Can we use an automated oscillometric device instead of vascular doppler to measure the ankle brachial pressure index in general practice?

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Samenvatting

Doel: De Enkel-arm-index (EAI) is algemeen aanvaard als het initiële onderzoek in de diagnosestelling van perifeer vaatlijden. De conventionele manier om de EAI te bepalen is met een doppler toestel. De nieuwere automatische oscillometrische toestellen zouden het meten van de EAI in de eerstelijnsgeneeskunde een stuk gemakkelijker kunnen maken. Het doel van onze studie is om na te gaan of een automatisch oscillometrisch toestel even accuraat is als een conventioneel doppler toestel om perifeer vaatlijden op te sporen in een hoog-risico populatie in de huisartsenpraktijk. Daarnaast hebben we dit ook nagekeken voor een subgroep van diabetespatiënten.
Methode: Van 109 patiënten tussen 50 en 70 jaar oud die presenteerden met symptomen van perifeer vaatlijden, rookgedrag, diabetes of twee van de volgende risicofactoren: bloeddruk > 140/90mmHg, LDL >115 mg/dl en/of triglyceriden >150mg/dl en/of totaal cholesterol >190mg/dl, BMI>30kg/m² , cardiovasculaire incidenten in de voorgeschiedenis (CVA/TIA, AMI, angor), werd de EAI berekend met zowel doppler als oscillometer. Duplex onderzoek werd uitgevoerd als gouden standaard test. Verschillen tussen de dichotome resultaten (normaal-abnormaal) voor elk been afzonderlijk zijn getest gebruik makend van de Chi² of Fisher-exact test.
Resultaten: We vonden geen significante verschillen tussen de doppler en de oscillometrische methode (sensitiviteit 51% en 62%, specificiteit 93% voor beide) voor het meten van de EAI. De resultaten voor de subgroep van diabetespatiënten was vergelijkbaar.
Conclusie: Beide methoden kunnen gebruikt worden met dezelfde diagnostische accuraatheid om de diagnose te stellen van perifeer vaatlijden in de huisartsenpraktijk.

Kenrwoorden: Enkel-arm index, perifeer arterieel vaatlijden, automatisch oscillometrisch toestel, doppler, diabetes.

Abstract

Objective: The ankle-brachial-index (ABI) is widely accepted as the initial method for diagnosing Peripheral arterial disease (PAD). The conventional method for measuring the ABI is by doppler, but the use of the newer automated oscillometric devices could make the measurement of the ABI in primary care more practical. We therefore aimed to determine if the automated oscillometric device is as accurate as the conventional doppler method to diagnose PAD in a high-risk population in primary care. We additionally studied this in a specific subgroup of patients with diabetes.
Method: In 109 patients between age 50 and 70 and presenting with symptoms of PAD, smoking, diabetes or at least two among the following: blood pressure > 140/90mmHg, LDL >115 mg/dl and/or triglycerides >150mg/dl and/or total cholesterol >190mg/dl, BMI>30kg/m² and cardiovascular incidents in the past (CVA/TIA, AMI, angor), we measured the ABI both with doppler and oscillometry. Duplex investigation was used as the gold standard test. Differences between the dichotomized results (normal-abnormal) for each leg separately were tested using a chi² or Fisher exact test.

Results: We found no significant differences between the doppler and the oscillometric results (sensitivity 51% and 62%, specificity both 93%) for measuring the ABI. Results for diabetic patients were largely similar.
Conclusions: Both methods can be used with the same diagnostic accuracy for diagnosing PAD in primary care.

Key words: ankle-brachial index, Periferal arterial disease, automated oscillometric device, doppler, diabetes.

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1. Introduction

Peripheral arterial disease (PAD) is defined as atherosclerosis of the abdominal aorta, iliac, and lower-extremity arteries. In the limb, the clinical course of PAD is relatively benign, meaning that claudication remains stable in 70% to 80% of the patients[1, 2]. Less than one-third will require surgery or further investigation, and 5% will need an amputation[3].
The prevalence of PAD in an adult population ranges from 4% to 16% with 29% in high-risk groups[2,4,5,6]. More than 20% of adults older than 70 years have some degree of PAD[2]. However, more than half of these patients are asymptomatic[2,7].
Patients with PAD are at higher risk for developing myocardial infarction, stroke, and cardiovascular death and have a higher rate of all-cause mortality compared with patients without PAD[2,4,8,9,10].
Screening for PAD is warranted in high-risk patients but still controversial[8,11,12].
Risk factors that are associated with PAD are increasing age, smoking (4-fold), diabetes mellitus (1.5-4-fold), hyperlipidemia (2-fold) and Hypertension (2.5-4-fold)[1,2].
Using history taking and pulse palpation of the foot arteries as the only screening test will result in under-diagnosis, and thus under-treatment of PAD patients[12,13,14,15,16].
The ankle brachial index (ABI) is the easiest, most cost-effective and non-invasive initial method for screening for PAD[14,17,18]. It is highly specific (96%-99%) but a wide range of sensitivities has been reported depending on the study population(30%->90%) [7,17,19,20,21,22,23]. It correlates with disease severity but not with symptoms and is an important predictor of future vascular events[2,18,24].
ABI $\leq$ 0,9 indicates the presence of PAD. In this case further investigation by duplex ultrasonography, CT angiography of MRI angiography, is warranted.

The conventional method for measuring the ABI is by doppler, using a manual pneumatic pressure cuff and a hand held doppler probe to asses arterial flow[13]. Its use in primary care is uncommon because of limited time, lack of training and related costs [19,25]. These problems could be avoided by using an automated oscillometric blood pressure monitor. Its diagnostic accuracy has not been thoroughly examined yet for the measurement of ABI. Some studies indicate that an oscillometric device is no reliable method for ABI measurement[13,25].
Its diagnostic accuracy of the ABI may also be limited in diseases that lead to noncompressible blood vessels like diabetes[2].

We therefore aimed to determine if the automated oscillometric device is as accurate as the conventional doppler method to diagnose PAD in a high-risk population in primary care. We additionally studied this in the subgroup of patients with diabetes.

2. Method

2.1. Study design

The study ran in one group practice of three GPs in a Belgian municipality with 37.000 inhabitants. The electronic medical record was used to select eligible patients and to collect patient data, including age, sex, and cardiovascular risk factors. GPs identified patients who met the study entry criteria during the daily routine consultations. One GP gained expertise in the appropriate technique for doppler

measurement of the ABI at the department for vascular surgery of the regional hospital in Genk. Afterwards the technique was passed on to the three nurses of the practice who would perform the investigations. They were fully trained before the start of the study. In all participants the ABI measurement was performed twice for each leg, once with the oscillometric device and once with the hand held doppler. The doppler measures the ABI separately for both the arteria tibialis posterior and arteria dorsalis pedis. The oscillometric device automatically measures the highest value. In both cases therefore the highest systolic pressure of both arteries was used to calculate the ABI. Patients were sent for further investigation by duplex sonography when one of the two techniques indicated an ABI below the threshold of 0,90. When the duplex sonography came back with positive results these patients were sent to a vascular surgeon for further evaluation. A poster in the waiting room informed patients of the ongoing investigation and asked for active participation. From all patients oral informed consent was obtained. Approval from the Ethical board of the Catholic university of Leuven for this protocol was obtained (ML7252).

2.2. Patiënt selection

Patients were eligible if they were between age 50 and 70 and presenting with symptoms of PAD, smoking, diabetes or at least two among the following: blood pressure > 140/90mmHg, LDL >115 mg/dl and/or triglycerides >150mg/dl and/or total cholesterol >190mg/dl, BMI>30kg/m², cardiovascular incidents in the past (CVA/TIA, AMI, angor). Symptoms of PAD were exertional leg symptoms, non-healing wounds in the lower limb, leg pain at night which is relieved with the feet hanging down[2], trofic disorders from legs and/or feet. We excluded patients considered too ill to participate by the GP and patients with significant cognitive impairment.

2.3. Materials

For the automated oscillometric method we used the Screening CardioVascular Laboratory (SCVL) device from Healthworks Global. It is a cardiovascular and blood pressure monitoring system with multiple sensors that allow the user to make simultaneous measurements on several limbs in real time. This device was validated against the protocol of the British Hypertension Society (BHS)[26].
For the doppler method we used the Huntleigh healthcare Multi Dopplex II (Model No MD2).

2.4. Data analysis

Doppler and oscillometric ABI were calculated for each leg by dividing the higher of the two systolic pressures in the dorsalis pedis and the posterior tibial arteries by the higher of the two brachial systolic pressures. Sensitivity, specificity, positive and negative predictive value, positive and negative likelihoodratio of the automated oscillometric and the doppler measurements to predict a PAD of the lower limb were both determined with their 95% confidence intervals (CI) using the duplex as the gold standard. Patients who were not sent for duplex examination (because all ABI measurements were normal) were considered to have a normal gold standard result. Statistical significance of differences between both dichotomized ABI results (normal-abnormal) for each leg separately was tested using a chi² or Fisher exact test.

The duplex investigation results (used as gold standard) were reported normal, atherosclerosis with non-significant stenosis or atherosclerosis with significant stenosis. With this data we performed two analyses. In our basic analysis, the legs with a positive standard test were the ones with both non-significant and significant stenosis and the legs with a negative standard test the ones who were normal on the duplex protocol. In a sensitivity analysis we used for a positive standard test only the legs with significant atherosclerotic stenosis and combined the non-significant stenosis and normal protocols in the group with a negative standard test.

3. Results

3.1. Patient characteristics

Table 1 shows basic patient characteristics of all patients. The average age was 61 years. From 127 patients that entered the study, 18 were excluded because of age (n = 8), refusal to undergo duplex (n = 8) or incomplete duplex investigation (n = 2) (Fig 1). Of 109 patients, complete data were available for analysis. 23 of those patients had diabetes

In 18 legs, from the 218 that were investigated, one or two pulses of the foot arteries could not be detected (2 with oscillometer and 16 with doppler). This means that either the automated oscillometer could not calculate an ABI or the nurse could not find a systolic murmer during pressure relief from the blood pressure cuff when using the doppler device. From the 109 patients 58 (53%) had an abnormal ABI detected with either the oscillometric or the doppler method.

Table 1 Patient characteristics

Characteristic		Number (%) (n=109)
Gender	Male	67 (61)
	Female	42 (39)
Age	50-60	46 (42)
	61-70	63 (58)
Claudication	Yes	7 (6)
	No	102 (94)
Smoking	Current	29 (27)
	Previous	31 (28)
	No	44 (40)
	Unknown	5 (5)
Diabetes	Yes	23 (21)
	No	86 (79)
Hyperlipidemie	Yes	88 (81)
	No	21 (19)
Hypertension	Yes	69 (63)
	No	40 (37)
CV history	Yes	32 (29)
	No	77 (71)
Overweight	Yes	38 (35)
	No	71 (65)

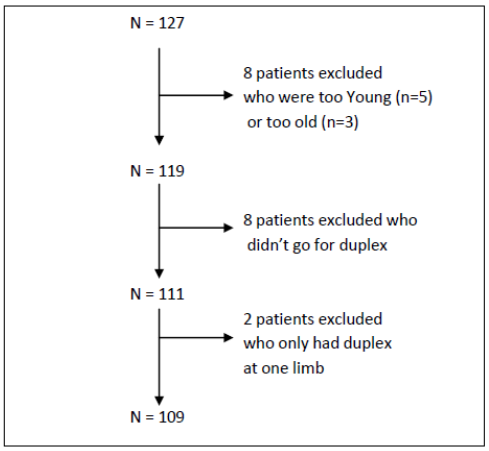


Figure 1: Flow chart of all included patients

3.2. Bivariate analysis

Using doppler the mean sensitivity of both legs was 51% compared to 62% for the oscillometric method. The mean specificities were both 93%. In both analyses, differences between the results for each leg separately were small and non-significant (P-value between 0.27 and 1.00) (table 2).

The agreement between the two ABI measurement methods is illustrated using

the Bland and Altman method (Fig. 2). The inter-method reliability is good and does not differ according to the average value. During sensitivity analysis, the mean sensitivity of both legs for doppler was 56% compared to 67% for the oscillometric method. The mean specificity for doppler was 91% compared to 90% for the oscillometric method (table 3).

Table 2: Diagnostic performances to detect PAD of oscillometric method and doppler method, including both significant and non-significant stenosis for a positive reference standard.

	T+S+	T+S-	T-S+	T-S-	Sens (95%CI)	Spec (95%CI)	PPV	NPV	LR+	LR-
Oscillometric left	10	8	5	86	67 (38-88)	91 (84-96)	67	95	7.4	0.4
Oscillometric right	8	5	6	90	57 (29-82)	94 (88-98)	62	94	9.5	0.5
Doppler left	7	8	8	86	46 (21-73)	91 (84-96)	47	91	5	0.6
Doppler right	8	4	6	91	57 (29-82)	95 (90-99)	67	94	11.4	0.5

T+: positive test, T-: negative test, S+: positive standard, S-: negative standard, Sens: Sensitivity, Spec: specificity, PPV: positive predictive value, NPV: negative predictive value, LR+: positive likelihoodratio, LR-: negative likelihoodratio.

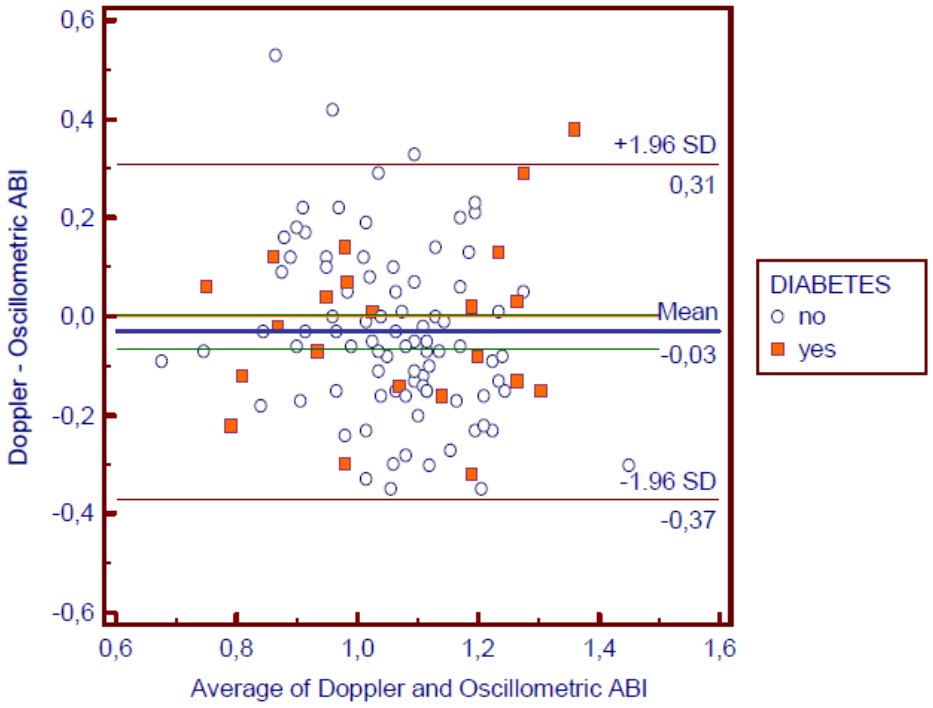


Fig. 2: Bland and Altman plot of the differences between the oscillometric and doppler method against their mean.

Table 3: Sensitivity analysis: Diagnostic performances to detect PAD of oscillometric method and doppler method, including significant stenosis only for a positive reference standard

	T+S+	T+S-	T-S+	T-S-	Sens (95%CI)	Spec (95%CI)	PPV	NPV	LR+	LR-
Oscillometric li	6	12	3	88	67 (30-93)	88 (80-94)	33	97	5,6	0,4
Oscillometric re	4	9	2	94	67 (22-96)	91 (84-96)	31	98	7,4	0,4
Doppler li	4	11	5	89	44 (14-79)	89 (81-94)	27	95	4	0,6
Doppler re	4	8	2	95	67 (22-96)	92 (85-97)	33	98	8,4	0,4

T+: positive test, T-: negative test, S+: positive standard, S-: negative standard, Sens: Sensitivity, Spec: specificity, PPV: positive predictive value, NPV: negative predictive value, LR+: positive likelihoodratio, LR-: negative likelihoodratio,

3.3. Subgroup analysis for patients with diabetes only

The ABI obtained by the doppler and the oscillometric method were compared for a subgroup of patients with diabetes, only for the left leg (table 4). The sensitivity and specificity of the doppler method were 67% and 85% respectively. The oscillometric method had a sensitivity of 100% and a specificity of 95%. Numbers were very low however.

4. Discussion

In our high-risk general practice population, to calculate ABI, the doppler and oscillometric method correlate well (Table 2). The small differences in sensitivity and specificity found between the two techniques are non-significant and can also result from inter-observer variation between the three different nurses who performed the investigation, especially during doppler testing.
Three other studies also found that the results of automated oscillometric ABI determination correlate well with the doppler assisted measurements while it was faster and without important inter-observer error[7,19,27].

For both measurement techniques we found, in our high-risk population, a weak sensitivity (51% for doppler and 62% for oscillometric method). Literature gives a wide range of sensitivities for ABI depending on the study population[7,17,19,20,21,22,23].

The interpretation of an ABI can be difficult in diseases which cause arterial rigidity with non compressible blood vessels like diabetes[2,13]. However, some studies implicate that the ABI can be used in patients with diabetes with careful interpretation of values according to the clinical situation[19,28,29]. In our small subgroup analysis on patients with diabetes only (n = 23), the sensitivity was not less compared to the other.

Using the automated oscillometric device was not always faster than the doppler device. When there are technical problems with the computer or the device itself, the investigation can absorb quite some time. On average this happened in one out of

seven measurements. This might be better or worse with other oscillometric devices. On the other hand the oscillometric measurement was easier to demonstrate and perform with a faster learning curve than the doppler measurement.
The costs for both devices are comparable at around 600 euros.
Another limitation is that we only used one type of automated oscillometric device and that we cannot extrapolate our results to all other devices available on the market.
In 18 legs one or two pulses of the foot arteries could not be detected. Because the highest of the two measurements was selected, this did not interfere with the interpretation of results.

This investigation took place during normal working hours with the normal staff of the group practice. This demonstrates that the measurement of the ABI can easily be performed during the daily routine.
Some risk factors for PAD were used as inclusion criteria. These are a combination of classical risk factors we found in a series of selected articles and guidelines that form the background of this study[2,30,31]. However we did not consequently ask for symptoms or complaints of PAD. Therefore some people with PAD may not have been included in our study.

5. Conclusion and consequences for daily practice

According to this study performed in a high-risk general practice population, the ABI results obtained by the automated oscillometric device correlate well with the doppler results, even in patients with diabetes. The oscillometric device is faster in use, with a better learning curve and no inter-observer error, but not necessarily cheaper. Both measurement techniques have a very high specificity but rather low sensitivity which makes us wonder if calculating the ABI is really the best initial methods for screening PAD.
In countries where duplex is easy available for GPs, it may be wise to immediatly refer a patient at high risk for duplex without screening. In countries where this is more difficult, however, both methods for measuring an ABI can be used.

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