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

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1 **Short title:** Ankle Brachial Index by Multicuff Oscillometric Device

2

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

5

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18

19 **WHAT THIS PAPER ADDS**

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

27

28 **Objective:** Ankle brachial index (ABI) is widely used for the diagnosis of lower extremity artery
29 disease (LEAD). The purpose of this prospective study was to validate the diagnostic ability and
30 reproducibility of a four cuff automated oscillometric device versus the Doppler method.

31 **Methods:** Patients with suspected LEAD or asymptomatic individuals at risk because of the
32 presence two or more cardiovascular risk factors were enrolled. For each patient, Doppler and
33 oscillometric ABI measurements were repeated by two observers to address intra- and
34 interobserver reproducibility.

35 **Results:** In total, 118 patients were evaluated. The prevalence of Doppler ABI (Dop-ABI) ≤ 0.90
36 was 45.8%. Taking the Dop-ABI as the reference, the sensitivity, specificity, accuracy, positive
37 predictive value, and negative predictive value of oscillometric ABI (Osc-ABI) during the first
38 measurement by the first observer were 89.1%, 94.4%, 94.1%, 91.8%, and 92.4%, respectively.
39 The concordance for diagnosing ABI ≤ 0.90 between both methods was excellent (kappa
40 coefficients ranging from 0.80 to 0.88 with different observers). Intra-observer reproducibility
41 assessed by intraclass correlation (ICC) between both methods were 0.94 for observer 1 and 0.96
42 for observer 2. The intra-observer reproducibility using the same method was also excellent (ICC
43 0.94, 95% confidence interval [CI] 0.91 – 0.95) for Dop-ABI and 0.95 (95% CI 0.93 – 0.97) for
44 Osc-ABI). The ICC for interobserver reproducibility using the same method was 0.95 (95% CI
45 0.92 – 0.96) for Dop-ABI and 0.96 (95% CI 0.94 – 0.97) for Osc-ABI.

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

49
50 **Keywords:** Ankle brachial index, Atherosclerosis, Peripheral arterial disease

51 52 INTRODUCTION

53 Lower extremity artery disease (LEAD) is a common atherosclerotic disease.¹ Accurate
54 screening and timely diagnosis of LEAD can help to identify patients with a high risk of
55 cardiovascular events or mortality.² The ankle brachial index (ABI) is a non-invasive, simple
56 method to diagnose either symptomatic or asymptomatic LEAD, and can serve as a prognostic
57 marker for cardiovascular events and functional impairment.³⁻⁶ The standard method for the
58 measurement of ABI requires a Doppler device, with sequential systolic blood pressure (SBP)
59 measurement of the four limbs.³ However, this method is time consuming, which was regarded
60 as one of its disadvantages in United States Prevention Service Task Force statement for the
61 screening of LEAD.² It also requires trained personnel. All these are barriers to its widespread
62 use in primary care.⁷⁻⁹ The sensitivity and specificity of the Doppler method are reported to be
63 between 17% –100% and 80% – 100%, respectively,⁷⁻⁹ and the diagnostic performance of the
64 ABI varies depending on the population studied (ABI is of limited value in patients with chronic
65 limb threatening ischaemia [CLTI]), the cutoff threshold, and the measurement skills. In the
66 2012 American Heart Association (AHA) statements, the need for easier and faster alternative
67 methods for ABI measurement was highlighted.³ As an alternative, an oscillometric method
68 using an automatic blood pressure device has gained strong attention as it is a simple, fully
69 automatic test, that can theoretically minimise observer biases and eliminate the need for special

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

83

84 **MATERIALS AND METHODS**

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

94

95 ***Measurement***

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

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

107 For the Dop-ABI, a similar cuff was used (aneroid sphygmomanometer with cuff, Model No.
108 513260; Spengler, Paris, France) in both sites, and the flow was detected by a hand-held 5 MHz
109 continuous Doppler probe (Huntleigh Diagnostics [Cardiff, UK] and Hadeco ES-1000SPM
110 [Kawasaki, Japan]). The cuffs were placed on the arm with the lower edge ≤ 1 inch above the
111 antecubital fossa and on the lower calf with the lower edge $\leq 1 - 2$ inches above the ankle's
112 medial malleolus. Each Dop-ABI measurement involved two people. In order for an observer to
113 remain blinded for the following measurement, the observer wrapped the cuffs, held a Doppler
114 probe, and the other person (called "the reader") inflated/deflated a cuff. The reader pumped
115 twice more after the disappearance of the Doppler sound so as to inflate the cuff beyond the
116 systolic pressure and then slowly deflated it to identify the moment the Doppler sound
117 re-appeared. Next, the observer sent a "Go" signal to observer 2 immediately after the
118 reappearance of the Doppler sound. The reader monitored blood pressure and recorded the
119 values. For all series of Dop-ABI measurements, the sequence was always as follows: right arm;
120 right ankle; left ankle; and left arm. If the reader noted a difference in SBP between the arms of
121 > 10 mmHg, he/she asked to the observer to repeat the right arm measurement,⁴ and the second
122 measure of the right arm was recorded. Dop-ABI was calculated according to the AHA
123 statement: for the denominator, the highest SBP of both arms was recorded. For each ankle, the
124 highest of the two ankle pressures (posterior tibial or dorsalis pedis) was used as the ipsilateral
125 ABI numerator. For every lower extremity, the interobserver variability was the comparison
126 between the first set of measurements from observer 1 and the only set of measurements from
127 observer 2. Regarding intra-observer variability, the first and the second measurements by
128 observer 1 were compared.

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

133

134 ***Statistical analysis***

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

139 appropriate. Analysis of concordance for diagnosing $ABI \leq 0.90$ between both methods was
140 performed using Cohen's kappa coefficient.

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

149

150 RESULTS

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

160 The diagnostic performances of the Osc-ABI to detect Dop-ABI ≤ 0.90 are presented in
161 Table 3. The accuracy (patients classified correctly by Osc-ABI in reference to Dop-ABI) was
162 94.1% for the first measurement of observer 1, 92% for observer 2, and 90.3% for the second
163 measurement of observer 1. Analysis of concordance for diagnosing $ABI \leq 0.90$ between both
164 methods was excellent (kappa coefficient 0.80 – 0.88 with different observers). The intra- and
165 interobserver reproducibility in each method were analysed by the ICC (Table 4). The
166 intra-observer reproducibility of observer 1 between Dop-ABI and Osc-ABI was excellent, with
167 an ICC of 0.94 (95% CI 0.91 – 0.96) (Table 5). The Bland–Altman plots were created to
168 visualise the intra-observer difference between the both methods (Fig. 2) and the
169 inter-/intra-observer difference for each method (Fig. 3). The paired mean difference between
170 two methods was -0.01 (95% CI $-0.19 - 0.18$), 0.00 (95% CI $-0.15 - 0.15$), and 0.00 (95% CI
171 $0.17 - 0.17$). The paired mean difference between two observers was -0.01 (95% CI $-0.17 -$
172 0.16) with the Doppler method, and 0.00 (95% CI $-0.14 - 0.15$) with the oscillometric method.

173

174 **DISCUSSION**

175 The latest European Society of Cardiology and European Society for Vascular Surgery
176 guidelines on LEAD⁶ describe ABI measurement with Doppler, without any documentation of,
177 or argument about, the oscillometric method. As those guidelines emphasised, training is
178 necessary to obtain a reliable ABI value with the Doppler method. This is also in line with the
179 2012 AHA statements on ABI measurement.³ This last document highlighted unmet needs
180 requesting further research for easier and faster alternative methods for ABI measurement
181 facilitating the use of ABI in primary care. This study provides an important contribution by
182 proposing a valid alternative to the Doppler method, which is easier and faster to use. In this
183 collaborative prospective validation study, ABI using a four cuff automated oscillometric device
184 was compared with the Dop-ABI based on the methods in the AHA statements. Both inter- and
185 intra-observer reproducibilities of the Dop-ABI were comparable to what have been reported so
186 far.^{12,23-25} As the key finding of this study, Osc-ABI presented excellent agreement with
187 Dop-ABI, as well as high intra-/interobserver reproducibilities. In previous reports, the
188 diagnostic abilities of Osc-ABI were not consistent.^{3,10,11,14,15,26} The reported sensitivity and
189 specificity ranged, respectively, from 34% to 94% and from 89% to 98% with Dop-ABI as the
190 reference. Possible reasons for the inconsistencies between studies could have been owing to the
191 different oscillometric devices used and the recruited population (LEAD patients/healthy
192 volunteers). Some past studies evaluated oscillometric devices with a single cuff designed to
193 measure brachial blood pressure,²⁷ rendering measurements at the ankle level uncertain as these
194 devices have not been designed for and validated at the ankle level. Korno *et al.* evaluated
195 CASMED 740, a single cuff device, and demonstrated that the sensitivity and specificity of the
196 device for detecting Dop-ABI ≤ 0.90 were 71% and 92%, respectively, with an overall accuracy
197 of 82%.¹⁴ Kollias *et al.* described that Osc-ABI was highly correlated with Dop-ABI, with a
198 sensitivity of 83% and a specificity of 97%.¹⁰ Herraiz-Adillo *et al.* evaluated the OMRON-M3
199 oscillometric device (HEM-7200-E-Omron Healthcare, Kyoto, Japan) and found a sensitivity of
200 66.7%, a specificity of 96.8%.¹³ Aboyans *et al.* reported that the interobserver reproducibility for
201 Osc-ABI determined with a single cuff device (ProM; Spengler, Cachan, France) was poor.¹²
202 The sensitivities and specificities evaluated by the two observers were 76% versus 58.3% and
203 96.4% versus 89.3%, respectively, and concluded that Osc-ABI was unreliable.

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

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

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

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

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

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

258

259 *Conclusion*

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

263

264 **CONFLICT OF INTEREST**

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

268

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271 unrestricted and the investigators were totally free and independent to interpret and present the
272 results.

273

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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
	<i>Asymptomatic individuals with ≥ 2 cardiovascular risk factors of the following:</i>
	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

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

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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 (<i>n</i> = 118)
Age — years	73.0 \pm 9.0
Female	30 (25.4)
Height — cm	164 \pm 10.0
Weight — kg	68.5 \pm 18.2
BMI — kg/m ²	25.1 \pm 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)

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

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

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

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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)

407 ICC = intraclass correlation coefficient, CI = confidence interval.

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Table 5. Intra-observer reproducibility between Doppler and oscillometric ankle brachial indexes (ABI) of 118 patients with lower extremity artery disease and \geq 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-observer 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)

433 ICC = intraclass correlation coefficient; CI = confidence interval.

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458 **FIGURE LEGENDS**

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

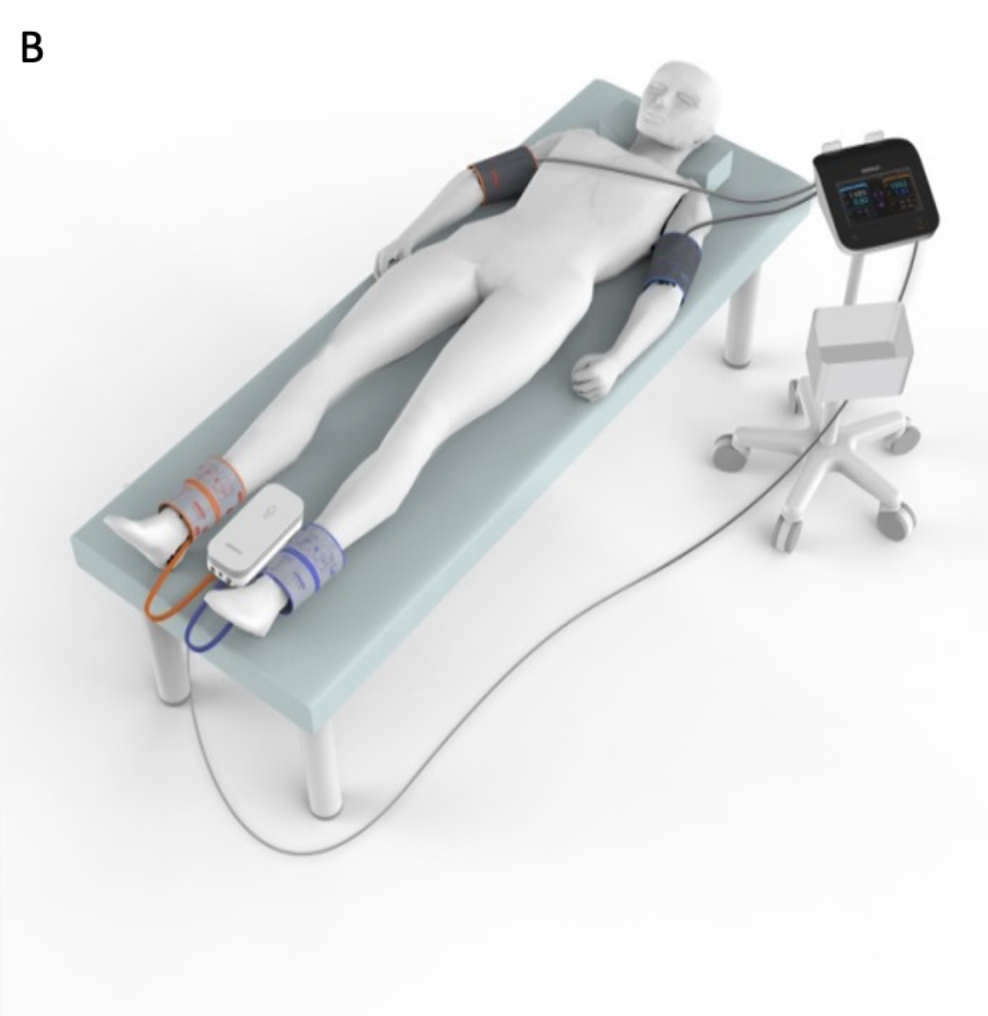
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464 **Figure 2.** Bland–Altman plots for intra-observer differences of (A) observer 1, (B) 2, and (C) 1
465 on second time between oscillometric (Osc) and Doppler (Dop) methods of ankle brachial index
466 measurement in 118 patients with lower extremity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

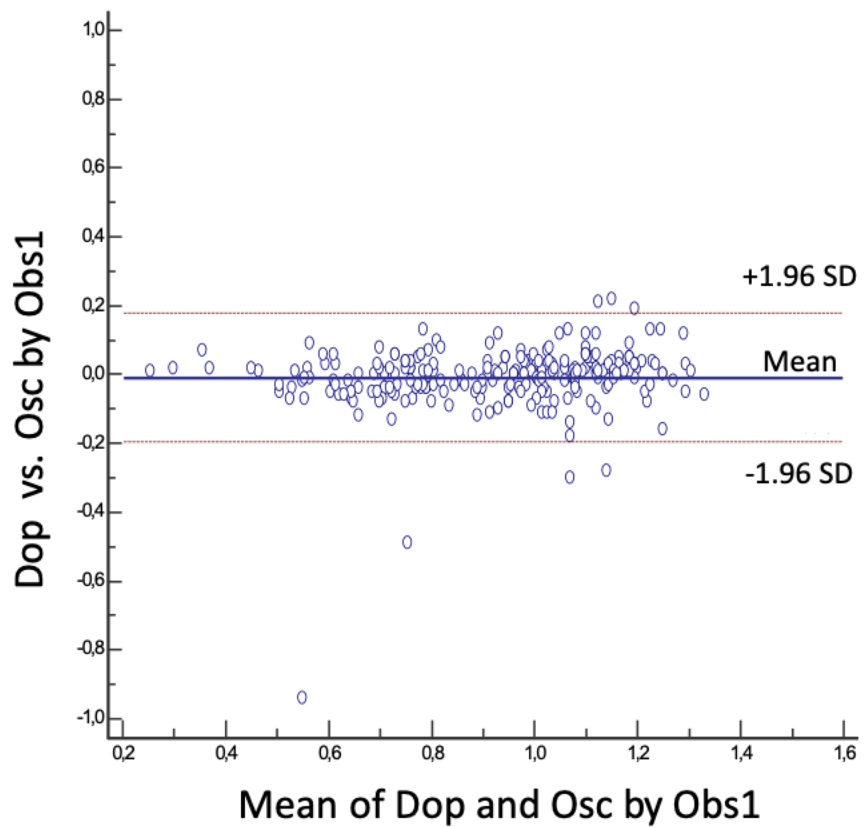
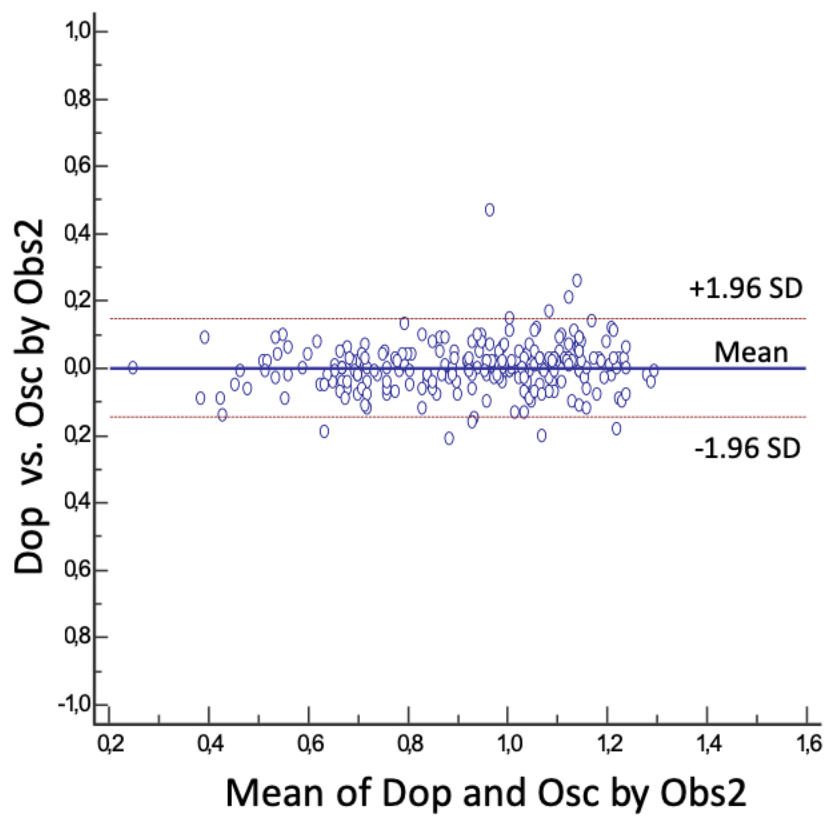
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471 **Figure 3.** Bland–Altman plots for the interobserver differences of observer 1 and 2 using the (A)
472 Doppler method and the (B) oscillometric method for ankle brachial index measurement in 118
473 patients with lower extremity artery disease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

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