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Research Article

Comparison of Ankle-Brachial Index (ABI) Measurement between a New Oscillometric Device (MESI ABPI MD®) and the Standard Doppler Method in the Diagnosis of Lower Extremity Arterial Disease (LEAD)

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Abstract

The measurement of the Ankle-Brachial Index (ABI) performed with standard method based on Doppler procedure is a non-invasive diagnostic assessment useful for the diagnosis of Peripheral Artery Disease (PAD) now best defined as Lower Extremity Artery Disease (LEAD), which requires time and experience.

The new oscillometric device MESI ABPI MD® provides a simple solution for an accurate and rapid evaluation of the Ankle Brachial Pressure Index (ABPI) with no need of specialized operators. We reported the results of a prospective multicentric comparative study of 185 patients promoted by the executive board of the Italian Society for Vascular Investigation (ISVI). Said patients were M = 116 (62.7%) mean age = 72.5, age s.d = 13.6. Of those, 116 (62.7%) already had a diagnosis of LEAD, while 97 (75.1%) presented with hypertension, 46 (24.9%) with diabetes, 42 (22.7%) suffered from CAD and 80 (43.2%) were active or ex-smokers. We confirmed the reproducibility of both standard Doppler method and the MESI method, but we observed a significant, even if slight, over estimation, of ABI values in MESI group. Mean executive time of ABI measurement in MESI group was 4:02 min, compared to the 5:28 min of Standard Doppler Method (Bland-Altman p < 0.0001). We can admit that MESI ABPI MD® is a valid screening method to detect early stages of AOP even in a non-specialized setting.

Keywords: Ankle Brachial Index (ABI); Automated oscillometric method; CV risk; Doppler method; Lower Extremity Artery Disease (LEAD); Peripheral Arterial Disease (PAD)

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Introduction

The incidence of LEAD is increasing over the years, according with the longer like expectancy. In Western countries LEAD prevalence and incidence are both sharply age-related, rising > 10% among patients in their 60s and reaching up to 20% in 70s. In more than 50% of cases patients are asymptomatic [1-3]. ABI measurement is a non-invasive assessment with the advantages of high sensibility, specificity and simplicity for an early diagnosis of LEAD [1, 4-6]. In the latest Guidelines of the European Society of Vascular Surgery (ESVS) it is also recognized as a strong marker of generalized atherosclerosis and Cardiovascular (CV) risk. Moreover, an ABI ≤ 0.90 is associated on average with a 2- to 3-fold increased risk of total and CV death. An ABI > 1.4 represents arterial stiffening and it is associated with a higher risk of CV events and mortality [7-9]. The gold standard method of ABI measurement is performed using a Continuous Wave (CW) Doppler. The blood pressure cuff is inflated proximal to the artery in question. Measured by the Doppler wand, the inflation continues until the pulse in the artery ceases. The blood pressure cuff is then slowly deflated. When the artery's pulse is re-detected through the Doppler probe the pressure in the cuff at that moment indicates the systolic pressure of that artery. Ankle-brachial index is then the ratio of the highest Systolic Blood Pressure (SBP) obtained either from tibial or dorsalis pedis arteries to the highest SBP of both brachial arteries.

Since the eighties, the necessity for rapid and automatic methods of measuring ankle pressure, for screening purposes or following a revascularization, pushed for the introduction of new devices, many of which used cuff-wrapping techniques and pletismographic signal to detect systolic pressure [10,11]. Many such diagnostical tools were then progressively developed. In recent years, oscillometric ABI measurement has gained a reputation as a fast method for LEAD screening. A 2012 review individuated 25 studies, ranging from 1985 to 2011, and concluded that cuff-based measurement shows good correlation with the established Doppler method, even if with a small overestimation of ABI value [12]. Half of the studies in said review were performed between 2010 and 2011, indicating an increasing trend of interest and adoption of these devices in common clinic practice. Accordingly, even more studies were published in the latest years.

A 2017 review came to the same conclusions of the aforementioned [13], and others articles from the same year indicated that oscillometric-based ABI [14,15] and automated oscillometric ABI [16] are a reliable diagnostic tool for LEAD diagnosis, only suffering from minor overestimation and a slightly higher failure rate when compared with traditional Doppler-based methods. Same considerations were made by another article analyzing the same devices that is investigated in the present research [17].

MESI (Lubiana, Slovenia) developed a new system, called MESI ABPI MD®, with the same principles of an oscillometric device, but less time-consuming and characterized by a minimal training. Three cuffs, one positioned at an arm and the other two at both ankles, are used simultaneously to provide readout within 1 minute of application. ABI value is determined through sequential simultaneous insufflation and desufflation of the cuffs, during which the arterial pulse produces a volume variation read by the instrument as an oscillating pletismographic signal. This is processed by the proprietary software to determine the value of brachial and ankle systolic pressures, then ABI are automatically calculated with the same ratio employed for the Doppler method. It also provides in one simple reading the blood pressure and heart rate of the patient.

Materials and Methods

185 consecutive subjects were enrolled in 4 centers (2 hospital wards and 2 outpatient clinics) from September 2017 to May 2018 and ABI was thus calculated on 370 limbs. Anamnesis was obtained for first-comer patients or it was downloaded from medical records. Following a period of rest in supine position, four ABI measurements were obtained for each subject, using two pairs of ankle and brachial pressure assessed a single operator. The operator sequentially registered systolic pressures using the Doppler and MESI ABPI methods twice per instrument. The order of the methodic was casual. Measurement of ABI by means of Doppler probe was performed with a calibrated sphygmomanometer and 8 MHz Doppler probes. ABI was calculated as the ratio of the highest Systolic Blood Pressure (SBP) obtained from both tibial and dorsalis pedis arteries at one ankle to the highest SBP of both brachial arteries. Measurement of ABI with the ABPI MESI MD device was performed according to the manufacturer's instructions and following the procedure previously reported in the introduction section.

Following current consensus, values of ABI by doppler means < 0.90 were regarded as being diagnostically of LEAD, whereas values > 1.40 indicated incompressible ankle arteries and values in between were regarded as normal. Time taken by the operator and his different means to assess ABI was also measured.

Statistical analysis was performed using R software (v.3.5.1). Reproducibility between the two measures in each couple of doppler and automated ABI methods was assessed using Wilcoxon test after testing for normality in data subsets with Shapiro-Wilk test. Inter-medical reproducibility was tested in the same way. Correlation between the two methods was then investigated by Kendall's Tau correlation coefficient and a linear regression model was constructed. Differences in ABI values and testing time obtained with the different techniques were assessed by using Bland-Altman test. Correlation of LEAD diagnosis with risk factors and comorbidities was investigated by chi-square testing the difference of the proportion of subjects between patients designated as affected by LEAD versus those deemed as healthy with the two different diagnostic techniques. Limits of agreement were always determined by 95% confidence interval.

Results

The Italian Society for Vascular Investigation (ISVI) has recently collected the results of a prospective controlled multicentric study which enrolled 185 patients (M = 116, (62.7%) mean age = 72.5 years) who underwent vascular consultation. We collected the anamnestic data and we performed, for each patient, ABI measurement with both standard Doppler method and MESI ABPI MD®, reaching the total number of 370 measures. The following table illustrates clinical presentation and investigated comorbidities of enrolled patients.

N=185		
Parameter	**Value**	**Percentage**
M/F	116/69	62.7%/37.3%
Mean Age ± s.d	72.5 ± 13.6	
Arteriopathy	116	62.7%
Diabetes	46	24.9%
Hypertension	139	75.1%
Smoker or ex-smoker	80	43.2%
Prior revascularization/amputation	49	26.5%
CAD	42	22.7%

Table 1: Patients characteristics.

The first results confirmed a high reproducibility of both standard method and MESI method, without significant differences of the index values in the same patient. (Wilcox on test Doppler = 0.85; Wilcox on test MESI = 0.42). On the contrary, comparing the two methods we observed a significant difference between them Wilcox on test con $p < 0.0001$) reason why we cannot consider them identical. Nevertheless, ABI Doppler and ABI MESI values showed a good correlation (Kendall's Tau = 0.63, $p < 0.0001$) and a linear regression of values has been performed ($R^2 = 0.72$, $p < 0.0001$). Bland-Altman test showed a mean difference value of 0,069 (confidence interval 95% from 0.052 to 0.085; $p < 0.0001$), with a slight overestimation of ABI assessment made by MESI when compared to standard method. We also have to consider that statistical analysis has been conducted on 314 of the 370 measures because of the severity of LEAD or errors in the measurement of ABI. We also studied the mean time required to the assessment which was 4:02 min for ABI MESI and 5:28 for ABI Doppler ($p < 0.0001$).

Discussion

In our study we compared two different methods for an outpatient setting of ABI assessment in a heterogeneous population of patients admitted to a vascular consultation. MESI method is certainly a valid screening method to detect early stages of LEAD in particular it allows an assessment without the need of a specialized staff with a significant reduction of executive time, as reported previously by Span et al. [17]. The statistical analysis showed a similar trend between them but slightly different absolute values. Our results demonstrated however a technical limitation of MESI ABPI MD®; in fact we were not able to obtain a value with MESI method in 19 % of cases, compared to the 11 % of the standard technique ($p = 0.02$). In standard method, the explanation is the arterial incompressibility in extensive calcifications; in 2 of these cases we obtained an ABI > 1.5

with MESI method. Furthermore, due to the overestimation of MESI values, we had 34 cases of false negatives (mean ABI: 0.8 range 0.59-0.9). The greater amount of measurement error and over estimation is an issue previously reported in several articles and confirmed by our experience [13,17]. The source of these differences is still debated and needs further investigation. Proposed mechanisms [12] includes, beside arterial calcification impairing oscillometric detection, intrinsic characteristic of the different methods, one using Doppler signal manually detected and the other a software-based process of pletismographic oscillations, and observer error introducing a delay in the manual method between the time at which Doppler signal is heard and sphygmomanometric desufflation is stopped and registered. Moreover, recent studies [18] described patient's weight and ankle circumference as factor promoting the differences between oscillometric and Doppler detected ABI. Border line values of systolic pressure were also associated by the same study with more marked differences and are probably associated with instrumental sensitivity of the different methods varying across systolic pressure range.

Several studies have recently showed ABI as a strong marker of generalized atherosclerosis and CV risk with an increased risk of total and CV death [7-9]. We have seen that patients with a documented LEAD with Doppler means showed strong association with hypertension, prior revascularization and the incidence of CV events. On the contrary, we did not find the same association in MESI group. An explanation for this result could be the presence in this latest subgroup of false negatives in the earlier stages of LEAD with this method. A common proposed method [12] is thus to define a higher cutoff value if LEAD is to be diagnosed with automated devices, placing it in the ABI=1 range, in order to mitigate this issue and regain predictivity.

Overall, MESI ABPI MD constitutes a faster method of diagnosing LEAD, which can be operated by a non specialized physician or even in a nurse-care setting, making it accessible to the wide public and useful for everyday screening even in general pratictioner clinic. This comes however at a cost, as this method shows a slight degree of overestimation and a consequential higher rate of false negatives and lack of cardiovascular event predictivity when compared with traditional Doppler measurement. Overestimation is however minimal and as noted by current literature [18] its clinical impact may be very little, not influencing the clinical decision process of the major part of screened patients. Moreover, the lack of sensitivity on early-stage-LEAD can be mitigated with a revision of current cutoffs and interpreting borderline (0.9-1) values, more so if in presence of relatable symptoms and risk factors, as worthy of further investigation. Higher rate of detection is another recognized issue, however, its value (19% vs 11%) may suggest that the time-effectiveness of the methodic can still reduce overall time used in general practice to screen for LEAD, even accounting for the necessity of conducting further testing on that 8% more of subjects on which automatic ABI measurement fails. In this direction, however, proprietary software is also regularly updated, increasing its detection capabilities. A new update has been released following the completion of the present study and new data are actually getting collected to test for improvements. From a cost-effectiveness point of view, finally, automated methods requiring dedicated equipment are generally more expensive than their Doppler counterpart. No dedicated analysis were found regarding this issue in literature, however, the reduced time of examination needed with automated methods and the lack of necessity of dedicated training for the operator could offer a boost in cost-effectiveness sufficient to cope with the greater purchase cost of the instrument. Moreover, technical improvements and wider employment of these instruments are expected to progressively reduce the retail cost.

Conclusion

In conclusion, we admit that this new method of ABI assessment, MESI ABPI MD®, despite its less sensibility, which can be mitigated by aforementioned clinical cutoff revision, clinical correlation with patient's history and by continuous software improvements could be used as a valid tool of general population LEAD screening, especially in asymptomatic patients. These subjects would be identified in early stages, in an outpatient setting and not necessarily in a specialized center, and its suitability to this purpose is enhanced by fact that it does not need dedicated operators and offers faster times of screening, making it useful on larger scale.

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