

Role of duplex-guided infragenicular angioplasty in saving limbs

Sameh E. Elimam^a, Hala M. Shereif^b

Departments of ^aVascular Surgery, ^bRadiology, Al-Azhar Faculty of Medicine for Girls (AFMG), Cairo, Egypt

Correspondence to Sameh E. Elimam, MD, EVF, Z3G1 Galleria Moon Valley Compound, Cairo 11835, Egypt. Tel: +20 106 741 1164, fax: 0020225406870; e-mail: elimam1982@gmail.com

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Background/aim

Critical limb ischemia (CLI) is known as ischemic rest pain at rest or tissue loss with peripheral arterial disease. Endovascular intervention has many advantages than surgical bypasses and it is used frequently with fragile patients, at the same time, it has many adverse effects for both surgeon and patient such as radiation effect for both and renal-induced nephropathy for the patient. Worldwide duplex-guided infragenicular angioplasty is a new method that has been started to emerge and to be a common technique in such patients, That is why the present study aims to assess the feasibility and efficacy of duplex-guided infragenicular angioplasty to save limbs and to detect if it is applicable or not.

Patients and methods

Twenty CLI patients were admitted to the vascular unit from 2015 to 2017 in Al-Zahraa University Hospital, Al-Azhar University, Cairo, Egypt. We included patients with good femoral pulse and significant infragenicular lesions. We excluded those with proximal outflow lesions and with acute embolic or thrombotic insults. Percutaneous transluminal angioplasty was done to all the patients through ipsilateral femoral access by using 0.014 and 0.018 wires 4 F catheters and low-profile balloons, then we followed them clinically and with duplex ultrasound at 1, 3, 6, and 12 months with calculating the hemodynamic studies.

Results

The present study enrolled 20 patients, six (30%) of them are females and 14 (70%) males, with mean age of 59.2. The clinical history of smokers, cardiac, diabetics, renal, and hypertensive were 65, 60, 50, 85, and 80%, respectively. Technical success was 90%. Groin hematoma, distal thrombosis, and vessel perforation were technical complications, with 5% for each. Optimal procedural success was achieved in 70%, of suboptimal in 20%, and then we failed in 10%. Rest pain completely disappeared from 75% of patients. Sixteen limbs were saved postintervention, Kaplan–Meier curve showed 70% survival rate at 6 months, while at 9 months, the drop occurred to be 28%, which was still to be the percent at 12 months.

Conclusion

Modern duplex ultrasound can be used to map the arterial disease and to show guide wires, sheaths, balloons, and stents for the treatment of infragenicular arterial lesions. Also, it seems to be safe, easy and effective technique, a bedside procedure, and cost-effective as well. It has a crucial role in saving limbs for CLI patients.

Keywords:

critical limb ischemia, duplex-guided angioplasty, limb salvage

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Introduction

Critical limb ischemia (CLI) is defined as ‘ischaemic rest pain’ or grade II category IV on the Rutherford–Baker classification of peripheral arterial disease. Rest pain is defined as a severe unremitting pain in the foot, which is aggravated by lying supine. It is partially relieved by dangling the foot over the edge of the bed or standing on a cold floor. Patients may also have gangrene or ulceration of the tissue [1].

Below-knee angioplasty has traditionally been reserved for patients with CLI because of the fear of limb loss should a complication occur [2]. Moreover, current practice standards have broadened somewhat in that

patients with severe claudication who have extensive, multilevel disease may have this intervention performed to improve ‘outflow’ in their infrapopliteal vessels, although no systematic study data exist to support this indication for intervention. Isolated tibioperoneal disease does not generally cause lifestyle-limiting claudication, unless it occurs in the proximal tibioperoneal trunk and affects the common inflow to all three vessels [2].

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Over the last 12 years, Ascher *et al.* [3] and Bibbo *et al.* [4] have explored the advantages and limitations of preoperative duplex scan of lower extremities as an image modality and described that duplex scanning offers multiple features such as arterial visualization regardless of its patency, imaging of the arterial wall, real-time visualization in the presence of limb motion, five-times magnification, precise measurements, and hemodynamic parameters such as flow direction, velocity, and waveform. These features have assisted to establish the field of vascular ultrasound (US) intervention.

The former preliminary experiments with transcutaneous US in the guidance of infrainguinal arterial procedures reported by Ahmadi *et al.* [5] and Ramaswami *et al.* [6] have helped us more and more in this study. The present study aim was to assess the feasibility and efficacy of duplex-guided infragenicular angioplasty to save limbs and to detect if it is applicable or not.

Patients and methods

Patients

The present study included 20 patients with critical arterial occlusive disease affecting the infragenicular arteries. Patients were admitted to the vascular surgery unit, of Al-Zahraa University Hospital from 2015 to 2017. Patients greater than 30 years old with CLI indicated by computed topographic angiography with significant infragenicular arterial disease in the form of stenosis greater than 75% or complete occlusion, having good femoral pulse, were included in this study. Patients with inflow problems and age less than 30 years old, patients with evident full-thickness gangrene of the foot or having embolic occlusions or acute thrombotic occlusions were excluded.

Study design

Twenty patients were collected and subjected to infragenicular angioplasty under duplex US guidance. Follow-up was on 1, 6, and 12 months. Preoperative risk factors, intraoperative variables, postoperative morbidity, and mortality data were collected. The various risk factors were analyzed in this study, including age, comorbidities including coronary artery disease, renal impairment, chronic heart failure, cerebrovascular disease, hypertension, and diabetes mellitus.

Ethical considerations

The present study was conducted with Code of Ethics of the World Medical Association according to the

principles expressed in the Declaration of Helsinki. This study has been approved by the local ethics committee of Faculty of Medicine for girls, Al-Azhar University, under number 1293.

Methods

After taking consents, patients were subjected to history taking, clinical examination, and investigations under duplex guidance for selected cases in the vascular surgery unit laboratory. A linear 4–7-MHz probe is used in a sterile plastic cover with coupling gel that is used for insonation of the arteries of 4-cm deep or less. A curved 2–5-MHz transducer is used to visualize deeper arterial segments, including the distal Superficial Femoral Artery (SFA) and above-the-knee Popliteal Artery (PA). The length of the stenosis is measured with a linear 4–7-MHz probe. The hemodynamic study is recorded preprocedure and postprocedure.

Patient clinical-condition progress, relief of symptoms, and recovery from the critical situation. Estimation of the patency rate at 1 day, 1, 3, 6 months, and after 1 year with duplex US and observations of wound healing with recording the ankle brachial pressure index. Complications whether early or late, general or local, were recorded.

Statistical analysis

All the collected data were coded on the computer and the statistical analysis was done using SPSS program (Statistical Package for Social Science). Mean, median, and *p* value were used methods. Life table with Kaplan–Meier curve method was also calculated.

Results

The present study was conducted on 20 patients, 6 (30%) females and 14 (70%) males, their ages ranged from 46 to 73 years with mean age of 59.2. Their risk factors were as shown in Table 1.

Analysis by Kaplan–Meier survival curve was used to calculate the survival after 12 months, which was one of our outcomes of the study.

Table 1 Risk factors of studied patients

Risk factors	<i>n</i> (%)
Smoking	13 (65)
Cardiac	12 (60)
Renal	17 (85)
Diabetes mellitus	16 (80)
Hypertension	10 (50)
Hypercholesterolemia	10 (50)

It showed 70% survival rate at 6 months, while at 9 months, the drop occurred to be 28%, which was still to be the same percent at 12 months (Fig. 1).

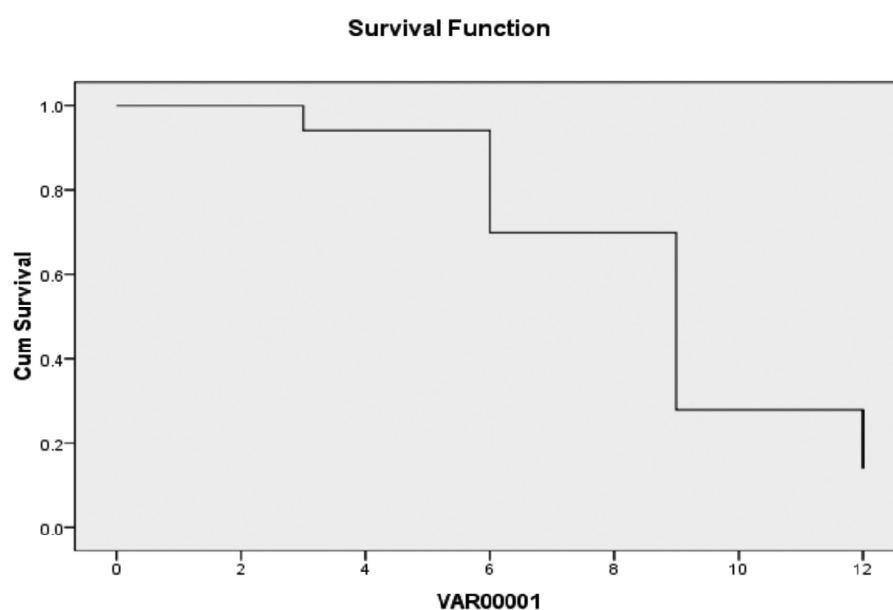
Patency at follow-up was documented in Fig 2 as a means of colored duplex US as follows:

- (1) Less than 50 diameter reduction (peak systolic velocity index < 2.4).
- (2) About 50% or more diameter reduction (PSV 2.4).
- (3) Complete occlusion.

Primary patency at 1, 3, 6, and 12 months was defined as freedom from restenosis. Restenosis was defined as PSVI greater than equal to 2.4 at the target lesion.

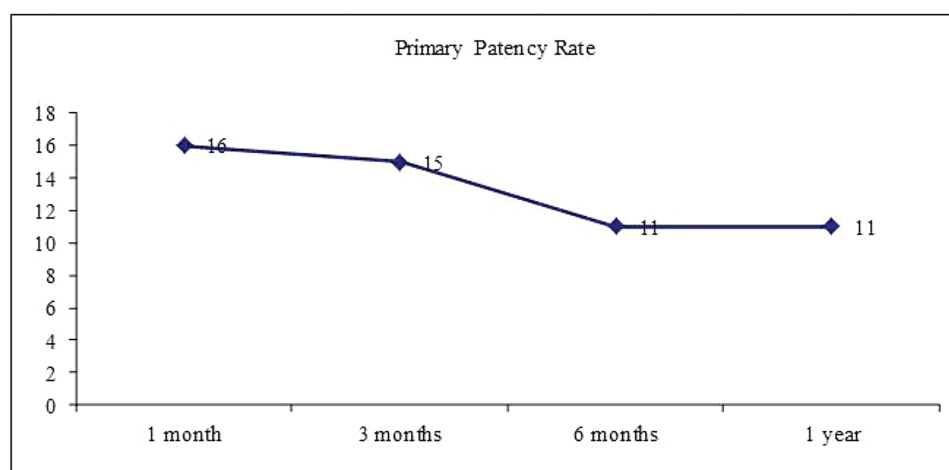
Patency at follow-up was documented as a means of colored duplex US as follows: at 1 month, 16 patients were free from restenosis. At 3 months, 15 patients were free from restenosis. They dropped to 11 patients at 6 months and continue with the same number till the end of the study, 12 months, as shown in Figs 2 and 3a-d, respectively.

Figure 1



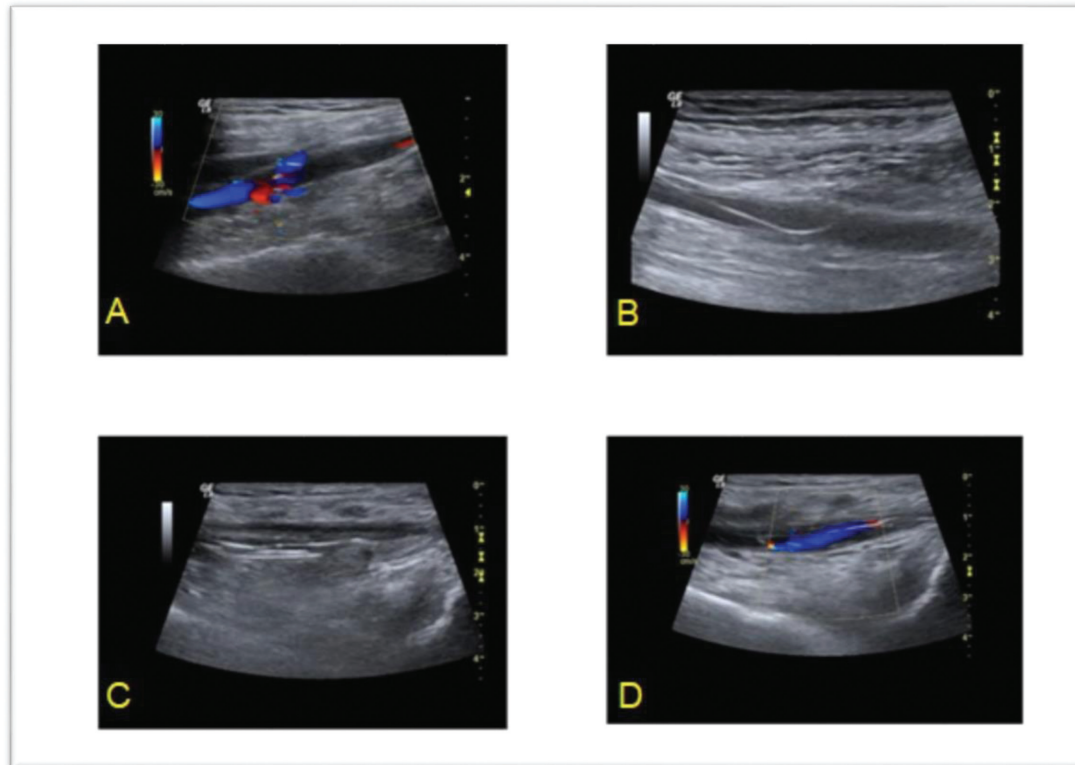
Kaplan–Meier curve shows the survival rate of studied patients.

Figure 2



Primary patency rate of studied patients.

Figure 3



(a) Occluded middle part of peroneal artery with no color flow. (b) The guide wire 0.035 is traversing the occluded part of peroneal artery. (c) Balloon dilation of the artery. (d) The regaining of color flow and patency of peroneal artery after dilation.

Discussion

Dotter and Judkins were the first to describe an angioplasty for treatment of occlusive arterial disease involving the tibio-peroneal trunk in 1964. However, until 1974, with the introduction of coaxial catheters by Gruentzig and Hopff, the angioplasty became widespread for treatment of stenosis located in the infragenicular arteries [7].

Despite recent technologic advances, Wang *et al.* [8] reported a 21% procedural complication rate, including embolization and thrombosis in patients with CLI undergoing balloon angioplasty.

Whereas Dorros *et al.* [9] demonstrated that percutaneous transluminal angioplasty (PTA) of below-knee arteries could be performed with relative safety and with satisfactory results. In our study, we found 15% procedural complications in the form of distal embolization, groin hematoma, and vessel perforation.

Although reports are being published about the usefulness of endovascular treatment of infrapopliteal athero-occlusive changes in selected patients with chronic critical limb ischemia. Extensive use of PTA in arteries below the knee was made possible by

advances in balloon catheter and digital imaging technology with the use of 0.014–0.018-inch steerable guide with blunt, flexible tip [10,11].

Passage through stenosis in small arteries below the knee is almost feasible with the monorail technique derived from coronary angioplasty. A recent meta-analysis of infrapopliteal angioplasty for CLI reports that the durability of PTA is limited compared with bypass surgery. Nevertheless, for this kind of patients, the main result is not to avoid restenosis and maintain distal pulse, but to restore a straight-line blood flow (temporary bypass) for the time that is necessary to provide wound healing and limb salvage, favoring the treatment of infections where needed [12].

In our study, the aim was to create a straight line of blood flow to alleviate the rest pain that was realized in 75% of studied patients. Also, to save a limb, which happened in 85% and to give a chance for the wound to be healed, which happened in 65%.

The present studies have shown that the most important factor to improve the quality of life for CLI patients is limb salvage. Compared with other factors such as rest pain and minor tissue loss, limb salvage should be considered as the first goal to deal

with in CLI patients. So, leaving the patient with an ambulatory foot should be the main goal for vascular surgeon. It has been shown that limb salvage by means of revascularization in CLI by using duplex US is more beneficial moneywise, with better quality of life, and is associated with lower perioperative complication rate compared with amputation [13], which was the main pillar to be achieved in our study.

Similar to Giles *et al.* [14], our study showed that duplex-guided endovascular option for the treatment of CLI appears safe, with high procedural success (90%), low-procedure-related complication rate (15%), and a mean hospital stay less than 3 days.

Conclusion

Modern duplex US can be used to map the arterial disease and to show guide wires, sheaths, balloons, and stents for the treatment of infragenicular arterial lesions. Also, it seems to be safe, easy and effective technique, a bedside procedure, and cost-effective as well. It has a crucial role in saving limbs for CLI patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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