

# Proficiency of medical students at obtaining pressure measurement readings using Automated ankle and toe measuring devices for diagnosis of lower extremity peripheral artery disease

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- 1 Title: Proficiency of medical students at obtaining pressure measurement readings using
- 2 Automated ankle and toe measuring devices for diagnosis of lower extremity peripheral artery
- 3 disease.
- 4
- 5 Short Title: Medical students and automated pressure devices
- 6

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- 28 ABSTRACT:
- 29

30 OBJECTIVE: Pressure measurement is a key component in the diagnosis of lower extremity 31 peripheral artery disease (PAD) but is technically challenging and time-consuming for non-32 vascular specialists, thus hindering its wider implementation. The aim of this study was to 33 assess the proficiency of students at obtaining satisfactory ankle or toe pressure readings for 34 PAD diagnosis using two automated devices.

35 METHODS: Medical students followed a training session after which they performed ankle 36 and toe pressure measurements to calculate the ankle-brachial index (ABI) using the MESI 37 ABP MD® device, and the toe-brachial index (TBI) using the SYSTOE® device. Blinded 38 vascular specialists took the same measurements. Use of the automated devices was 39 considered satisfactory when a valid reading was measured in as few attempts as possible. A 40 comparison was made of each student's proficiency at performing valid ankle and toe 41 pressure measurements. The secondary objective was to compare the readings taken by the 42 vascular specialists with those of the students.

43 RESULTS: Forty-three medical students were included. Mean number of attempts was 1.23 44 +/- 0.48 with the MESI ABP MD<sup>®</sup> device and 1.44 +/- 0.55 with the SYSTOE<sup>®</sup> device (p =45 0.04). There was no statistically significant difference between ABI readings taken by the students and those taken by the vascular specialists, 1.17 [0.90; 1.39] versus 1.18 [0.86; 1.39] 46 p = 0.33, contrary to TBI readings 0.70 [0.22; 1.74] versus 0.72[0.23; 1.16] (p = 0.03). 47 48 Measurement duration for the students and vascular specialists was 3.75 min±1.12 and 2.26 49 min  $\pm 0.82$  (p < 0.01) with the MESI ABP MD® device and 4.30 min  $\pm 1.23$  and 3.33 min  $\pm 1.49$  (p = 0.03) with the SYSTOE® device. Correlation coefficients between the students 50 51 and the vascular specialists were 0.56 and 0.34 with the MESI ABP MD® and SYSTOE® 52 devices (p < 0.05).

53 CONCLUSION: After a brief theoretical training session, the medical students were better at 54 taking ankle pressure measurements than toe pressure measurements with an automated 55 device for the purposes of PAD diagnosis. It would be of value to assess the advantages of 56 these automated devices in primary care practice in future research.

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#### 59 INTRODUCTION

Lower extremity peripheral artery disease (PAD) is a common medical condition affecting almost 202 million people worldwide(1). The European Society of Cardiology (ESC) and the American Heart Association (AHA) recommend ankle-brachial index (ABI) pressure measurement as a first-line non-invasive examination technique to investigate and establish diagnosis of PAD(2,3).

Although pressure measurement plays a major role in establishing diagnosis of PAD, little
research has focused on how this measurement technique is taught(4) and the knowledge of
French medical students on this subject leaves much to be desired(5,6).

Wider implementation of this technique however is hampered, especially among non-vascular physicians, by its high requirements in terms of technical and learning skills. A previous study revealed that even after following a practical training course, only 11 of 20 students succeeded in measuring systolic pressure and even then had lost their proficiency six months later through lack of practice in the intervening period(7,8).

In terms of screening, follow-up and overall coordination primary care physicians are key players in the management of PAD, which represents a serious public health concern with regard to morbidity and mortality rates and financial impact(9,10). And yet wider implementation of ABI measurement in primary care settings is severely hindered by timerestricted primary care consultations, insufficient clinical criteria for the diagnosis of PAD(11), and the technical and practical skills required to ensure reliable continuous-wave Doppler readings.

Several automated methods for the detection of PAD have been discussed(12), with reference to certain factors such as diagnostic thresholds or particular populations (for example patients with diabetes) that are liable to affect their validity(13,14). These methods would, however, make it much quicker and easier for non-specialists to measure systolic pressure and would open up new prospects for wider implementation of screening for PAD. This is especially true given that the training methods for these techniques are potentially far simpler than those of previously validated systolic pressure techniques.

Moreover, medical students as budding physicians are an ideal population to target for greater awareness of ABI measurement and its training programs(15). On another point, training resources for these automated methods have yet to be investigated. 90 The main aim of the present study was to assess the proficiency of medical students at 91 obtaining satisfactory pressure readings (i.e. valid reading obtained in as few attempts as 92 possible) for diagnosis of PAD using two automated devices: the MESI ABP MD® and the 93 SYSTOE®. Secondary aims were to assess i) measurement duration, and ii) concordance of 94 readings taken by the vascular specialists with those taken by the students with the various 95 devices

#### 97 MATERIALS AND METHODS

#### 98 Study Design

99 This was a single center controlled prospective study conducted at the Vascular Medicine 100 Unit of the university hospital of Rennes in France from December 2018 to February 2019. It 101 was approved by the ethics committee of Rennes Hospital (no. 16.150). Second to 6th year 102 medical students with no prior training or knowledge of the devices involved were invited by 103 electronic mail to participate in the trial having first provided written consent. Patients with 104 scheduled Doppler ultrasound appointments were included and oral consent was provided. 105 Patients with wounds were excluded.

#### 106 Initial training session

107 The initial hour-long training session, dispensed by a vascular specialist, was composed of an 108 introduction to the pathophysiology of PAD, an update on PAD guidelines and introduction to 109 standard Doppler ABI measurement. The students then viewed a video presentation of how to 110 use each device. The MESI ABP MD® simultaneously records systolic ankle and brachial 111 pressures using three color-coded cuffs (one on the arm and the other two on the ankles with 112 the tubes pointing upwards)(16). Systolic pressure is calculated within minutes and does not 113 require pre-measurement resting. The SYSTOE® employs photopletysmography to record 114 systolic pressure in the hallux (TBI) after first taking the temperature of the toe with an infra-115 red thermometer (16,17). Indeed, when toe temperature is low, the measured pressure may be 116 falsely low(18). A cuff is placed at the base of the toe with the tube pointing downwards. The 117 sensor is positioned at the top of the toe by means of an adhesive pad and pressure is applied 118 to the sensor by the operator during deflation then released. The diagnostic threshold adopted 119 for PAD was 0.70(19) regarding TBI and 0.90 regarding ABI(20). In the absence of any 120 research validating the SYSTOE® threshold, a value of 0.70 was adopted.

121 Real-life patient assessment:

Each student was called individually to measure patient's pressure with both devices withinone week to one month of the initial training session.

The procedure consisted of obtaining one pressure reading with the MESI ABP MD® and another with the SYSTOE® from each foot. Brief written instructions were provided to facilitate the smooth running of the procedure. The stopwatch used to time measurement acquisition was started once the first cuff had been put in place. The SYSTOE® was used in semi-automatic mode (in view of the fact that automatic mode requires applying two cuffs and this can be problematic depending on the specific features of certain toes) and the student was responsible for determining the inflection point of the curve. Arterial pressure was measured by an automatic device(21).

A blinded vascular specialist present in the unit then took measurements following the same procedure and concluded by taking Doppler pressure measurements in line with standard procedure (i.e. right brachial artery, right posterior tibial artery, right anterior tibial artery, left posterior tibial artery, left anterior tibial artery, left brachial artery and right brachial artery)(20,22). The highest brachial and ankle pressure values were used to calculate the ABI.

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138 Patient characteristics:

During the 10 minute pre-measurement rest period, the following information was gathered:
cardiovascular risk factors, previous history of kidney failure or cardiovascular disease,
anticoagulant treatment (vitamin K antagonists or direct oral anticoagulants), weight and
height(23).

143

144 Statistical Analysis:

Descriptive analysis was used to investigate each variable collected. Quantitative variables 145 146 were expressed as mean, standard deviation, median, and maximal and minimal values. 147 Qualitative variables were expressed as counts and percentages. Systolic pressure readings 148 from the various devices and time taken by each operator were compared using the Student's 149 t-test for paired data that followed a Gaussian distribution and the Wilcoxon signed-rank test 150 for paired data where this was the opposite. A linear mixed effects model was used to assess 151 time spent on each device and operator status. Measurement concordance was summarized 152 using the Pearson correlation coefficient, the Bland-Altman plot(24) and Lin's concordance 153 correlation coefficient(25). The latter simultaneously calculates correlation with and deviation 154 from perfect agreement between the two measuring devices. Statistical analysis was 155 conducted using R software (version 3.5.3) and the Tidyverse packages (R core Team 2019, 156 Hadley Wickham 2017). A p-value of p < 0.05 was regarded as statistically significant.

157

158 RESULTS

Forty-three medical students participated in measuring systolic pressure (37.2% 2nd year
students, 20.9% 3rd year students, 16.3% 4th year students, 7.0% 5th year students and 18.6%
6th year students).

162 Forty-three patients (67% male) were included. Their characteristics are shown in Table 1.

163 Prevalence of lower extremity PAD in the 43 subjects as measured by the MESI ABP MD<sup>®</sup>,

164 the SYSTOE® and Doppler ultrasound was 4.6 %, 55.0 % et 11.0% respectively (according

165 to vascular specialist data).

166

167 Proficiency of students at obtaining satisfactory ABI and TBI readings:

Mean number of attempts was  $1.23 \pm 0.48$  regarding the MESI ABP MD® and  $1.44 \pm 0.55$  (p = 0.04) regarding the SYSTOE® (Figure 1). Forty students (93%) used the MESI ABP MD® correctly and 31 (72%) used the SYSTOE® correctly (p = 0.28). Errors in relation to the MESI ABP MD® occurred due to incorrect placement (such as cuff tubes pointing in the wrong direction, incorrect cuff placement or incorrect cuff size). As for the SYSTOE® device, problems essentially arose from the positioning of the sensor and cuffs applied back to front.

Ninety-three percent of the students took toe temperature before using the SYSTOE®. The
MESI ABP MD® screen displayed a total of 8 readings indicating PAD and 2 messages
indicating inflation error (error E2).

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180 Comparison of measurement duration on each device:

The different duration of the measurements are presented in figure 2. As determined by a multiple regression model, MESI ABP MD® measurement took 3.7 times less time than Doppler ultrasound (-3.713+/-0.170) and SYSTOE® measurement took 2.9 times less time (-2.913+/-0.171), demonstrating statistical significance. The vascular specialists on the whole took 1.2 times less time than the students irrespective of the device used (-1.238+/-0.130).

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187 Comparison of systolic pressure readings

No statistically significant difference was found between ABI readings obtained by the students and those obtained by the vascular specialists with the MESI ABP MD®: 1.17 [0.90; 1.39] versus 1.18 [0.86; 1.39] (p = 0.33), unlike TBI readings with the SYSTOE®: 0.70 [0.22; 1.74] versus 0.72[0.23; 1.16] (p = 0.03). There were 20 missing ABI values in student data (23.3%) versus 22 (25.6%) in specialist data and 14 missing TBI values (16.3%) versus 15 (17.4%).

The correlation coefficient (r) between the readings obtained by the students and those obtained by the vascular specialists was 0.56 using the MESI ABP MD® and 0.34 using the SYSTOE® p < 0.05. The Lin concordance correlation coefficient was 0.55 [0.36; 0.70] and 0.34 [0.12; 0.53] respectively. Correlation between systolic pressure readings obtained by the specialists and students per device is shown in Figure 3. With respect to the vascular specialists, the correlation coefficient between the MESI ABP MD® and Doppler ultrasound was 0.2 (p = 0.11) and the Lin concordance correlation coefficient was 0.18 [-0.04; 0.39].

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#### 203 DISCUSSION

This is the first research project to focus on the efficacy of training in ABI and TBI measurement using automated measuring devices and its subsequent implementation by medical students in the diagnosis of PAD.

207 This study highlights the fact that the learning benefits of a single training session are not the 208 same from one automated measuring method to the next. For example, the MESI ABP MD® 209 system entailed less attempts at obtaining a satisfactory reading and was found to be more user-friendly than the SYSTOE®. Thus, a single hour-long session combined with a video 210 211 presentation is not enough to acquire the skills required for toe measurement, unlike the MESI 212 ABP MD<sup>®</sup>. Donnou et al. illustrated that students failed to obtain systolic pressure readings 213 using continuous-wave Doppler ultrasound after a single theoretical session combined with a 214 video presentation(8). Mahe demonstrated that the teaching of systolic pressure measurement 215 in medical faculties was predominantly based on theoretical training(26). Lecturers in 216 medicine keen for students to learn how to obtain reliable pressure readings should introduce 217 the measuring devices into their theoretical training sessions. Automated measuring devices 218 have greater benefits than standard Doppler techniques, whose measurement duration 219 produced statistically lower values irrespective of the operator. The vascular specialists, 220 however, outperformed the students in terms of measurement duration, emphasizing that 221 practice is required. This is an important point in the light of increasing patient numbers and 222 time-restricted consultations in general practice (mean time of 16.4 minutes)(27,28). And yet 223 it is precisely during these consultations that patients should have access to this type of 224 screening. Moreover, correlation between the students and the specialists was only 0.56 with 225 the MESI ABP MD® and 0.34 with the SYSTOE®. This may result from lack of experience, 226 especially when using the SYSTOE® which requires a certain level of technical skill to 227 obtain a reading and identify the point of inflection that determines the pressure value. This is 228 moreover corroborated by Bland-Altman results that were indicative of lower measurement 229 variability between the students and the vascular specialists with the MESI ABP MD®.

230 A further point of importance aside from learning is the reliability of the readings obtained for 231 the diagnosis of PAD. The MESI ABP MD® and the SYSTOE® have already been endorsed 232 in clinical trials over corresponding gold standard measurement methods, namely continuous-233 wave Doppler ABI measurement and laser Doppler velocimetry respectively(15,16). In the 234 present study, only the performance of the MESI ABP MD® was compared with continuous-235 wave Doppler ultrasound, yielding an extremely low Lin concordance coefficient of 0.18. 236 One possible explanation is that MESI ABP MD<sup>®</sup> measurement was done first and Doppler 237 measurement last. There was therefore a time lapse of at least 15 minutes between the two 238 readings. Furthermore, it is important to note that our population had no links with PAD 239 screening program but was a pre-selected, hospital population. In fact the present study 240 accentuates the importance of selecting a method of diagnosis adapted to the population in 241 question. The discrepancy found between PAD prevalence determined by the SYSTOE® and 242 that determined by Doppler ultrasound may be attributed to the participation of 11 diabetic 243 patients and 16 renal insufficiency patients (of whom 2 were patients with both diabetes and 244 renal failure), meaning 25 patients (58%) from our population were potentially at risk of 245 increased arterial stiffness. Hence the possibility of falsely normal systolic pressure readings 246 in these patients.

247

The present study also indicated a slight upward bias in the systolic pressure readings obtained from the MESI ABP MD® versus Doppler ultrasound (mean ABI 1.18+/-0.12 versus 1.15+/-0.20). These results are consistent with those found in the literature and may stem from observer bias where Doppler ultrasound is concerned, such as the time required to perceive the signal and stop deflating the cuff(18,28). This raises the issue of whether lower extremity PAD detection thresholds using these automated tools should be redefined, as previously suggested by other authors(16). A meta-analysis by Verberk *et al.*(29) expresses a preference for a cut-off in the region of 1 for the purposes of improving the PAD detection sensitivity in these devices.

257 Unlike Doppler ultrasound, the MESI ABP MD® provides no precise details on the artery 258 used for recording, and placing the cuff on the right arm may be questionable in the event of 259 subclavian artery stenosis, whose prevalence is estimated to be between 2% and 5% in the 260 general population(30). The scope of both the MESI ABP MD® and continuous-wave 261 Doppler ultrasound is also limited in certain patient groups (such as diabetic, elderly or renal 262 failure patients) where readings may be falsely reassuring, contrary to the SYSTOE® whose 263 measuring technique is unaffected by increased arterial stiffness. This is exemplified by 264 disparity in prevalence from one measuring tool to another.

#### 265 Limitations

This study has several limitations. Firstly, each system involves different pressure 266 267 measurement sites. Toe-brachial pressure is undoubtedly more difficult to measure for the 268 inexperienced, even with an automated device. Our aim was to assess the training methods for 269 these automated tools. As such, it was found that following an hour-long training session, the 270 students were more proficient at measuring ABI. A further limitation is that the participating 271 students all came from the same faculty of medicine, although we made very sure that they 272 were novices in measurement to avoid any previous training interfering with the results. The 273 level of study of the student cohort taking the measurements was diverse and it was 274 impossible to assess any influence of this diversity on proficiency at taking measurements. On 275 another note, it was unfeasible to randomize the order of assessment of the measuring tools. It 276 is impossible to rule out any potential impact of this factor on the results. However, the 277 students were tested first on the easier MESI ABP MD®, conceivably making them feel more 278 confident about measuring with the SYSTOE® second. A final limitation accounting for 279 variation in the readings was inter-operator variability regarding the vascular specialists when 280 measuring ABI and TBI.

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282 CONCLUSION

283	Following an hour-long theoretical training session, the medical students were more proficient
284	at obtaining ABI readings using an automated device than at obtaining TBI readings and were
285	able to execute both far more quickly than with the gold standard Doppler ultrasound method
286	used by the vascular specialists. This research project has demonstrated that even where
287	automated devices are concerned it is of fundamental necessity to adopt specific training
288	methods for pressure measurement, without disregarding the importance of practical
289	experience. The benefits of implementing routine use of these tools in primary care practice
290	have yet to be assessed.
291	
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- 412 Figure 1 Title: Proficiency of students at obtaining satisfactory Ankle brachial index (MESI
- 413 device) and Toe Brachial index (SYSTOE) readings
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- 415 Figure 2 Title: Comparison of measurement durations on each device.

- 417 Figure 3 Title: Bland and Altman representation between systolic pressure readings obtained
- 418 by the specialists and students per device.







Table 1: Patients' characteristics

Clinical characteristics	n=43
Men, n (%)	29 (67)
Age (Years), mean ± standard deviation	66 ±14,4
Body mass index (Kg/m <sup>2</sup> ) mean $\pm$ standard deviation	26,9 ±4,9
Hypertension, n (%)	30 (70)
Tobacco, n (%)	4 (9)
Diabetes, n (%)	11 (25)
Dyslipidemia, n (%)	18 (42)
Renal insufficiency, n (%)	16 (37)
Cardiovascular diseases, n (%)	20 (46)
Anticoagulants, n (%)	8 (19)

Table 1 legend: Hypertension was defined as patients receiving antihypertensive drugs or an arterial pressure >140/90 mmHg. Dyslipidemia was defined as patients receiving statins. Diabetes was defined as patients receiving antidiabetic drugs. Renal insufficiency was defined as creatinine clearance <60ml/min. Cardiovascular diseases was defined as a history of coronary artery disease or peripheral artery disease.