A comparison between Dopplex Ability and the Doppler method for obtaining ankle brachial pressures.

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Abstract

Aim: The purpose of this study is to establish whether ABPI with the new device is in good agreement and can be performed quicker than with Doppler, and negates the need to rest the patient.

Method: A randomized cross-over study design of 295 limbs was chosen so that unbiased comparisons between unrested patients with the new device and Doppler, and patients rested with the new device and Doppler could be made. The time taken for each test was noted. The analysis methods used were Bland Altman agreement plots, equality plots and Pearson's correlation.

Results: Results show good correlation between unrested patients with the new device and Doppler ($r=0.89$, $p<0.05$) and patients rested with the new device and Doppler ($r=0.89$, $p<0.05$). 95% limits of agreement were ±0.22 with a bias of -0.06 for unrested patients with the new device and Doppler and ±0.22 with a bias of -0.04 for rested patients with the new device and Doppler. Mean time taken to perform the tests was 7.1 minutes for the new device and 16.5 minutes plus resting time for Doppler.

Conclusion: These early results show that the new device has comparable results with Doppler and a considerable reduction in time to perform the tests. The simplicity, speed and accuracy of the new device give it the potential to be used in the community measurement of ABPI prior to compression bandaging and treatment planning for non healing foot wounds.

Introduction

Peripheral arterial disease (PAD) is a reliable marker of future vascular disease such as Congestive Heart Disease (CHD) and stroke, and is a substantial public health issue[1]. In the UK around 100,000 people are diagnosed every year and as a result 60% of PAD patients die from MI and 12% from stroke, and people with PAD are six times more likely to die from CHD within 10 years than those without PAD[1,2].

The prevalence of PAD increases markedly with age, affecting 3% of people under the age of 60 years, rising to >20% in people over 75 years[1,3]. However, whilst 40% of PAD patients have symptomatic disease ranging from intermittent claudication to critical limb ischaemia, around 60% are asymptomatic. There is also growing evidence that the vascular contribution to diabetic foot disease is greater than has previously been realised[4,5,6]. Ischemia in itself is not only a 'risk-factor' for the development of a foot ulcer, but it also complicates and delays wound healing. In fact it has been demonstrated to be a greater 'risk-factor' than neuropathy in both foot ulceration and lower limb amputation in patients with diabetes[7,8], and can be present in 30% of this diabetic population[9].

The detection of peripheral arterial disease is paramount particularly in treating diabetic foot disease, as vascular insufficiency is potentially treatable. National guidelines recommend palpation of pedal pulses however clinically this is known to be wholly inadequate[10]. In cases of diabetic

patients with foot ulceration, the Second European Consensus Document recommends additional, non-invasive vascular assessments, to include the Ankle-Brachial Pressure Index (ABPI)[11].

The ABPI allows the clinician to identify PAD and also provides information regarding its severity that can assist in guiding a treatment approach. If the ABPI is < 0.9, it is 95% sensitive in detecting angiogram positive disease (i.e. >50% stenosis) and almost 100% specific in excluding healthy individuals[12]. The ABPI is a well proven technique and has been used for 20 years to assess for the presence of PAD in wound care. An ABPI < 0.9 is also highly predictive of morbidity and mortality from cardiovascular events.

In the UK national guidelines for 'The Management of Patients with Venous Leg Ulcers', it states that all patients should be given the benefit of ABPI measurements to ensure detection of arterial insufficiency which could result in the commencement of inappropriate and even dangerous therapy[13]. Absent or very weak foot pulses indicate poor peripheral blood supply and are regarded as signs of arterial disease[11]. However, research has shown that diagnosis should not be solely based on the absence or presence of pedal pulses because there is generally a poor agreement between manual palpation and ABPI[13]. Two large studies have shown that up to 67% of limbs with an ABPI of < 0.9 had palpable foot pulses, with the consequent risk of applying compression to people with arterial disease[14,15]. European Guidelines on bandaging now state that an ABPI should always be undertaken before applying compression therapy, to identify the presence and extent of arterial disease. Compression therapy is contraindicated in patients with an ABPI of < 0.8 unless the patients are carefully monitored or reduced compression is used. An ABPI of < 0.5 indicates severe arterial disease and an urgent vascular referral is required[16].
The handheld Doppler (the current method for PAD assessment) requires the patient to be rested for 15 minutes before the assessment can take place. This method involves manual inflation and deflation of the blood pressure cuff and relies on the clinician to audibly identify the returning blood flow to document the systolic pressure. This is repeated on each arm in turn and on two vessels in each foot before manually calculating the ABPI result, and is therefore open to operator error in a number of areas. Doppler measurements of ABPI should be done by staff that are adequately trained to undertake this measure. The overall time for measurement including rest is typically 25-30 minutes[13].

Aims

The aim of the clinical study was to determine the accuracy and agreement between conventional Doppler based ABPI measurements and Dopplex Ability, a new system recently developed by Huntleigh Healthcare, Cardiff. The Dopplex Ability automatically inflates simultaneously, specially designed two chamber cuffs placed on each limb, negating the need for patients to be rested. It records the returning systolic pressures, automatically deflates the cuffs, and then automatically calculates the ABPI result.

Patients

Inclusion: Male/female; aged over 18yrs; identified by a Healthcare Professional as having at least one absent/ monophasic pedal pulse or describing symptoms of claudication pain and/or nocturnal pain; must be able to give informed consent.
Exclusion: Under 18yrs, bilateral limb amputation or unable to give informed consent.

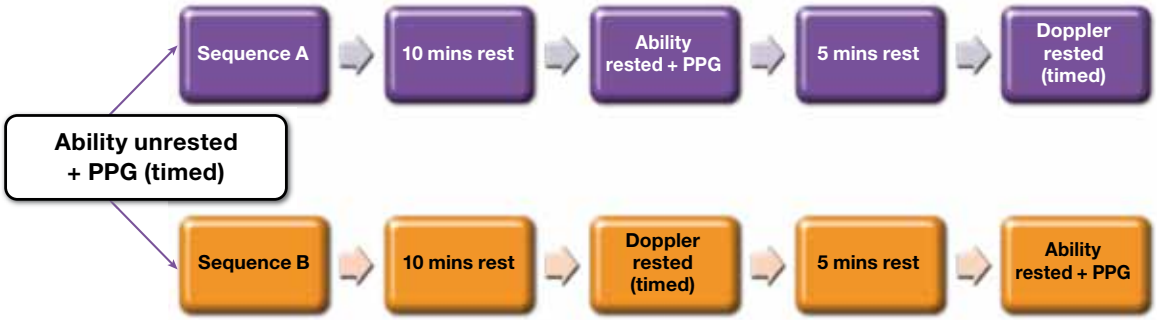
Method

The randomized cross-over study design was chosen as three methods of blood pressure assessment were carried out on the same person. Adopting this study design allowed each subject to be their own control[17]. The three assessments were the Dopplex Ability with photoplethysmography (PPG) unrested (timed), the Dopplex Ability with PPG rested and the Doppler rested (timed). The participant was randomly assigned to one of the two sequence groups, using a computer generated randomisation table[18].

Total sample size n=200 (100 subjects randomly assigned to each sequence)

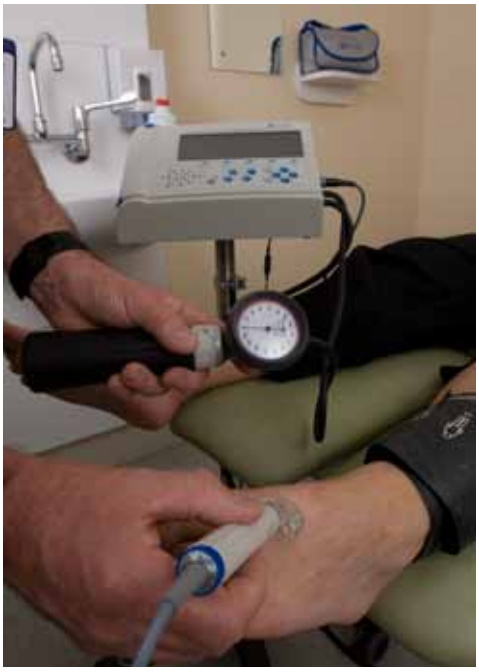
Dopplex Ability data was collected automatically within the data collection device, however it was not displayed and therefore the Podiatrist was blinded to the recordings and results. All data collected using the handheld Doppler was entered into the data collection device manually with times taken to carry out each of the methods also being recorded within the data collection device.

The scores were initially grouped by method regardless of which order they were given for analysis. Scores were also analyzed within their sequence groups to identify any order influence on results. The data was analyzed graphically using simple scatter plots and correlation to determine whether measurement methods were comparable. Means were also compared to assess bias but were not formally tested. Bland Altman plots were used to assess possible bias and to determine the accuracy of the two methods[17]. 95% Limits of agreement were then calculated and compared to acceptable criteria decided upon before data collection. In order that the traditional method of measuring ABPI can be replaced by the new method outlined, 95% limits of agreement should be within ±0.23.



Results

Initial results of 295 limbs show good correlation between unrested Dopplex Ability and Doppler ($r=0.89$, $p<0.05$) and rested Dopplex Ability and Doppler ($r=0.89$, $p<0.05$). 95% limits of agreement were ±0.22 with a bias of -0.064 for unrested Dopplex Ability and Doppler and ±0.22 with a bias of -0.035 for rested Dopplex Ability and Doppler. The correlation between unrested & rested Ability was $r = 0.90$ ($p<0.05$) with 95% limits of agreement were ± 0.21 with a bias of -0.026. Mean times taken to perform the tests were 7.1 minutes for Dopplex Ability and 16.5 minutes plus resting time for Doppler.



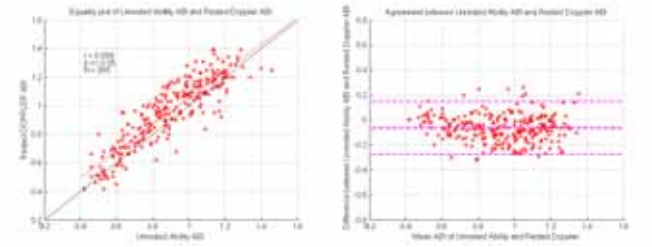
Doppler Assisted ABPI

Conclusion

The study has shown that there was good agreement between:
Rested Ability and Doppler
Unrested Ability and Doppler
Unrested and rested Ability

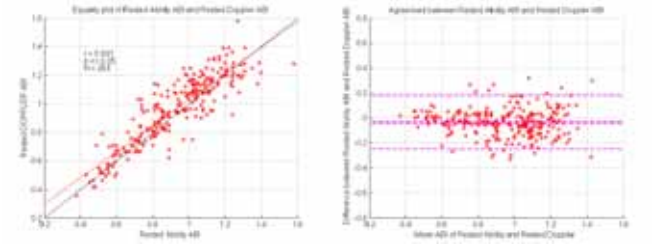
The Ability measurement takes significantly less time than Doppler. The need to rest the patient is eliminated by the simultaneous cuff inflation and its simplicity allows it to be operated by a Healthcare Support Worker. This gives the Dopplex Ability unit the potential to be used as a cost effective screening tool for PAD in primary care settings.

Agreement of Unrested Ability and Doppler



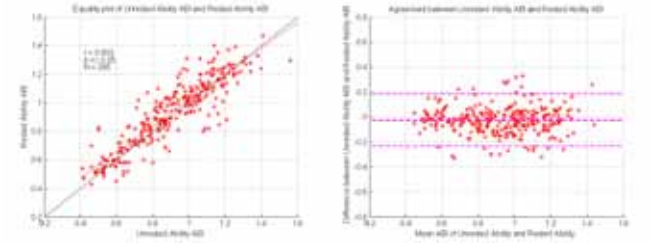
Bias = -0.064
95% limit of agreement = ±0.22

Agreement of Rested Ability and Doppler



Bias = -0.035
95% limit of agreement = ±0.22

Agreement of Unrested and Rested Ability



Bias = -0.026
95% limit of agreement = ±0.21

Test Timings

	Ability Unrested	Ability Rested*	Doppler†
Mean time	7.1 min	4.6 min	16.5 min
Range	4.35 – 11 min	3 – 10.7 min	7.8 – 24.5 min

* Times do not include fitting of cuffs
† Excludes resting time.

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