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REVIEW

Automated oscillometric determination of the ankle-brachial index: a systematic review and meta-analysis

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Measurement of the ankle-brachial index (ABI) using a Doppler device is widely used to identify subjects with peripheral artery disease (PAD), and those who are at high risk of cardiovascular disease. This paper presents a systematic review (Medline/PubMed, Embase and Cochrane) and meta-analysis of studies assessing the usefulness of automated oscillometric devices for ABI estimation and PAD detection compared with the conventional Doppler method. A total of 25 studies including 4186 subjects were analyzed. A random-effects model analysis showed that the average oscillometric ABI was similar to the Doppler ABI (mean difference ± s.e. 0.020 ± 0.018, $P = 0.3$) but that the absolute differences were significant (0.048 ± 0.009, $P < 0.01$). The pooled correlation coefficient (r) between the oscillometric and Doppler ABI was 0.71 ± 0.05. Simultaneous arm–leg measurements resulted in a smaller difference between the average oscillometric ABI value and the average Doppler ABI value than did sequential measurements (−0.012 ± 0.022 *vs.* 0.040 ± 0.026, respectively, $P < 0.01$). The average sensitivity and specificity of the oscillometric ABI estimation in PAD diagnosis was 69 ± 6% and 96 ± 1%, respectively (with Doppler ABI taken as the reference). These data suggest that an automated ABI measurement obtained by oscillometric blood pressure monitors is a reliable and practical alternative to the conventional Doppler measurement for the detection of PAD. To increase the sensitivity of the PAD diagnosis based on an oscillometric ABI, a higher threshold of 1.0 might be preferable.
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Keywords: ankle-brachial index; blood pressure measurement; Doppler; oscillometric; peripheral arterial disease

INTRODUCTION

Peripheral artery disease (PAD) is a prevalent manifestation of systemic atherosclerosis that can have serious consequences for health-related quality of life.[1] In particular, PAD is a strong predictor of subsequent cardiovascular morbidity and mortality as a result of concomitant coronary artery and cerebrovascular disease.[1,2] Patients with PAD have a threefold higher risk of myocardial infarction, stroke and death than those without PAD.[3]

As a consequence of the Western lifestyle, the prevalence of PAD is high in industrialized countries. The symptoms of PAD include intermittent claudication or rest pain.[1] However, more than 50% of PAD patients are symptomless.[4] Thus, PAD remains largely underdiagnosed and undertreated.[4,5] PAD is particularly common among subjects with hypertension (20%), current smokers (27%) and patients complaining of exercise-induced leg pain (30%).[6] Diabetes mellitus also increases the risk of PAD by 2- to 4-fold and is present in 12–20% of PAD patients.[2,7] Based on several epidemiological studies, the total prevalence is estimated at between 3 and 10%[5] of the general adult population, increasing with age to 15–20% in those older than 65.[5,8,9] Thus, assessing the ankle-brachial index (ABI) in all subjects older than 70 years, or in diabetics or smokers older than 50 years yields a positive result in ~30% of subjects.[10]

PAD detection is important not only because its presence indicates a high cardiovascular risk, but also because it becomes worse overtime if left untreated.[11] The estimation of the ABI by measuring systolic blood pressure (BP) at the ankle and the arm with a Doppler device is widely used in clinical practice and considered to be the reference method for PAD screening.[12] The current guidelines of the European Society of Hypertension-European Society of Cardiology propose that ABI measurement should be a 'recommended' test in hypertensive patients, with values <0.9 indicating advanced atherosclerosis and increased cardiovascular risk.[13] However, the conventional Doppler ABI measurement is time-consuming and requires specific skills and therefore is not performed as frequently as it should be.[14]

Several studies have evaluated ABI measurements obtained using automated oscillometric BP monitors. These devices are devoid of observer biases and errors, and have the potential to reduce the time required for ABI measurement. This paper presents a systematic review of studies that compared ankle and arm BP measurements by oscillometric devices and Doppler devices, and assessed the usefulness

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of oscillometric BP monitors for automated ABI estimation and PAD screening.

MATERIALS AND METHODS

Study selection

Systematic searches for studies that assessed ABI using the oscillometric method were performed in PubMed, EMBASE and the Cochrane databases using several keywords (oscillometric; automated; ankle; ABI; and peripheral arterial disease). Additional studies were found in reference lists of identified articles and reviews. For inclusion, two investigators (WJV and AK) screened the full text of all the potentially relevant articles. In the case of disagreement, the papers were discussed to reach consensus. Studies that fulfilled the following criteria were included in this review: (i) studies published after 1985 in the English and Spanish languages; (ii) studies that provided ABI values or ankle systolic BP measurements with the oscillometric and Doppler devices.

Device types

The oscillometric devices used for assessing ABI were divided into the following categories: (i) devices specifically developed for ABI measurement (specifically designed ankle cuff and the ability to perform simultaneous ankle-arm BP measurements), and devices not developed for this purpose; (ii) devices developed for arm BP measurement; (iii) validated according to the European Society of Hypertension International Protocol,[15] the American Association for the Advancement of Medical Instrumentation protocol[16] or the British Society of Hypertension protocol;[17] or (iv) not validated for arm BP measurement or that have failed the validation.

Statistical analysis

Analyses were performed with meta-analysis random-effects meta-regression using the command 'meta-reg' in Stata/IC 11.1, (StataCorp LP, College Station, TX, USA). The results were weighted for inverse variances (direct pooling).[18] When the s.d.s of the ABI differences between the oscillometric and Doppler measurements were missing, the highest available s.d. was imputed. From the selected studies, the average values pooled by the random-effects meta-analysis and accounting for heterogeneity were estimated for (i) the oscillometric and Doppler ABI correlation, (ii) the oscillometric-Doppler ABI difference and (iii) the sensitivity and specificity in diagnosing PAD (from studies providing such data). Heterogeneity was tested using I^2 statistics. Two-sided P values <0.05 were considered significant. The data are given as means ± s.e., unless otherwise stated.

The analyses were performed according to the type of the oscillometric device that was used (validated or non-validated and designed for measuring or not designed for measuring the ABI) and the BP measurement method (simultaneous or sequential arm–leg measurements). When the results from different groups were provided, the results for the total population were used.

RESULTS

The initial literature search identified 567 abstracts to be screened, from which 63 full papers were studied. From these papers, 25 studies from 1985 to 2011[7,14,19–41] fulfilled all of the inclusion criteria and were included in the analysis. The details of these studies are provided in Tables 1a and 1b. These studies included 4186 subjects, most of whom had been referred to a vascular clinic, indicating that they had vascular disease and/or cardiovascular risk factors (patient characteristics in Table 2). Of the 20 devices used in these studies, 5 were designed for ABI measurements,[19–23,37,38,41] 8 were validated for arm BP measurement[19,24–31] and 10 had not been validated[7,14,20–23,32–41] (Table 1). The heterogeneity (I^2) among the studies was 73%, and a Funnel plot indicates a minor publication bias (Figure 1).

Doppler ABI measurement

The Doppler method used in these studies differed in terms of the number of observers who performed the Doppler measurements (1–4 observers) and the number of readings obtained (1–3 readings). In most cases, arm systolic BP was measured with a Doppler device, but it was occasionally measured with an auscultatory BP monitor (mercury or aneroid).[20,23,27,35,41] The ankle systolic BP measurements were performed in the posterior tibial and dorsalis pedis arteries, or only in the posterior tibial artery (or only in the dorsalis pedis artery when the posterior tibial artery could not be found). Most studies performed the measurements on both sides, but one used the right side only.[20] In a single study, two observers performed simultaneous Doppler measurements.[39]

Several methods have been used for the ABI calculation using the Doppler device (Table 1). The most common method (10 studies) was to select the higher pressure (posterior tibial artery or dorsalis pedis artery) for each ankle divided by the higher brachial pressure of the two arms (left or right).[7,14,19,21,24,26,31–35] Two studies used the average of both arms as the denominator unless the inter-arm BP difference was larger than either 10 mmHg[27] or 15 mmHg[29], in which case the higher pressure was used. One study only considered the right arm.[41] One study selected the lower ankle pressure as the numerator.[23] Finally, some studies performed multiple measurements to assess ABI, with two of those studies discarding the first measurement.[26,31]

Doppler *vs.* oscillometric ABI

Eighteen studies ($n=3290$) reported the difference in ABI values assessed by the Doppler *vs.* oscillometric methods. The average ABI difference (oscillometric-Doppler) was 0.020 ± 0.018 ($P=0.28$), (absolute difference 0.048 ± 0.009; $P<0.001$), which indicates that the overall oscillometric method gave slightly higher ABI values than did the Doppler device (Figure 2). Overall, the average correlation between the oscillometric and Doppler ABI values, and between the oscillometric and Doppler systolic ankle BP when the ABI values were not reported, as calculated from 16 studies ($n=2447$), was 0.71 ± 0.05. Studies that assessed the association between the Doppler and oscillometric ABI in the subgroups of patients reported a correlation coefficient (r) of 0.70 ± 0.06 in PAD patients (four studies, $n=664$), 0.58 ± 0.18 in diabetic patients (four studies, $n=548$) and 0.68 ± 0.07 in non-diabetics (four studies, $n=370$).

Doppler *vs.* oscillometric methods in PAD diagnosis

Ten studies ($n=2015$) provided the sensitivity and specificity values of the oscillometric method in diagnosing PAD, with the Doppler taken as the reference method. The average sensitivity and specificity was $69 \pm 6\%$ and $96 \pm 0.8\%$, respectively.

Method and device type analyses

When the arm–leg BP measurements were performed simultaneously with the oscillometric device, there was a significantly lower average ABI difference from the Doppler value than when the measurements were performed sequentially ($P<0.01$; Table 3). However, this finding did not apply to the absolute ABI differences. Neither the number of readings (single compared with two or more readings) nor the oscillometric device that was used (ABI adapted or validated) showed significant differences, although devices designed for measuring the ABI tended to show a smaller difference from the Doppler ABI than did regular oscillometric devices. ($P=0.07$; Table 3).

Positive and negative study conclusion

In 18 of the 25 studies reviewed in this paper (72%; $n=3449$),[7,14,19–23,25–28,31,34–36,38,40] the authors arrived at a conclusion in favor of oscillometric ABI measurement. Studies with

Table 1a Studies that compared the oscillometric with Doppler method for ankle-brachial index measurement

Ref.	Study population	n	Age (years)	Men (%)	Doppler ABI	Oscillometric device	Oscillometric ABI	Results
41	General population	839	54.3	47	↑ DPA or PTA/R BA	Boso ABI system 100[a]	NR	ΔABI −0.1 ± 0.11 Sens 77%; Spec 98% r 0.45
23	Primary care subjects	69	42.6	NR	↓ DPA or PTA/↑BA	ABIgram Vasocor[a]	Ankle/↑BA	ΔABI −0.01
22	Population study	946	43.5	49	R PTA/R BA	Colin VP1000[a]	R ankle/R BA	ΔABI −0.03
20	Random population sample	105	56.5	48	(1) R DPA/R BA (2) R PTA/R BA (3) Average of R DPA + R PTA/R BA	Colin VP2000[a]	R ankle/R BA	(1) ΔABI 0.03 ± 0.01 (2) ΔABI −0.02 ± 0.01 3) ΔABI 0.01 ± 0.01
21	Patients with symptomatic PAD	50	65	62	(1)↑DPA or PTA/↑BA (2)↓DPA or PTA/↑BA	Boso ABI system 100[a]	NR	1) ΔABI 0.06, r 0.77 (2) ΔABI 0.13, r 0.75
19	Referred to cardiovascular clinic	93	62.5	62	↑ DPA or PTA/↑BA	Microlife watchbp office ABI[a,b]	Ankle/R BA or BA[d]	ΔABI 0.02 ± 0.09, r 0.80 Sens 83%; Spec 97%
36	Patients with vascular disease	19	NR	NR	NR	Dinamap	NR	ΔABI −0.02, r 0.78
35	Referred to vascular clinic	110	68.9	99	↑ DPA or PTA/↑BA	VascuMAP AP- 102 V	Ankle/BA	ΔABI 0.1
34	Healthy volunteers and PAD patients	40	57.5	90	↑ Of DPA & PTA/↑BA	Hewlett-Packard M1275A	NR	ΔABI −0.06, r 0.89
31	Referred to Cardiology Department	219	55	62	↑ DPA or PTA/↑BA	Omron M4b	Ankle/↑BA	ΔABI 0.03, r 0.63 Sens 76%; Spec 95%
33	Healthy volunteers	50	23	50	↑ DPA or PTA/↑BA	Dinamap vitalcare DOX model 506DXN	Ankle/↑BA	ΔABI −0.02, r 0.40
14	Referred to vascular clinic	173	66	47	↑ DPA or PTA/↑BA	CasMed740	Ankle/↑BA	ΔABI 0.05 ± 0.10, r 0.78 Sens 81%; Spec 90%
30	Hypertensive subjects	100	66	39	PTA or DPA if PTA undetected/↑BA	Omron HEM 705CP[b]		Sens 29%; Spec 95%
27	Referred to vascular clinic	57	65	84	↑ DPA or PTA/average (L + R) BA or↑BA[c]	Omron HEM 711C[b]	Ankle/average (L + R) BA or ↑BA[c]	ΔABI 0.08, r 0.71 Sen 71%; Spec 89%
28	Referred to vascular clinic	36	69	69	NR	Omron HEM 705CP[b]	NR	ΔABI 0.02, r 0.75
29	Referred to vascular clinic	54	58	52	↑ DPA or PTA/average (L + R) BA or↑BA[d]	Spengler ProM[b]	Ankle/↑BA or BA[e]	ΔABI 0.05 Sens 76%; Spec 96%
26	Referred for annual check-up	196	NR	NR	PTA/↑BA	Omron HM 722[b]	Ankle/↑BA	r 0.83 Sens 92%; Spec 98%
32	Referred to vascular clinic	61	67	NR	↑ DPA or PTA/↑BA for each leg	CasMed740	Ankle/↑BA	ΔABI 0.08 ± 0.15 Sens 71%; Spec 92%
7	Referred to vascular clinic	146	62	68	DPA and/or PTA/↑BA	Dinamap 8100	Ankle/↑BA	ΔABI 0.02 ± 0.27, r 0.53
24	Hospitalized patients	223	79.6	48	↑ DPA or PTA/↑BA	Omron M6[b]	Ankle/↑BA	ΔABI 0.08 ± 0.14 Sens 35%; Spec 96%.
25	Hypertensive subjects	228	62.8	51	NR	Omron M7[b]	NR	Total r 0.86; DM r 0.88
40	Healthy volunteers	71	NR		PTA	Dinamap 1846 sx	Only ankle measurements	Δankle BP −1.5 and −3.9 mmHg
39	Referred to vascular surgery and endocrinology outpatient clinic	81	NR	58	↑ DPA or PTA	SenSym 2 142SC05D	Only ankle measurements	Normals r 0.81; PAD r 0.38
38	Normo- and hypertensive subjects	52	46	NR	PTA	Colin VP2000[a]	Only ankle measurements	Δankle BP 2.2 ± 6.8 mmHg r 0.95
37	Referred to vascular clinic	168	64.8	92	↑ DPA or PTA	Colin[a]	Only ankle measurements	r 0.93

Abbreviations: ABI, ankle-brachial index; BA, brachial artery; DPA, dorsalis pedis artery; L, left; NR, not reported; PAD, peripheral arterial disease; PTA, posterior tibial artery; R, right; ↑, the highest value was used; ↓, the lowest value was used.
[a]Devices developed for ABI measurement; DM, diabetes mellitus; ΔABI, Oscillometric-Doppler ABI difference; Δankle BP, Oscillometric-Doppler ankle BP difference; r, correlation coefficient between oscillometric and Doppler values; Sens, sensitivity in diagnosing peripheral artery disease; Spec, specificity in diagnosing peripheral artery disease.
[b]Validated devices.
[c]The highest BA was used in case of a persistent difference > 10 mmHg.
[d]The highest BA was used in case of a persistent difference > 12 mmHg.
[e]The highest BA was used in case of a persistent difference > 15 mmHg.

Table 1b Ankle-brachial index values and prevalence of peripheral artery disease and cardiovascular risk factors in studies comparing the oscillometric with Doppler ankle-brachial index measurements

Ref.	*n*	*Doppler*	*Oscillometric*	*PAD*	*DM*	*HT*	*Smoking*
41	839	1.16 ± 0.11	1.06 ± 0.09	2	9	46	
23	69	1.06 ± 0.074	1.05 ± 0.075				
22	946	1.15 ± 0.11	1.12 ± 0.09			29	31
20	105	1.12 ± 0.10	1.13 ± 0.07			25	27
21	50	0.70 ± 0.22 0.62 ± 0.25[a]	0.63 ± 0.39	100	38	54	82
19	93	1.08 ± 0.17	1.11 ± 0.17	17	45	83	15
36	19	0.89 ± 0.22	0.87 ± 0.20				
35	110	0.84 ± 0.27	0.94 ± 0.24	27	48		
34	40	0.83 ± 0.03 (s.e.)	0.87 ± 0.02 (s.e.)	75	35	45	
31	219	1.00 ± 0.20	1.03 ± 0.18	24	18	26	37
33	50			0	0	0	
14	173			32	36		
30	100				38		16
27	57	0.97 ± 0.09	1.03 ± 0.10		26	79	33
28	36				42		
29	54	1.03 ± 0.26	1.09 ± 0.31		35	39	22
26	196			14			
32	61			71	25		
7	146			30	57	63	34
24	223			25	17	58	6
25	228				30	100	
40	71						
39	81						
38	52						
37	168			87	0		

Abbreviations: DM, diabetes mellitus; HT, hypertension; PAD, peripheral artery disease.
[a]modified (low) ankle-brachial index value.

Table 2 Participants' characteristics

	Studies	*Subjects*	*Mean ± s.d.*	*Range*
Age (years)	19	2980	56.6 ± 12.1	23–80
Men (%)	17	3260	57.6 ± 15.3	39–99
Diabetes (%)	14	1808	32.0 ± 12.9	6–100
Peripheral artery disease (%)	11	1529	36.0 ± 26.1	0–100
Hypertension (%)	9	2211	45.1 ± 25.6	0–100
Smokers (%)	9	1314	28.5 ± 12.5	6–82

a positive conclusion compared with those with a negative one reported a lower but not significant average Doppler-oscillometric ABI difference (0.012 ± 0.010 *vs.* 0.047 ± 0.035 $P = 0.38$) and absolute ABI difference (0.044 ± 0.011 *vs.* 0.060 ± 0.021; $P = 0.51$), and a significantly higher sensitivity for PAD diagnosis (80 ± 3% *vs.* 51 ± 5%; $P < 0.001$).

Ankle BP values

Four studies[37–40] compared only ankle BP values. Of these, two studies used devices designed for measuring the ABI and reported a high correlation with the Doppler measurements (0.93[37] and 0.95[38]).

Threshold values

Although all of the studies used the ABI threshold of 0.9 for diagnosing PAD, for both the Doppler and oscillometric measurements, three studies performed a receiver operating characteristics curve to determine the optimal threshold for PAD diagnosis using the oscillometric device. In one study, this analysis led to changing the oscillometric cutoff value for diagnosing PAD from 0.9 to 1.02 in unselected subjects, and to 1.04 in diabetic patients and 1.0 in non-diabetic patients.[7] Kollias *et al.*[19] found that the optimal sensitivity and specificity (92%) is achieved with a cutoff value of 0.97, and Korno *et al.*[32] reported a cutoff value of 0.92 (sensitivity 71% and specificity 92%).

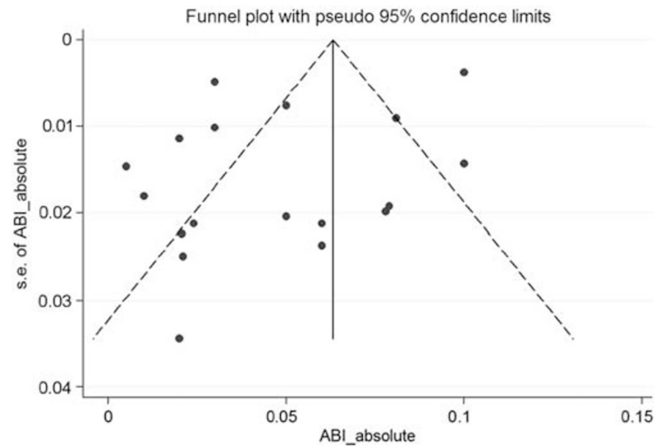

Figure 1 Funnel plot (with pseudo 95% confidence limits) of the differences in the absolute ankle-brachial index (ABI) obtained with the oscillometric and Doppler devices against the standard error (s.e.) for the publication bias. A full color version of this figure is available at *Hypertension Research* online.

Patient characteristics

We found no significant relationships between patient characteristics (diabetic status, PAD, age and gender) and ABI differences, correlations or sensitivity and specificity values of PAD diagnosis (data not shown).

DISCUSSION

This paper presented a systematic review of the evidence from 25 studies that assessed the performance of automated oscillometric devices for ABI measurement. Half of these studies were performed in the last 2 years, indicating an increasing interest in the application of the oscillometric technique for PAD screening. The main findings of this review and meta-analysis are the following: (i) oscillometric ABI determination appears to be feasible and accurate in clinical practice; (ii) the oscillometric and Doppler methods agree in terms of the ABI associations and differences, as well as the diagnosis of PAD; (iii) oscillometric ABI values tend to be slightly higher than Doppler values and therefore a higher ABI threshold for PAD diagnosis might be required; and (iv) differences between these studies regarding the methodology applied (simultaneous *vs.* sequential BP measurements) seem to account for the observed variability in the results.

Oscillometric ABI feasibility

The oscillometric method for measuring the ABI was characterized by high feasibility and applicability in the studies reviewed. In most of these studies, the participants had several cardiovascular risk factors or established cardiovascular disease and therefore represent the typical population for whom ABI measurement is recommended.[13]

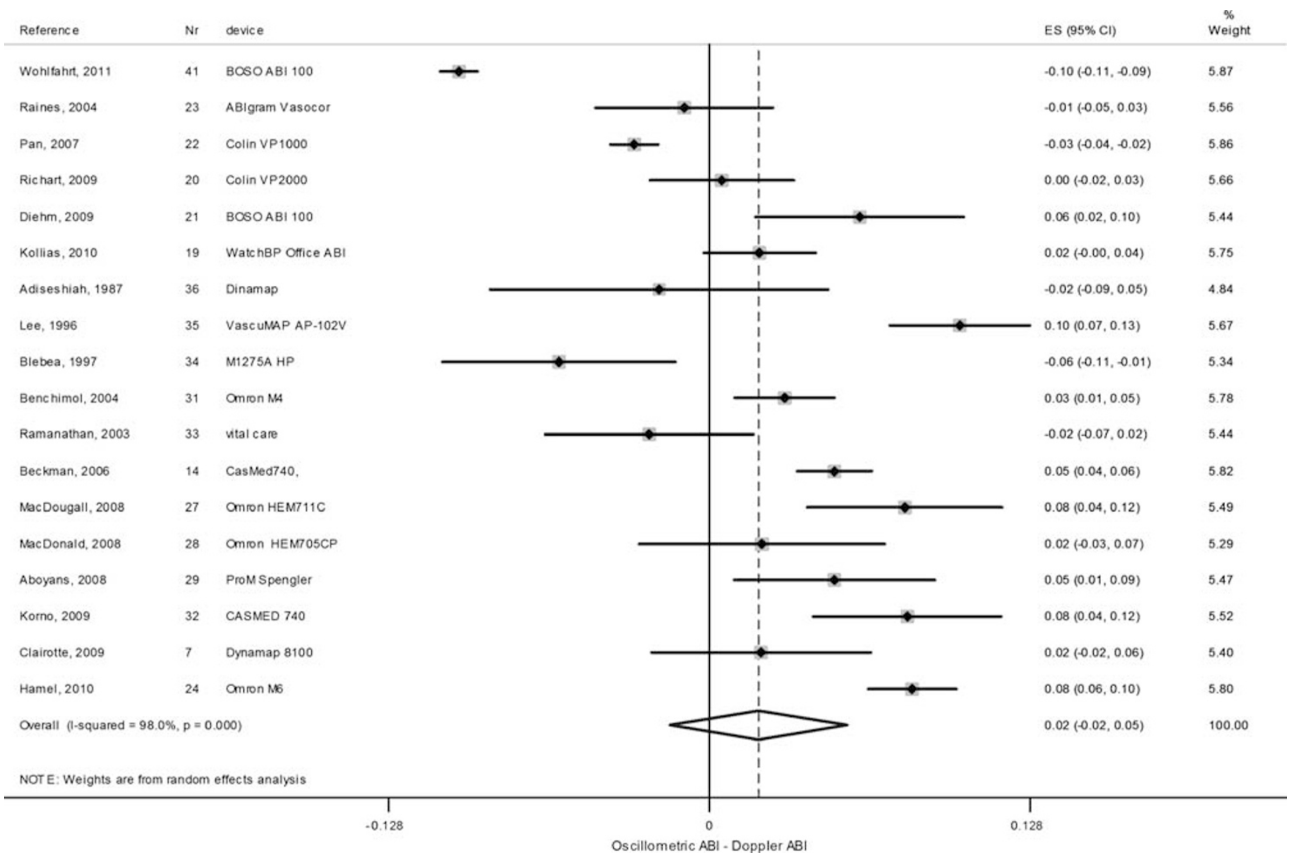

Figure 2 Forest plot differences in ankle-brachial index (ABI) obtained using the oscillometric and Doppler devices. A full color version of this figure is available at *Hypertension Research* online.

The only issue arising with regard to the applicability of the oscillometric method was in patients with very low ankle BP values. Some studies reported that measurements could not be obtained when the ankle BP was <70 mmHg.[6,27,28,31,42] Another study reported that the oscillometric device failed to measure BP in three legs from three patients, all of whom had a Doppler ABI <0.90.[19] Some oscillometric devices have been suggested to potentially be unable to determine low BP values, such as <50 mmHg[36] or <30 mmHg.[14] However, the automated oscillometric ABI estimation is simpler and faster than the Doppler ABI measurement,[14,19,21] which makes it more suitable for wide use and mass screening in general practice.[35] In the case of an erroneous or '0' oscillometric reading, the presence of PAD is highly probable, and the clinician should refer the patient for a lower extremity ultrasound. Notably, in two studies, the diagnostic ability of the oscillometric method was improved when the erroneous oscillometric measurements were considered to be indicative of an abnormal ABI.[19,43]

Oscillometric *vs.* Doppler method

The diagnostic ability of the oscillometric method in assessing the ABI was investigated by applying the following criteria: (i) oscillometric-Doppler ABI differences, (ii) oscillometric-Doppler ABI correlations and (iii) sensitivity and specificity in diagnosing PAD using Doppler as the reference method. An interesting finding in these analyses is that the oscillometric ABI values were slightly higher than the Doppler ABI values. From the cardiovascular physiology point of view, this difference is improbable because lower limb BP is assessed more distally by the Doppler method than by the oscillometric method. The Doppler ABI should be higher because of a greater amplification of systolic BP distally, which is generated by the pressure–wave reflections and arterial stiffness gradient within the arterial tree.[44] Therefore, the difference found between the oscillometric and Doppler ABI cannot be attributable to the slightly different points of the ankle BP measurement but rather to the intrinsic characteristics of each method. Taking the BP a few inches more proximally may avoid arterial occlusive disease that might be present between the cuff and the two pedal pulses.[14] A systematic error in assessing Doppler ABI, likely due to observer error (the time between hearing the Doppler signal, viewing it and then recording the pressure on the sphygmomanometer could differ for the arm and ankle) cannot be excluded. In addition, the posterior tibial artery and the dorsalis pedis artery are measured separately with the Doppler method, whereas the higher of the two arteries is commonly measured automatically with the oscillometric device.[29,36] Because of this difference, determining the so-called modified ABI with the automated method, that is, using the lower instead of the higher ankle pressure, is not possible. The modified ABI has been suggested as a more sensitive measure for identifying patients with cardiovascular risk than the conventional method.[45,46] However, this sensitivity comes at the cost of specificity,[46] and thus the modified ABI might be less suitable as a screening method in general practice among a population with a lower PAD prevalence than the populations studied by Espinola-Klein *et al.*[45] and Schröder *et al.*[46]

As a result of the higher oscillometric ABI values, some investigators used receiver operating characteristics analysis to propose the use of a higher oscillometric ABI cutoff value for PAD diagnosis, varying

Table 3 Ankle-brachial index values obtained with the automated oscillometric compared with the Doppler method (mean ± s.e.)

			Device				Arm–leg BP measurements			
Examined parameter	Overall	P	ABI adapted[a] (Yes/No)	P	Validated[b] (Yes/No)	P	Number of readings (1/≥2)	P	Simultaneous (Yes/No)	P
Average ABI difference[c]	0.020 ± 0.018	0.275	Yes: −0.011 ± 0.023 No: 0.036 ± 0.015	0.07	Yes: 0.047 ± 0.013 No: 0.006 ± 0.020	0.23	1: 0.017 ± 0.021 ≥2: 0.027 ± 0.016	0.78	Yes: −0.012 ± 0.022 No: 0.040 ± 0.026	0.01
Absolute ABI difference[c]	0.048 ± 0.009	0.001	Yes: 0.038 ± 0.020 No: 0.053 ± 0.013	0.49	Yes: 0.047 ± 0.013 No: 0.048 ± 0.012	0.96	1: 0.052 ± 0.011 ≥2: 0.035 ± 0.013	0.43	Yes: 0.036 ± 0.021 No: 0.055 ± 0.013	0.38
Doppler-oscillometric ABI correlation (*r*)	0.71 ± 0.05	—	Yes: 0.66 ± 0.13 No: 0.72 ± 0.05	0.56	Yes: 0.77 ± 0.04 No: 0.65 ± 0.06	0.18	1: 0.71 ± 0.07 ≥2: 0.70 ± 0.06	0.95	Yes: 0.69 ± 0.0.13 No: 0.72 ± 0.05	0.56
PAD diagnosis sensitivity (%)	69 ± 6	—	Yes: 79 ± 3 No: 66 ± 8	0.44	Yes: 66 ± 10 No: 76 ± 13	0.50	1: 64 ± 7 ≥2: 83 ± 6	0.14	[d]	—
PAD diagnosis specificity (%)	96 ± 1	—	Yes: 98 ± 1 No: 95 ± 1	0.12	Yes: 96 ± 1 No: 95 ± 2	0.57	1: 95 ± 1 ≥2: 96 ± 2	0.53	[d]	—

Abbreviations: ABI, ankle-brachial index; BP, blood pressure; PAD, peripheral artery disease.
[a]Devices specifically developed for ABI measurement (specific ankle cuff design; potential ability to perform simultaneous ankle-arm BP measurements).
[b]Validated for arm blood pressure measurement according to the established protocols.
[c]Difference between the values obtained with the oscillometric *vs.* Doppler method.
[d]Not enough data for analysis.

from 0.92 to 1.04.[7,19,32] Therefore, the use of a higher oscillometric ABI threshold close to 1.0 is expected to increase the diagnostic accuracy of PAD.

The findings regarding the comparison of the oscillometric with the Doppler method for the ABI measurement were mainly influenced by the methodology used. When simultaneous instead of sequential measurements were performed, significantly smaller ABI differences for the oscillometric device *vs.* the Doppler device were observed. Interestingly, there were no differences between the validated and non-validated oscillometric devices. However, some non-validated devices have not actually failed but rather have just not been subjected to validation, which should be noted. In addition, by assessing a BP ratio instead of a BP value, a potential systematic BP measurement error by a non-validated device would have a lesser impact. Moreover, in some studies involving non-validated devices, simultaneous BP measurements were performed, which might have improved the measurement accuracy. The number of readings did not seem to have any influence on the relationship of oscillometric and the Doppler values.

There were no significant differences between devices designed for ABI measurement and regular oscillometric devices, although there was a tendency toward better results for the ABI designed devices. This observation is expected because devices that have been designed for ABI measurement use cuffs adapted to the shape of the ankle, thus avoiding several erroneous BP readings due to inappropriately sized and non-fitting cuffs. Moreover, an additional advantage of the ABI designed oscillometric devices is that they are equipped with two or four cuffs, thereby allowing simultaneous BP measurements on the ankle and arm. This feature prevents the error due to random BP variation and is a clear advantage of the oscillometric device compared with the Doppler ABI device, which uses sequential measurements.

In the present study, five types of devices designed for measuring the ABI were used. However, the second largest study with a device designed for measuring the ABI that was analyzed has a significant influence on the overall difference of ABI designed devices with Doppler. The study shows an ABI difference of the oscillometric device with Doppler that largely deviates from the remaining studies with regard to ABI differences between oscillometric devices designed for measuring ABI and Doppler.[41] Remarkably, the results of Wohlfahrt *et al.*[41] are opposite from those of Diehm *et al.*[21] with regard to the ABI difference of ABI designed devices with Doppler even though the same type of device was used. The latter study showed higher oscillometric ABI values than Doppler ABI values.[21] These differences might be related to the lower average ABI values in the study of Diehm *et al.*[21] than the study of Wohlfahrt *et al.*[41] (0.62 *vs.* 1.16), indicating that the oscillometric device used tends to overestimate at lower Doppler ABI values and to underestimate at higher Doppler ABI values. This indication of over and underestimation is in line with the study of Benchimol *et al.*,[26] who divided the study participants into quartiles (from low to high values) based on the Doppler ABI values: the first quartile showed significantly higher oscillometric ABI values, whereas the fourth quartile showed significantly lower oscillometric ABI values, than those measured by a Doppler device. However, we could not find such a significant relationship in our mega-analysis.

The automated nature of the oscillometric BP measurement avoids other well known major sources of error, including those due to observer prejudice, bias and error (such as fast deflation and terminal digit preference).[47] An additional important advantage of the oscillometric ABI assessment with simultaneous measurements is the significant reduction in the time needed for the ABI determination compared with the classic Doppler method. Two studies showed that with simultaneous measurements, the average time needed for the automated oscillometric ABI determination was shorter by 34% (that is, 62% of the time required using the Doppler method).[19,21]

The impact of repeated measurements is another interesting point. A study that investigated the influence of multiple measurements showed that the correlation between the oscillometric and Doppler ABI was only slightly improved when 2 or 3 oscillometric measurements were averaged compared with a single measurement ($r=0.85$, 0.86 and 0.80, respectively).[19] The present analysis could not demonstrate whether an increasing number of oscillometric measurements results in a smaller differences or an improved association with the Doppler ABI.

With respect to the patients' characteristics, several studies reported problems with the oscillometric ABI measurement in PAD patients. One study showed that the oscillometric device systematically overestimated the ABI values in patients with reduced ankle pressure, leading to patients falsely classified as having an ABI >0.9.[32] In other studies, the ankle measurements could not be obtained in patients with very low BP values.[6,27,28,31,42] Diehm *et al.*[21] found that oscillometric ankle BP measurements yielded falsely low values in patients with a mean Doppler ABI value of 0.48 ± 0.12. Nukumizu *et al.*[37] mentioned that there were significantly fewer patients with crural artery occlusion having similar oscillometric ABI values as Doppler than patients without major arterial lesions. Finally, Kollias *et al.*[19] demonstrated that the presence of PAD was an independent predictor of the oscillometric-Doppler ABI difference. However, the present review did not reveal a significant impact of the presence of PAD on oscillometric device performance, which might be related to the fact that only a few studies clearly specified the number of subjects with PAD. Finally, our analysis did not identify any other patient characteristics affecting the differences between the oscillometric and Doppler ABI measurements.

Cost-effectiveness

No studies investigated the cost-effectiveness of the oscillometric ABI measurement. However, this method is likely to be more cost-effective than the Doppler method because, as mentioned above, it is faster to perform[14,19,21] and requires less training.[19,48] Although the Doppler measurement of ABI is considered to be the reference method,[43] its outcome cannot always be trusted because it is often not well performed, leading to an unreliable diagnosis.[48,49] As ABI measurement is usually not performed on a routine basis, there is a lack of experience in the general practitioner setting.[48] In addition, Doppler measurements might not be suitable for routine PAD screening because of the time and skills that are required for its optimal measurements.[48,50]

Limitations

The results of the present review should be interpreted within the context of its limitations. There was a considerable heterogeneity among the studies with regard to the patient characteristics, methodology and devices, which makes comparisons among the studies difficult. This heterogeneity was not only caused due to the use of different oscillometric devices but also due to differences in the protocols used for the Doppler ankle brachial measurements. Moreover, there were differences in the Doppler devices used, and some studies did not provide the brand names and specifications of these devices. Therefore, the differences between the oscillometric and Doppler ABI measurements might have been influenced, at least in part, by the devices.

Similar to the arm BP measurements, not all patients are suitable for PAD screening with the oscillometric device: for example, patients with atrial fibrillation. Therefore, these issues need to be verified before the ankle-arm measurements are performed.

The Funnel plot shows a slightly asymmetrical pattern, which might indicate that some small studies with large differences between the Doppler and oscillometric device have not been published. However, the inclusion of these studies would be unlikely to have a major influence on the outcome because large differences are also observed for the large trials in the present review. In some studies, important methodological information has not been reported (ABI calculation, order of measurement methods, and so on.), which might have affected the outcome. Moreover, although there are published guidelines for the Doppler ABI calculation,[2] several different approaches for the Doppler ABI calculation have been applied in the reviewed studies. The wide diversity in the ABI calculation can lead to a wide diversity in the outcome, even in the same subjects. If the systolic pressures of two brachial arteries or two ankle arteries are measured, the highest, average or lowest pressure might be used, which can result in more than 25 different possible combinations to calculate the ABI.[48] Therefore, the method for the ABI calculation has likely influenced the differences between the oscillometric and Doppler derived ABI values. In addition, the finding of the present analysis, which showed that even in research settings several different methods are used for calculating ABI, underscores the urge for standardization and uniformity with regard to calculation of the ABI. The oscillometric method has the potential to eliminate this problem by automated standardized measurement and calculation of the ABI value, as is the case with most of the ABI designed devices.

PERSPECTIVES

There is increasing interest in automated oscillometric determination of ABI, which appears to be highly applicable in clinical practice. Its agreement with the reference Doppler method seems to be satisfactory in terms of several criteria. In general, the characteristics of the oscillometric ABI assessment do not appear to have a significant impact on the absolute difference in the ABI measured with the Doppler method, although devices designed for measuring the ABI tend to have a closer agreement with the ABI measured by Doppler devices than do devices that were not designed for measuring the ABI. In addition, simultaneous measurements show smaller ABI differences from the Doppler method than do the sequential measurements. As some studies showed that the oscillometric devices become less accurate in patients with lower ankle BP values, more studies in PAD patients are required. Until such data become available, the oscillometric device should be recommended as a screening tool that can facilitate the detection of undiagnosed PAD. To improve the accuracy of PAD diagnosis, using an oscillometric ABI threshold of 1.0 for diagnosing PAD appears to be reasonable. The straightforward and unbiased nature of the oscillometric technique provides a faster ABI determination and automated measurement and calculation, which implies a high applicability of this method in routine clinical practice

CONFLICT OF INTEREST

Willem Verberk is an employee of Microlife, Taipei, Taiwan. GS Stergiou has received speaker fees from Omron and consultation fees from Microlife. Anastasios Kollias declares no conflict of interest.

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