

Importance of Accurate Identification of Arterial Perfusion in the Lower Limb Using Different Non-Invasive Physiological Tests

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Published Date: 15-10-2016

ABSTRACT

Background: Although diagnostic and therapeutic decisions in patients with peripheral arterial disease are guided primarily by the history and physical examination, the use of non-invasive investigations has increased significantly in recent years, mainly as a result of technological advances in ultrasonography. Ultrasonic hand held doppler velocimeters are widely utilized by healthcare professionals for the assessment of lower limb arterial perfusion. However, a clinical assessment tool is only of value if the interpretation of the results is correct and repeatability has been clinically established. Ankle Brachial Pressure Index, TBIs, toe pressures and spectral waveforms at the ankle are all used to assess arterial perfusion especially in high risk populations. This chapter presents the findings of two studies conducted to compare the accuracy of different physiological tests used by various health care professionals for the identification of arterial perfusion in the foot and prediction of wound healing. Vascular testing included assessment of arterial spectral waveforms at the ankle, absolute toe pressures, Toe-Brachial Pressure Index (TBI), Ankle-Brachial Pressure Index (ABPI) and Pulsatility Index (PI).

Outcomes: TBIs, toe pressures and spectral waveforms at the ankle are better predictors of arterial perfusion and the likelihood of wound healing and non-healing after minor amputation than ABPIs. ABPI alone is a poor indicator of tissue perfusion and the likelihood of healing of minor amputations and should not be relied on to determine the need for revascularization procedures in the high risk foot. The PI, being a continuous variable allows classification of patients on a scale, making it easier to diagnose severity of disease, thus resulting in a more accurate interpretation of the extent of disease. The advantage of PI over spectral waveforms is that it is a quantitative measure, rather than a subjective assessment of spectral waveforms thus ensuring no variability in user interpretation between waveforms especially in severely diseased arteries which can prove to be difficult to interpret correctly.

Keywords: Diabetes; Ankle blood pressure; Toe blood pressure; Wound healing; Atherosclerosis; Pulsatility index

INTRODUCTION

Peripheral Arterial Disease [**PAD**] is a condition characterized by blockage or narrowing of the main arteries, most commonly the superficial femoral artery in the thigh or the common and external iliac artery in the lower abdomen which carry blood to the legs [1]. Although diagnostic and therapeutic decisions in patients with peripheral arterial disease have been guided primarily by the history and physical examination of the lower limb, it is imperative that this condition is diagnosed as early as possible in order to avoid devastating further complications including atherosclerotic cardiovascular complications. Sudden loss of arterial blood supply to the lower limbs is a clinical emergency. Arterial ischaemia is known to lead to ulcerations, tissue necrosis and ultimately the need for possible amputations of the limb [2]. It has been estimated that only approximately 25% of patients living with PAD receive treatment since most people are not aware that they are living with this condition. Despite the lack of symptoms such patients still share the same prognosis as symptomatic patients, showing a risk profile comparable to patients with symptomatic lower extremity PAD or with chronic heart disease [3]. This highlights the importance of early identification of disease.

The use of non-invasive investigations to identify PAD has increased significantly in recent years, mainly as a result of technological advances in ultrasonography [4]. Furthermore, as the incidence of lower leg ulcerations and surgical interventions increases as a result of atherosclerotic disease, the need to establish accurate and reliable testing modalities and algorithms to predict the likelihood of wound healing increases.

Ultrasonic hand held doppler velocimeters are widely utilized by healthcare professionals for the assessment of lower limb arterial perfusion [5]. The Ankle Brachial Pressure Index [**ABPI**], Toe Brachial Pressure Index [**TBI**], toe pressures and spectral waveforms at the ankle are all used to assess arterial perfusion especially in high risk populations [6]. Originally, the Pulsatility Index [**PI**] was also introduced to detect peripheral vascular disease [7], however today this

index is rarely used to diagnose this condition [8]. The Pulsatility Index (**PI**), which is equal to the difference between the peak systolic velocity and the minimum diastolic velocity divided by the mean velocity during the cardiac cycle, is one parameter to quantify the changes in velocity during the cardiac cycle. This value decreases with distance from the heart [9]. Increasing arterial disease results in progressive dampening of the waveform with loss of reversed flow and the development of a monophasic pattern. The lower the PI the greater the degree of proximal arterial disease [10]. The PI has been shown to correlate with arteriographic findings and with ankle systolic pressure [11].

This chapter presents the findings of two studies which were conducted with the aim of comparing the accuracy of different non-invasive physiological tests used by various health care professionals for the identification of arterial perfusion in the foot. The use of a tool that requires interpretation and is user dependent introduces an undesired variable in the diagnosis and management of these patients. Although large clinical randomized studies on arterial disease are limited, this chapter provides evidence from recent studies on the importance of using different non-invasive modalities when assessing patients with arterial disease and when results do not concur, further extensive evaluations should be performed. Such information will undoubtedly go a long way towards alleviating to some extent, the burden and costs related to atherosclerotic disease and its complications.

METHODS

Prospective study designs were employed in the two studies to measure and compare the Ankle Brachial Pressure Index [**ABPI**], Toe Brachial Pressure Index [**TBI**], toe pressures, Spectral Waveforms at the ankle and Pulsatility Index [**PI**] in patients living with Type 2 diabetes mellitus. The clinical measurements used during this research were based on validated and previously published methods following a thorough review of the literature on international guidelines and recommendations. Room temperature was kept at 21 to 23 degrees Celsius (68 to 75 F) during the assessments to avoid vasoconstriction of digital arteries from the cold. A database was constructed to record all the information. The studies were approved by the University Research Ethics Committee. All investigations were carried out in accordance with the principles of the Declaration of Helsinki as revised in 2000.

Blood Velocity Measurements

Ankle Brachial Pressure Index [**ABPI**]

Measurement of Ankle Brachial Pressure Index [**ABPI**] was performed using a portable hand held Doppler and blood pressure cuffs. Apart from ABPI assessment, quantitative pedal waveform analysis was obtained from all recruited subjects utilizing the continuous wave Doppler. The Doppler waveforms and the measurement of the ankle brachial pressure index were obtained using the 'Huntleigh® Dopplex Assist vascular package (Cardiff, UK)' as the principal study tool.

The Huntleigh® hand held continuous wave Doppler with an 8MHz probe, part of the Dopplex Assist vascular package, was used to measure the waveforms of the dorsalis pedis and the posterior tibial arteries. The probe was held steadily on the anatomical artery location at an angle between 45 to 60 degrees against the flow of arterial blood. Interpretation of arterial pressure waveforms results was based on standards from the literature. Waveforms were classified as triphasic, biphasic, monophasic discontinuous and monophasic continuous [Figure 1]. The triphasic and biphasic waveforms were considered as normal, whereas the monophasic discontinuous and monophasic continuous waveforms were interpreted as abnormal and indicative of PAD. Measurements were carried out after a 5-minute rest in supine position with the upper body as flat as possible. Patients were also asked to undo all tight clothing around the waist and the arm. The series used for this study included an electric pump which deflates the pressure cuffs, requiring the investigator to simply press a button. When measured, the systolic blood pressures are automatically saved onto the system's software with the saved results then used to calculate the ABPI ratios by the system.

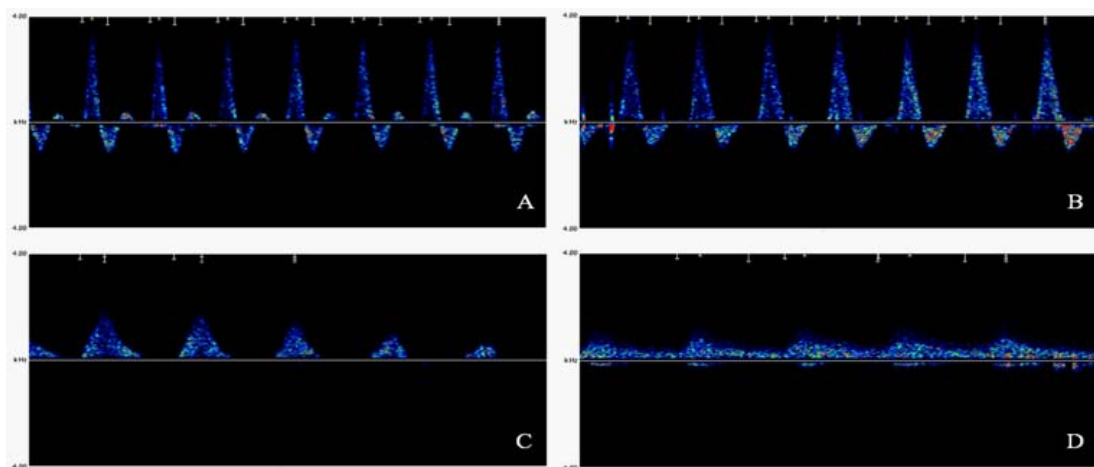


Figure 1: Spectral Doppler waveforms as visualized on the proprietary 'AR2 software' (Huntleigh®, Cardiff, Wales). Waveforms depicted as triphasic (A), biphasic (B), monophasic (C) and monophasic continuous (D).

A blood pressure cuff was applied to the arm [to measure the brachial systolic pressure] and the ankle [to measure the dorsalis pedis and posterior tibial pressures] to determine the ankle pressure. The cuff was inflated to occlude the arterial pressure. The systolic pressure was obtained by listening and noting the pressure on the manometer. The systolic pressure was noted and the higher values of the brachial and the ankle pressures were used to calculate the ABPI. Values were interpreted according to the criteria proposed by the American Heart Association and the American Diabetes Association [12]. ABPI calculations were interpreted as 0.9– 1.29 normal, lower-extremity vascular disease was defined an ankle brachial index < 0.90 in either foot. An ABPI of >1.3 was considered significantly elevated and indicative of vascular calcification.

Pulsatility Index

For the purpose of this study, the Pulsatility Index was also automatically calculated by the Huntleigh® Dopplex Assist Series. PI is calculated according to the method of Gosling [7]. Briefly, PI is calculated from the difference in the systolic and diastolic flow velocity divided by the mean flow velocity as illustrated in the formula below when available equipment does not calculate this measure automatically. The higher the PI value the better perfusion in the lower limb.

$$PI = \frac{v_{systole} - v_{diastole}}{v_{mean}}$$

Calculating the PI [7].

Toe pressures and toe brachial pressure index

The procedure for obtaining toe pressures and TBI's involved applying a cuff of approximately 1.5cm width on the proximal aspect of the hallux or 2nd toe (when the hallux had been amputated) and the photoplethysmography probe was applied to the pulp of the hallux. Patients were examined in the supine position. When a regular waveform was observed, the sphygmomanometer was pumped up slowly to inflate the digital cuff and occlude digital blood flow, to a maximum of 200 mmHg. Upon slow release, the point at which the waveform was observed the toe systolic pressure was measured. Using PPG, the actual TBI was obtained during gradual deflation of the cuff at the moment the pulsatile signal reappeared. Toe pressures and the TBI were automatically calculated by the dopplex unit and a print out was obtained.

DISCUSSION

The two studies reported in this chapter [13,14] aimed to identify any significant differences in different non-invasive physiological test results when evaluating tissue perfusion in people with possible Atherosclerotic Vascular Disease and in determining the possibility of wound healing.

The aim of the first study presented in this chapter [13] was to determine whether distal blood pressure measurements or waveforms could predict wound healing after foot or toe amputations. Subjects underwent physiological testing preoperatively on the day of surgery or the day before surgery. Patients aged 18 years and over requiring an elective toe or foot amputation were eligible. The choice of amputation level was made on clinical grounds by the attending vascular surgeon. The patients were assessed 6 weeks following the surgical intervention. The amputation sites were assessed for healing. These were recorded as healed, was healing, or having complications and/or not healing. A healed wound was defined as one where the skin cover was complete with no defects at site of skin closure. A healing wound was one where skin cover was not complete but where areas of lack of skin cover showed healthy granulation tissue. Failure of wound healing was defined as incision breakdown requiring re-amputation at a more proximal level. Complications included infection (defined as erythema around the wound or amputated digit with or without discharge, with or without positive cultures, and sinus formation with exposure of underlying bone or joint).

Study results conclude that TBPIs and toe pressures are better predictors of likelihood of healing after toe amputation than ABPIs. ABPIs alone cannot be relied upon as an indicator of perfusion to the toes in the diabetic population. The distribution of disease in diabetes makes it possible for patients to have relatively adequate ABPIs and yet have very poor perfusion to the toes. ABPIs are notoriously unreliable in diabetes when there is concomitant high risk of arterial calcification or in patients on hemodialysis, where the reliability of ABPI's seems to be limited since a falsely elevated reading can be produced. Another important finding is that the waveforms are also predictive of wound healing. All patients in this study presenting with triphasic waveforms healed their amputation wounds within six weeks. Patients with monophasic continuous waveforms have a significantly higher risk of developing complications or failing to heal their amputation sites.

The Independent Sample T-Test was used to compare the mean ABPI, TBPI and toe pressures between the two independent groups [healing/is healing (group 1) versus not healed/having complications (group 2)]. TBPI and toe pressures were considerably higher for group 1 when compared to group 2 ($p=0.031$ and 0.014 respectively). There was no significant difference in ABPI between the two groups. The Chi-square test was used to assess the association between waveforms and outcome. There was a significantly higher proportion of patients with Continuous monophasic waveforms in group 2 (43.8%) when compared to group 1 (10.7%). There was a significant difference in the type of waveforms between the two groups ($p=0.028$).

As the incidence of lower leg surgical interventions increases the need to establish accurate algorithms to predict tissue perfusion and the likelihood of wound healing after minor amputations increases. This would help clinicians decide on whether potentially risky revascularization procedures should be performed. Results from this study support the evidence that toe pressures above 30mmHg could predict healing as proposed by the European Consensus Document [15] but also indicate that spectral waveforms at the ankle could be useful in predicting healing and non healing. As importantly it highlights the fact that reliance on ABPIs to predict healing is inadvisable.

The second study [14] employed a prospective design with the aim to measure and compare qualitative spectral waveforms to automatically computed pulsatility index in patients with Type 2 diabetes mellitus. Current literature has shown considerable variability amongst clinicians and educators in defining and classifying qualitative spectral peripheral arterial waveforms.

Spectral waveforms were assessed in 208 lower limbs of patients with diabetes mellitus. Fifty five limbs had triphasic waveforms, 50 biphasic, 51 monophasic discontinuous and 52 monophasic continuous waveforms. The results of this study indicate that there is a good correlation between spectral waveforms and PI in patients with diabetes mellitus implying that PI can safely be used instead of spectral waveforms in the diagnosis of peripheral arterial disease in this patient group. These observations were seen to be statistically significant, with the One- Way Anova test

registering statistically significant difference in the mean pulsatility index across the four spectral waveform categories with a p-value of 0.000.

Inaccurate interpretation of Doppler ultrasound outputs by clinicians could contribute to the sub-optimal management of PAD or conversely subject patients to further unnecessary investigation or misdiagnosis [15]. The advantage of the use of the PI is that whilst in spectral waveforms clinicians classify patients into four categories namely triphasic, biphasic, monophasic discontinuous and monophasic continuous, the PI, being a continuous variable allows classification of patients on a scale making it easier to diagnose severity of disease, thus resulting in a more accurate interpretation of the extent of disease. However, despite the inherent limitations of Doppler waveforms including poor technique when recording waveforms which would affect reliability of results, the PI also requires an accurate technique since one still needs to have “good” waveforms to have a reliable PI reading as this is indirectly calculated from the waveform itself as discussed earlier in this paper. The advantage of PI over spectral waveforms is that it is a quantitative measure, rather than a subjective assessment of spectral waveforms thus ensuring no variability in user interpretation between waveforms especially in severely diseased arteries which can prove to be difficult to interpret correctly. The additional advantages of PI is that in patients where the hallux or second digit have been amputated or are gangrenous and where toe pressures cannot be assessed at all, the PI can provide an additional tool for assessment of perfusion. The authors recommend that pulsatility index should be included as one of the diagnostic tools in international recommendations on assessment of lower limb perfusion particularly since it has the main advantage of eliminating errors of interpretation associated with use of qualitative spectral waveform analysis. In addition PI provides a quantitative estimate of the perfusion to the limb compared to spectral waveforms analysis.

CONCLUSION - RELEVANCE/IMPACT OF STUDY RESULTS IN CLINICAL PRACTICE

Results from these studies confirm that non-invasive physiological tests can be used to detect arterial perfusion in the lower limb. Furthermore, these tests could also be used to predict wound healing following minor amputations. Results from the two studies presented support the evidence that toe pressures above 30mmHg are good predictors of arterial perfusion could predict healing as proposed by the European Consensus Document [ECD] but also indicate that spectral waveforms at the ankle are also good predictors of arterial perfusion. As importantly it highlights the fact that reliance on ABPIs to predict accurate perfusion is inadvisable. Results also conclude that pulsatility index can safely be used to identify patients' with peripheral arterial disease. Using PI, which is a quantitative measure, rather than a subjective assessment of spectral waveforms removes the variability of user interpretation when predicting arterial perfusion in the lower limb.

ACKNOWLEDGEMENT

The authors would like to thank all participants who consented to participate in this study. The authors would also like to thank Prof Liberato Camilleri [University of Malta] for his help in statistical advice.

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