Accuracy and Reliability of the Ankle Brachial Index Measurement Using a Multicuff Oscillometric Device Versus the Doppler Method

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Short title: Ankle Brachial Index by Multicuff Oscillometric Device

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WHAT THIS PAPER ADDS

Ankle brachial index (ABI) measurement is proposed as a first line screening test to detect lower extremity artery disease with high diagnostic accuracy, but the Doppler method, considered to be the gold standard, needs skilled operators, precluding its generalisation in primary cares. This study demonstrates the high diagnostic accuracy obtained by oscillometric ABI to be comparable to Doppler ABI, with high reproducibility. The automated oscillometric device could, potentially, be implemented in general and cardiovascular practices, as well as health screening centres as a first line test.

Objective: Ankle brachial index (ABI) is widely used for the diagnosis of lower extremity artery disease (LEAD). The purpose of this prospective study was to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device versus the Doppler method.
Methods: Patients with suspected LEAD or asymptomatic individuals at risk because of the presence two or more cardiovascular risk factors were enrolled. For each patient, Doppler and oscillometric ABI measurements were repeated by two observers to address intra- and interobserver reproducibility.

Results: In total, 118 patients were evaluated. The prevalence of Doppler ABI (Dop-ABI) ≤ 0.90 was 45.8%. Taking the Dop-ABI as the reference, the sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of oscillometric ABI (Osc-ABI) during the first measurement by the first observer were 89.1%, 94.4%, 94.1%, 91.8%, and 92.4%, respectively. The concordance for diagnosing ABI ≤ 0.90 between both methods was excellent (kappa coefficients ranging from 0.80 to 0.88 with different observers). Intra-observer reproducibility assessed by intraclass correlation (ICC) between both methods were 0.94 for observer 1 and 0.96 for observer 2. The intra-observer reproducibility using the same method was also excellent (ICC 0.94, 95% confidence interval [CI] 0.91 – 0.95) for Dop-ABI and 0.95 (95% CI 0.93 – 0.97) for Osc-ABI). The ICC for interobserver reproducibility using the same method was 0.95 (95% CI 0.92 – 0.96) for Dop-ABI and 0.96 (95% CI 0.94 – 0.97) for Osc-ABI.

Conclusion: This study validates the excellent diagnostic performances of a four cuff oscillometric device specifically designed for screening LEAD. The simple measurement method could therefore be advocated in primary care where fast, easy, and reliable methods are suitable.

Keywords: Ankle brachial index, Atherosclerosis, Peripheral arterial disease

INTRODUCTION

Lower extremity artery disease (LEAD) is a common atherosclerotic disease.[1] Accurate screening and timely diagnosis of LEAD can help to identify patients with a high risk of cardiovascular events or mortality.[2] The ankle brachial index (ABI) is a non-invasive, simple method to diagnose either symptomatic or asymptomatic LEAD, and can serve as a prognostic marker for cardiovascular events and functional impairment.[3–6] The standard method for the measurement of ABI requires a Doppler device, with sequential systolic blood pressure (SBP) measurement of the four limbs.[3] However, this method is time consuming, which was regarded as one of its disadvantages in United States Prevention Service Task Force statement for the screening of LEAD.[2] It also requires trained personnel. All these are barriers to its widespread use in primary care.[7–9] The sensitivity and specificity of the Doppler method are reported to be between 17% –100% and 80% – 100%, respectively,[7–9] and the diagnostic performance of the ABI varies depending on the population studied (ABI is of limited value in patients with chronic limb threatening ischaemia [CLTI]), the cutoff threshold, and the measurement skills. In the 2012 American Heart Association (AHA) statements, the need for easier and faster alternative methods for ABI measurement was highlighted.[3] As an alternative, an oscillometric method using an automatic blood pressure device has gained strong attention as it is a simple, fully automatic test, that can theoretically minimise observer biases and eliminate the need for special

training.[10,11] Several studies have attempted to validate the oscillometric method against the Doppler method, with mixed results.[10,12–18] Under these circumstances, an oscillometric device dedicated to ABI measurement has been available in Asia and the USA.[19,20] The device has four cuffs, enabling blood pressure measurement of the four extremities simultaneously, with the total measurement time being much shorter. Previous studies demonstrated the sensitivity and specificity of the device for detecting ≥ 50% stenosis on computed tomography (CT) angiography were 90% and 85%, respectively.[21,22] However, the entire spectrum of diagnostic performances and reliability of the oscillometric method needs comparison to the standard Doppler method. Therefore, a prospective validation study was conducted to compare ABI measurement by the oscillometric device to the standard Doppler method in two different vascular laboratories. It was hypothesised that this oscillometric device provides reliable ABI readings, as compared to the standard Doppler method, with reproducibility at least as good as the latter.

MATERIALS AND METHODS

This was a prospective, international, bi-centre study comparing two methods of measuring ABI: the Doppler method (Dop-ABI) and the one using the oscillometric device HBP-8000 (Osc-ABI), conducted in the vascular laboratories of Nara Medical University Hospital, Nara, Japan, and Dupuytren University Hospital, Limoges, France. The study protocol was approved by ethics committees of both sites and was carried out in accordance with the Declaration of Helsinki. The trial has been registered in the UMIN Clinical Trials Registry (CTR; UMIN000037436). Patients who were referred to the vascular laboratory for LEAD assessment and fulfilling all inclusion/exclusion criteria were recruited. The inclusion and exclusion criteria are summarised in Table 1. Informed consent was obtained from all enrolled subjects.

Measurement

All measurements were done following the rigorous measurement protocol recommended by the AHA.[4] Measurements were started after 10 minutes of rest in a supine position, in a quiet and adequately heated examination room, with no cigarette smoking or drinking of alcohol for at least two hours before examination. For each patient, 21 measurements were performed as follows: each patient had his/her four limbs systolic pressures measured first using the oscillometric device, but the purpose of the first measurement was to avoid recording high blood pressure caused by the white coat effect and therefore the value was not used. From the second measurement, there were two patterns of measurement order, pattern A or B (supplementary Table 1). The measurement began with the oscillometric method in pattern A, and the Doppler

method in pattern B. This alternate measurement order allowed the avoidance of any effect related to the order of measurements.

For the Dop-ABI, a similar cuff was used (aneroid sphygmomanometer with cuff, Model No. 513260; Spengler, Paris, France) in both sites, and the flow was detected by a hand-held 5 MHz continuous Doppler probe (Huntleigh Diagnostics [Cardiff, UK] and Hadeco ES-1000SPM [Kawasaki, Japan]). The cuffs were placed on the arm with the lower edge ≤ 1 inch above the antecubital fossa and on the lower calf with the lower edge ≤ 1 – 2 inches above the ankle's medial malleolus. Each Dop-ABI measurement involved two people. In order for an observer to remain blinded for the following measurement, the observer wrapped the cuffs, held a Doppler probe, and the other person (called "the reader") inflated/deflated a cuff. The reader pumped twice more after the disappearance of the Doppler sound so as to inflate the cuff beyond the systolic pressure and then slowly deflated it to identify the moment the Doppler sound re-appeared. Next, the observer sent a "Go" signal to observer 2 immediately after the reappearance of the Doppler sound. The reader monitored blood pressure and recorded the values. For all series of Dop-ABI measurements, the sequence was always as follows: right arm; right ankle; left ankle; and left arm. If the reader noted a difference in SBP between the arms of > 10 mmHg, he/she asked to the observer to repeat the right arm measurement,[4] and the second measure of the right arm was recorded. Dop-ABI was calculated according to the AHA statement: for the denominator, the highest SBP of both arms was recorded. For each ankle, the highest of the two ankle pressures (posterior tibial or dorsalis pedis) was used as the ipsilateral ABI numerator. For every lower extremity, the interobserver variability was the comparison between the first set of measurements from observer 1 and the only set of measurements from observer 2. Regarding intra-observer variability, the first and the second measurements by observer 1 were compared.

Osc-ABI measurement was performed using the HBP-8000 (OMRON HEALTHCARE Co., Ltd, Kyoto, Japan) equipped with four dedicated cuffs (Fig. 1). An ankle cuff installs a double cuff methodology in which one cuff compresses the tibial and peroneal arteries, and the other detects an oscillation. The observer performing Dop-ABI was blinded to the Osc-ABI results.

Statistical analysis

Normality distribution was always tested with the Shapiro–Wilk test. The mean ABI (both Doppler and oscillometric) were compared by the Student's paired *t* test. Assessment of the diagnostic capacities (sensitivity, specificity, accuracy, positive predictive value, negative predictive value) of the Osc-ABI to detect a low (≤ 0.90) Dop-ABI were determined as

appropriate. Analysis of concordance for diagnosing ABI ≤ 0.90 between both methods was performed using Cohen's kappa coefficient.

The intra- and-interobserver variability of measurements were first assessed by the determination of the intraclass correlation coefficient (ICC) of agreement for each method. In order to determine methods with the best reproducibility (the lowest variability), the 95% confidence interval (CI) of these ICCs were then compared. A second analysis of intra- and interobserver reproducibility was done with the Bland–Altman method. For each method, the number of measurements exceeding the 95% CI of the mean difference was calculated. Reproducibility was considered as acceptable when < 5% of measurements exceeded this interval.

RESULTS

A total of 120 participants (70 in Japan and 50 in France) were enrolled in the study. Two (1.7%) were excluded from the analysis because of incompressible artery (SBP > 250 mmHg when measured manually), leaving 118 subjects for inclusion in the analysis. The basic characteristics of the study participants are shown in Table 2. The results of the measurements by the two independent observers are presented in supplementary Table 2. The proportion of LEAD defined as ABI ≤ 0.90 with the Doppler and oscillometric method was, respectively, 42% and 39.5% at the first measurement performed by the first observer. For each observer, there were no statistically significant or clinical differences between the mean oscillometric and Doppler ABI in either limb.

The diagnostic performances of the Osc-ABI to detect Dop-ABI ≤ 0.90 are presented in Table 3. The accuracy (patients classified correctly by Osc-ABI in reference to Dop-ABI) was 94.1% for the first measurement of observer 1, 92% for observer 2, and 90.3% for the second measurement of observer 1. Analysis of concordance for diagnosing ABI ≤ 0.90 between both methods was excellent (kappa coefficient 0.80 – 0.88 with different observers). The intra- and interobserver reproducibility in each method were analysed by the ICC (Table 4). The intra-observer reproducibility of observer 1 between Dop-ABI and Osc-ABI was excellent, with an ICC of 0.94 (95% CI 0.91 – 0.96) (Table 5). The Bland–Altman plots were created to visualise the intra-observer difference between the both methods (Fig. 2) and the inter-/intra-observer difference for each method (Fig. 3). The paired mean difference between two methods was –0.01 (95% CI –0.19 – 0.18), 0.00 (95% CI –0.15 – 0.15), and 0.00 (95% CI –0.17 – 0.17). The paired mean difference between two observers was –0.01 (95% CI –0.17 – 0.16) with the Doppler method, and 0.00 (95% CI –0.14 – 0.15) with the oscillometric method.

DISCUSSION

The latest European Society of Cardiology and European Society for Vascular Surgery guidelines on LEAD[6] describe ABI measurement with Doppler, without any documentation of, or argument about, the oscillometric method. As those guidelines emphasised, training is necessary to obtain a reliable ABI value with the Doppler method. This is also in line with the 2012 AHA statements on ABI measurement.[3] This last document highlighted unmet needs requesting further research for easier and faster alternative methods for ABI measurement facilitating the use of ABI in primary care. This study provides an important contribution by proposing a valid alternative to the Doppler method, which is easier and faster to use. In this collaborative prospective validation study, ABI using a four cuff automated oscillometric device was compared with the Dop-ABI based on the methods in the AHA statements. Both inter- and intra-observer reproducibilities of the Dop-ABI were comparable to what have been reported so far.[12,23–25] As the key finding of this study, Osc-ABI presented excellent agreement with Dop-ABI, as well as high intra-/interobserver reproducibilities. In previous reports, the diagnostic abilities of Osc-ABI were not consistent.[3,10,11,14,15,26] The reported sensitivity and specificity ranged, respectively, from 34% to 94% and from 89% to 98% with Dop-ABI as the reference. Possible reasons for the inconsistencies between studies could have been owing to the different oscillometric devices used and the recruited population (LEAD patients/healthy volunteers). Some past studies evaluated oscillometric devices with a single cuff designed to measure brachial blood pressure,[27] rendering measurements at the ankle level uncertain as these devices have not been designed for and validated at the ankle level. Korno *et al*. evaluated CASMED 740, a single cuff device, and demonstrated that the sensitivity and specificity of the device for detecting Dop-ABI ≤ 0.90 were 71% and 92%, respectively, with an overall accuracy of 82%.[14] Kollias *et al*. described that Osc-ABI was highly correlated with Dop-ABI, with a sensitivity of 83% and a specificity of 97%.[10] Herraiz-Adillo *et al*. evaluated the OMRON-M3 oscillometric device (HEM-7200-E-Omron Healthcare, Kyoto, Japan) and found a sensitivity of 66.7%, a specificity of 96.8%.[13] Aboyans *et al*. reported that the interobserver reproducibility for Osc-ABI determined with a single cuff device (ProM; Spengler, Cachan, France) was poor.[12] The sensitivities and specificities evaluated by the two observers were 76% versus 58.3% and 96.4% versus 89.3%, respectively, and concluded that Osc-ABI was unreliable.

The oscillometric device evaluated in the present study is automated and designed to measure ABI from simultaneous blood pressure measurements of the four extremities. There have been several studies evaluating automated devices dedicated for ABI measurement. Richart *et al*. evaluated an earlier version of the automated oscillometric device in a general Flemish population sample versus the Doppler technique.[16] The difference in ABI between both

measurement methods was negligible. The intra-observer variability of repeat ABI measurement was even smaller on Osc-ABI measurement, which was possibly owing to simultaneous measurement of four extremities by the automated device. Ma *et al*. evaluated the device and demonstrated that the automated Osc-ABI was highly consistent with those by Dop-ABI, with a sensitivity and specificity of 94.5% and 98.3%, respectively.[15] In another study, the sensitivity and specificity of the automated oscillometric device were 90% and 85%, respectively, taking CT angiography as reference.[21] These high diagnostic properties reported by their automated oscillometric device are reinforced by the present, favourable results.

Another potential interest of oscillometric methods is that they may be more rapid and reproducible than the Doppler method by omitting additional procedures such as pulse palpation, the application of gel, signal viewing, and operational levels. It has been reported that the time needed for Dop-ABI was 9.0 – 16.9 minutes, and significantly longer than needed for Osc-ABI methods (4.0 – 8.6 minutes).[10,11,15,28] It was expected that the reproducibility of the Dop-ABI was lower than the Osc-ABI because of its sequential and multiple blood pressure measurements. However, contrary to what was predicted, the intra- and interobserver reproducibilities were comparable between both methods in the present study. Notably, the highly reproducible results with the Dop-ABI were obtained by skilled, professional observers and cannot be applicable to measurements conducted in primary care, as Dop-ABI is highly dependent on the level of experience of the examinors.[29] It is thought that because of its automated property, the oscillometric method would have more reproducible results than the Doppler method carried out by unskilled caregivers.

In a previous paper, there was a trend for ABI overestimation when using Osc-ABI for low ABI values,[10,12,13,25] which has not been found in the present study. Another problem reported with oscillometric measurement was higher rates of measurement errors (i.e., inability to provide any result),[4] particularly in the case of low ankle pressures, with rates of measurement errors reported from 1.6% to 12.7%.[10,13,19] Kollias *et al*. reported that the frequency of errors with the oscillometric method was higher in limbs with LEAD than in those without LEAD.[10] In the current study, in which 45% of participants had an ABI ≤ 0.90, measurement errors were only seen in two patients. However, this result should be interpreted with caution because the current study did not enrol patients with CLTI who had extremely impaired arterial perfusion with very low ankle blood pressures. Patients with CLTI are better evaluated with other diagnostic modalities, such as transcutaneous oximetry, skin perfusion pressure, or angiography. The aim of this study was to validate this oscillometric device for LEAD screening in general practice and population settings, where patients with CLTI are rare, and where a measurement “error message” (i.e., the device is unable to provide a numerical result) could still be an alert signal requesting

further evaluation in a vascular laboratory. In line with this, it should be emphasised that this oscillometric device inflated the ankles cuffs up to 250 mmHg, and the lower limit of SBP detection is set at 40 mmHg. Also, both the Doppler and oscillometric methods may give unreliable results in case of ankle oedema. Hence, patients with severe CLTI, and those at high risk of medial calcinosis (i.e., elderly patients with longstanding diabetes and/or dialysis), are not good candidates for ABI measurement, especially with the oscillometric method.

The findings of this study should be interpreted in light of some limitations. Firstly, the study mainly recruited Japanese and Caucasian individuals. The applicability of the results to the other ethnic groups needs to be evaluated, although ethnic specific limitations are not foreseen. Secondly, the good results obtained with this oscillometric device cannot be extrapolated to other oscillometric devices. The dedicated device using a double cuff methodology should be compared with conventional oscillometric devices with single cuff. Thirdly, oedematous limbs make it difficult to detect the vibrations by oscilloscopes, as is the case with Dopper measurements.

Conclusion

A high diagnostic accuracy was obtained with Osc-ABI, comparable to Dop-ABI, with high reproducibility. The automated oscillometric device could potentially be implemented, in general, and cardiovascular practices, as well as health screening centres as a first line test.

CONFLICT OF INTEREST

TH is an employee of Omron Healthcare Co., Ltd. All other authors declare no association with any individual, company, or organisation having a vested interest in the subject mentioned in this article.

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Table 1. Inclusion and exclusion criteria for patients with lower extremity artery disease (LEAD) and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method.	
Inclusion criteria	Patients suspect for LEAD because of intermittent claudication or more atypical pain when walking
	Asymptomatic individuals with ≥ 2 cardiovascular risk factors of the following:
	Men ≥ 60 y or women ≥ 65 y
	Regular cigarette smoking (current or in the past) ≥ 10 y, treated type 2 DM ≥ 5 y or type 1 DM ≥ 20 y, treated hypertension or SBP ≥ 140 mmHg
	High blood cholesterol (either total cholesterol ≥ 240 mg/dL or LDL-C ≥ 160 mg/dL) or treated by statins or other lipid lowering agents
	Documented history of CAD (PCI or CABG or previous MI, or documented by coronary angiography)
	Documented history of ischaemic stroke
	Patients revascularised for LEAD
Exclusion criteria	Cardiac arrhythmia: atrial fibrillation, atrial flutter, frequent supra- and ventricular ectopic beats
	Patients under dialysis
	Ankle pressure > 250 mmHg measured by any of the two methods.
	Patients with ischaemic gangrene or rest pain

DM = diabetes mellitus; SBP = systolic blood pressure; LDL-C = low density lipoprotein cholesterol; CAD = coronary artery disease; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting; MI = myocardial infarction.

Table 2. Baseline characteristics of 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method.	
Variables	**Patients (*n* = 118)**
Age — years	73.0 ± 9.0
Female	30 (25.4)
Height — cm	164 ± 10.0
Weight — kg	68.5 ± 18.2
BMI — kg/m²	25.1 ± 5.1
Smoking history	54 (45.8)
CAD	31 (26.3)
CVD	17 (14.4)
Hypertension	82 (69.5)
Dyslipidaemia	71 (60.2)
Diabetes	60 (50.8)
CKD	6 (5.1)

Data are presented as *n* (%) or mean ± standard deviation. BMI = body mass index; CAD = coronary artery disease; CVD = cerebrovascular disease; CKD = chronic kidney disease.

Table 3. Diagnostic performances (95% confidence interval [CI]) of oscillometric ankle brachial index (ABI) measurement device to detect ABI ≤ 0.90 (both legs) measured with the Doppler method by two observers in 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors.

	Observer 1 First time Accuracy (95% CI)	Observer 2 Accuracy (95% CI)	Observer 1 Second time Accuracy (95% CI)
Sensitivity — %	89.1 (81.3–94.4)	89.0 (81.2–94.4)	89.0 (81.2–94.4)
Specificity — %	94.4 (89.2–97.6)	94.2 (88.9–97.5)	91.3 (85.3–95.4)
Accuracy — %	94.1 (91.1–97.1)	92.0 (88.6–95.5)	90.3 (86.6–94.1)
PPV — %	91.8 (84.5–96.4)	91.75 (84.3–96.4)	88.1 (80.2–93.7)
NPV — %	92.4 (86.7–96.2)	92.2 (86.5–96.0)	92 (86.1–95.9)
Kappa*	0.88 (0.82–0.94)	0.84 (0.77–0.91)	0.80 (0.73–0.88)

PPV = positive predictive value; NPV = negative predictive value. *Oscillometric ABI detecting an ABI ≤ 0.90 (both legs) vs Doppler.

Table 4. Inter- and intra-observer reproducibility in Doppler and oscillometric ankle brachial indexes (ABI) of 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method.

	Interobserver ICC (95% CI)	Intra-observer ICC (95% CI)
Doppler ABI	0.95 (0.92–0.96)	0.94 (0.91–0.95)
Oscillometric ABI	0.96 (0.94–0.97)	0.95 (0.93–0.97)

ICC = intraclass correlation coefficient, CI = confidence interval.

Table 5. Intra-observer reproducibility between Doppler and oscillometric ankle brachial indexes (ABI) of 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method.

	Intra-observer 1 First time ICC (95% CI)	Intra-bserver 2 ICC (95% CI)	Intra-observer 1 2nd time ICC (95% CI)
Oscillometric vs Doppler ABI	0.94 (0.91–0.96)	0.96 (0.94–0.97)	0.93 (0.91–0.95)

ICC = intraclass correlation coefficient; CI = confidence interval.

FIGURE LEGENDS

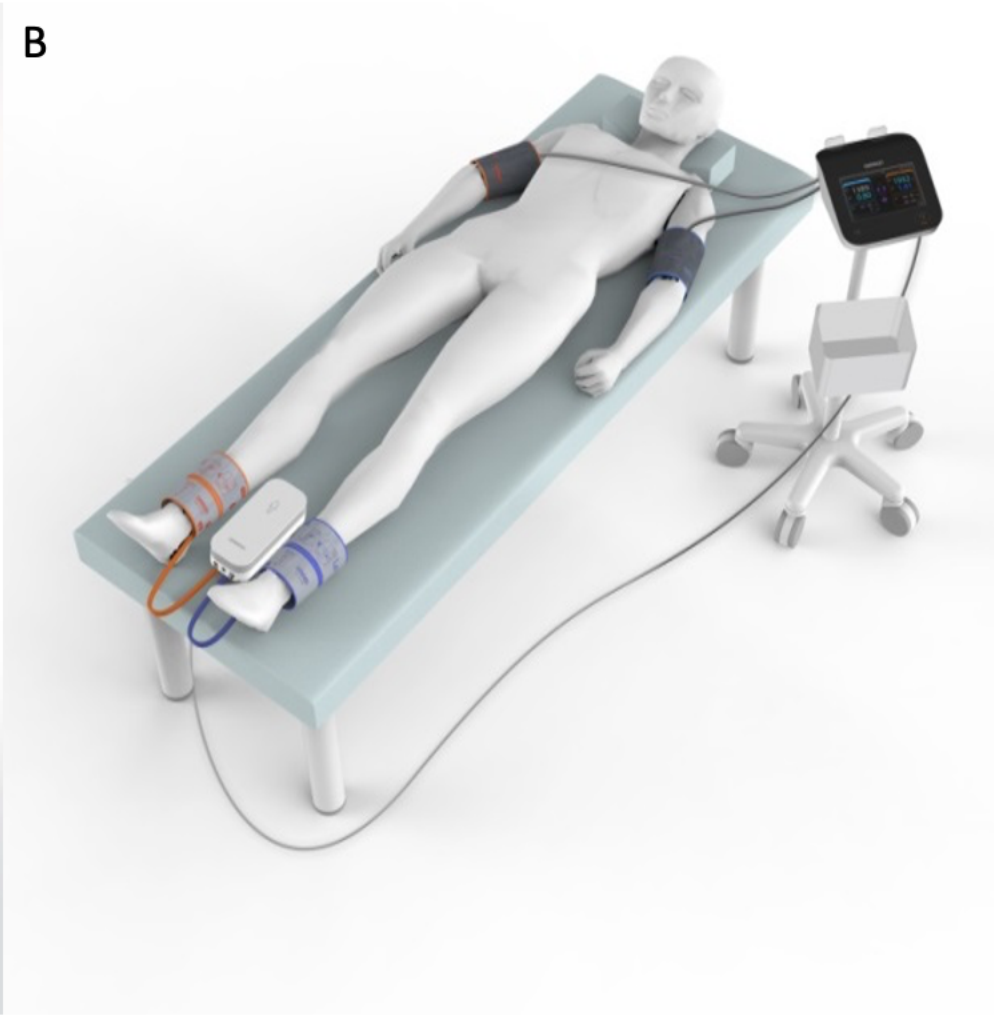
Figure 1. (A) Automated measurement of ankle brachial index by dedicated oscillometric device HBP-8000 with four measurement cuffs (Omron Healthcare Co., Ltd, Kyoto, Japan). (B) Four measurement cuffs equipped with the device enable blood pressure measurement for four extremities simultaneously at one time.

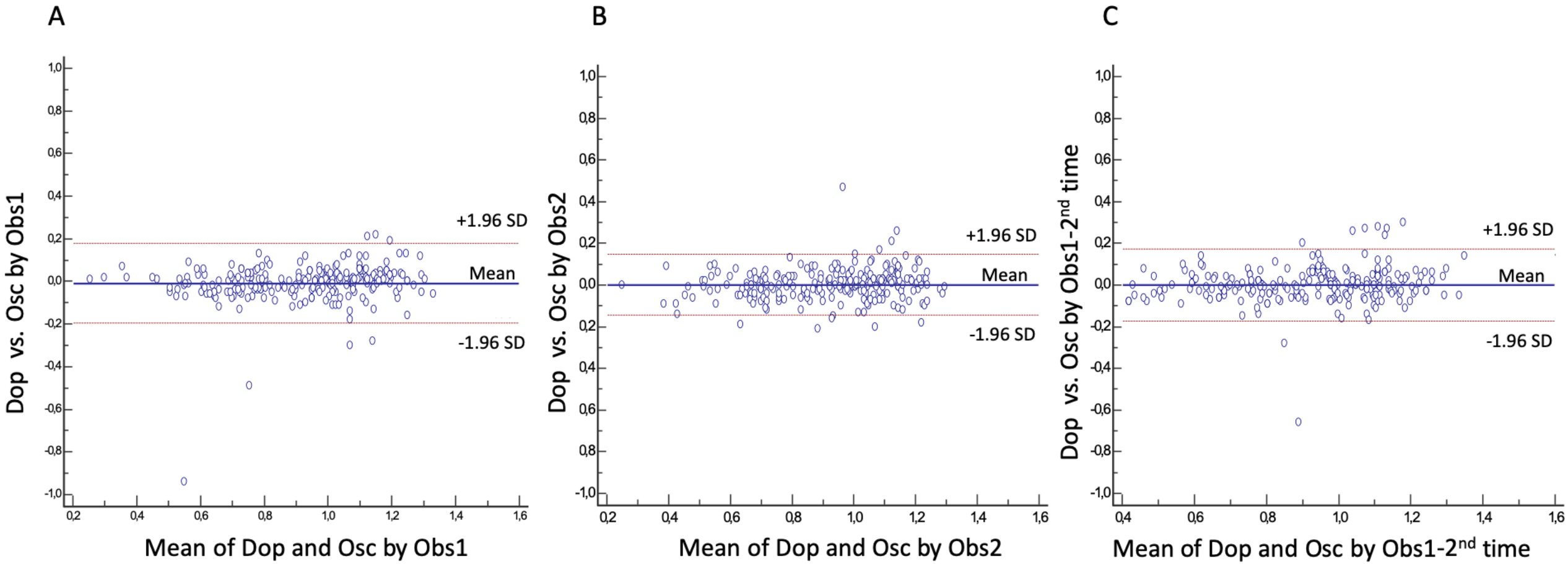
Figure 2. Bland–Altman plots for intra-observer differences of (A) observer 1, (B) 2, and (C) 1 on second time between oscillometric (Osc) and Doppler (Dop) methods of ankle brachial index measurement in 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method. The blue lines and the dashed lines show the mean difference and 95% confidence interval. SD = standard deviation.

Figure 3. Bland–Altman plots for the interobserver differences of observer 1 and 2 using the (A) Doppler method and the (B) oscillometric method for ankle brachial index measurement in 118 patients with lower extremity artery disease and ≥ 2 cardiovascular risk factors to validate the diagnostic ability and reproducibility of a four cuff automated oscillometric device vs the Doppler method. The blue lines and the dashed lines show the mean difference and 95% confidence interval. SD = standard deviation.

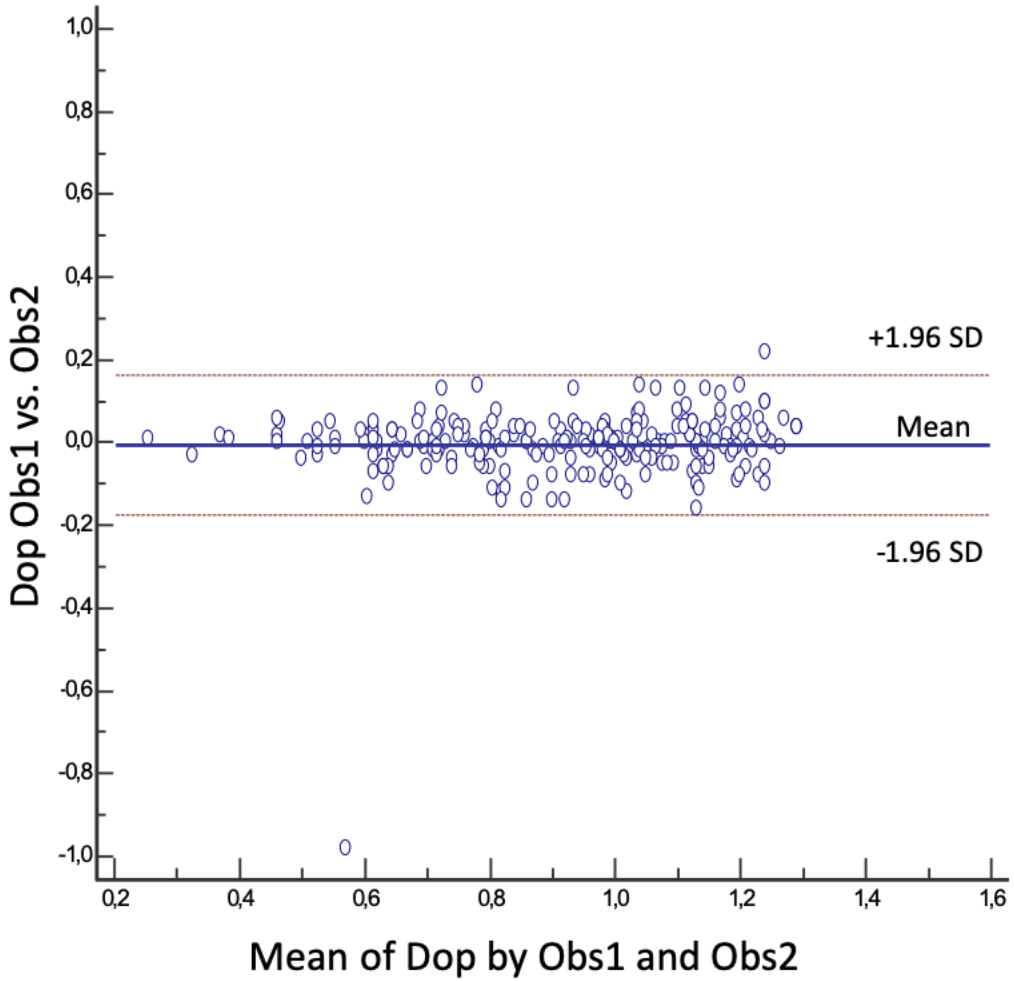
A

B




A
B
C
Dop vs. Osc by Obs1
Dop vs. Osc by Obs2
Dop vs. Osc by Obs1-2nd time
+1.96 SD
Mean
-1.96 SD
Mean of Dop and Osc by Obs1
Mean of Dop and Osc by Obs2
Mean of Dop and Osc by Obs1-2nd time

A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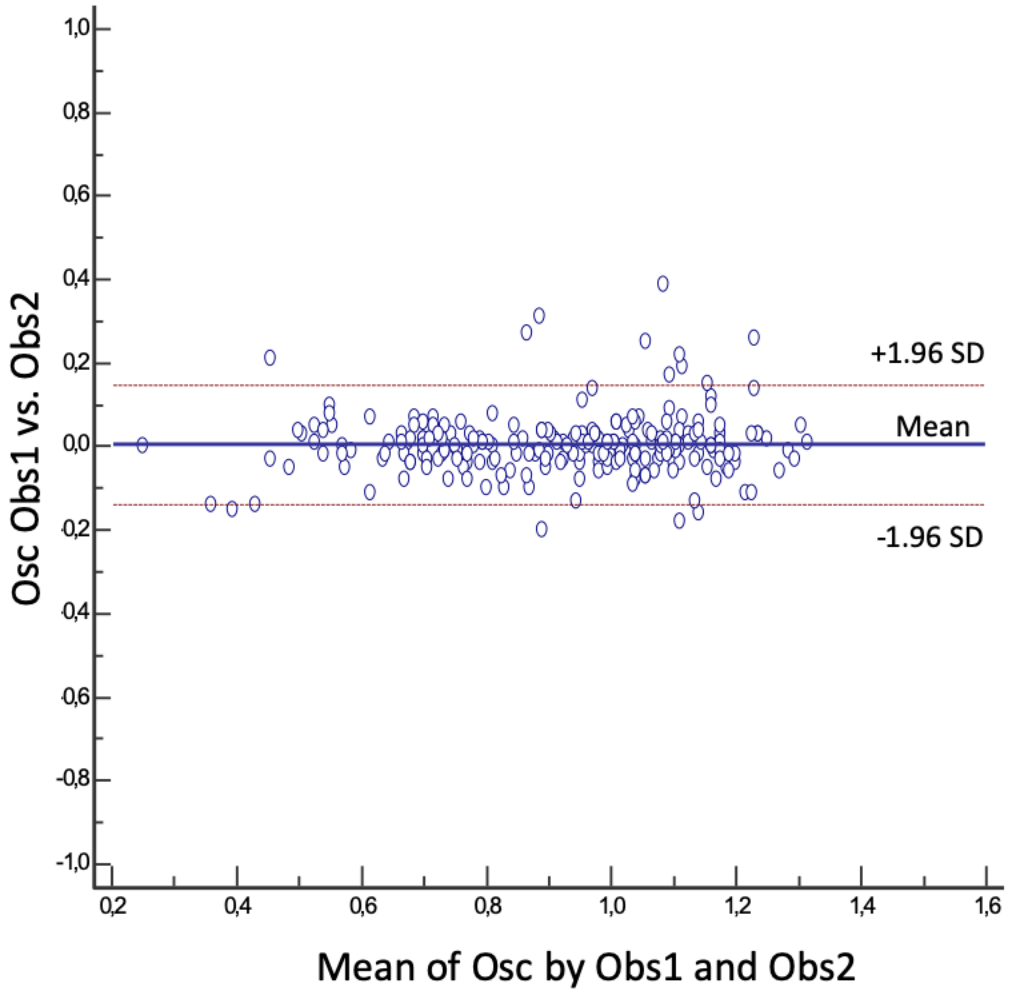
+1.96 SD
Mean
-1.96 SD
Dop Obs1 vs. Obs2
Mean of Dop by Obs1 and Obs2

B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1,4
1,6
+1.96 SD
Mean
-1.96 SD
Osc Obs1 vs. Obs2
Mean of Osc by Obs1 and Obs2