Sheffield Teaching Hospitals NHS
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A Single-Trust Service Evaluation to Identify if the Ankle Brachial Pressure Index Test Alone Can Accurately Diagnose Peripheral Arterial Disease without a Duplex Ultrasound in Primary Care Referred Patients

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Overview

Peripheral Arterial Disease (PAD) is an atherosclerotic process caused by accumulation of fatty deposits on the walls of affected arteries (Morley et al., 2018). The presence of diabetes increases the risk fourfold of developing PAD. National Institute of Clinical Excellence (NICE) guidelines (2018) recommend assessing suspected PAD by examining the femoral, popliteal and foot pulses using duplex ultrasound (DUS) and measuring the ankle brachial pressure index (ABPI). However, the sensitivity of ABPIs is varied in the general population, especially concerning diabetic patients and the influence of calcification associated with the condition (Chung et al., 2010; Jelinek, Thompson and Tinley, 2014). In 2018 NICE guidelines (CG147) changed to state ABPIs should not be interpreted in isolation and should not exclude a diagnosis of PAD in diabetic patients.

The vascular ultrasound service at the Trust is seeing an increasing demand for combined lower limb arterial DUS and ABPIs, particularly General Practitioner (GP) referrals for suspected lower limb PAD. Current Trust protocol is to perform DUS and ABPI simultaneously for PAD. The Trust has hypothesised that DUS and ABPIs provide the same diagnosis. To improve the pathway for GP patients referred with suspected PAD and reduce scan time, the Trust has proposed to remove DUS from the examination if the ABPIs are within normal range

Aims and objectives

Aim: To investigate whether ABPIs can provide reliable, diagnostic results for PAD unaccompanied by a DUS in primary care referred patients.

Objectives:

- Determine the agreement between the results of ABPIs and arterial DUS
- Evaluate the effectiveness/reliability of ABPIs in isolation at diagnosing PAD in non-diabetic and diabetic patients
- Develop an evidence-based argument for the removal of the DUS in patients referred from primary care for suspected PAD
- Disseminate findings to inform Trust A staff members and create an evidence-based local protocol

Methodology

A retrospective service evaluation was performed. Consecutive patients referred by their GP for a lower limb arterial DUS and ABPI were identified between 01 September 2017 and 28 February 2018. All imaging was performed on a Philips iU22 (The Netherlands), using a 17-5MHz or a 9-3MHz transducer, by a team of 14 vascular trained sonographers. The DUS and ABPI result was recorded for each patient along with the diabetic status and agreement of the two tests.

To assess the validity of the ABPI, the sensitivity**,** specificity, positive predictive value (PPV), negative predictive value (NPV), positive and negative likelihood ratios (PLR, NLR) and accuracy were calculated using DUS as the reference standard. McNemar's χ2-test and Cohen's Kappa (K) were used to calculate the degree of agreement between DUS and ABPIs. These tests were performed on all patient then non-diabetic and diabetic patient.

Ethical approval was granted by the Trust.

Results

A total of 122 patients were identified via the CRIS search. 79 met the study inclusion criteria. There was a total of 136 cases. The number of diabetic cases was 26 (figure 1).

Figure 1 – Flow chart of participant sampling

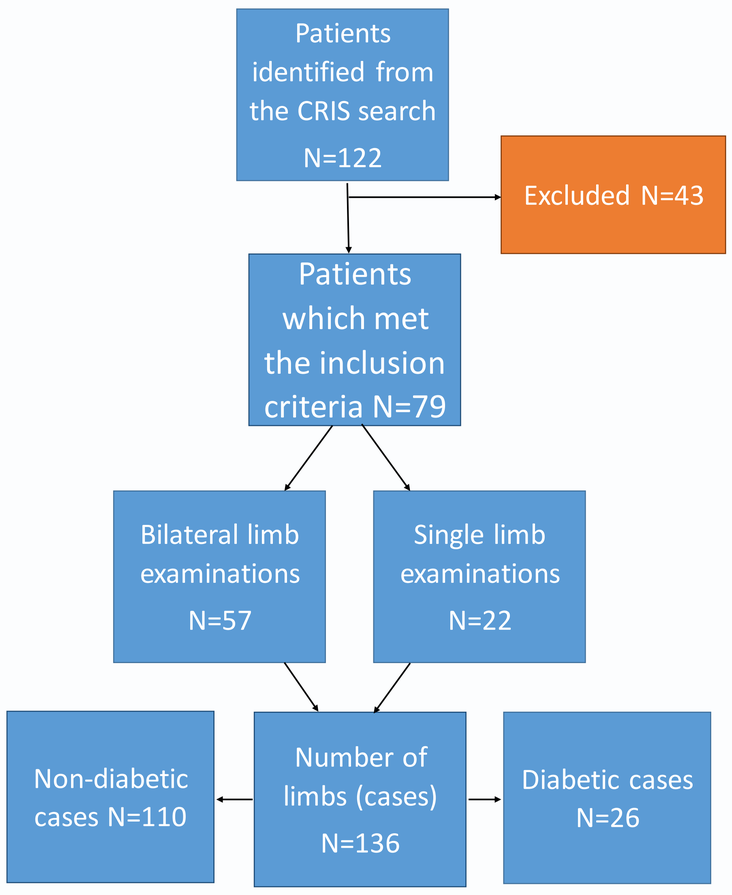

Table 1 shows the diagnostic accuracy of ABPIs using DUS as the "reference standard".

	Study popultation (CIs)	**Diabetic population (CIs)**	**Non-diabetic population (CIs)**
Sensitivity %	78.57 (63.19 - 89.87)	40.00 (5.27 - 85.34)	83.78 (67.99 - 93.81)
Specificity %	95.74 (89.46 - 98.83)	95.24 (76.18 - 99.88)	95.89 (88.46 - 99.14)
LR+	18.46 (6.99 - 48.80)	8.40 (0.94 - 75.31)	20.39 (6.67 - 62.31)
LR-	0.22 (0.13 - 0.40)	0.63 (0.31 - 1.30)	0.17 (0.08 - 0.35)
PPV %	89.19 (75.74 - 95.61)	66.67 (18.24 - 94.72)	91.18 (77.18 - 96.93)
NPV%	90.91 (84.84 - 94.70)	86.96 (76.41 - 93.21)	92.11 (84.85 - 96.05)
Accurary %	90.44 (84.21 - 94.81)	84.62 (65.13 - 95.64)	91.82 (85.04 - 96.19)

There were 123 cases where the DUS and ABPI test agreed on a diagnosis in the study population. The levels of agreement and association for each sub-group are given in table 2 and 3 respectively.

Using DUS as the reference standard the results demonstrate "good" to "very good" agreement between ABPIs and DUS in the study population (K=0.768) and non-diabetic cases (K=0.813). For diabetic patients the agreement was "moderate" (K = 0.416) and the sensitivity of ABPIs was 40% indicating a reduced performance by ABPIs in this patient group.

Table 2 – McNemar's χ2-test results

	Study Population	**Diabetic Cases**	**Non-Diabetic Cases**
McNemar's χ2-test	0.267	0.625	0.508

Table 3 – Cohen's Kappa test results

	Study Population (CIs)		**Diabetic Cases (CIs)**		**Non-Diabetic Cases (CIs)**	
	Value (CIs)	**P value**	**Value (CIs)**	**P value**	**Value (CIs)**	**P value**
Cohen's Kappa (K)	0.768 (0.65-0.89)	P=0.000	0.416 (-0.05-0.88)	P=0.027	0.813 (0.70-0.93)	P=0.000

Discussion

The results support the agreement of DUS and ABPIs for the study population. ABPIs had a moderate sensitivity (78.57%) and a high specificity for PAD (95.74%). An important PLR also indicated good test performance (18.46).

The diabetic sub-group results identified "moderate" agreement between the DUS and ABPI (K=0.416) (Bowers, 2014). Whilst the Kappa result supported agreement, its significance is reduced (p=0.027) and the 95% CIs are wide. The specificity (95.25%) marginally decreased compared to the study population however, the sensitivity reduced significantly to 40% and the PLR indicated reduced test performance (8.40).

The results support the literature and the NICE guidelines that ABPIs independently are not reliable for diagnosing PAD in diabetic patients.

Recommendations

Whilst diabetes influenced this result, there were six non-diabetic, false-negative cases. Despite significant statistical evidence, if the proposed removal of the DUS for GP referred patients with suspected PAD went ahead, these six patients would be missed and not receive timely, appropriate care. Therefore, it is unjustifiable to suggest that ABPI tests can diagnose PAD without DUS in primary care referred patients.

The data strongly points to continuing with current protocol of performing DUS and ABPI simultaneously for GP referred patients.

References

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