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ABSTRACT

Objective: Peripheral artery disease (PAD) is underdiagnosed in primary care settings, partly because of limited accuracy of the Doppler ankle-brachial index (ABI). This study aimed to assess the diagnostic accuracy of an automated oscillometric ABI device compared with reference standard vascular laboratory Doppler ABI equipment and to examine the influence of oscillometric errors on performance.

Methods: Consecutive patients who were referred to a large general hospital for an ABI measurement were invited to participate. In each patient, the oscillometric analysis was followed by the Doppler analysis. Legs with incompressible ankle arteries were excluded from analysis. ABI values were compared using the Bland-Altman method. Oscillometric errors were defined as the incapacity of the oscillometer to report a value of ABI. A receiver operating characteristic curve was constructed, and the area under the curve was computed.

Results: A total of 201 patients participated. The Bland-Altman plot showed a mean difference of 0.05 ± 0.12 (limits of agreement, −0.20 to 0.29), representing a small ABI overestimation after oscillometry. Oscillometric errors occurred more commonly in limbs with PAD than in limbs without PAD (28% and 7%, respectively; $P < .001$). Considering a 0.9 threshold and after oscillometric error exclusion, the oscillometric ABI showed a 74% sensitivity and a 97% specificity for a diagnosis of PAD. When oscillometric errors were considered as abnormal ABIs, sensitivity increased to 86% and specificity was maintained at 95%. The receiver operating characteristic curve showed an area under the curve of 0.96. The best oscillometric ABI cutoff point was 1.00. Using this threshold and when considering oscillometric errors as abnormal ABIs, sensitivity improved to 94% while maintaining specificity at 92%.

Conclusions: Oscillometric ABI showed good diagnostic accuracy compared with the reference standard. However, the high incidence of oscillometric errors and the challenges to correctly interpret readings may limit the use of the oscillometric method in PAD diagnosis. (J Vasc Surg 2021;73:652-60.)

Keywords: Peripheral artery disease; Intermittent claudication; Ankle-brachial index; Blood pressure; Oscillometry; Doppler

Peripheral artery disease (PAD) is underdiagnosed in primary care settings.[1] However, screening for PAD using values of ankle-brachial index (ABI), the ratio of the highest ankle systolic blood pressure (SBP) divided by the highest brachial SBP, remains an area of controversy. According to guidelines, the ABI is recommended to establish the diagnosis in individuals with symptoms or signs suggestive of PAD.[1-3] Furthermore, measurement of the ABI may be reasonable in asymptomatic individuals who are at increased risk of PAD if it is used to improve risk stratification, preventive care, and medical management. However, in the absence of risk factors or a suggestive history or physical examination findings, the ABI is not indicated.

Calculation of an ABI using Doppler analysis is considered the noninvasive reference standard for diagnosis of PAD.[1,4] A pocket Doppler, as commonly used in general practice, currently serves as a pragmatic tool for these readings. However, measures that are performed in a vascular laboratory are likely to be more precise. With use of an ABI value of 0.9 as the threshold for identifying PAD, an ABI has a 95% sensitivity and a specificity approaching 100% compared with digital subtraction angiography.[5,6] However, a conventional Doppler ABI measurement is time-consuming, requires specific skills, and is therefore underused, particularly in primary care settings.[7,8]

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ABI measured by oscillometry is a simple, fast, and fully automatic test that is increasingly proposed in primary care settings as it has advantages compared with Doppler regarding equipment, training, and time constraints.[9,10] The oscillometric method uses sphygmomanometer cuffs with electronic pressure sensors observing cuff pressure oscillations that are caused by the arterial pulse wave, electronics for an automatic interpretation, and automatic cuff inflation and deflation. However, the diagnostic accuracy of oscillometric ABI is controversial.[11] In addition, most studies failed to provide an interpretation of patients with oscillometric errors.

This study aimed to assess reliability, validity, and diagnostic accuracy of an automated oscillometric ABI device compared with reference standard vascular laboratory Doppler ABI equipment and to examine the influence of oscillometric errors on performance. We intended to investigate whether the oscillometric ABI measurement may possibly be useful for diagnosis and screening of PAD in general practice.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, prospective cross-sectional study
- **Key Findings:** In a group of 201 patients, oscillometric errors occurred more commonly in limbs with peripheral artery disease (PAD) than in limbs without PAD (28% and 7%, respectively; $P < .001$). The best oscillometric ankle-brachial index (ABI) cutoff point was 1.00. Using this threshold and when considering oscillometric errors as abnormal ABIs, sensitivity was 94% and specificity was 92%.
- **Take Home Message:** Oscillometric ABI showed good diagnostic accuracy compared with the reference standard. However, the high incidence of oscillometric errors and the challenges to correctly interpret readings may limit the use of the oscillometric method in PAD diagnosis.

METHODS

Study population. Consecutive patients who were referred to the vascular laboratory of the Catharina Hospital in Eindhoven, The Netherlands, between November 1, 2016, and June 30, 2017, for an ABI measurement were invited to participate. Exclusion criteria were inability to consent, major limb amputations, marked edema in one or both feet, inability to tolerate supine position, upper extremity arteriovenous fistulas, axillary lymphadenectomy, and spasms or tremor of any kind. The study was approved by the medical ethical committee of the Catharina Hospital and reported according to the Standards for Reporting Diagnostic Accuracy guidelines.[12] Each patient provided written informed consent. Patients' characteristics were acquired after consent was obtained.

ABI measurements. ABI measurements were performed under standardized conditions in a quiet examination room in supine position after 3 to 5 minutes of rest. In each patient, the oscillometric analysis was followed by the Doppler analysis. Two authors performed the oscillometric measurements, whereas a trained vascular technician did the Doppler measurements in a separate room.

Automated oscillometric measurements were obtained with a validated device that was specifically designed for ABI measurements (MESI ABPI MD; MESI development of medical devices, Ltd, Ljubljana, Slovenia). This device measures arterial blood pressure simultaneously in three extremities using appropriate cuff sizes. Therefore, a long rest period to stabilize the patient's blood pressure before performance of all measurements is not required. The cuffs are inflated to a suprasystolic pressure and then deflated to a subdiastolic pressure. When blood flow is absent or unimpeded, cuff pressure will be essentially constant. When blood flow is present but impeded, cuff pressure will oscillate in synchrony with the cyclic expansion and contraction of the artery. The amplitude of these oscillometric pulses increases to a maximum at the mean arterial pressure and then decreases with further deflation. Systolic and diastolic arterial pressures are estimated using algorithms. ABIs are automatically calculated and displayed on the device screen within only 1 minute.

To assess the reliability of the device, three series of measurements were performed in each patient. After each measurement, cuffs were removed and repositioned for the next trial. Operator 1 (D.H. or M.vdH.) obtained the first two series, and operator 2 (M.vdH. or D.H.) obtained the third series. For each series, the ABI was measured twice with a 1-minute pause between the measurements: first, at the left brachial artery and both ankle arteries; and second, at the right brachial artery and both ankle arteries. ABIs based on the arm with the highest of the two SBPs were used in the analyses, as is standard practice. To assess the validity of the device, the average of the three series was used for calculations. ABI results were blinded for the patients and the other operator. When a signal was not detected by the device, a new measurement was made after a 1-minute pause. An oscillometric error was recorded when a meaningful signal was undetectable twice. It took us a total of 12 to 24 minutes for each patient to complete the oscillometric analysis, depending on the frequency of oscillometric errors.

In each patient, ABI measurements were repeated with vascular laboratory Doppler equipment (ELCAT vasolab 320; ELCAT Medical Systems, Wolfratshausen, Germany) some 15 minutes after the oscillometric measurements. SBPs of the brachial and ankle arteries (dorsal pedal and posterior tibial) were measured with sphygmomanometer cuffs, which were automatically inflated and

deflated. SBP cutoff points of all arteries were defined as the systolic upstroke of the first arterial waveform. At the first characteristic arterial sound and at the simultaneous appearance of the first arterial waveform, the monitor screen was frozen and the SBP cutoff point was defined by precise retrospective positioning of an adjustable marker line. The ABI was calculated in each leg by dividing the highest systolic ankle pressure (either posterior tibial or dorsal pedal) by the highest systolic brachial pressure of both arms.[2,13-15] An abnormal ABI was defined as a value <0.9 (normal, ABI ≥0.9).[1,2] Legs with incompressible ankle arteries (ABI >1.4) suggesting arterial calcification were excluded from analysis.

Statistical analysis. A sample size calculation was conducted before patient recruitment to determine an appropriate number of study participants. Assuming an α value of .05, a total sample of 142 participants provided an 80% power to detect a mean difference of 0.05 ± 0.15 between the oscillometric and Doppler ABI readings.

Categorical variables are presented as number (percentage) and continuous variables as mean ± standard deviation. ABI measurements were compared using a paired samples *t*-test. Correlation between measures was determined by linear regression using the Pearson correlation coefficient (*r*). The intraobserver and interobserver variabilities of oscillometric ABI measurements were assessed by determination of the intraclass correlation coefficient of agreement. A correlation coefficient was considered strong if ≥0.7, moderate if between 0.3 and 0.7, and weak if ≤0.3. The coefficient of variation (CV) was defined as the standard deviation of the differences divided by the mean of the averages (good, CV <15%). Agreement between oscillometric and Doppler measurements was investigated using the Bland-Altman method.[16] A stepwise multivariate regression analysis was applied to identify predictors of differences between the oscillometric ABI and Doppler ABI.

Agreement, sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios, and diagnostic odds ratio (DOR) of the oscillometric measurement were determined using the Doppler measurement as the reference standard. The intermethod concordance was determined by Cohen's κ. Conventionally, $\kappa < 0$ is considered poor; 0 to 0.2, slight; 0.2 to 0.4, fair; 0.4 to 0.6, moderate; 0.6 to 0.8, substantial; and >0.8, almost perfect.[17] Separate analyses were conducted according to oscillometric error consideration. Oscillometric errors were defined as the incapacity of the oscillometer to report a value of ABI. When oscillometric errors were included in the analysis, they were considered abnormal ABIs. A receiver operating characteristic (ROC) curve was constructed, and the area under the curve (AUC) was computed. The best oscillometric ABI cutoff point for optimal values of sensitivity and specificity was estimated using Youden's index.

In the reliability and validity analyses, each leg was considered an independent unit of analysis. Conversely, in the diagnostic accuracy analyses, patients rather than legs were the unit of analysis. Here, a participant with at least one leg having an ABI <0.9 was considered a PAD patient. Subgroup analyses of diabetic and nondiabetic patients were also conducted. A *P* value <.05 was considered statistically significant. Statistical analysis was performed using SPSS 24 software (IBM, Armonk, NY). Graphs were created with GraphPad Prism 6 software (GraphPad Software, La Jolla, Calif).

RESULTS

Patient recruitment. Fig 1 shows the flow diagram of the study. Of the 215 patients who participated, 201 fulfilled inclusion and exclusion criteria. Patients' characteristics are shown in Table I. Participants represented a population with risk factors characteristically referred to a hospital's vascular laboratory for analysis of potential PAD.[8]

Doppler and oscillometric ABI measurements. Doppler ABI was measurable in 401 legs (100%). In total, 227 legs (57%) had normal values (ABI ≥0.9), and 162 legs (40%) had values consistent with PAD (ABI <0.9). Twelve legs (3%) had values suggesting arterial calcification (ABI >1.4) and were excluded from analysis.

An oscillometric ABI was available from 339 legs (84%), whereas in 63 legs (16%), oscillometric ABI was not measurable after two trials (oscillometric errors). Of these 63 legs, 3 (5%) had arterial calcifications, 45 (71%) had values consistent with PAD, and 15 (24%) had normal values as determined by vascular laboratory Doppler equipment. Mean Doppler ABI in the last two groups was 0.75 ± 0.23. The frequency of oscillometric errors was higher in limbs with PAD than in limbs without PAD (28% and 7%, respectively; $P < .001$). However, the incidence of oscillometric errors was similar in patients thought to have new-onset PAD compared with patients with a history of revascularization (24% and 27%, respectively; $P = .680$).

Reliability of ABIs obtained by the oscillometric method. Intraoperator and interoperator differences between repeated measurements were not significant (Table II). The intraclass correlation coefficient of agreement was 0.91 for ABI measurements by the same operator and 0.86 for ABI measurements by different operators. The CV was 8% for measurements by the same operator and 9% for measurements by different operators, demonstrating excellent repeatability.

Validity of ABIs obtained by the oscillometric method. Oscillometric ABI values were highly correlated with Doppler ABI values ($r = 0.87$; Fig 2). The error between the two methods exhibited a normal distribution, and the Bland-Altman plot showed a mean difference of 0.05 ± 0.12 (limits of agreement, −0.20 to 0.29; Fig 3),

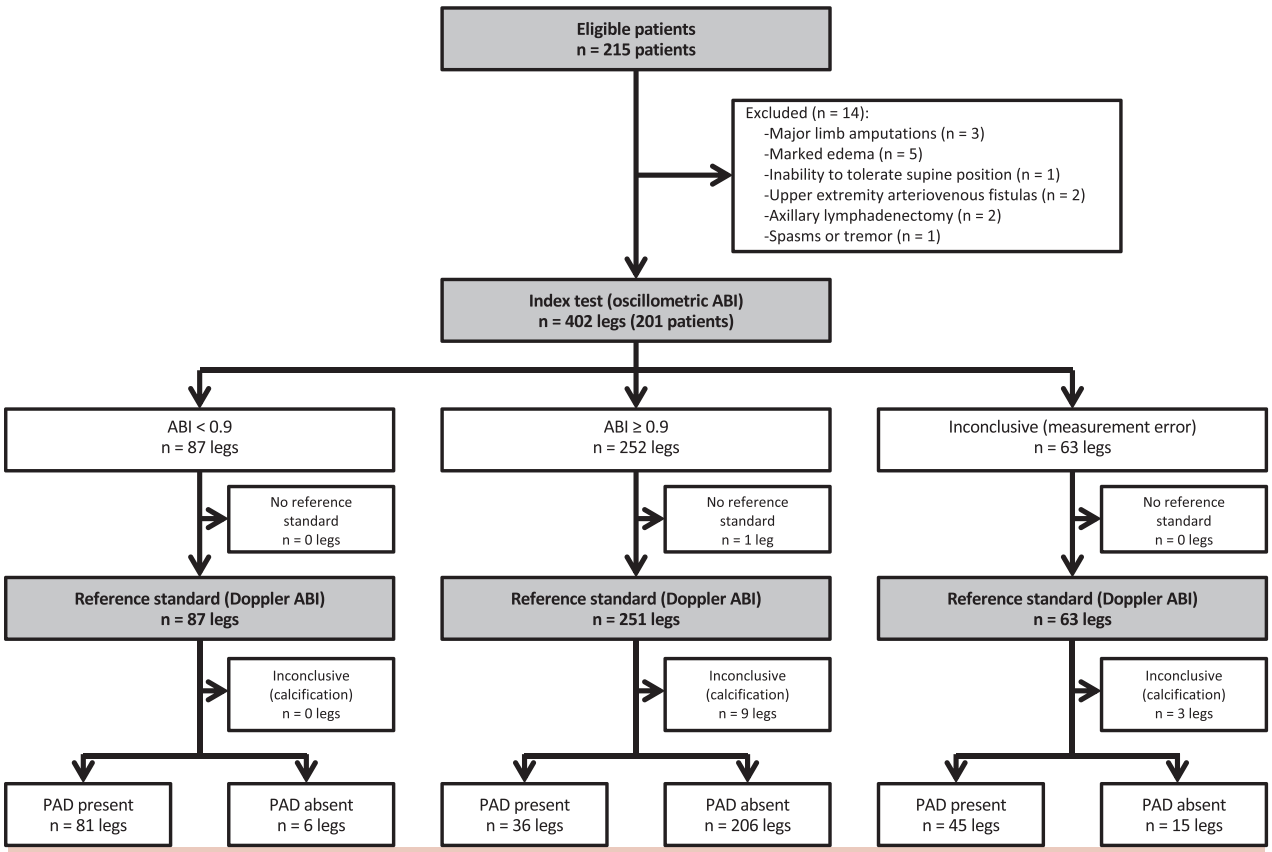

Fig 1. Flow diagram. *ABI*, Ankle-brachial index; *PAD*, peripheral artery disease.

representing a small ABI overestimation after oscillometry. A small but significant bias across ABI range was observed, suggesting that lower values were slightly more overestimated than higher values. The CV was 13%, demonstrating that the oscillometric method can be accepted as an alternative to the Doppler method regarding this methodologic aspect. A stepwise multivariate regression analysis including patients' characteristics as independent variables demonstrated that only the presence of PAD was a predictor of differences between the oscillometric ABI and Doppler ABI ($\beta \pm$ standard error $= 0.113 \pm 0.014$; $P < .001$). The difference between the oscillometric ABI and Doppler ABI was 0.12 ± 0.11 in limbs with PAD ($P < .001$; $r = 0.76$) and 0.01 ± 0.11 in limbs without PAD ($P = .299$; $r = 0.49$). The presence of PAD accounted for 26% of the total variance.

Diagnostic accuracy of the oscillometric method. The diagnostic accuracy for selected oscillometric ABI cutoff points is shown in Table III. Considering a 0.9 threshold and after oscillometric error exclusion (n = 149 patients), the oscillometric ABI showed a 74% sensitivity and a 97% specificity for a diagnosis of PAD ($\kappa = 0.73$; DOR = 82). When oscillometric errors were considered abnormal ABIs (n = 198 patients), sensitivity increased to 86% and specificity was maintained at 95% ($\kappa = 0.80$; DOR = 107). The ROC curve that was constructed for oscillometric ABI with Doppler ABI <0.9 defining PAD showed a high diagnostic accuracy with an AUC of 0.96 (Fig 4). The best oscillometric ABI cutoff point was 1.00. Using this threshold and when considering oscillometric errors as abnormal ABIs, sensitivity improved to 94% while maintaining specificity at 92% ($\kappa = 0.86$; DOR = 175).

Oscillometry in diabetic vs nondiabetic patients. An oscillometric ABI was available from 83% of 122 legs (n = 101) of diabetic patients and from 85% of 280 legs (n = 238) of nondiabetic patients ($P = .668$). The mean ABI in diabetic (n = 59) compared with nondiabetic (n = 136) patients was similar using oscillometry (0.98 ± 0.19 and 1.02 ± 0.21, respectively; $P = .105$) but lower using Doppler (0.89 ± 0.27 and 0.95 ± 0.26, respectively; $P = .032$). The mean difference between oscillometric and Doppler ABI measurements in diabetic and nondiabetic patients was similar (0.06 ± 0.14 and 0.04 ± 0.12, respectively; $P = .368$). The correlation between oscillometric and Doppler ABIs was strong in both diabetic and nondiabetic patients ($r = 0.84$ and $r = 0.88$, respectively). Considering a 0.9 threshold, agreement between the oscillometric and Doppler methods was obtained in 82% of diabetic patients (68% sensitivity, 95% specificity, $\kappa = 0.64$, DOR = 45) and in 90% of nondiabetic patients

Table I. Patients' characteristics

	(N = 201 [100%])
Male sex	112 (56)
Age, years	67 ± 11
Length, cm	171 ± 9
Weight, kg	77 ± 17
BMI, kg/m^2	26 ± 5
Heart rate, beats/min	71 ± 12
Pulse pressure, mm Hg	67 ± 16
Smoking	
Never	20 (10)
Former	92 (46)
Current	89 (44)
Hypertension	118 (60)
Hypercholesterolemia	85 (43)
Obesity	38 (19)
Diabetes mellitus	61 (31)
Renal insufficiency	17 (9)
Atrial fibrillation	11 (6)
Coronary artery disease	73 (37)
Cerebrovascular disease	33 (17)
Prior revascularization for PAD	60 (30)[a]
Endovascular	59 (30)
Surgical	11 (6)
Presentation[b]	
Asymptomatic/atypical complaints	57 (28)
Claudication[c]	121 (60)
Rest pain	5 (3)
Ulceration	18 (9)
Symptomatic leg	
None	56 (28)
Right	39 (19)
Left	37 (18)
Both	69 (34)

BMI, Body mass index; *PAD*, peripheral artery disease.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.
[a]Some patients were treated with both endovascular and surgical revascularization.
[b]Symptoms may have an arterial or nonarterial cause. In some patients, PAD was ruled out after testing.
[c]Patients described muscle fatigue, aching, or cramping on exertion that was relieved by rest.[18]

(76% sensitivity, 97% specificity, κ = 0.77, DOR = 109). The ROC curves revealed an AUC of 0.96 with an optimal oscillometric ABI cutoff point of 1.00 in diabetic patients (96% sensitivity and 96% specificity) and 1.02 in nondiabetic patients (91% sensitivity and 90% specificity).

DISCUSSION

Principal findings. This study compared the performance of an automated oscillometric ABI device that allows simultaneous arm-leg SBP measurements with reference standard vascular laboratory Doppler ABI equipment. In general, test-retest reliability of oscillometric ABI was good, whereas oscillometric and Doppler methods showed a high agreement. Moreover, oscillometric ABI showed good diagnostic accuracy compared with the reference standard. However, the device provided an error message instead of a valid ABI reading in 28% of PAD legs (16% of all legs). Furthermore, the device demonstrated the most reliable ABI measurements within the normal ABI range and overestimated ABI values, leading to a risk of underdiagnosis of PAD, particularly when a 0.9 threshold is used. In addition, the number of false positives in the oscillometric error group was 24%. Given these significant numbers, the usefulness of this device may seem limited in PAD diagnosis.

Strengths and weaknesses. The strength of our study is its design as we assessed the potential assets of oscillometry for ABI measurement in a mixed population including patients at risk for PAD as well as patients clinically suspected of having PAD. The results of this study should be interpreted in the light of its limitations. First, it should be noted that our results were achieved in a hospital's vascular laboratory and not in a primary care practice. Despite all automation, it is not evident that corresponding results will be found in a random general practice. Second, although Doppler ABI is considered the noninvasive reference standard, it also has some flaws, especially in nonexpert hands.[11] In this study, measurements were performed by skilled technicians, warranting their accuracy. Nevertheless, our calculations did not consider the possible errors in the reference standard. Third, in the context of the study aim, we used the ankle artery with the highest SBP obtained in the vascular laboratory for the ABI calculations. However, a modified approach using the ankle artery with the lowest SBP may identify more patients with PAD.[19] Fourth, a number of important hemodynamic factors, in particular medical treatment and left ventricular stroke volume, may have had an effect on study findings. Specifically, treatment with beta blockers affects the rate at which the pressure wave develops and thus the rate of change in arterial wall expansion. Fifth, we used only one type of automated oscillometric device, precluding extrapolation to other devices. Sixth, legs with arterial incompressibility (ABI >1.4) were excluded. Therefore, conclusions regarding accuracy of oscillometric ABI determination in patients with medial sclerosis cannot be drawn. Seventh, the percentage of oscillometric errors (16% of legs) was higher than recorded in other studies.[10,11,20] However, our study was performed in a vascular laboratory, which means that the proportion of patients with severe PAD was relatively high. Eighth, in the reliability and validity analyses, each leg was considered an independent unit of analysis. However, left and right ABIs are correlated observations, and

Table II. Reliability and validity of automated oscillometric ankle-brachial index (*ABI*) compared with vascular laboratory Doppler ABI

ABI	No.[a]	Measurement A, mean ± SD	Measurement B, mean ± SD	Difference, mean ± SD (95% CI)	*P* value	*r*	ICC (95% CI)	CV, %
Intraobserver variability (operator 1.1 vs operator 1.2)	287	1.04 ± 0.19	1.04 ± 0.18	−0.00 ± 0.08 (−0.01 to 0.01)	.679	0.906	0.905 (0.882-0.924)	8.0
Interobserver variability (operator 1 vs operator 2)	288	1.04 ± 0.18	1.05 ± 0.18	−0.01 ± 0.10 (−0.02 to 0.01)	.324	0.861	0.860 (0.827-0.888)	9.4
Validity (oscillometry vs Doppler)	329	1.01 ± 0.20	0.96 ± 0.25	0.05 ± 0.12 (0.04-0.06)	**<.001**	0.869	0.850 (0.817-0.878)	13.2

CI, Confidence interval; *CV*, coefficient of variation; *ICC*, intraclass correlation coefficient; *r*, Pearson correlation coefficient; *SD*, standard deviation. Boldface *P* values represent statistical significance.
[a]Calcified legs (Doppler ABI >1.4) were excluded from analyses.

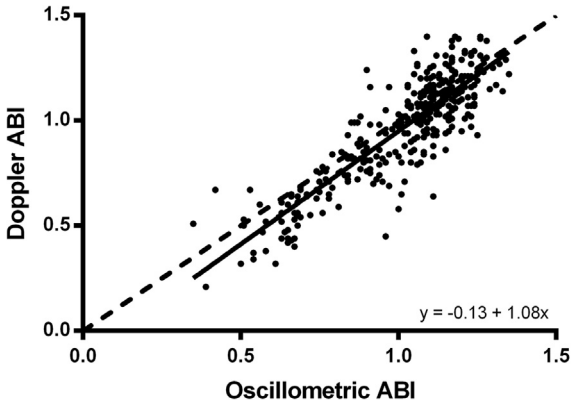

Fig 2. Correlation of automated oscillometric ankle-brachial index (*ABI*) and vascular laboratory Doppler ABI (n = 329 legs). The *dashed line* is identity line.

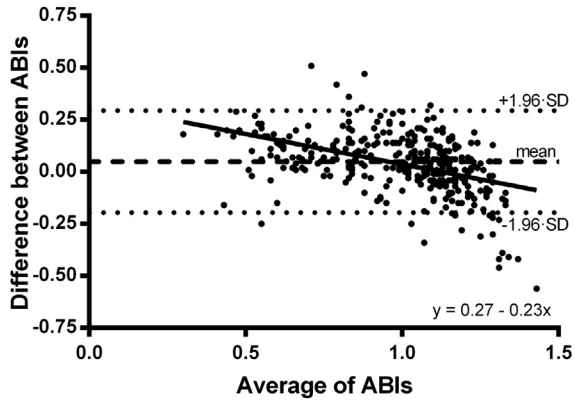

Fig 3. Agreement between automated oscillometric ankle-brachial index (*ABI*) and vascular laboratory Doppler ABI using Bland-Altman plot (n = 329 legs). Average of ABIs = (oscillometric ABI + Doppler ABI) / 2. Difference between ABIs = oscillometric ABI − Doppler ABI. *SD*, Standard deviation.

accounting for the correlations may yield slightly different *P* values. Diagnostic accuracy as well as the cost-effectiveness of this novel diagnostic tool needs to be determined in a primary care setting reflecting the prevalence of PAD in the general population.

Comparison with other studies. Two meta-analyses have compared the performance of the oscillometric method with the Doppler method.[21,22] The first study showed that the pooled correlation coefficient between the oscillometric and Doppler ABIs was 0.71.[21] The average sensitivity and specificity of the oscillometric ABI estimation in PAD diagnosis were 69% and 96%, respectively. In the second study, the pooled DOR for the oscillometric ABI was 32 (the odds for a positive test among patients with PAD is 32 times higher than the odds for a positive test among patients without PAD), with a 65% sensitivity and a 96% specificity.[22] Our estimates seem to corroborate these favorable findings. Specifically, our data revealed a DOR of 82 with a high specificity (97%) and a moderate sensitivity (74%), indicating an excellent ability of the oscillometric test to confirm PAD. However, its ability to rule out PAD was modest, potentially leading to shortcomings in PAD screening because of a high prevalence of false negatives. We observed a better diagnostic accuracy when considering oscillometric errors as abnormal ABIs and increasing the oscillometric ABI cutoff point (94% sensitivity, 92% specificity, DOR = 175). As a consequence, we recommend that oscillometric errors be considered abnormal ABIs and an oscillometric ABI threshold of 1.00 for PAD diagnosis as a means to improve sensitivity and to detect individuals at high cardiovascular risk as earlier suggested by others.[21,22]

A novel technique ideally covers the complete spectrum of abnormalities. A probable disadvantage of oscillometry is its inability to measure ankle blood pressure values <50 mm Hg.[7,10,11,23-25] Thus, oscillometry

Table III. Diagnostic accuracy of automated oscillometric ankle-brachial index (*ABI*) compared with vascular laboratory Doppler ABI

Oscillometric ABI cutoff point	No.[a]	Agreement, %	κ (95% CI)	Sensitivity, %	Specificity, %	PPV, %	NPV, %	LR+	LR−	DOR[b]
0.9										
Oscillometric errors excluded	149	87.9	0.734 (0.620-0.848)	73.7	96.7	93.3	85.6	22.3	0.272	82.0
Oscillometric errors included as abnormal ABIs	198	89.9	0.798 (0.714-0.882)	85.6	94.7	94.7	85.6	16.2	0.152	106.6
1.0										
Oscillometric errors excluded	149	91.9	0.830 (0.738-0.922)	89.5	93.5	89.5	93.5	13.8	0.112	123.2
Oscillometric errors included as abnormal ABIs	198	92.9	0.858 (0.785-0.931)	94.2	91.5	92.5	93.5	11.1	0.063	175.1
1.1										
Oscillometric errors excluded	149	73.2	0.496 (0.378-0.614)	98.2	57.6	58.9	98.1	2.32	0.031	74.1
Oscillometric errors included as abnormal ABIs	198	78.8	0.566 (0.460-0.672)	99.0	56.4	71.5	98.1	2.27	0.018	128.2

CI, Confidence interval; *DOR*, diagnostic odds ratio; *LR−*, negative likelihood ratio; *LR+*, positive likelihood ratio; *NPV*, negative predictive value; *PPV*, positive predictive value; *κ*, Cohen's kappa.
[a]Patients with calcified legs (Doppler ABI >1.4) were excluded from analyses.
[b]The DOR combines sensitivity and specificity into a single number (DOR = LR+/LR−). Higher values represent better discriminatory test performance. A good diagnostic test has LR+ >10 and LR− <0.1.

may seem a valid tool in PAD screening but not to monitor its possible evolution toward severe PAD. In this study, oscillometric errors occurred more commonly in limbs with PAD than in limbs without PAD. This observation is in line with data reported by Kollias et al[10] and Herráiz-Adillo et al[11,22] and suggests that the inability of the oscillometric method to measure an ABI should be interpreted as an abnormal ABI. Indeed, when the inability of the oscillometric method to measure an ABI was considered an indication for the presence of PAD, agreement between the two methods increased. However, the number of false positives in the oscillometric error group is 24%, and these patients carry a risk of receiving unnecessary and potentially dangerous medication. Therefore, it is necessary in case of an oscillometric error to seek confirmation using the reference standard.

An interesting feature of this study is the finding that oscillometric values were slightly higher than Doppler values, which was consistent with other studies.[7,10,11,21] As a result of these higher oscillometric ABI values, some investigators proposed the use of a higher oscillometric ABI cutoff point for PAD diagnosis.[10,11,20,21,26] By increasing the threshold, the number of false negatives is lowered. In this study, an ROC curve was computed as a means to optimize the diagnosis of PAD, demonstrating that optimal values of sensitivity and specificity were achieved at a 1.00 cutoff point. Using this threshold and considering oscillometric errors as abnormal ABIs, the diagnostic accuracy of the oscillometric test is judged as good (94% sensitivity, 92% specificity, DOR = 175). In our study, having a 53% PAD prevalence, positive predictive value and negative predictive value are 93% and 94%, respectively. In a scenario with a lower prevalence, such as in primary care settings, the ability to rule out PAD would be even greater because negative predictive value will increase with decreasing prevalence, demonstrating the potential usefulness of oscillometric ABI in PAD screening. Optimized diagnostic criteria for oscillometric ABI need to be prospectively validated in a primary care setting.

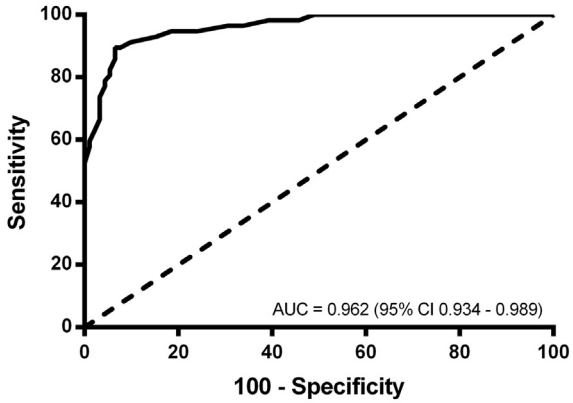

Fig 4. Receiver operating characteristic (ROC) curve of automated oscillometric ankle-brachial index (ABI) compared with vascular laboratory Doppler ABI (n = 149 patients). The *dashed line* is identity line. *AUC*, Area under the curve; *CI*, confidence interval.

Another advantage of the oscillometric device is its ability to allow simultaneous blood pressure measurements on both ankles and one arm. This feature minimizes a potential error due to random blood pressure variation that occurs with sequential Doppler ABI measurements. However, it may have been more practical if the device measured blood pressure simultaneously in all four extremities. In addition, automated calculation of the ABI avoids other sources of bias, such as observer prejudice and calculation errors.[10,21] Moreover, oscillometric measurements do not need extensive training and are less time-consuming than Doppler measurements because additional steps, such as pulse palpation, application of gel, and signal viewing, are not required. A meta-analysis even found that oscillometric measurements were almost twice as fast compared with Doppler measurements (5.9 minutes and 10.1 minutes, respectively).[22] Moreover, early recognition as in primary care settings would improve PAD management in the general population, allowing more appropriate counseling of modifiable cardiovascular risk factors.

The role of oscillometry for PAD identification in diabetic patients is controversial. Studies previously reported the lack of accuracy of the oscillometric ABI in diabetic patients.[9,20] This study also performed subgroup analyses of diabetic and nondiabetic patients and found that detection problems occurred in similar percentages of limbs. We also reported similar correlation coefficients and differences between the two methods in diabetic and nondiabetic patients. Thus, our results indicate that oscillometric ABI measurements are feasible in diabetic patients. However, agreement and sensitivity were slightly better in nondiabetic (90% and 76%, respectively) compared with diabetic (82% and 68%, respectively) patients, which emphasizes the use of a higher oscillometric ABI cutoff point. Nevertheless, this comparison of patients with and without diabetes mellitus is potentially flawed because all legs with pathologically high ABI values were excluded from analysis.

Implications and future research. There is increasing interest in the automated oscillometric determination of ABI in primary care settings. It may be argued that the general practitioner may not be educated enough to understand the pitfalls of an automated oscillometric ABI device. However, this is a matter of education and communication between primary and secondary care. Vascular surgeons should increase communication about PAD as a disease but more importantly as a significant risk factor.

Given its advantages compared with Doppler, oscillometry could be used as the first-line diagnostic tool in primary care settings. In case of an oscillometric error (25% of patients), a Doppler ABI measurement would be needed. Thus, 75% of patients diagnosed using oscillometric ABI are saved a formal vascular laboratory assessment. Nevertheless, this sequence may be time-consuming and impractical. Future studies should focus on determining the application of oscillometry in a primary care setting.

CONCLUSIONS

Automated oscillometric ABI determination showed good diagnostic accuracy compared with vascular laboratory Doppler equipment. However, the high incidence of oscillometric errors and the challenges to correctly interpret readings may limit the use of the oscillometric method in PAD diagnosis. Future studies in a primary care setting are needed.

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AUTHOR CONTRIBUTIONS

Conception and design: DH, LG, MS, JT
Analysis and interpretation: DH, MvdH, NP, LG, MS, JT
Data collection: DH, MvdH
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