



# Diagnosis of peripheral vascular disease for diabetic foot risk assessment



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## ABSTRACT

**Background:** Within Australia, peripheral arterial disease (PAD) affects 10–25% of people over the age of 55, which can lead to foot ulceration and gangrene. PAD is more common in people with type 2 diabetes, who if ulcers appear, have a lower recovery rate. Therefore it is important to find diagnostic tools, which are accurate and identify PAD early in disease development. The ankle-brachial-pressure index (ABPI) is most often used in primary health care. However these lack sensitivity.

**Methods:** Using convenience sampling 60 participants were recruited at Charles Sturt University and divided into two age groups of <30 and >30 years as well as into females and males. The ABPI and pulse wave analysis, using peak blood flow velocity (PBFV) were compared. Both parametric and nonparametric statistics were used depending on the data source. Significance was set at  $p < 0.05$ .

**Results:** Twenty-nine participants were under 30 years of age and the remainder above 30 years of age with no known pathology. ABPI results ranged between 0.91 and 1.17 and PBFV between 7.6 and 51.8 cm/s. No participants had abnormal ABPI. Only PBFV showed significant differences for age and gender ( $p < 0.05$ ). Post hoc analysis indicated that both ABPI and PBFV were significantly different between the younger males compared to the older females; older males to older females and younger females to older females.

**Discussion:** Normative data in a healthy younger population is an important adjunct to clinical reviews and the method used to determine abnormal blood flow. Of interest is that the ABPI results fall between 0.91 and 1.17 suggesting that the currently used lower cut-off of 0.9 is appropriate but that the higher cut-off could be moved down from 1.3 for clinical decision making.

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## 1. Introduction

Within Australia, peripheral arterial disease (PAD) affects 10–25% of people over the age of 55 [1]. Insufficient tissue perfusion resulting from PAD can contribute to the progression of foot ulceration and gangrene, and may result in amputation especially in people with diabetes [2]. Several diagnostic methods exist for the detection of PAD. These include angiography, the ankle brachial pressure index (ABPI), pulse palpation (PP), and the Edinburgh Claudication Questionnaire (ECQ) [3–6]. Of these, the ABPI is currently considered the most reliable, non-invasive clinical measure for identification of PAD. However, it fails to produce useful results in people with advanced diabetes due to the calcification of the arteries, as the arteries become noncompress-

ible. Pulse palpation and the ECQ similarly have shortcomings; of which, absence of pulses and a lack of painful symptoms associated with PAD are respective examples.

Pulse wave analysis (PWA) does not have these shortcomings as it is based on the recording of the pulse wave velocity changes associated with changes in intra-arterial blood pressure (BP) caused by each beat of the heart and is obtainable regardless of condition [7]. Traditionally the pulse waveform is inspected for the presence of one to three main peaks for diagnosis of pathology. A more recent method determines the amplitude of the first peak, which indicates blood flow velocity associated with contraction of the ventricle [8]. Pulse wave analysis has until now only been utilized for characterizing upper limb arterial blood flow characteristics and used for identification of heart disease [9].

### 1.1. Effect of age and gender on blood flow

The large elastic arteries become stiffer with advancing age due to dilation of these arteries along with intimal thickening. A

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decrease in elasticity then leads to a decreased compliance of the vessel wall and causes an increase in velocity which increases the systolic BP [10]. These changes can occur in a healthy population (no cardiovascular disease) with the increases that occur still being within the normal range. Increases outside of this normal range can be linked with an increased cardiovascular risk [11].

Gender may also have an influence on blood flow. Some controversy surrounding this area has been noted, as studies measuring arterial stiffness by looking at pulse wave velocity, have found that there is either an increase in elderly women, or no difference between the two genders. Berry et al. (2004) states that postmenopausal women whether normotensive or with untreated hypertension, may experience greater stiffening of the large arteries than men of similar age due to the decrease in oestrogen and a concomitant increase in collagen synthesis, leading to an increase in vascular resistance [12,13]. In view of this research, it is vital that age and gender be considered in evaluating the results of any diagnostic test.

### 1.2. The ankle brachial pressure index (ABPI)

The current podiatric method for PAD diagnosis uses the ABPI [6]. This index is derived from comparing the arm (brachial) and ankle systolic pressures by dividing the ankle systolic pressure by the arm systolic pressure. However, there is controversy related to the accuracy, reliability, and validity of this measure, especially in a clinical population [6,14–18]. This finding has significant implications for people with diabetes as calcification affects a large proportion of individuals with diabetes. In fact, there is no agreement on the most appropriate way to determine the ABPI nor the cut-off value to use to identify PAD and thus is left to the individual clinician to decide [19,20]. Areas of skin breakdown, ulceration or recent lower limb surgery may also contraindicate the use of the blood pressure cuff.

### 1.3. Pulse wave analysis (PWA)

PWA relies on detecting changes in blood flow through the vessels and is independent of calcification. Calcification changes compliance of the blood vessel and as a result the flow characteristics are altered and can be recorded using a transducer such as a Doppler ultrasound instrument. Pulse wave analysis has been shown to be effective in the early screening for cardiovascular disease using the carotid and/or radial artery and in early detection of possible peripheral vascular disease [9,21,22]. The amplitude of the peaks and time delays between peaks pulse wave velocity have both been measured in the past [8,23].

The current study aimed to compare results of peak blood flow velocity (PBFV) and ABPI to determine the clinical validity of PBFV in two age groups and between the sexes.

## 2. Methods

This study was granted ethics approval from the Charles Sturt University School of Community Health Ethics Committee (Approval Number EA/THOM/0707). Participants were recruited from staff and students of the Albury campus at Charles Sturt University and participants of the Diabetes Complication Screening Initiative at Charles Sturt University and the Allied Health Podiatry Clinic. An appropriate sample size was determined using the power analysis incorporated in MedCalc (<http://www.softpedia.com/progDownload/MedCalc-Download-25693.html>). The following values were used in determining the sample size: Type 1 error = 0.05; Type 2 error = 0.20; Power = 0.8. A total sample size of 58 was recommended (approx. 30 per group). All participants had to be healthy without any previous or current pathology such as

diabetes, kidney disease, stroke, cardiovascular, or peripheral vascular disease. The group consisted of a <30 age group and a >30 age group. Exclusion criteria were: skin allergies associated with tapes, gels present; smoking >5 cigarettes/day; consume >2 alcoholic drinks/d; presence of cardiovascular disease, kidney disease, and/or diabetes; skin breakdown in the lower limb or recent lower limb surgery.

The ABPI was determined by Doppler ultrasound with an 8 MHz probe (Hadeo Es-100 SP11, Haysashi Denki Co) and sphygmomanometer that measures BP. It was ensured that each participant had been resting supine for a minimum of 5 min. Four pulse waveforms were recorded and the peak blood flow velocity (cm/s) determined. A pilot study was first carried out to see if the same waveform characteristics were obtainable for a second Doppler recording two to four weeks later for the first eleven participants. A chi-square test was then performed to see if there was any statistically significant difference.

ABPI and PWA are represented by a ratio scale; ABPI was converted to a nominal scale that represents the clinical diagnosis of PAD if a cut-off score below 0.9 and above 1.3 was exceeded. The data for the PWA (peak blood flow velocity is shown as minimum and maximum values as well as mean and standard deviation. For an indication of a possible normal range, the 5th and 95th percentile was determined. Test results for PWA were then compared to the ABPI results by using a chi-square test to discover significant differences between the outcomes of the test procedures. Both age and gender were considered in the data analysis using a univariate analysis of two groups where possible for parametric data or the chi-square for non-parametric data. When the parameters of gender and age were combined an analysis of variants test was used.

## 3. Results

The pilot study indicated that PWA was robust over the period investigated and therefore a good measure for identification of possible foot pathology. A total of 60 participants were included in this analysis. In the age range of <30 ( $n = 31$ ) there were 9 males and 22 females and in the age range of >30 ( $n = 29$ ) there were 9 males and 20 females. Left and a right foot results were combined. In this study, all participants were classed as having normal ABPI results (0.9–1.3). We determined the 5th and 95th percentile for PBFV for the total group being 9.9–37.3 cm/s (Table 1).

### 3.1. Age comparisons

A significant statistical difference exists for age and peak blood flow velocity, with the >30 age group having the higher values (Table 2).

### 3.2. Gender comparisons

To discover gender differences in the results a univariate analysis (Table 3) was performed.

The only statistical difference found for age or gender was with PBFV ( $p < 0.5$ ).

**Table 1**  
Descriptive statistics for parametric data.

	Age	ABPI	PBFV (cm/s)
N	60	60	60
Mean	36	1.03	21.18
Std. deviation	15.62	0.05	9.36
Range	44	0.26	44.2
Minimum	20	0.91	7.60
Maximum	64	1.17	51.8

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