Original Article

Efficacy of Oscillometric Method for Screening Periferic Arterial Disease in Primary Care

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INTRODUCTION

Peripheral arterial disease (PAD) develops as a result of atherosclerosis which causes arterial stenosis and occlusion in the main arteries of the lower extremity. PAD is not just a localized disease but also has an association with some systemic diseases.^[1-3] For people older than 50 years of age, with coronary heart disease and cerebrovascular disease, PAD is one of the three atherosclerotic vascular diseases with serious mortality and morbidity.^[4]

PAD is usually underdiagnosed and poorly treated in primary care.^[5-7] This may be due to the presence of intermittent claudication, a distinctive symptom of PAD, only in one-third of the patients.^[8] Physicians' reluctance of using screening tests for PAD in primary care may also

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Background: In primary care, measurement of the ankle-brachial index (ABI) by using hand Doppler is recommended for screening of peripheral arterial disease. Despite being relatively a simple procedure, the ABI is rarely measured in primary care due to unpracticality of the hand Doppler method. Oscillometry is an accessible, reliable, and an easy to use method for the measurement of ABI. With a little training, it can be used by anybody. Aim: The aim of the study is to compare the oscillometric method with a reference test (i.e. hand Doppler) for the screening of peripheral arterial disease (PAD) and arterial stiffness (AS) in primary care. Methods: A prospective observational diagnostic study was designed. Participants were 45 years of age or older. A survey including demographic data, risk factors, and symptoms of the peripheral arterial disease was applied to the participants besides measuring ABI both by Doppler and oscillometric methods. **Results:** Three hundred and forty participants included in our study with 59.78 ± 9.8 mean age. 60.9% of the participants were men. Even though the results of the oscillometric calculations were higher, a strong correlation was observed between the measurements of two methods. Using the Doppler-derived ABI, as the gold standard, and 0, 9 as a cutoff point, the sensitivity and specificity of the oscillometric method was 74.4% and 100%, respectively, with an area under the curve of 0.98 (95% CI: 0.96-0.99). Conclusion: Oscillometry seemed to be a reliable screening method in primary care both for peripheral arterial disease and AS.

KEYWORDS: Diagnostic test, Doppler method, oscillometry, peripheral arterial diseases

contribute to these low diagnosis rates. Ankle-brachial index (ABI) is a reliable diagnostic tool for identifying risk groups in primary care.^[8,9] ABI is a good predictor of cardiovascular and non-cardiovascular mortality.^[10-12] Despite being relatively a simple procedure, ABI is rarely measured in primary care due to time constraints, unpracticality of measuring blood pressure from four extremities, and need some expertize for measuring blood pressure from popliteal arteries. Many studies have been conducted to find accurate, reliable but also cheap and easy-to-use tests in primary care.^[13-15]

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Oscillometric (automatized) blood pressure calculation is an accessible, reliable, and easy-to-use method for detecting PAD. With a little training, it can be used by anybody. Since 1987, a diagnostic agreement between hand Doppler and oscillometry was investigated by many studies yielded contradictory results. Some studies revealed a strong correlation with good sensitivity and specificity,^[16-18] whereas according to other studies, as an alternative for hand Doppler, the oscillometric method should be used with caution.^[19,20] Especially, in the presence of comorbidities such as diabetes mellitus and coronary artery disease, the reliability of the oscillometric method should be investigated.

On the other hand, the development of stiffness in arteries due to other pathologies also makes diagnosis difficult. ABI values greater than 1.4 are indicative of arterial stiffness (AS) and it is known that some of these patients have also PAD.^[19] Many of the before-mentioned studies focused on PAD diagnosis with ABI below 0.9. Therefore, the comparison of the oscillometric method with hand Doppler also for ABI values greater than 1.4 (i.e. presence of comorbidity), will contribute to an unexplored area in the literature.

Our aim is to compare the oscillometric method with a reference test (i.e. hand Doppler) for the diagnosis of PAD and AS in subjects older than 45 years of age with or without comorbidities.

MATERIALS AND METHODS

A prospective observational diagnostic study was designed to compare the oscillometric method with the hand Doppler method (reference test) for the diagnosis of PAD and AS. The study was conducted in family medicine centers and cardiovascular surgery outpatient clinic of a university hospital between October 1 and December 1, 2014.

The sample size was calculated according to Simel's formula^[21] with the following considerations: Positive likelihood ratio (LR+) >8, sensitivity is 70%, specificity is 95%, and case/control ratio is $\frac{1}{4}$. The number of cases and controls was found to be at least 40 and 160, respectively.

Participants were \geq 45 years of age and voluntarily applied in family health centers or cardiovascular surgery outpatient clinic of the university hospital. Eligible patients informed about the study and written informed consent was obtained. Individuals with lower limb amputation, serious ischemia (necrosis) on the leg, atrial fibrillation, those who have to use wheelchairs, canes, or walking aids and those who are unable to communicate were excluded. The ethical approval was obtained from Dokuz Eylul University Ethical Committee for Non-Invasive Studies, on 8 March 2012 with the decision number 2012/09-17.

Study tools

Questionnaire

Participants' age, gender, height, weight, comorbid health conditions such as diabetes, hypertension, hyperlipidemia, cerebral vascular disease, renal disease, chronic obstructive lung disease, coronary artery disease, cardiovascular disease, their smoking status and use of acetylsalicylic acid, or antiplatelet agents were asked. 200 m claudication-free walking distances were asked by using an easily understandable location (distance between the health center and local shopping center).

Ankle-brachial index (ABI) measurement

After the informed consent, subjects were asked to rest for 15–20 min. Then, ABI was measured by using both methods applied consecutively to each participant in random order. There was an interval of 10 min between two measurements without any other clinical intervention. All measurements were done by the same researcher (UB) who received training for both methods.

ABI measurement with hand Doppler

A continuous-wave hand Doppler (Echo Sounder ES-101ex, Hadeco, Inc. Japan) was used. The distal edge of the cuff is placed 2 cm above the malleoli and elbow flexure, by placing the Doppler probe on the dorsalis pedis artery or posterior tibial artery and brachial artery. After the measurement of blood pressure from all of the four extremities, the higher values of both upper and lower extremities were used for ABI calculation. For obese patients, 32–42 cm of width cuffs were used.

ABI measurement with oscillometer

The same procedure was followed for the oscillometric method (Watch BP Office-ABI, Microlife Watch BP AG, Switzerland) by applying the cuffs to the patient's arm and ankle of the same side at once, then the other side. After repeating the same procedure for both sides of the patient, the highest values that are measured from the upper and lower extremities were proportioned and ABI was calculated. The device we used was only calculating the ABI during the measurement (i.e. proportioning the measurements of upper and lower extremities of the same side). Since the device does not have a memory function, the ABI was calculated by writing the measurements of the four limbs and proportioning the highest values in the upper and lower extremities. There were also two different width cuffs in the oscillometric device, 22-32 cm and 32-42 cm. For obese patients, the larger cuff was sufficient to make a healthy measurement. The device only gave an error when the patient moved.

In this case, the measurement was repeated. The device has no problem to measure blood pressures of diabetic or obese patients.

Analysis

Results were analyzed via SPSS 15.0 software. Continuous variables are compared via Student's *t*-test and for categorical variables, the Chi-square test was used. Correlation and agreement between two methods were analyzed by Pearson's correlation and Bland-Altman tests respectively. Multivariate logistic regression analysis was done for both methods. In the logistic regression "enter" method was used and independent variables that had a category less than 10% of all subjects (such as renal disease, cerebrovascular disease or presence of necrosis/gangrene) were not included in the model.

The statistical significance level was accepted as P < 0.05.

RESULTS

Descriptive data

340 individuals were included in the study as a sample (i.e. 680 limbs). The mean age of the participants was 59.8 \pm 9.8 years and 207 (60.9%) of them were males. The mean body mass index (BMI) was 26.7 \pm 4.0 kg/m². According to their BMIs, 171 (50.3%) patients were overweight (BMI = 25.0–29.9), 54 (15.9%) were obese (BMI \geq 30.0).

Almost half of the participants had hypertension and/or hyperlipidemia whereas more than one fifth had diabetes. Again nearly half of the subjects were currently smoking. Although 147 patients (43.2%) stated that they have claudication, only one-fourth of them experienced pain shorter than 200 m walking distance. Comorbid conditions, health status and PAD symptoms of participants are presented in Table 1.

Diagnostic tests

Even though mean blood pressures measured with two methods were significantly different; they also showed strong and significant correlation. Since higher measurements were taken for ABI calculation, the relationship between higher measurements was also explored. [Table 2]. The intra-observer correlation was 0.918 for hand Doppler measurements and 0.880 for oscillometric measurements considering right and left leg measurements.

Using the hand Doppler-derived ABI as the reference test, the sensitivity and specificity of the oscillometric method for diagnosis of PAD (ABI < 0.9) was 74.4% and 100%, respectively, with an area under

Table 1:	Health status, comorbidities, and	PAD
	symptoms of the participants	
Medical	Medical Condition	n (%)
History		
Comorbidities	Diabetes mellitus (DM)	75 (22.1)
	Hypertension (HT)	165 (48.5)
	Hyperlipidemia	150 (44.1)
	Cerebrovascular disease	12 (3.5)
	Coronary artery disease (CAD)	54 (15.9)
	Chronic obstructive pulmonary disease	11 (3.2)
	Renal disease	7 (2.1)
	Other	152 (44.7)
Family history	Coronary artery disease	54 (15.9)
Personal	Smoking	163 (47.9)
background	Acetylsalicylic acid/antiplatelet usage	114 (33.5)
	Necrosis/Gangrene	6 (1,8)
PAD	Claudication	147 (43.2)
symptoms	Symptoms occurring before 200 m	35 (10,3)
	Rest Pain	95 (27.9)
PAD: periphera	l arterial disease	

Table 2: Comparison and correlation of the measurements done by classic hand Doppler and the oscillometric method

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	Mean (mm-Hg)		<i>t</i> -te	st	Correlation				
	Doppler	Oscillometry	t	Р	r	Р			
Right arm	125.9	132.8	-14.809	0.001	0.897	0.001			
Left arm	128.2	133.7	-10.091	0.001	0.877	0.001			
Right leg	145.6	154.5	-16.972	0.001	0.938	0.001			
Left leg	140.6	156.7	-17.742	0.001	0.926	0.001			
Higher arm	132.1	138.0	N/A	N/A	0,853	0.001			
Higher leg	151.50	162.23	N/A	N/A	0,926	0.001			

Table 3: Accuracy of oscillometric method considering different conditions

	Sensitivity	Specificity	PPV	NPV
PAD	74.4	100.0	100.0	96.4
AS	95.3	80.8	41.8	99.2
PAD in DM	69.2	100.0	100.0	93.9
PAD in HT	73.1	100.0	100.0	95.2
PAD in overweight/obesity	75.0	100.0	100.0	95.5

AS: arterial stiffness; PPV: positive predictive value; NPV: negative predictive value

Table 4	l: Area	under	the	curve	(AUC)	values	for	different
		c	linic	cal con	ditions			

	n	AUC	95% confidence interval	
			Lower	Upper
PAD diagnosis (AS cases excluded)	281	0.98	0.96	0.99
AS diagnosis (PAD cases excluded)	297	0.93	0.90	0.96
PAD diagnosis in CAD	54	0.95	0.90	1.01
PAD diagnosis in DM	75	0.95	0.92	1.01
PAD diagnosis in HT	165	0.98	0.96	1.00
PAD diagnosis in obesity (BMI >30)	54	0.99	0.97	1.00

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Figure 1: Receiver operating characteristic (ROC) curves of oscillometric diagnosis. (a) ROC curve of oscillometric diagnosis for peripheral arterial disease (PAD). (b) ROC curve of oscillometric diagnosis for arterial stiffness (AS). (c) ROC curve of oscillometric diagnosis for PAD in patients with coronary artery disease (CAD). (d) ROC curve of oscillometric diagnosis for PAD in patients with hypertension (HT). (f) ROC curve of oscillometric diagnosis for PAD in patients with obesity



Figure 2: Bland-Altman Plots of Doppler and oscillometric methods in various clinical conditions. (a) Bland-Altman Plots of Doppler and oscillometric methods in all participants. (b) Bland-Altman Plots of Doppler and oscillometric methods in PAD + normal patients (AS cases excluded). (c) Bland-Altman Plots of Doppler and oscillometric methods in patients (for patients of Doppler and oscillometric methods in patients with CAD. (e) Bland-Altman Plots of Doppler and oscillometric methods in patients with DM. (f) Bland-Altman Plots of Doppler and oscillometric methods in patients with Obspler and Obsp

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Table 5: Logistic regression analysis of oscillometric and Doppler methods for the diagnosis of PAD							
Doppler	B	St. Err.	Р	Risk	95%	6 CI	
				coefficient	Lowest	Highest	
PAD							
Hyperlipidemia	1.085	0.471	0.021	2.959	1.175	7.454	
CAD	1.467	0.585	0.012	4.336	1.377	13.654	
Walking Distance <200 m	2.053	0.550	0.000	7.790	2.652	22.889	
Rest pain	1.404	0.517	0.007	4.071	1.478	11.209	
Oscillometer	В	B St. Err.		Risk	95% CI		
				coefficient	Lowest	Highest	
PAD							
Hyperlipidemia	1.557	0.599	0.009	4.745	1.466	15.355	
CAD	1.546	0.649	0.017	4.693	1.314	16.758	
Walking distance <200 m	2.013	0.580	0.001	7.483	2.403	23.307	
Rest pain	1.149	0.584	0.049	3.154	1.004	9.903	

ABI: ankle-brachial index

Table 6: Bland-Altman analysis of Doppler and oscillometric methods in various clinical conditions							
	п	Mean±SD	Р	95% confide	ence interval		
				Lower	Upper		
All subjects	340	-0.028 ± 0.089	0.001	-0.0376	-0.0186		
PAD + normal (AS cases excluded)	281	-0.035 ± 0.089	0.001	-0.0457	-0.0248		
AS + normal (PAD cases excluded)	297	-0.024 ± 0.089	0.001	-0.0339	-0.0136		
CAD (only CAD cases)	54	-0.047 ± 0.086	0.001	-0.0702	-0.0235		
DM (only DM cases)	75	-0.029 ± 0.082	0.003	-0.0483	-0.0104		
HT (only HT cases)	165	-0.036 ± 0.083	< 0.001	-0.0490	-0.0233		
Obesity (only BMI >30)	54	-0.028 ± 0.106	0.056	-0.0571	0.0008		

the curve of 0.98 (95% CI: 0.96–0.99) [Figure 1a]. Sensitivity and specificity of the oscillometric method for determining AS (ABI >1.3) was 82.4% and 83.8% respectively with an area under the curve of 0.93 (95% CI: 0.90–0.96) [Figure 1b]. Sensitivity and specificity for the diagnosis of PAD were also determined for comorbidities such as DM, HT, CAD and overweight/obesity. Results are shown in Table 3 and Figure 1(a–f). All AUC values with 95% CI's for different comorbidities are provided in Table 4.

The Bland-Altman analysis revealed that mean values of blood pressures measured with these two methods were differed significantly except in patients whose BMI's >30 kg/m². Results and Bland-Altman Plots are given in Table 5 and Figure 2(a–g). Logistic regression analysis showed that common determinants of diagnosis of PAD with both methods were the same. The results of logistic regression analysis for the diagnosis of PAD is given in Table 6.

DISCUSSION

The compatibility of oscillometric and hand Doppler methods in ABI measurement has been shown by many studies.^[22,23] Our study yielded similar results. One of the most remarkable findings of our study was high

specificity (100%) and negative predictive value (96.3%) of the oscillometric method. Beckman *et al.* calculated these performance characteristics of an oscillometric method for right and left legs, they found the specificity as 85% and 95% and the negative predictive value as 88% and 96% respectively.^[24] Our findings suggested that the oscillometric method is very good at excluding PAD diagnosis. This makes the oscillometric method a useful screening test for primary care.

Additionally, according to our findings, the sensitivity of the oscillometric method for diagnosis of PAD is 74.4% when the classical hand Doppler method is accepted as the reference. This is consistent with other studies^[19] and confirms that even though the oscillometric method is efficient at excluding PAD diagnosis, it is not that good at finding the PAD patients due to low sensitivity levels. But when the oscillometric method says "it is PAD", considering the 100% positive predictive value, it is definitely true.

Our study also shows that oscillometric measurements yield significantly higher results than Doppler measurements, however, there is a high and significant correlation between the two. Diehm *et al.* studied in 50 patients with PAD and showed that the results of both methods results were correlated with each other for ABI < 0.9. They stated that systolic pressure tends to result in a bit higher with the oscillometric method but when rated they are in accordance with the usual method.^[25] In our study, according to Bland-Altman analysis, mean ABI measurements with both methods are significantly different. Although it is significant, this difference is so small to be clinically meaningful. Since the Bland-Altman method only defines limits of agreement and does not say anything about the acceptability of these limits, this decision should be based on clinical realities.^[26] In the diagnosis of PAD, especially for specificity, this difference has no impact on the outcome. Hence, oscillometry seemed to be reliably used as a screening test for PAD.

Regression analysis showed that both methods share the same determinants for the diagnosis of PAD. This finding, somehow, may also contribute to the reliability of the oscillometric method.

There are many studies suggesting that the oscillometric method can be used for screening of PAD but, there are conflicting views on its reliability in the presence of comorbidities. Premanath et al. compared the oscillometric method with Duplex ultrasound in diabetic patients and stated that, despite some limitations, oscillometry can be used reliably.^[27] On the other hand, Clairotte et al. proposed that the oscillometric method should be used cautiously in diabetic patients.^[28] Such disagreements generally originate from methodological differences. For instance, Clairotte et al. excluded oscillometric measurements which gave an error, whereas in our study when oscillometry gave error measurement was repeated thus obtaining measurements from all participants. However, it is known that ABI is affected in diabetic patients in case of the presence of complications such as diabetic foot or neuropathy.^[29,30] In our study, we did not ask the duration of diabetes and the presence of complications.

In patients with coronary artery disease, Rosenbaum *et al.* found the specificity of oscillometry similar to our study although sensitivity was a bit low.^[20]

Collias *et al.* studied 93 patients with different comorbidities such as diabetes, hypertension, dyslipidemia, cardiovascular disease, and smoking. They compared measurements of Doppler and automated oscillometry and similar to our results, their receiver operating characteristic curve revealed area under the curve at 0.98, with a 0.97 oscillometric ABI cutoff for optimal sensitivity (92%) and specificity (92%) in diagnosing PAD.^[31] In our study, when examined separately, accuracy (sensitivity,

specificity and cut-off value) of the oscillometric method did not change in patients with hypertension, diabetes, coronary artery disease and obesity. These findings suggest that the oscillometric method can also be used reliably in the presence of commonly seen comorbidities.

As it is known that ABI >1.4 measured group is considered non-compressible, AS and 60-65% of this group is known to have PAD.^[13-19] For this reason, the accurate determination of this group is of particular importance. According to our findings, the sensitivity and specificity of the oscillometric method in the diagnosis of AS were 82.4% and 83.8% respectively. This suggests that for AS diagnosis the oscillometric method is less reliable than it is for PAD diagnosis.

Although Takahashi *et al.* stated that the oscillometric method results better with the elderly, our study results did not confirm this finding.^[11-17]

Our study is among the biggest studies regarding the number of participants. On the other hand, it differs from most of the similar studies because it includes both healthy participants and patients with different levels of the disease, which is normally a fundamental need in a diagnostic study. In many studies, the number of participants is below 100 and only symptomatic patients are included.^[16,25]

As the conclusion, due to its high specificity, the oscillometric method can be regarded as an efficient method for screening PAD in primary care. It can be used for the patients who have risk factors such as DM, obesity/overweight and HT. For the detection of AS, it showed lower diagnostic performance, still an acceptably reliable method in primary care. It was also concluded that patients who turn out to have positive results would still require hand Doppler-derived ABI measurement, still available in primary care both for PAD and AS detection.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient (s) has/have given his/her/their consent for his/ her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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