

Combining diabetic foot and retinopathy screening: A step in the right direction? – a feasibility study

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Abstract

Objectives: Peripheral artery disease is a major cardiovascular disease affecting more than 200 million people globally and up to 4 times more frequent in the diabetic population. It can lead to lower extremity amputations or revascularisation and is associated with an increased risk of myocardial infarction, stroke and early mortality. This novel cross-sectional study aimed to explore the feasibility and acceptability of incorporating diabetic foot screening at routine diabetic retinopathy screening appointments.

Methods: Participants underwent foot screening during the interval between pupil dilatation and retinal photography as part of the eye screening procedure. Lower limb arterial assessment included ankle brachial index, pulse volume waveform and protective light touch sensation.

Results: Of 364 participants invited, 88% (n=321) met the inclusion criteria. About 26.4% (n=86) had asymptomatic peripheral artery disease and 3% (n=10) had peripheral sensory neuropathy. Binary logistical regression analysis identified age ($p < 0.005$), existing coronary heart disease ($p < 0.005$) and gender ($p = 0.03$) as predictors of peripheral artery disease.

Conclusion: Incorporating foot examination during eye screening appointments is feasible and was well received by participants and staff alike. Undiagnosed early peripheral artery disease was evident in a third of the study population emphasising the benefit of introducing foot surveillance into eye screening appointments for the early identification of lower limb arterial disease and peripheral sensory neuropathy.

Keywords

Diabetes foot screening, peripheral arterial disease, diabetic peripheral neuropathy, diabetic retinopathy screening

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Introduction

Cardiovascular disease (CVD) is the main cause of death in persons with diabetes worldwide.^{1,2} In 2010, peripheral arterial disease (PAD) was estimated to affect more than 200 million people globally, and approximately 20% over the age of 60 years in the United Kingdom.^{3,4} PAD is considered to be one of the most prevalent of morbid diseases⁵ with the associated disability and mortality increasing in the last two decades, more so in women than men, and no longer restricted to the elderly population and thereby representing a major public health challenge worldwide.⁶

Intermittent claudication is the commonest complaint in symptomatic PAD, but non-invasive vascular assessments such as ankle brachial index (ABI) reveal asymptomatic PAD to be several times more common.^{7,8} Delaying the diagnosis of PAD can potentially lead to the need for revascularisation

and lower extremity amputation (LEA) associated with an increased risk of myocardial infarction (MI), stroke and early mortality.⁹ Diagnosis of PAD at the asymptomatic stage will therefore facilitate interventions to modify known risk factors.⁷

Diabetes is one of the main causes of non-traumatic LEA due to micro and macro-vascular complications such as peripheral neuropathy (DPN) and/or PAD. Co-existing micro-vascular disease (MVD) such as diabetes-related retinopathy

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and nephropathy increases the amputation risk, by more than 20 times^{10,11} and death following amputation.¹²

In 2019, there were an estimated 463 million people with diabetes globally which is anticipated to increase to 700 million by 2045.^{13,14} The International Diabetes Federation (IDF) has stated that every 30 seconds a lower limb or part of a lower limb is lost to amputation somewhere in the world as a consequence of diabetes which amounts to as many as 20 per day in the United Kingdom.^{13,15} Approximately 55% of those with diabetes, who have undergone an LEA, will require amputation of the contralateral limb within 2–3 years with an increased mortality rate of up to 77% within 5 years.¹⁶ A delayed diagnosis can lead to critical limb ischaemia (CLI) which has a very poor prognosis with the mortality rate at 15%–30% within 1 month increasing to 50% at 1 year and reaching 74% after 5 years¹⁷ which is higher than breast cancer, colon cancer, and prostate cancer.¹⁸ Good diabetes control, including improvement in diet, increased activity levels and eliminating unhealthy behaviours (e.g. excessive alcohol, smoking and unhealthy sleep patterns) along with medication adherence can however contribute to delaying the onset or progression of diabetes-related complications such as peripheral neuropathy and peripheral arterial disease.^{19,20}

NICE recommends foot examination for persons with diabetes as part of their annual review.²¹ NICE and several other guidelines recommend ankle brachial pressure index (ABI) as the preferred non-invasive method for detecting PAD and the 10-g monofilament for detecting impaired peripheral sensory neuropathy, in primary and community care settings.^{22–24} However, inconsistencies in diabetic foot screening guidelines exist between regional, national and international recommendations which contributes to inequalities of care.²⁵

The recommended use of ABI for PAD diagnosis is not however without its limitations as highlighted in a recent guideline update by NICE.²¹ The presence of distal peripheral neuropathy, medial arteriosclerosis and incompressible arteries particularly affect the performance of ABI.^{26–28} The recognised limitations of ABI in the diabetic population, therefore, suggests that other methods for detecting PAD should be explored.

Pulse volume waveform (PVW) is usually used to locate arterial lesions and is especially useful in the setting of calcified vessels as it does not require the vessel to be occluded, as needed to perform an ABI, and therefore results are not influenced by the presence of arteriosclerosis.²⁹ PVW analysis carried out at ankle level provides a qualitative assessment of peripheral arterial blood flow.

In an attempt to combat the rising number of diabetes-related LEAs, integrating foot checks into established diabetic eye screening programmes could therefore be a viable option. Diabetic retinopathy screening (DRS) programmes have contributed to relegating diabetes-related retinopathy from being the leading cause of certifiable blindness among working age adults in England and Wales,³⁰ and in a retrospective analysis

of newly recorded certifications of visual impairment in Wales during 2007–2015, sight loss was reduced by almost 50%.³¹ It is well recognised that the success of any screening intervention is dependent on the early detection of complications and timely referral for treatment.³² In the context of PAD if not picked up early, disease will progress to non-healing ulcerations which often necessitate challenging distal revascularisation or angioplasty to improve distal blood flow.³³

In the recent Fourth National Diabetes Foot-care Audit (2019), it was reported that 2.7% of people with diabetes presenting with severe foot ulceration underwent major amputation within 6 months, with 14% dying within 1 year.³⁴

Methods

This cross-sectional feasibility study aimed to explore the acceptability of targeted screening for PAD and peripheral sensory neuropathy on the same occasion as diabetes retinopathy screening. This study was conducted over an 8-week period during 2017 at two hospital sites in Wales (University Hospital of Wales and Royal Glamorgan Hospital) where diabetic retinopathy screening was being carried out.

Ethical approval was granted by both the Chelsea Research Ethics Committee, London and Cardiff Metropolitan University Ethics Committee, Cardiff.

Persons with diabetes registered on the Diabetic Eye Screening Service Wales (DESW), Optimize database, due for eye screening appointments at the two designated hospital sites in Wales during the recruitment period were sent the study information and invitation letter offering foot screening at their forthcoming eye screening appointment. For inclusion into the study, participants had to be at least 18 years of age and able to give informed consent, be transferrable to a patient couch, lie supine for up to 10 min and have at least one lower limb.

The DESW Healthcare Assistants identified participants fulfilling the inclusion criteria. Following the assessment of visual acuity and the administration of Tropicamide eye drops, those agreeing to take part were then escorted by the Podiatry Assistant to an adjacent room for their foot checks. For the arterial assessment, measuring ABI and PVW, required the participant to lay supine with the dual chamber blood pressure cuffs from an automated device (Dopplex Ability, Huntleigh Healthcare), attached to all four limbs. The participant remained supine, motionless and not allowed to talk or smoke for the duration of the test of approximately 3–5 min. All mobile phones were required to be at least 1 metre away from the device. Systolic blood pressures and PVW of each limb were measured automatically and simultaneously, negating the need to rest the participant between measurements. The device automatically calculated the ABI (the highest ankle pressure divided by the highest brachial pressure for each lower limb) and visually displayed the PVW profile. ABI

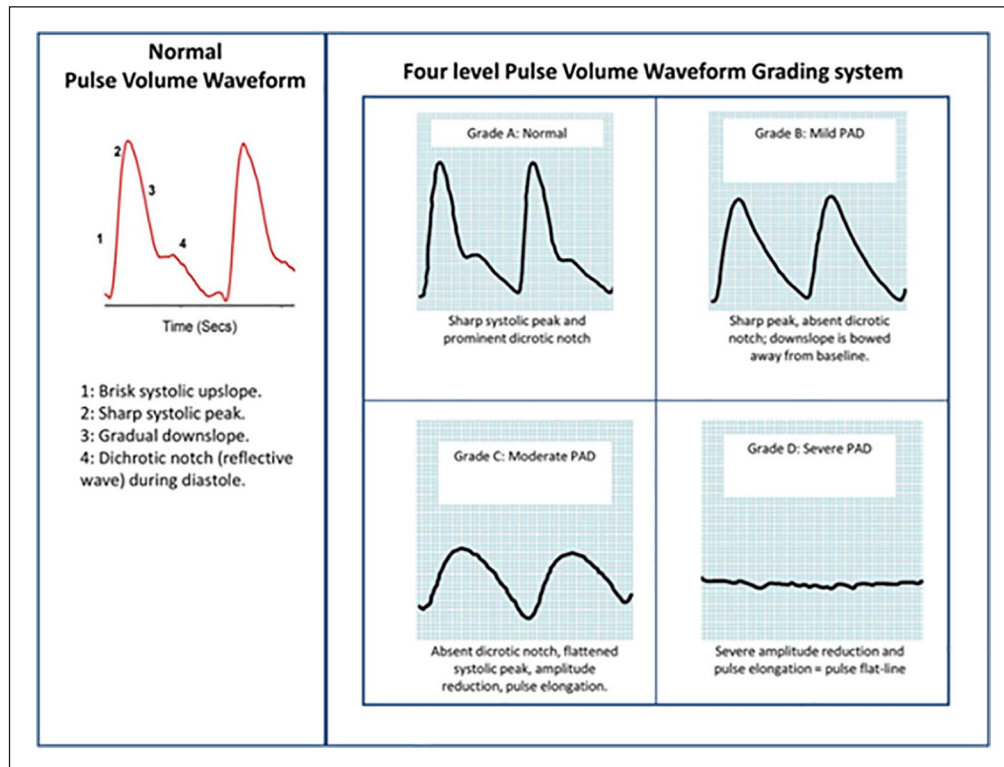


Figure 1. Pulse volume waveform grading system (Rumwell and McPharlin).³⁶

measurements were classified as normal (0.9–1.30), mild obstruction (0.7–0.89), moderate obstruction (0.4–0.69), severe obstruction (<0.4) or poorly compressible (>1.30).³⁵

The Rumwell and McPharlin³⁶ grading system was used to grade the PVW profiles as normal (Grade A), mild obstruction (Grade B), moderate obstruction (Grade C) and severe obstruction (Grade D) (Figure 1).

Light touch peripheral sensory neuropathy was assessed using the 10-g monofilament²¹ at five plantar load bearing sites on each foot. Following the foot screening, the participant was accompanied back to the original room where retinal photography was conducted. All results were stored on computer software for scrutiny and analysis.

The results of the retinal images were sent to the Diabetic Eye Screening Wales central grading centre with the foot screening results being sent to the chief investigator (JL). Onward referrals were according to the locally agreed pathways. GPs received copies of both eye and foot screening reports. Randomly selected participants (n=100) took part in a short telephone questionnaire, exploring their combined screening experience.

Statistical analysis

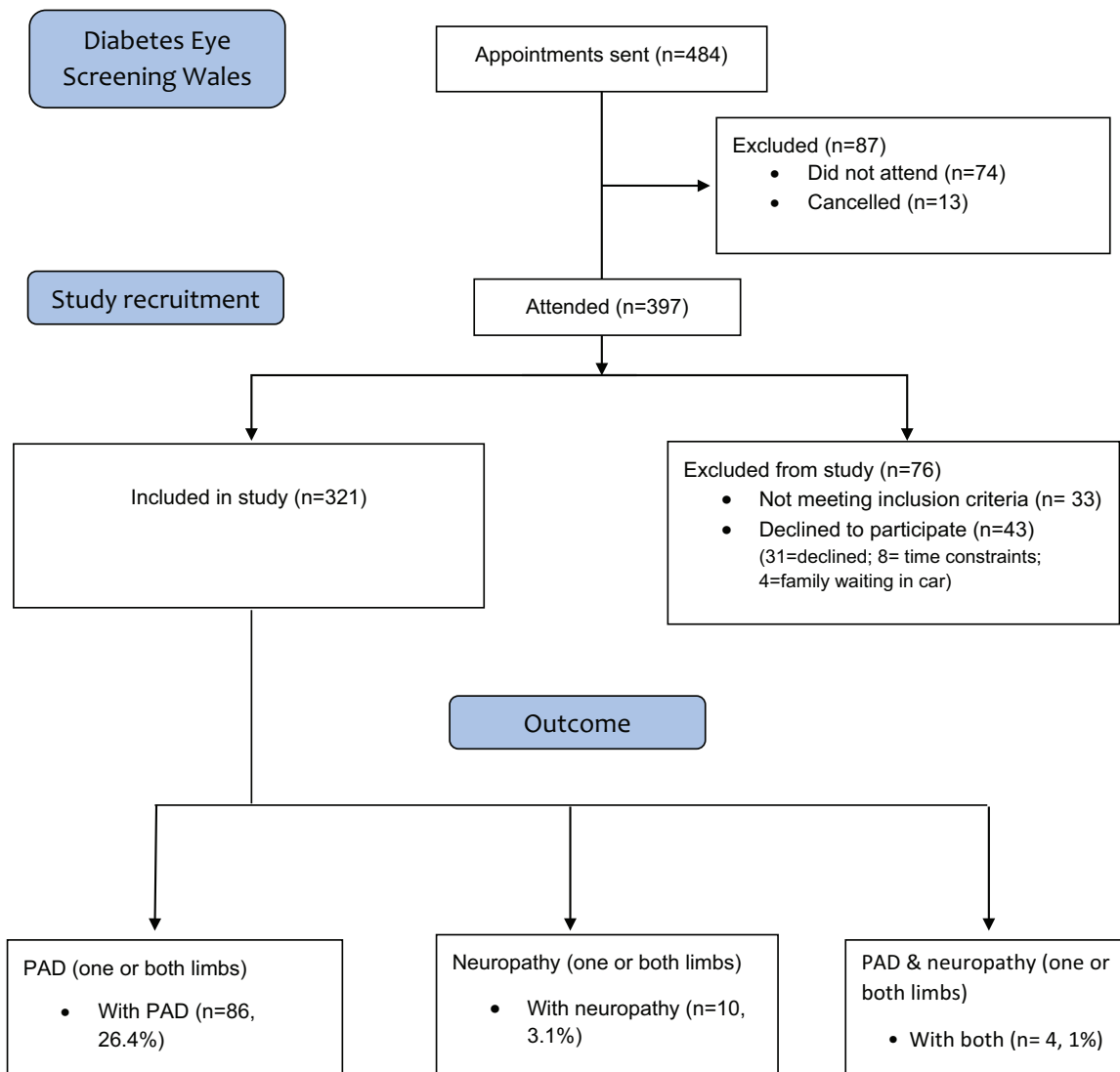
Contingency tables were analysed using Pearson's chi-square test and continuous variables were tested for normality using the Kolmogorov–Smirnov test. Normally distributed data are

presented as mean values plus standard deviation (SD) and comparisons made with the independent-samples t-test. Data not normally distributed are presented as median values and interquartile ranges (IQR), and non-parametric analyses performed using the Mann–Whitney U test. All comparisons were two-sided and correlation analysis undertaken using Pearson's method. Binary logistic regression was used to identify predictors of PAD, with variance inflation used to confirm the absence of multi-collinearity between individuals and this was confirmed by goodness of fit determined using Pearson's and Hosmer–Lemeshow's test. Statistical significance was deemed present with a $p < 0.05$. Statistical analyses were performed with the IBM SPSS Statistics software version 22.0 (IBM Corp., Armonk, NY and Minitab® version 19).

Results

Of the 484 individuals invited for diabetic retinopathy screening, 13 cancelled their appointment and a further 74 did not attend. Of the 397 that did attend, 33 did not meet the study's inclusion criteria and of 43 who did not take part, 31 declined, 8 had time constraints and 4 had family member awaiting in a car. Finally, of the 364 individuals invited, 321 (88%) participated in the combined screening service (Table 1).

The mean age of the study cohort was 64 years, 56% were males, 7% were current smokers with 53% considering themselves to be non-smokers and 40% were ex-smokers (Table 2).

Table 1. Participant recruitment flow diagram.

PAD: peripheral artery disease.

Whereas 64% were known to have hypertension, other vascular complications, that is, coronary heart disease (CHD), stroke, and previous PAD were recorded in only 10% or less of the participants. There were 3% with impaired peripheral sensory neuropathy with two or more sites insensate using the 10 g monofilament, in one or both feet.

In this study, those with an ABI < 0.9 and/or PVW Grades B, C or D were considered as having PAD. About 26.4% (n=86) were found to have previously undetected, asymptomatic PAD as self-reported by the participants (Figure 2(a)–(c)).

Binary Logistical regression was used to explore for the potential risk factors for PAD. Of the variables investigated in this study, the following predictors were found to be significantly associated with the presence of PAD, age, coronary heart disease, gender and ABI (Table 3).

The combined adjusted R^2 value of 17.2% confirms that this is a predictive model of PAD. The model was also adjusted for the effect of age as it could be argued that the effect of all the variables was due to age. ABI, gender and CHD remained significant even when the age of the sample was adjusted for. The analysis of variance confirms that this is highly significant both combined ($p < 0.001$) and individually (Table 4).

Interestingly, body mass index (BMI) was not found to be significantly related to PAD in this group, neither was smoking habits. When considering differences between those with PAD and those without, age, gender, CHD and previous vascular intervention were the only variables to show a statistically significant difference between the two groups.

Although specific data were not collected regarding diabetes complications due to lack of GP engagement, a large

Table 2. Demographic characteristics of the PAD and non-PAD groups.

| Variables | Number of individuals n = 321 (%) | Number with PAD n = 86 (%) | Number No PAD n = 235 (%) | Significance between PAD and no PAD groups (p value) |
|------------------------------------|---|----------------------------------|------------------------------------|---|
| Age, years (mean/SD) | 63.88 / 14.05 | 71.1 / 11.5 | 61 / 14.2 | <0.005 |
| Gender, males/female | 180/141 (56/44) | 40/45 (22/32) | 140/96 (78/68) | 0.03 |
| Smoking | | | | |
| Current | 23 (7) | 5 (23) | 18 (78) | |
| Previous | 128 (40) | 23 (18) | 105 (82) | NS |
| Non | 170 (53) | 57 (34) | 113 (66) | |
| Hypertension | 206 (64) | 70 (34) | 136 (66) | NS |
| Dyslipidaemia | 210 (7) | 69 (33) | 141 (67) | NS |
| Stroke | 31 (10) | 31 (100) | 0 (0) | NS |
| CHD | 61 (3) | 61 (100) | 0 (0) | <0.005 |
| Previous PAD | 23 (7) | 3 (13) | 20 (87) | NS |
| Previous DVT | 9 (3) | 1 (11) | 8 (89) | NS |
| Neuropathy | 10 (3) | 3 (30) | 7 (70) | NS |
| Previous vascular intervention | 36 (11) | 2 (6) | 34 (94) | <0.005 |
| BMI (mean/SD) | 31.61 / 6.14 | 31.44 / 6.36 | 31.74 / 6.12 | NS |
| Waist circumference (cm) (mean/SD) | 104.63 / 13.24 | 106.4 / 16.7 | 104.1 / 13.9 | NS |

PAD: peripheral artery disease; DVT: deep vein thrombosis; SD: standard deviation; NS: nonsignificant; CHD: coronary heart disease; BMI: body mass index.

proportion of participants (between 70–80%) were ‘unaware’ of the impact that diabetes can have on the circulation to the lower limb and feet, and therefore, did not recognise the importance of regular foot checks, thereby increasing the risk of ulceration and potential amputation. After the completion of the study, a random selection of participants (n = 100) were contacted by telephone and asked about their combined screening experience. All of those contacted said they would welcome the addition of foot screening to the eye screening service in the future.

Discussion

Diabetic foot disease is one of the most devastating chronic complications of diabetes worldwide with widely different amputation rates, due to variations in foot care to include examination procedures and frequency and the inadequate detection and modulation of cardio-metabolic risk factors. Screening for PAD in studies involving the general population without cardiovascular risk has proven to be unyielding.³⁷ However, in this novel, targeted feasibility study in people undergoing screening for diabetes-related retinopathy, determining both ABI and PVW, and assessing peripheral neuropathy we revealed that almost a third of the participants had previously undiagnosed PAD with a much small proportion (3%), having DPN. The mean age of those with PAD were a decade older than those without; however, similarly to Sampson,⁶ this study also highlighted that more females than males were found to have PAD.

Although the non-invasive assessment of ABI and pulse volume waveforms (PVW) are well recognised and recommended means of identifying asymptomatic PAD, they are predominantly utilised in secondary care. PVW has been shown to be more reliable than ABI in the diabetic population, being uninfluenced by the presence of arteriosclerosis³⁸ and ABI is also considered less reliable in those with lower levels of disease.^{27,38} However, in this study, a device combining ABI with PVW was used allowing both results to be ascertained simultaneously. The use of PVW in this study also supports NICE recommendations for research into other modalities for identifying PAD, other than ABI, in this high-risk population.³⁹

Those reporting CHD were also found to have asymptomatic PAD. Treating PAD in its asymptomatic stage is highly beneficial, particularly with respect to mitigating common risk factors of atherosclerotic disease in the different vascular beds⁷ with long-term health care cost benefits.⁴⁰

Feedback from both participants and staff confirmed that they would welcome a combined foot and eye screening service, thereby limiting the number of outpatient sessions, a strategy which has also been suggested by others³² with the potential to also reduce cardiovascular disease and premature mortality in this vulnerable high-risk population.

It is not only important for all health professionals to be more astute in identifying PAD to ensure timely management of associated risk factors but there is also a real need to further increase awareness of PAD especially in people with diabetes. A public education programme by the Peripheral

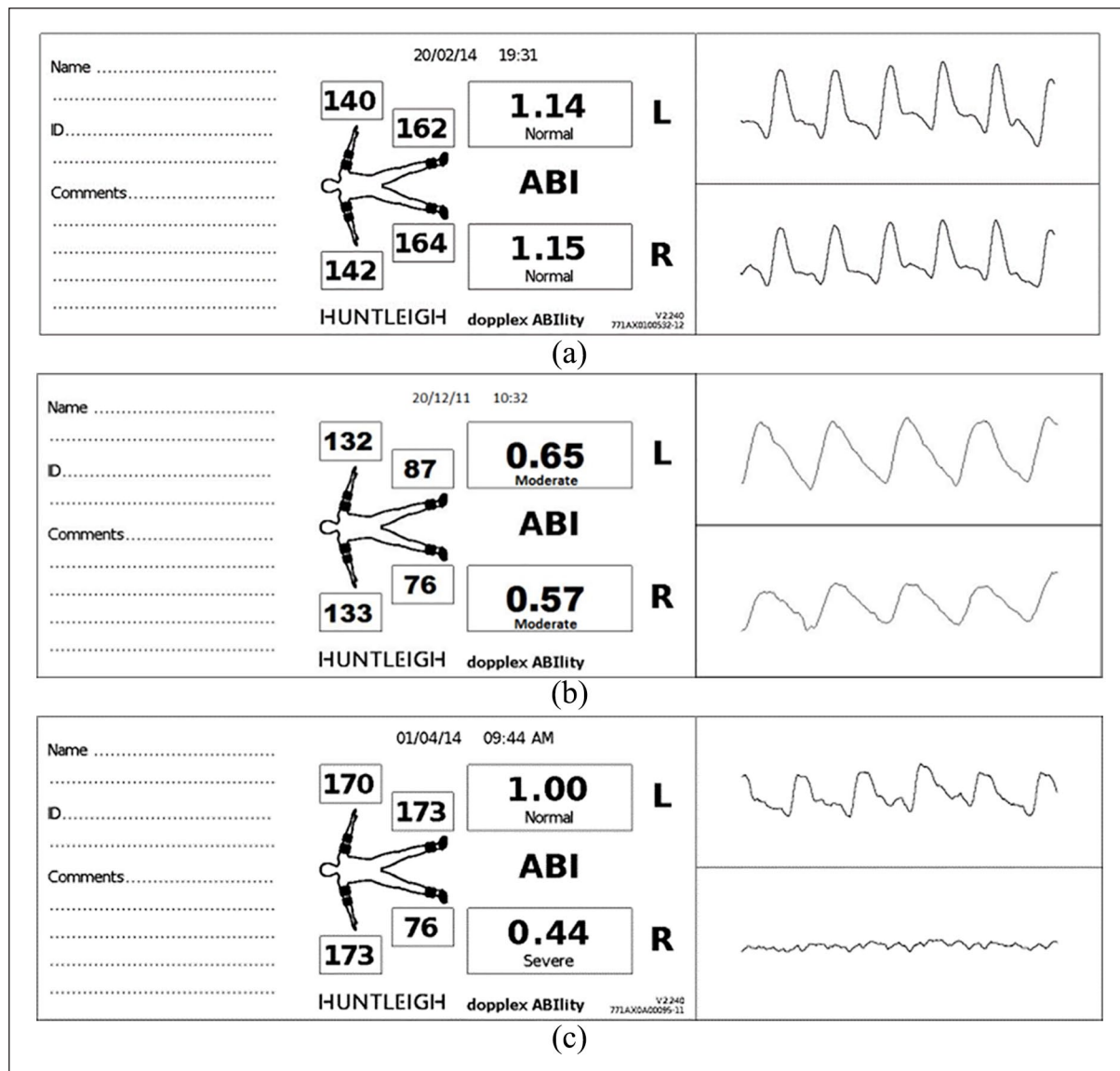


Figure 2. Example of (a) both limbs normal ABI/Grade A PVW, (b) both limbs moderate ABPI/Grade B PVW and (c) left limb normal ABI/Grade A PVW, and right limb severe obstruction ABI/severe obstruction Grade D PVW.

Arterial Disease Coalition for the early detection and prevention of PAD, but also to improve the quality of life of people with PAD,⁴¹ developed for both health care professionals and the public could be adopted and incorporated into diabetes education.

This feasibility study confirms the acceptability, to both the people with diabetes and health care professionals, of introducing a foot care assessment element on the same occasion as diabetic retinopathy screening.

Limitations

This feasibility study was limited in its scope, due to the absence of data from the diabetic screening service and

primary care, to relate the foot examination findings with the retinopathy status and associated risk factors.

Health economic evaluation was not intended at this stage.

Conclusion

Screening for diabetes-related retinopathy and PAD has the ability to detect early disease which can facilitate timely interventions to reduce the risk of vision loss, lower limb and cardiovascular disease, premature death and reduce health care costs while also improving quality of life. This study demonstrated that combining foot and eye screening service is feasible and was well received by participants and staff alike, who

Table 3. Binary logistic regression analysis to determine significant predictors of PAD.

| Predictors of PAD | p value | OR | 95% CI |
|-------------------|---------|--------|------------------|
| Age | <0.005 | 1.0368 | (1.0095, 1.0649) |
| CHD | <0.005 | 2.8651 | (1.4390, 5.7048) |
| Gender | 0.03 | 2.0291 | (1.1017, 3.7372) |
| ABI | <0.005 | 0.0265 | (0.0033, 0.2128) |

The adjusted R² value = 17.2%

PAD: peripheral artery disease; OR: odds ratio; CI: confidence interval; CHD: coronary heart disease; ABI: ankle brachial index.

Table 4. The analysis of variance confirming significance both combined ($p < 0.001$) and individually.

| Source | DF | Wald test | |
|-------------------------------|----|------------|---------|
| | | Chi-square | p value |
| Regression | 4 | 41.79 | <0.001 |
| Age | 1 | 7.05 | 0.008 |
| ABI | 1 | 11.67 | 0.001 |
| CHD 0=No 1= YES | 1 | 8.97 | 0.003 |
| Gender 1 = male 2 = female | 1 | 5.16 | 0.023 |

DF: degrees of freedom; ABI: ankle brachial index; CHD: coronary heart disease.

expressed a wish to see such a service being routinely provided in the future. Combined screening for diabetes-related complications would empower the people with diabetes by increasing their knowledge and awareness of the existence and importance of co-morbidities such as diabetes-related retinopathy, cardiovascular disease, diabetic neuropathy and nephropathy.

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The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

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Informed consent

Written informed consent was obtained from all subjects before the study.

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