

## Evaluation of Lower Limb Arterial Angioplasty using Doppler Ultrasound in Diabetic Patients

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### Abstract

Duplex scanning considered the imaging modality of choice for detection and follow up of patients suffering from Peripheral arterial disease as it is inexpensive, radiation-free and provides both anatomic and hemodynamic information about the lesion. Lower limb arterial angioplasty is now has the greatest role in management of patients suffering from lower limb ischemia.

**Keywords:** Peripheral arterial disease, Lower limb arterial angioplasty, Duplex scanning.

### 1. Introduction

Peripheral arterial disease (PAD) affects almost 12 % of the general population and is responsible for substantial healthcare costs. PAD primarily results in a decreased functional capacity and deterioration in quality of life and is associated with an increased risk of limb amputation, myocardial infarction, stroke, and death [1].

Two-thirds to three-fourths of patients initially presenting with intermittent claudication (IC) symptoms will remain stable for several years after the initial diagnosis, whereas the remaining one-third to one-fourth will show progressive disease, but only 1–5 % of the PAD population will eventually undergo amputation. Patients suffering from PAD typically present with symptoms of IC or Critical limb ischemia [2]. Patients with CLI are at high risk of major amputation, ranging from 10–40 % at one year after their diagnosis, with mortality approaching 25% [3].

The commonest indication for duplex ultrasound in lower extremity arterial disease is to identify potential percutaneous intervention in patients with intermittent claudication. It establishes the diagnosis, the anatomical site of disease, and can define the severity of a focal stenosis. It can help decide whether to proceed with angiography, and aid the planning of the optimum treatment approach to a lesion. The goals of treatment for patients with CLI (critical limb ischemia) include limb salvage, as well as reduction of major adverse cardiovascular events. In the past decade, endovascular techniques have been increasingly employed for prevention of major amputation among patients with CLI. This endovascular first approach has been accompanied by the development of many new technical approaches for treatment of peripheral arterial disease (PAD) [4].

### 2. Diagnostic criteria of PAD

Patients suffering from PAD typically present with symptoms of IC (intermittent

claudication) or CLI. IC is defined as an intermittent cramping pain during walking caused by an inadequate supply of blood to the musculature of the lower limb. IC typically develops on exertion and is relieved at resting conditions. CLI is the final clinical manifestation of PAD and is typically characterized by either chronic ischemic rest pain and/or ischemic tissue loss of the limb (ulcers or gangrene) attributable to objectively proven arterial occlusive disease [5]. CLI is defined by an ankle systolic pressure of 50 mmHg or less. In case of incompressible arteries at the ankle, a toe systolic pressure of 30 mmHg or less can be used [6]. Resting ABI measurements are to be classified and reported as >1.4 (non-compressible values), 1.0–1.4 (normal), 0.90–0.99 (borderline), and <0.9 (abnormal) according to the Ankle Brachial Index Collaboration [7]. An ABI <0.9 is considered as highly sensitive (95 %) and specific (100 %) for the diagnosis of PAD [8]. Measurements of Toe pressure (critical level <30 mmHg) are suggested in case of diabetic patients with ulcers both for baseline evaluation and for assessment of response to revascularization [9]. The ankle peak systolic velocity is defined as the mean of peak systolic velocity of the anterior tibial and posterior tibial arteries. Normally it is above 75cm/sec, if it is below 25 cm/sec it is an index of critical limb ischemia [10].

### 3. Imaging of PAD

#### 3.1 Doppler imaging of PAD

The Doppler measurements show an increase of velocity up to a maximum near the point of critical stenosis, followed by steady decline down to zero velocity at occlusion. Velocity begins to increase noticeably at about 30% diameter reduction, and then increase rapidly at above 50%. Flow remains substantially unaffected until about 75-80% diameter reductions. After about 85%, the critical point has been exceeded, both velocity and flow drop.

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There are four particular Doppler features of disturbed flow:

- 1- Increased jet velocity.
- 2-Spectral broadening.

3-Simultaneous forward and reverse flow (turbulence).

- 4-Fluctuations of flow velocity with time [11].

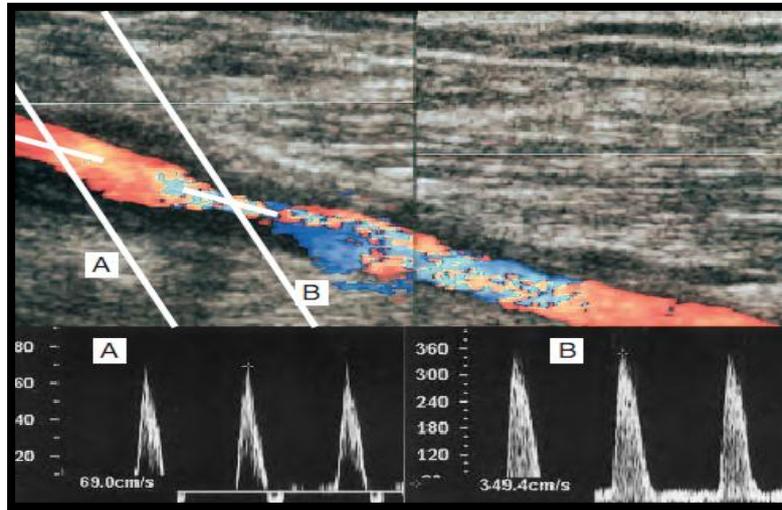


Fig (1) Superficial femoral artery stenosis is assessed using spectral Doppler. A- Measurement of the PSV just proximal to the stenosis. B- Measurement of the PSV across the stenosis indicating severe stenosis [12].

### 3.2 Angioplastic imaging

Multidisciplinary decision-making for treatment must take into account the patient's clinical symptoms, the anticipated life-expectancy, morphological classification of the femoropopliteal atherosclerosis, anatomical challenges, renal failure, contrast allergy, and the availability of vein conduits. In patients with limb-threatening ischemia and a life-expectancy of <2 years or in the absence of a suitable vein conduit, percutaneous transluminal angioplasty is recommended as the first-line treatment regardless of the anatomical extent of disease. Patients with heavily calcified femoropopliteal

lesions and a life-expectancy of >2 years may be first considered for vein bypass surgery [1].

The main steps of angioplasty could be summarized in three steps; how to gain an access to the target vessel, how to cross the lesion and reentry of the main lumen with balloon dilatation or stent placement according to the number, type of lesion, degree and the hemodynamic effect of the lesion. The choice between antegrade and contralateral retrograde access will depend on body habitus and the presence of concomitant inflow iliac disease. Any significant inflow disease must be treated before treating SFA and popliteal lesions [13].



Fig (2) Roadmap technique in inserting distal access; the right one: Needle headed the popliteal artery, the left; angiography did after the popliteal sheath inserted [14].



**Fig (3)** Double balloon technique illustrating two different sized balloon one from different access (one proximal and the other distal) inflated at the same time to crush the atherosclerotic plaque in-between [14].

#### 4. Aim of the study

Doppler assessment for lower limb angioplasty in diabetic patients with peripheral arterial diseases.

#### 5. Patients and methods

##### 5.1 Patient selection

This study was conducted at the Radiology department– National Institute of Diabetes – Cairo Governorate – Ministry of health in the time frame from April 2016 till April 2018, included 25 clinically diagnosed PAD patients who referred from Vascular Department and outpatient clinics. They were 11 females and 14 males. All patients have done Doppler study pre and post angioplasty.

##### Patient inclusion criteria

- 1- Incapacitating claudication interfering with the work or life style, severe claudication, cannot complete treadmill exercise and ankle pressure after exercise was less than 50 mmHg.
- 2-Critical limb ischemic with rest pain, resting ankle pressure was less than 40 mmHg, minor tissue loss, non-healing ulcer or focal gangrene and major tissue loss.
- 3-Patients with lesions, A (single stenosis<1cm in length), B [Multiple focal (<1 cm) stenoses of the tibial or peroneal arteries (including up to 2 focal stenoses at the tibial trifurcation) and short tibial or peroneal stenoses in conjunction with femoropopliteal disease], C (longer stenoses 1-4 cm and occlusions 1-2 cm as well as extensive stenoses at the tibial trifurcation and D (occlusions longer than 2 cm and diffusely diseased tibial vessels).

##### Patient exclusion criteria

- 1- Proximal aorto-iliac disease.
- 2-Amputated foot or leg below knee.
- 3-Known intolerance to study medications or contrast agents.

##### 5.2 Technique

All of the 25 patients had lower limb arterial Doppler study in National Diabetic Institute. The patients were scheduled for duplex scanning before intervention, immediately 1 to 7 days after intervention. At first the patient lie in supine position then arterial tree is scanned from CFA down to distal tibial arteries or by reverse.

Color and spectral Doppler scan were done by the same operator .A day prior to the angioplasty all subjects were examined with B-mode, color and duplex US using a 7 - 12-MHz linear array transducer for infra-inguinal arterial assessment, sometimes a 2 - 5-MHz convex array transducer used for obese patients and for assessment of the distal part of the superficial femoral artery in the Hunter area in some cases. We detect the following:

- 1- Anatomical site, occlusion or stenosis (single or multiple).
- 2-Ankle peak systolic velocity(APSv)
- 3-Ankle-brachial index (ABI).
- 4-Toe brachial index (TBI).

The patients were admitted one day before or on the day of the procedure, a loading dose of clopidogrel 300 mg was given the night of the procedure, both groins were prepared using an antiseptic solution (povidin). All equipment were checked including monitors, connections, light system, catheters, wires, sheaths, different sized balloons, stents and emergency kits. The

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patient lies in the supine position and a local anesthetic is given (xylocaine 2%). We used an ipsilateral or contralateral antegrade femoral access following anatomical localization of the CFA (common femoral artery) in all patients.

##### 5.3 Data analysis and Statistical data display

To obtain diagnostic values, we shall measure sensitivity, specificity, positive and negative predictive values of the analyzed data using commercially available PC-based software package (SPSS).

##### 6. Results

The results recorded in table (1) shows that the study included 25 patients, 14 males and 11 females, where males represented 56% and females represented 44%.

Table (2) shows risk factors for peripheral arterial disease as following: Diabetic 25 patients represents 100%, HTN 16 patients represents 64%, Cardiac 11 patients represents

44%, CVS 4 patients represents 16% and Smokers 13 patients represents 52%.

Table (3) shows Clinical presentation of all patients as following: Claudication 8 patients represents 32%, rest pain 2 patients represents 8% and ischemic ulcer 15 patients represents 60%.

Table (4) shows type of lesion as following: Stenosis 11 patients represents 44%, occlusion 10 patients represents 40% and Mixed 4 patients represents 16%.

Table (5) shows comparison between pre and post procedural status regarding the ankle peak systolic velocity (APSV), the ankle brachial index (ABI) and toe brachial index (TBI).

Table (6) shows the overall result of the study: twenty five patients underwent an infrainguinal angioplasty, twenty three of them had a successful procedure (92%) and two had a partial successful procedure (8%).

**Table (1)** Distribution of patients according to sex.

	Number	Percentage
<b>Males</b>	14	56%
<b>Females</b>	11	44%

**Table (2)** Risk factors of lower limb ischemia

	Number	Percentage
<b>Diabetic</b>	25	100%
<b>HTN</b>	16	64%
<b>Cardiac</b>	11	44%
<b>CVS</b>	4	16%
<b>Smoker</b>	13	52%

**Table (3)** Clinical presentation of all patients

	Number	Percentage
<b>Claudication</b>	8	32 %
<b>Rest pain</b>	2	8 %
<b>Ulcers</b>	15	60 %

**Table (4)** Type of lesion

	Number	Percentage
<b>Stenosis</b>	11	44%
<b>Occlusion</b>	10	40%
<b>Mixed</b>	4	16%

**Table (5)** Comparison between pre and post procedural status regarding the ankle peak systolic velocity (APSV), the ankle brachial index (ABI) and toe brachial index (TBI)

	Mean	Standard Deviation	Median	Minimum	Maximum	P value
<b>ABI pre</b>	0.585	0.11	0.60	0.40	0.72	<0.01
<b>ABI</b>	0.848	0.05	0.85	0.80	0.90	
<b>APSV</b>	22.85	12.39	22.0	7.00	50.00	<0.002
<b>APSV</b>	46.92	21.65	40.0	22.00	94.00	
<b>TBI pre</b>	0.557	0.05	0.55	0.50	0.68	<0.01
<b>TBI</b>	0.671	0.04	0.67	0.59	0.74	

**Table (6)** The overall result of the study

	Count	%	P value
<b>Success</b>	23	92 %	
<b>Partial success</b>	2	8 %	< 0.001

## 7. Discussion

Peripheral arterial disease affects almost 12 % of the general population and is responsible for substantial healthcare costs. PAD primarily results in a decreased functional capacity and deterioration in quality of life and is associated with an increased risk of limb amputation, myocardial infarction, stroke, and death [1].

Percutaneous angioplasty and stenting of the superficial femoral and popliteal artery is the proposed treatment of choice in the majority of patients with IC or CLI on the basis of its reduced perioperative morbidity and mortality, and reduced in-hospital stay [15].

To date, several new technologies, such as bare metal stents made from nitinol, drug-eluting stents (DES), covered stents, and drug-coated balloons (DCB), have emerged with the aim to improve long-term patency outcomes following angioplasty of the femoral and popliteal arteries [16].

Over the last three decades, color duplex ultrasonography has gained acceptance and established itself as a fundamental component of diagnostic evaluation and management of arterial disease. Duplex technology is suitable for directing endovascular interventions and revascularization, permitting not only the identification of disease, but also assessment of its response to intervention [17].

In the current study, we used color duplex ultrasonography as a diagnostic study for assessment of the pre interventional status of the lower limb arterial tree and detection of the site, type, degree and the hemodynamic effect of any stenosis or occlusion.

Among our study, we have 25 patients unlike Cho Set al., 2006, Tan M et al., 2010 [18]

and Zou J 2012 [19]. 14 patients are males (56%) and 11 patients are females (44%).

All the patients are diabetics (100%) the same as Tan M et al [18], (2010), 16 patients are hypertensive (64%), eleven patients are cardiac (44%), 4 patients with history of cerebrovascular stroke (16%) and 13 patients are smoker (52%).

Fifteen of them presented by non-healing ulcers (60%) in agreement with Kudo T et al (2005) [20] and not similar to Ghoneim B et al (2014) [21], and Lida et al (2012) [22].

Eight patients presented with incapacitating intermittent claudication (32%) while two patients presented with rest pain (8 %) with disagreement to Ghoneim B et al (2014) [21], Lida et al (2012) [22], Tan M et al (2010) [18] which is not similar to Kudo et al (2005) [20].

Post interventional color duplex ultrasound was done to the twenty five patients for assessment of the technical success of the procedure by assessing the ABI, APSV, TBI and the percentage of remaining stenosis if present.

We found that there is sufficient elevation of above parameter after angioplasty.

The overall complete technical success in our study was 92% with two partial success patient (8%), while the technical success for (Ghoneim B et al., 2014[21]) was 96.8%, (Dosluoglu et al., 2009[23]) was 97% and (Lida et al., 2012[22]) was 94%.

As regards these two patients with partial success, the pre interventional duplex assessment of these patients revealed total occlusion of the distal third of the SFA and the supragenicular segment of the popliteal artery, they underwent balloon dilatation of the diseased segments but the post procedural duplex scan revealed a significant stenosis

resulting in about 57% and 60% diameter reduction.

### 8. Conclusion

To sum up the endovascular approach is recommended as the first-line treatment in the majority of lesions of the superficial femoral and/or popliteal arteries. Recanalization can be achieved using either intraluminal or subintimal techniques. In more challenging cases, more complex techniques (i.e., SAFARI technique) and advanced devices (re-entry devices, atherectomy catheters) may be required to achieve crossing of the occluded segment. However, preservation of long-term patency remains a challenge, mainly due to progressive neointimal hyperplasia and vascular restenosis.

The uses of Duplex ultrasound is considered the best imaging modality for early diagnosis and follow up of patients suffering from lower limb ischemia as it is reliable, inexpensive, radiation-free and provides both anatomic and hemodynamic information about the degree of any lesion.

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