Validation of an automated measurement method for determination of the ankle-brachial index

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ABSTRACT

Objective. Lower extremity atherosclerotic disease (LEAD) diagnosis is largely based on ankle-brachial index (ABI) recordings. Equipment that could automatically determine ABI may facilitate LEAD identification within a broad range of health services. We aimed to test the measurement properties of an automated oscillometric ABI measurement device (MESI ABPI MD®) as compared to manual reference ABI measurements in patients with and without LEAD.

Design. A total of 153 patients with and without LEAD visiting a vascular surgery clinic underwent manual and automated ABI measurements. In total, 306 limbs were investigated. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated to assess the automated ABI device overall validity, with the manual method as reference. Correlation analysis (Spearman) was used to assess patterns of correlation between measurement methods while Bland–Altman plots were used to quantify measurement agreement.

Results. Sensitivity and specificity for the automated ABI device were 75 and 67% whereas PPV and NPV were 72 and 71%, respectively. The correlation coefficient (automated versus manual measurements) was \( r = 0.552, p < .01 \). Bland–Altman plots revealed proportional bias and a tendency by the automated device to overestimate lower ABI values and underestimate higher ABI values. The best agreement between automated and manual ABI recordings was observed within the normal ABI range. Conclusions. The ABPI MD® device performance was unfavorable. The automated device tended to overestimate lower ABI values while underestimated higher values, which may lead to underdiagnosis of LEAD. Our data do not support the use of this automated ABI measurement device in clinical practice.

Introduction

The definition of lower extremity atherosclerotic disease (LEAD) is atherosclerosis in the arteries distal to the aortic bifurcation. LEAD is a large and increasing health problem worldwide, with an estimated global prevalence at 200 million individuals [1]. LEAD can manifest with or without lower limb symptoms and the proportion of symptomatic versus non-symptomatic LEAD varies across studies [2]. Overall, only a minor proportion of all LEAD patients are symptomatic [3]. One study suggested that 27 million in Europe and North America are afflicted by LEAD, of which 10.5 million have symptomatic and 16.5 million have non-symptomatic disease [4]. Hence, the overall diagnosis of LEAD relies heavily on the determination of the ankle-brachial index (ABI). An ABI < 0.9 or > 1.3 at rest is required for diagnosing LEAD, and identification of LEAD could be used in broad populations to stratify future CV risk [5–9].

The ABI is currently measured by using a sphygmomanometer cuff and a non-directional pen Doppler probe. This is a manual and somewhat time-consuming procedure that when undertaken repeatedly on a daily basis places burden on vascular service staffs. Moreover, in health care facilities that are not regularly exposed to patients with vascular problems, the manual method also entails a relatively high risk for measurement errors and subsequent under- or over-diagnosis of LEAD [10].

A new automated oscillometric ABI measuring device (ABPI MD®, MESI, Ljubljana, Slovenia) has recently been made available. The ABPI MD® device automatically and simultaneously measures the ankle pressure in both legs as well as the systolic blood pressure in the right arm, and directly generates the numerical ABI values in both legs on a display. The estimated time required for the automatic method is about two minutes, which may result in a more efficient care process as well as more homogenous measurement results. The automated method also reduces the risk of strain injuries to the caregivers. There is some prior experience of using an automated oscillometric method for measuring ABI, but the validity and measurement properties across the entire ABI spectrum as compared to a manual reference method is largely unknown [5–9].
The overall aim with the study was to investigate the overall diagnostic accuracy of the automated ABI device and whether the automated ABI measurement method could distinguish "healthy" individuals (normal ABI according to the reference method) from "diseased" individuals (pathological ABI according to the reference method).

Material and methods

Study design

This was a prospective observational cohort study conducted at the vascular surgery outpatient clinic at the Sahlgrenska University Hospital (SU) in Gothenburg, Sweden. All participating patients were informed about the study by the attending vascular nurse or vascular surgeon, and all study participants provided written informed consent to the study. The study-specific measurements were conducted and collected from May 2018 to February 2019.

Ethics of experimentation

The study conduct followed the principles outlined in the Declaration of Helsinki. The study was approved by the Regional Ethical Review Board at the University of Gothenburg (reference number 909-17) and all participants provided written informed consent to the study. Participants were informed about the study by the attending vascular nurse or vascular surgeon. All study activities were undertaken.

Inclusion and exclusion criteria

All patients (i.e. both patients with and without known LEAD) who visited the vascular surgery clinic at SU Hospital and underwent a routine ABI measurement and accepted participation were included in the study. Patients with extensive ulceration at the ankle level (rendering ABI measurements painful) were excluded from participation.

Data collection

Demographic data and risk factors were prospectively collected and compiled in a database according to a pre-specified data collection sheet (sex, age, height, weight, smoking status, hypertension, hyperlipidemia, diabetes, cardiac disease, pulmonary disease, renal disease, aortic aneurysm, aortic dissection, LEAD, or other vascular diseases). Lower limb symptom status was prospectively collected (asymptomatic, intermittent claudication, rest pain, and/or ulcers/gangrene) and added to the database. Following ten minutes of supine rest, the ABI for left and right leg was measured and calculated using standard manual techniques, followed by the corresponding ABI measurements as obtained from the automated oscillometric method using the ABPI MD® MESI device, and all ABI measures were added to the database. For the manual measurements, a non-directional vascular pen doppler (Huntleigh Dopplex® D900, Arjo Inc., Addison, IL) and a standard manual blood pressure cuff were used for the measurements, and the highest recorded pressure at ankle level was used in the ABI calculations.

Definitions

Normal ABI range was defined at 0.9 – 1.3. Everything below and above this was considered to be abnormal and a sign of LEAD [6,11]. The automated device either delivers a numerical ABI recording, or a specific measurement code that should be considered as decisive for LEAD according to the device’s instructions for use. Occasionally, the automated device will instead return a specific measurement error code. These specific error codes are either caused by a measurement value out of the measurement range or by that the device is unable to measure due to a technical reason. Specific error codes that were consistent with measurements out of measurement range, also indicative of LEAD according to the manufacturer’s instructions for use, were defined as LEAD for the purpose of the study.

Statistical methods

Descriptive summary statistics of categorical variables are presented as absolute and relative frequencies whereas continuous data are presented as mean, range, and standard deviation. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for the automated ABI device with the manual ABI method as reference method. Sensitivity was calculated as the proportion of pathological cases obtained with the automated device among all pathological cases obtained by the manual method, while specificity was calculated by dividing the normal cases classified by the automated device with all normal reference method measurements. PPV was calculated as the number of cases deemed to be pathological over the total normal and pathological reference method measurements. NPV was calculated as the number of cases estimated to be normal over the total normal and pathological reference method measurements. Correlation analysis was performed using Spearman rank correlation and Bland–Altman plot was used to quantify the agreement between the manual and automated ABI measurements. Data was assembled in a Microsoft Excel database. All data analysis was performed using the statistical software IBM SPSS Statistics version 24 (IBM, Armonk, NY) or Excel version 16.21 (Microsoft, Redmond, Washington, US).

Results

Patient demographics and baseline data

Some 153 (100%) patients entered the study, and of these 97 (63%) were males. In total, 306 legs were examined. The mean age among the participants was 72 years. Twenty-six (17%) were smokers, 78 (51%) were former smokers and 49 (32%) were non-smokers. Altogether, 110 (72%) had hypertension, 68 (44%) had hyperlipidemia, and 35 (23%) had diabetes, whereas cardiac disease was prevalent in 42 (27%)
Eighty individuals (52%) suffered from LEAD while the prevalence of aortic dissection and other vascular diseases was low. Demographic data, risk factors, and intercurrent diseases, presented separately for men and women, are displayed in Table 1.

**Automated ABI device sensitivity, specificity, positive, and negative predictive value**

Out of the 306 measured legs, the automated device delivered 194 numerical ABI recordings whereas 84 were classified as LEAD by a specific measurement code rather than a numeric ABI recording. In addition, 28 error codes (out of which only 14 were pathological according to the manual method) were delivered by the device, out of which 22 were due to measurements outside the measurement range (indicative of LEAD) whereas the remaining 6 error codes were measurements where the automated device was unable to measure for technical reasons, rendering analysis of these impossible (Figure 1). Sensitivity and specificity analysis of overall diagnostic performance (i.e. capability to distinguish healthy from diseased) were therefore performed on 300 legs. Out of 157 manual reference standard measurements that were classified as pathological, 118 were also classified as pathological by the automated ABI device. In 143 reference standard measurements classified as normal, the automated ABI device correctly classified 96 of them. Thus, the sensitivity and specificity for the tested automated ABI device were 77%, the specificity 62%, the PPV 74%, and the NPV 66%.

**Table 2. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).**

| Automated ABI | Pathological | Normal | Manual ABI |
|---------------|--------------|--------|------------|
| Pathological  | 118          | 47     | PPV 72%    |
| Normal        | 39           | 96     | NPV 71%    |

(300 legs were analyzed) Sensitivity 75% Specificity 67% –

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**Table 1. Demographic data, risk factors, and comorbidities in the study population.**

|                       | Total population | Female | Male |
|-----------------------|------------------|--------|------|
|                       | n = 153 (100%)   | n = 56 (37%) | n = 97 (63%) |
| Age (SD)              | 72 (10)          | 75 (9)  | 70 (9)  |
| BMI (SD)              | 26 (4)           | 25 (4)  | 27 (4)  |
| Smoking               |                 |         |       |
| Current n (%)         | 26 (17%)         | 12 (8%) | 14 (9%) |
| Former n (%)          | 78 (51%)         | 43 (28%)| 35 (24%)|
| Hypertension n (%)    | 110 (72%)        | 43 (28%)| 67 (44%)|
| Hyperlipidemia n (%)  | 68 (44%)         | 29 (19%)| 39 (25%)|
| Diabetes n (%)        | 35 (23%)         | 9 (6%)  | 26 (17%)|
| Cardiac disease n (%) | 42 (27%)         | 13 (8%) | 29 (19%)|
| Pulmonary disease n (%)| 22 (14%)    | 9 (6%)  | 13 (8%) |
| Renal disease n (%)   | 10 (7%)          | 4 (3%)  | 6 (4%)  |
| Peripheral artery disease n (%) | 80 (52%) | 43 (28%)| 37 (21%)|
| Lower limb pain during physical activity n (%) | 77 (50%) | 40 (26%)| 37 (21%)|
| Rest pain n (%)       | 30 (20%)         | 19 (12%)| 11 (7%)  |
| Ulceration/gangrene n (%) | 13 (9%)  | 9 (6%)  | 4 (3%)  |
| Aortic aneurism n (%) | 53 (35%)         | 9 (6%)  | 44 (29%)|
| Aortic dissection n (%)| 3 (2%)          | 0 (0%)  | 3 (2%)  |
| Other vascular disease n (%) | 9 (6%) | 4 (3%)  | 5 (3%)  |

SD: standard deviation; BMI: body mass index
The diagnostic accuracy of the automatic method was also investigated in males and females separately. In males, the sensitivity was 70%, the specificity 68%, PPV 62%, and NPV were 75%. The corresponding values in females were 81% for sensitivity and 65% for specificity whereas PPV was 84% and NPV was 61%.

Table 3 demonstrates the measurement validity in terms of sensitivity, specificity, PPV, and NPV across several intercurrent disease subgroups. There was a tendency toward more accurate measurement properties for the automated device in patients with established LEAD. In patients with known LEAD, the sensitivity was 87% and the specificity was 71% whereas PPV and NPV were 89 and 67%, respectively. Other displayed subgroups observations should be interpreted with caution due to low patient numbers in each subgroup.

**Correlation and agreement between the manual and the automated ABI method**

A correlation analysis was performed based on measurements from the 194 (63%) legs where accurate numeric ABI readings were available for both the automated and the manual ABI method. The correlation coefficient between manual and automated ABI measurements was moderate ($r = 0.552$, $p < .01$). Furthermore, the automated device displayed a tendency to slightly overestimate lower ABI values, while the automated device tended to underestimate the higher ABI values. The automated device performed best at ABI values centering within the normal ABI range (Figure 2).

The Bland–Altman plot showed a mean inter-measurement difference of $-0.067$ (limits of agreement: $-0.52$–$0.38$) (Figure 3). Linear regression indicated presence of proportional bias ($p < .05$), where lower ABI values were slightly overestimated and higher ABI values were underestimated.

**Table 3.** Measurement properties for the automated ABI method across a range of intercurrent diseases.

| Condition          | (N) | Sensitivity% | Specificity% | PPV% | NPV% |
|--------------------|-----|--------------|--------------|------|------|
| Hypertension       | Yes (110) | 77          | 75          | 79   | 61   |
|                    | No (43) | 69          | 53          | 52   | 70   |
| Cardiac disease    | Yes (42) | 62          | 76          | 76   | 61   |
|                    | No (111) | 81          | 64          | 70   | 76   |
| Pulmonary disease  | Yes (22) | 70          | 53          | 70   | 53   |
|                    | No (131) | 76          | 69          | 72   | 74   |
| LEAD               | Yes (80) | 87          | 71          | 89   | 67   |
|                    | No (73) | 46          | 65          | 36   | 73   |
| Renal disease      | Yes (10) | 78          | 100         | 100  | 33   |
|                    | No (143) | 75          | 67          | 69   | 73   |
| Diabetes           | Yes (35) | 74          | 75          | 82   | 66   |
|                    | No (118) | 76          | 65          | 69   | 73   |
| Aortic aneurysm    | Yes (53) | 50          | 68          | 43   | 74   |
|                    | No (100) | 82          | 67          | 81   | 69   |
| Aortic dissection  | Yes (3) | 0           | 75          | 0    | 60   |
|                    | No (150) | 76          | 65          | 70   | 72   |
| Vascular disease   | Yes (9) | 80          | 50          | 67   | 67   |
|                    | No (144) | 75          | 68          | 72   | 71   |
| Hyperlipidemia     | Yes (68) | 72          | 71          | 80   | 61   |
|                    | No (32) | 79          | 60          | 61   | 78   |
| Smoking            | Yes (26) | 77          | 65          | 82   | 58   |
|                    | No (49) | 69          | 63          | 52   | 78   |
| Stopped (78)       | 77      | 72          | 79          | 70   |

**Discussion**

The main result from this study is that the measurement properties for the automated ABI measurement method – as compared to the manual reference measurement technique – were generally poor. The measurement precision for the automated device was also markedly poorer at low and high ABI values, where the device in some cases either under or overestimated the reference ABI value or delivered an error code rather than an accurate numeric reading. In agreement with previous studies [6,9], our study also found that the device had a tendency to overestimate the lower ABI values and underestimate higher ABI values.

This result was observed in a patient cohort where 58% of the patients already suffered from LEAD and/or other vascular diseases, i.e. in a relevant clinical context where the
The suggestion that MESI device may detect pathologic LEAD diagnosis in the study by Jorge Vega et al. [12]. The suggestion that MESI device may detect pathological ABI better when vascular disease is clinically present would mean that the device would not be appropriate to use in primary care where the expected number of patients with vascular disease is low and the main purpose with the ABI measurement is to establish diagnosis.

The scientific literature on measurement properties for automated ABI measurement devices is sparse. In a study from 2016 undertaken on a population with high diabetes prevalence (43%) for diagnosis of LEAD (cut-off 0.9), the automated ABI showed a sensitivity of 66.7%, a specificity of 96.8%, a PPV of 81.1%, and a NPV of 93%. When legs with calcified arteries and error codes were considered as LEAD equivalents, sensitivity rose to 78.2%. The authors primarily related their findings to measurement bias that preferably occurs in patients with diabetes and at extreme ABI values and concluded that the automated method could still be useful for LEAD diagnosis [7]. However, we uncovered similar tendencies toward potentially severe measurement errors with the automated device despite that more than 75% of our population were non-diabetics, indicating that this bias might not preferably occur in just diabetic patients but might be a more universal problem related to the measurement properties of the device. This, especially in combination with our finding that only 14 out of 22 measurements that were classified as error codes consistent with LEAD by the automated device were found to be pathological according to the manual method, could lead to misdiagnosis of LEAD.

Overall, our findings pointed toward poor diagnostic precision across the entire ABI spectrum (sensitivity 75%, specificity 67%, PPV 72%, and NPV 71%, 300 analyzed legs). These observations are only marginally better than corresponding analysis undertaken on earlier generations of oscillometric automated ABI devices [8]. Although the correlation coefficient ($r=0.552$, $p<.01$) indicated a moderate relationship between the two methods in our study, the coefficient was substantially lower than should be expected for two different methods that attempts to measure the same value. Furthermore, the Bland–Altman plot showed relatively poor agreement between the both methods and the presence of proportional bias, findings that reinforce observations in a previous study [13].

The authors of a study from 2016 found that the best overall cut-off for oscillometric ABI was 0.97, i.e. within the normal ABI range. It has been suggested in previous research that both sensitivity and specificity could be increased by raising the cutoff for PAD to ABI 1.0 [9]. We therefore examined if the validity of the automated method was affected by such a change in the cutoff ABI. This changed ABI definition did only affect the measurement properties marginally, as slight improvement in sensitivity and PPV was noted at the expense of a lower specificity and NPV. Thus, such previously suggested adjustment of the ABI cutoff value did not increase the method’s clinical usefulness.

In theory, the automated device would be potentially more useful to discriminate between healthy and diseased individuals within a vascular surgery clinic with a higher expected amount of vascular disease patients. However, in vascular surgery practice, the exact ABI value is important not only to establish LEAD diagnosis but also to evaluate results from invasive LEAD procedures. The seemingly unreliable measurement properties of the automated device found in this study would therefore still limit the clinical usefulness also within vascular surgery departments.

One important limitation with this study was that it was not deemed possible to blind the research nurses performing the ABI measurements in terms of measurement method (i.e. automated versus manual). And although all measurements were performed by trained vascular nurses, we cannot exclude that any interoperator differences in measurement skills affected our results. This study also included patients only at one hospital, involvement of other medical centers might have impacted the results due to differences in case mix and ABI measurement skills.

In conclusion, the overall ABPI MD$^{\circ}$ device performance – as compared to the manual ABI measurement method – was generally poor, limiting clinical usefulness. The automated device tended to overestimate lower ABI values and underestimate higher values, a tendency that potentially would lead to underdiagnosis of LEAD. Our data therefore does not currently support the use of this automated ABI measurement device in clinical practice.

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**Disclosure statement**

The authors report no conflicts of interest.

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