SYSTEMATIC REVIEW

# Selecting Portable Ankle/Toe Brachial Pressure Index Systems for a Peripheral Arterial Disease Population Screening Programme: a Systematic Review, Clinical Evaluation Exercise, and Consensus Process

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**WHAT THIS PAPER ADDS**

This paper provides a review of the currently available diagnostic accuracy data from six devices deemed to be suitable for use in a community peripheral arterial disease (PAD) screening programme. Further to this, it provides feedback from community abdominal aortic aneurysm (AAA) screening staff on the usability of these devices. These two elements were combined during a consensus conference where the devices were ranked in order of both diagnostic accuracy and the practicality of using them within the AAA screening programme. This provides information on the most appropriate device to consider using within a community PAD screening programme.

**Objective:** To provide an overview of systems available for peripheral arterial disease (PAD) screening, together with respective accuracies and a clinical evaluation to identify a system suitable for use in a community screening programme.

**Methods:** A systematic review of the diagnostic accuracy of six ankle brachial pressure index (ABPI) and toe brachial pressure index (TBPI) devices deemed to be portable, which were Conformité Européenne (CE) marked, and were automated or semi-automated was carried out compared with gold standard handheld Doppler and duplex ultrasound. The devices were MESI-ABPI-MD, Huntleigh Dopplex Ability, Huntleigh ABPI and TBPI systems, Systoe TBPI system, and BlueDop. Seven databases (MEDLINE, EMBASE, Scopus, Web of Science, Cochrane Database of Systematic Reviews, Cochrane Register of Controlled Trials (CENTRAL), and Cumulative Index to Nursing and Allied Health Literature (CINAHL)) were searched, and 11 studies were identified as eligible for review. This was followed by hands on clinical evaluation by abdominal aortic aneurysm (AAA) screening staff ($n = 39$). During this, devices were demonstrated to staff which they then tested on volunteers and gave feedback using pre-designed questionnaires on their suitability for use in a screening programme. Finally, accuracy data and staff preferences were combined during a consensus conference that was held between study and screening staff to determine the most appropriate device to use in a community screening programme.

**Results:** Generally, the evaluated systems have a moderate level of sensitivity and a high level of specificity: Dopplex ability sensitivity 20% — 70%, specificity 86% — 96%; MESI sensitivity 57% — 74%, specificity 85% — 99%; BlueDop sensitivity 95%, specificity 89%; and Systoe sensitivity 71%, specificity 77%. Clinical evaluation by screening staff identified a preference for the MESI system. The consensus conference concluded that the MESI device was a good candidate for use in a community PAD screening programme.

**Conclusion:** The MESI system is a good candidate to consider for community PAD screening.

**Keywords:** Device accuracy, Peripheral arterial disease, Screening
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## INTRODUCTION

Cardiovascular disease is a major contributor to poor health globally, affecting around seven million people,[1] and the most common cause of death in England, responsible for one third of all deaths.[2] The rate of reduction in national cardiovascular mortality has slowed in the last decade.[3] Cardiovascular morbidity has a major impact not only on patients but also on health and social care.[4]

The UK NHS abdominal aortic aneurysm (AAA) screening programmes invite all men for an abdominal ultrasound in the year of their 65th birthday, with an uptake of around 80%.[5] In 2017, the Danish Viborg Vascular (VIVA) trial demonstrated that inviting men for peripheral arterial disease (PAD), high blood pressure (BP), and AAA screening reduced all cause mortality compared with no screening.[6] Given the large numbers of men that are seen through the existing UK AAA screening programme, this infrastructure is an ideal platform to add additional screening for PAD to provide early preventative care. As women are not invited for AAA screening in the UK, PAD screening for women would need to be provided through an alternative mechanism.

The National Institute for Health and Care Excellence (NICE) guidelines and European Society for Cardiology (ECS) guidelines recommend that PAD presence and severity are assessed by measuring ankle brachial pressure index (ABPI).[7,8] The gold standard method for conducting ABPI measurement is handheld Doppler (HHD), which requires specialist training[9] and can lead to poor diagnostic accuracy, and under treatment if used incorrectly.[10] Automated ABPI systems have been identified as a solution.[11] They are capable of performing automated readings and calculations making them more efficient, unbiased, and requiring less training.[10] Therefore, they may be more appropriate for use in screening programmes.[12] There are a variety of these systems on the market, but these vary considerably in cost, portability, and level of automation, and therefore amount of training that would be required. As AAA screening programmes are largely community delivered, any system would need to be portable (i.e., carried within one bag and not too heavy), cost effective, with fast and accurate measurement.[8] Therefore, an up to date systematic review of their accuracy is warranted to help identify suitable systems to be used in a screening programme together with a clinical evaluation from AAA screening staff to determine usability. This work forms the first part of a much larger programme of work funded by the National Institute of Health and Care Research. A study, named "Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial" (PHAST), has been designed to test the feasibility of introducing PAD screening to the AAA screening programme. As such, systems are considered in this context.

The first aim of this study was to perform a systematic literature review to determine the diagnostic accuracy of lower limb pressure measurement by portable CE (Conformité Européenne) marked ABPI or TBPI systems with published accuracy data compared with a gold standard method (part A). The second aim was to determine acceptability of, and preferences for these systems among a cohort of screening service providers to determine real world usability (part B) and to gather opinions on the feasibility of the inclusion of PAD screening into AAA screening. The system that is identified as the most suitable by this work will be taken forward to the next part of the PHAST study in which it will be used in a feasibility study of community PAD screening.

## MATERIALS AND METHODS

### *Selection of systems for inclusion in study*

Automated or semi-automated ABPI or TBPI systems were identified for inclusion based on UK availability and CE marking. Systems were excluded if they were not easily portable (i.e., in a single bag and easily transported between clinical sites by screening staff), were deemed too expensive ($>$ £5 000, a limit determined by grant funder, National Institute of Health and Care Research, NIHR200601), or were not available on loan from the manufacturer if they exceeded this cost limit.

A flow diagram depicting the process used to select devices to take forward into the systematic review and for clinical evaluation is shown in Fig. 1. Due to the context of PAD screening to take place in the community as part of the AAA infrastructure, six systems were taken forward for study based on portability, cost, and availability within the UK: MESI-ABPI-MD, Huntleigh Dopplex Ability, Huntleigh ABPI and TBPI systems, Systoe TBPI system, and BlueDop. Three systems were excluded: Vicorder (cost $>$ £5 000),

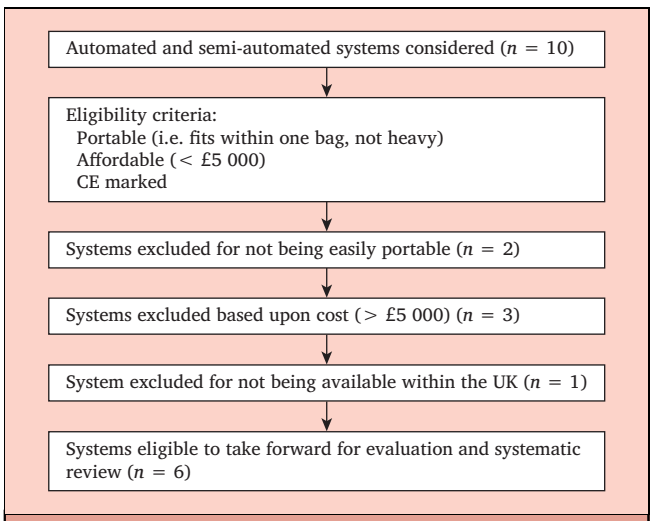


**Figure 1.** Flow diagram to show system selection for inclusion in this systematic review, clinical evaluation exercise, and consensus process on the use of portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme.

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**Table 1. Eligibility criteria for inclusion of studies into systematic review on portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| | Inclusion criteria | Exclusion criteria |
|---|---|---|
| Types of studies | Diagnostic accuracy studies (sensitivity and specificity) of lower limb pressure measurement comparing using a portable automated or semi-automated device available and Conformité Européenne marked in the United Kingdom, handheld Doppler, duplex ultrasound or angiography<br>Randomised controlled trials<br>Cross sectional studies<br>Cohort studies | Literature reviews<br>Meta-analyses<br>Conference abstracts<br>Expert opinions<br>Studies not translated into English<br>No ankle brachial pressure index reported |
| Target condition | Symptomatic or asymptomatic peripheral arterial disease | |
| Participants | Individuals with a risk of, or confirmed to have, peripheral arterial disease were included | Participants < 18 y<br>Entirely healthy control cohort<br>Systems used in the post-operative setting |
| Types of systems | <£5 000<br>Available in the European Union (Conformité Européenne marked)<br>Portable | > £5 000<br>Bulky or attached to a cart |

ATYS BASIC (cost > £5 000 and portability), and VIASONIX Falcon/Pro (cost > £5 000 and portability) and one system was not available within the UK (OMRON HBP-8000). In addition, one system that is on the market now, was not on the market at the time of study design (MESI m-tablet). Four additional systems were identified during the systematic review. This was after the system evaluation process started, preventing further inclusion. One of these systems was potentially useable in the context of community screening (Microlife WatchBP). The three other systems did not meet the cost and portability inclusion criteria: Casmed 740, Dinamap 8100, and Boso Abi 100.

### *Part A: Systematic review*

The systematic review was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) approach[13] and according to the Cochrane Handbook for Diagnostic Test Accuracy Reviews framework using HHD as a gold standard comparator. The protocol was registered prospectively on PROSPERO (CRD42021242031).

**Eligibility criteria.** A list of eligibility criteria is shown in Table 1.

**Outcome measures.** The primary outcome measure was the diagnostic accuracy of lower limb pressure measurement compared with gold standard methods (according to the National Institute for Health and Care Excellence guidelines, this is the handheld Doppler technique, but other validated methods were included, duplex ultrasound and laser Doppler, to identify systems with an acceptable sensitivity/specificity for PAD > 80%. The value of 80% was chosen as the lower limit for diagnostic test accuracy as a cutoff for inclusion in this study. Absolute and relative diagnostic test accuracy for each device was considered as part of the consensus process in part B of the study. Secondary outcome measures included reliability, test failure rate, portability, and time for diagnostic test.

**Information sources and search strategy.** Peer reviewed studies were identified using MEDLINE, EMBASE, Scopus, Web of Science, Cochrane Database of Systematic Reviews, Cochrane Register of Controlled Trials (CENTRAL), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) — from database inception to August 2021 (for full search strategies developed in consultation with a librarian [C.P.] see Supplementary methods). Duplicates were excluded and full texts obtained and assessed for inclusion by two authors (E.W. and S.J.M.) and checked by a third (M.J.B.). Manufacturer websites were consulted for unpublished information. Reference lists of eligible articles were also examined.

**Data extraction and quality assessment.** Data were extracted by E.W. and S.J.M. independently using a standardised form. Studies were assessed for bias and applicability by one investigator (E.W.) using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) 2 tool.[14] Studies were judged across four domains for bias (patient selection, index test, reference standard, flow and timing) and three domains for applicability (patient selection, index test, reference standard). If a study was judged as low on all domains relating to bias and applicability, it was given a judgement of "low risk of bias" or "low concern regarding applicability". If a study is as high or unclear on one or more domains, it was judged "at risk of bias" or having "concerns regarding applicability".

### *Part B: Clinical evaluation by screening providers*

**Participants.** Screening technicians, managers, and clinical scientists from the national AAA screening programme were invited to clinical evaluation days at the University of Leicester, UK by email to all programmes and invitations at research meetings. All participants gave informed consent and the study received ethical approval from the University of Leicester's Medicine and Biological Sciences Research Ethics Committee (26165).

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**Clinical evaluation.** The aim of the clinical evaluation was to provide AAA screening staff with the opportunity to test the systems on live volunteers to get their feedback on usability and preferences for devices. Participants were given demonstrations of all systems prior to testing and were supervised by a member of the study team. A standardised questionnaire following each test collected information on portability, system usage, and data interpretation (see Supplementary material for further details), but no diagnostic accuracy data were gathered.

**Consensus conference.** All programme investigators and participants from the clinical evaluation days were invited to take part in a consensus conference, the purpose of which was to determine a preference rank order for the PAD systems based on considerations around accuracy, but also usability as assessed earlier by screening staff during the system evaluation days. The objective was to achieve a group consensus regarding which system is most suitable for PAD community screening (see Supplementary methods for more details).

## RESULTS

### *Part A: Search results*

From the database and website search, 1 386 studies were identified. Eleven were included in the final review after deduplication and screening[15–25] (Fig. 2). Of these 11 studies, four evaluated the Dopplex Ability,[15,17,20,21] four the MESI,[16,18,23,25] two Systoe Atys Medical,[22,24] and one the BlueDop.[19] The most commonly used reference test was HHD ($n$ = 6).[16–18,21,23,25] Four studies used duplex ultrasound[15,19,20,22] and one used laser Doppler.[24]

**Study characteristics.** Characteristics of included studies ($n$ = 11) are presented in Table 2. A total of 1 860 patients were included and sample size varied from 54 to 303. Nine of the 11 studies included diabetic patients,[15,16,18,20–25], one study did not include any patients with diabetes,[17] and the other did not report on diabetic status.[19] In terms of smoking status, 9/11 studies reported this[15,16,18–23,25] and two did not.[17,24] Eight of the 11 studies used the conventional ABPI cutoff to diagnose PAD of $<$ 0.9.[15–18,20,21,23,25] One study reduced this to $<$ 0.8 when assessing the BlueDop[19] and another used a TBPI cutoff of $<$ 0.7 when evaluating the Systoe system,[22] while one study did not report their diagnostic cutoff for diagnosing PAD.[24]

**Risk of bias assessment.** The majority of studies were considered to be at risk of bias (Fig. 3). Eight of the 11 studies were judged as low risk in terms of patient selection[15–20,23,24] and index test,[15,17–23] and 7/11 studies were judged as low risk of bias for the reference standard.[15,17–21,23,25] Only one study was deemed to have a low risk of bias for flow and timing.[17] Concerns for bias in applicability were only seen in 3/11 studies.[16,24,25]

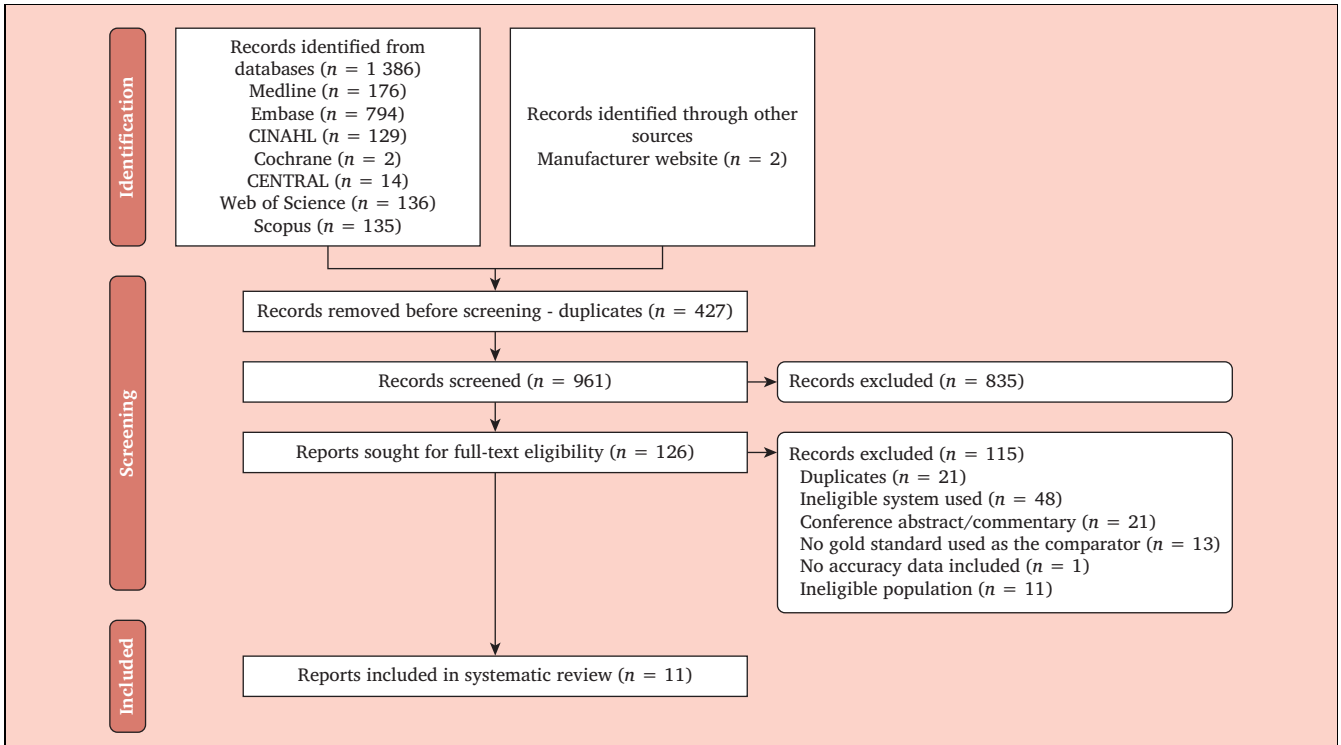


**Figure 2.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram showing search and study selecting processes in this systematic review, clinical evaluation exercise, and consensus process on the use of portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme.

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**Table 2. Characteristics of included studies in this systematic review on portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| Author, year | Patients | Sample size – participants [limbs] | PAD patients | DM patients | Age – *y* | Clinical setting | System | Index test and diagnostic threshold | QUADAS risk of bias | QUADAS applicability |
|---|---|---|---|---|---|---|---|---|---|---|
| Babaei, 2020[15] | Diabetic patients | 303 [606] | NR (2.2) | 303 (100) | 60.1±0.3 | Institute of Endocrinology and Metabolism | Dopplex Ability | DUS <0.9 | At risk | Low concern |
| Boilley, 2020[16] | Suspected PAD patients | 102 | 82 (80) | NR (20) | 63.0±11.0 | Vascular medical unit | MESI system | HHD <0.9 | At risk | Concern |
| Davies, 2016[17] | PAD patients | [724]* | 41 (5.7) | 0 (0) | 64.0±9.0 | Primary care and secondary care at a vascular unit | Dopplex Ability | HHD <0.9 | Low risk | Low concern |
| Hageman, 2021[18] | Suspected PAD patients | 201 [402] | 61 (31) | 61 (31) | 67.0±11.0 | Vascular laboratory | MESI system | HHD <0.9 | At risk | Low concern |
| Kordzadeh, 2018[19] | Medical patients | 166 [276] | NR | NR | 73 (65, 81) | Vascular outpatient department | BlueDop | DUS <0.8 | At risk | Low concern |
| Lewis, 2016[20] | Medical patients | 189 | 68 (36) | 49 (26) | 67.0±12.0 | Medical physics / vascular outpatients department | Dopplex Ability | DUS <0.9 | At risk | Low concern |
| Millen, 2018[21] | Medical patients | 66 [129] | 28 (43) | 18 (27) | 69.5±12.0 | Vascular laboratory | Dopplex Ability | HHD <0.9 | At risk | Low concern |
| Sonter, 2017[22] | Podiatry clinic / vascular outpatient department | 90 | 39 (43) | 50 (56) | 73.0±7.0 | Podiatry patients | Systoe Atys Medical | Colour duplex ultrasound <0.7 and <0.75 | At risk | Low concern |
| Span, 2016[23] | Medical patients | 136 | 14 (10) | 19 (14) | 64.0±7.8 | GP office | MESI system | HHD <0.9 | At risk | Low concern |
| Varetto, 2019[25] | PAD patients | 185 [370] | NR | 16 (25) | 72.5±13.6 | Inpatient vascular ward and outpatient vascular clinic | MESI system | HHD <0.9 | At risk | Concern |
| Widmer, 2012[24] | PAD patients | 54 [107 toes] | NR | 27 (50) | 68.6 (48, 87) | Vascular surgical outpatient clinic | Systoe Atys Medical | Laser Doppler | At risk | Concern |

Data are presented as *n* (%), mean ± standard deviation, or median (IQR). DM = diabetes mellitus; GP = general practitioner; HHD = handheld Doppler; PAD = peripheral arterial disease; NR = not recorded; QUADAS = Quality Assessment of Diagnostic Accuracy Studies; DUS = duplex ultrasound.

* This study did not state the number of participants, only the number of limbs.

**Diagnostic accuracy.** A summary of the results from the systemic review can be found in Table 3.

***Sensitivity and specificity.*** Data were recorded in 9/11 studies and are listed in Table 3.

A systematic review[12] suggested that the sensitivity of PAD diagnosis could be improved by using a higher threshold value than the conventional value of 0.9 when using oscillometric devices. Five studies that were reviewed have determined how the sensitivity values change when this threshold value is raised, and have presented the optimal threshold for the detection of PAD, which does appear to differ device to device (Table 4). The optimal diagnostic threshold for the Dopplex Ability was cited between 0.98 and 1.2, which increased the sensitivity to 75% and specificity to 78%.[15,17,20] The optimal diagnostic threshold for the MESI was cited by both studies to be 1.0 giving a sensitivity of 89.5% and specificity of 94%.[18,23]

Two studies carried out a subanalysis in a diabetic compared with a non-diabetic population.[18,22] In patients with diabetes, the Systoe system was found to have a sensitivity of 74% and specificity of 67% when a diagnostic threshold of $< 0.7$ was implemented. This fell to a sensitivity of 70% and specificity of 61.5% when this threshold was raised to $< 0.75$.[22] The second study used the MESI system. The correlation between results generated by the MESI and HHD in diabetic patients was strong ($r = 0.84$) and not different to that of non-diabetic patients. With the diagnostic threshold for PAD diagnosis at 0.9, the authors calculated 68% sensitivity and 95% specificity values for the diabetic population.[18]

***Reproducibility.*** One study reported intra-operator and interoperator differences for the MESI system.[18] Intraclass correlation coefficient of agreement for the same operator was 0.9 with a CV of 8%, and 0.86 for different operators with a CV of 9%. Span and colleagues[23] also reported that CV of repeated measurements by the MESI system were 3.5% on the left and 3.2% on the right, demonstrating excellent reproducibility.

## PART B: CLINICAL EVALUATION PARTICIPANTS

Thirty-nine individuals participated in the evaluation days. Of these 21 were screening technicians, one ultrasonographer, eight screening programme managers, three AAA screening specialist nurses, one vascular scientist, and five respondents did not provide this information. They had on average 6.5 years' experience in the AAA screening programme (range 1 – 12 years). Eight individuals had some experience in performing ABPI measurements.

### *Questionnaire results*

Data were available from all 39 participants; however, responses were not given to all questions. Overall comparison of systems over the three domains showed that participants scored the MESI the highest (Table 5). Individual domain analysis is provided in Supplementary Table S1.

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### Set up and portability

The Systoe system scored the highest overall for setup/portability with the MESI and BlueDop ranked second (Supplementary Fig. S1).

### System use

MESI achieved the highest score for use, with the Systoe and BlueDop systems second and third. In particular, the MESI scored highly on ease of use and time it took to perform the test. The amount of training that the staff felt they would need to learn to use it was lower than for some of the other systems. However, they did not feel it could be used at the same time as the AAA scan, and that extra time would be required in the appointment. On average, they estimated an additional 10.4 minutes would be required to perform the screening using the MESI system. This is less time than was estimated for the other systems: Systoe 11.9 minutes, BlueDop 13.6 minutes, Huntleigh TBPI 13.9 minutes, Dopplex ability 14.3 minutes, and Huntleigh ABPI 14.5 minutes. In general, the staff considered all systems would be acceptable to the individuals being screened, would be easy to clean, and would not put them at risk of musculoskeletal disorders (Supplementary Fig. S2).

### Results

MESI scored the highest for results interpretation, with BlueDop and the Dopplex Ability second and third. The Huntleigh ABPI and TBPI systems scored poorly for both of these questions (Supplementary Fig. S3).

**Consensus conference participants.** Eighteen individuals attended, four were AAA screeners and four were AAA screening programme managers (44%), and 10 were from the investigator team (55%). Seven of the 10 investigators did not feel in a position to offer an opinion having not seen all systems, so elected not to vote. Eleven participants voted, with 27% of the votes coming from PHAST investigators and 73% from screening staff.

**Consensus conference results.** During the first stage of the nominal group session, the MESI received eight votes as the favourite system. Dopplex ability, BlueDop, and Huntleigh ABPI all received one vote each, while the Huntleigh TBPI and Systoe systems received no votes. Only 10 participants submitted votes for their least favourite system; Dopplex ability, Systoe, and Huntleigh TBPI all received three votes each, the BlueDop received one vote, and the MESI and Huntleigh APBI received no votes. Reasons for votes are provided in Supplementary Tables S2 and S3.

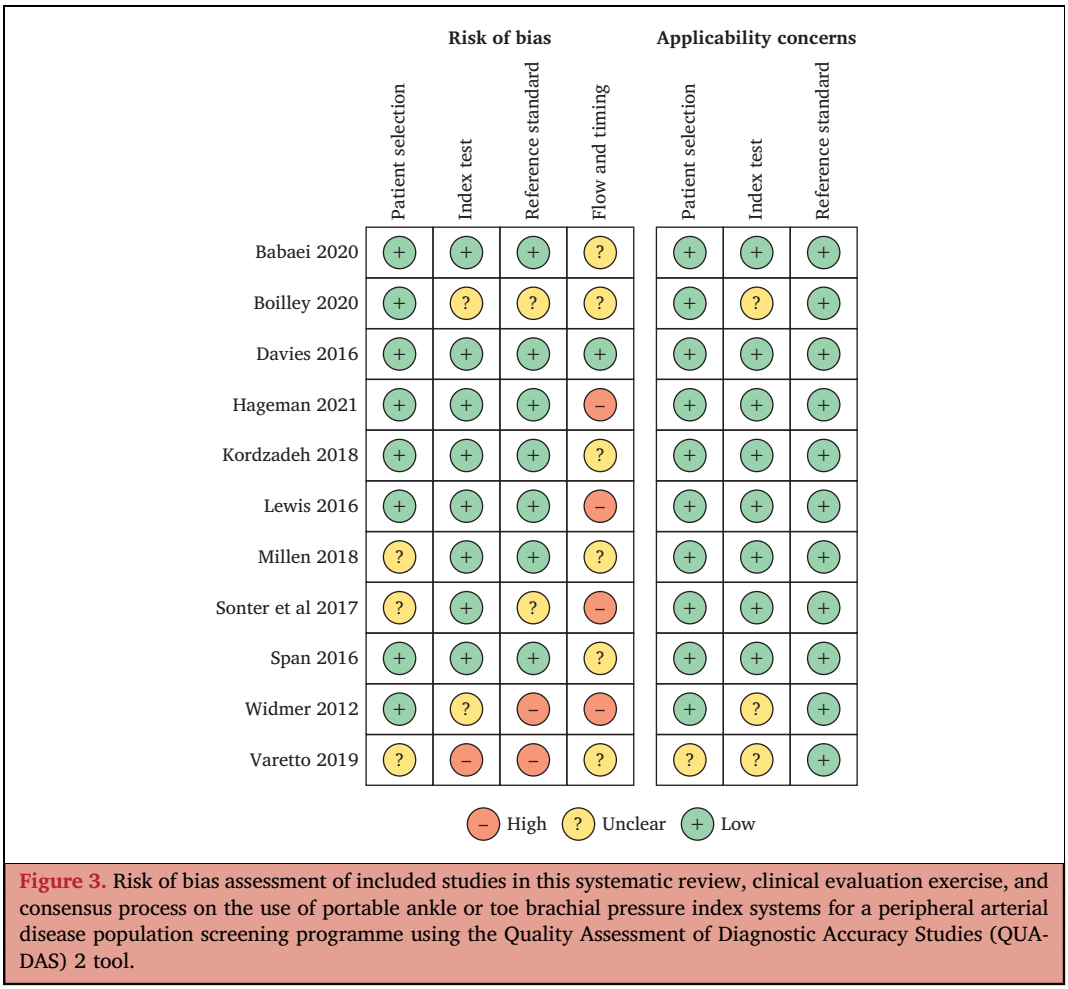


**Figure 3.** Risk of bias assessment of included studies in this systematic review, clinical evaluation exercise, and consensus process on the use of portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) 2 tool.

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**Table 3. Diagnostic accuracy of included systems in this systematic review on portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| Author, year | System | Sensitivity − % | Specificity − % | Accuracy − % | Positive predictive value − % | Negative predictive value − % | ROC (95% CI) | Correlation coefficient | Test failure rate | Time to perform test (automated *vs.* gold standard) |
|---|---|---|---|---|---|---|---|---|---|---|
| Babaei, 2020[15] | Dopplex Ability | 20 | 95 | 98 | NR | NR | 0.48 (0.44−0.52) | NR | NR | NR |
| Boilley, 2020[16] | MESI | 66 | 85 | NR | 95 | 38 | NR | $r$=0.63 | NR | NR |
| Davies, 2016[17] | Dopplex Ability | 70 | 96 | 94 | 52 | 98 | 0.96 (0.94−0.98) | NR | 28 Ability<br>0 Doppler | 7 min 55 sec *vs.*<br>17 min 45 sec |
| Hageman, 2021[18] | MESI | 74 | 97 | NR | 93 | 85 | 0.96 | $r$=0.86 | 63 MESI | NR |
| Kordzadeh, 2018[19] | BlueDop | 95 | 89 | NR | NR | NR | 0.92 (0.88−0.94) | NR | NR | NR |
| Lewis, 2016[20] | Dopplex Ability | 79 | 91 | 88 | 76 | 92 | 0.88 (0.83−0.93) | NR | NR | NR |
| Millen, 2018[21] | Dopplex Ability | 59 | 86 | NR | NR | NR | NR | $r$=0.17 | 3 Ability | NR |
| Sonter, 2017[22] | Systoe Atys Medical | 71 | 77 | NR | NR | NR | 0.83 (0.74−0.91) | NR | NR | NR |
| Span, 2016[23] | MESI | 57 | 99 | NR | NR | NR | NR | $r$=0.61 | 14 MESI<br>14 Doppler | 2 min *vs.* 14 min |
| Varetto, 2019[25] | MESI | NR | NR | NR | NR | NR | NR | Bland-Altman =0.0669 | NR | 4 min2 sec *vs.*<br>5 min 28 sec |
| Widmer, 2012[24] | Systoe Atys Medical | NR | NR | NR | NR | NR | NR | NR | 11 Systoe | NR |

NR = not reported; min = minutes; sec = seconds; ROC = receiver operating characteristic.

During the third stage, in which individuals ranked the six systems in preference order from best to worst, the MESI again was ranked highest with a score of 53. Huntleigh ABPI was second, and the BlueDop and Dopplex Ability joint third. The Systoe and Huntleigh TBPI were ranked the lowest (Table 6).

### *Summary*

Table 7 displays a summary of the results of parts A—C where systems are ranked highest to lowest. This demonstrates that the MESI device consistently ranked highly in all areas of investigation.

## DISCUSSION

This systematic review has evaluated the diagnostic accuracy of four portable ABPI or TBPI systems compared with a gold standard that was reported in 11 published studies. Generally, these automated and semi-automated systems have a moderate level of sensitivity and a high level of specificity: Dopplex ability sensitivity range 20% — 70%, specificity 86% — 96%; MESI sensitivity range 57% — 74%, specificity 85% — 99%; BlueDop sensitivity 95%, specificity 89%; Systoe sensitivity 71%, specificity 77%. A clinical evaluation of the usability of these systems in the context of the AAA screening programme revealed that the MESI was the preferred device of the screening staff. Finally, a consensus meeting that brought together these two elements of diagnostic accuracy and usability, highlighted that MESI was a good candidate for use in a community screening programme. This work was performed with the intention of selecting an automated ABPI or TBPI device that would then be used in a feasibility study of the inclusion of PAD screening within the existing AAA infrastructure. If all the criteria are met, the final part of this programme of work will be to perform a randomised controlled trial to assess the impact of PAD screening on cardiovascular health.

Due to the heterogeneity of the studies included in the systematic review of device accuracy it is hard to draw any firm conclusions around accuracy; however, the results from this systematic review demonstrate that, generally, these automated systems have a moderate level of sensitivity and a high level of specificity. The BlueDop had the highest sensitivity (95%) suggesting that it would correctly identify PAD in 95% of cases. With a high level of specificity,[19] it was the only system for which both accuracy measurements exceeded the pre-defined threshold of 80%. However, it is important to note that this was data from only one paper and therefore needs to be replicated. The Dopplex ability had the lowest sensitivity, suggesting that a high number of positive PAD cases would be missed. One of the studies that evaluated this system included only diabetic patients,[15] which may explain the very low sensitivity reported. One important point of note from these studies is that the automated methods tend to overestimate ABPI values and as such, several have identified the optimal threshold for the diagnosis of PAD in their analysis, which has consequences for sensitivity and specificity values. Two studies identified 1.0 as a more accurate threshold value for the MESI system,[18,23] which vastly improved sensitivity and specificity to above 80%. Three studies explored this for the Dopplex ability;[15,17,26] however, these results are very varied and sensitivity was only improved to approximately 75%. These results indicate that the MESI islikely to be the most accurate portable system for measurement of ABPI.

For all the devices that were tested during the clinical evaluation, the AAA staff felt they would need additional time during existing appointments to carry out PAD screening, with the MESI likely to require the least amount of time and the Huntleigh APBI the most. Importantly, screeners felt men attending for appointments would find the additional screening acceptable especially in the case of the BlueDop, MESI, and Systoe systems.

Analysis of the data collected during the system evaluation days demonstrated that, overall, the AAA screening

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**Table 4. Re-evaluation of optimal cutoff values for the detection of PAD according to five studies included in this systematic review on portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme, which reported on the optimal threshold with different systems for the detection of PAD**

| Authors | System | Optimal diagnostic threshold for PAD detection | Sensitivity − % | Specificity − % |
|---|---|---|---|---|
| Babaei et al.[15] | Dopplex Ability | <1.2 | 40 | 80 |
| Davies et al.[17] | Dopplex Ability | <1.04 | 98 | 75 |
| Lewis et al.[20] | Dopplex Ability | <0.98 | 87 | 80 |
| Hageman et al.[18] | MESI | <1.0 | 94 | 92 |
| Span et al.[23] | MESI | <1.0 | 85 | 96 |

staff preferred the MESI, with the Systoe system second, and the BlueDop third. The Dopplex ability scored the lowest for portability and system use, but the screeners scored it highly for results interpretation. Based on this and the accuracy data, the consensus conference ruled out the Dopplex Ability and the Systoe. During the consensus meeting these two elements were brought together and discussed to reach an agreement on the most suitable device to take forward into a feasibility test of PAD community screening. It was concluded that the MESI would be the best candidate as it scored high for accuracy within the systematic review, and also for usability, comprehension of results, and setup and portability in the clinical evaluation sessions. Screeners commented that it was easy to transport to venues as it came in a backpack, and it was the quickest and easiest test to perform.

It is important to highlight that the inclusion of PAD screening into the AAA screening infrastructure in the UK would only include men, as women are not invited for this screening. However, as PAD commonly affects women, an alternative strategy to test PAD screening for women is also needed. This will be addressed as part of the PHAST study, in which a pilot clinical PAD screening programme for women is being undertaken and evaluated.

**Table 5. Overall comparison of different systems from questionnaire data obtained from 39 participants and collected during the clinical evaluation part in this systematic review, clinical evaluation exercise, and consensus process study on the use of portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| System | Overall total score | Total responses | Average score/ response |
|---|---|---|---|
| MESI (automated ABPI) | 1998 | 514 | 3.89 |
| Systoe TBPI | 1934 | 518 | 3.73 |
| BlueDop | 1924 | 528 | 3.64 |
| Handheld ABPI | 1710 | 524 | 3.26 |
| Ability (automated ABPI) | 1643 | 527 | 3.12 |
| Huntleigh TBPI | 1636 | 509 | 3.21 |

If all participants had given a response to every question in the questionnaire there would have been 585 data points (15 questions × 39 participants). However, there were missing data, so to account for this, the total score was divided by the total number of questions that were answered (total responses) to give an average score per question. ABPI = ankle brachial pressure index; TBPI = toe brachial pressure index.

This study has a few limitations. First, the risk of bias analysis identified four studies to have a high risk of bias and a further four to have an unclear risk. The small number of studies included in the review may have influenced the results. There is only one study for each of the Systoe and BlueDop systems and clearly these data need to be replicated to determine validity. In addition, there was a large heterogeneity in these studies, that included differences in the gold standard comparator, this makes comparison between studies difficult. Second, diabetes is known to influence accuracy of the ABPI result due to arterial incompressibility, which is why measures of TBPI were also included. However, few studies performed a subanalysis of system accuracy in diabetic *vs.* non-diabetic populations. The clinical evaluation days included only a small number of screening staff. However, analysis of the feedback did consistently show a preference for the MESI system, but it is unclear whether this would have been different in a larger sample size. Finally, the systematic review and the clinical evaluation were performed in parallel, which unfortunately meant that a suitable device was identified during the literature searches that was not included in the clinical evaluation (Microlife WatchBP), introducing a bias in the results.

In conclusion, a number of portable automated and semi-automated systems are available for detection of PAD; however, based on the need to strike a balance between

**Table 6. Preference of systems in rank order following the consensus conference in this systematic review, clinical evaluation exercise, and consensus process study on the use of portable ankle or toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| Rank | System | Overall total score | Total responses | Average score/ response |
|---|---|---|---|---|
| 1 | MESI (automated ABPI) | 53 | 9 | 5.8 |
| 2 | Handheld ABPI | 33 | 9 | 4.0 |
| 3 | BlueDop | 32 | 8 | 3.6 |
| 4 | Ability (automated ABPI) | 32 | 9 | 3.5 |
| 5 | Systoe TBPI | 22 | 9 | 2.4 |
| 6 | Huntleigh TBPI | 11 | 6 | 1.8 |

ABPI = ankle brachial pressure index; TBPI = toe brachial pressure index.

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**Table 7. System ranking summary of results of diagnostic accuracy study, clinical evaluation, and consensus conference in this study on the use of portable ankle/toe brachial pressure index systems for a peripheral arterial disease population screening programme**

| Rank | Diagnostic accuracy | Clinical evaluation | Consensus conference |
|---|---|---|---|
| 1 | BlueDop | MESI (automated ABPI) | MESI (automated ABPI) |
| 2 | MESI (automated ABPI) | Systoe TBPI | Handheld ABPI |
| 3 | Ability (automated ABPI) | BlueDop | BlueDop |
| 4 | Systoe TBPI | Handheld ABPI | Ability (automated ABPI) |
| 5 | – | Ability (automated ABPI) | Systoe TBPI |
| 6 | – | Huntleigh TBPI | Huntleigh TBPI |

No accuracy data are presented for handheld ABPI (considered a gold standard method) or Huntleigh TBPI (no accuracy data were available). ABPI = ankle brachial pressure index; TBPI = toe brachial pressure index.

diagnostic accuracy and usability, the present analysis suggests that the MESI is a good candidate to consider for use in a community screening programme. The next stage in this programme of work will use the MESI device in a feasibility study to determine whether the incorporation of PAD screening into the AAA screening programme affects attendance rates, before a randomised controlled trial which will access impact on cardiovascular health.

## CONFLICT OF INTEREST

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## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2022.08.008.

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