.3 in nonhealed patients, $P<0.049$). Our results show that the preprocedural and postprocedural foot scores represent important predictive factors for ulcer healing, thus suggesting the need for further technical improvements to provide direct blood flow to the target area [24].

This finding might represent further confirmation of the unnecessary achievement of an 'optimal' angiographic result, by revascularizing each single infrapopliteal artery, while efforts should focus on improving the direct blood flow to the wounded area as confirmed by good healing percentage and the low percentage of major amputations. Attempts at recanalization of all the infrapopliteal arteries may increase the risk of complications because of increased manipulations and longer procedural time, with no available proof of a substantial clinical benefit [25].

Totally, 91% of the patients in the healed group had a patent pedal artery before PTA, whereas only 25% of the patients in the nonhealed group had a patent pedal artery before PTA; this means that clinical PTA success was associated significantly with the presence of at least one patent pedal vessel (dorsal pedal and/or common plantar arteries) on arteriography before PTA (Table 11).

PTA was successful in only three of 12 patients with no patent pedal vessel (Table 11). Moreover, obtaining a continuous patent artery at the malleolar level did not dependently predict clinical success. Similarly, in a study of 32 diabetic patients with foot ulcers, the number of patent crural arteries after PTA was not associated with ulcer healing [26].

Thus, we may assume that improving arterial flow in the tibial area is necessary but not sufficient to obtain a good clinical result. Further support for this conclusion comes from a prospective trial in CLI, in which improving arterial filling in the most severely ischemic area, even by collaterals, was associated more closely with the success of PTA than obtaining a continuous artery at the tibial level [20].

The results that we observed are in agreement with the recent guidelines of the European Society for Vascular Surgery on the treatment of diabetic foot [27], which notes 'Endovascular therapy for infrapopliteal arterial

Table 11 Factors associated with the clinical success of percutaneous transluminal angioplasty for patients with diabetic foot ulcers and severe ischemia

Variables	Healed group	Nonhealed group	*P* value
Number	45	12	
Age (mean±SD) (years)	70.7±10	73.2±8.4	0.10
Sex (male/female)	92/29	39/21	0.12
Co-morbidity [*n* (%)]			
Coronary artery disease	13 (29)	4 (33)	0.29
Other cardiac disease	7 (14)	3 (25)	0.39
Cerebrovascular disease	5 (11)	2 (16)	0.32
Hypertension	26 (57)	8(67)	0.17
Retinopathy	24 (53)	6 (50)	0.49
Neuropathy	7 (14)	2 (17)	0.75
Charcot	3 (6)	1 (8)	0.83
HbA1c (mean±SD) (%)	8.1±1.7	7.7±1.8	0.22
Diabetes type 1/2	1/44	1/12	0.20
Diabetes duration (mean±SD) (years)	16.6±5.3	18.2±6.1	0.19
Lesion duration (mean±SD) (weeks)	17±28	14±17	0.49
$TcP0_2$ before PTA (mmHg)	34.7±4.7	30.2±3.8	0.39
$TcP0_2$ after PTA (mmHg)	53.3±6.2	42.1±4.3	0.03*
Patent pedal artery before PTA	41 (91)	6 (50)	0.034*
Calf score before PTA (mean±SD)	7.5±1.8	8.0±1.5	0.095
Calf score after PTA (mean±SD)	4.5±2.2	4.8±2.4	0.241
Foot score before PTA (mean±SD)	7.0±2.5	7.8±2.0	0.047*
Foot score after PTA (mean±SD)	5.5±2.7	6.3±2.3	0.049*

HbA1c, hemoglobin A1c; PTA, percutaneous transluminal angioplasty; $TcP0_2$, transcutaneous O_2 pressure. *Significant at the 0.05 level.

disease is gaining acceptance as a first line revascularization method to improve ulcer healing and limb salvage'.

Conclusion

Our study indicated that PTA in diabetic patients with infrapopliteal disease is a safe and effective option. Long and multiple stenotic and occlusive lesions can be treated successfully and the lesion extension was not a determining factor for worse outcome. The foot score represents the most significant angiographic parameter to evaluate chances for ulcer healing, and, consequently, to determine the success of the revascularization procedure and with the presence of at least one patent pedal vessel (dorsal pedal and/or common plantar arteries) on arteriography before PTA.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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