Evaluation of an automated ankle-brachial pressure index calculator in a nurse-led leg ulcer clinic

KEY WORDS
- Leg ulceration
- Ankle-brachial pressure index (ABPI)
- Doppler ultrasound
- Dopplex Ability

The Dopplex Ability® is a new automated ankle-brachial pressure index (ABPI) calculator, the increased use of which the authors are witnessing in clinical practice. Proposed benefits over the traditional hand-held Doppler machine and manual blood pressure (BP) sphygmomanometer include: ease of use, reduced procedure time and reduced time lying flat for patient, which may lead to more cost-effective treatment outcomes. Since it is routine practice in a number of clinical areas for two members of staff to carry out the holistic leg ulcer assessment process, an additional benefit may be the ability of a single member of staff with minimum training to use the Dopplex Ability. An evaluation of the Dopplex Ability was carried out at a busy nurse-led community leg ulcer clinic over a period of 3 months. A total of 22 patients who attended the clinic for Doppler assessment consented to participate. Participants underwent ABPI calculation using both the Dopplex Ability and the hand-held Doppler. Overall 56% of readings were marginally higher with the Dopplex Ability than with the hand-held Doppler; 9% of readings were lower and 34% were equal. ABPI readings from the Dopplex Ability equipment were on average 0.067 higher than corresponding readings taken from hand-held equipment; this difference was statistically significant (p=0.014). Differences between methods were greater in patients who had readings taken by the Dopplex Ability first than in patients who had hand-held readings taken first. The majority of patients found the Dopplex Ability to be tolerable and staff found it easy to use. The Dopplex Ability was found to be a useful adjuvant to the hand-held Doppler.

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Holistic assessment of leg ulceration is vital prior to the implementation of effective, person-centred treatment pathways and should include the following: past medical and social history, physical examination, structured wound assessment, pain assessment, mobility assessment, clinical investigations and assessment of arterial blood flow (Moffatt, 2008). The Management of Chronic Venous Leg Ulcers guideline (Scottish Intercollegiate Guidelines Network [SIGN], 2010) recommends carrying out an ankle-brachial pressure index (ABPI) using a Doppler ultrasound and blood pressure (BP) sphygmomanometer to determine the presence of arterial disease prior to implementing compression therapy; however, as with any diagnostic procedure, results should be interpreted within the context of additional holistic factors and should not be viewed in isolation. Additionally, clinicians should be aware that there is currently no diagnostic test for venous disease available in the community setting and that ABPI only confirms the presence or absence of peripheral arterial disease (PAD), therefore, assessing patients' suitability for compression therapy (Vowden and Vowden, 2001).

Doppler assessment comprises two important diagnostic components: determination of ABPI and interpretation of audible waveforms (Ruff, 2003). ABPI provides a ratio of arterial blood flow in the brachial arteries compared to those in the foot, and is therefore a useful diagnostic indicator in determining how perfused a limb is. The type of the waveform can also provide important information about the quality of arterial circulation. For example, a person may have a normal ABPI (which ranges from 0.8 to 1.3 in some areas of the

Table 1. Examples of ankle-brachial pressure index (ABPI) calculation			
Left brachial	150*	Right brachial	145
Left anterior tibial	160*	Right anterior tibial	164*
Left posterior tibial	100 (>15 mmHg difference from other pulses)	Right posterior tibial	150
Left peroneal	155	Right peroneal	98 (>15 mmHg difference from other pulses)
Left dorsalis pedis		Right dorsalis pedis	
Left ABPI	1.06 (normal)	Right ABPI	1.09 (normal)

UK, but is set between 0.8 and 1.5 in SIGN 120 [2010]), but present with monophasic low-pitched pulse sounds, which are associated with vessel stenosis and occlusion (Worboys, 2006). An ABPI reading is calculated using the best of the two or three pedal pulse readings that are obtained, with the result that a normal ABPI does not necessarily exclude the presence of arterial disease in other vessels (*Table 1*). Although the ABPI might give an indication as to whether a patient has arterial disease, holistic assessment must also include recognition of any significant deviations in pulse readings between pedal pulses on the same foot, which can have clinical significance and affect the construct validity of the ABPI measurement (Keen, 2008). However, factors unrelated to PAD can also affect ability to detect pulses in all three pedal arteries and should be considered as part of the holistic assessment process (i.e. the dorsalis pedis pulse is congenitally absent in certain individuals).

HAND-HELD DOPPLER MACHINE

The hand-held Doppler, in conjunction with a BP sphygmomanometer, is the most widely used machine for calculating ABPI in the UK (*Figure 1* and *Figure 2*). In addition to the requirement for 10–20 minutes patient rest time to ensure accurate blood pressure readings (Moffatt et al, 2007; Whayman, 2014), the hand-held Doppler requires measurements of arterial pressure to be carried out by placing a blood pressure cuff on each limb at a time. This means that the procedure typically takes 25–30 minutes (Royal College of Nursing [RCN], 2006), although in the clinical area in which the evaluation was carried out, an hour is allocated to each appointment to allow for additional elements of holistic assessment. In order to ensure accuracy of results, it is routine practice in a number of clinical areas for two adequately trained practitioners to participate in the procedure: one to hold the probe in place and one to inflate and deflate the cuff. Benefits of the hand-held Doppler machine include: accuracy, cost-effectiveness (approximate cost per unit £470) and portability. Limitations include: resource implications in clinical areas where two adequately trained members of staff carry out leg ulcer assessment, prolonged time of procedure, prolonged time lying flat and possible discomfort for the patient. An additional limitation for both machines is that ABPI is only accurate if an appropriate size of BP cuff is used during the procedure.

DOPPLEX ABILITY AUTOMATED MACHINE

More recently, the Dopplex Ability automated ABPI calculator has been launched, which the authors have seen in increasing use in clinical practice

Figure 1. Hand-held doppler.

Figure 2. Hand-held doppler in application.

Figure 3. Dopplex Ability.

Figure 4. Dopplex Ability in application.

as part of the holistic process for leg ulcer assessment (*Figure 3*). The Dopplex Ability places all four attached blood pressure cuffs on the patient at a single time and calculates the ABPI in 3 minutes without the need for patient rest time (*Figure 4*). Additionally, ease of use means that one clinician can safely and accurately carry out the procedure. The Dopplex Ability also provides printout information, including a recording of ankle Pulse Volume Waveforms (PVR), which differ from, but clinically resemble, information obtained from interpretation of Doppler waveforms; however, signals are inaudible and therefore cannot be interpreted. Although the cost per unit is considerably higher than for hand-held Doppler machines (approximate cost not including all available fixings and sundries £5,700), the machine is being proposed to promote cost-effective use of resources (i.e. those associated with time and staff), as well as reducing assessment waiting lists and ineffective care pathways, the latter of which are estimated to cost individual UK health boards £0.9–£2.1 million per annum (Carr et al, 1999). Prevalence data relating to the effectiveness of leg ulcer care pathways in the UK are recognised to be considerably out of date, with even the most recent consensus documents relying upon figures published 15 years ago (Harding et al, 2015); therefore the burden associated with leg ulcer care pathways might be argued to be much higher than current figures suggest. Proposed benefits of the Dopplex Ability include: ease of use, requirement for only one member of staff with minimal training, quick procedure and reduced time lying flat for patient. Since the machine is a recent innovation, evidence of accuracy and effectiveness are yet to be adequately determined. Additional limitations may include: high unit cost, no provision of pulse sounds, no provision of readings for all pedal pulses for assessor (only the highest reading for each foot provided).

AIM OF STUDY

The aim of this study is to evaluate the accuracy and effectiveness of the Dopplex Ability compared to the hand-held Doppler and BP cuff in determining ABPIs. The primary endpoint was ABPI readings. The secondary endpoints were clinician ease of use and patient experience.

INCLUSION AND EXCLUSION CRITERIA

Inclusion

Patients aged ≥18 years attending a local community leg ulcer clinic for holistic Doppler assessment; active ulceration and annual recall; able to give informed consent.

Exclusion

Patients <18 years; patients unable to consent to procedure; patients with marked oedema/lymphoedema; patients with signs of severe ischaemia/arterial disease.

METHODOLOGY

Data collection

Over a 3-month period, 22 patients who were scheduled to attend the community leg ulcer clinic for holistic assessment were invited to have the Dopplex Ability carried out in addition to the hand-held Doppler and BP cuff, which were the standard ABPI measurement tools used in the clinic. Prior to giving informed consent for each procedure, all participants were provided with an overview of information on both machines, along with rationale for their use as diagnostic tools in line with recommendations by local health board policy. Since Doppler ultrasound was an integral component of the scheduled clinical intervention and not an adjuvant activity for research purposes, no formal ethical approval was required to carry out this evaluation. A full holistic assessment was carried out for all patients using a recognised local leg ulcer assessment pathway as per national and local recommendations (RCN, 2006; SIGN, 2010). Although there is no rest time required with the Dopplex Ability, all patients were rested for 15 minutes prior to commencing ABPI measurement, since this is routine when additional aspects of the holistic assessment component (i.e. past medical history, clinical examination, etc) are carried out. Patients were randomly allocated to have their ABPI readings obtained from either hand-held equipment first, followed by the Dopplex Ability equipment; or by the Dopplex Ability equipment first, followed by hand-held equipment. Restricted randomisation was utilised to ensure that groups were of equal size. This was to ensure that the rise in blood pressure that is often associated with repeated cuff inflation was not inaccurately attributed to either machine (Moffatt et al, 2007). To reduce clinician skill and experience as potential confounding variables, the assessments were carried out by the same two investigators: a Community Vascular Specialist Nurse and a Leg Ulcer Clinic Coordinator, both of whom had significant post-registration education and experience in leg ulcer assessment. Data from the two methods were compared using paired-samples *t*-tests using aggregated data, and with data disaggregated by 'order of method' (i.e. hand-held method first or Dopplex Ability method first).

A repeated measures analysis of variance (ANOVA) was also conducted to assess differences in method, controlling for order of method. The significance of any difference between left and right-hand readings was also assessed as a controlling factor in the repeated measures ANOVA procedure

Results of each procedure were immediately recorded into an electronic spreadsheet, which was stored in a hard drive with encryption-only access and all patient details were anonymised to ensure confidentiality. At the end of each clinical session, the clinicians self-assessed their experience of using the Dopplex Ability.

RESULTS

Overall, 56% of readings were higher with the Dopplex Ability than with the hand-held Doppler, 9% of readings were lower and 34% were equal (a difference of <0.05 was considered to be equal). Considering aggregated data, and including both left and right readings, the mean hand-held ABPI reading was 1.05 (SD 0.212); and the mean Dopplex Ability ABPI reading was 1.12 (SD 0.203). The mean difference between the two methods was 0.068 (SD 0.175). A paired samples t-test conducted on aggregated data found evidence for a significant difference between readings obtained from the two methods (t_{43}=2.57, p=0.014), with a 95% confidence interval for the difference given by (0.0145, 0.121).

When the procedure with the Dopplex Ability was carried out first, the proportion of higher readings decreased to 50%; increasing to 63% when the procedure with the hand-held Doppler was carried out first. This finding might be expected, since repeated cuff inflation can increase the blood pressure and therefore affect ABPI results (Moffatt et al, 2007). An analysis on disaggregated data (considering patients who were given the hand-held method first and those who were given the Dopplex Ability method first) indicated that both methods, particularly the Dopplex Ability method, appeared sensitive to whether or not the procedure was given first. Mean hand-held readings were 1.10 in patients where this method was given first and 1.00 for patients where this method was given second. Mean Dopplex Ability readings were 1.04 in patients where this method was given first and 1.20 for patients where this method was given second. Hence Dopplex Ability readings were higher in both sub-groups of patients.

Table 2. ABPI readings in patients receiving hand-held (HH) Doppler first

Participant number	HH left ABPI	HH right ABPI	DA left ABPI	DA Right ABPI
1	1.19	1.21	1.45	1.24
2	0.65	1.06	0.73	1.04
3	1.04	1.04	1.38	1.55
4	1.00	0.97	1.19	1.17
5	1.07	0.99	1.17	1.21
6	1.56	1.36	1.23	1.33
7	0.97	0.99	1.01	1.04
8	1.42	1.42	1.34	1.46
9	0.94	0.94	1.05	1.07
10	1.20	1.09	1.19	1.18
11	1.10	1.03	1.25	1.18

Key: Dopplex Ability reading higher than hand-held Doppler (>0.05 difference)
Dopplex Ability reading lower than hand-held Doppler (>0.05 difference)
Dopplex Ability reading equal to hand-held Doppler (< 0.05 difference)

Table 3. ABPI readings in patients receiving Dopplex Ability (DA) first

Participant number	DA left ABPI	DA right ABPI	HH left ABPI	HH Right ABPI
12	1.20	1.28	**1.16**	**1.25**
13	1.21	1.07	0.99	0.98
14	1.30	1.15	1.09	1.10
15	1.31	1.14	1.02	0.97
16	0.64	0.52	0.53	0.48
17	1.03	0.93	1.03	0.94
18	1.05	1.13	1.06	1.09
19	1.01	1.12	0.86	0.94
20	0.87	0.95	1.32	1.36
21	1.02	1.00	1.23	0.86
22	0.86	1.07	0.81	1.03

Key: Dopplex Ability reading higher than hand-held Doppler (>0.05 difference)
Dopplex Ability reading lower than hand-held Doppler (>0.05 difference)
Dopplex Ability reading equal to hand-held Doppler (< 0.05 difference)

Corresponding paired samples *t*-tests conducted on disaggregated data found evidence for a significant difference between readings obtained from the two methods (mean difference 1.00, t_{21}=2.88, p=0.009), with a 95% confidence interval for the difference given by (0.0282, 0.174) for cases in which the hand-held reading was given first; however, no evidence was found for a significant difference between readings obtained from the two methods (mean difference 0.0346, t_{21}=0.887, p=0.385), with a 95% confidence interval for the difference given by (-0.116, 0.0467) for cases in which the Dopplex Ability reading was given first.

A repeated measures ANOVA considering the effect of method on ABPI reading, and controlling for order of method also revealed evidence for a significant difference between readings obtained from the two methods ($F_{1,42}$=6.69, p=0.013), with a 95% confidence interval for the difference given

by (0.0145, 0.121). The order of method was also significant ($F_{1,42}$=5.87, p=0.020).

A further repeated measures ANOVA including side as an additional between-groups factor revealed no evidence that the differential between the two methods was affected by readings being taken from either left or right sides ($F_{1,40}$=0.167, p=0.685).

Hence it may be concluded that although order of procedure did affect results, overall the Dopplex Ability indicated a higher percentage of higher readings than the corresponding hand-held procedure (*Tables 2* and *3*).

Both investigating clinicians found the Dopplex Ability to be easier to use and more time-efficient than the hand-held Doppler. Excluding additional components of assessment, ABPI calculations using the hand-held Doppler and BP cuff took an average of 15 minutes, while ABPI calculations with the Dopplex Ability took 3–5 minutes. The majority of patients found the Dopplex Ability to be easy to tolerate; however, a small number found the highest point of cuff inflation uncomfortable.

DISCUSSION

ABPIs

The Dopplex Ability was found to give significantly higher ABPIs overall than the hand-held Doppler, both based on a comparison of mean values and on consideration of the number of cases where the absolute difference between the two methods was >0.05. This threshold was selected to ensure that perimeters of accuracy were strict, and might be argued in the absence of further evidence to be both a minute and unsubstantial differential. The higher readings may be accounted for by the advanced ability of the automated machine to pick up the first returning pulse sounds that are often undetectable to the human ear. Additionally, 34% of readings showed a difference of <0.05, which supports that overall readings of the Dopplex Ability and the hand-held Doppler were consistently very similar. A comparison of methods according to the calculated mean difference of 0.068 might also suggest this difference to be of little substantive importance, despite the evidence revealed by the *t*-test for a significant difference between mean readings obtained from the two methods.

Based on the results of this evaluation, the authors were satisfied that the Dopplex Ability produced accurate ABPI measurements that corresponded closely with those obtained with the hand-held Doppler. However, the contrast between the magnitude of the differential in the two patient groups is worthy of consideration since the mean discrepancy between the two readings was about three times larger in patients who received the hand-held equipment first.

Ease of use

The investigating authors found the Dopplex Ability easy to use compared to the hand-held Doppler in terms of time taken to complete procedure, level of clinical skill required and ability to carry out ABPI measurements without the assistance of an additional member of staff. The instruction information and DVD provided were considered to be user-friendly and easy to follow, and additional information (available from the company website) was comprehensive and supportive to ensure correct use. The majority of patients, many of whom had been attending the Leg Ulcer Clinic for a number of years and had several previous hand-held Doppler assessments carried out, found the Dopplex Ability easy to tolerate; however, a small number found maximum cuff inflation to be tight and uncomfortable even though the duration of the inflation time was reduced compared to the hand-held Doppler.

Limitations

Although the Dopplex Ability evaluated well in terms of accuracy in measuring ABPIs and ease of use, the following proposed limitations should be identified and discussed. Firstly, although the machine measures all three pedal pulses and uses the highest to calculate the ABPI as one would when carrying out a hand-held Doppler assessment, only the highest pulse reading is made available to the investigating clinician. As noted in the background section of this paper, a marked difference between pedal pulses can be clinically significant and can indicate the presence of arterial disease, even if ABPI measurements are within normal range (Keen, 2008). Therefore it might be argued that, in order to carry out a suitably comprehensive ABPI assessment, all pedal pulses should be assessed and considered by the investigating clinician prior to treatment

planning. A second potential limitation is the absence of audible pulse sounds, which are an equally important clinical component of Doppler assessment. In addition to the potential for a gradual decrease in clinician skill and ability to recognise and interpret Doppler sounds, there is a possibility that clinical information that is potentially relevant (i.e. abnormal Doppler sounds with normal ABPI readings) might be overlooked without a facility to sound Doppler waveforms. A counter-argument might be that the majority of blood pressure measurements are now routinely calculated using automated machines within acute and clinic settings and many nurses have consequently lost the skill to complete a BP measurement using a traditional sphygmomanometer and stethoscope. However, this is not necessarily linked to a detriment in clinical practice, or indeed, patient care.

A third limitation is the proposed cost-effectiveness of the Dopplex Ability with regards to reduced clinic appointment and therefore clinician time, both of which are proposed to have positive resource implications for NHS managers, service providers and users. Although the reduced need for lying flat is arguably beneficial for patient comfort, additional components of holistic assessment (i.e. past medical history, clinical examination) still take a considerable amount of time to complete and are often carried out during the period of patient rest time prior to the ABPI measurement. With this in mind, it might be argued that the reduction in overall consultation would not, in fact, be considerably shorter with the Dopplex Ability than with the hand-held Doppler. Furthermore, although shortened rest times have been linked with inaccuracies in ABPI results (Ruff, 2003; Moffatt et al, 2007), consensus on appropriate pre-assessment rest time is difficult to achieve due to the reliance upon historic clinical practice rather than scientific evidence to shape guidance in this capacity and the need for further uniformity is recognised (Sihlangu and Bliss, 2012). However, ease of use and the need for only one clinician to carry out the procedure may still have long-term cost benefits, which could provide justification for the high unit cost if waiting times and ineffectual care pathways for leg ulcer patients are significantly reduced. Ease of use means that there may also be a potential role for health care assistants to carry out the ABPI measurement component, freeing up trained staff to concentrate on the holistic assessment, interpretation of results and planning of treatment pathways. This might have particularly positive implications for the continued drive to raise the profile of the nurse-led clinic model as being optimum in the delivery of leg ulcer service provision (SIGN, 2010).

Limitations of this evaluation

This study describes a small-scale clinical evaluation rather than a methodological, full-scale randomised controlled trial and it is recommended that results are interpreted as being more akin to expert opinion and experiential knowledge than of empirical evidence. For example: although a randomised approach and statistical analysis were applied, the sample size was relatively small with no power calculation completed. Nonetheless, certain significant findings were obtained, despite a study design that was not powered to detect significant effects. Although attempts to control potential confounding variables were identified (i.e. random allocation to groups, consistent involvement of investigating clinicians, defined inclusion and exclusion criteria), the authors recognise the limitations of the findings of the evaluation and the need for further clinical study level evidence on the Dopplex Ability. However, it is hoped that findings will be of interest to all those involved in the management and clinical provision of leg ulcer services.

RECOMMENDATIONS AND GUIDELINES FOR PRACTICE

With clinical use of the Dopplex Ability in practice, it is understandable that service managers and clinicians are seeking guidance on its suitability as a useful and effective adjuvant to the hand-held Doppler and BP cuff. In the absence of a sound evidence base from which to establish recommendations, clear guidance is difficult to provide and further research is therefore recommended. As an innovative product, continuous clinical feedback and evaluation are necessary to ensure that subsequent product versions (i.e. models that provide readings of all pedal pulses on each foot, as well as Doppler sounds)

address proposed limitations for practice. In the meantime, the following interim processes for using the Dopplex Ability are being increasingly adapted in the authors' clinical areas:

- Dopplex Ability may be appropriate for use in annual review and healed ulcer patients who have had previous Doppler assessment with no concerns or indicators for arterial disease; however, ABPIs are recognised to decrease over time in patients with venous disease (Vowden and Vowden, 2001), and in the case of any change or concern, a hand-held Doppler assessment might be a preferable alternative/adjuvant measurement tool
- Dopplex Ability might be used in first-time patients with no indicators or proposed risk factors for arterial disease; however, if at any point during the holistic assessment process there are indicators for arterial disease or any other concern, hand-held Doppler assessment might be a preferable alternative/adjuvant measurement tool
- Following satisfactory ABPI measurement using the Dopplex Ability, it might be useful to use a hand-held Doppler to sound all pedal pulses on each foot to check for significant differentials between pulses; if there are any concerns, ABPI measurement with the hand held Doppler would be recommended
- Dopplex Ability may be a cost-effective alternative/adjuvant to the hand-held Doppler and BP cuff in clinical areas, where it is routine practice for two members of staff to carry holistic leg ulcer assessments.

The holistic components of a leg ulcer assessment are arguably the most revealing and therefore significant aspects of the procedure. ABPI readings, while providing what might be regarded as the 'final piece of the jigsaw,' will in themselves provide limited information unless interpreted within the context of additional holistic factors. It is the multifactorial assessment — not the ABPI results as is commonly misinterpreted — which determines a diagnosis and leg ulcer aetiology. With this in mind, it might be argued that a good clinical picture has already been painted by the time a competent clinician has reached the Doppler component of assessment. In a large number of cases, forthcoming ABPI ranges can be loosely predicted on the basis of thoroughly gathered holistic factors for which Doppler should provide final confirmation. There are, of course, cases where ABPI readings do not match additional findings from the assessment; however, these are likely to be the exception rather than the rule. If this is an uncomfortable notion, it may be considered that specialist lymphoedema services across the UK have yet to reach consensus regarding the role of ABPI measurement prior to the instigation of compression bandaging (Todd et al, 2008; White et al, 2014).

CONCLUSION

In this evaluation, the Dopplex Ability was found to be an accurate and reliable ABPI measurement tool that provides similar ABPI measurements to the hand-held Doppler; with potential patient, service and cost benefits for leg ulcer management. Investigating clinicians in the evaluation found it easy to use, with the majority of patients finding it tolerable; however, until there is wider evidence on its efficacy, the hand-held Doppler may be the preferred ABPI measurement tool where risk factors for arterial disease and additional concerns are identified during the holistic leg ulcer assessment process. WUK

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