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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Short Title: Medical students and automated pressure devices

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ABSTRACT:

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

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

RESULTS: Forty-three medical students were included. Mean number of attempts was 1.23 +/- 0.48 with the MESI ABP MD® device and 1.44 +/- 0.55 with the SYSTOE® device ($p = 0.04$). 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] ($p = 0.33$), contrary to TBI readings 0.70 [0.22; 1.74] versus 0.72[0.23; 1.16] ($p = 0.03$). Measurement duration for the students and vascular specialists was 3.75 min±1.12 and 2.26 min ±0.82 ($p < 0.01$) with the MESI ABP MD® device and 4.30 min ±1.23 and 3.33 min ±1.49 ($p = 0.03$) with the SYSTOE® device. Correlation coefficients between the students and the vascular specialists were 0.56 and 0.34 with the MESI ABP MD® and SYSTOE® devices ($p < 0.05$).

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

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 time-restricted 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.

The main aim of the present study was to assess the proficiency of medical students at obtaining satisfactory pressure readings (i.e. valid reading obtained in as few attempts as possible) for diagnosis of PAD using two automated devices: the MESI ABP MD® and the SYSTOE®. Secondary aims were to assess i) measurement duration, and ii) concordance of readings taken by the vascular specialists with those taken by the students with the various devices

MATERIALS AND METHODS

Study Design

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

Initial training session

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

Real-life patient assessment:

Each student was called individually to measure patient’s pressure with both devices within one 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.

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).

Statistical Analysis:

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

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).

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

Prevalence of lower extremity PAD in the 43 subjects as measured by the MESI ABP MD®, the SYSTOE® and Doppler ultrasound was 4.6 %, 55.0 % et 11.0% respectively (according to vascular specialist data).

Proficiency of students at obtaining satisfactory ABI and TBI readings:

Mean number of attempts was 1.23+/-0.48 regarding the MESI ABP MD® and 1.44+/-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).

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).

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].

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.

This study highlights the fact that the learning benefits of a single training session are not the same from one automated measuring method to the next. For example, the MESI ABP MD® 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 presentation is not enough to acquire the skills required for toe measurement, unlike the MESI ABP MD®. Donnou et al. illustrated that students failed to obtain systolic pressure readings using continuous-wave Doppler ultrasound after a single theoretical session combined with a video presentation(8). Mahe demonstrated that the teaching of systolic pressure measurement in medical faculties was predominantly based on theoretical training(26). Lecturers in medicine keen for students to learn how to obtain reliable pressure readings should introduce the measuring devices into their theoretical training sessions. Automated measuring devices have greater benefits than standard Doppler techniques, whose measurement duration

produced statistically lower values irrespective of the operator. The vascular specialists, however, outperformed the students in terms of measurement duration, emphasizing that practice is required. This is an important point in the light of increasing patient numbers and time-restricted consultations in general practice (mean time of 16.4 minutes)(27,28). And yet it is precisely during these consultations that patients should have access to this type of screening. Moreover, correlation between the students and the specialists was only 0.56 with the MESI ABP MD® and 0.34 with the SYSTOE®. This may result from lack of experience, especially when using the SYSTOE® which requires a certain level of technical skill to obtain a reading and identify the point of inflection that determines the pressure value. This is moreover corroborated by Bland-Altman results that were indicative of lower measurement variability between the students and the vascular specialists with the MESI ABP MD®.

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

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.

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

Limitations

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

CONCLUSION

Following an hour-long theoretical training session, the medical students were more proficient at obtaining ABI readings using an automated device than at obtaining TBI readings and were able to execute both far more quickly than with the gold standard Doppler ultrasound method used by the vascular specialists. This research project has demonstrated that even where automated devices are concerned it is of fundamental necessity to adopt specific training methods for pressure measurement, without disregarding the importance of practical experience. The benefits of implementing routine use of these tools in primary care practice have yet to be assessed.

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Conflict of interest: None

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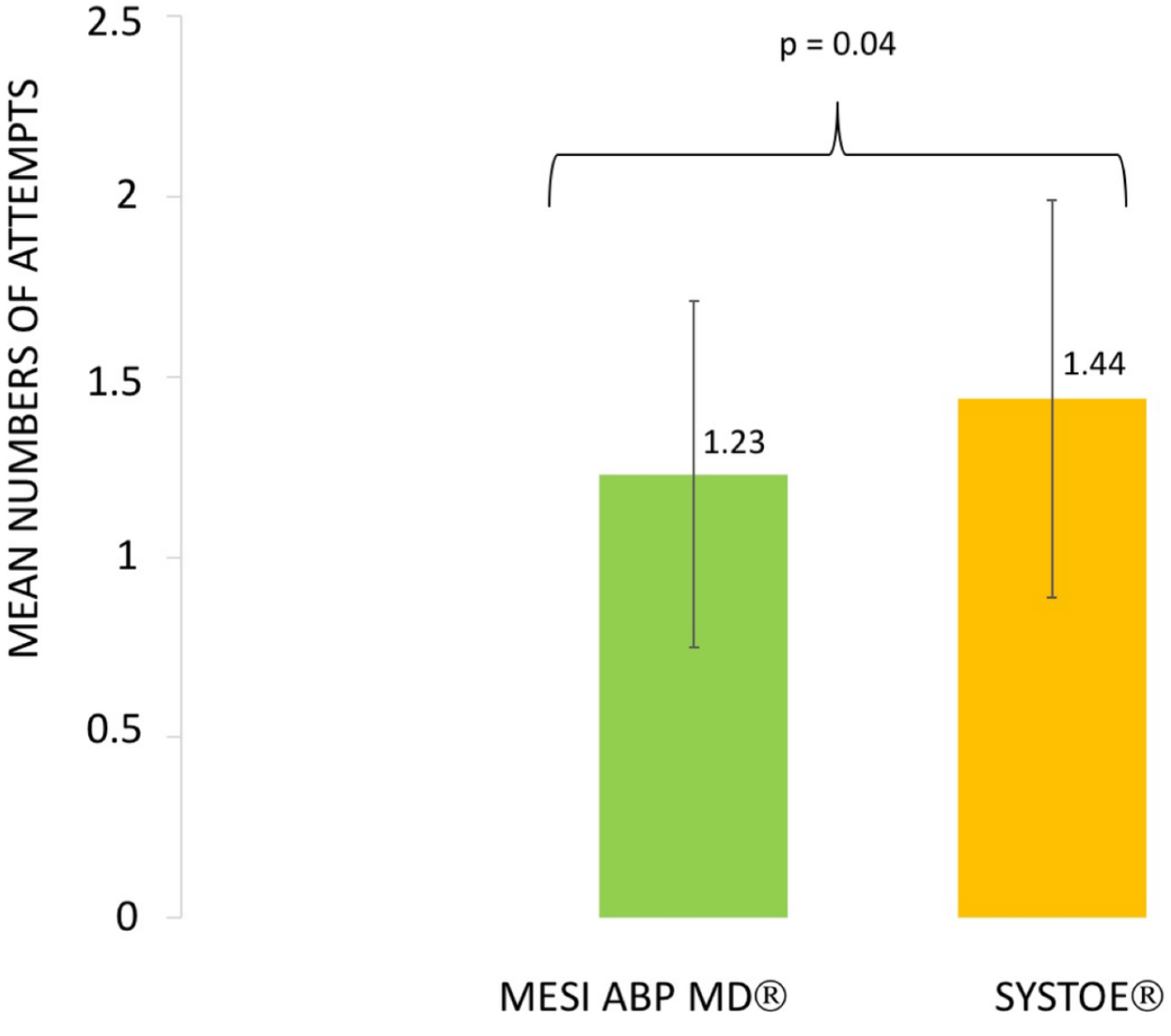
Figure 1 Title: Proficiency of students at obtaining satisfactory Ankle brachial index (MESI device) and Toe Brachial index (SYSTOE) readings

Figure 2 Title: Comparison of measurement durations on each device.

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


MEAN NUMBERS OF ATTEMPTS
2.5
2
1.5
1
0.5
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p = 0.04
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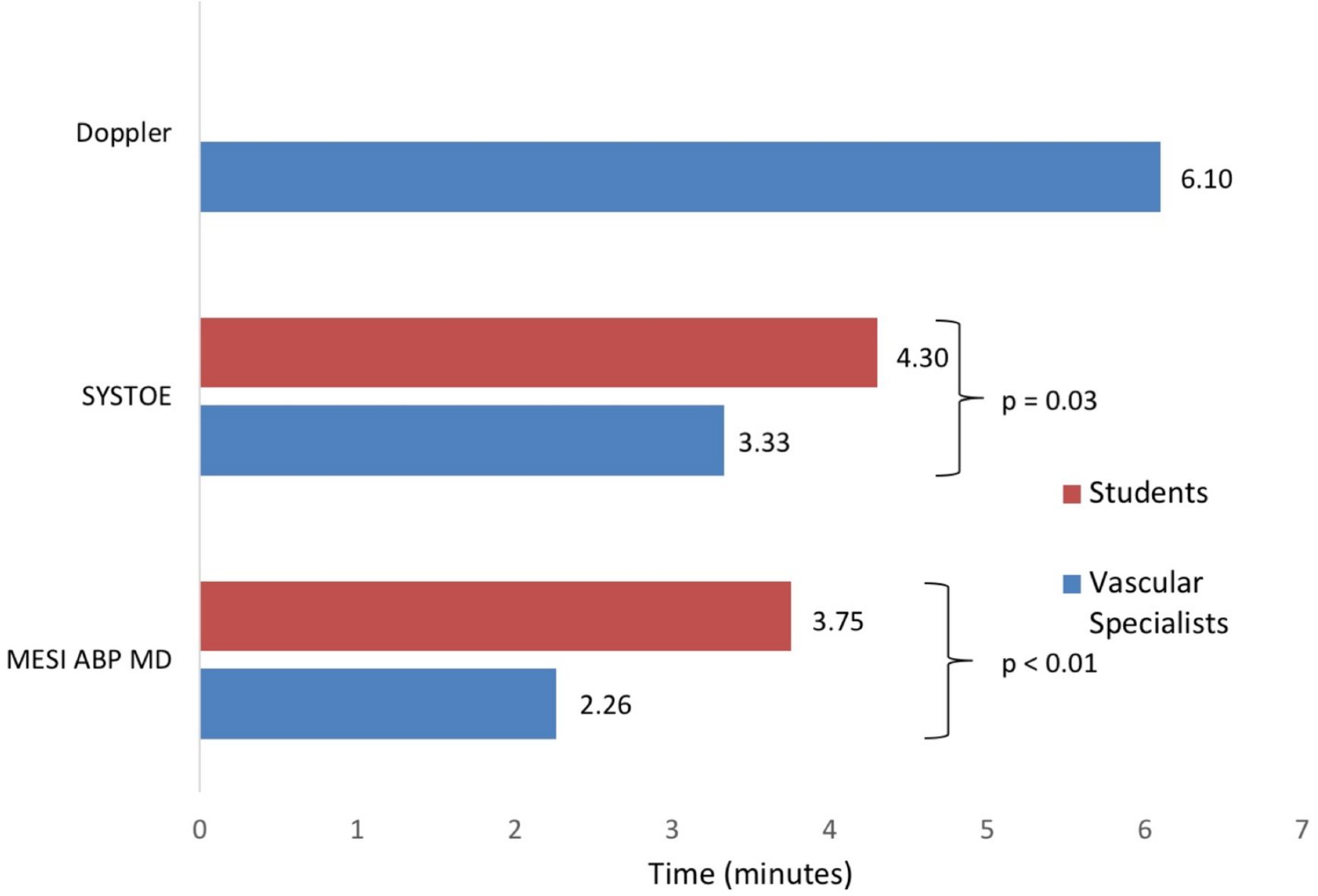
1.44
MESI ABP MD®
SYSTOE®


Doppler
6.10
SYSTOE
4.30
3.33
p = 0.03
Students
Vascular Specialists
MESI ABP MD
3.75
2.26
p < 0.01
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2
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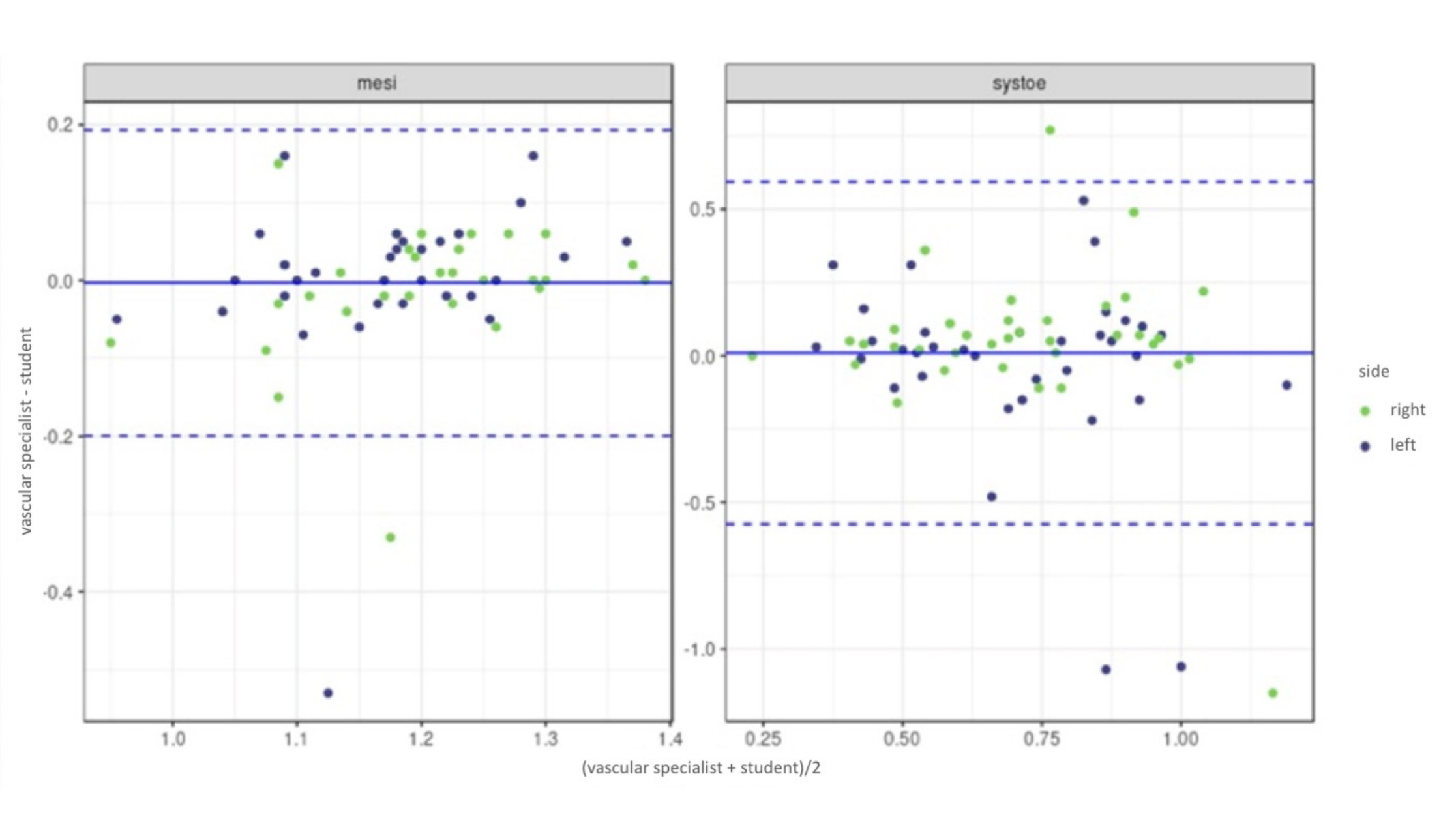
Time (minutes)


mesi
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side
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0.2
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1.00

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^2) mean ± 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.