Evaluation of predictors of patency of infrapopliteal angioplasty in diabetic occlusive lesions

Mohamed A. Elbegawy[a], Mohamed Sabry[b], Sherif A. Elgazzar[a]

[a]Department of General Surgery, Benha University, Benha, [b]Department of Vascular Surgery, Cairo University, Cairo, Egypt

Correspondence to Mohamed A. Elbegawy, MD, Department of General Surgery, Benha University Hospitals, Tukh, Kaliobia 13516, Egypt. Tel: 01274056123 or 01553053588; e-mail: mohamedatefelbegawy@gmail.com

Received: 16 October 2020
Revised: 5 November 2020
Accepted: 3 December 2020
Published: 18 May 2021

The Egyptian Journal of Surgery 2021, 40:201–208

Backgroundand purpose
To evaluate technical success as a predictor of patency of infrapopliteal angioplasty in diabetic occlusive lesions.
Patients and methods
This prospective study included 134 cases (critical limb ischemia 100%) that underwent tibial percutaneous transluminal angioplasty. The end point of follow-up was major adverse clinical outcome of the treated segment, which was defined as healing or clinical failure, that is, need for subsequent intervention such as endovascular or surgical revascularization or amputation. Follow-up period was 12 months.
Results
All patients passed uneventful intervention course, and technical success was reported in 128 (95.5%) cases with minimal complications in ~36 (26.9%) cases. There was a significant correlation between major adverse clinical outcome and major tissue loss, lesion occlusion, subintimal intervention, and complications (*P*=0.0001, 0.002, 0.001, and 0.002, respectively).
Conclusion
There are many predictors of patency after infrapopliteal angioplasty in diabetic occlusive lesions, including patient risk factors. Moreover, type and site of the lesion and technical success may play a role. However, the most important predictors of patency are major tissue loss, lesion occlusion, subintimal intervention, or complications.

Keywords:
diabetic occlusive disease, infrapopliteal angioplasty, predictors of patency, technical success

Egyptian J Surgery 40:201–208

1110-1121

Introduction

Diabetic foot disease poses a growing global public health challenge and a major financial burden on health care systems worldwide. Beyond their devastating complications such as amputation, diabetic foot ulcers have also been associated with poor quality-of-life outcomes and a significant financial burden, both to the patient and to the economy through direct costs and lost productivity [1,2].

Arterial disease contributes to the development of 50% of diabetic foot ulcers and plays a role in 70% of the mortality among diabetic patients. Arterial occlusive disease may be present in isolation or in combination with neuropathic disease in up to 45% of lower extremity ulcerations. Although femoral artery disease occurs in an equal incidence with the nondiabetic population, infrapopliteal occlusive disease with heavy calcification is the classic picture of diabetic arterial disease [3,4].

Despite the relatively common occurrence of an incomplete pedal arch in diabetic patients, tibial revascularization, especially to the angiosome in which the ulceration is located, is possible in the vast majority of diabetic patients to overcome foot ischemia [5].

Lower extremity arterial disease in diabetic patients is characterized by tibial artery involvement and the sparing of the microvascular circulation. Lower extremity revascularization with open or endovascular interventions can contribute in a significant way to limb preservation in this patient population. The indications for treating arterial occlusive disease in diabetics are similar to nondiabetic patients: lifestyle limiting claudication, rest pain, and tissue loss, which is associated with nonhealing ulcers and gangrenous changes [1,6].

The digital arteries are often spared the heavy calcification that occurs in the tibial arteries, and their measurements of flow more accurately reflect foot perfusion. As such, toe-brachial index (TBI) measurements may be more useful in diabetic

 DOI: 10.4103/ejs.ejs_289_20

patients with a suspected falsely elevated ankle-brachial index. A TBI greater than 0.6 is predictive of tissue healing. Further noninvasive imaging, such as computed tomography angiography (CTA) and magnetic resonance angigraphy, is often the next step for arterial imaging based on the vascular laboratory assessment [1,7–10].

Endovascular interventions continue to play an increasingly prominent role in the treatment of patients with diabetic foot ulcer. However, tibial artery occlusive disease remains a challenge for a catheter-based approach. There are several predictors of patency after infrapopliteal angioplasty that have been demonstrated in diabetics [11,12].

Perfusion is arguably the most critical element in diabetic foot ulcer healing and must be addressed early. Peripheral arterial disease is a major causative factor for amputation. There are a few important concepts that must be addressed. One concept relates to angiosomes, blocks of tissue fed by a source artery, that correspond to different regions of the lower extremity, as angiosomes may enhance the wound-healing rate. However, indirect revascularization still provides benefit when it is the most practical or the only choice [13,14].

Ischemic ulcers should not be debrided until revascularization has been performed. Although necrotic areas or frankly gangrenous digits will ultimately require some sort of amputation, this must be performed at a level where perfusion is adequate for healing. As long as there is no significant infection, debridement and amputation for dry necrosis should also be delayed until after revascularization [15,16].

The aim of this study was to evaluate technical success as a predictor of outcomes of tibial angioplasty in diabetic patients.

Patients and methods

The current prospective study included 134 cases and was conducted after approval from local ethical committee of Kasr Alainy and Benha universities and obtaining written fully informed patient consent. Diabetic patients of different age and sex undergoing treatment for symptomatic tibial occlusive lesions either rest pain or ulcer, who underwent percutaneous transluminal angioplasty (PTA) of a below-knee arterial lesions, at the vascular surgery department, Kasr Alainy and Benha universities hospitals, were included in this study from March 2018 till the end of September 2020. The expected study duration was 30 months. The enrollment period was 18 months, and follow-up period was 12 months.

Patients included in this study were suffering from diabetic symptomatic; Resting ankle-brachial index less than 0.9, Rutherford class (category 4–6), target lesions has a preprocedure percent diameter stenosis of more than or equal to 60% or chronic total occlusion.

However, patients excluded from this study were those having lesions lying within or adjacent to an aneurysm; lesions (treated in previous session) proximal to the midpopliteal arterial segment; nondiabetic cases; restenosis of the target tibial arteries; failed lesion crossing; arteritic lesions; thrombophilia; cerebral vascular disease; who require interventional management first; inability to comply with the follow-up schedule (as mental disability) or if there were contraindications of contrast; allergy or renal impairment; contraindication to aspirin or clopidogrel (patient must be able to receive dual antiplatelet treatment for 3 months after the procedure); or patients had prior major amputation, bypass surgery, and endarterectomy on any vessel of the ipsilateral (target) extremity.

All patients underwent evaluation by complete history taking, full clinical examination for blood pressure in both upper limbs, and peripheral and carotid pulsations. Preprocedural investigations included laboratory investigations, duplex scanning, and CTA.

Procedure details

Patients were given 300 mg loading dose of oral clopidogrel at least 1 day before ET or during the procedure. Under local anesthesia, access by sheath 6 F to the target tibial lesion was done by antegrade ipsilateral common femoral artery puncture in ∼90% of cases (n=120) or contralateral femoral puncture and performing a crossover technique in the remaining cases (n=14). Then 5000 IU intra-arterial heparin was injected through the sheath before balloon angioplasty. Angiography was done to confirm data obtained preoperatively using nonionic low osmolar dye diluted to 50% with normal saline. Tibial lesions were identified. A guidewire was positioned through the lesion: a 0.035 or 0.018 hydrophilic guidewire (standard type; Terumo, Tokyo, Japan) for stenosis and stiff type (Terumo) for chronic total occlusion supported by an angled-tip angiographic catheter (Bernstein 4 or 5 F) (Merit Medical, South Jordan, Utah, USA).

Then a balloon catheter [Admiral xtreme, Invatec S.p.A. Roncadelle (BS), Italy] of suitable diameter (2.5 or 3 mm) and length was introduced over the wire to the distal extent of the lesion. The balloon was inflated till any waist has been abolished then deflated and should be reinflated with overlaps until the whole lesion had been dilated. The inflation time was standardized: 2–3 min with heparinized saline injection after deflation. The balloon was withdrawn completely. Angiography was done to assess the result. Associated inflow lesions were also treated. The technical result was assessed by digital subtraction angiography. Manual compression was applied for number of sheath multiplied by 3 min (6 F×3=18) and mobilization was delayed for 6–12 h.

A number of cases required subintimal angioplasty (*n*=18, 13%) owing to lesion length and occlusion. The subintimal angioplasty followed Bolia's previously described techniques. With arterial spasm, 0.1 mg nitroglycerine was given as intra-arterial bolus. After the intervention, all patients were prescribed an antiplatelet drug (clopidogrel 75 mg daily for 3 months followed by acetylsalicylic acid 150 mg daily thereafter), and together with lipid-lowering agents (atorvastatin 40 mg once daily) in dyslipidemic patients.

Postoperative follow-up

Appropriate medical management was commenced, along with risk factor modification. Success of the procedure depends on angiographic success; hemodynamic success, where TBI greater than 0.6 is predictive of tissue healing and demonstration of biphasic or triphasic waveforms; and clinical success, that is, absence of symptoms or improvement by at least one (claudication) or two (tissue loss) categories according to Rutherford classification that were documented before discharge.

All patients were re-examined after 1 week to check for access site problems and to confirm patency. All patients were followed for 12 months with regular visits at 1, 3, 6, and 12 months. Follow-up was in the form of clinical examination and duplex ultrasound ±CTA if needed in cases of absent or diminished pulse or recurrence of symptoms. Parameters of follow-up included patency, limb salvage, healed wound, and independent living status (Fig. 1).

Statistical analysis

The collected data of major adverse clinical outcome (MACO) were tabulated and analyzed using SPSS, version 16 software (SPSS Inc., Chicago, Illinois, USA) and Microstat W software (India, CNET Download.com). Categorical data were presented as number and percentages, using χ^2 test for their analysis. Continuous data were expressed as mean±SD. Data were tested for normality using Shapiro–Wilks test, assuming normality at *P* value more than 0.05. Differences between groups were tested using Student *t* test for normally distributed variables.

Results

All cases completed their follow-up, and no mortality related to surgery was reported. So, the current study was conducted on 134 patients with symptomatic tibial occlusive disease, with the following data: age 56.4±5.6 years, most cases were male [84 (62.7%)], and duration of symptoms was 4.3±1.39 months. Hyperlipidemia [132 (98.5%)] was the most risk factors, then hypertension [122 (91.1%)], and remote atherosclerosis was the least [52 (38.8%)] (Table 1 and Figure 2).

All patients passed uneventful intervention course; the passage route was either intraluminal in 116 (86.6%) cases or subintimal in 18 (13.4%) cases. The technical success was reported in 128 (95.5%) cases with minimal complications in ~36 (26.9%) cases in the form of spasm, which was treated by intra-arterial nitroglycerin injection (Table 2, Figure 3).

Regarding the correlation between MACO and patient characteristics, there was a significant correlation between MACO and major tissue loss and lesion occlusion, with *P* values of 0.0001 and 0.002, respectively (Table 3, Figure 4).

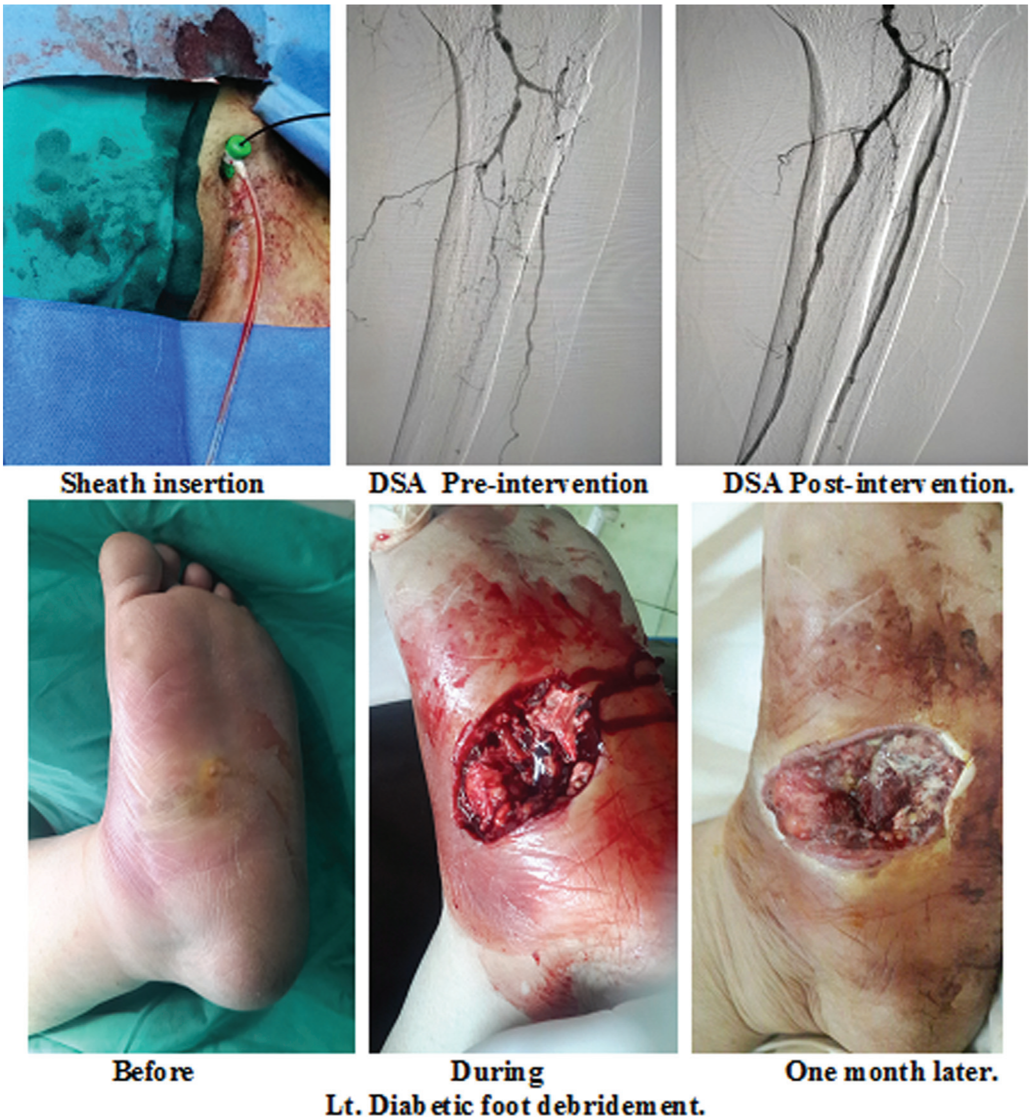
On reviewing correlation between MACO and intervention data, there was a significant correlation between MACO and subintimal intervention and complications, with *P* values of 0.001 and 0.002, respectively (Table 4, Figure 5).

Discussion

The outcomes of lower limb revascularization on the natural history of diabetic cases with critical limb ischemia (CLI) remains doubtful. Most of the previous studies that evaluated the effect dealt with incidence of amputation and survival of cases after PTA. As diabetic patients have complex comorbidities, and their vascular system is entirely involved, they have greater risks of life-threatening ischemic cardiovascular and cerebral strokes [17].

Wound Ischemia Foot Infection classification is a grading and staging system especially in diabetics, in whom wound extent and severity of infection affecting threat to the limb are assessed [1].

Figure 1



A case of tibial angioplasty followed by debridement.

Diabetics are up to 15 times more likely than nondiabetics to experience major amputation. Diabetes is also associated with decreased primary patency following endovascular interventions [18,19].

In the current study, 134 limbs of 134 cases were included. Their mean age was of 56.4±5.6 years, most cases were male [84 (62.7%)], and mean duration of symptoms was 4.3±1.39 months. Gallagher *et al.* [20] found that in patients with chronic limb ischemia receiving PTA for tibial disease, women had superior primary and secondary patency rates at all time points when compared with men.

Regarding other studies, another study by Kassaian *et al.* [21] treated 45 diabetic cases. Most of them were men (76%), 70% of them were hypertensive, and 4% were current smokers.

In a multicenter study by Iida *et al.* [22], history of hyperlipidemia and remote atherosclerosis was positive in 31 and 51% of their cases, respectively, and 36% of their cases were current smokers. Freedom from major adverse limb events rate was 57 and 47% at 1 and 2 years, respectively.

In the present study, the larger the volume of tissue loss or occlusive lesions may predict MACO; healing was 53.8 and 61.3% (P=0.0001 and 0.002, respectively). These results were comparable to the study of Giles *et al.* [23] who reported in 176 limbs at a mean follow-up of 12 months, complete healing or improvement in 57% of limbs, with stable wounds in 22%, and worsening of the wound in 21%.

Infrapopliteal endovascular interventions in case of CLI have been reported with mixed results. In our study, primary patency rates were observed in about 102 (79.7%) cases. This result was more than that described by Romano *et al*. [24], who performed a meta-analysis of tibial angioplasty and showed 1-year primary patency rates of 58%, with a limb salvage rate of 86% because most of our cases had stenotic lesions.

Table 1 Patients' characteristics

Variables	Finding (*N*=134)
Age (years)	56.4±5.6
Sex	
Female	50 (37.3)
Male	84 (62.7)
Duration of symptoms (months)	4.3±1.39
Risk factors and comorbidities	
Smokers	86 (64.2)
Hypertensive	122 (91.1)
Remote atherosclerosis	52 (38.8)
Hyperlipidemia	132 (98.5)
Clinical presentation	
R4	26 (19.4)
R5	82 (61.2)
R6	26 (19.4)
Type of lesions	
Stenosis	20 (14.9)
Occlusion	62 (46.3)
Both	52 (38.8)
Site of lesions	
Infrapopliteal 3-vessel disease	32 (23.9)
PTA-ATA	2 (1.49)
SFA+infrapopliteal	100 (74.6)
Access site	
Ipsilateral femoral	120 (89.6)
Crossover femoral	14 (10.45)
TASC classification	
TASC (C)	40 (29.9)
TASC (D)	94 (70.2)

Data are presented as *n* (%)and mean±SD. ATA, anterior tibial artery; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery.

Limb salvage rate is not directly correlated with patency rates. This demonstrates the dilemma of determining the right time to amputate. We reported a limb salvage rate of ~79.7% at 24 months of follow-up. This result was less than discussed in a review of 10 largest studies on the endovascular treatment of CLI by Graziani and Piaggesi [17]. Limb salvage was 80–98% at 6–18 months of follow-up. Another study reported limb salvage rate of 82% at 6 months after PTA. This was because we reported longer follow-up period [25].

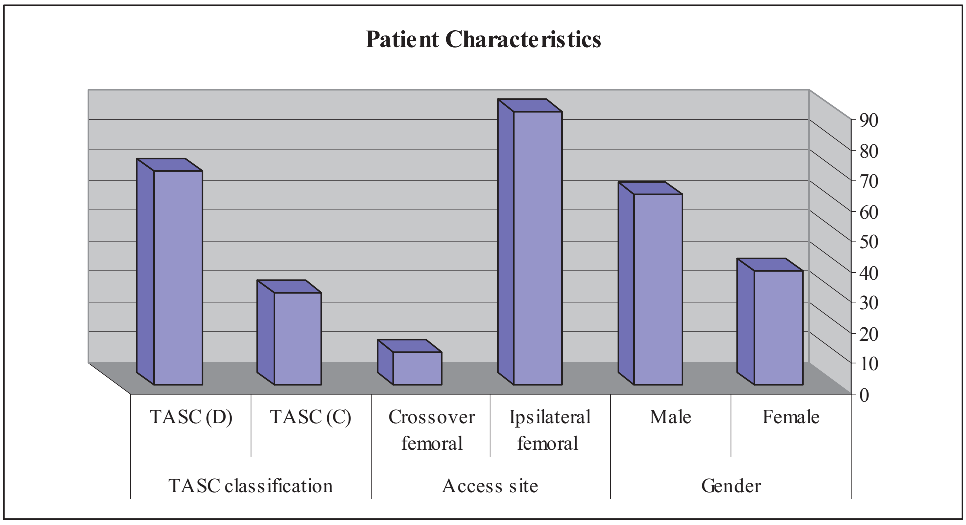
There was a significant correlation between MACO and major tissue loss and lesion occlusion, with *P* value of 0.0001 and 0.002, respectively. Against our results, Abdul Raouf *et al*. [26] concluded that there was no significant difference in clinical outcome or amputation rates when we comparing patients with stenotic vessels with those with occluded segments, in accordance with previous studies.

Table 2 Intervention data

Variables	Finding (*N*=134)
Technical success	128 (95.5)
Passage route	
Intraluminal	116 (86.6)
Subintimal	18 (13.4)
Complications	36 (26.9)

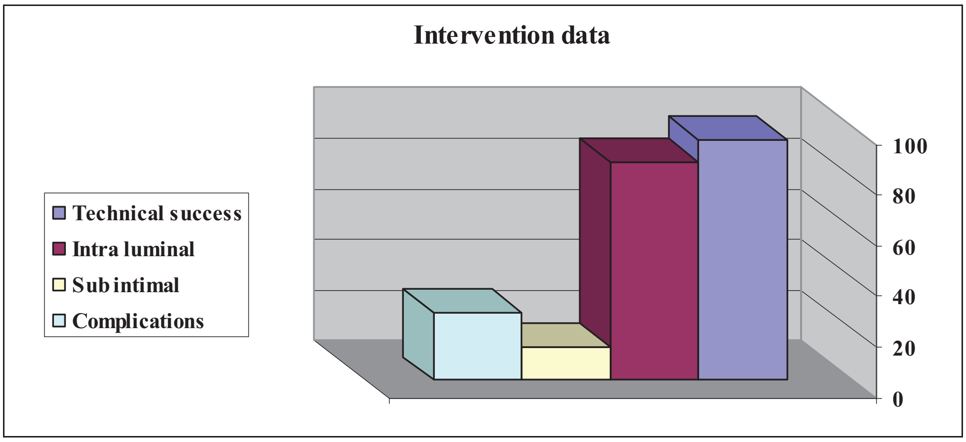
Data are presented as *n* (%).

Figure 2



Patients' characteristics.

Figure 3



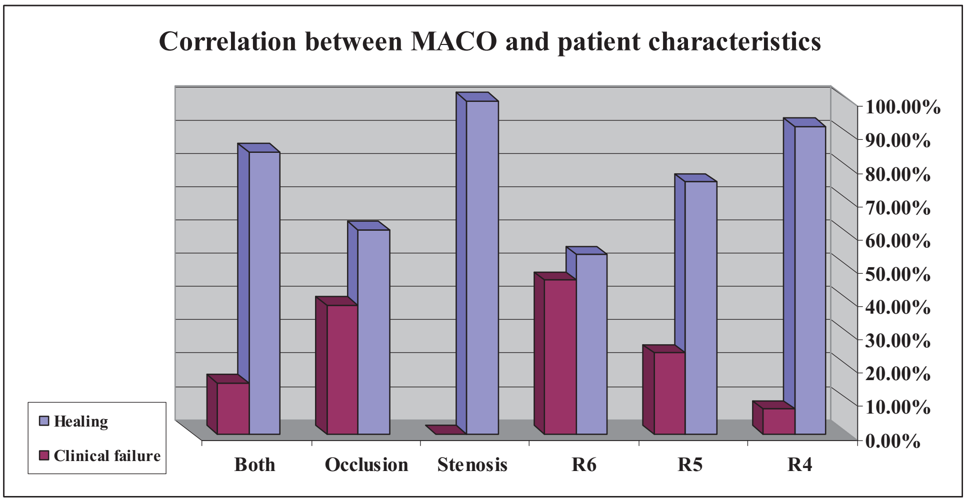
Intervention data.

Table 3 Correlation between major adverse clinical outcome and patients' characteristics

Variables	Healing	Clinical failure	Total	*P* value
Smokers	66 (76.7)	20 (23.3)	86 (64.2)	0.569
Hypertensive	96 (78.7)	26 (21.3)	122 (91.1)	
Remote atherosclerosis	38 (73.1)	14 (26.9)	52 (38.8)	
Hyperlipidemia	100 (75.8)	32 (24.2)	132 (98.5)	
R4	24 (92.3)	2 (7.6)	26 (19.4)	0.252
R5	62 (75.6)	20 (24.4)	82 (61.2)	0.872
R6	14 (53.8)	12 (46.2)	26 (19.4)	0.0001
Stenosis	20 (100)	0	20 (14.9)	0.019
Occlusion	38 (61.3)	24 (38.7)	62 (46.3)	0.002
Both	44 (84.6)	8 (15.4)	52 (38.8)	0.069
Infrapopliteal 3-vessel disease	22 (68.75)	10 (31.25)	32 (23.9)	0.641
PTA-ATA	2 (100)	0	2 (1.49)	
SFA+infrapopliteal	78 (78)	22 (22)	100 (74.6)	
TASC (C)	26 (65)	14 (35)	40 (29.9)	0.064
TASC (D)	76 (80.9)	18 (19.1)	94 (70.2)	0.241

Data are presented as *n* (%)using *P* value. ATA, anterior tibial artery; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery.

Figure 4



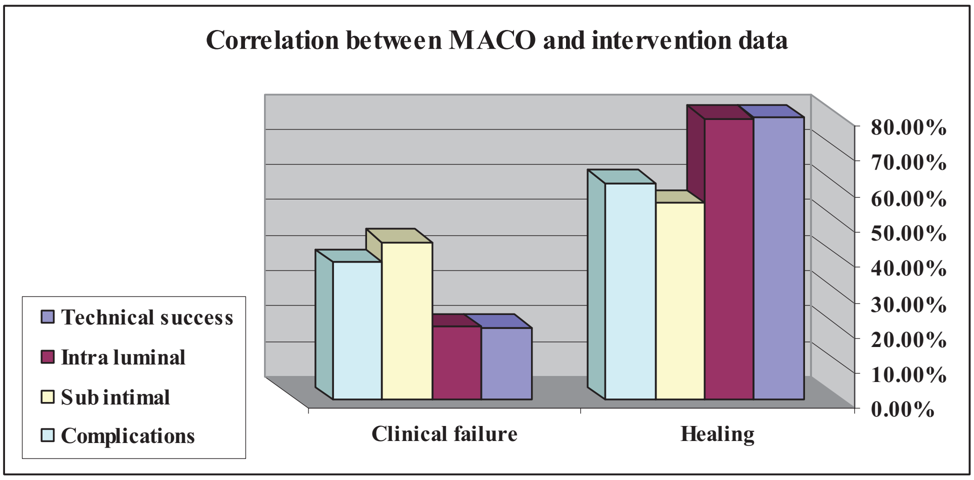
Correlation between MACO and patients' characteristics. MACO, major adverse clinical outcome.

Table 4 Correlation between major adverse clinical outcome and intervention data

Variables	Healing	Clinical failure	Total	*P* value
Technical success	102 (79.7)	26 (20.3)	128 (95.5)	0.522
Intraluminal	92 (79.3)	24 (20.7)	116 (86.6)	0.120
Subintimal	10 (55.6)	8 (44.4)	18 (13.4)	0.001
Complications	22 (61.1)	14 (38.9)	36 (26.9)	0.002

Data are presented as *n* (%)using *P* value.

Figure 5



Correlation between MACO and intervention data. MACO, major adverse clinical outcome.

There was no significant correlation between MACO and TASC classifications. These results came in agreement with Irene *et al.* [27] who concluded that TASC classifications are inadequate to describe peripheral arterial disease and to provide treatment guidelines in the diabetic population.

Conclusion

There are many predictors of patency after infrapopliteal angioplasty in diabetic occlusive lesions, including patient's risk factors. Moreover, type and site of the lesion and technical success may play a role. However, the most important predictors of patency are major tissue loss, lesion occlusion, subintimal intervention, or complications.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Kayssi A, Rogers L, Neville R. General considerations of diabetic foot ulcers. In: Anton NS, Bruce AP editors Rutherford's vascular & endovascular therapy. Philadelphia: 2018. 5001–5028.
2 Gok U, Selek O, Selek A. Survival evaluation of the patients with diabetic major lower-extremity amputations. Musculoskelet Surg 2016; 100:145–148.
3 Noor S, Zubair M, Ahmad J. Diabetic foot ulcer-a review on pathophysiology, classification and microbial etiology. Diabetes Metabol Syndr 2015; 9:192–199.
4 Frykberg R, Zgonis T, Armstrong D. Diabetic foot disorders. A clinical practice guideline (2006 revision). J Foot Ankle Surg 2006; 45: S1– S66.
5 Neville RF, Attinger CE, Bulan EJ. Revascularization of a specific angiosome for limb salvage: does the target artery matter? Ann Vasc Surg 2009; 23:367–373.
6 Gibbons GW, Shaw PM. Diabetic vascular disease: characteristics of vascular disease unique to diabetic patient. Semin Vasc Surg 2012; 25:89–92.
7 Sahli D, Eliasson B, Svensson M. Assessment of toe blood pressure is an effective screening method to identify diabetes patients with lower extremity arterial disease. Angiology 2004; 55:641–651.
8 Teodorescu V, Chen C, Morrissey N. Detailed protocol of ischemia and the use of noninvasive vascular laboratory testing in diabetic foot ulcers. Am J Surg. 2004; 187:75S–80S.
9 Blankensteijn J, Schultze Kool L. Computed tomography. In: Anton NS, Bruce AP editors. Rutherford's vascular & endovascular therapy. Philadelphia: 2018. 1179–1200.
10 Carpenter J, Litt H, Gowda M. Magnetic resonance imaging and arteriography. In: Anton NS, Bruce AP editors. Rutherford's vascular & endovascular therapy. Pennsylvania: 2018. 1209–1212.
11 Camargo MR, Barela JA, Nozabieli AJ, Mantovani AM, Martinelli AR, Fregonesi CE. Balance and ankle muscle strength predict spatiotemporal gait parameters in individuals with diabetic peripheral neuropathy. Diabetes Metabol Syndr 2015; 9:79–84.
12 Clark TW, Groffsky JL, Soulen MC. Predictors of long-term patency after femoropopliteal angioplasty: results from the STAR registry. J Vasc Interv Radiol 2001; 12:923–933.
13 Kim PJ, Lavery LA. Diabetic foot abnormalities and their management. In: Anton NS, Bruce AP editors Rutherford's vascular & endovascular therapy. China: xx; 2018. PL 5053–5055.
14 Attinger C, Evans K, Bulan E, Blume P, Cooper P. Angiosomes of the foot and ankle and clinical implications for limb salvage: reconstruction, incisions, and revascularization. Plast Reconstr Surg 2006; 117:261S–293S.

15 Spillerova K, Sorderstrom M, Alback A, Venermo M. The feasibility of angiosome-targeted endovascular treatment in patients with critical limb ischemia and foot ulcer. Ann Vasc Surg 2016; 30:270–276.

16 Spillerova K, Biancari F, Leppaniemi A, Alback A, Soderstrom M, Venermo M. Differential impact of bypass surgery and angioplasty on angiosome-targeted infrapopliteal revascularization. Eur J Vasc Endovasc Surg 2015; 49:412–419.

17 Graziani L, Piaggesi A. Indications and clinical outcomes for below knee endovascular therapy: review article. Catheter Cardiovasc Interv 2010; 75:433–443.

18 Abularrage CJ, Sidawy AN, Aidinian G, Singh N, Weiswasser JM, Arora S. Evaluation of the microcirculation in vascular disease. J Vasc Surg 2005; 42:574–581.

19 Stratton IM, Adler AI, Neil HW, Matthews DR, Manley SE, Cull CA, *et al.* Association of glycemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. Br Med J 2000; 321:405.

20 Gallagher KA, Meltzer AJ, Ravin RA, Graham A, Connolly P, Escobar G, *et al.* Gender differences in outcomes of endovascular treatment of infrainguinal peripheral artery disease. Vasc Endovasc Surg 2011; 45:703–711.

21 Kassaian SE, Mohajeri Tehrani MR, Dehghan Nayyeri A, Saroukhani S, Annabestani Z, Alidoosti M, *et al.* Major adverse events, six months after endovascular revascularization for critical limb ischemia in diabetic patients. Arch Iran Med 2013; 16:258–263.

22 Iida O, Soga Y, Hirano K, Kawasaki D, Suzuki K, Miyashita Y, *et al.* Midterm outcomes and risk stratification after endovascular therapy for patients with critical limb ischemia due to isolated below-the-knee lesions. Eur J Vasc Endovasc Surg. 2012; 43:313–321.

23 Giles KA, Pomposelli FB, Spence TL, Hamdan AD, Blattman SB, Panossian H, *et al.* Infrapopliteal angioplasty for critical limb ischemia: relation of TransAtlantic InterSociety Concensus class to outcome in 176 limbs. J Vasc Surg. 2008; 48:128–136.

24 Romano M, Mainenti PP, Imbriaco M, Amato B, Markabaoui K, Tamburrini O, *et al.* Multidetector row CT angiography of abdominal aorta and lower limbs in patients with peripheral arterial occlusive disease: diagnostic accuracy and interobserver agreement. Eur J Radiol 2004; 50:303–308.

25 Mendiz OA, Fava CM, Valdivieso LR, Lev GA, Villagra LG. Angioplasty for treatment of isolated below-the-knee arterial stenosis in patients with critical limb ischemiat Angiology 2011; 62:359–364.

26 Abdul Raouf A, Rouleau Y, Clement A, Le Roux P, Genay P, Ricco JB. Endoluminal angioplasty of the popliteal artery. Review of 54 consecutive patients. Eur J Vasc Endovasc Surg 2005; 30:610–613.

27 Irene B, Piaggesi A, Cicorelli A, Rizzo L, Cervelli R, Iacopi E, *et al.* Predictive value of angiographic scores for the integrated management of the ischemic diabetic foot. J Vasc Surg 2013; 57:1204–1212.