Angiology: Open Access

Qunaibet et al., Angiol 2016, 4:1
DOI: 10.4172/2329-9495.1000164

Research article Open Access

Repeatability of Oscillometric Determinations of the Ankle-Brachial Index. The Atherosclerosis Risk in Communities (ARIC) Study

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Rec date: December 11, 2015; **Acc date:** January 19, 2016; **Pub date:** January 25, 2016

Abstract

Background: The ankle-brachial index (ABI) is a noninvasive and inexpensive means to assess lower extremity artery patency with established validity. Low ABI values are predictive of cardiovascular morbidity and all-cause mortality. Automated, oscillometric devices are commonly used to measure ABI in population studies for time-efficiency and to reduce observer-dependent variability. The repeatability of multi-limb systolic blood pressure (SBP) and of ABI using oscillometric devices has not been evaluated in depth.

Methods: Two examinations 4-8 weeks apart were conducted on 79 participants using standardized protocols. Using the VP-1000 Plus system bilateral systolic blood pressure (brachial and ankle) and ABI were measured twice five minutes apart, during each examination. The intra-class correlation coefficient (ICC), the corresponding 95% confidence intervals (95% CI), minimal detectable change (MDC95), and minimal detectable difference (MDD) were calculated.

Results: The ICCs (95% CI) were 0.62 (0.49, 0.75) for right brachial SBP, 0.65 (0.53, 0.77) for left brachial SBP, 0.61 (0.48, 0.74) for right ankle SBP, 0.66 (0.55, 0.78) for left ankle SBP, 0.48 (0.34, 0.64) for right ABI, and 0.61 (0.48, 0.73) for left ABI. The MDC95 was 0.22 for right ABI, and 0.20 for left ABI. The MDD for two independent samples (N=100) was 0.06 for both right ABI and left ABI.

Conclusion: The 4-8 week repeatability measures of the arm and ankle SBP, and of the left ABI are substantial, and the estimated repeatability of the right ABI is moderate. Reliability estimates based on this study can be used to correct for bias when using ABI.

Keywords: Repeatability; Reliability; Lower extremity atherosclerotic disease

Introduction

The ankle-brachial index (ABI)–the ratio of the systolic blood pressure measured in the ankles and the arms – is the first line measurement in the evaluation of impaired arterial flow to the lower extremities due to atherosclerotic occlusive disease [1] a marker of peripheral arterial disease (PAD). Low values of ABI also are indicative of a greater probability and extent of atherosclerosis in arterial territories other than the lower extremities, and are associated with greater risk of subclinical atherosclerosis, clinically manifest coronary artery disease, incident ischemic strokes, and recurrent strokes [2-9].

ABI has been incorporated into risk prediction equations to identify persons with moderate to high risk of cardiovascular morbidity and mortality [3,5,7]. The ABI is therefore widely used in population-based studies, and its use in clinical practice has been recommended as a marker of subclinical CVD in asymptomatic individuals (beyond the use of standard risk factor scores). The measurement of the ABI using hand-held Doppler probes is considered the gold standard technique. Because hand-held Doppler measurements are observer-dependent and take significant time, a number of automated, oscillometric devices have been adopted to measure ABI to improve data quality and efficiency of data acquisition [10-13]. There is however a paucity of studies examining the measurement properties of these devices, and specifically the repeatability of oscillometric measurements of ABI. Establishing ABI repeatability is important to quantify measurement error and the precision with which threshold values and conventional clinical cut points are assessed. The published information on the repeatability of oscillometric measures of the ABI is mostly based on individuals with PAD or cardiovascular risk factors [14,15] or limited to within-visit repeatability [12,14,15]. The aim of the study reported here was to characterize the 4-8 week repeatability of side-specific measurements of ABI and limb-specific systolic blood pressure measured with an automated oscillometric device.

Citation: Qunaibet AA, Meyer ML, Couper D, Tanaka H, Cheng S, et al. (2016) Repeatability of Oscillometric Determinations of the Ankle-Brachial Index. The Atherosclerosis Risk in Communities (ARIC) Study. Angiol 4: 164. doi:10.4172/2329-9495.1000164

Methods

Study population

This study was nested within the 5th examination of the Atherosclerosis Risk in Communities (ARIC) study cohort (2011-2013) sponsored by the National Heart, Lung, and Blood institute (NHLBI). ARIC is a prospective epidemiologic study of adults aged 45 and 64 years at intake in 1987-89, drawn as probability samples from four communities (Washington County, Maryland; suburban Minneapolis, Minnesota; Jackson, Mississippi; and Forsyth County, North Carolina) [16]. The repeatability study population was systematically selected from members of the ARIC cohort in the course of its 2011-2013 examination, based on the day of the week during a specified time window, with a target of 25 individuals from each of the four ARIC communities. Staff at the field centers invited the first participant meeting these criteria to return for a repeat examination in 4-8 weeks, including an ABI measurement. If the participant declined, staff asked the next participant on the schedule. A standardized protocol was followed. At each examination visit participants were asked to fast for 8 hours and refrain from vigorous physical activity, smoking, and caffeinated beverages the morning of the visit. Participants were also asked to bring all prescription and nonprescription medications used during the two weeks preceding the visit. A total of 20 participants at Washington County; 19 at Minneapolis; 23 at Jackson; and 20 at Forsyth County took part. The mean time elapsed between examination visits was 40.3 days with a standard deviation (SD) of 9.5 days.

Of the 82 participants in the repeatability study, 3 were excluded from these analyses for characteristics that could affect the ABI measurements: a body mass index (BMI) ≥ 40kg/m^2 (n=1), aortic stenosis (n=1), and evidence of a major arrhythmia (Minnesota code 8-3-1) on a 12-lead electrocardiogram (n=1). The study was approved by the Institutional Review Board at each participating institution. Written informed consent was provided by the participants for each examination.

Ankle-brachial index

ABI measurements were performed using the automated waveform analyzer VP-1000 Plus (Omron Co., Ltd., Kyoto, Japan) 11 following a standardized procedure. The participant was in the supine position with both arms resting along his/her side while bent 90 degrees at the elbows (PMID: 26045531). Two electrocardiogram clips were attached on the inner side of both wrists, and blood pressure cuffs were placed on both arms and ankles. Blood pressure was measured simultaneously in the four limbs at least twice at a 2-5 minute interval. The VP-1000 Plus estimates ABI for each lower extremity as ABI = ankle systolic blood pressure / (higher of left and right arm systolic blood pressure). ABI was estimated twice for each visit (ABI1 and ABI2) for the first visit and (ABI3 and ABI4) for the second visit.

Statistical analysis

We calculated means and standard deviations of ABI, brachial and ankle systolic blood pressure for the right and left sides. We used a nested random-effects analysis of variance model to parse the variance of ABI and limbic systolic blood pressure into between-participant (σ^2p), between-visit (σ^2bv), and within-visit components (σ^2wv). The repeatability of ABI and of brachial and ankle systolic blood pressure was estimated by the intra-class correlation coefficient (ICC), calculated by dividing the between-participant variance by the total variance [σ^2p/σ^2total = σ^2p/ (σ^2p+σ^2bv+σ^2wv)]. We also calculated the within-visit ICC for each visit by dividing the between-participant variance by the sum of between-participant variance and error (σ^2wv). The standard error of measurement (SEM) was calculated [SEM=√(σ^2bv+σ^2wv)]. We estimated changes in ABI based on the variance and sample size for one- and two-sample study designs. The minimal detectable change with 95% confidence (MDC95) between two time points for an individual that reflects true change above that of measurement error was calculated as MDC95 = SEM*√2*1.96. For a two-sample study design, we calculated the minimal detectable difference (MDD) between two measurements as MDD = [(√2*σ^2total)/N]*(tα(df)+tβ(df))], using the MDD as a percent of the grand mean. Further, we calculated the absolute and average difference for between-visit and within-visit pairs of measurements. A Bland-Altman plot was used to plot the difference between the averages per visit against the mean for each subject. Since in practice repeat measurements are often taken to improve precision, we also averaged the two ABI values taken at each visit and calculated the between-visit difference based on the two averages.

All statistical tests are 2-sided with a nominal significance level of $p<0.05$. All analyses were performed using SAS, version 9.2 (SAS Institute, Inc., Cary, NC).

Characteristic	**Mean ± SD** **N (%)**
Age, Mean(years) ± SD	75.7 ± 4.6
Body mass index, Mean(kg/m^2) ± SD	29.6 ± 4.0
Female, N (%)	46 (58.2)
African American, N (%)	26 (32.9)
Current smoker, N (%)	1 (1.3)
Diabetes, N (%)	34 (43.6)
Hypertension, N (%)	58 (74.4)
Medication Use, N (%)	
Beta-blocker	28 (37.8)
Alpha-Blocker	3 (4.1)
Diuretic	33 (44.6)
Angiotensin-converting-enzyme	23 (31.1)
inhibitor	
Calcium channel blocker	16 (21.6)
Angiotensin II Receptor Blocker	18 (24.3)
ABI: Ankle-brachial Index	

Table 1: Characteristics of the participants in the ABI repeatability study (N=79).

Results

Of the 82 individuals in the repeatability study 79 met our criteria for inclusion in analysis. As shown in (Table 1), 26 (32.9%) were

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African American and 46 (58.2%) women. The mean age and BMI were 75.7 years and 29.6 kg/m^2, respectively.

The mean within- and between-visit values for ABI and its component systolic brachial and ankle blood pressures were similar (Table 2). The between-visit absolute difference was consistently higher than the within-visit absolute difference for brachial and ankle systolic blood pressure. For ABI, the between-visit absolute difference was higher than the within-visit absolute difference and the between-visit average difference was lower than the within-visit average difference (Table 2).

	Visit 1		Visit 2		Within-Visita		Between-Visitb		Between-Visitc Based on average
Variable	1st measure mean ± SD	2st measure mean ± SD	1st measure mean ± SD	2st measure mean ± SD	Average Difference mean ± SD	Absolute Difference mean ± SD	Average Difference mean ± SD	Absolute Difference mean ± SD	Absolute Difference mean ± SD
RbSBP (mmHg)	140.4 ± 17.2	136.9 ± 16.1	137.4 ± 16.5	135.8 ± 16.1	-2.7 ± 4.5	5.2 ± 3.5	-2.1 ± 13.6	10.7 ± 8.9	12.9 ± 15.6
n	76			77	78	78	76	76	
LbSBP (mmHg)	141.1 ± 16.0	137.5 ± 16.0	138.1 ± 16.9	136.2 ± 16.2	-3.0 ± 4.3	5.4 ± 3.3	-2.4 ± 12.6	11.0 ± 7.0	13.2 ± 15.7
n	77			77	78	78	77	77	
RaSBP (mmHg)	166.4 ± 22.5	161.9 ± 23.4	161.8 ± 24.3	159.3 ± 24.2	-3.4 ± 7.9	8.4 ± 6.5	-3.2 ± 19.0	16.1 ± 11.5	17.1 ± 17.7
n	78			78	79	79	77	77	
LaSBP (mmHg)	165.5 ± 23.8	160.9 ± 23.4	161.1 ± 22.5	159.5 ± 22.3	-3.1 ± 6.6	7.8 ± 5.1	-2.7± 17.1	14.9 ± 10.1	14.9 ± 13.1
n	77			77	78	78	77	77	
RABI	1.16 ± 0.11	1.16 ± 0.12	1.16 ± 0.11	1.16 ± 0.11	0.0004 ± 0.06	0.05 ± 0.05	-0.0008 ± 0.1	0.08 ± 0.07	0.09 ± 0.11
n	78			77	78	78	77	77	
LABI	1.15 ± 0.12	1.15 ± 0.10	1.15 ± 0.11	1.15 ± 0.11	0.002 ± 0.04	0.04 ± 0.03	0.002 ± 0.1	0.07 ± 0.06	0.08 ± 0.11
n	78			77	77	77	76	76	

a(1st visit/2nd measure - 1st visit/1st measure) and (2nd visit/2nd measure - 2nd visit/1st measure)
b(2nd visit/1st measure - 1st visit/1st measure) and (2nd visit/2nd measure - 1st visit/2nd measure)
c(average of 2nd visit - average of 1st visit)

Table 2: Descriptive statistics for the ABI and its components by examination visit, and differences within and between visit.

For bilateral systolic blood pressure and ABI there was negligible variation between the average between-visit difference and the average within-visit difference (Table 2). The between-visit difference based on the average of the two ABI measurements at each visit was similar to the between-visit difference based on the individual values (Table 2). The highest component of total ABI measurement variation was due to between-participant variation, and between-visit variation was higher than within-visit variation (Table 3).

The ICCs (95% confidence interval) were 0.48 (0.34, 0.64) for right ABI, and 0.61 (0.48, 0.73) for left ABI (Table 5). For the ABI components, the corresponding ICCs were 0.62 (0.49, 0.75) for right brachial systolic blood pressure, 0.65 (0.53, 0.77) for left brachial systolic blood pressure, 0.61 (0.48, 0.74) for right ankle systolic blood pressure, and 0.66 (0.55, 0.78) for left ankle systolic blood pressure (Table 5). The SEM was 0.08 for right ABI and 0.07 for left ABI (Table 5).

	ABI			
Source of variation	**Right ABI**		**Left ABI**	
	SD	**% total**	**SD**	**% total**
Between-participant	0.08	48.4	0.09	60.8
Between-visit	0.06	28.9	0.06	25
Within-visit	0.05	22.7	0.04	14.2

SD: standard Deviation
%: Percent

Table 3: Components of short-term (4-8 weeks) variation for the ABI.

Systolic blood pressure								
	Brachial SBP (mmHg)				Ankle SBP (mmHg)			
Source of variation	Right SBP		Left SBP		Right SBP		Left SBP	
	SD	% total	SD	% total	SD	% total	SD	% total
Between-participant	13.1	61.7	13.3	65.2	18.6	60.8	18.8	66.4
Between-visit	9	29.3	8.3	25.3	12.3	26.6	11.2	23.5
Within-visit	5	9	5.1	9.6	8.5	12.6	7.3	10.1

SD: Standard Deviation
%: percent

Table 4: Components of short-term (4-8 weeks) variation for ankle and brachial systolic blood pressures.

For ABI components, the SEM was 10.3 mmHg for right brachial systolic blood pressure, 9.7 mmHg for left brachial systolic blood pressure, 14.9 mmHg for right ankle systolic blood pressure, and 13.4 mmHg for left ankle systolic blood pressure (Table 5). The MDC95 was 0.22 for right ABI and 0.20 for left ABI (Table 5). This was also the case for the respective brachial and ankle systolic blood pressure measurements (Table 4).

For ABI components, the MDC95 was 29 mmHg for right brachial systolic blood pressure, 27 mmHg for left brachial systolic blood pressure, 41 mmHg for right ankle systolic blood pressure, and 37 mmHg for left ankle systolic blood pressure (Table 5). The MDD for two independent samples (N=100) was 0.06 for right and left ABI (Table 5). For ABI components, the MDD for two independent samples (N=100) was 9 mmHg for right brachial systolic blood pressure, 8 mmHg for left brachial systolic blood pressure, and 12 mmHg for right and left ankle systolic blood pressure (Table 5). The Bland-Altman plot for right ABI shows 96% of the differences to be less than two standard deviations (Figure 1) and 93.7% of the difference for left ABI to be less than two standard deviations. The Bland-Altman plots do not show a clear dependence between the pair differences and the average means for the right or left ABI (Figure 1).

Discussion

The short-term (~40 days) repeatability of ABI and its components (right and left brachial and ankle systolic blood pressures) were observed to be 'fair' based on the Fleiss guidelines for interpreting ICCs18, and the repeatability was slightly higher for left-sided measurements compared with right-sided measurements. As expected the largest source of variation was between-participant variability and between-visit variation was higher than within-visit variation for all measures. Contrary to our expectation using the average ABI per visit to calculate the between-visit difference did not decrease the absolute difference.

Automated oscillometric devices measuring ABI have been used for more than two decades, yet studies examining the repeatability of ABI are sparse and most do not examine its individual components. To our knowledge the short term repeatability of ABI measured by the VP-1000 Plus has not been reported. The available repeatability studies examine other devices and are short term [12,14,15,17,18], except for a one year long repeatability study conducted using the DINAMAP™ device [19]. Other devices examined include: Omron HEM 711C, BOSO, and ProM, Spengler.

	Systolic blood pressure				ABI	
	Brachial SBP (mmHg)		Ankle SBP (mmHg)		Right ABI	Left ABI
	Right SBP	Left SBP	Right SBP	Left SBP		
ICC (95% CI)	0.62 (0.49, 0.75)	0.65 (0.53, 0.77)	0.61 (0.48, 0.74)	0.66 (0.55, 0.78)	0.48 (0.34, 0.64)	0.61 (0.48, 0.73)
SEM mmHg	10.3	9.72	14.9	13.4	0.08	0.07
MDC95 mmHg	28.5	26.9	41.3	37.0	0.22	0.20
MDD mmHg	8.5	8.4	12.2	11.8	0.06	0.06

ICC: Intra-class Correlation Coefficient; SEM: Standard Error of Measurement;
MDC95: Minimal Detectable Change; MDD: Minimal Detectable Difference

Table 5: Repeatability estimates, standard error of measurement (SEM), minimal detectable difference (MDD), and the minimal detectable change (MDC95) for systolic blood pressure and ABI.

The study designs and parameters found in the published reports on reliability and reproducibility of the ABI measured by oscillometric devices vary, but there are some commonalities in their conclusions. A study using an automatic oscillometric blood pressure device (ProM, Spengler, Cachan, France) which predominantly included participants with atherosclerotic conditions and those suspected of intermittent claudication yielded low repeatability results based on measurements taken on the same day. The inter-observer ICC was 0.44, 15 compared to 0.48 for the ICC of right ABI and 0.61 for the ICC of left ABI in our study, taken 4-8 week parts.

We estimated the SEM to be 0.08 for the right ABI and 0.07 for the left ABI, similar to that estimated in a study using the Omron HEM 711C where the SEM for normal individuals was 0.08 but higher in patients with cardiovascular risk factors and vascular lab patients 16. The long term ABI repeatability was estimated by Weatherley et al. using the DINAMAP™ 1846 SX based on two measures taken within a year 20. The reliability coefficients (interchangeably used with ICC) for ABI and its components ranged from 0.61 to 0.7420. The ICC values for the brachial and ankle systolic blood pressures were similar in our study. On the other hand Weatherley et al. [19] estimated the reliability coefficient for arm systolic blood pressure to be 0.74 compared to 0.68 for ankle systolic blood pressure, and attributed the lower reliability for the latter to the less than optimal technique in applying a conventional blood pressure cuff on conically-shaped ankles.

A repeatability study based on a random sample representative of the Czech post-MONICA study (n=450) estimated ICC values based on a repeat measure taken after 5 minutes. The observed ICC value was 0.75 (95% CI 0.72-0.78) [12]. In our study the ICC estimates based on repeat measures taken after 5 minutes ranged from 0.90 to 0.93, thus higher than those reported by the Czech post-MONICA study.

Both the brachial and ankle systolic blood pressure measurements had slightly higher ICC values than the ABI in our study, ranging from 0.61 and 0.66, which is not surprising when a ratio is taken. Considerably higher ICC values were reported based on a different automated oscillometric device (VitalCare DOX (Model 506DXN)), namely 0.85 for the brachial systolic blood pressure and 0.83 for ankle systolic blood pressure. The difference in ICC performance is likely due to the time elapsed between the repeat measures. The estimates reported by Ramanathan et al. [20] are based on a 30 minute interval, compared to the 4-8 week interval for our study. The within-visit ICC values for brachial and ankle systolic blood pressure measurements taken 5 minutes apart in our study were higher than those for measures taken 30 minutes apart using the VitalCare DOX device.

The sources of variability in measurements taken 4 to 8 weeks apart can include biological variation, environmental factors, and measurement variability associated with the technician or the process. Our study design does not permit estimation of the variation attributed to technicians. Although a standardized measurement protocol was in place and technicians were comparably trained and certified, process variability likely contributed to the overall measurement variability. However, the largest component of measurement variability was to between-participant variability.

We calculated the MDC95 and MDD for the ABI and its component systolic blood pressures (Table 5) to estimate the impact of measurement variability on desirable study sizes, and to evaluate whether differences in ABI values within individuals and between groups exceed measurement error. The MDD can be reduced by increasing the sample size (N) (Supplemental Table 1).

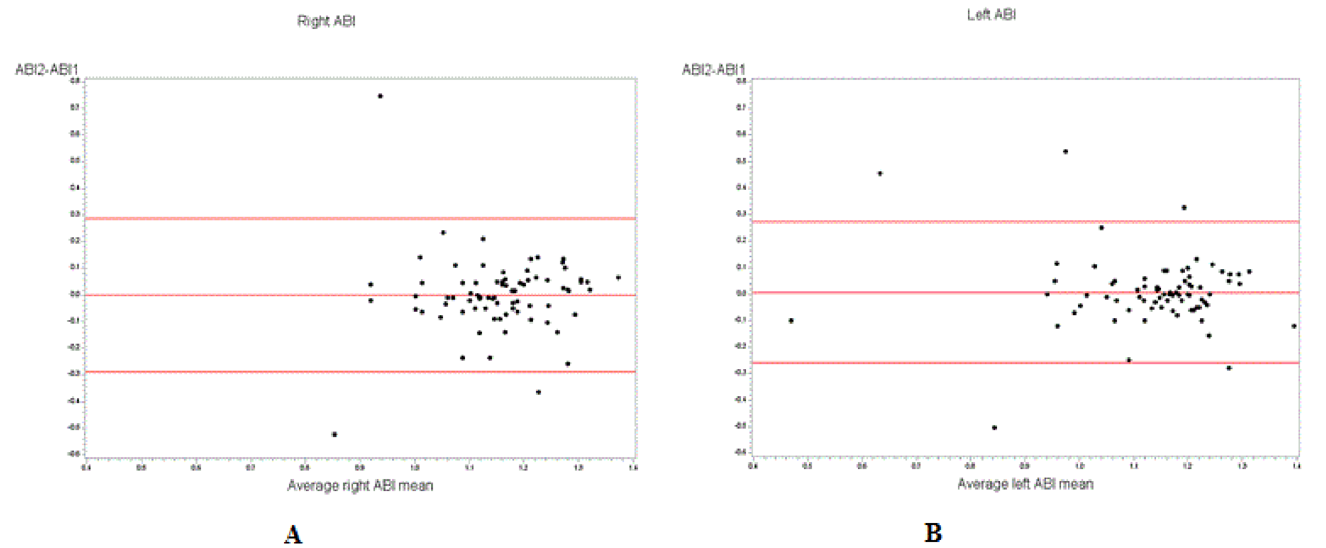

Figure 1: A. Bland-Altman plot showing the repeatability of the right ankle-brachial index. B. Bland-Altman plot showing the repeatability of the left ankle-brachial index.

Measurement repeatability estimates such as the ones presented here can be used to adjust for measurement error, and to correct for regression dilution bias [21] in estimating associations between ABI measured with this commonly used oscillometric device and parameters of interest such as health outcomes. The reciprocal value of the ICC estimates is typically used in regression analysis or risk prediction equations to adjust for the bias introduced by this variability. In clinical practice, awareness of measurement error and lack of repeatability can improve decision-making for diagnosis and management based on interpretation of ABI values. If the measurement instrument and the observer are accurate (unbiased), measurement precision (SEM) estimates such as presented here can be used by practitioners to assess individual change in ABI. Calculators or reference tables can be developed to facilitate their use in clinical settings.

A number of methods can be used to identify PAD, such as the ratio of ankle and brachial systolic pressures measured by Doppler ultrasound or various oscillometric devices, duplex ultrasonography, Doppler waveform analysis, pulse volume recordings, segmental pressures, and toe-brachial indices. Guidelines by the American College of Cardiology (ACC) and the American Heart Association (AHA) recommend the use of a resting ABI to identify PAD (Level of evidence: C). The ACC/AHA guidelines focus on the measurement of ABI using hand held Doppler ultrasound [22,23]. Although time consuming and subject to observer error, the Doppler-based ABI measurement protocol is considered the gold standard. Comparisons between oscillometric vs. Doppler-based measurements of the ABI have been reported, but are beyond the scope of this repeatability study. Briefly, a meta-analysis estimated an average difference of -0.02 ± 0.02 SD between oscillometric and ABI measured by Doppler [13] Of note, Pan and colleagues reported good agreement between Doppler and oscillometric measurements below an ABI value of 1.0, with progressively greater disagreements above ABI values of 1.225. It was also estimated that an ABI measured by the Doppler technique in primary care is on average 0.02 ± 0.24 SD higher than that measured in the vascular lab [24,25]. Compared to Doppler measurements, the sensitivity of oscillometric ABI to classify PAD ranges between 50%-92% and specificity ranges 73%-96% [13,26-28]. It has thus been proposed to use higher thresholds for oscillometric ABI values to improve validity14. Measurements of the ABI using hand-held Doppler probes are time consuming which limits their use in general clinical practice, and highly trained technicians to reduce observer error are not readily available. A wider adoption of the recommendation for periodic assessments of the ABI in general clinical practice would therefore benefit from the use of automated measurement devices, with consideration of their measurement properties, i.e., their validity and reproducibility.

In conclusion, the within-visit repeatability of the ABI measured with the Omron VP-1000 Plus is excellent, and it assumes values of 0.49-0.61 after a 4-8 week interval between repeat measures. The repeatability of the ABI was lower on the right than the left side. The influence of the observed variability on changes in ABI between repeated examinations should be considered in clinical practice and in research. Reliability estimates can be used to correct for bias when using the ABI, and to guide decisions relating to study size and/or the desirable number of repeat measurements.

Acknowledgements

The Atherosclerosis Risk in Communities Study is carried out as a collaborative study supported by National Heart, Lung, and Blood Institute contracts (HHSN268201100005C,HHSN268201100006C, HHSN268201100007C,HHSN268201100008C,HHSN268201100009C, HHSN268201100010C,HHSN268201100011CandHHSN26820110001 2C). The authors thank the staff and participants of the ARIC study for their important contributions.

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