Does rest time affect the automated ankle-brachial pressure index results in healthy volunteers?

KEY WORDS
- Ankle-brachial pressure index
- Automatic and manual ankle-brachial pressure index
- Doppler
- Mesi-automated device
- Peripheral arterial disease

Aim: To investigate if rest time will affect ankle-brachial pressure index (ABPI) scores when using a MESI-automated device on healthy volunteers. Background: Peripheral arterial disease (PAD) is a common condition describing the deposition of fatty plaques in the arteries of the lower limb. PAD is most commonly diagnosed using the manual Doppler ABPI. Automated devices such as the MESI ABPI MD are thought to reduce time constraints by negating the need for a rest period prior to testing. This study sought to investigate this claim and determine the necessity of rest time prior to ABPI testing when using the MESI ABPI MD. **Methodology:** This repeated cross-sectional study was conducted at the Peninsula Allied Healthcare Centre (PAHC) of Plymouth University. Participants were recruited via convenience sampling. Four sequential ABPI measurements were performed at 0, 10, 20 and 30-minutes on healthy individuals. **Results:** 28 participants completed the study, 9 males and 19 females, with ages ranging from 18 to 52 years. All 28 participants had ABPI scores within normal ranges (1.0–1.4). A repeated measures ANOVA was performed to calculate the effect of rest time on ABPI scores (p=0.107). A significant positive correlation (p=0.007) was found between mean ABPI score and age. A significant negative correlation (p=0.005) was found between mean ABPI scores and mean pulse rate (BPM). **Conclusion:** The key finding of this study is that rest time does not significantly affect ABPI scores in healthy individuals, when tested with the MESI automated device. The MESI device negates the need for rest time prior to ABPI measurement and does not need a specialist clinician to operate. These factors could contribute to the increased implementation of ABPI screening within a clinical setting, possibly resulting in earlier diagnosis of PAD, minimising both physiological and economic impact.

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Peripheral arterial disease (PAD) is a common condition, synonymous with atherosclerosis, a process that describes the deposition of fatty plaques within the arterial lumens of the legs (Conte et al, 2015). PAD often progresses with age and is an indicator of more widespread cardiovascular disease (Joosten et al, 2012). Tertiary to coronary artery disease (CAD) and stroke, PAD is the leading cause of atherosclerotic cardiovascular morbidity (Fowkes et al, 2013). There are several known risk factors for the development of PAD, including family history, smoking, obesity, diabetes and increasing age (Dormandy and Rutherford, 2000). Here the signs and symptoms of PAD:

- Intermittent claudication — pain in legs when walking
- Hair loss on your legs and feet
- Numbness or weakness in the legs
- Brittle, slow-growing toenails
- Ulcers (open sores) on your feet and legs, which do not heal
- Changing skin colour on your legs, such as turning pale or blue
- Shiny skin

- In men, erectile dysfunction
- The muscles in your legs shrinking (wasting)

50 % of patients with PAD are asymptomatic.

In 2010, 202 million people worldwide were living with PAD (Fowkes et al, 2013). In the UK alone, PAD is the largest cause of lower limb amputation (National Institute of Health and Care Excellence [NICE], 2014) leading to increased mortality and morbidity rates (Pande et al, 2011). Recent UK healthcare guidelines suggest costs following PAD diagnosis and associated comorbidities may amount to over £700 per patient (NICE, 2014), with arterial leg ulcerations totalling an estimated £46.5 million annually (Guest et al, 2015).

The manual ABPI is the main diagnostic and cost-effective tool used in the detection of PAD in primary care, deemed the gold standard method by national guidelines (Perlstein and Creager, 2009; NICE, 2012). The manual method of ABPI measurement is performed using an ultrasound Doppler probe, blood pressure cuffs and a sphygmomanometer. The blood pressure cuff is placed around the ankles first before testing the brachial arteries. With the Doppler probe detecting arterial blood flow, the cuffs are inflated until the arterial pulse sound ceases. The pressure cuff is then slowly deflated and, once the pulse is re-detected through the Doppler probe, the pressure in the cuff will indicate the systolic pressure of that artery (Varetto et al, 2019). The ABPI is the ratio of the highest systolic blood pressure obtained from the two ankle arteries (dorsalis pedis and posterior tibial) divided by the highest systolic blood pressure of both brachial arteries (Varetto et al, 2019).

Despite the prevalence of subclinical PAD, with only 50% of patients presenting with symptoms, the ABPI is currently underused within the clinical setting. This is thought to be due to time constraints (Benchimol et al, 2012) and staff training (Yap et al, 2016) resulting in only 16% of patients with a wound having ABPI testing (Guest et al, 2015). The manual ABPI can be time consuming in the clinical setting, where patients are often advised to rest supine before testing, with rest time durations ranging between 0 and 40 minutes (Al-Qaisi et al, 2009; Suominen et al, 2010; Alahdab et al, 2015; Span et al, 2016; Varetto et al, 2019). Mild-to-moderate peripheral vascular disease causes a fall in the ABPI after exercise, therefore the resting period may require adjustment — increasing the rest time, depending on the severity of the arterial disease (Vowden, 2012). However, as PAD patients may not present with symptoms (NICE, 2012) this may not be clear until after the initial assessment has been undertaken.

These advisory rest times may relate to national guidelines recommending that patients should be resting and supine if possible (NICE, 2012). Despite this, a standardised rest time has not yet emerged within the literature, with the effect of the duration of the rest period on the reliability of ABPI measurement currently unknown (Aboyans et al, 2012). Many studies include some period of rest prior to an ABPI (Suominen et al, 2010; Span et al, 2016), though most offer no rationale for the inclusion of such rest periods. Other literature reviews found that many studies omit the use of rest times entirely (Al-Qaisi et al, 2009; Alahdab et al, 2015), raising questions regarding the necessity of rest time prior to ABPI.

Advances in technology have resulted in the production and distribution of automated devices such as the MESI ABPI MD. This system is similar to other oscillometric devices, but is characterised by minimal training and less time involved in taking measurements. Pressure cuffs are positioned over the posterior tibial arteries in both ankles and the right brachial artery of the arm. The cuffs are then simultaneously inflated. The machine detects arterial blood flow and measures an oscillating plethysmographic signal, which is used to automatically calculate the ABPI ratio (Varetto et al, 2019). The MESI device is thought to negate the need for rest time due to simultaneous arterial compression, eliminating systemic variations in blood pressure (Span et al, 2016).

There is a scarcity of research comparing the MESI device to the manual Doppler method, however, the study carried out by Span et al (2016) shows interesting results regarding the sensitivity and specificity of the MESI device. In comparison to the manual Doppler method, the MESI device shows 57% sensitivity when using 0.90 as the cut off value between normal and abnormal results. However, when using the adjusted scale *(Table 1)* and taking

Table 1. ABPI screening reference scale (Norgen et al, 2007)

1.40 or more	1.40–1.00	0.99–0.91	0.90–0.51	0.50 or less
Non-compressible	Normal	Borderline	Abnormal	Severe

1.00 as the cut off value, the MESI device gives a much higher sensitivity value of 85% when compared with the manual method. When taking either 0.90 or 1.00 as cut off values, specificity of the MESI device is 99% and 96% respectively in comparison to the manual method. Despite having slightly lower levels of sensitivity and specificity, the claim that the MESI device does not require a period of rest before testing could lead to greater use within a clinical setting. This could potentially lead to a greater number of patients being screened with automated devices, without the implementation of time-consuming rest periods.

In addition, when comparing automated and manual methods using non-specially trained clinicians, Vega et al (2011) found that automated methods produced greater levels of sensitivity and specificity (97% and 89% respectively) to that of the manual method (95% and 56% respectively). This provides further evidence that devices such as the MESI ABPI negate the need for specialist training whilst still providing accurate readings, again increasing the likelihood of implementation within a clinical setting.

To our knowledge, no studies have been undertaken to investigate the effect of rest time on automated ABPI results. Research into this area could increase the likelihood of implementation of ABPI in the clinical setting (Benchimol et al, 2012) ultimately leading to earlier diagnosis of PAD, minimising both physiological and economic cost. With this in mind, this study aimed to disprove the null-hypothesis that rest time does affect ABPI results in healthy individuals when using the MESI automated device. The manual Doppler/ABPI does provide a brachial pressure index from each arm, which enables the clinician to take the highest reading for the calculation. This can be overcome using the MESI, by undertaking the brachial pressure initially on each arm, before undertaking the MESI ABPI to ensure that the most appropriate arm is utilised and there is no variation between the two limbs (Lindsey and Whiteley, 2019).

METHODOLOGY

This repeated cross-sectional study was conducted at the Peninsula Allied Healthcare Centre (PAHC) of Plymouth University, UK. Exclusion criteria were as follows (1) <18 or >60 years of age, (2) known cardiovascular disease, (3) unable to partake in 5 minutes of moderate exercise, (4) known arrhythmia, (5) known hypertension (6) symptomatic critical limb ischaemia, (7) active lower limb ulceration (8) lower limb amputations. Baseline data was obtained from participants.

Participants pulse rates were taken in a supine position before completing 5 minutes of moderate exercise prior to ABPI testing. This consisted of walking a set route along corridors and up/down stairs, accompanied by a designated research assistant to ensure consistent walking speed over 5 minutes. This period of exercise was included to mimic the typical exertion of a patient prior to attending a hospital appointment. Upon completion of the standardised exercise protocol, participants laid in a supine position while a second pulse measurement was obtained using a pulse oximeter. This ensured the efficacy of the exercise protocol in raising the participants' pulse rate. Following this, cuffs were fitted over the right brachial artery, and the arteries at both ankles and the machine was operated according to manufacturer's instructions. Four sequential ABPI measurements were performed at 0, 10, 20 and 30-minutes, giving a left and right ABPI score. The system inflated and then deflated the three cuffs simultaneously. During measurement, the MESI device is capable of identifying two types of errors: measurement errors and calculation errors. If an error occurred, the operator was required to re-run the test immediately after checking the positioning of the cuffs. All data was collected over a period of 5 weeks in 2018.

Ethical justification

The study protocol was approved by the Undergraduate Ethics Committee for the School of Health Professions and a signed consent form was provided by each participant.

Statistical analysis

Results were analysed using Statistical Package for the Social Sciences (SPSS version 24 IBM) with numerical data presented as standard deviations. Means are reported unless indicated. Differences between ABPI scores at each time interval were analysed using a repeated measure

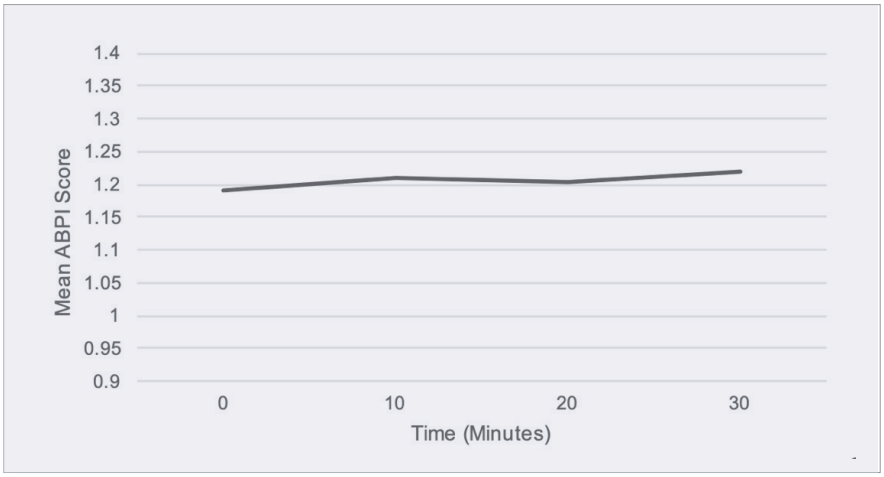

Figure 1. Line graph to show mean ABPI scores over time

analysis of variance (ANOVA). The independent and dependant variables were rest time and ABPI readings respectively. Bivariate correlation was used to investigate the relationship between the change in ABPI values and life style factors such as:

- Age
- Gender
- Waist-height ratio
- Food
- Caffeine consumption two hours prior to testing
- Hours of exercise per week.

Results were taken as significant if $p<0.05$.

RESULTS

Demography

Of 30 recruited participants, 28 went on to complete the study. One was excluded for hypertension and the other was unable to complete the required five minutes of exercise. Of the 28 qualifying participants, there were 9 males and 19 females, with ages ranging from 18 to 52 years and a mean age of 29.89 years (median, 26 years).

For each participant, a left and a right ABPI score was obtained at each time interval, giving a total of eight readings per participant. A mean of these scores was calculated, allowing grouping of participants for statistical analysis. Although data was collected regarding alcohol consumption and smoking prior to ABPI testing, these variables were eliminated from data analysis as no participants had consumed alcohol within 2 hours prior to ABPI testing. Similarly, only one participant had smoked within 2 hours prior to testing. A lack of data within these groups would not have led to meaningful results for data analysis.

All 28 participants had ABPI scores within normal ranges (1.0–1.4) as defined by the MESI operating instructions. Five participants ABPI scores ranged between 1.01 and ≤1.10; seven ranged between 1.11 and ≤1.20, thirteen ranged between 1.21 and ≤1.30 and three ranged between 1.31 and ≤1.40. The data collected shows that the majority of participants had ABPI scores in the middle of the 'normal' range. This finding is expected given the healthy demographic recruited for this study.

At each time interval (0, 10, 20, 30 minutes), a mean ABPI score for each participant was calculated using the left and right ABPI readings. Using this data, a repeated measures ANOVA was performed to calculate the effect of rest time on ABPI scores. *Figure 1* shows mean ABPI scores did not change significantly over time ($p=0.107$).

DISCUSSION

Within the clinical setting, it has been suggested that ABPI tests are currently underused (Benchimol et al, 2012), most notably due to the rest time recommended prior to measurement when adopting the manual method (NICE, 2012). Measurement of the ABPI when using an automated device is unique in that no pre-test rest is recommended (Span et al, 2016). A literature review carried out by Al-Qaisi et al (2009) reported that there is currently no consensus agreement on the methodology of the ABPI including the rest periods used. Our search of the literature is in agreement with this, revealing that rest prior to ABPI measurement is currently unsubstantiated when adopting the manual Doppler method of measurement. However, the omittance of rest prior to automated measurement is based on the theory that simultaneous arterial compression effectively eliminates systolic blood pressure variations (Span et al, 2016). Our study, seemingly the first of its kind, revealed that rest time of up to 30-minutes does not significantly affect the results of automated ABPI measurements when using the MESI ABPI MD device ($p=0.107$), confirming previously unsubstantiated manufacturer claims of the effect of rest time on automated ABPI results.

As this was seemingly the first study looking into the effects of rest time on ABPI results, a healthy cohort was recruited to limit variables and therefore

maximise the power of the study. However, trials in low-risk populations usually require a large sample which was made unobtainable in this case by recruitment restraints. Using a healthy population is not directly comparable to a typical clinical setting or population. Extrapolating these results to an elderly or symptomatic population with comorbidities must, therefore, be taken with caution. Additional research in this area using a symptomatic population may produce more clinically relevant results.

A further limitation of this study was that environment in which the data collection was carried out was relaxed with most participants knowing the researchers. This is contrary to a clinical setting where ABPIs are most likely to be carried out by someone unfamiliar to the patient. With the additional factor of white coat syndrome (Kapoor and Kapoor, 2013), blood pressure readings and thus ABPI score may be affected in a healthcare environment.

During the ABPI measurement of two participants, an error occurred during systolic pressure calculation (indicated by error code E8). This required an additional measurement to be undertaken which may have affected ABPI readings due to a shorter period of recovery between arterial compression. Further studies should consider investigating the effect of rest time on ABPI values obtained with the gold standard Doppler device, given the higher sensitivity and specificity of this method (Span at el, 2016). However, if the challenges facing the clinician is to locate the time and gain/maintain the skills to undertake the manual method, then the automated method appears to be a real solution (Fletcher et al, 2019).

Whilst this study is unable to provide evidence to disregard the use of rest times with the manual method, standardisation of such rest times should be made a priority, in order to increase the implementation of ABPI testing in the clinical setting, whether automated or manually. Given that national guidelines (NICE, 2016) state that the manual Doppler is preferred over an automated system, further evaluation of this study is required to validate the implementation of automated ABPI tools into clinical practise as a screening tool for PAD.

CONCLUSION

The key finding of this study suggests that rest time does not significantly affect ABPI scores in healthy individuals, when tested with the MESI automated device. These results suggest that automated devices such as the MESI could play a role in the screening of PAD. The MESI device negates the need for rest time prior to ABPI measurement and does not need a specialist clinician to operate. These factors could contribute to the increased implementation of ABPI screening within a clinical setting, possibly resulting in earlier diagnosis of PAD, minimising both physiological and economic impact. WUK

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