Duplex-guided infra-popliteal balloon angioplasty in critical limb ischemia

Maisa A. Abdel Wahab[a], Ola I. Saleh[b], Randa S. Elshahat[b]

Background Angioplasty carries lower morbidity and mortality in comparison with surgery and would be considered as the treatment of choice in majority of patients with critical limb ischemia,. Endovascular procedures conventionally employ ionic contrast agent and radiation.

Aim of the work We aim to evaluate infra-popliteal balloon angioplasty in critical limb ischemia under duplex ultrasound (U/S) guidance to avoid the potential side effects of ionic contrast agent and radiation.

Patients and methods A prospective study on 28 patients with infra-popliteal steno-occlusive disease was admitted to our Vascular Department during a period from July 2016 to June 2018. Duplex guidance was used for patients with stenotic and occlusive lesions to perform balloon dilation. Seven patients presented with diagnostic computed tomography angiography preprocedure in the outpatient clinic and confirm the diagnosis with duplex U/S study and the rest of the patients was diagnosed by duplex U/S to avoid the hazards of angiography and then follow-up scanning by duplex U/S were done after 1 week, 1 month, and 6 months.

Results The early technical success rate was 92.9%. Primary patency rate was 92.9, 85.7, and 78.6% after 1 week, 1 month, and 6 months, respectively. Immediate clinical success to all patients with rest pain (100%) and there was clinical improvement in wound healing after 1 month and 6 months (91.7%).

Conclusion Angioplasty of infra-popliteal arterial occlusive disease under Duplex guidance should be more harmless than using fluoroscopy and effective procedure with accepted results.

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Departments of, [a]Vascular Surgery, [b]Radio-Diagnosis, Faculty of Medicine (for Girls), Al-Azhar University, Cairo, Egypt

Correspondence to Maisa A. Abdel Wahab, MD, El Obour City, Cairo, 11828, Egypt. Tel: +20 100 678 9203;
e-mail: maisa932006@yahoo.com

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Introduction

Endovascular treatment under ultrasound (U/S) guidance has been considered the standard choice for popliteal arterial disease. However, most centers have studied the endovascular outcomes of iliac and superficial femoral artery (SFA), and only three researches have focused on popliteal artery angioplasty [1].

Endovascular treatment is a minimally invasive technique with lesser morbidity and mortality than other more invasive procedures and carries lower risk, lesser cost, and faster procedure with shorter hospital stay [2].

Duplex U/S offers several features such as imaging of the arterial wall, lumen patency, real-time, up to five-time magnifications, accurate measurements, and availability of several hemodynamic parameters such as flow direction, velocity, and waveform [3].

PTA techniques usually employ contrast agent and fluoroscopy. The usage of duplex U/S as a guide for infra-popliteal balloon angioplasties in patients with renal impairment was confirmed in a challenge to avoid the use of nephrotoxic dye and radiation exposure [4].

Patients and methods

The research was performed according to the World Medical Association Declaration of Helsinki. It was approved by the Institutional Review Board of our institution and a written informed consent was obtained from research patients.

This prospective study was conducted during the period from July 2016 to June 2018 in our Al-Zahraa University Hospital on 28 patients 22 (78.5%) men and six (21.5%) women aged from 42 to 73 years with a mean±SD of 57.2±11.2 years. The selected patients presented clinically with stages III and IV Fontaine or IV and V Rutherford and diagnosed by computed tomography angiography as significant infra-popliteal arterial occlusive disease types A, B, and C according to Trans-Atlantic Inter-Society Consensus classification.

The patients underwent balloon angioplasty under duplex guidance for stenotic and occlusive lesions.

A good femoral pulse is obligatory in all patients to exclude the inflow disorders presented at the time of U/S-guided procedure as the inflow has been already treated before by bypass or was now treated in a combined way. We excluded the patients with severe foot infection or gangrene (beyond salvage), acute embolic or thrombotic occlusions, Trans-Atlantic Inter-Society Consensus D, and finally patients not fit generally such as those with heart failure with an ejection fraction of less than 25% or liver cell failures.

All patients were subjected to the following:

(1) History: personal data, risk factors. (a) Complain: rest pain. (b) Minor tissue loss: ulcer, infected wound, and gangrene. (c) Color change: pallor, cyanosis, mottling, and black. (d) Coldness and numbness.
(2) Examination: including general examination and local examination by (a) inspection: color, trophic changes, tissue loss, and gangrene. (b) Palpation: skin temperature, capillary refilling time, arterial pulsation, venous refilling time, and ankle–brachial index.
(3) Laboratory: including complete blood count, liver and kidney functions, blood sugar level, lipid profile, and coagulation profile.
(4) Radiology: color duplex U/S of the arterial system of the affected lower limb. All cases were examined using General Electric (UK) logic 9 machine using linear 7–10 MHz probe in a sterile plastic cover with gel to confirm the diagnostic computed tomography which presented with seven patients in outpatient clinic and the rest of the patients diagnosed by duplex U/S to avoid the hazards of angiography; the length of stenosis or occlusion are measured and the hemodynamic study is recorded preprocedure and postprocedure. The hemodynamic stenosis is detected if the peak systolic velocity (PSV) was more than or equal to 180 cm/s or the PSV velocity ratio was more than or equal to 2.0.

Technique

All duplex examinations were done in the Vascular Department of our university hospital using U/S machine (Logic 9; GE) with a linear 7–10 MHz probe. It was performed by the radiologist in the presence of the vascular surgeon. The probe was introduced in a sterile plastic cover with a covering gel. Unfractionated heparin 5000 IU (Cal-Heparin; Global Pharmaceutical Industries) was directed intravenously to all cases.

The lesion is determined using both B and color modes; the common femoral artery was punctured by the vascular specialist under U/S guide. A 0.014 guide (GW Terumo; Ghalioungui Trading Co.) wire was used for tibial intervention, all lesions were dilated with a pressure of 6–10 atm for 1 min with 2–4 mm balloon diameter (normal diameters to tibial vessels) and the length of the balloon according to the length of each lesion (Balloon Medtronic, Ireland; BM-Egypt).

Balloon diameters and length were selected from a data obtained from duplex measurement of the diseased segment. The agent used to inflate the balloons was normal saline (sono-opaque), which is preferable to increase visibility.

The guidewire is left in position after deflating and withdrawing the balloon; the PSV ratio was measured again. Following removal of the endovascular material, the manual pressure was performed and a compression bandage was placed on the puncture site.

Follow-up

Follow up by duplex U/S is done at 1 week, 1 month, and 6 months for the evaluation of patency which is detected by duplex U/S at the site of the lesion before and after balloon angioplasty, resulting in less than 30% residual stenosis of the original lesion after dilation and PSV ratio of less than 1.5. Technical success is known as patency of the angioplasties segment without distal emboli.

Statistical analysis

The Statistical Package for Social Sciences (SPSS, USA) was used for statistical analysis after collection and coding of the data A P value of less than 0.05 is a level of significance and highly significant at a P value of less than 0.0001.

Results

Patients presented with rest pain in four (14.3%) cases and minor tissue loss in 24 (85.7%) cases and underwent balloon angioplasty of the infra-popliteal lesions under duplex guidance U/S.

There were 10 (35.7%) cases with occlusion of the tibio-peroneal trunk, four (14.3%) cases with single stenotic segment in peroneal artery, and four (14.3%) cases with small occluded segment of anterior tibial artery (ATA), and 10 cases with small stenotic segment in ATA combined with focal stenosis in the mid-SFA (35.7%) (combined balloon angioplasties were done to SFA and ATA lesions).

Technical success was achieved immediately in 26 (92.9%) cases by improvement of PSV at the site lesion before and after balloon angioplasty when resulting in less than 30% residual stenosis of the original lesion after dilation. The PSV ratio is less than 1.5, while one (3.6%) case had technically failed to pass the lesion by different manipulations of the guidewire (tibioperoneal trunk occlusion), and one case complicated with distal embolization and development of pain followed with forefoot gangrene (3.6%) in the tibioperoneal trunk occlusion as in Table 1.

Follow-up was done after 1 week, 1 month, and 6 months postprocedures for 26 patients showing primary patency rate and for all patients after 1 week (92.9%), 24 patients after 1 month (85.7%), and only 22 patients after 6 months (78.6%%) due to restenosis that occur in four patients (two peroneal lesions after 1 month and another two tibioperoneal trunk lesions after 6 months) as in Table 2.

Immediate clinical success to all four (100%) patients with rest pain and clinical improvement in wound healing after 1 month and 6 months in all 22 patients in spite of four (91.7%) restenosis as in Table 3.

Discussion

Duplex U/S with high technology and resolution is considered a unique diagnostic tool in vascular surgery; it is a reliable method for the measurement of diameter and length of stenosis in peripheral arterial disease [5].

Also, the used balloon size can be measured accurately and after balloon dilation, it directly measures the improvement by a change in PSVs [6].

Owing to no exposure to ionic contrast agents, the endovascular guided by duplex U/S is favorable in patients with renal impairment or at high risk of developing nephropathy caused by the contrast [7].

With the endovascular approach, mostly local anesthesia is applied with short-time hospital stay and low rates of morbidity and mortality [8].

The aim of this study was to regain blood flow to relieve the rest pain which was achieved in 100% of studied patients, also to give a chance for the wound to be healed which occurred in 91.7% after 6 months, by infra-popliteal balloon angioplasty under duplex guidance as a new procedure to escape the use of contrast agent, radiation contact, and study the results of its procedure.

The present study demonstrates technical success as well as safety, efficacy, and estimates the primary patency rates and clinical success of infra-popliteal balloon angioplasty for critical limb ischemia under duplex guidance; there is no general or spinal anesthesia required, there are no or fewer surgical wounds, the hospital stay is shorter and with lower complications. Bolia and colleagues showed that the endovascular options for the treatment of critical limb ischemia appears safe with high procedural success (90%), low complications rate (15%), and the mean hospital stay is 5 days without the need to general anesthesia [9].

In this study, immediate technical success was achieved in 92.9%, while 3.6% has technically failed to pass the lesion by different manipulations of guidewire and 3.6% complicated by forefoot gangrene due to distal embolization.

Table 1 Relation between the site of lesion and immediate technical success of the studied group (*N*=28)

	Immediate technical success		
	N		
Site of lesion	Case	Success	%
Tibioperoneal trunk	10	8	80
Peroneal artery	4	4	100
ATA	4	4	100
ATA and SFA	10	10	100
P value	*P*<0.0001, highly significant		

ATA, anterior tibial artery; SFA, superficial femoral artery.

Table 2 Relation between the site of lesion and patency rate of the studied group (*N*=28) after 1 week, 1 month, and 6 months

	Primary patency rate								
	1 week			1 month			6 months		
	N			*N*			*N*		
Site of lesion	Cases	Patency rate	%	Cases	Patency rate	%	Cases	Patency rate	%
Tibio-peroneal trunk	10	8	80	10	8	80	10	6	60
Peroneal artery	4	4	100	4	2	50	4	2	50
ATA	4	4	100	4	4	100	4	4	100
ATA and SFA	10	10	100	10	10	100	10	10	100
P value	*P*<0.0001, highly significant								

ATA, anterior tibial artery; SFA, superficial femoral artery.

Table 3 The clinical success of the studied group (*N*=28)

Complaint	Immediate clinical success		1 month clinical success		6 months clinical success	
	n	%	*n*	%	*n*	%
Rest pain	4	100	4	100	4	100
Wound healing	24	–	22	91.7	22	91.7
P value	*P*<0.0001, highly significant					

One patient has technically failed, one patient was complicated with distal embolization in tibio-peroneal trunk occlusion (tibio-peroneal lesion), and restenosis occurred in four patients (two tibio-peroneal trunk lesions and two peroneal lesions).

Primary patency rate for all patients after 1 week (92.9%), 1 month (85.7%), and only 22 (78.6%) patients after 6 months was due to restenosis occurring in four patients (two patients had tibioperoneal trunk lesions and another two patients had peroneal lesions).

Clinical improvement in wound healing was seen after 1 month and in all 22 patients after 6 months in spite of four restenosis.

Conclusion

The treatment of patients with infra-popliteal lesions using duplex U/S to guide a balloon angioplasty shows accepted results, effective technique, and safe process with major benefits in abolishing the use of contrast in patients at high possibility for developed nephropathy; moreover, there is chance of radiation exposure to patients and the medical staff.

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Conflicts of interest

There are no conflicts of interest.

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