Measuring ankle brachial index for peripheral artery disease in selected population using improved oscillometric method and standard Doppler probe method

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Running title: Comparison of Doppler probe method and oscillometric method in determining ankle brachial index

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Summary

Background: In Western countries more than 20% of people older than 65 years have PAD in lower extremities either in symptomatic or in asymptomatic phase. More than 50% of asymptomatic patients are unaware of the PAD and are therefore untreated. The disease is usually not diagnosed unless a measurement of ankle brachial index (ABI) is performed. Therefore, current guidelines advise to measure ABI in all people older than 65 years, older than 50 years if they have diabetes or currently smoke and in patients with clinical symptoms of PAD. A recent study showed that general practitioners are unable to comply with the current guidelines due to time consuming Doppler probe method examination. In this study we evaluate ABI measurements obtained by improved automated oscillometric type-measuring device, which could improve the drawbacks of the ABI measurement using Doppler probe method.

Patients and methods: We included 136 subjects, aged 40 to 87 years, with the mean age of 62.8 (7.4) years. There were 16% of smokers, 22% had diabetes mellitus, 42% had hyperlipidaemia, 50% had hypertension and 59% were physically active. In all subjects 4 ABI measurements were taken; two with Doppler probe method and two with automatic oscillometric device (ABPI MD by MESI, d.o.o.). There were two skilled operators who performed Doppler probe measurements on each subject separately and a third operator who performed both oscillometric measurements.

Results: In upper arm Doppler probe method measurements, comparison of the left and right arm systolic blood pressures of both operators didn't show any difference as well as comparison of both operators on the same arm. Analysis of the ABI obtained by Doppler probe method showed no difference between the operators. Analysis of the oscillometric method measurements showed no difference in repeated systolic arm blood pressure. Analysis of the ABI obtained by oscillometric method indicated that the mean values did not differ between the two measurements. When comparing ABI measurements obtained by both

methods it was evident that oscillometric measurements were more precise than Doppler probe measurements; 17% vs. 19% respectively. Bland Altman plot showed bias of +0.06 and scatter diagram showed good correlation (slope: 0.75). In oscillometric method analysis percentage error was 0.26. Furthermore, assessment of the concordance index revealed a very good agreement between both methods in terms of clinical relevance: concordance index of 0.88 (95% CI: from 0.76 to 0.97). Measuring error of automated oscillometric device was typically less than 0.1 and the expanded measuring uncertainty was approximately equal to the measuring uncertainty of the reference Doppler method equalling 0.08. Oscillometric measurements were completed three times faster than Doppler probe measurements.
Conclusions: We can conclude that in our method comparing study ABI measurements provided by improved automated oscillometric device were comparable to golden standard Doppler probe measurements. At the same time, oscillometric method offered faster, more precise and more accurate measurements of ABI. We are convinced that the tested oscillometric method could be used as screening tool for the patients in general practice and would enable family doctors to comply with the current guidelines for peripheral artery disease.

Introduction

The incidence of the peripheral arterial disease (PAD) in lower extremities is increasing with age in the population. In Western European countries more than 20% of people older than 65 years have PAD in lower extremities either in symptomatic or asymptomatic phase [1]. More than 50% of patients with present PAD are asymptomatic and are therefore untreated [2]. Progress of the PAD in the lower extremities can lead to onset of symptoms. First, leg pain during activity (intermittent claudication) occurs. If not treated, symptoms worsen and progress to critical limb ischemia, ulcer or gangrene. Even more importantly, patients with PAD have 4-6 fold higher risk of cardio-vascular or cerebro-vascular events in comparison to the healthy population [3-5]. Progression and severity of PAD can be altered by risk factor management and preventive medical treatment [6].

The diagnosis of symptomatic PAD is typically based on a patient's medical history and clinical examination. The presence of intermittent claudication and alteration in palpation of the pedal pulses confirms the diagnosis in symptomatic patient. In asymptomatic patients, on the other hand, PAD is usually not diagnosed unless a measurement of ankle brachial index (ABI) is performed. ABI was shown to have high sensitivity and specificity and is a reliable non-invasive diagnostic tool for determining the level of PAD [7]. Therefore, current guidelines for management of peripheral artery disease advise to measure ABI in all subjects older than 65 years, older than 50 years if they have diabetes or currently smoke and in subjects with clinical symptoms of PAD [6].
In daily practice, ABI is usually obtained by measurement according to the Doppler probe method, which is considered the golden standard [8]. But there are some drawbacks of this method where continuous-wave Doppler ultrasound handheld probes and a sphygmomanometer are used. Namely, the method is time consuming and requires a skilled operator. A recent Dutch study showed that general practitioners were unable to comply with the current PAD guidelines only due to time consuming Doppler probe method measurement of ABI [9]. Some studies have shown that ABI measurements vary significantly with the skill level of the operator performing Doppler probe measurements [10]. In addition, ABI measurements can also be influenced by the "blood pressure drifting" phenomenon due to "white coat" hypertension. To eliminate the drawbacks of the ABI measurement using Doppler probe method, an automated ABI measuring device based on the oscillometric method was developed. This paper provides an evaluation of ABI measurements obtained by this automated ABI measuring device compared to the standard Doppler probe method measurements of ABI in selected population.

Methods

Subjects were approached at the general practitioner's office during their regular visits. They were invited to participate in the study if they were: (i) older than 65 years or (ii) older than 50 years with smoking habit or have diabetes, or (iii) have pain in the lower extremities during exercise. Subjects who fulfilled at least one of these criteria were included in the study after signing the study protocol agreement. Subjects with upper extremity arteriovenous fistulas and symptomatic critical limb ischemia with ulcers or major lower leg amputations were not invited.
After enrolment, subject's medical history was taken for cardiovascular risk by a general practitioner. ABI measurements were obtained in supine position after a few minutes of rest. ABI measurement was taken 4 times in one individual, two times by Doppler probe method and two times by automatic oscillometric

device (ABPI MD by MESI, d.o.o.). Measurement method was chosen randomly and the results of the oscillometric method were hidden and not visible to the subjects or operators. There were two skilled operators who performed Doppler probe measurements on each subject separately and a third operator who performed both oscillometric measurements.

Measurement of ABI by means of Doppler probe method (ABId) was performed according to the standard protocol [8] and was calculated as a ratio of the highest systolic blood pressure obtained from both arteries at each ankle by the highest systolic blood pressure of both brachial arteries. Measurement of ABI with automated oscillometric device (ABIo) was performed according to the manufacturer's instructions of use and was determined by the improved algorithm for determining arterial pressure on extremities [22]. Values of ABI below 0.90 were regarded as being a significant sign of PAD, whereas values above 1.40 are indicating incompressible ankle arteries and values in between are regarded as normal.

Statistical analysis

Numerical data are presented as a mean with standard deviation (SD), while categorical data are expressed as proportions. Measurements with one or more missing values in one single comparison (at least two values are involved) are eliminated case by case. Subjects with values above 1.40 indicating incompressible ankle arteries and with notable irregular heart rhythm were excluded from the study. The most powerful statistical significance test was selected to obtain the reported p- values. For each comparison, assumptions of paired t-test were verified using Lilliefors test (normality of distributions) and if it was met we used paired t-test and if it was not met we used Sign test. Accuracy, precision and degree of agreement of the methods was quantified and graphically presented using Bland-Altman approach [11]. The degree of agreement is shown by a plot of differences between the two methods against their mean for each measurement pair, and presented as mean difference with limits of agreement (bias± 1.96 SD). Limits of agreement were determined by 95% confidence interval. Furthermore, percentage error and precision were used to determine validity of the oscillometric method compared to the Doppler probe method [12]. For estimating the degree of agreement between the methods in determining the presence and severity of PAD, the concordance index was calculated. Statistical analysis was performed using Matlab v. 7, MedCalc v. 12 and SPSS v.18.

Results

Demographics

Out of 150 invited subjects, 14 (9,3%) were not included in the study. They didn't complete the measurements either with Doppler probe or oscillometric device. In those cases, subjects could have critical limb ischemia or incompressible arteries. Six subjects with detected atrial fibrillation of the heart were also excluded from the final analysis. Finally, 136 subjects from 40 to 87 years of age, with the mean age of 62.8 (7.4) years were analysed. Prevalence of cardiovascular risk factors is presented in Table I.

In upper arm Doppler probe method measurements, comparison of the left and right arm systolic blood pressures of both operators didn't show any difference (Table II). When comparing systolic blood pressure measurements of both operators on the same arm the computed p values were not significant for both arms as well (Table III).

Table I. Cardiovascular risk factors in the study group.

Risk factor	Subjects (n=136)
Smoking, n (%)	
Smoker	22(16)
Former smoker	39 (28)
Nonsmoker	75 (56)
Arterial hypertension, n (%)	69 (50)

Risk factor	Subjects (n=136)
Hyperlipidaemia, n(%)	58 (42)
Diabetes mellitus, n (%)	31 (22)
Physical activity, n (%)	
Active	80 (59)
Moderately active	44 (32)
Inactive	12 (9)

Table II. Statistical analysis of systolic pressure Doppler measurements (*Syst_d*) obtained from both arms (*leftArm, rightArm*) and provided by both operators (*m01, m02*).

	Mean (mmHg)	SD	P value
Syst_d_leftArm_m01 (n=136)	128,48	19,2	0,97
Syst_d_rightArm_m01 (n=136)	128,42	18,7	
Syst_d_leftArm_m02 (n=136)	128,43	18,0	0,91
Syst_d_rightArm_m02 (n=136)	128,63	17,5	

Table III. Statistical analysis of both arms systolic pressure measurements (*left_Arm and right_Arm*) obtained with the Doppler probe method (*Syst_d*) and provided by both operators (*m01, m02*).

	Mean (mmHg)	SD	P value
Syst_d_leftArm_m01 (n=136)	128,48	19,2	0,96
Syst_d_leftArm_m02 (n=136)	128,43	18,0	
Syst_d_rightArm_m01 (n=136)	128,42	18,7	0,96
Syst_d_rightArm_m02 (n=136)	128,63	17,5	

From analysis of the arm systolic blood pressures we conclude that the Doppler probe method showed good repeatability of the measurements between two operators. Furthermore, we can say that there is no evidence for differences in systolic arm blood pressures between both arms in our subjects.

Analysis of the ABId (ankle brachial index obtained by Doppler probe method) shows that the mean ABId was 1.091 (0.221) for the first operator and 1.098 (0.221) for the second operator. Difference between both operators was not significant. For further statistical analysis an average of 1.093 (0.213) for ABId was used.

Analysis of the oscillometric method blood pressure measurements

Analysis of the oscillometric method measurements of upper arm systolic blood pressures is presented in Table IV. Two consecutive measurements of systolic arm blood pressure in all subjects showed similar values. Furthermore, oscillometric mean systolic arm blood pressure measurement was 127.87 (16.50) mmHg and was comparable to Doppler probe arm blood pressure measurement (p=0.099 and p=0.477, in respect to the first and the second operator).

Analysis of the ABIo (ankle brachial index obtained by oscillometric method) shows similar mean values of the two consecutive measurements: the mean (SD) of ABIo measurements was 1.155 (0.203) for the first measurement and 1.152 (0.200) for the second. There was no statistical difference between both measurements. For further statistical analysis an average of 1.153 (0.198) for ABIo was used.

Comparison of ABI obtained by Doppler probe and oscillometric method

The oscillometric method measurements were compared to the golden standard- Doppler method measurements, using Bland-Altman approach, which is graphically illustrated in Figures 1, 2 and 3. In the scatter diagram (Figure 1) one can observe strong association of 272

Table IV. Descriptive statistic of the oscillometric method measurements of arm systolic pressures (*syst_o_arm*) obtained by the repeated measurements of the operator (*m01, m02*).

	Mean (mmHg)	SD	P value
Syst_o_arm_m01 (n=136)	128,27	16,79	>0,05
Syst_o_arm_m02 (n=136)	127,48	16,22	

oscillometric and Doppler method ABI measurements (slope= 0.75, 95% CI 0.68 to 0.81, p<0.0001).
The difference between ABIs (ABIo- ABId) is plotted against the mean of both methods in Figure 2. The Bland Altman plot shows a bias of +0.06 with the 95% confidence interval from +0.04 to +0.07 and limits of agreement, which span from -0.191 to 0.311 around the bias. Standard deviation of the differences is 0.128. There were 11 outliers out of 272 comparisons (4.0%), 4 exceeded the upper limit and 7 exceeded the lower limit. Positive bias shows that ABI values obtained by oscillometric method were slightly higher than those obtained by Doppler probe method, which corresponds to other studies [13-15]. In our opinion the magnitude of the bias is not clinically relevant.
The difference scores approximately follow the superimposed normal distribution presented by histogram (Figure 3). Therefore we can estimate that 95% of the difference scores for other similar subjects measured under similar conditions will fall between the limits of agreement.
To provide additional insight into the comparison of both methods we added calculation of precision and percentage error according to statistical analysis derived from Bland and Altman approach. Calculated precision of Doppler method was 0.195 compared to 0.171 of tested oscillometric method. This shows that the oscillometric method was more precise. According to some authors [12], percentage error should be less than 0.30 when deciding upon acceptance of the tested method compared to the standard one. In our tested oscillometric method percentage error is 0.26. Therefore we can conclude that the tested oscillometric method can provide accurate and precise measurements of ABI and can be accepted as an alternative to the Doppler probe method.

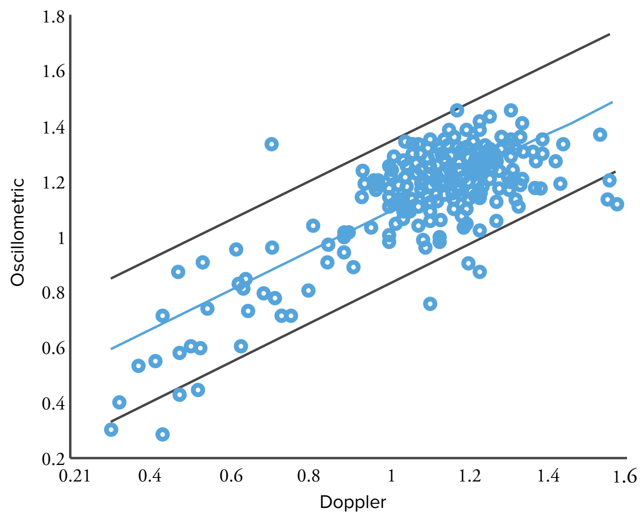

Figure 1. Scatter diagram, correlation (green line) and 95 % confidence interval (grey lines) for ABI obtained by both methods.

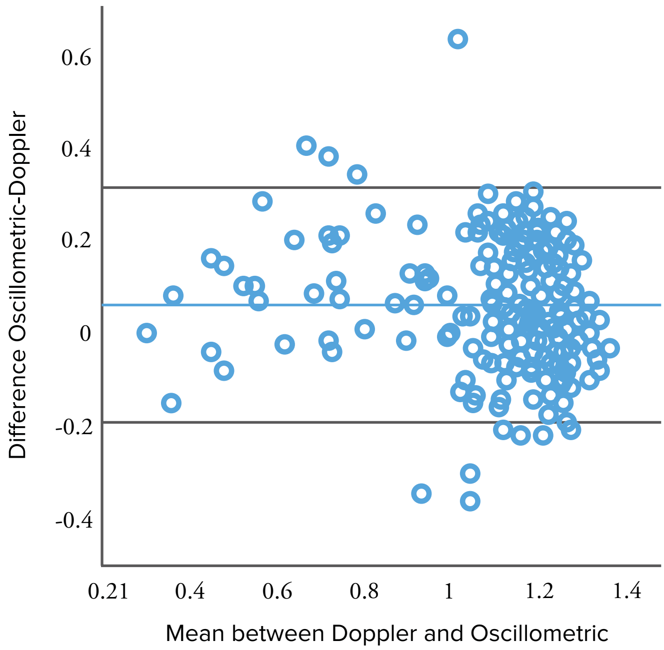

Figure 2. Bland-Altman plot of Doppler and oscillometric ABI comparison with bias (black line) and limits of agreement (red lines).

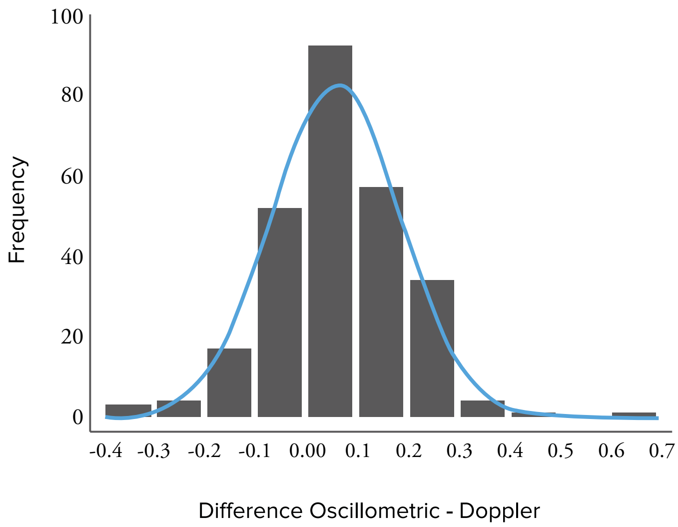

Figure 3. Histogram of differences scores in ABI measured with the oscillometric and Doppler methods.

Clinical relevance of ABI calculated using Doppler probe and using automated oscillometric method

The agreement between Doppler probe method and automated oscillometric method was assessed also by comparing ABI values in respect to clinical levels of PAD. The incidence of ABI values for both methods is shown in Figure 4. Paired comparisons for each level of PAD proved that there were no significant differences between the two methods in detecting PAD. Furthermore, assessment of the concordance index revealed a very good agreement between ABId and ABIo in terms of clinical relevance: concordance index of 0.88 (95% CI: from 0.76 to 0.97).

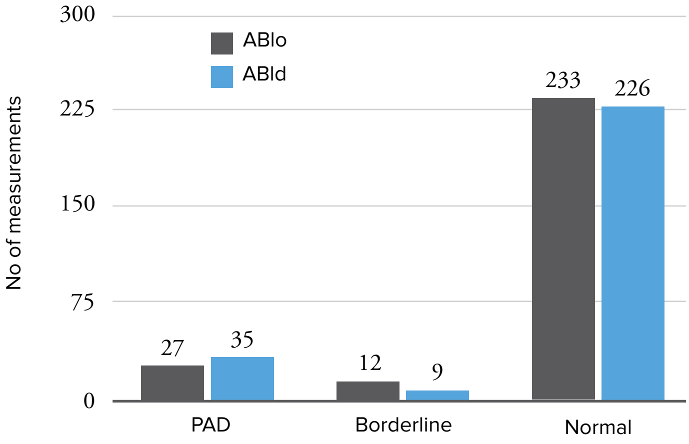

Figure 4. *Agreement of ABIo and ABId in respect to clinical levels of PAD. Normal ABI values are between 1.0 and 1.4, borderline from 0.9 to 1.0 and PAD below 0.9.*

Metrological validation of the automated oscillometric device

Measuring error was defined as the difference between value of ABIo and ABId. Measuring result and the measuring error are not the only important metrological parameters in every medical measuring device. Apart from the information of the measured value the user should also be interested in additional information about the quality of the result- the measuring uncertainty. According to the Guide to Expression of Uncertainty in Measurement [16], every measured value should be accompanied with an explicit statement of measuring uncertainty and conditions under which the calibration was performed. In our case, the measurement uncertainty of the ABI automated device was composed of several contributions, which were geometrically added; a) uncertainty of blood pressure measurement by means of an oscillometric device, which was estimated to the worst-case scenario 4 mmHg (according to ESH, BHS and AAMI clinical trials protocol for NIBP monitors and IEC/ISO 80601-2-30 standard [16-21], b) uncertainty due to device resolution (for automated oscillometric device 1 mmHg, for Doppler probe device 5 mmHg) and uncertainty due to repeatability of measurements (because only two values were measured, the rectangular probability distribution was assumed). Other uncertainty contributions, such as the ones caused by time drifts of instrumentation, environmental conditions, health status of the patients and possible psychophysiological effects were neglected. Our results that are graphically illustrated in Figure 5 indicate that measuring error of automated oscillometric device was on average 0.08. Expanded uncertainty of the automated oscillometric device of 0.08 (0.03) was comparable to 0.12 (0.04) of the reference Doppler probe device. Here the reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2, which for a normal probability distribution corresponds to a coverage probability of approximately 95 %.

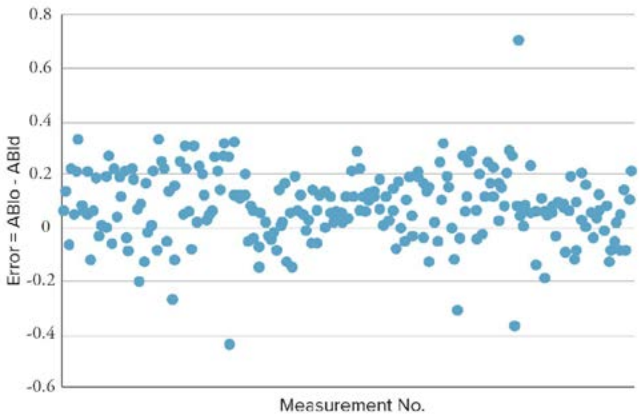

Figure 5. *Measuring error of the ABI measurements obtained by both methods.*

Analysis of the time consumption for Doppler probe and oscillometric method measurements

In addition to recording ABI measurements for each subject, we also measured time needed to complete each measurement. Results are presented in Table V. There have been observed significant differences in time consumption between both methods. Oscillometric method measurements have been completed almost three times faster than Doppler probe method measurements. In addition, operators reported great deal of confidence in handling the oscillometric device compared to the Doppler handheld probe.

Discussion

A close examination of the collected data showed important findings in comparison between the golden standard Doppler probe method and improved automated oscillometric method in measuring ABI in our group of subjects. First, there is no notable difference between arm pressure measurements taken by two Doppler probe operators. Both operators measured similar left and right arm systolic blood pressures, as well as similar arm systolic blood pressures in one arm. Second, there were no significant differences in ABI results obtained by Doppler and oscillometric methods. Actually, statistical analysis of our data according to Bland- Altman approach showed close agreement between methods. Correlation coefficient showed strong association of measurements. Probability

Table V. Mean time needed to complete ABI measurement using either Doppler or Oscillometric method

	Mean (mmHg)	SD	P value
Oscillometric method	5,9	± 0,9	<0,05
Doppler probe method	15,2	± 3,1	<0,05

that this association is due to chance was less than 1 in 10.000. Furthermore, we have detected a positive bias (0.06) of the oscillometric method, which seems clinically irrelevant. If one considers that PAD index has normal range from 0.90 to 1.4, than bias of 0.06 cannot influence the clinical management or outcome of the subject. Limits of agreement are wider apart as expected but are comparable to other oscillometric devices [26]. The precision of tested oscillometric device is greater than the precision of Doppler probe method (0.171 compared to 0.195) and the percentage error is 0.260. Finally, employing metrology principles to the validation of the tested oscillometric device provided additional information. The data showed that the tested oscillometric device had measuring errors of less than 0.1 and their expanded measuring uncertainty was approximately equal to the measuring uncertainty of the reference Doppler method and equalled 0.08. Therefore, the tested oscillometric device could represent a suitable alternative to the golden standard Doppler probe method.

There is quite a lot of controversy in the literature regarding the use of oscillometric devices for ABI measurements. Some studies show that oscillometric devices give comparable results to the Doppler method measurements [13-15,23-26]. But in a recent study Hamel, Foucaud and Fanello concluded that the oscillometric method is inferior to Doppler method [25]. The reasons for such conflicting evidence can be numerous. Although it seems, that the obvious reason would be the calculation protocol of the tested oscillometric device. In our study the calculation protocol of the tested device was dedicated to the measurement of ABI [22]. The protocol uses many electronic innovative filters to obtain the most relevant information from every measurement. Further meticulous analysis of that information is probably the key to good results. Furthermore, the sensitivity of our device was greater compared to the regular oscillometric devices for upper arm blood pressure measurement used in other studies (1 mmHg vs. 5mmHg). In addition, our tested oscillometric device has modified cuffs for calves, which are conical in shape for better alignment to the distal calf. The lightest possible material of the cuffs was used to maximize the sensitivity of the measurement.

Further controversies exist regarding the statistical methods used for validation analysis of the measuring methods. At first, many authors used correlation coefficients and linear regressions to judge the agreement between both methods. But they conclude that the correlation is not a measure of agreement but a measure of association. Later, several other approaches for assessing agreement between different clinical measurement methods were developed. The most widely used approach is the Bland and Altman method, even though some flaws in the method were found [27]. One of the novel approaches in evaluating oscillometric devices is employing metrology principles in its validation. It is clear that a consensus regarding the use of statistical methods for validity or method- comparison studies is needed.

Drawbacks of the Doppler probe method can be avoided with the use of our tested oscillometric device. Subjectivity of the Doppler probe method due to interoperator difference is well documented [9] but it can also be influenced by the “blood pressure drifting” phenomenon. Namely, when blood pressure is measured in clinical setting, patients often have elevated level of anxiety and “white coat” hypertension can occur. During repeated ABI measurements on limbs, patients become less anxious and their blood pressure decreases significantly. This is called “blood pressure drifting”, which could influence ABI measurement with Doppler probe method. To avoid the error due to the blood pressure drifting two approaches are possible. In the first approach the patient’s blood pressure must be stabilized prior to performing all blood pressure measurements. Usually, patients are advised to rest for 10 to 15 minutes, which adds a lot of time to the ABI measurement method. In the second approach the required blood pressure measurements are performed simultaneously, which is not possible with a single operator performing Doppler probe measurements. Therefore our tested automated oscillometric device simultaneously measures air pressure oscillations in the cuffs placed on the patient’s limbs and computes values of systolic, diastolic and mean blood pressure for each cuff [22]. Since blood pressure is measured simultaneously, blood pressure drifting does not affect the calculated ABI.

Our tested oscillometric device is equipped with one arm cuff and two calf cuffs. ABI is calculated from the one arm blood pressure for both legs. Data from our study showed that there is no significant difference in measuring ABI using left or right arm blood pressure. Therefore, the second arm cuff is redundant and would not increase accuracy of the measurement. Some data exist about the difference in pressures between the arms among general population [23], but the difference was not detected in our study group. Furthermore, one arm cuff design of the device enables measurements of ABI in a special group of patients, namely chronic dialysis patients. They have arterio-venous fistulas constructed on one of the arms. We can avoid damaging the fistula by placing the arm cuff to the other arm. In chronic dialysis patients, atherosclerosis progress is much faster than in other patients, therefore frequent measurements of ABI are required.

Conclusion

In our method- comparison study, tested oscillometric device showed good agreement to the standard Doppler probe measurements. Oscillometric device eliminated known drawbacks of the Doppler probe method, namely the measurements are performed simultaneously, are more precise and are obtained three times faster. On the basis of presented data we believe that Doppler probe method could be replaced by automated oscillometric method in providing ABI measurements in general population. The automated oscillometric method could be used as a screening tool for the population and could enable family doctors to comply with the current guidelines for peripheral artery disease.

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