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Ultrasonography for the optimal selection of patients suitable for single session arteriography and endovascular revascularization in severe peripheral artery disease

Mihail Spînu[1,2]*, Rareș Ioan Gligor[1]*, Maria Olinic[1,2], Călin Homorodean[1,2], Mihai Claudiu Ober[2], Dan Tătaru[1,2], Bogdan Săbiescu[2], Laurențiu Onea[1], Alexandru Achim[1], Leontin Lazăr[1], Dan Mircea Olinic[1,2]

** the authors share the first authorship*

[1]1st Internal Medicine Department, "Iuliu Hatieganu" University of Medicine and Pharmacy, [2]Interventional Cardiology Department, Emergency County Hospital, Cluj-Napoca, Romania

Abstract

Aims: Peripheral artery disease (PAD) represents a high burden on the healthcare and social assistance systems. Revascularization reduces symptoms, amputation rate and increases the chances of social reintegration. Our aim was to evaluate the benefits of vascular duplex ultrasonography (DUS) for identifying patients suitable for direct percutaneous transluminal angioplasty (PTA) without the need for a prior angiography. **Material and methods**: We included in the study 251 patients with PAD evaluated by DUS. Depending on the DUS findings the patients were split in two groups: group I, 143 patients (57%), in which selective angiography and direct PTA was performed and group 2, 108 patients (43%), in which invasive arteriography was considered necessary prior to a decision for revascularization.

Results: The first group had a similar success rate (92.3% vs. 86.1%; p=0.111), but with a reduction in radioscopy time (minutes) (17.2 vs. 20.8; p=0.013), iodine contrast volume (ml) (190 vs. 227.5; p<0.001), days of hospitalization (4 vs. 7; p<0.001) and by 44.75% (p<0.001) of hospitalization costs when compared to the second group. **Conclusions**: DUS allows the optimal selection of patients who can benefit from direct PTA. This strategy has a high success rate, with a significant decrease in radioscopy exposure time, volume of iodine contrast needed, duration and hospitalization costs, when compared to arteriography and PTA in two different sessions**.**

Keywords: peripheral artery disease; duplex ultrasonography; percutaneous transluminal angioplasty; angiography

Introduction

Peripheral artery disease (PAD) of the lower extremity is a medical condition caused by reduction of the blood flow to the limbs due to incomplete (stenosis) or complete (occlusion) narrowing of the arterial lumen. In the vast majority of the cases the main cause of PAD is atherosclerosis. It is usually asymptomatic in the early stages (Fontaine stage I) but becomes symptomatic as the atherosclerotic burden increases over time, with symptoms like intermittent claudication (as seen in Fontaine stage II patients), rest pain (Fontaine stage III) or arterial ulcers and gangrene (Fontaine stage IV). The two latter stages are usually regarded as critical limb ischemia (CLI) [1].

On Globe, 236 million people were living with PAD in 2015, with a higher prevalence in high-income countries, but with a majority of PAD patients living in the

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Corresponding author: Maria Olinic
1st Internal Medicine Department,
"Iuliu Hatieganu" University of
Medicine and Pharmacy
3-5 Clinicilor Street,
400006, Cluj-Napoca, Romania
Phone: +40 0745 522 781
E-mail: maria_olinic@yahoo.com

low and middle-income countries [2]. From 2000 to 2015 the prevalence of PAD increased by 45% globally, the European Union (EU) reporting a 3.4% PAD prevalence [3,4], while in the United States the prevalence of CLI was 1.3%, accounting for 11% of the PAD patients [5].

While conservative medical treatment is indicated in the early stages of the PAD (especially PAD Fontaine stage II), endovascular - percutaneous transluminal angioplasty (PTA) or surgical revascularization is usually considered in CLI and in patients with stage II PAD with severe symptoms that affects the quality of life despite maximal drug therapy [1,6]. Vascular imaging is an essential step following the diagnosis of PAD. It provides information about the extent of the disease, the arterial anatomy and guides future therapeutic interventions, both PTA and surgical procedures. In order to plan a successful revascularization, the chosen imaging modality should be able to localize the target lesion and to evaluate its extension, and to assess the involvement of both proximal and distal segments of the arterial bed [7,8].

At this moment, digital subtraction angiography (DSA) is considered the gold standard for lower limb arterial anatomy and disease extent assessment [1,6]. However, it is an invasive procedure with a rate of major complication ranging from 2.7 to 2.9% [9], depending on the vascular access site, the atherosclerotic burden of the arteries and the experience of the physician. Moreover, the procedure involves exposure to radiation and adverse reaction to contrast media (allergic reactions and contrast induced nephropathy – CIN) [9,10], and therefore should be used for cases where noninvasive imaging is insufficient [11].

Vascular duplex ultrasonography (DUS) is the primary imaging technique in PAD both for the initial assessment of the disease and for post treatment follow-up examinations, due to its noninvasive nature, the low cost and the lower risks. However, DUS has anatomical limitations (obesity, gas interposition, calcifications), is operator dependent and time consuming, but in the hands of an experienced examiner, it has a good diagnostic accuracy when compared to DSA [1,7]. DUS has a sensitivity of 95-90% and a specificity of >90% for aortoiliac lesions when compared to DSA [12] and a sensitivity of 88% and a specificity of 95% for superficial femoral artery (SFA) and popliteal artery lesions [13]. The peak velocity ratio assessed by DUS has a strong correlation with the percent diameter reduction seen in DSA [14].

Even though DUS plays an important role in PAD management planning, there is a lack of studies regarding the benefits of a DUS guided endovascular revascularization [15,16]. The aim of this study is to assess the benefit of DUS for the selection of severe PAD patients suitable for a single session direct PTA, without the need for a prior session invasive diagnostic procedure.

Material and methods

Study population

This study retrospectively analyzes the global results of all DUS guided PTAs performed for CLI and severely symptomatic stage IIB Fontaine PAD patients, evaluated in a single tertiary center from Romania (Cluj County Emergency Hospital, Department of Interventional Cardiology), over a period of one year (01 August 2022– 31 July 2023).

Informed consent for the interventional procedure was obtained from all subjects prior to the procedure. Due to the retrospective nature of this study, informed consent was waived. Clinical data and angiographic examinations were stored in the hospital database and in a dedicated catheterization laboratory database.

Patients who underwent in the same procedure, in addition to peripheral arteriography, another invasive evaluation of other territories (coronary, carotid, etc.), were excluded, due to erroneous interferences in terms of contrast media volume, possible CIN, radioscopy time and dose and total cost of the procedure.

Arterial hypertension was defined as known or newly diagnosed blood pressure values above 140/90 mmHg [17]. Diabetes mellitus was defined as known or newly diagnosed, based on the following criteria: fasting plasma glucose of ≥126 mg/dL (7.0 mmol/L), plasma glucose after 2-h oral glucose tolerance test (OGTT) ≥200 mg/dL (11.1 mmol/L), HbA1c ≥6.5% (48 mmol/mol) or a random plasma glucose ≥200 mg/dL (11.1 mmol/L) along with symptoms of hyperglycemia [18]. Dyslipidemia was defined as low-density lipoprotein (LDL) cholesterol >130 mg/dL and/or triglycerides >150 mg/dL [19,20]. Smoking habit was defined by active smoker or recently stopped (six months or less prior to the procedure). Chronic kidney disease (CKD) was defined as abnormalities of kidney structure or function, present for ≥3 months, with a glomerular filtration rate <60 mL/min/1.73 m^2 and/or the presence of markers specific for kidney damage, such as persistent albuminuria (>30 mg/day), urine sediment abnormalities, electrolyte and other abnormalities due to a tubular disorder, structural abnormalities detected by either histology or imaging or a history of kidney transplant, according to KDIGO-CKD guidelines [21]. End stage renal disease was defined as a reduced glomerular filtration rate <15 mL/min/1.73 m^2 [22]. CIN was defined as either a 25% increase in serum creatinine from baseline or a 0.5 mg/dL increase in absolute serum creatinine value within 48-72 hours after

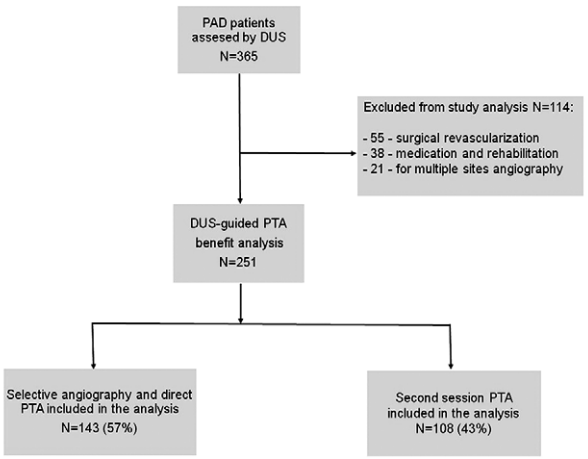


Fig 1. Flowchart of patients' selection.

intravenous contrast administration [23,24]. Successful revascularization was defined as recanalization achieving ≥ 70 % patency, with no evidence of embolization, recoiling or dissection in the treated vessel [25].

All patients underwent an extensive DUS assessment one day prior to the procedure, which provided diagnostic information on the entire vascular bed: site(s), type (atherosclerosis, dissection, thrombosis) and severity of arterial lesions and, respectively, on the potential arterial access site for PTA. DUS and PTAs were performed by 6 interventional cardiologists, with a certification in peripheral vascular DUS on a Philips Affiniti 30 ultrasound machine using a linear probe and the predefined settings for lower limb arteries (Philips Medical Systems International B.V., Best, Netherlands) and on Siemens Artis Zee angiograph (Siemens Healthineers, Erlangen, Germany).

Based on DUS results, patients were divided into two categories: those who could undergo direct PTA (for whom DUS provided enough data in order to select the optimal PTA strategy) – the first group, and the category of patients in whom DUS diagnostic information was not detailed enough to allow the direct decision for PTA, therefore needing an invasive arteriography in a first session, prior to a decision for revascularization – second group. The flowchart of the study is detailed in figure 1.

For the purpose of our study, in order to quantify the benefit of DUS guided PTA, we compared all clinical, procedural and cost data between the first group – direct single session arteriography and PTA and the group of patients with PTA performed in a second session, after a first session diagnostic arteriography.

We followed the general demographic data: sex, age, risk factors, diagnosis at admission; procedural data regarding the location of the lesions, PTA strategy, procedural outcome, complications and amputation rate. Of primary interest, we tracked and compared the difference between the two groups regarding radioscopy time, the amount of contrast media used, the duration of hospitalization and the change in total hospitalization costs between the two approaches. Patients that underwent rotational atherectomy were excluded from the cost analysis given the higher cost of the procedure and unequal distribution between groups.

Statistical Analysis

Statistical analysis was performed in SPSS 29.0 (IBM Corporation, Armonk, New York, USA).

Categorical variables were expressed as absolute value and frequencies and compared with Chi square test or Fischer exact test when appropriate. Continuous variables were assessed for normal distribution using Kolmogorov-Smirnov Test. Variables that followed a normal distribution were expressed as mean with standard deviation (SD) and were compared using Student's t-test. Continuous variables without normal distribution were expressed as median with inter-quartile range (IQR) and differences between groups were assessed using Mann-Whitney U test. A two-sided p-value of 0.05 was considered significant for the above-mentioned tests.

Results

Data regarding the demographics and comorbidities of the patients within groups as well as the stage of PAD are shown in Table I.

Data about lesion site, treatment modalities, radiation dose, time of radioscopy and the volume of iodine contrast used in each group can be found in Table II. For the first group of patients, DUS provided excellent data regarding all arterial bed, with correct lesion evaluation.

Differences between approaches regarding procedural outcomes, complications rate, amputations rate and length of hospital stay are found in Table III. The single step approach led to a 44.75% decrease in the median hospitalization costs when compared to the two step approach ($p<0.001$).

Regarding gender differences, female patients were older (71 (64.5-78) vs. 68.5 (62-76), p=0.047), had higher rates of end stage renal disease (8.5% vs. 2.2%, p=0.023) and CLI (85.9% vs. 74.4%, p=0.049). No difference was found between sexes regarding procedural outcomes and technique, except for a slight increase in radioscopy time in female patients (21.5 (12.6-29.5) vs. 18.0 (10.7-26.6), p=0.049).

Discussion

Out of the total number of patients diagnosed with PAD over the course of one year included in this study,

Table I. Demographic characteristics, comorbidities and PAD stage differences between single session arteriography and PTA group (Group 1) and two sessions arteriography and PTA group (Group 2).

Category	Group 1 (n=143)	Group 2 (n=108)	Total (n=251)	p value
Demographics				
Age (years)	69 (61-76)	70 (62-77)	70 (62-77)	ns
Female	44 (30.8)	27 (25.0)	71 (28.3)	ns
Comorbidities				
Coronary artery disease	22 (15.4)	20 (18.5)	42 (16.7)	ns
Smoking	105 (73.4)	83 (76.8)	188 (74.9)	ns
Diabetes mellitus	59 (41.3)	49 (45.4)	108 (43)	ns
Arterial hypertension	89 (62.2)	81 (75)	170 (67.7)	**0.032**
Dyslipidemia	80 (55.9)	62 (57.4)	142 (56.6)	ns
Chronic kidney disease	34 (23.8)	13 (12)	47 (18.7)	**0.018**
End stage renal disease	9 (6.3)	1 (0.9)	10 (4)	**0.031**
PAD stage				
Intermittent claudication	42 (29.4)	14 (13)	56 (22.3)	**0.002**
CLI	101 (70.6)	94 (87)	195 (77.7)	

Data are expressed as number (%) or as median with IQR for continuous variables

Table II. Anatomical and procedural characteristics differences between single session arteriography and the PTA group (Group 1) and two sessions arteriography and the PTA group (Group 2).

Category	Group 1 (n=143)	Group 2 (n=108)	Total (n=251)	p value
Level of angioplasty				
Aortoiliac	30 (21)	10 (9.3)	40 (15.9)	**0.012**
Femoropopliteal	53 (37)	55 (50.9)	108 (43.0)	**0.028**
BTK	20 (14)	10 (9.3)	30 (12.0)	ns
Combined	40 (28)	33 (30.6)	73 (29.1)	ns
Aortoiliac & Femoropopliteal	8 (5.6)	1 (0.9)	9 (3.6)	ns
Femoropopliteal & BTK	32 (22.4)	32 (29.6)	64 (25.5)	ns
Angioplasty technique				
Balloon angioplasty	58 (40.6)	46 (42.6)	104 (41.4)	ns
Stent angioplasty	19 (13.3)	6 (5.6)	25 (10.0)	**0.043**
Balloon & Stent	60 (42.0)	44 (40.7)	104 (41.4)	ns
Rotational atherectomy	0 (0)	2 (1.9)	2 (0.8)	ns
Radioscopy time (minutes)	17.2 (9.6-26.5)	20.8 (13.1-30.4)	19.2 (11-27.7)	**0.013**
Dose-area product (μGy/m^2)	1728 (1002-4909)	1877 (1091-4238)	1802 (1064-4675)	ns
Iodine contrast media volume (ml)	95 (75-115)	113.7 (98.5-141.9)	102.5 (85-125)	**<0.001**

Data are expressed as number (%) or as median with IQR for continuous variables

in 39.2% of cases DUS findings were sufficient for establishing the correct diagnosis, by identifying the culprit lesions (type and length) and correctly describing the entire arterial bed. Based on these findings, we were able to properly select the optimal PTA strategy – vascular access site (brachial or femoral) and direction (antegrade or retrograde), as well as the patient position on the operating table. Because 87% of the patients in the second group were intense symptomatic CLI patients, the decision of performing invasive diagnostic arteriography over the non-invasive Computed Tomography angiography (CT angiography) was made both for the better quality vascular bed analysis [1,6], and for the quicker way of obtaining high performance imaging, greatly needed for the selection of revascularization method. For this latter group of patients, PTA was also the main revascularization method, raising the percentage of total PTAs to 74.5%, similar to other high-volume vascular centers [25].

The use of DUS as a sole assessment tool prior to angiography and PTA in a single procedure was found to be

Table III. Outcome differences between single session arteriography and the PTA group (Group 1) and two sessions arteriography and the PTA group (Group 2)

Category	Group 1 (n=143)	Group 2 (n=108)	Total (n=251)	p value
Rate of success	132 (92.3)	93 (86.1)	225 (89.6)	ns
Postprocedural events				
Contrast nephropathy	14 (9.8)	17 (15.7)	31 (12.3)	**0.045**
Access site complications	0 (0)	1 (0.92)	1 (0.39)	ns
Rate of amputations				
Total	11 (7.7)	27 (25)	38 (15.2)	**0.002**
Minor amputations	9 (6.3)	21 (19.4)	30 (12)	**0.009**
Major amputations	2 (1.4)	6 (5.6)	8 (3.2)	ns
Hospitalization duration				
Length of hospital stay (days)	4 (2-6)	7 (5-14)	5 (3-10)	**<0.001**

Data are expressed as number (%) or as median with IQR for continuous variables

a cost-effective strategy, significantly reducing the median total cost of hospitalization by more than 44% when compared to the two-step approach and the median duration of hospitalization from 7 to 4 days ($p<0.001$). No significant difference was found regarding the PTA success rate between the two approaches (92.3% vs 86.1%, $p=0.111$), thus proving the non-inferiority of the single step procedure. Similar success rate of revascularization (90.3%) following PTAs were reported in a prospective multi-center observational study conducted by Schulte at al that followed over 1500 patients [25,26].

Furthermore, the single step approach was associated with a significant decrease in iodine contrast media usage, that translated into a lower rate of CIN among these patients, despite a higher prevalence of patients diagnosed with CKD and end-stage kidney disease in this group. Median radioscopy time was reduced using the single step approach from 20.8 to 17.2 minutes ($p=0.013$); however, no statistical difference was found regarding the total ionizing radiation dose estimated by the dose-area product (DAP) between approaches (1728 vs 1877 $\mu Gy/m^2$).

Regarding the stage of PAD there was a significant difference between the two groups namely a higher proportion of patients with CLI being treated with a two-step approach. A possible explanation for this distribution could be the higher atherosclerotic burden in these patients and multiple level stenosis, making a vascular DUS evaluation impracticable, therefore requiring an extensive assessment of the peripheral arteries by a prior arteriography (especially important for the assessment of BTK lesions), followed by a decision within the vascular team regarding the best therapeutic option for such patients. Furthermore, there was a significant difference regarding the rate of total and minor amputations between groups, with more amputations being seen in the second group. Major amputations followed a similar trend; however, no significant difference was found. These findings could also be explained by the higher number of patients with CLI found in the second group.

No significant difference between groups were found regarding gender, age, risk factors and comorbidities, except arterial hypertension and chronic kidney disease. Among patients with kidney disease 78% (n=34) and 90% (n=9) of those with end stage kidney disease, underwent a single step procedure, demonstrating a higher preference for this approach, given the higher risk of CIN among these patients [23]. Hence, a single step procedure should be considered in patients with impaired renal function undergoing PTA, when other techniques, such as carbon dioxide angiography, are not available or they are contraindicated (patients undergoing combined cerebral or coronary angiography, known right to left shunts, patients with chronic obstructive pulmonary disease or pulmonary hypertension) [27,28].

A higher number of patients with aortoiliac lesions were treated using a DUS-guided single session arteriography and PTA, while more patients with femoropopliteal lesions were treated with a two sessions approach. These results can, at least partially, be explained by the anatomical differences between the two sites when it comes to their accessibility for ultrasound assessment: femoral superficial artery has a large profound segment, making it difficult to evaluate, especially in obese patients. No differences in distribution were found for BTK and combined lesions.

A separate comparison between males and females, regarding demographic characteristics, comorbidities, PAD stage, technical characteristics and procedural outcome was done, showing that female patients were older, had higher rates of end stage renal disease and CLI. No difference was found between sexes regarding proce-

dural outcomes and technique, with the exception of a slight increase in radioscopy time in female patients. Our results differ from other studies, which reported higher rates of death, myocardial infarction, major amputation, complex lesions, procedural complications, and limb-specific adverse events in women [29].

Given the fact that the incidence of PAD is increasing and that a larger number of patients are referred to specialized centers for PTA, DUS can play a greater role not only in the diagnosis of PAD but also in the assessment of disease extension, thus facilitating the performing of arteriography and PTA in a single session. We demonstrate in this study that DUS guided single session arteriography and PTA can be performed with a similar success rate compared to the two sessions approach, while reducing the cost and duration of hospitalization and certain complications, such as CIN. However, there are still several limitations for DUS as a sole assessment tool prior to PTA: on one hand anatomical difficulties (mediocalcinosis or severe obesity) and, on the other, the fact that DUS is operator dependent and time consuming. Extensive vascular lesions and procedures deemed by the performing physician to have a high risk of failure might require a two-step approach, since such cases are best managed within a vascular team (cardiologists and vascular surgeons) in order to choose the optimal treatment strategy [30-32].

To our knowledge, this is the first study that evaluates the cost-effectiveness of a DUS assessment followed by arteriography and PTA in the same session, hence no comparison can be made with other studies. Further research is required in order to assess the feasibility of this approach in different subgroups of patients, especially patients with advanced PAD and multiple sites lesions, and to determine the role that other non-invasive imaging techniques, including CT angiography and magnetic resonance imaging, play in choosing one strategy or another. Clinical follow-up of our patients is beyond the purpose of our study.

Limits of the study - being an observational, retrospective, single-center study, with a limited sample size, our results should be interpreted with caution and considered hypothesis generating.

Conclusions

Using DUS by experienced operators, the management of patients with PAD, especially CLI, can be greatly improved, by ensuring a high-quality selection of patients who can benefit from arteriography and PTA in a single session. This method, which is similar to coronary interventions, offers a high rate of therapeutic success, faster improvement of symptoms, a low rate of complications, but with a significant decrease in the radioscopy time, use of contrast media, hospitalization period, as well as the procedural and total cost of hospitalization, compared to the classic procedure of endovascular revascularization – arteriography in one session and PTA in a second one.

Conflict of interest: none

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