ORIGINAL RESEARCH

Comparison between oscillometric- and Doppler-ABI in elderly individuals

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Abstract: Peripheral arterial disease (PAD) generally remains under-recognized, mainly due to the specialized technical skills required to detect the low values of the ankle-brachial index (ABI). As a simpler and faster alternative to the standard method using continuous-wave Doppler ultrasound, we evaluated automated oscillometric ABI measurement by VP-2000 with an elderly cohort of 113 subjects (age range, 61 to 88 years). The standard deviation in ABIs measured by the Doppler method was statistically greater than that measured by the oscillometric method for each of the two legs ($P < 0.001$). Correlations in ABIs between the two methods were 0.46 for the left leg and 0.61 for the right leg; this result appears to have been caused by interobserver variation in the Doppler ABI measurements. While the trend showing greater differences between average oscillometric- and Doppler-ABIs was significant at the lower ABI ranges, there was little indication of differences in measurements having an average ABI > 1.1. The difference between the methods was suggestively larger in subjects who were smokers than in non-smokers ($P = 0.09$), but the difference was not affected by other potential atherosclerotic risk factors, including age at examination ($P > 0.50$). A larger difference at lower ABIs led to better PAD detection by the Doppler method compared to the oscillometric method (sensitivity = 50%, specificity = 100%), although the overall agreement was not small (Cohen's Kappa = 0.65). Our findings indicate that oscillometric devices can provide more accurate estimation of the prevalence of PAD in elderly individuals than the conventional Doppler method.

Keywords: ankle-brachial index, oscillometry, Doppler, peripheral arterial disease

Introduction

Peripheral arterial disease (PAD) is a common atherosclerotic condition among elderly Japanese individuals: 5% of men aged 60 to 79 years,[1] and 3.4% of men and women aged 65 years or greater are affected by the disease.[2] Diagnosis of PAD has important prognostic implications in reducing cardiovascular morbidity and mortality. Half of patients remain undiagnosed,[3] given that asymptomatic PAD is common and is independently associated with impaired lower extremity functioning,[4] especially in elderly populations.[5] Although intermittent claudication has been considered the most classic manifestation of PAD, recent data show that most PAD cases do not have classic intermittent claudication symptoms.[6,7] Moreover, many PAD patients also have arthritis or back ailments, which might also cause exertional leg pain.[4] A more accurate estimation of the prevalence of PAD in the elderly should rely upon a validated and reproducible test, such as the ankle-brachial index (ABI). One of the barriers to recognition of PAD is the time-consuming skill acquisition required of the examiner applying the Doppler method, the gold standard for ABI testing.[8] As a simple and fast

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alternative to facilitate disease diagnosis, several investigators have reported the feasibility of oscillometric-ABI in epidemiological settings among middle-aged subjects,[9] and in general European[10] and American populations.[11] Recent studies indicate that the VP-2000 (Omron Healthcare, Kyoto, Japan), an automated oscillometric device, can provide accurate ABI measurements with minimal examiner technical skill.[9,10] The US Food and Drug Administration has approved the VP-2000 device for clinical use.[10] To our knowledge, however, few studies have evaluated the use of oscillometric-ABI among elderly subjects, in which ankle systolic blood pressure (SBP) may not be accurately measured when arterial blood flow cannot be abolished by inflation of an air-filled blood pressure cuff.[12] The aim of the current study was to validate oscillometric-ABI using the VP-2000 on elderly patients in an epidemiological setting.

Methods
Subjects
The Adult Health Study (AHS) cohort at the Radiation Effects Research Foundation (RERF) consists of atomic-bomb survivors who have undergone biennial health examinations since 1958. Between January 11 and February 29, 2008, 115 subjects provided written informed consent prior to their participation in this validation study at the Hiroshima laboratory. The study protocol was approved by the RERF ethics committee.

Measurements of ankle and brachial blood pressures
ABI is the ratio of SBP at the ankle to that in the arm. To obtain ABIs, trained technicians measured SBPs on subjects in the supine position in a quiet room after the subjects had rested for 10 minutes. Participants had been instructed to abstain from smoking and drinking, except for water, for at least two hours prior to the examination. ABI was measured twice on each participant by one of seven randomly assigned technicians using two methods, the oscillometric and Doppler methods, on both the subjects' left and right legs. The oscillometric-ABI was calculated as the ratio of ankle SBP to the highest of the right and left brachial SBPs. For the Doppler-ABI, SBP was measured twice at the right brachial and the right and left posterior tibial arteries with a handheld 5-MHz Doppler probe (MedaSonics 5 MHz Doppler Ultrasound Stethoscope, model BF4B, MedaSonics, Fremont, CA). As commonly used as a diagnostic criterion for PAD, we classified ABI <0.90 as low. Two subjects with Doppler-ABI ≥1.4 were excluded from the analysis

because such results usually reflect arterial rigidity preventing arterial compression, leaving 113 subjects for the subsequent analyses. The intraclass correlation coefficients for interobserver agreements were 0.95 in the Doppler-ABI and 0.80 in the oscillometric-ABI, and intraobserver agreements were 0.71 in the Doppler-ABI and 0.87 in the oscillometric-ABI.

Atherosclerotic risk factors and cardiovascular disease
We obtained patient information for the factors that could potentially influence SBP measurements. The subjects' smoking and drinking habits were obtained from medical interviews. Hypertension (HT) was defined as an auscultatory SBP/DBP of ≥140/90 mmHg, or under treatment for HT. Hyperlipidemia (HLp) was defined as a serum cholesterol level of ≥220 mg/dL or under treatment for HLp. Diabetes mellitus (DM) was defined as a casual plasma glucose level of ≥200 mg/dL, or under treatment with oral hypoglycemic agents. Cardiovascular disease (CVD) was defined as evidence of ischemic changes on a 12-lead ECG, or a history of coronary bypass surgery, coronary angioplasty, or stroke. Body mass index (BMI, kg/m^2) was calculated from the patient's height and weight at the examination.

Statistical analysis
Standard deviation of the ABI measurements between the oscillometric and Doppler methods was compared by the F-test. To assess the agreement in measurements by the two methods, we conducted linear regression analyses for the difference of the two measurements within each individual, and the pattern of the agreement was graphically assessed by a Bland-Altman plot.[14] In the regression analyses, we evaluated variations in the differences due to other factors – smoking and drinking habits, HT, DM, CVD, HLp and BMI – with or without adjustment by the examiners (assumed to be normally distributed with mean zero). In addition to separate analyses for the right and left legs, we performed combined data analyses for both legs with random effects to account for within-individual correlations between the left and right leg measurements. All presented *P*-values are two-sided. The agreement in PAD diagnosis (ABI < 0.9) between the methods was checked with Cohen's Kappa statistic, as well as sensitivity and specificity, using the Doppler measurement as the gold standard. Conventionally, a Cohen's Kappa statistic of <0.2 is considered poor agreement, 0.21–0.4 fair, 0.41–0.6 moderate, 0.61–0.8 strong, and >0.8 is considered near complete agreement.

Results

Among the 113 study participants, mean ages (standard deviation [SD]) were 73.9 years (8.1) for women and 70.0 years (7.6) for men. Table 1 presents the distribution of the study subjects by selected characteristics with means (SD) of ABIs measured by the two methods. The standard deviation in ABIs measured by the Doppler method was statistically larger than that measured by the oscillometric method for each of the two legs ($P < 0.001$). Correlations in ABIs between the two methods were 0.46 for the left leg and 0.61 for the right leg. Doppler ABIs tended to vary significantly by examiner ($P = 0.006$ for the right leg and $P = 0.02$ for the left leg), while the examiner effect was not significant in oscillometric-ABIs ($P > 0.5$ for each leg).

Without any adjustment, the level of the oscillometric ABIs was significantly greater than that for the Doppler-ABIs for right legs (95% CI = 0.02–0.06, $P < 0.001$), while the difference was not significant in left legs (−0.01; 0.04, $P = 0.31$). The difference between the two methods appeared to vary significantly over the subgroups

by examiner ($P < 0.001$ for both legs). With adjustment for examiners, the significance of the difference was reduced ($P = 0.04$ in the right leg and $P = 0.15$ in the combined analysis). While the difference between the methods might be larger among smokers than non-smokers ($P = 0.07$ in the left leg and $P = 0.09$ in the combined analysis), there was no evidence for variations in the difference over the other clinical condition categories, including age at examination ($P > 0.5$).

The Bland-Altman plot in Figure 1 indicates that the oscillometric-ABI tended to yield larger values than the Doppler-ABI for those individuals with relatively smaller ABI averages on both legs. This trend of the difference decreasing with average was significant, with a coefficient of −0.55 for the left leg and −0.41 for the right leg ($P < 0.001$ for both legs); however, there was little indication of difference among those having average ABI > 1.1 ($P > 0.1$ for each leg).

The Doppler method detected 10 subjects with low-ABI (<0.9) in either leg, among which, 5 had measurements

Table 1 Mean ankle brachial index (ABI) measurements and the difference between oscillometric and Doppler methods in the study subjects by selected characteristics

	n	Left				Right				P^c
		Mean ABI (SD)		Difference		Mean ABI (SD)		Difference		
		Oscillo	Doppler	P^a	P^b	Oscillo	Doppler	P^a	P^b	
Total	113	1.13 (0.09)	1.12 (0.14)	0.31	0.41	1.15 (0.10)	1.11 (0.14)	0.00	0.04	0.15
Sex										
Women	67	1.12 (0.08)	1.10 (0.12)	>0.5	>0.5	1.14 (0.07)	1.10 (0.12)	>0.5	>0.5	>0.5
Men	46	1.14 (0.11)	`			1.15 (0.13)	1.11 (0.17)			
Age at examination										
−74	57	1.14 (0.10)	1.13 (0.13)	>0.5	>0.5	1.15 (0.11)	1.12 (0.15)	>0.5	>0.5	>0.5
75−	56	1.11 (0.09)	1.10 (0.15)			1.14 (0.09)	1.09 (0.14)			
Smoking										
No	95	1.13 (0.09)	1.13 (0.13)	0.07	0.09	1.15 (0.09)	1.12 (0.13)	0.15	0.22	0.09
Yes	18	1.12 (0.10)	1.06 (0.17)			1.13 (0.14)	1.05 (0.19)			
Alcohol drinking										
No	68	1.12 (0.09)	1.11 (0.14)	>0.5	>0.5	1.15 (0.10)	1.11 (0.14)	0.26	0.39	>0.5
Yes	45	1.13 (0.09)	1.12 (0.14)			1.15 (0.11)	1.09 (0.15)			
CVD										
No	97	1.13 (0.09)	1.12 (0.14)	0.19	0.36	1.15 (0.11)	1.11 (0.15)	0.25	0.18	>0.5
Yes	16	1.14 (0.08)	1.09 (0.13)			1.12 (0.07)	1.11 (0.11)			
Diabetes mellitus										
No	90	1.14 (0.08)	1.13 (0.11)	0.36	0.45	1.16 (0.08)	1.12 (0.12)	0.25	0.31	0.33
Yes	23	1.07 (0.13)	1.04 (0.20)			1.10 (0.15)	1.03 (0.19)			
Hyperlipidemia										
No	39	1.15 (0.07)	1.17 (0.13)	0.08	0.11	1.17 (0.09)	1.13 (0.15)	>0.5	>0.5	0.25
Yes	74	1.11 (0.10)	1.09 (0.14)			1.14 (0.10)	1.09 (0.14)			
BMI (kg/m²)										
<22.5	48	1.12 (0.08)	1.10 (0.13)	0.28	0.21	1.14 (0.10)	1.09 (0.14)	>0.5	>0.5	0.30
≥22.5	65	1.13 (0.10)	1.13(0.14)			1.15 (0.10)	1.12 (0.14)			

Notes: [a]P value for homogeneity of the difference over categories of the given factor in the leg-specific analysis without adjustment for examiners; [b]P value for homogeneity of the difference over categories of the given factor in the leg-specific analysis with adjustment for examiners; [c]P value for homogeneity of the difference over categories of the given factor in the combined analysis with adjustment for examiners.
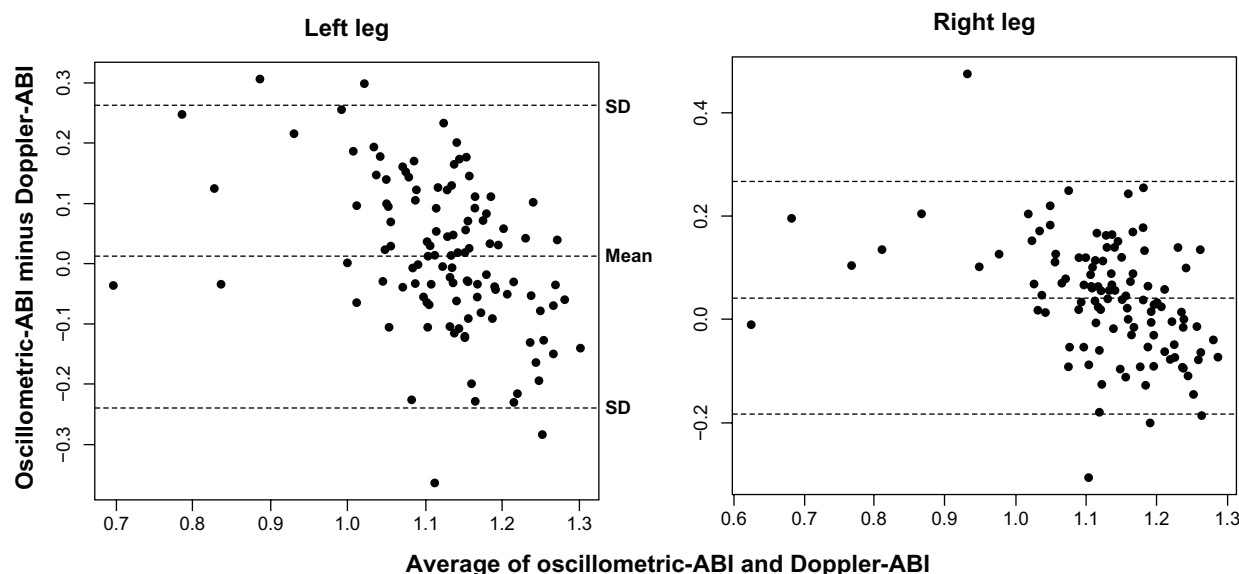
Figure 1 Bland-Altman Plots for ankle-brachial blood pressure index (ABI).

below the cutoff by oscillometric-ABI (<0.9). There was no over-diagnosis by the oscillometric method compared to the Doppler method, thus, specificity = 100% and sensitivity = 50%. Despite the small sensitivity, no strong overall disagreement in diagnosis was indicated by Kappa measures (κ = 0.65 (95% CI = 0.40–1.0), conventionally considered strong agreement). When we also tested agreement between the two methods using the worst legs based on ABIs, sensitivity = 40% and Kappa = 0.55 (95% CI = 0.20–0.90).

Discussion

Peripheral artery disease generally remains under-recognized, which has been a limiting factor in the reduction of cardiovascular morbidity and mortality in these patients. This is mainly due to the specialized skills required by technicians to detect low ABI values using the gold-standard method of continuous-wave Doppler ultrasound. To examine a potential simple and fast alternative,[15] we evaluated automated oscillometric-ABI measurement using a cohort of elderly individuals in Japan.

Consistent with many other studies,[10,11,16–19] our observations indicate that the mean oscillometric-ABI value using the VP-2000 might be higher compared to the Doppler counterpart, particularly at lower-range ABIs. While this might be attributed to the intrinsic differences in the oscillometric and Doppler blood pressure measurement techniques, our analysis demonstrated that deviation in the difference was explained, to some extent, by variation in the Doppler measurements due to interexaminer differences.

In contrast, the oscillometric method was not affected by the examiner. It is also worth noting that, in our analysis, the difference was not affected by age, which indicates that use of the oscillometric method may not be limited by the age of the patient.

The reliability of automated oscillometric-ABI values for PAD diagnosis is controversial. As in many other studies,[16,18,19] we found that the automated oscillometric device led to a conservative detection of PAD compared to the Doppler method, as a result of the differences at lower ABIs. Beckman et al[11] and Kollias et al[15] concluded that oscillometric devices could provide a reliable and simple method of PAD detection with relatively good agreement with the Doppler method. Another recent study reported poor agreement in PAD diagnosis between primary care facilities and vascular laboratories (κ, 0.41); over-diagnosis of PAD was made in primary care facilities compared with vascular laboratories, and over 60% of cases were assessed by a Doppler device in primary care.[17]

In our analysis, the agreement between the two methods for detecting PAD was not good (sensitivity = 50%) if PAD was diagnosed for ABI <0.9. Due to the limited number of PAD cases detected in this study (10 by the Doppler method and 5 by the oscillometric method), rationalizing this diagnostic disagreement is not straightforward. Our observed pattern of differences suggests that raising the cutoff level should facilitate an improvement in the screening of PAD by oscillometric devices. For example, when an oscillometric-ABI of less than 1.0, instead of 0.9, was considered low, the agreement somewhat improved

with sensitivity = 60%, specificity = 97%. In this cohort, the PAD prevalence generally reported for Japanese elderly populations (3%–5%)[1,2] was closer to the observed prevalence by the oscillometric method (4.4%) than that by the Doppler method (8.8%). That evidence, together with our findings of increased variability in Doppler measurements, indicates that the oscillometric-ABI may not necessarily be inefficient in detecting PAD compared with Doppler-ABI. Further comparison between Doppler and oscillometric tools among known PAD patients is necessary because, in the current study, few subjects had low ABIs.

In conclusion, the oscillometric method to measure ABI using the VP-2000 can provide more accurate estimation of the prevalence of PAD, independent of the examiner's skill, than the conventional Doppler method, and may be beneficial in reducing the health burden of this condition in the elderly population.

Acknowledgment

Disclosure

The authors report no conflicts of interest in this work.

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