Original communication

A randomized cross-over trial in patients suspected of PAD on diagnostic accuracy of ankle-brachial index by Doppler-based versus four-point oscillometry based measurements

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Summary: *Background:* For diagnosis of peripheral arterial occlusive disease (PAD), a Doppler-based ankle-brachial-index (dABI) is recommended as the first non-invasive measurement. Due to limitations of dABI, oscillometry might be used as an alternative. The aim of our study was to investigate whether a semi-automatic, four-point oscillometric device provides comparable diagnostic accuracy. Furthermore, time requirements and patient preferences were evaluated. *Patients and methods:* 286 patients were recruited for the study; 140 without and 146 with PAD. The Doppler-based (dABI) and oscillometric (oABI and pulse wave index – PWI) measurements were performed on the same day in a randomized cross-over design. Specificity and sensitivity against verified PAD diagnosis were computed and compared by McNemar tests. ROC analyses were performed and areas under the curve were compared by non-parametric methods. *Results:* oABI had significantly lower sensitivity (65.8%, 95% CI: 59.2%–71.9%) compared to dABI (87.3%, CI: 81.9–91.3%) but significantly higher specificity (79.7%, 74.7–83.9% vs. 67.0%, 61.3–72.2%). PWI had a comparable sensitivity to dABI. The combination of oABI and PWI had the highest sensitivity (88.8%, 85.7–91.4%). ROC analysis revealed that PWI had the largest area under the curve, but no significant differences between oABI and dABI were observed. Time requirement for oABI was significantly shorter by about 5 min and significantly more patients would prefer oABI for future testing. *Conclusions:* Semi-automatic oABI measurements using the AngE^{R}-device provide comparable diagnostic results to the conventional Doppler method while PWI performed best. The time saved by oscillometry could be important, especially in high volume centers and epidemiologic studies.

Keywords: Peripheral arterial occlusive disease, ankle brachial index, oscillometry, Doppler sonography, comparative diagnostic accuracy

Introduction

The presence of peripheral arterial occlusive disease (PAD) is associated with increased cardiovascular morbidity and mortality as well as increased overall mortality [1–4]. According to the Get-ABI-Study in every fifth patient above 60 years of age consulting a general practitioner in Germany, PAD can be confirmed [5]. The cumulative incidence of PAD over seven years was about 13% [6]. Nevertheless, only about 10% of those patients suffer from intermittent claudication. The vast majority might thus go undiagnosed unless actively screened [5, 7]. Due to the demographic development as well as the progressive prevalence of diabetes mellitus in all industrial countries this problem will even further increase in the future [8, 9].

According to current guidelines, diagnosis of PAD is made according to a step-by-step investigational approach, including medical history and physical examination, sensitive non-invasive measurements like ankle-brachial-index (ABI) or oscillometry, and duplex ultrasound. More sophisticated imaging like MR-angiography is cost- and time-consuming and is thus only indicated if duplex ultrasound remains undiagnostic and/or if the patients is dedicated for invasive therapeutic procedures [3, 10].

Primarily ABI is recommended to diagnose PAD, while oscillometry might be used as an alternative [3]. For ABI the lowest calculated quotient between the systolic arm blood pressure and the calf occlusion pressure is recommended, as sensitivity increases using this method [11].

Nevertheless, there are well known limitations of the ABI in the diagnosis of PAD like dependency of the test result on the method of pressure measurement, the selection of the ankle artery, the position and the width of the cuff, presence of PAD in the upper extremity arteries, and the presence of media sclerosis, which increases with age, presence of diabetes mellitus or renal incompetence, and other conditions [12]. On the other hand, many of these limitations do not seem to influence the diagnostic results of volume pulse recordings or oscillometric determination of ABI to the same extent [13–16].

Thus, the aim of our study was to investigate whether a semi-automatic four-point oscillometric device (AngE, SOT Medical Systems, Maria Rain, Austria) provides comparable diagnostic accuracy as cw-Doppler-based ABI measurements using color-coded duplex sonography, MR-angiography, or digital subtraction angiography as references and to examine and compare the time needed for both methods.

Patients and methods

Patient enrollment

Patients referred to one of the participating specialty outpatient clinics for vascular diseases (Hanusch Hospital, Vienna; Gesundheitszentrum Mariahilf, Vienna; and Helios Klinikum, Berlin-Buch) due to known or suspected PAD were asked to participate in the study. From December 2016 to December 2017, 286 patients gave their written informed consent and were included in the study. The study was approved by the local ethics review boards.

Inclusion criteria were known or suspected PAD, age > 18 years and written consent. Exclusion criteria were circumstances making ABI and oscillometric measurements impossible.

The following patient characteristics were obtained: age, gender, smoking habits, cardiovascular risk factors (hypertension, diabetes, hyperlipidemia), body mass index (BMI) and renal function. PAD parameters were patient history, disease stage and localization.

Patient characteristics

Overall, 286 individuals were recruited (n = 140 without PAD, n = 146 with PAD). After assessment of clinical records 2 controls were excluded due to toe gangrenes that were possibly due to micro-angiopathy. Among patients with PAD 58 had unilateral, and 88 had bilateral PAD.

Patients without PAD were significantly younger (66.1 ± 12.6 years) compared to patients with PAD (70.0 ± 9.8 years), 72 (52%) of them were males; they differed from patients with PAD in smoker rates (25% vs. 42%), arterial hypertension (67% vs. 79%), hyperlipidemia (67% vs. 76%), and renal dysfunction (7% vs. 28%). A larger number of patients with PAD had their diagnosis verified by MRA or DSA (35% compared to 4% in controls) (Table I).

On average, PAD was present since about 2 years (median 26 months, interquartile range (IQR): 12–56 months). Patients with bilateral disease had a somewhat longer duration of PAD (median 29 months vs. 24 months in unilateral PAD), but this difference was statistically not significant (Table II). Among patients with PAD, 32% were in Fontaine stage I, 56% in stage II, and around 10% in stage III or IV. In 6% a gangrene or ulcus was recorded. Patients with unilateral PAD had a significantly higher prevalence of affected thighs (60% vs. 23% in bilateral PAD) (Table II).

Study design

The examination was performed as a randomized crossover design with both measurements (sonographic and oscillometric measurements) on the same day with at least a 20-minute pause between measurements. The choice for the initial examination was randomized for each center separately with a computerized allocation procedure.

Measurements

Doppler-based ABI measurement

After a 10-minute rest, blood pressure measurement was taken according to Riva-Rocci in supine position on both upper extremities. Afterwards, ankle pressure of the dorsalis pedis artery and tibial posterior artery were taken using approved and calibrated compression cuffs adequately fit to the limbs' circumference by a mono- or bidirectional Doppler ultrasound. The ABI was calculated both as the lowest ankle pressure (dABI low) and as the highest ankle pressure (dABI high) of each extremity divided by the highest pressure of the upper extremities. PAD was indicated at an ABI < 0.9.

Oscillometric ABI measurement

The measurements were made using an AngE Pro8 (SOT Medical Systems, Maria Rain, Austria) with software version 1.06.15. Applying the Gesenius-Keller method, the pulse waves are recorded at different cuff pressures. The mean arterial pressure is determined by the maximal amplitude and the ratio of the amplitude between upper

Table I. Demographic and clinical characteristics of participants stratified by PAD status (controls = no PAD, uni- and bilateral PAD).

		Controls (n = 138)		Unilateral PAD (n = 58)		Bilateral PAD (n = 88)		Comparison Controls/PAD
	Unit/ category	mean ± SD or n	Md (IQR) or %	mean ± SD or n	Md (IQR) or %	mean ± SD or n	Md (IQR) or %	p-value
Age	Years	66.1 ± 12.6	70 (58–74)	68.9 ± 11.1	69 (61–76)	70.8 ± 8.7	70 (64–77)	0.031
Gender	Males	72	52.2%	30'	51.7%	54	61.4%	0.406
BMI	kg/m^2	27.7 ± 6.0	27 (24–31)	27.8 ± 4.9	28 (24–30)	27.2 ± 6.8	27 (24–29)	0.840
Smoking	Current	35	25.4%	26	44.8%	35	39.8%	0.004
	Former	44	31.9%	19	32.8%	24	27.3%	
Arterial hypertension	Yes	93	67.4%	47	81.0%	69	78.4%	0.019
Hyperlipidemia	Yes	93	67.4%	42	72.4%	69	78.4%	0.027
Diabetes mellitus	Type II	39	28.3%	23	39.7%	33	37.5%	0.079
Renal dysfunction	Yes	10	7.2%	16	27.6%	25	28.4%	< 0.001
Serum creatinine	mg/dL	0.90 ± 0.25	0.88 (0.75–1.01)	1.08 ± 0.51	0.85 (0.76–1.25)	1.04 ± 0.34	1.00 (0.80–1.23)	0.025
	µmol/L	79.6 ± 22.4	78 (66–89)	95.1 ± 45.0	75 (67–110)	92.3 ± 30.3	88 (71–109)	0.025
GFR	mL/min	60.1 ± 4.2	60.0 (60.0–60.0)	57.0 ± 19.4	60 (56–60)	60.0 ± 14.9	60 (53–62)	0.405
Diagnosis verified by[1]	CCDS	128	92.8%	43	74.1%	58	65.9%	< 0.001
	MRA	2	1.4%	8	13.8%	13	14.8%	
	DSA	3	2.2%	9	15.5%	21	23.9%	

[1]could be more than one method.
BMI: Body mass index; CCDS: Color coded duplex sonography; DSA: Digital subtraction angiography; GFR: Glomerular filtration rate; IQR: Interquartile range; MRA: Magnetic resonance angiography; Md: Median; PAD: peripheral arterial occlusive disease; SD: Standard deviation.

Table II. PAD characteristics stratified by uni- and bilateral PAD.

		Unilateral PAD (n = 58)		Bilateral PAD (n = 88)		Comparison uni-/bilateral
	Unit/category	mean ± SD or n	Md (IQR) or %	mean ± SD or n	Md (IQR) or %	p-value
PAD since	Months	33.2 ± 33.9	24 (8–45)	49.5 ± 60.1	29 (12–60)	0.399
Fontaine stage[1]	I	22	37.9%	24	27.3%	0.433
	II	29	50.0%	53	60.2%	
	III	2	3.4%	3	3.4%	
	IV	5	8.6%	4	4.5%	
Clinical symptoms	Claudication	17	29.3%	35	39.8%	0.448
	Rest pain	15	25.9%	22	25.0%	
	Gangrene	4	6.9%	3	3.4%	
	Ulcus	1	1.7%	1	1.1%	
Involved region[1]	Hip	6	10.3%	7	8.0%	< 0.001
	Thighs	35	60.3%	20	22.7%	
	Calves	11	19.0%	16	18.2%	
	Feet	3	5.2%	12	13.6%	
	More than one	3	5.2%	32	36.4%	
Wound infection[1]	Yes	2	3.4%	6	6.8%	0.471

[1]at the more affected side.
IQR: Interquartile range; Md: Median; SD: Standard deviation.

and lower extremity is termed oscillometric ABI (oABI). The cuffs were placed according the manufacturer's instructions and the measurements were started after 10 minutes rest and in the supine position or 20 minutes after obtaining the Doppler-based ABI. The second parameter was the Pulse Wave Index (PWI). PWI is calculated as the maximal amplitude of the upper extremity (left or right) divided by the maximal pulse amplitude measured at the lower leg (left or right) and then multiplied by the peak time of the pulse wave. PAD is indicated at an oABI < 0.9 and a PWI > 300.

Verification of diagnosis

For PAD verification and localization, color-coded duplex sonography (CCDS) was performed by an experienced physician. If further imaging techniques were available (MR angiography, MRA; digital subtraction angiography, DSA), they were also included in the evaluation.

Time requirements

Measurement of time requirement for the dABI measurement began when the first cuff was placed on the supine patient and ended with the last ankle pressure measurement using a stop watch. The oscillographic measurement also started when the first cuff was placed on the patient and ended with the appearance of the results on the computer screen. The measurements of the time needed were made with the same watch for both methods.

Patient satisfaction and preference

Immediately after each measurement, patients were asked to rate their annoyance invoked by the procedure on a 1–10 visual analogue scale (VAS) from 1 = no annoyance to 10 = maximal annoyance. Finally, after both measurements were completed, patients were asked about which method they would prefer for examinations in the future.

Statistical methods

Sample size determination was based on the results of a previous investigation [11]. It was assumed that dABI would be associated with a sensitivity of 89% and a specificity of 93%. Based on the differences obtained by diverse methods to obtain dABI, a non-inferiority margin for sensitivity of 10% and for specificity of 5% was specified. In order to reject the hypothesis of non-inferiority with a power of 80% at a significance level of 5%, a sample of n = 106 patients with PAD, and of n = 162 controls without PAD is required assuming a rate of 0.4 discordant pairs.

Comparison of PAD patients and controls was done by chi-square tests or Fisher's exact probability tests for categorical data and by Mann-Whitney tests for continuous data. In addition, patients with unilateral PAD were compared with bilaterally affected patients by the same methods.

Sensitivity was calculated separately for left and right side. Results were then combined, and 95% confidence interval computed considering the correlation between sides in those with bilateral PAD. Comparison of sensitivity of dABI (low and high) to that of oABI, PWI and the combination of both (i.e. assigning a patient to suspected PAD if either oABI or PWI or both were in the range indicating PAD) was done by McNemar tests separately for the left and right side.

For determination of specificity two methods were applied: first, all legs without PAD were included and specificity calculated for each side separately. Estimates were then combined, and 95% confidence intervals computed based on the variance of the estimate with correlation between sides in controls considered. Differences between measurement methods were tested by McNemar tests. The other method omitted unaffected legs in those with PAD and used only control patients.

A ROC analysis was performed comparing area under the curve of all methods separately for left and right side. The non-parametric method of DeLong et al. [17] was used to compare ROC curves.

Ratings of annoyance from the two methods and the time requirements were compared by Wilcoxon matched-pairs test. Preferences for these methods were tested by sign test.

Results

oABI had a significantly lower sensitivity of 65.8% (95% CI: 59.2%–71.9%) as compared to dABI low (87.3%, 81.9%–91.3%) and dABI high (80.3%, 74.2%–85.3%). However, PWI had a comparable sensitivity of 83.5% (79.2%–87.0%) and the combination of both (oABI and PWI) had even a slightly higher sensitivity of 88.8% (85.7%–91.4%), which was significantly higher compared to dABI high. Specificity of oABI was significantly higher than that of dABI low (79.7%, 74.7%–83.9% vs. 67.0%, 61.3%–72.2%) but not dABI high (78.1%, 72.8%–82.6%) if only patients without PAD were considered, but the same holds if all negative legs are included (Table III). Specificity of PWI (80.0%, 75.0%–84.2%) was similar to oABI but became lower if the combination of oABI and PWI was applied (69.7%, 63.4%–75.4%) reaching the level of dABI low, and was lower compared to specificity of dABI high.

A ROC analysis revealed that PWI had the largest area under the curve, but no significant differences between oABI and dABI low or dABI high were observed (Figure 1).

In general, patients were not annoyed by neither procedure (Figure 2). However, oscillometry had still significantly lower scores ($p < 0.001$). Consequently, 175 (61%) of patients expressed no preference for any method but significantly ($p < 0.001$) more (25% vs. 11%) would prefer oscillometry for further testing.

Time requirement for Doppler ABI was 9 ± 3.7 minutes, for oscillometric ABI measurement it was about 5 minutes less: 4 ± 0.9 minutes (see Figure 3). This difference was statistically significant ($p < 0.001$).

Discussion

This is the first randomized controlled study comparing the diagnostic accuracy of the semi-automated AngE^R-four-point oscillometric system with conventional cw-Doppler based ABI measurements for the identification of patients with PAD confirmed by duplex ultrasound, MR-angiography, and/or digital subtraction angiography.

Our results suggest a higher sensitivity of dABI compared to oABI and a higher specificity of oABI compared to dABI, while PWI performed best with sensitivity and

Table III. Specificity and sensitivity and 95% confidence intervals (CI) of the diagnostic tests.

			dABI low		dABI high		oABI		PWI		oTotal	
		N legs	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
Specificity	All negative legs	334	63.8%	58.0%–69.3%	73.7%	67.8%–78.9%	78.8%	73.6%–83.1%	76.3%	70.7%–81.0%	66.4%	59.8%–72.5%
	Controls only	276	67.0%	61.3%–72.2%	78.1%	72.8%–82.6%	79.7%	74.7%–83.9%	80.0%	75.0%–84.2%	69.7%	63.4%–75.4%
Sensitivity		234	87.3%	81.9%–91.3%	80.3%	74.2%–85.3%	65.8%	59.2%–71.9%	83.5%	79.2%–87.0%	88.8%	85.7%–91.4%

dABI: Doppler based ankle-brachial index; high: highest ankle pressure; low: lowest ankle pressure; oABI: Oscillometric ABI; oTotal: Combination of oABI and PWI; PWI: Pulse-wave index.

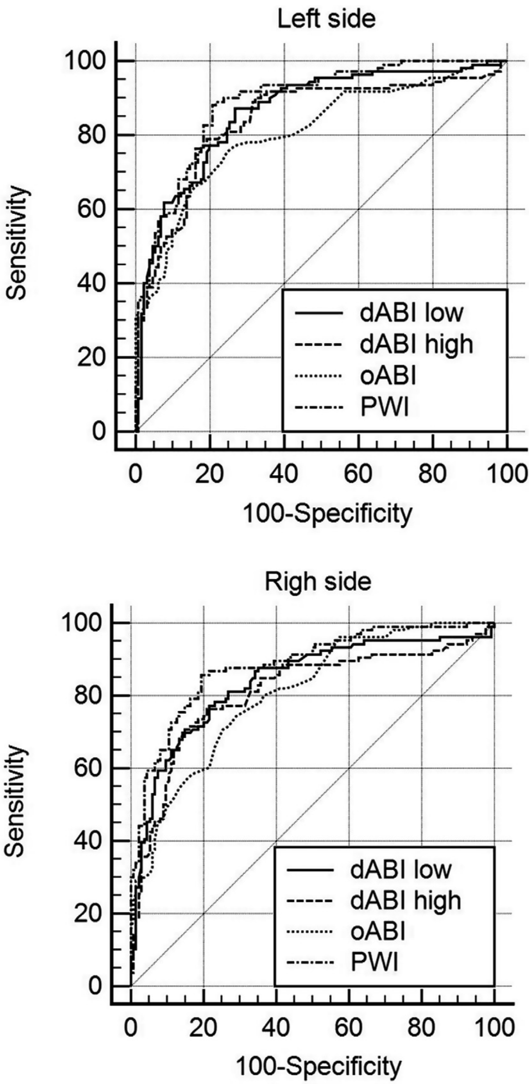

Figure 1. ROC curves (left and right side) of Doppler based ABI (dABI low = lowest ankle pressure and high = highest ankle pressure in numerator), oscillometry based ABI (oABI) and pulse wave index (PWI).

specificity values exceeding 80%. Using ROC analysis PWI also showed the largest area under the curve, while oABI and dABI performed comparably. Combining the results of oABI and PWI, i.e. evaluating the result as positive if either oABI or PWI is positive and negative of both are negative, resulted in the highest sensitivity of almost 89% but with a specificity of 70% not much higher than that of dABI.

These results are more or less the same whether dABI was obtained with the lowest ankle pressure or with the

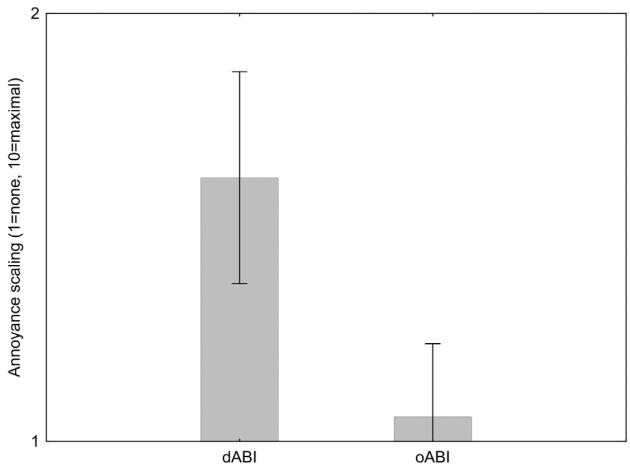

Figure 2. Means (95% confidence intervals) of annoyance ratings after Doppler and oscillometry based ABI measurements.

highest ankle pressure in the numerator of ABI. As expected, dABI high had a significantly higher specificity and a significantly lower sensitivity compared to dABI low. Using dABI high revealed a performance similar to oABI but with superior sensitivity. However, also with respect to dABI high, PWI from AngE^{R}-four-point oscillometric measurement had better performance.

Many studies report correlation coefficients between dABI and oABI, but only few studies determined sensitivity and specificity of both methods including PWI. In 2012, Verberk et al. [16] published an overview including 25 studies comparing oABI with dABI measurements. Sixteen of them reported correlation coefficients (on average 0.71 ± 0.05), eighteen studies reported differences in ABI between the two methods with an average difference of 0.02. The average sensitivity and specificity were 69% ± 6% and 96% ± 0.8%, respectively. In a more recently published meta-analysis including 20 studies with 1263 subjects and 3695 legs, Herráiz-Adillo et al. [14] found a sensitivity of 65% (95% CI: 57–74) and a specificity of 96% (95% CI: 93–99) for oABI with a somewhat better performance in the "per subjects" than in the "per legs" analysis. The inclusion of oscillometric errors as PAD equivalents also improved diagnostic performance.

Concentrating on studies which confirmed the presence of PAD by duplex ultrasound or angiography, a systematic Cochrane database review published in 2016 [18] identified only one prospective study comparing dABI with an automated oscillometric device. The limb-based results indicated that the accuracy of the ABI in detecting significant

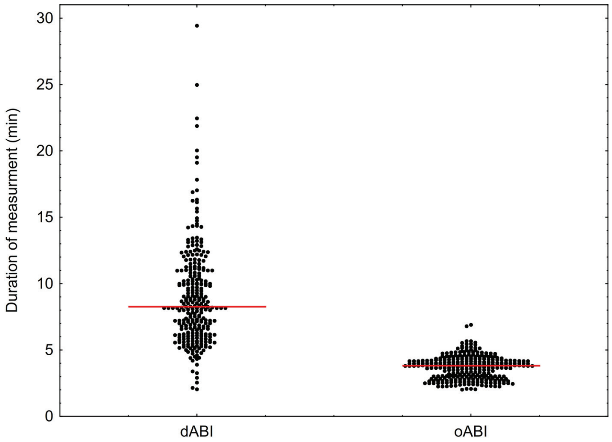

Figure 3. Dot plot of time requirement (minutes) for Doppler based ABI measurement (dABI) and oscillometry based measurement (oABI).

arterial disease is superior when stenosis in the femoropopliteal vessels is present, with a sensitivity of 97% (95% CI: 93% to 99%) and a specificity of 89% (95% CI: 67% to 95%) for oABI, and a sensitivity of 95% (95% CI:89% to 97%) and specificity of 56% (95% CI 33% to 70%) for dABI. The authors thus speculated that the superiority of a semi-automated oscillometric method for obtaining an ABI over the manual method might be clinically relevant, especially in relatively inexperienced examiners.

There are significant intrinsic differences in the oscillometric and Doppler-based measurement techniques contributing to the different results. Particularly, one has to be aware of the fact, that Doppler-based measurement and oscillometric based measurement of the ABI do not measure the same thing. While the Doppler-probe examines systolic pressure values in single lower leg arteries the oscillometric measurement is based on the oscillometric index as an integrative pressure value over the cross-section of the lower leg. Different test results might – to some extend – be also explained by the higher variation in the Doppler measurements due to inter-examiner differences [19]. These authors reported 8% intra-operator and 9% inter-operator variability for dABI measurements, but larger variation was reported for ABI values > 1.2 [20, 21] as well as for low ABI-values [15], whereas others found stable correlation coefficients between dABI and oABI for high and low dABI values in nondiabetic patients, but poor performance of dABI in diabetics [22]. Furthermore, dABI highly depends on the level of experience of the operator [18], while in semiautomatic oscillometry devices, there is practically almost no operator bias. Nevertheless, oABI is not perfect. Numerous factors influencing test results have been identified and published [14, 15, 23].

In our study, PWI performed better than oABI and dABI. This finding is new, but not surprising as PWI is highly influenced by the time-to-peak of the volume curve. This parameter is known since long to be very sensitive for post-stenotic flow curves and tends to be less affected by vessel wall characteristics like media sclerosis [20, 21].

One of the most striking results in our study was a highly significant difference in time required in favor of oscillometry which is economically relevant as time saving summed-up to approximately eight hours for every 100 examinations. A comparable time saving of 4.16 min was reported in the meta-analysis by Herráiz-Adillo et al. [14] indicating a time-saving potential of about seven hours for every 100 examinations. These findings are especially relevant for high-volume centers and epidemiologic studies, relating directly to manpower requirements of vascular laboratories. Furthermore, oscillometric measurements are easier to perform than Doppler based ABI procedures [24]. The participants of our study where not annoyed by none of the two procedures, but significantly more participants would favor oscillometric over dABI measurement for further testing, indicating a preference towards oscillometry.

Limitations

Strict validation of PAD by non-invasive duplex testing, MR-angiography and/or invasively by angiography as well as the strict adherence to a common protocol and a high experience level of all operators in the study centers accounts for the strengths of our study. Limitations arise from the comparatively low number of patients suffering from diabetes mellitus, which do not represent the percentage of diabetics among PAD-patients in most centers and which did not allow a separate analysis of diagnostic performance in this group. Thus, further studies are necessary to determine the diagnostic accuracy of oscillometric assessment using the AngE-device in patients with diabetes.

Conclusions

Semi-automatic oscillometric measurements of ABI using the AngE^{R}-device provide comparable diagnostic results in ROC analysis than conventional Doppler method in our study, while PWI performed best. Time consumption for testing was significantly lower using the semiautomated AngE^{R}-device – a finding that is economically important, especially in high volume centers and epidemiologic studies.

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