

A Prospective Study on Patients with Peripheral Chronic Limb Ischemia: Assessment of Pedal Acceleration Time Pre and Post Revascularization

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ABSTRACT

Background: Chronic Limb Ischemia (CLI) is a severe form of peripheral arterial disease that often requires revascularization to restore blood flow and prevent limb loss. Pedal Acceleration Time (PAT) is a non-invasive ultrasound measure of distal perfusion and may offer a reliable method to assess treatment response.

Objective: To provide a better, non-invasive diagnostic and surveillance method, especially to vulnerable groups with chronic lower limb threatening ischemia (CLTI).

Patients and Methods: This prospective cross-sectional study was carried out on 41 patients aged above 18 years old with peripheral chronic limb ischemia presenting with rest pain or tissue loss. All patients were subjected to complete history taking, general, peripheral arterial, neurological examinations, laboratory [CBC, coagulation profile and kidney function tests] and diagnostic investigations. Duplex ultrasound measurements of Pedal acceleration time (PAT) of the lateral plantar artery.

Results: High significant ($P < 0.001$) correlation between PAT class and revascularization in patients with ulcer healing. No significant ($P = 0.452$) correlation between PAT class after revascularization and ABI in patients with ulcer healing. No significant ($P = 0.223$) correlation between PAT class before revascularization and ABI in all studied patients.

Conclusions: This study found that PAT represents a reliable diagnostic and prognostic tool for CLTI, particularly in populations where traditional assessments fail. Its ability to detect successful intervention and predict wound healing makes it a strong candidate for incorporation into vascular assessment protocols. However, further large-scale, multicenter studies are needed before it can be adopted as a standard of care.

Keywords: Peripheral Chronic Limb Ischemia, Pedal Acceleration Time, Pre and Post Revascularization, Ankle Brachial Index.

INTRODUCTION

Narrowing and obstruction of the antegrade flow of major systemic arteries other than the cerebral and coronary arteries is known as peripheral arterial disease (PAD) or peripheral vascular disease (PVD) ⁽¹⁾.

Numerous non-atherosclerotic factors, including as vasculitis, dysplastic syndromes, degenerative diseases, thrombosis, and thromboembolism, may contribute to PAD. However, atherosclerosis is by far the most prevalent cause. This results in a variety of clinical symptoms and is most often seen in the lower limbs. Even in clinically silent forms, it is a significant contributor to increased morbidity and death, even though the majority of cases are asymptomatic ⁽²⁾. "Poor peripheral circulation" is the term used to describe the reduced lower extremity arterial perfusion seen in patients with PAD. Atherosclerotic plaques often cause PAD by narrowing the arterial flow lumen, which limits blood flow to the distal extremities. Because the leg muscles temporarily ischemia during effort, reduced blood supply might result in thigh or calf discomfort during walking. Intermittent claudication (IC) is the term used to describe walking discomfort caused by PAD. Many mild PAD patients either don't have any symptoms at all or have unusual complaints that don't quite fit the criteria of claudication. Emergent intervention may be required for more advanced types that manifest as limb-threatening blood flow compromise ⁽³⁾. Standard techniques for evaluating lower limb arterial perfusion include the Ankle Brachial

Index (ABI) and the Toe-Brachial Index (TBI). Nonetheless, published research indicates that TBIs and ABIs may be unachievable in some people or inaccurate in patients with diabetes and/or non-compressible arteries. Noninvasive duplex ultrasonography DUS has not been used to examine the pedal arteries in a satisfactory manner ⁽⁴⁾.

For all patients with suspected PAD, duplex ultrasonography (DUS) has proven a crucial diagnostic technique. Resistance index and peak systolic velocity are two examples of spectral waveform measures that may be obtained during a DUS scan. These metrics have been validated and are often used in clinical practice to evaluate blood flow and offer anatomic features ⁽⁵⁾.

The pedal acceleration time (PAT) is a straightforward, noninvasive procedure that can be quickly completed at the patient's bedside and in settings that might benefit from quick data collection, such as emergency, operating, and angiographic rooms, using pulsed-Doppler analysis of the lateral plantar artery ⁽⁶⁾.

The assessment of occlusive arterial disease has made use of acceleration time. It has been discovered that systolic acceleration is more accurate than velocity alone in forecasting flow and diameter decrease ⁽⁷⁾.

Accurate information about the severity of PAD cannot be obtained from patients with non-compressible ankle pressures, unavailable transcutaneous oxygen pressure (TcPO₂), or toe pressures. The sensitivity of ankle-brachial and toe-brachial indices in identifying

arterial occlusive disease is poor, particularly in individuals with diabetes. Arterial stiffness and medial wall calcifications are to blame for this. The next best test for predicting wound healing has been proposed to be TcPO₂ ⁽⁸⁾. However, it may be challenging to measure TcPO₂ directly in patients with large foot wounds and/or edema, and the results might be inaccurate. Another method for determining perfusion is indocyanine green angiography (ICGA), however it is intrusive, has subjective findings, is expensive, and is not generally accessible.

On the other hand, PAT uses direct duplex imaging of the pedal vasculature to offer physiological data on the hemodynamics of pedal flow in real time. Its accuracy and compatibility with other conventional diagnostic techniques have been questioned. However, this method may be used with common arterial duplex imaging, which is accessible in the majority of vascular labs, and recent research has shown that it is reliable for evaluating PAD patients with or without diabetes ⁽⁶⁾.

Therefore, the purpose of this research was to evaluate pedal acceleration time before and after revascularization, evaluate the relationship with ABI, and determine if wound healing after revascularization could be predicted. An improved, non-invasive diagnosis and monitoring strategy for susceptible individuals with chronic lower limb threatening ischemia (CLTI) at Suez Canal University Hospitals was the goal of this investigation.

PATIENTS AND METHODS

This prospective cross-sectional study was carried out on 41 patients aged above 18 years old with peripheral chronic limb ischemia presenting with rest pain or tissue loss.

Ethical considerations:

The study was done after approval from Research Ethics Committee, Head of Vascular Surgery Unit, Chief of Surgery Department, Chief of Clinical Department and Ethics Committee, Suez Canal University Hospitals, Ismailia, Egypt. An informed written consent was obtained from the patient. The Helsinki Declaration was followed throughout the study's conduct.

Exclusion criteria were severe wound infection or a deep extensive ulcer, no distal run-off on angiography, vasculitis, arterial aneurysmal disease or acute limb ischemia.

All patients were subjected to complete history taking, general, peripheral arterial, neurological examinations, laboratory [CBC, coagulation profile and kidney function tests] and diagnostic investigations (ABI using a handheld continuous 8-megahertz (MHz) Doppler device, Toshiba Medical Systems, Tokyo, Japan). Duplex imaging of the lateral plantar artery was performed by a single, trained radiologist using a linear array transducer (frequency 9–3 MHz) with a Toshiba Aplio XG US system L9-3 (Toshiba Medical Systems,

Tokyo, Japan). DUS spectral waveform was obtained in a vessel identified below the medial malleolus. The transverse axis was used to assess the posterior tibial artery bifurcation; the lateral plantar artery was identified in the long axis, in the mid aspect of the foot, lying above the metatarsal bony mark ^(9,10). Images demonstrating areas of occlusion or changes in blood flow was saved into the computer system ⁽⁹⁾.

Pedal acceleration time (PAT) can be obtained at four arteries: medial plantar artery, lateral plantar artery, deep plantar artery, and arcuate artery. The ankle brachial index (ABI) should be obtained in the usual fashion for correlation purposes. Most of the published literature focused their assessment on LPA due to its easy accessibility and traceability. In this study we only assessed the Lateral Plantar Artery (LPA) ⁽¹¹⁾.

Reduce the color scale and raise the color gain while assessing the acceleration time in each pedal artery to fill the artery appropriately. The color box has been oriented correctly. Apply the Doppler sample volume, which can be acquired at 60° or less to the artery's center. With the sweep speed set to medium, the Doppler waveform needs to occupy three-fourths of the spectral window once the spectral waveform goes live. The waveform contour should be sufficiently visible with the appropriate spectral Doppler gain. Depending on the ultrasound technology, the calculation tool "acceleration time or time/slope" is chosen to properly quantify PAT after the waveform has been frozen. The PAT is then calculated from pedal waveform as the duration, in milliseconds (ms), between the beginning of the systolic increase and the systole peak ⁽¹²⁾.

Duplex ultrasound measurements of Pedal acceleration time (PAT) of the lateral plantar artery was categorized into 4 classifications; Class 1: (40-120 msec), Class 2: (121-180 msec), Class 3: (181-224 msec), and Class 4: (Greater than 225 msec) ⁽¹³⁾.

After the assessment of pre-intervention initial PAT, patients were offered endovascular revascularization according to their individual case -as endovascular-first approach is the mainstay practice in our facility. Each case had a detailed DUS with informative anatomical lesions and their extent. If DUS was inconclusive, CTA was ordered. According to lesions, access puncture was done from ipsilateral common femoral artery if isolated tibial disease was present. If only SFA disease was present or concomitant with tibial disease, a retrograde contralateral access puncture was done.

SFA angioplasty was done via 0.035 hydrophilic wire with a support catheter, and dilation was done with 4- and 5-mm balloons. Tibial angioplasty was done using 0.018 metal wire with 3 mm balloon and dilation was done with the same balloon.

Post dilation angiogram was done. If flow-limiting dissection was noted in SFA or recoil more than 30%, a bare metal stent was deployed. If the same happened in tibial vessels, prolonged inflation (more than 3 minutes) was done.

After revascularization patients were directed immediately to perform another DUS to assess PAT. Afterwards PAT was assessed after 3 months in this study. To reach the sample size of this study, we have seen 50 patients in total. 9 of which at initial assessment were included but have failed to be in the end results of this clinical trial.

Revascularization outcome yielded technical success in 41 patients (82%), rupture or perforation was reported in 4 patients (8%), failed access was reported in 3 patients (6%), and finally, primary amputation was done in 2 patients (4%) of all studied patients. We only included 41 patients in our results that had technical success in their revascularization.

Sample Size Calculation:

The sample size was calculated using the following formula ⁽¹⁴⁾: Where: n = sample size, $Z_{\alpha/2} = 1.96$ (The critical value that divides the central 95% of the Z distribution from the 5% in the tail), $Z_{\beta} = 0.84$ (The critical value that separates the lower 20% of the Z distribution from the upper 80%), $\sigma = 47$ = the estimate of the standard deviation, $\mu_1 = 244$ = mean PAT preprocedure, $\mu_2 = 213$ = mean PAT preprocedure ⁽¹³⁾. So, by calculation $n=37$, after the addition of 10% drop-out proportion, the sample size was equal to 41 participants. Convenience sampling of all patients presented to Suez Canal University Hospitals meeting the inclusion criteria were enrolled into the study.

Statistical analysis

All statistical analyses were performed using the SPSS statistical package for social science version 26. Descriptive statistics were applied in numerical form (mean, SD) to describe the quantitative variables and frequency (%) to describe the qualitative variables. Associations between variables were tested for significance by using Chi-square test or Fisher exact tests for categorical variables and Kruskal Wallis test for continuous variables with normally distributed data. Results were statistically significant if p is less than 0.05.

RESULTS

As regard age, the mean was (66.2 ± 7.9) years. Regarding sex, there were 24 males (58.5%). For smoking, there were 25 smokers (61%) in all studied patients (Table 1).

Table 1: Description of demographic data

		n= 41
Age		66.2 $\pm$ 7.9
Sex	Males	24 (58.5%)
	Females	17(41.5%)
Smoking	Smoker	25(61.0%)
	Non-smoker	16(39.0%)

Data are presented as mean $\pm$ SD or frequency (%).

As regards comorbidities, the most common were DM (92.68%) and HTN (70.75%), As regards clinical data, tissue loss was reported in 31 patients (75.6%),

while rest pain was found in 20 patients (48.75%) of all studied patients (Table 2).

Table 2: Description of comorbidities and clinical data

		n= 41
Comorbidities		
HTN		29(70.73%)
Ischemic Heart Disease (IHD)		19(46.34%)
End-stage kidney disease (ESKD)		7(17.1%)
DM		38(92.68%)
Stroke history		7(17.1%)
Clinical data		
Tissue loss		31(75.61%)
Rest pain		20(48.78%)

Data are presented as frequency (%), HTN: Hypertension, IHD: Ischemic Heart Disease, ESKD: End-stage Kidney Disease, DM: Diabetes Mellitus.

High significant decreased PAT was found after revascularization when compared with that before revascularization with an average reduction of (67 ± 15) in patients with ulcer healing. High significant difference was found between PAT classes before and after revascularization in patients with ulcer healing. Before revascularization, majority of patients (58.5%) were with class 3. On the other hand, after revascularization, majority of patients (63.4%) were with class 2 (Table 3).

Table 3: comparison of PAT and PAT classes before and after revascularization

		Revascularization		T	P-value
		Before (n= 41)	After (n= 41)		
PAT (msec)		224.2 $\pm$ 42.7	157.1 $\pm$ 27.7	10.98	<0.001 HS
		Before (n= 41)	After (n= 41)	X²	P-value
PAT Class	Class 1	0(0.0%)	6(14.6%)		
	Class 2	4(9.8%)	26(63.4%)	41.95	<0.001 HS
	Class 3	24(58.5%)	9(22.0%)		
	Class 4	13(31.7%)	0(0.0%)		

Data are presented as mean $\pm$ SD or frequency (%), HS: Highly Significant, T: Paired sample T test, X²: Chi-square test, PAT: Pedal Acceleration Time.

As regards rest pain after revascularization, it was absent in 36 patients (77.8%) still persisted/recurred in 5 patients (12.2%) after 3 months. As regard ulcer healing after 3 months, it was not available in 10 patients (24.4%) as they only had rest pain as initial complaint. It ranged between 50% – 75% in 9 patients (22%), and reached 100% in 9 patients (22%), while death occurred in 1 patient (2.4%). The type of angioplasty procedures done in this study was mostly (53.65%) tibial angioplasty (Table 4).

Table 4: Description of rest pain, ulcer healing after 3 months and types of angioplasty procedures

		n= 41
Rest pain after revascularization		5(12.2%)
Fate	N/A	10 (24.4%) (rest pain only)
	BKA	1(2.4%)
	AKA	1(2.4%)
	Died	1(2.4%)
Ulcer healing after 3 months (%)	< 50	5(12.2%)
	50 – 75	9(22.0%)
	75 – 100	5(12.2%)
	100	9(22.0%)
Types of angioplasty procedures		
Tibial disease only	Tibial ballooning	22(53.7%)
	Pedal arch and tibial ballooning	6(14.6%)
SFA disease only	Ballooning	1(2.4%)
	Stent and ballooning	2(4.8%)
SFA and Tibial disease	Ballooning	6(14.6%)
	SFA stent and ballooning	4(9.8%)

Data are presented as frequency (%), BKA: Below-Knee Amputation, AKA: Above-Knee Amputation, SFA: Superficial Femoral Artery.

There was highly significant correlation between PAT class and revascularization in patients with ulcer healing. Among patients with PAT class 1, revascularization was tibial in 6 patients (100%). While in patients with PAT class 2, revascularization was tibial in 21 patients (80.8%). Finally, among patients with PAT class 3, revascularization was tibial plus SFA in 5 patients (55.6%). High statistically significant correlation was found between PAT class and revascularization in patients with ulcer healing. Among patients with PAT class 1, it was 100 in 5 patients (83.3%). While in patients with PAT class 2, it was (50 – 75) in 9 patients (34.6%). Finally, in patients with PAT class 3, it was <50 in 5 patients (Table 5).

Table 5: Correlation between PAT class and revascularization and ulcer healing

	PAT class after revascularization			X ²	P-value
	Class 1 (n= 6)	Class 2 (n= 26)	Class 3 (n= 9)		
Revascularization					
Tibial	6(100.0%)	21(80.8%)	1(11.1%)	21.78	<0.001 HS
SFA	0(0.0%)	0(0.0%)	3(33.3%)		
Tibial and SFA	0(0.0%)	5(19.2%)	5(55.6%)		
Ulcer healing					
N/A	1(16.7%)	7(26.9%)	2(22.2%)	46.56	<0.001 HS
BKA	0(0.0%)	1(3.8%)	0(0.0%)		
AKA	0(0.0%)	0(0.0%)	1(11.1%)		
Died	0(0.0%)	0(0.0%)	1(11.1%)		
< 50	0(0.0%)	0(0.0%)	5(55.6%)		
50 – 75	0(0.0%)	9(34.6%)	0(0.0%)		
75 – 100	0(0.0%)	5(19.2%)	0(0.0%)		
100	5(83.3%)	4(15.4%)	0(0.0%)		

Data are presented as frequency (%), PAT: Pedal Acceleration Time, BKA: Below-Knee Amputation, AKA: Above-Knee Amputation, SFA: Superficial Femoral Artery, HS: Highly Significant, X²: Chi-square test.

No significant correlation was found among PAT classes, both after and before revascularization, and ABI in patients with ulcer healing (Table 6).

Table 6: Correlation between PAT class and ABI after and before revascularization

	PAT class after revascularization			Kruskal-Wallis test	P-value
	Class 1 (n= 6)	Class 2 (n= 26)	Class 3 (n= 9)		
ABI	0.89 ± 0.04	0.79 ± 0.14	0.84 ± 0.31	2.119	0.452 NS
	PAT class before revascularization				P-value
	Class 2 (n= 4)	Class 3 (n= 23)	Class 4 (n= 14)		
ABI	0.68 ± 0.02	0.57 ± 0.04	0.75 ± 0.56	3.451	0.223 NS

Data are presented as mean ± SD, NS: Non-significant, Kruskal-Wallis test, PAT: Pedal Acceleration Time, ABI: Ankle Brachial Index.

DISCUSSION

In the diagnosis and prognosis of Chronic Limb-Threatening Ischemia (CLTI) and Peripheral Arterial Disease (PAD), Pedal Acceleration Time (PAT) becomes a crucial tool. For many years, traditional diagnostic techniques like the Ankle-Brachial Index (ABI) and Toe-Brachial Index (TBI) have been used for diagnosis and follow-up. However, they often don't work for individuals with non-compressible arteries, medial artery calcification, or diabetic mellitus (DM). PAT provides an alternate technique for determining foot perfusion, especially in complicated situations when conventional non-invasive testing is not accurate (15).

As long as they were classified as salvageable limbs in accordance with international recommendations, all of our patients who had CLTI limbs received revascularization (16).

However, two patients had primary amputation due to widespread infections that crossed the ankle joint. Out of the 48 patients that received endovascular intervention, only 41 had a successful index surgery and were followed up for three months. In this sample, the other seven patients were not monitored.

Following a successful endovascular operation, PAT values significantly decreased, with an average decrease of 67 ± 15 msec. As a result, there was a considerable decrease of 1 to 2 PAT classes both before and after revascularization. The outcomes of post-procedure class changes seen in another study (13) are comparable to this. After three months following the index treatment, we looked at the patient outcomes. All of the patients who had rest discomfort and a successful intervention had their symptoms go away. Ten of the 41 patients had only complained of Rutherford 4 rest discomfort before to the operation, which was alleviated after the treatment. Two of our patients required below-knee and above-knee amputations due to heel gangrene that spread over the ankle level. After eight days, another patient who had a big stroke and had worsened right after surgery passed away in the intensive care unit. In addition, there were five patients (12.2%) who had less than 50% healing of their ulcers, which corresponded to class 3 PAT; nine patients (22%), who had 50-75% healing ulcers, which corresponded to class 2 PAT; five patients (12.2%) who had 75-100% healing ulcers, which also corresponded to class 2 PAT; and nine patients (22%), who had complete ulcer healing, of which four were in class 2 PAT and five in class 1 PAT.

In light of this, we have shown a correlation between PAT class and wound healing, with PAT class 1 being linked to full wound healing, class 2 producing inconsistent results, and class 3 producing the poorest wound healing outcomes.

This is in line with findings from **Moneta et al.** (17) that demonstrated that PAT class 1 had the best results after a year, while classes 2 through 4 had lower amputation free survival (AFS) (class 2, odds ratio [OR] 2.86, 95% CI 1.64 - 5.0, $p < 0.001$; class 3, OR 5.1, 95%

CI 1.71 - 15.22, $p = 0.003$; class 4, OR 12.59, 95% CI 4.34 - 36.56, $p < 0.001$) and worse wound healing (class 2, hazard ratio [HR] 0.62, 95% confidence interval [CI] 0.43 - 0.9, $p = 0.012$; class 3, HR 0.21, 95% CI 0.08 - 0.58, $p = 0.002$; class 4, HR 0.12, 95% CI 0.04 - 0.34, $p = 0.001$; class 4, HR 0.12, 95% CI 0.04 - 0.34, $p = 0.001$; class 4, OR 12.59, $p = 0.001$). Additionally, **Sommerset** showed that in 54 diabetic limbs with isolated infrapopliteal illness that had a mean PAT class of 237 msec and CLTI, 10 needed higher level amputations, and 44 had wound healing after a successful revascularization. A mean PAT of 114.2 msec was linked to complete wound healing, whereas a mean PAT of 278.4 msec was linked to limb loss (18).

In a two-year retrospective analysis of 73 diabetic patients with CLTI, **Teso et al.** (13) also shown that limb salvage is linked to an improvement in PAT classes to class 1 or 2. In order to maintain an in-line inflow to the foot, patients were provided revascularization in accordance with GLASS guidelines. To enable inclusive real-life scenarios, patients with SFA illness, tibial disease, or both were included in this research. Of the forty-one patients, twenty-eight (68.3%) had just tibial revascularization, three (7.3%) had only SFA revascularization, and ten (24.4%) had both. It was statistically inaccurate to associate the tiny sample in each group with either ABI or PAT changes, despite the fact that we had data on angioplasty operations.

Subgroup analysis of the only tibial disease group revealed that PAT had a significant reduction after angioplasty, making it a better prognostic tool for predicting wound healing in isolated tibial disease, even though we have observed a highly significant reduction in PAT class following revascularization in all types of endovascular interventions.

Although acceleration time ratios have been suggested as a remedy in other contexts and the potential influence of proximal input on PAT has been discussed for decades, tibial illness has not yet been the subject of research on this topic (19).

The difficulties of PAT evaluation have also been mentioned, such as the fact that it is an operator-dependent inquiry that requires vascular ultrasound knowledge, much like any DUS research. About 20 supervised ultrasound exams are required, according to a PAT investigation specialist. These studies typically take 15 to 35 minutes apiece, depending on the patient's circumstances and prior experience. Additionally, patients' mobility and anatomical heterogeneity are sometimes seen as difficulties (11).

Additionally, inter-observer and intra-observer repeatability have been identified as an issue, particularly when contrasted with resistance index (20) or peak systolic velocity (21). The absence of a standardized measuring technique may help to explain this. **Sommerset** established the framework for a manual for assessing PAT (11).

Intra-observer repeatability employing an intraclass correlation (ICC) to examine the relationship between two measurements has only been reported in one research, and the result was 0.98. However, additional research in this area is required ⁽²²⁾.

Lastly, we think that we have shown—for the first time in the Arab world—that PAT may be used as a supplement or substitute for conventional non-invasive techniques, particularly in patients with diabetes and ESKD who have non-compressible arteries. Additionally, we have shown that PAT is a reliable indicator of wound healing in patients with CLTI, and it has been linked to effective endovascular treatments, particularly in patients with isolated tibial illness. However, in order to select the best tools for future assessments and management of PAD and CLTI patients, we still need large sample studies in numerous centers throughout the region that assess intra/inter-practitioner reproducibility of examinations, as well as long-term follow-up and randomization in patient selection.

The tiny sample size was one of the limitations. the need for high technical skills, which necessitated specialized training, extended assessment periods, and recurrent investigations. There was no focus on intra- or inter-examiner variability in this single-institution study with a single radiologist, brief follow-up research, inability to establish PAT threshold values to forecast intervention success or wound healing.

CONCLUSION

PAT is a valid diagnostic and predictive tool for CLTI, especially in groups where conventional evaluations are ineffective, according to this research. It is a good contender for inclusion in vascular evaluation procedures because of its capacity to identify effective interventions and forecast wound healing. However, before it can be embraced as a standard of treatment, further extensive, multicenter research is required.

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