

Comparison of Doppler and Oscillometric Methods of Assessing Ankle-Brachial Index in Non-diabetic Premenopausal Women in Ghana

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Abstract

Introduction: Peripheral arterial disease (PAD) is a common cardiovascular disorder less commonly diagnosed in female patients. Peripheral arterial disease is objectively diagnosed using the ankle-brachial index (ABI), which can be measured using the “gold standard” Doppler method or the oscillometric method. The agreement between these 2 methods is less investigated in the sub-Saharan African population. Therefore, we compared the diagnostic characteristics of the oscillometric method of measuring ABI with the Doppler method in premenopausal female patients in Ghana. **Methods:** The ABI was measured in non-diabetic premenopausal women suspected of having PAD using the Doppler method with an 8 MHz handheld Doppler (LifeDop 250, Summit Doppler) and an oscillometric device (Vasera I500N, Fukuda Denshi) in 160 patients (320 legs). Peripheral arterial disease was defined as an ABI <0.90 in at least one leg. Leg symptoms were assessed using the Edinburgh claudication questionnaire. **Results:** Leg pain on exertion was present in 101 patients screened with similar mean ABIs in the right and left legs. The prevalence of PAD as screened by the Doppler method was 25.7% (18.9%-33.4%) and that of the oscillometric method was 32.2% (24.9%-40.3%). In comparison with the Doppler method, the accuracy of the oscillometric method was 88.2%, and the sensitivity, specificity, positive predictive value, and negative predictive value were 89.7%, 87.6%, 71.4%, and 96.1%, respectively. The overall agreement between the Doppler and oscillometric methods was high, $\kappa = 0.78$ (0.62-0.91), $P < .001$, with an intraclass correlation of 0.89 (0.87-0.92, $P < .001$). In receiver-operating characteristic (ROC) curve analysis, the oscillometric method showed an area under the curve of 0.925 compared with the Doppler method in the diagnosis of PAD. **Conclusion:** In non-diabetic premenopausal women in our study, oscillometric ABI performed acceptably in the diagnosis of PAD when compared with Doppler ABI.

Keywords

peripheral arterial disease, ankle-brachial index, Doppler ultrasound, oscillometric blood pressure, claudication

Introduction

Peripheral arterial disease (PAD) is a progressive disorder characterized by stenosis or occlusion of large and medium-sized arteries, excluding those that supply the heart (coronary artery disease) or the brain (cerebrovascular disease).¹ The global population is in an epidemiological transition, with the burden of PAD shifting from high-income to low- and middle-income countries (LMICs).² It was estimated that the prevalence of PAD worldwide between 2000 and 2010 was 200 million, with the majority living in LMIC. The regional analysis also showed that about 14.2 million people are living with PAD in sub-Saharan Africa.²

In LMIC, PAD is more common in women, especially at a young age,² but is less represented in clinical studies.³ PAD affects the lower extremities more commonly than the upper

extremity vessels and may lead to recurrent fatigue, cramping sensation, or pain that is known as intermittent claudication, which is the most recognized symptomatic subset of lower extremity PAD.⁴ Peripheral arterial disease can affect walking and, in severe cases, can lead to tissue loss, infection, and amputation. In addition to morbidity directly caused by PAD,

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patients with PAD are at increased risk of cardiovascular disease events, because atherosclerosis is a systemic disease that also causes coronary and cerebrovascular events.^{5,6} The ankle-brachial index (ABI) is a simple, reproducible, non-invasive hemodynamic test used for screening patients suspected of having atherosclerosis in the arteries of the lower extremities.^{5,7} An ABI <0.90 has been shown to have a high sensitivity and accuracy in detecting stenosis greater than 50% in peripheral arteries with digital subtraction angiography as a gold standard.^{8,9}

The American Heart Association and American College of Cardiology recommend the use of the Doppler method for measuring ABI in suspected PAD patients.¹ However, conventional Doppler ABI measurement is time-consuming, requires specific skills, and is therefore underused in resource-constrained clinical settings in sub-Saharan Africa.¹⁰ To address this challenge, the use of automated oscillometric cuff-based equipment to measure ABI is gaining popularity. Compared with the Doppler method, the oscillometric method requires less training, a short duration of measurement, and is operator-independent.^{11,12} The major drawback to the utility of oscillometric devices is their accuracy because earlier devices were considered less accurate.^{7,13,14} However, current reports indicate acceptable accuracy of the oscillometric devices.^{10,15,16} Based on our literature search, no study has assessed the accuracy of oscillometric devices in the sub-Saharan African population. In this study, we assessed the reliability, validity, and diagnostic accuracy of an automated oscillometric ABI device compared with the reference standard vascular laboratory Doppler ABI equipment in non-diabetic premenopausal women suspected of having PAD. We hypothesized that the automated oscillometric ABI device would provide similar results to Doppler ABI in the diagnosis of PAD.

Methods

Patients

The study was conducted at the Cardiovascular and Metabolic Research Laboratory at the University of Ghana Medical School, Korle Bu, Accra, Ghana. Consecutive female patients, between 18 and 40 years of age, who were referred for vascular evaluation were included in the study. Patients with psychiatric or psychological disorders that made them unable to provide voluntary informed consent, major limb amputations, marked oedema in one or both feet, inability to tolerate a supine position, upper extremity vascular disease, and spasms or tremors of any kind were excluded from the study. The study protocol was approved by the College of Health Ethical and Protocol Review Committee of the University of Ghana. Each patient provided voluntary written consent before being included in the study. The clinical history of the participants was taken from their case notes, and leg symptoms were evaluated using the Edinburgh claudication questionnaire.

ABI Measurements

ABI measurements were performed under standardized conditions in a quiet examination room in a supine position after 3 to

5 minutes of rest. Both oscillometric and Doppler measurements were obtained from patients in random order. All ABI measurements were performed in 3 replicates, and the last 2 ABI measurements were averaged for analysis if they did not differ by more than 0.05. When the difference in ABIs was greater than 0.05, the patient was allowed to rest for another 5 to 10 minutes and a new set of measurements was performed. Doppler systolic brachial blood pressure (BP) was measured with an 8 MHz continuous wave Doppler (LifeDop, Summit Doppler) in both arms, after which the systolic ankle BPs of the dorsalis pedis and posterior tibial arteries were measured at the level of the malleoli. The ABI was calculated for each leg by dividing the highest systolic ankle pressure by the highest brachial systolic pressure.¹³ Study participants were categorized into those with PAD (ABI <0.90 in at least one leg) or normal (ABIs ≥ 0.90).

The oscillometric ankle and brachial systolic BPs were measured in all participants after a minimum of 5 minutes of rest in a supine position on an examination table in a room using a validated automated method (Vasera 1500N, Fukuda-Denshi, Tokyo). The Vasera cuffs were applied to both arms and ankles to simultaneously measure BP. The ABI was calculated for each leg using the highest ankle pressure (HAP) method as the ratio of systolic BP in the ankle divided by the highest of the systolic BPs in the arms. An ABI ≥ 0.90 was considered normal, and PAD was defined as an ABI <0.90 in at least one leg. The ABIs were measured in 2 sessions separated by more than 30-minute intervals. When the equipment failed to measure an ABI after 2 trials, it is considered as an oscillometric device error.

Sample Size Estimation

The minimum sample size for the study was calculated based on the assumption that the prevalence of PAD in our study population is 10% and the oscillometric method of measuring ABI would be able to correctly identify 90% of the patients as having PAD compared with the Doppler method (sensitivity of 90%). Assuming a null hypothesis that the oscillometric method of measuring ABI has equal probabilities of correctly and incorrectly identifying PAD compared with the Doppler method (sensitivity of 50%), then at the power of 90% and a level of significance, the minimum sample size required for a 2-tailed test would be 120 patients.¹⁷ To allow for measurement errors due to device error and non-compressible arteries, we recruited 175 patients into the study.

Statistical Analysis

The analyses were performed using the IBM SPSS ver 27 and R statistical package. Data are presented as mean $\pm$ standard deviation for continuous variables and counts and percentages for categorical variables. The comparison of variables between 2 groups was performed using an independent *T*-test and analysis of variance (ANOVA) for 3 or more variables. Correlational analyses were performed using the Pearson correlation test. The reproducibility of the oscillometric ABI was assessed

Table 1. General Characteristics of Study Participants.

	All participants (n = 160)	Leg pain (n = 101)	No leg pain (n = 59)	P
Age, y	31.4 ± 8.6	32.9 ± 9.3	28.7 ± 6.5	.025
Previous smoking, No. (%)	12 (7.5)	5 (4.9)	7 (11.9)	.109
Alcohol usage, No. (%)	34 (21.3)	23 (22.8)	11 (18.6)	.538
Body height, cm	165 ± 7	165 ± 6	166 ± 8	.578
Bodyweight, kg	70 ± 15.4	69.6 ± 13.6	70.5 ± 18.6	.823
BMI, kg/m ²	25.8 ± 5.6	25.8 ± 5.1	25.7 ± 6.6	.96
Hip circumference, cm	102 ± 13	102 ± 14	101 ± 13	.808
Waist circumference, cm	85 ± 14	85 ± 14	85 ± 13	.97
Waist-hip ratio	0.83 ± 0.07	0.83 ± 0.08	0.84 ± 0.07	.648
Systolic BP, mm Hg	123 ± 24	122 ± 29	125 ± 12	.371
Diastolic BP, mm Hg	77 ± 17	77 ± 20	77 ± 9	.964
Pulse BP, mm Hg	47 ± 7	47 ± 7	48 ± 7	.26
Mean BP, mm Hg	95 ± 12	96 ± 13	93 ± 11	.41
Heart rate, beats/min	76 ± 23	75 ± 25	79 ± 20	.269
Clinical history, No. (%)				
Hypertension	64 (40)	46 (45.5)	18 (30.5)	.061
Hypercholesterolemia	33 (20.6)	25 (24.8)	8 (13.6)	.091
Chronic kidney disease	32 (20)	26 (25.7)	6 (10.2)	.017
Sickle cell disease	18 (11.2)	10 (9.9)	8 (13.6)	.499
CVD	57 (35.6)	39 (38.6)	18 (30.5)	.302
Stroke	11 (6.9)	7 (6.9)	4 (6.8)	.971
Doppler measurements				
Right ABI	0.97 ± 0.13	0.96 ± 0.13	0.98 ± 0.11	.546
Left ABI	0.98 ± 0.12	0.98 ± 0.13	0.96 ± 0.09	.385
Right PAD, No. (%)	51 (31.9)	42 (41.6)	9 (15.3)	<.001
Left PAD, No. (%)	58 (36.3)	41 (40.6)	17 (28.8)	.135
Oscillometric measurements				
Right ABI	0.96 ± 0.11	0.96 ± 0.12	0.97 ± 0.09	.58
Left ABI	0.99 ± 0.11	0.98 ± 0.11	1 ± 0.11	.269
Right PAD, No. (%)	53 (33.1)	38 (37.6)	15 (25.4)	<.001
Left PAD, No. (%)	48 (30)	34 (33.7)	14 (23.7)	.186

Note. BMI = body mass index; BP = blood pressure; CVD = cardiovascular disease; ABI = ankle-brachial index; PAD = peripheral arterial disease.

using the correlation, coefficient, intraclass correlation, and Bland-Altman plot.

The agreement between oscillometric ABI and Doppler ABI in each limb was analyzed using Bland-Altman's statistics.¹⁸ Sensitivity, specificity, positive predictive value, negative predictive value, positive and negative likelihood ratios, and diagnostic odds ratio of the oscillometric method were determined using the Doppler measurement as the reference standard. A receiver-operating characteristic (ROC) curve was constructed, and the area under the curve (AUC) was computed for each limb. A *P*-value less than .05 was considered statistically significant.

Results

We excluded 15 participants from the analysis due to non-compressible arteries (2 patients) and oscillometric device errors (13 patients), leaving a total of 160 participants. When screened with the Edinburgh claudication questionnaire, 101 (63.1%) had exertional leg pain. Most of the patients with

exertional leg pain (72% or 71.3%) had intermittent claudication, while 25 (24.8%) had atypical claudication and 4 (4.0%) had rest pain.

Compared with those without exertional leg pain, patients with exertional leg pain were older, with high proportions of chronic kidney disease and PAD on the right side. There was no difference in their alcohol intake and previous smoking status, anthropometric indices, BP indices, and conditions such as hypertension, hypercholesterolemia, sickle cell disease, cardiovascular disease, and stroke among the 2 groups. Also, both right-side and left-side Doppler ABIs were similar among the 2 groups. There was an association in the prevalence of PAD and exertional leg pain using Doppler and oscillometric methods on the right side of the body, but not on the left side (Table 1).

In correlational analyses, Doppler ABI was positively correlated with oscillometric ABI in right ($r = 0.749$, $P < .001$) and left ($r = 0.787$, $P < .001$) sides of the body (Figure 1). This positive correlation was observed in patients with exertional leg pain and those without exertional leg pain (Figure 2). When the lowest ABI in either the right or left side of the body was

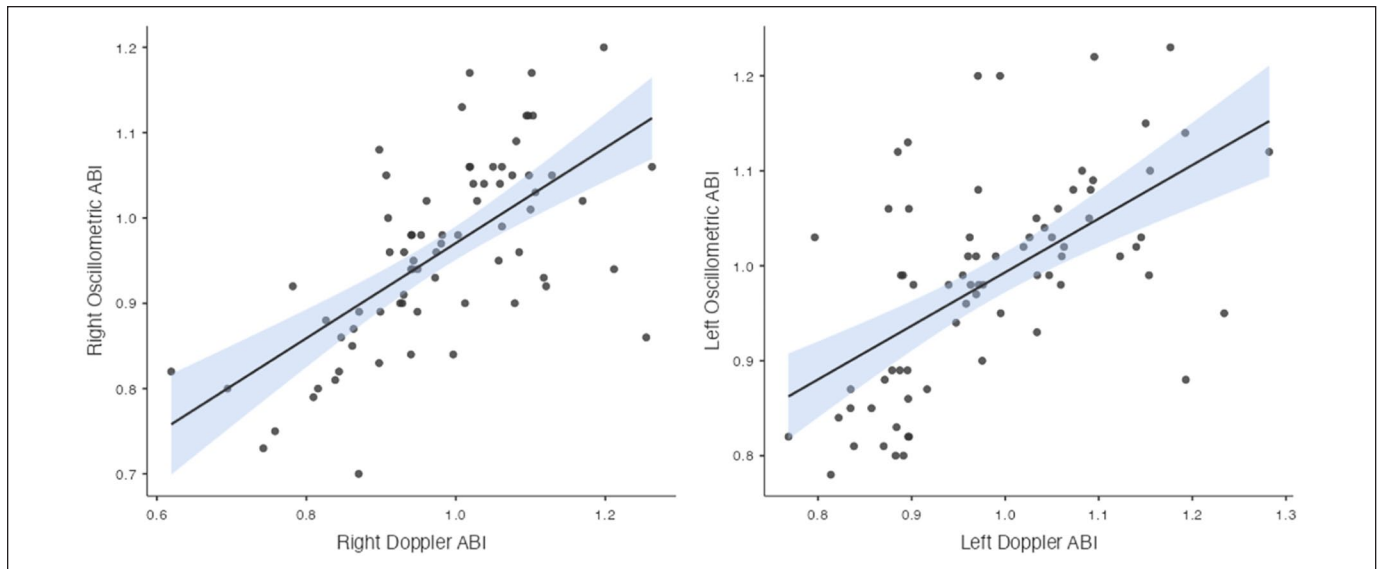


Figure 1. Scatterplot of the association between oscillometric ABI and Doppler ABI in the right ($r = 0.749$, $P < .001$) and left ($r = 0.787$, $P < .001$) sides of the body.

Note. ABI = ankle-brachial index.

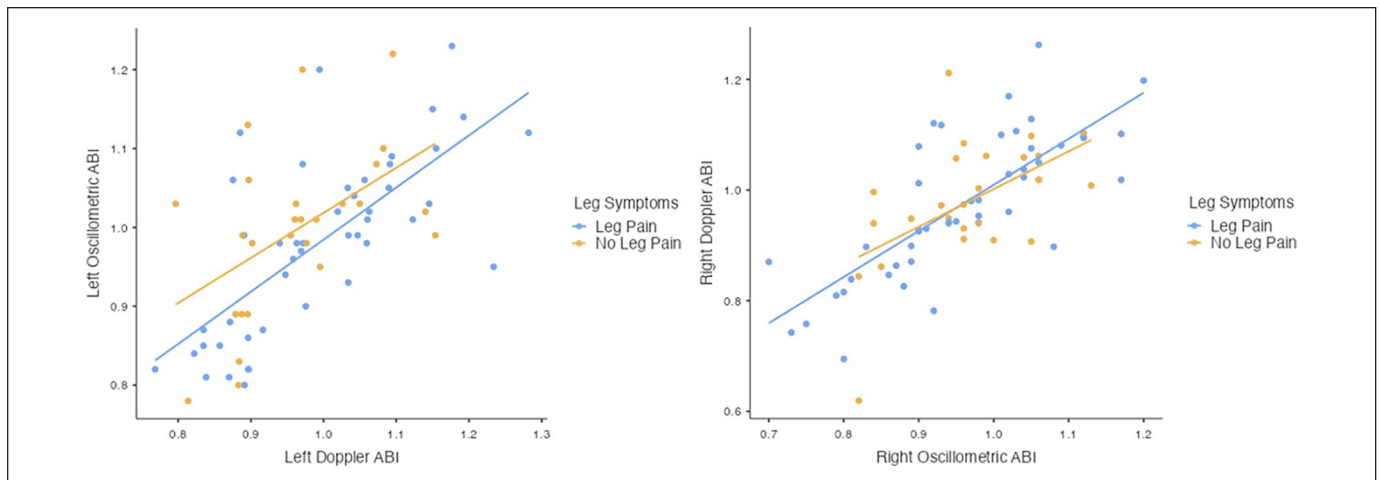


Figure 2. Scatterplot of the association between oscillometric ABI and Doppler ABI in the right and left sides of the body based on the presence or absence of leg pain on exertion.

Note. ABI = ankle-brachial index.

used in diagnosing PAD, the prevalence of PAD screened by the Doppler method was 25.7% (18.9%-33.4%) and that of the oscillometric method was 32.2% (24.9%-40.3%). Compared with the Doppler method, the accuracy of the oscillometric method was 88.2%. The sensitivity, specificity, positive predictive value, and negative predictive value were 89.7%, 87.6%, 71.4%, and 96.1%, respectively. The diagnostic odds ratio of the oscillometric method was 61.9, and 1.3 patients are required to correctly be assessed to diagnose PAD with the oscillometric method (Table 2). The overall agreement between the Doppler method and the oscillometric method is high, $\kappa = 0.78$ (0.62-0.91), $P < .001$, with an intraclass correlation of 0.89 (0.87-0.92, $P < .001$).

Data visualization by Bland-Altman graphs indicates that most ABIs fell within the upper and lower limits of agreement in the right and left legs (Figure 3). The histogram-density plot indicates that the mean differences in measurements between Doppler and oscillometric methods fell mostly between -0.1 and $+0.1$ (Figure 4). In ROC curve analysis, the oscillometric method showed an AUC of 0.93 compared with the Doppler method in the diagnosis of PAD (Figure 5).

Discussion

In this study, we investigated the agreement between Doppler and oscillometric methods for measuring ABI in non-diabetic

premenopausal female patients with or without exertional leg pain. The findings indicate a good level of agreement between the Doppler and oscillometric methods in our study participants with sensitivity, specificity, diagnostic odds ratio, and AUC of 89.7%, 87.6%, 61.9, and 0.93, respectively. To our knowledge, this is the first study from the sub-Saharan African population that has investigated the precision and reliability of oscillometric ABI, especially in the non-diabetic female population.

The findings in this study are consistent with recently reported studies that investigated the accuracy of oscillometric devices. A binational study in Japanese and French patients reported the sensitivity, specificity, and concordance of the oscillometric device in comparison with the Doppler method to be 89.1%, 94.4%, and 0.8, respectively.¹¹ Similarly, in Dutch patients, Hageman et al¹⁶ reported the sensitivity, specificity, diagnostic odds ratio, and AUC of the oscillometric device with an ABI cutoff of 0.90 to be 73.7%, 96.7%, 82, and 0.96,

respectively, in comparison with Doppler ABI. Systematic reviews reported high diagnostic accuracy of the oscillometric method compared with the Doppler method. It was previously reported in a meta-analysis that oscillometric ABI is a reliable and practical alternative to conventional Doppler ABI, with a sensitivity and specificity of 69% and 96%, respectively.¹² In a recent systematic review which utilized robust hierarchical summary receiver operator characteristics, the pooled diagnostic odds ratio for oscillometric ABI was 32.5 with a sensitivity of 65% and specificity of 96%, and the time required for the oscillometric ABI was reduced by almost half when compared with Doppler ABI assessment.¹⁰

This study showed that the prevalence of low or abnormal ABIs was lower using the Doppler method compared with the oscillometric method (25.7% vs 32.2%). This is contrary to other studies conducted in Japan,¹¹ the Netherlands,¹⁶ and the United States¹³ which reported a higher prevalence of low ABI with the Doppler method compared with the oscillometric method. Unlike these studies, our study participants were younger and had no diabetes. Chronological age and diabetes are known to stiffen the arteries,¹⁹ and this reduces the accuracy of the oscillometric BP measurement.⁹ This is because oscillometric devices measure BP from oscillations due to the “maximum buckling” of the specific artery under the cuff, which is nearly equal to the mean arterial pressure.²⁰ Systolic and diastolic BP calculated from this mean, rather than measured directly, can be affected by stiffened arteries, as observed in older and diabetic patients. In diabetic patients with a high proportion of stiffened arteries, ABI measurement has increased specificity, while sensitivity is compromised compared to duplex Doppler ultrasound or digital subtract angiography in a

Table 2. Diagnostic Accuracy of the Oscillometric Method Compared With the Doppler Method.

Decision statistics	Diagnostic parameters
Sensitivity	89.7 (75.8–97.1)
Specificity	87.6 (80.1–93.1)
Diagnostic accuracy	88.2 (81.9–92.8)
Positive predictive value	71.4 (56.7–83.4)
Negative predictive value	96.1 (90.4–98.9)
Diagnostic odds ratio	61.9 (19.1–200.6)
Number needed to diagnose	1.3 (1.1–1.8)

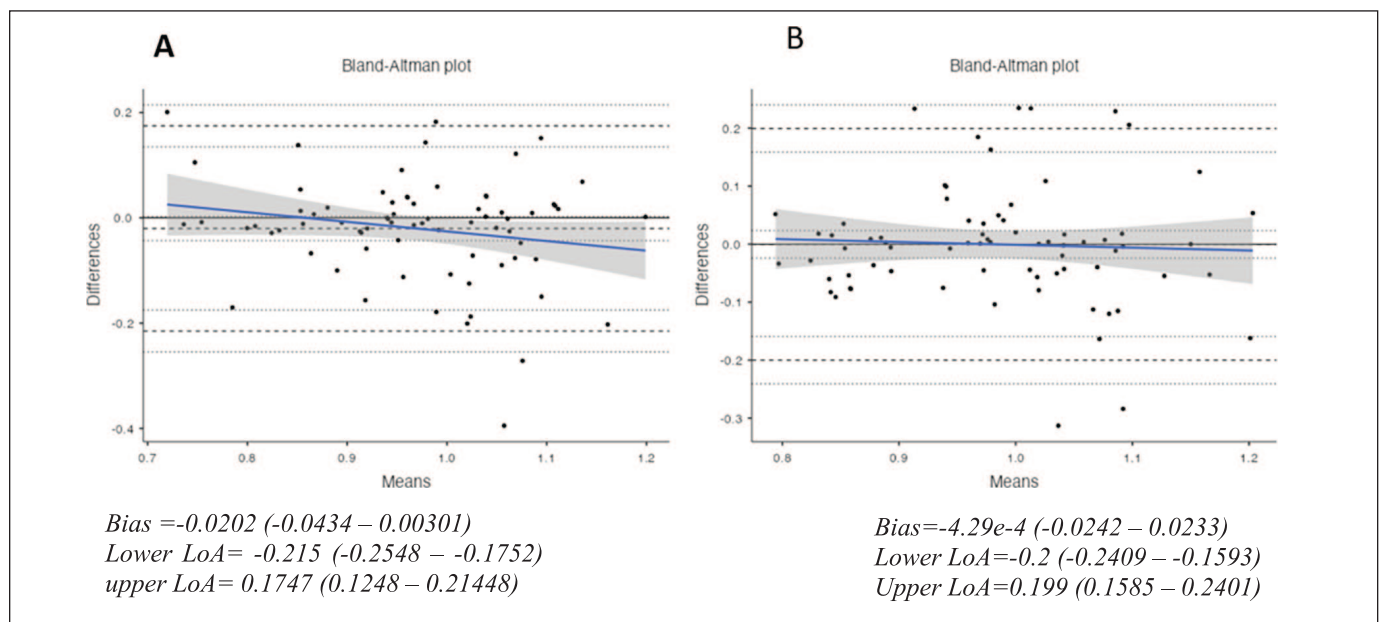


Figure 3. Agreement between the oscillometric method versus Doppler method in Bland-Altman's plot of the right side (A) and the left side (B) ABIs.

Note. ABI = ankle-brachial index; LoA = Limit of agreement.

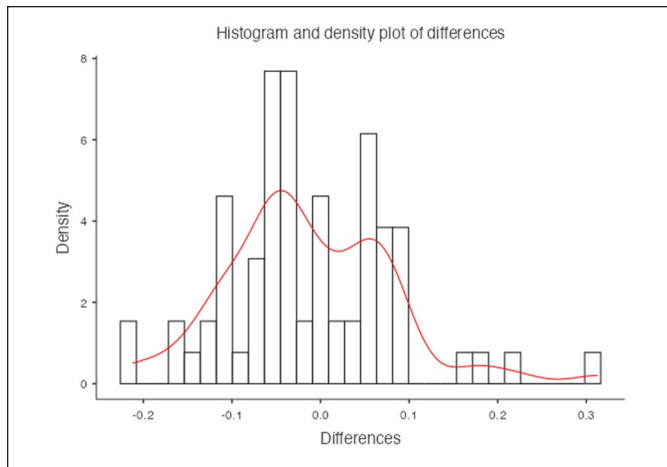


Figure 4. Density plot of the mean differences in oscillometric and Doppler ABIs showing >95% of the mean difference values between Doppler ABI and oscillometric ABI falling within -0.1 to $+0.1$.
Note. ABI = ankle-brachial index.

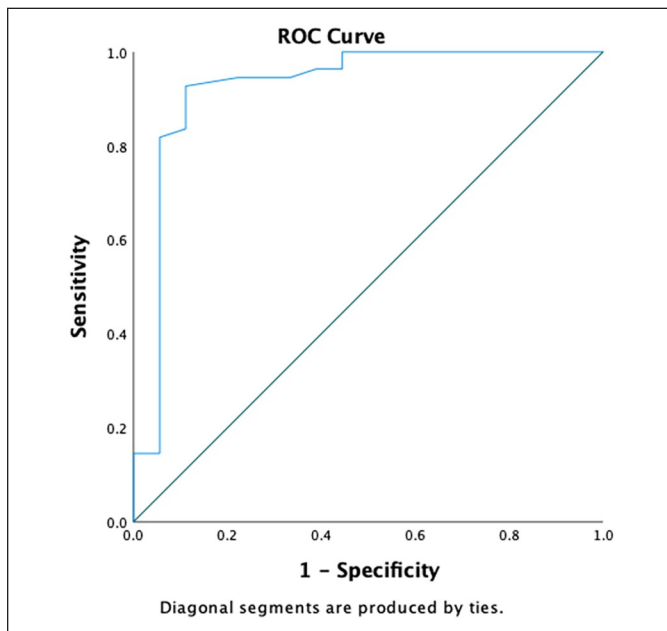


Figure 5. Receiver-operating characteristic curve for oscillometric diagnosis of PAD as defined by Doppler ABI <0.90 in the entire study participants.
Note. PAD = peripheral arterial disease; ABI = ankle-brachial index; ROC = receiver-operating characteristic.

meta-analysis.¹⁵ Excluding diabetic patients from our study population improved the sensitivity of the oscillometric method.

The findings in this study indicate that the diagnostic precision of the oscillometric method, using the Doppler method as the standard, is similar in patients with and without leg pains. There is a paucity of data about the accuracy of oscillometric devices in patients with leg pain on exertion. Early studies

reported that in patients with intermittent claudication, the use of an oscillometric device to measure brachial pressure only does not affect the computed ABI compared with brachial pressures measured by Doppler and auscultatory methods. However, the investigators did not measure ankle pressures with an oscillometric device.⁷ Another study compared the diagnostic accuracy of oscillometric and Doppler methods to angiography in patients with intermittent claudication when Doppler ABI was performed by physicians with no training in the performance of Doppler ABI. They found that the Doppler method has similar specificity to the oscillometric method, but lower sensitivity. However, they did not compare the oscillometric method with the Doppler method as done in this study.^{4,14} In this study, we did not find any difference in mean values of oscillometric and Doppler ABIs between patients presenting with leg pain and those without leg pain. This is contrary to a meta-analysis of 27945 patients from 7 studies that reported lower mean ABI in patients with leg pain.²¹

A major factor in the measurement of oscillometric ABI is the methodology utilized by the device applied.¹² In this study, we used a validated device with 4 cuffs that measured arm and ankle pressures simultaneously. This feature minimizes the potential error due to the random variation in BP that occurs with sequential Doppler ABI measurements.¹⁶ The device measures ankle pressures in both the dorsalis pedis artery and the posterior tibial artery and automatically computes ABI using the HAP method, avoiding sources of bias such as observer prejudice and calculation errors.

The ability to correctly identify PAD early in the course of the disease is important for reducing cardiovascular morbidity and mortality. The standard for diagnosing PAD, which is duplex Doppler ultrasound, requires robust equipment and training that are not readily available at many health facilities in sub-Saharan Africa. These constraints may be solved by the utilization of ABI measurement, which is a simple, fast, reproducible, and accurate alternative to duplex Doppler. Both the American²² and European¹ guidelines for PAD diagnosis recommend measurement of ABI in these patients using the Doppler method; however, the Doppler ABI method may be time-consuming and is operator dependent. In contrast, the oscillometric ABI method requires little training and can be performed in a relatively short time after adequate rest.¹⁰

Despite the advantages of oscillometric devices in assessing ABI, the main drawbacks to the implementation of these devices are the availability and affordability in sub-Saharan African countries. For example, the Vasera 1500N is currently available from suppliers in the European, Asian, and American markets at a cost of around US\$20000.²³ This amount is far beyond the budget in many public and private healthcare systems in sub-Saharan Africa, which has lowest health care expenditure per capita in the world.²⁴ Public expenditure by governments in this region was reported to be approximately 6% of gross domestic product (GDP) or about US\$97 per capita in 2011, and this is mostly applied in dealing with infectious diseases and child and maternal health.^{24,25} With low coverage

by the health insurance system, most of the population finance their health care “out-of-pocket.”²⁴ This situation may make it difficult to implement devices such as the Vasera 1500N in primary health settings in sub-Saharan Africa. Therefore, alternative devices at a lower cost may be needed to implement oscillometric ABI measurements in this region.

The findings from this study must be interpreted in light of its limitations. First, the study was conducted in a single tertiary healthcare facility in Ghana, and the results may not be generalizable to other healthcare facilities. In addition, only premenopausal women with suspicion of PAD were recruited. This means that the findings in this study cannot be extended to the general population and to men. Doppler ABI, which was used as the standard in this study, may also have some important limitations compared with digital subtraction angiography, computed tomography angiography, or magnetic resonance angiography.^{6,9} In this study, Doppler ABI was performed by an experienced technician, and that may have reduced measurement errors. The ABI was calculated using the HAP method, as recommended by the major guidelines^{1,22} Compared with the HAP method, the low ankle pressure calculation has been shown to have higher sensitivity, accuracy, and prediction in detecting PAD.²⁶

Conclusion

The findings in this study show that in the non-diabetic premenopausal female population with suspicion for PAD, oscillometric measurement of ABI can be used to diagnose PAD with performance similar to the Doppler ABI. This makes the oscillometric method suitable for PAD screening in resource-scarce settings such as sub-Saharan Africa.

Acknowledgments

The authors thank the technicians of the Cardiovascular and Metabolic Research Unit at the Department of Physiology, UGMS.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was supported by the University of Ghana-Building a New Generation of Academics in Africa (BANGA-Africa) project with funding from the Carnegie Corporation of New York.

Credit Author Statement

Kwame Yeboah conceptualized the study, analyzed the data, and drafted the manuscript. Jennifer A. Agyekum collected the data and made scientific contributions to the writing of the manuscript. Jared Oblitey revised the manuscript and made scientific contributions to the drafting of the manuscript. All authors approved the content of the manuscript.

Availability of Data

Data supporting the conclusions of this paper are available and can be requested from the lead author (Dr Kwame Yeboah).

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