Peer reviewed article

Oscillometric measurement of ankle-brachial index in patients with suspected peripheral vascular disease: comparison with Doppler method

Nicolas Diehm[a*], *Florian Dick*[b,c*], *Carsten Czuprin*[a], *Holger Lawall*[d], *Iris Baumgartner*[a], *Curt Diehm*[d]

Swiss Cardiovascular Centre, Division of Clinical and Interventional Angiology[a] and Cardiovascular Surgery[b], University Hospital Insel, Bern, Switzerland
[c] Imperial College Vascular Surgery Research Group, Division of Surgery, Oncology, Reproductive Biology and Anaesthetics, Charing Cross Hospital, London, UK
[d] Department of Internal and Vascular Medicine, Klinikum Karlsbad-Langensteinbach, University of Heidelberg, Germany

Summary

Question under study: Purpose was to validate accuracy and reliability of automated oscillometric ankle-brachial (ABI) measurement prospectively against the current gold standard of Doppler-assisted ABI determination.

Methods: Oscillometric ABI was measured in 50 consecutive patients with peripheral arterial disease (n = 100 limbs, mean age 65 ± 6 years, 31 men, 19 diabetics) after both high and low ABI had been determined conventionally by Doppler under standardised conditions. Correlation was assessed by linear regression and Pearson product moment correlation. Degree of inter-modality agreement was quantified by use of Bland and Altman method.

Results: Oscillometry was performed significantly faster than Doppler-assisted ABI (3.9 ± 1.3 vs 11.4 ± 3.8 minutes, *P* <.001). Mean readings were 0.62 ± 0.25, 0.70 ± 0.22 and 0.63 ± 0.39 for low, high and oscillometric ABI, respectively. Correlation between oscillometry and Doppler ABI was good overall (r = 0.76 for both low and high ABI) and excellent in oligo-symptomatic, non-diabetic patients (r = 0.81; 0.07 ± 0.23); it was, however, limited in diabetic patients and in patients with critical limb ischaemia. In general, oscillometric ABI readings were slightly higher (+0.06), but linear regression analysis showed that correlation was sustained over the whole range of measurements.

Conclusions: Results of automated oscillometric ABI determination correlated well with Doppler-assisted measurements and could be obtained in shorter time. Agreement was particularly high in oligo-symptomatic non-diabetic patients.

Key words: ankle-brachial index; atherosclerosis; adverse cardiovascular events

* N.D. and F.D. contributed equally

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Introduction

Presence of peripheral arterial disease (PAD) is an expression of a generalised atherosclerotic burden [1–3] since patients with PAD frequently exhibit coexisting coronary artery and cerebrovascular disease. [3–5] Hence, without dedicated secondary prevention the life expectancy of patients with PAD is substantially limited by an increased cardiovascular and all-cause mortality. [6–9] However, more than half of PAD patients are asymptomatic [10, 11] and therefore at risk of not being identified in time [10, 11].

Doppler-assisted measurement of ankle brachial pressure index, also known as ankle brachial index (ABI) or ankle arm index, is the accepted non-invasive gold standard for both diagnosing PAD and the assessment of disease severity. [12–15] However, ABI measurement may be more challenging in PAD patients in whom distal pulses are missing or difficult to detect by Doppler, and may require a degree of expertise that has precluded its widespread adoption in primary care so far. Moreover, the amount of time required to perform Doppler-assisted ABI measurements was found to be a drawback for widespread office-based application [16].

Oscillometric blood pressure measurement

(fig. 1) is commonly used for screening and follow-up monitoring of arterial hypertension since it is widely available, reliable and simple to use. [8] Accordingly devices can be successfully self-applied by patients for blood pressure measurement at brachial or forearm level. [17] Moreover, oscillometry is used for blood pressure evaluation at lower limbs after bypass surgery. [18] This has led to the emergence of automated tools for simplified ABI-measurements using oscillometry rather than pinpoint detection of a vessel by a Doppler probe. Thus, automated oscillometry is likely to overcome the characteristic limitations of conventional ABI assessment and might pave the way for cost-effective population based diagnosis of PAD.

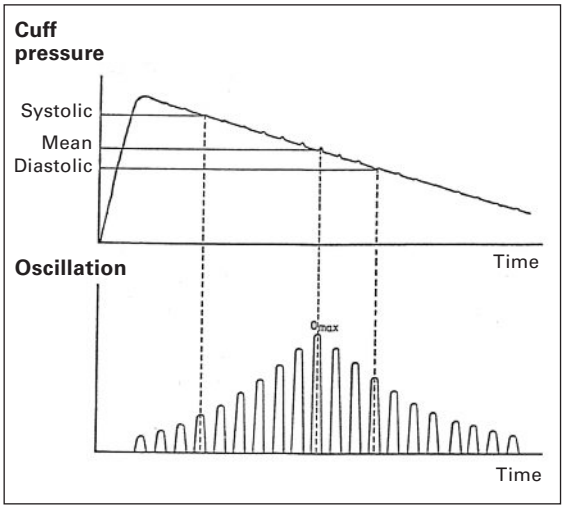


Figure 1

Oscillometric blood pressure measurement. With this method, the magnitude of the pressure vacillation under the cuff is measured as it deflates from suprasystolic pressures.

The purpose of the present study was to validate oscillometric ABI measurement by assessing inter-modality correlation and degree of agreement with the current gold standard of Doppler-assisted measurement in a vascular outpatient setting.

Methods

A consecutive series of 50 patients presenting in March 2008 at our outpatient clinic with chronic symptomatic PAD were included after informed consent for bimodal ABI measurement on both limbs (n = 100). Exclusion criteria were (1) major amputations in lower or upper limbs, (2) open wounds or ulcerations in lower limbs, (3) history of previous bypass surgery or angioplasty; (4) marked oedema of one or both feet, (5) body mass index >40 and (6) atrial fibrillation. The research protocol was in accordance with the institutional ethic's committee and with the Helsinki Declaration.

Cardiovascular risk factors were prospectively recorded following widely applied consensus guidelines. [15] Briefly, arterial hypertension was assumed when measurement of arterial blood pressure exceeded 140 mm Hg (systolic) and/or 90 mm Hg (diastolic) on at least two different occasions, or if the patient was on antihypertensive medication. Hyperlipidaemia was defined as a total serum cholesterol level of >5 mmol/L, serum HDL cholesterol level of <1 mmol/L, or serum triglyceride level of >2 mmol/L or if a patient was on lipid-lowering medication. Diabetes mellitus was defined by fasting blood sugar levels >120 mg/dL or HbA1c level >6%. Additionally, the presence of diabetes mellitus was assumed if the patient was taking any hypoglycaemic treatment. Current smoking habits were divided into either smoking or non-smoking. Renal insufficiency was defined by serum creatinine levels >130 μmol/L.

Ankle brachial pressure index measurements

All measurements were made in a temperature-controlled room (24° ± 1 °C) where each subject rested supine for 10 minutes before measurements were started. Both measurement protocols were performed by an examiner with experience in ABI measurements of over 30 years (CD) and who was blinded to all clinical baseline parameters. Due to the higher degree of subjectivity Doppler-assisted ABI measurements were invariably performed first. The time used for both Doppler-assisted and oscillometric ABI measurements (including the time needed for patient preparation and repeated measurements) was noted for every patient. Tibial artery incompressibility was assumed when ABI exceeded 1.3 as described earlier [19–21] and these measurements were excluded from analysis.

Doppler-assisted ABI measurements were performed according to the method described by Lovelace and Moneta [22] using a sphygmomanometer (Erka GmbH, Bad Toelz, Germany) with a cuff width ranging between 29 and 40 cm and a Doppler device with an 8.2 MHz continuous wave probe (Ultrasonic Flow Detector model 811–B, Parks Medical Electronic Inc., Aloha, Oregon, USA). In brief, the cuff was inflated to suprasystolic pressure (i.e., >30 mm Hg above expected systolic pressure) and deflated slowly until a flow signal was detected by Doppler over the dorsalis pedis artery and posterior tibial artery, respectively, thereby possibly indicating two different systolic pressures at the ankle level. These were recorded as "high" and "low" ankle systolic pressures. [23–25] Brachial artery systolic pressure was determined similarly on both upper extremities, the higher systolic brachial pressure being used for ABI calculations. Hence, for each limb a "high" and a "low" Doppler-assisted ABI was registered [23–25].

Oscillometric ABI measurements were carried out using a standard automated blood pressure cuff system (BOSO ABI system 100, BOSO, Jungingen, Germany). This device measures arterial blood pressure in all four extremities simultaneously using appropriate cuff sizes for arms and legs, thus avoiding a potential bias by variations of blood pressure. Essentially, the oscillometer measures the magnitude of the pressure vacillation under the cuff as it is deflated from suprasystolic pressures (i.e., >30 mm Hg above expected systolic pressure). Initially the oscillation amplitude increases as cuff pressure decreases but eventually reaches a peak amplitude at the mean arterial pressure after which further decrease of external compression causes the oscillation to decrease again (fig. 1). Systolic and diastolic blood pressures are then calculated at predefined percentages of the maximum oscillation amplitude. At the same time, the device records any arrhythmia.

Statistical analysis

Continuous variables are summarised as mean ± one standard deviation (SD) when normally distributed, and

as median (interquartile range) when asymmetrically distributed. Categorical variables are presented as numbers (percentages). Correlation of measurements obtained by Doppler-assisted method (low and high ABI values) and oscillometry was assessed by linear regression and Pearson product moment correlation. The resulting correlation coefficient (r) ranges between –1 and +1 where +1 and –1 stand for perfect correlation and zero for random distribution with absolute absence of correlation. In between, values >0.80 refer to excellent correlation, 0.61 to 0.80 to substantial correlation and 0.41 to 0.60 to moderate correlation. Any finding below 0.40 signifies poor correlation. [26] Coefficients of determination (r^2) were calculated to estimate the degree (in per cent) by which the regression model was able to approximate the actual data, and 95% confidence intervals were calculated around regression lines. The degree of inter-modality agreement was quantified by the Bland and Altman method. [27] For each measurement pair the arithmetic difference was plotted against the arithmetic mean. The mean of all measurement differences represents the centre of agreement and would be zero for identical readings. The observed degree of variability is quantified as 1.96 SD above and below this centre of agreement and allows informed interpretation of the quality of concordance. Systematic differences in readings were tested for by paired and two-sided *t*-test. Results were stratified for presence of diabetes. An α-error was accepted up to 5%, therefore *P*-values less than .05 were considered to indicate statistical significance. All analyses were performed using a computerised software package `SPSS for Windows Version 12.0.1´.

Results

One hundred lower limbs and 100 arms were analysed. Two limb readings were excluded from analysis due to incompressible arteries and all arm measurements could be used for correlation analyses. Demographic characteristics of the patient sample (n = 50) and prevalence of cardiovascular risk factors are summarised in table 1. Stratification for diabetes mellitus (38%) showed an even distribution of other cardiovascular risk factors between non-diabetic and diabetic patients (table 1). Oscillometric blood pressure detection at lower limb level initially yielded falsely low values (subsequently subsumed as '0') due to detection problems in 11 (18%, non-diabetic patients) and 13 limbs (33%, diabetic patients, *P* = .045), respectively. These measurements had to be repeated. Mean Doppler-assisted ABI (high ABI method) of limbs in whom oscillometric ABI measurement had to be repeated was 0.48 ± 0.12, and 20/24 (83%) of these limbs exhibited severe claudication or critical limb ischaemia.

Table 1

Characterisation of the investigated patient sample.

	All patients (n = 50)	Non-diabetics (n = 31)	Diabetics (n = 19)	P
White race, n (%)	50 (100%)	31 (100%)	19 (100%)	N/A
Age [years] ± SD	65 ± 6	64 ± 5	66 ± 6	.77*
Female gender, n (%)	19 (38%)	13 (42%)	6 (32%)	.56†
Mean height [m] ± SD	1.67 ± 0.15	1.72 ± 0.20	1.64 ± 0.17	.33*
Weight [kg] ± SD	75.2 ± 6.2	73.2 ± 5.5	76 ± 6.1	.19*
Body mass index (kg/m2) ± SD	26.8 ± 4.5	25.9 ± 4.4	27.6 ± 4.9	.28*
Arterial hypertension, n (%)	27 (54%)	16 (52%)	11 (58%)	.77†
Hyperlipidaemia, n (%)	30 (60%)	18 (58%)	12 (63%)	.77†
Current smoking, n (%)	41 (82%)	24 (77%)	17 (89%)	.76†
Renal insufficiency, n (%)	6 (12%)	3 (10%)	3 (16%)	.66†
Coronary heart disease, n (%)	17 (34%)	11 (35%)	6 (32%)	1.00†
Cerebrovascular disease, n (%)	7 (14%)	4 (13%)	3 (16%)	1.00†
Claudication, n (%) ‡	68 (68%)	42 (68%)	26 (68%)	1.00†
Critical limb ischaemia, n (%) ‡	32 (32%)	20 (32%)	12 (32%)	1.00†

Stratification for presence of diabetes showed similar distribution of cardiovascular risk factors, comorbidities and clinical presentation between diabetic and non-diabetic patients. *SD:* standard deviation; * Two-tailed and unpaired Student's *t*-test; † Two-tailed Fisher exact test; ‡ limb-based data

Correlation of calculated ankle brachial indexes

Mean ABI was 0.62 ± 0.25 for lower Doppler-assisted ABI and 0.70 ± 0.22 for higher Doppler-assisted ABI (*P* <.001, by two-tailed and paired *t*-test). Mean oscillometric ABI (0.63 ± 0.39) was similar to lower Doppler ABI (*P* = .60) and significantly lower than higher Doppler ABI (*P* = .012). However, correlation was substantial with both (*P* <.001, r = 0.77 with low Doppler ABI, and r = 0.75 with high Doppler ABI, respectively). Degree of agreement was 0.01 ± 0.49 (low Doppler ABI) and 0.07 ± 0.5 (high Doppler ABI). After correction for oscillometric '0' readings, correlation remained substantial (r = 0.75 and 0.77, respectively, *P* <.001), and degree of agreement was 0.13 ± 0.25 (low Doppler ABI) and 0.06 ± 0.24 (high Doppler ABI), respectively. However, oscillometric readings were systematically slightly higher (+0.06 in the mean, *P* <.001). Stratification of these results for diabetes is summarised in table 2 and figures 2 and 3.

Of note, correlation between oscillometry and Doppler-assisted ABI was best in non-diabetic patients after correction for oscillometric '0' readings (r = 0.81, *P* <.001). Similarly, the highest degree of agreement was found in these patients (± 0.23). As depicted in figure 3, the variation concentrated in a narrow band above the ideal centre of agreement thereby indicating a systematic tendency for higher readings using oscillometry. Correlation was somewhat less pronounced in diabetic patients after correction for oscillometric "0" readings, but still substantial (r = 0.64, *P* <.001). In these patients, degree of agreement was markedly better for the high ABI as compared to the low ABI method (fig. 3). Linear regression analysis reconfirmed these findings, displaying markedly smaller 95% confidence intervals in non-diabetic patients (fig. 2).

Figure 2

Linear regression analysis of correlation between oscillometric (OSC) and Doppler-assisted high (left) and low (right) measurement of ankle brachial index (ABI), respectively, including stratification for presence of diabetes. 95% confidence intervals (CI) are indicated for linear regression.

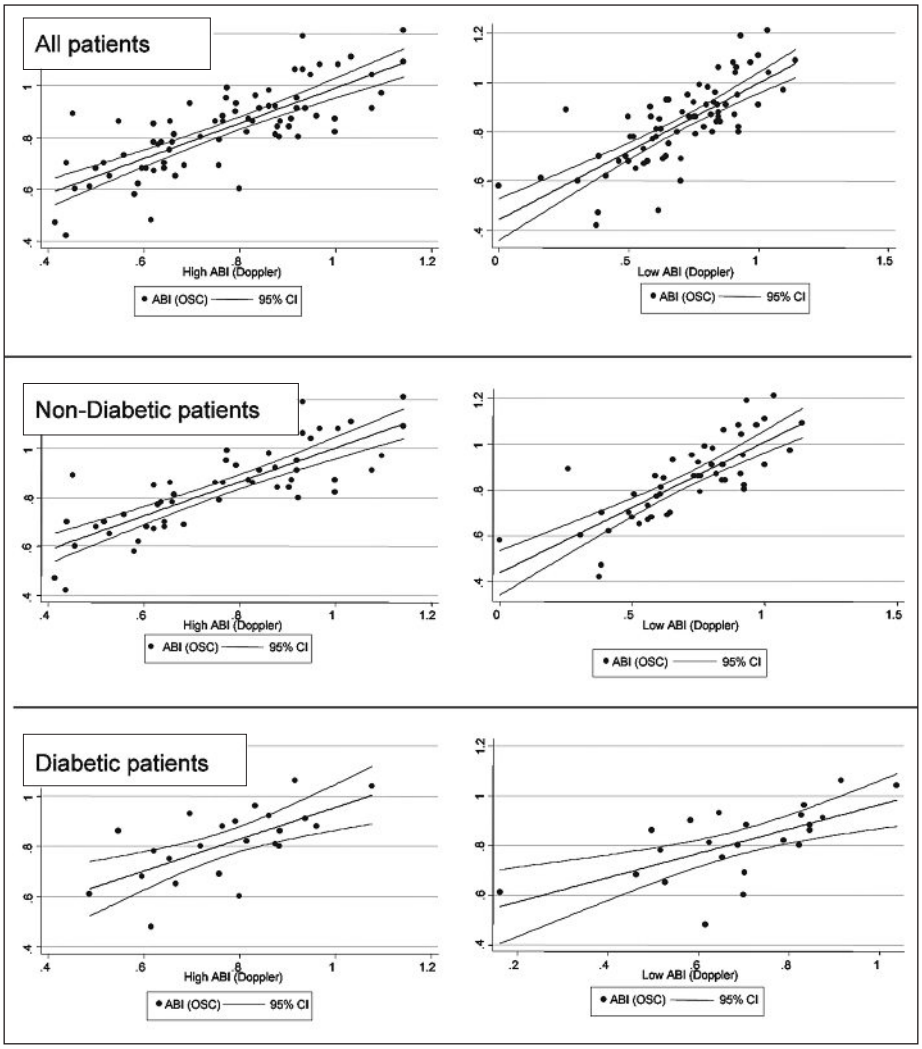
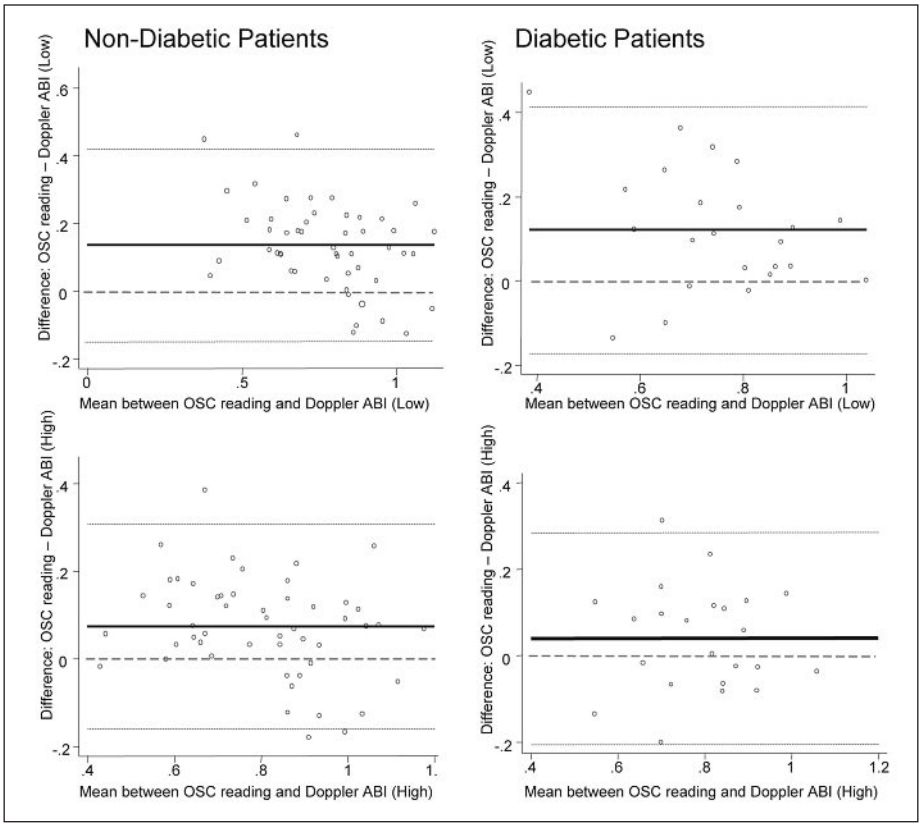


Figure 3

Bland-Altman plots of intermodality agreement between oscillometric (OSC) and Doppler-assisted low (top row) and high (bottom row) measurement of ankle brachial index (ABI), respectively. Horizontal line represents the actual centre of agreement, and the interrupted line the ideal centre of agreement. Dotted lines represent limits of agreement (i.e., 1.96 standard deviations of inter-modality difference).



Correlation of blood pressure measurement

The difference between right and left arm blood pressure measurements was nearly identical between the methods (table 2). Interestingly, correlation was markedly better in diabetic patients in this respect. Accordingly, correlation between oscillometry and Doppler-assisted blood pressure determination was markedly better in diabetic patients as compared to non-diabetic patients (r = 0.91 vs r = 0.72, table 2). However, overall correlation was excellent for all patients (r = 0.82, *P* <.001). Oscillometry had a tendency to measure systematically slightly higher values (+4.6 mm Hg, *P* = .046 by two-tailed and paired *t*-test). Results at lower limb level and stratification for diabetes are detailed in table 2.

Duration of measurement protocols

Time needed to perform Doppler-assisted ABI measurements was significantly longer (11.4 ± 3.8 minutes) than that for automated oscillometric ABI measurements (3.9 ± 1.3 min, *P* <.001 by paired two-tailed *t*-test).

Discussion

This prospective correlation study validated the accuracy and reliability of a new, fast and fully-automated ABI-measurement system. The main finding was that correlation between oscillometry and Doppler-assisted measurement was substantial for all patients studied and excellent in oligosymptomatic and non-diabetic patients, whereas reliability of oscillometric signal detection was limited in patients with severe PAD. The second important finding was that oscillometry was significantly faster than Doppler and produced systematically slightly higher readings.

Oscillometers have proven to be fast and reliant tools for self-applied assessment of blood pressure in the patient's hands. [17] The present study reconfirmed the substantial correlation between oscillometry and conventional measurement. For ABI calculations, all four extremities need to be assessed. [8] The oscillometric system allows simultaneous assessment of all four extremities and is free of observer bias. In contrast, Doppler measurements are performed successively and need interpretation by an observer. This was associated with unreliable evaluation of inter-site blood pressure ratios or differences [28] and may be prohibitively time-consuming for general practice. The present study was performed in a typical outpatient environment and showed that oscillometry was associated with a significant reduction of examination time as compared to Doppler ABI. Despite increased costs for the hardware required for oscillometric ABI measurement, the latter may represent an advantage in making ABI assessment generally more ac-

Table 2

Main validation results of oscillometric measurement of ankle brachial index, stratified for presence of diabetes.

	Non-Diabetic patients					Diabetic patients				
	n	Correlation r (Coefficient of determination, %)	P-Value*	Degree of agreement (mean difference (95%-CI) ± 2SD), mm Hg (pressure) or index	P-Value†	n	Correlation r (Coefficient of determination, %)	P-Value*	Degree of agreement (mean difference (95%-CI) ± 2SD), mm Hg (pressure) or index	P-Value†
Systolic blood pressure measurement (arm)	31					19				
Osc right vs left		0.88 (77%)	<0.001	–0.07 (–4.5 to 4.4) ± 24	>0.1		0.97 (94%)	<0.001	2.84 (–1.5 to 7.2) ± 18	>0.1
Doppler right vs left		0.78 (61%)	<0.001	–0.58 (–6.2 to 5.0) ± 30	>0.1		0.96 (92%)	<0.001	2.11 (–2.0 to 6.2) ± 17	>0.1
Osc vs Doppler (high)		0.72 (52%)	<0.001	2.87 (–3.5 to 9.2) ± 35	>0.1		0.91 (83%)	<0.001	7.42 (1.2 to 13.7) ± 26	0.023
Systolic blood pressure measurement (lower limb)	51					23				
Osc vs Doppler (low)		0.67 (45%)	<0.001	23.3 (16.1 to 30.6) ±52	<0.001		0.50 (25%)	0.044	24.6 (12.1 to 37.1) ±58	<0.001
Osc vs Doppler (high)		0.72 (52%)	<0.001	13.8 (7.8 to 19.8) ± 43	<0.001		0.57 (32%)	0.012	11.7 (1.2 to 22.3) ± 49	0.031
ABI measurement	62					36				
Osc vs Doppler (low ABI)		0.74 (55%)	<0.001	0.05 (–0.02 to 0.11) ±0.45	>0.1		0.79 (62%)	0.003	–0.04 (–0.13 to 0.05) ± 0.53	>0.1
excluding Osc '0'	51	0.78 (61%)	<0.001	0.14 (0.09 to 0.18) ±0.27	<0.001	23	0.64 (41%)	<0.001	0.12 (0.06 to 0.18) ± 0.58	<0.001
Osc vs Doppler (high ABI)		0.78 (61%)	<0.001	–0.02 (–0.08 to 0.04) ±0.45	>0.1		0.73 (53%)	0.003	–0.15 (–0.25 to -0.05) ±0.58	0.004
excluding Osc '0'	51	0.81 (66%)	<0.001	0.07 (0.04 to 0.11) ±0.23	<0.001	23	0.64 (41%)	<0.001	0.04 (–0.01 to 0.01) ± 0.24	>0.1
Doppler (low vs high ABI)		0.94 (88%)	<0.001	0.06 (0.04 to 0.09) ± 0.15	<0.001		0.87 (76%)	<0.001	0.11 (0.07 to 0.15) ±0.24	<0.001

ABI: ankle brachial index; Osc: oscillometric (measurement); * Two-tailed, single sample *t*-test; † Two-tailed and paired *t*-test

§ n = 2 limbs excluded due to arterial incompressibility

ceptable to real-world primary health care, where duration of examinations is not considered for reimbursement.

Oscillometric ABI determination has been assessed before. [29–32] In a recent study of 201 subjects, Beckman and co-workers reported a good correlation with Doppler ABI (r = 0.78). [29] However, there was concern that more than 70% of patients did not have PAD and thus presumably presented with normal ABI. In these cases correlation could be expected to be very high, which may have led to an overestimation of the correlation in patients with the disease. In the present series only patients with suspected PAD were included and all degrees of severity of disease were represented, with a wide distribution of ABI measurements. The degree of correlation was very similar. The correlation coefficient was 0.75 overall and, for non-diabetic patients, even better than that reported by Beckman et al. (i.e., r = 0.81). Aboyans and colleagues, however, investigated the use of a different oscillometric device in a mixed cohort including suspected claudicants, patients with known cardiac or cerebrovascular atherosclerosis and healthy volunteers. [32] The authors concluded that oscillometry was poorly reliable as compared with Doppler and that it thus might lead to underestimating ABI. In our series we confirmed a systematic tendency of the oscillometric device for higher readings, which, applying the established reference scale for Doppler-assisted ABI, would indeed underestimate the presence of PAD. However, this is not a generic shortcoming of the method, since, as long as the correlation is consistent over the whole range of expected measurements (fig. 2), diagnostic agreement simply depends on dedicated adaptation of the reference scale.

Unlike earlier reports, the present study assessed correlation between oscillometric ABI measurements and both low and high Doppler ABI, since lower ABI was recently shown to improve detection of patients at increased cardiovascular risk. [23, 24] Interestingly, correlation was equally good with low and high ABI in non-diabetic patients, whereas it was less satisfactory in diabetic patients with advanced disease (table 2).

Diabetes is one of the major risk factors of PAD. [20] In these patients the faster progression of media sclerosis renders vessels non-compliant at an early stage, particularly vessels with smaller diameter. Doppler-assisted ABI measurements have been reported before to be less reliable or falsely high in diabetic patients, [21] and often clinicians rely instead on photopletysmographic greater toe pressure measurements. [20] The influence of diabetes on oscillometry, however, has not been previously assessed. Although our results indicate that oscillometric ABI measurement was feasible in both diabetic and non-diabetic patients, its potential use is limited in diabetic patients. Whereas correlation with Doppler-assisted measurements at the brachial level was, astonishingly, better in diabetic patients, their readings were less reliable at ankle level which corroborates earlier findings regarding Doppler. Essentially, we found a good degree of agreement only with the higher Doppler ABI in diabetic patients. In the present study, detection problems occurred in 24% of limbs undergoing oscillometric ABI measurement. However, even after repetition of measurements due to an initial technical failure in almost every fourth patient, oscillometric ABI measurement could be carried out in a significantly shorter time. Oscillometric ABI determination was hampered in a substantial number of patients with diabetes mellitus and advanced peripheral arterial disease. Hence, and as for Doppler-assisted ABI, this subset of patients seems unsuited for standardised assessment but needs individual appraisal.

Study limitations

Certain limitations of our study must be considered when interpreting the data. As discussed above, the present series was limited to patients with known PAD in order to represent a wide spectrum of symptomatic PAD. Hence it was possible to investigate correlation and degree of agreement of oscillometry with the current gold standard of Doppler ABI in a reasonably large sample. However, population-based specificity and sensitivity remain obscure. For such an investigation, a different sample representing the prevalence of PAD in the general population would be needed. Such a sample would have been too large to justify a study with a novel methodology of unknown accuracy. Since there is currently no reliable data available, an appropriate screening pilot study, preferably including the concept of measuring high and low Doppler ABI, [23, 24] will have to be performed, before oscillometry can be recommended for population-based screening. Secondly, the present study investigated the use of only one type of oscillometric blood pressure device. Thus, we obviously cannot extrapolate our results to other available devices, which may contain different calculation algorithms. Thirdly, patients with arterial incompressibility as defined by ABI >1.3 [19–21] were excluded in the present series. Therefore, no conclusions about the accuracy of oscillometric ABI determination in patients with medial sclerosis can be drawn from the present study.

In conclusion, the present study demonstrated that automated oscillometric determination of ABI is feasible, fast and easy to perform and correlates well with conventional Doppler-assisted ABI measurements in patients with moderate PAD. The accuracy of oscillometry was best in oligo-symptomatic, non-diabetic patients, who represent the bulk of a potential screening target population. Sensitivity and specificity as well as cost-effectiveness of this novel diagnostic tool need to be validated in a prospective population-based study.

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Correspondence:
Florian Dick, MD
Swiss Cardiovascular Centre, Division of Cardiovascular Surgery
University Hospital Insel
CH–3010 Bern
Switzerland
E-Mail: florian.dick@gmail.com