Accuracy of ankle-brachial index using an automatic blood pressure device to detect peripheral artery disease in preventive medicine

Détection de l’artériopathie des membres inférieurs en médecine préventive par la détermination de l’index de pression systolique à l’aide d’un tensiomètre automatique

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Summary

Background. — Previously, we validated determination of ankle-brachial index using an automatic blood pressure device.

Aim. — To test the feasibility and accuracy of the automatic method in assessing pathological ankle-brachial indexes in routine preventive examinations.

Methods. — Two physicians enrolled 354 subjects (74\% men) randomly for automatic ankle-brachial index measurements using an OMRON HM 722 device. Ankle-brachial index was calculated by dividing the highest value obtained at each ankle by the highest arm value. Each subject with an abnormal (less than 0.90) automatic index and the six subsequent subjects underwent Doppler index determination.

Results. — Automatic ankle-brachial index determination was possible in both ankles in 350 subjects (99\%; mean time 8.1 ± 2.1 minutes). The incidence of abnormal automatic ankle-brachial index was 8\% (n = 28). Correlations between the automatic and Doppler methods were good in left and right legs (r = 0.84 and 0.78, respectively; p < 0.001). In subjects with an abnormal...
Background

PAD occurs frequently in the general population [1]. Like other atherosclerotic diseases, the risk of PAD increases with age, with the presence of classical cardiovascular risk factors and with a Western lifestyle. Detection of PAD is useful for the assessment of local ischaemic symptoms but it is also of major value in evaluating the risk of total mortality and cardiovascular morbidity and mortality in the general population [2–5]. The diagnosis of PAD identifies patients with a high risk of cardiovascular events or death, and leads to specific follow-up and therapeutic interventions.

The detection of PAD is often based on clinical examination — intermittent claudication being the most frequent exercise-induced ischaemic symptom [6–8]— together with alteration of peripheral pulse, especially posterior tibial pulse [9]. However, the most valuable simple index is the ankle-arm index or the ABI of systolic blood pressure [9].

Prevalence of PAD is usually estimated at 2 to 3% when assessed on the basis of claudication and at up to 10 to 20% when assessed by ABI in adults [10]. In a previous study [11], we validated the use of a simple, commercially available, automatic blood pressure device for determining ABI in patients consulting in a cardiology department, compared with intra-arterial measurements and the standard Doppler method. As mentioned by Simon et al. [12], it can be difficult to implement ABI measurement by general practitioners or preventive medicine physicians in routine examinations. This study was performed to assess the automatic method in the detection of pathological indexes in subjects undergoing their routine annual preventive medical examination at work, in terms of feasibility, time constraint and accuracy.

Methods

Study protocol

Over a 1-year period, two physicians of preventive medicine recruited one in every 15 referrals from a total cohort of 5402 subjects attending for an annual systematic check-up. Subjects aged 40 to 60 years who gave their informed
ABI using automatic blood pressure device

consent for the study were included; those with severe PAD (severe claudication or previous arterial procedure) were excluded.

Each subject first underwent a clinical examination. Clinical history was analysed in terms of previous cardiovascular diseases (such as hypertension, PAD, coronary disease, cerebrovascular disease, angioplasty or arterial surgery) and known diseases or classical risk factors predisposing to PAD (diabetes, hyperlipidaemia and smoking). Clinical symptoms (essentially intermittent claudication) were analysed according to the Rose questionnaire [13]. Physical examination detailed pulses in legs, especially posterior tibial pulse.

Determination of ankle-brachial index

In subjects resting in the supine position for 10 minutes, the ABI was determined by the automatic method using an OMRON HM 722 device (Omron Matsusaka Co. Ltd., Japan) at each limb and in a random order. The blood pressure cuff of the automatic instrument was placed just above the ankles and on the upper arms, thus measuring blood pressure automatically. A first measurement at any site served only to assess the systolic blood pressure level and reduce any stress effect, and was excluded from the calculation. ABI was calculated by dividing the highest value obtained at each ankle by the highest of the arm values. An index less than 0.90 was regarded as being pathological. Patients in whom systolic blood pressure could not be measured with the automatic device at one ankle but who had measurements in both arms were also classified as having a pathological index.

To facilitate comparison of the automatic and Doppler methods, systolic blood pressures were determined at each arm and ankle by the standard Doppler method in all subjects with a pathological automatic index and in a control group comprising the six subjects who followed each subject with a pathological index, who fulfilled the inclusion criteria but had a normal automatic ABI in both lower limbs. This 6:1 ratio was chosen to ensure that a very large group of subjects with normal automatic ABI also had determination of Doppler ABI, to guarantee a good assessment of negative predictive value, taking into consideration the number of patients seen in a day by a physician and the time needed for both determination methods.

The brachial and posterior tibial systolic pressures were measured using appropriately-sized blood pressure cuffs linked to a mercury sphygmomanometer placed successively on the upper arms and just above the ankles. Using a handheld, continuous-wave Doppler probe (8 MHz Micropod, Sonomed, Versailles, France), the systolic pressure in each artery was measured when the flow resumed after gradual and slow cuff deflation. Doppler ABI was calculated in the same way as automatic ABI and the index was classified in the same manner as normal or abnormal.

Statistical analysis

The mean values for systolic blood pressure and ABI measurements were compared using a paired Student’s t test. The series of values of systolic blood pressure and calculated indexes were correlated using linear regression. Incidence differences were tested with the chi-square test. The inter-method concordance on the binary determination (presence or absence) of a pathological index (less than 0.9) was determined by the kappa coefficient (κ). The sensitivity, specificity, and positive and negative predictive values of the new calculated indexes were determined in comparison with abnormal standard Doppler indexes. Agreement between the two methods was tested by the Bland & Altman test.

Results

Subject characteristics

A total of 354 subjects were selected: mean age 50.5 ± 6 years (range 40 to 60); 261 (74%) men; 93 (26%) women. Of these, 164 (46%) subjects were smokers or former smokers, 87 (25%) had hypertension, 20 (6%) had diabetes, 63 (18%) had hypercholesterolaemia, 13 (4%) had coronary artery disease (eight had myocardial infarction) and eight (2%) had PAD. Nine patients complained of an intermittent claudication (two with known PAD and seven without). Tibial posterior pulse was diminished or abolished in four patients (the two with known PAD and claudication and two of the seven with claudication but without known PAD). The mean cholesterol level was 5.69 ± 1.03 mmol/L, the mean triglyceride concentration was 1.43 ± 0.99 mmol/L and the mean body mass index was 25.8 ± 3.5.

Automatic ankle-brachial index measurements

The mean time for measurements with the automatic device was 8.1 ± 2.1 minutes. Automatic determination of blood pressure at the ankle was possible in both legs in 350 (99%) subjects and not possible in four (1%) subjects (three times in both ankles and once in only the left ankle). None of the subjects complained of any side effects.

The mean calculated ABI for the 354 subjects was 1.06 ± 0.12 for the right leg and 1.06 ± 0.13 for the left leg. Pathological automatic ABI was detected in 28 (8%) subjects, including the four subjects with a non-measurable automatic blood pressure at one ankle, who were therefore classified as having an abnormal index.

Correlations and agreements between Doppler and automatic methods

Mean ABI was measured by the two methods in 196 subjects (all those with a pathological automatic index [n = 28] and the control group who had a normal index [n = 168]). The incidences of different values of automatic and Doppler ABI of clinical relevance are shown in Fig. 1; no significant differences were observed for ABI less than 1.

The correlation between the two methods was very good for systolic blood pressure in the arms: $r = 0.95$, $p < 0.001$ in the right arm and $r = 0.96$, $p < 0.001$ in the left arm (Fig. 2). The correlation between the two methods was very good for systolic blood pressure in the lower limbs: $r = 0.91$, $p < 0.001$ in the right legs and $r = 0.93$, $p < 0.001$ in the left legs (Fig. 3).

Very low systolic blood pressure less than 80 mmHg could not be measured by the automatic blood pressure device, as noted during the previous validation study versus intraarterial measurements [11]. The correlation between the
Figure 1. Incidences of clinical relevance by ABI values.

Figure 2. Correlation between Doppler and automatic methods in terms of systolic blood pressures in arms.

Figure 3. Correlation between Doppler and automatic methods in terms of systolic blood pressures in lower limbs.

Figure 4. Correlation between Doppler and automatic methods in terms of ankle-brachial indexes.

Figure 5. Comparability of the Doppler and automatic methods according to the Bland & Altman test.

Figure 6. Correlation between Doppler and automatic methods in terms of systolic blood pressures in lower limbs.

Figure 7. Comparability of the Doppler and automatic methods according to the Bland & Altman test.

Among the eight patients with known PAD, four had normal ABI with both methods and four had abnormal ABI with both methods; among the seven patients with claudication but without known PAD, five had pathological ABI with both methods and two had normal ABI with both methods.

Sensitivity and specificity

Among the eight patients with known PAD, four had normal ABI with both methods and four had abnormal ABI with both methods; among the seven patients with claudication but without known PAD, five had pathological ABI with both methods and two had normal ABI with both methods.

The value-to-value comparison assessing the agreement of the two methods for all 196 patients in this subgroup is shown in Fig. 5; the comparison revealed several discrepancies that explain the significant statistical difference in ABI values (p < 0.001; two-tailed paired t test).

In the 28 patients with a pathological ABI, no statistical differences could be observed in ABI values (p = 0.40; two-tailed paired t test). Correlations between pathological automatic indexes and pathological Doppler indexes were good (r = 0.68, p < 0.001) in left and right legs (Fig. 6). Furthermore, the value-to-value comparison in this pathological subgroup showed good agreement between the two methods (Fig. 7).
The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of a pathological index determined using the automatic device were tested to predict an abnormal index in at least one leg with the standard Doppler measurement (analysis in terms of patients rather than limbs in the 196 patients with determination of ABI by both methods).

There were 166 true negatives, 24 true positives, two false negatives and four false positives. The four patients with an automatic index that was not measurable were classified correctly as true positives. Sensitivity was 92%, specificity was 98%, positive predictive value was 86% and negative predictive value was 99%. Accuracy (patients classified correctly by the automatic ABI in reference to standard Doppler indexes) was 97%. Analysis of concordance was excellent (κ = 0.87).

Discussion

Feasibility of use and incidence of pathological indexes

The automatic sphygmomanometer appeared to give very precise measurements of systolic pressure in lower limbs in the normal range of blood pressures in 99% of tested subjects, but seemed to be unsuitable for measuring very low systolic blood pressure. Very low systolic pressure in the lower limbs is a marker of severe deterioration of arterial flow when blood pressure is normal (or elevated) in the arms. In fact, this kind of automatic blood pressure device was developed to assess hypertension rather than hypotension. These observations are in agreement with the results of our intra-arterial validation in a previous study [11].

Patients did not complain of any severe side effects; two found the automatic method slightly more painful than the standard Doppler method, perhaps because of a longer period of cuff inflation/deflation.

The 8% incidence of PAD according to pathological automatic ABI seems to be in agreement with the incidences of around 10% reported at this age (40 to 60 years) in studies using Doppler measurements of ABI [10]. This new method appears to be very easy, does not need special equipment (such as a Doppler probe) and requires only minimal physician training. It is less costly than the standard Doppler method. The use of a single device rather than two different devices (Doppler probe and sphygmomanometer) seems a practical advantage and would probably lead a greater number of physicians to assess ABI routinely.

Accuracy and comparability with the Doppler method

The global comparison of the values obtained by the two methods showed good correlation. However, the value-to-value comparison showed some small differences, mainly in the normal values; this explains the weak agreement in the total range of values, which was not found in the pathological values. These differences could be due to technical principles (oscillometric versus auscultatory). Nevertheless, these differences in normal values do not affect the ability of the automatic method to detect pathological subjects.

This simple new method for determining ABI seems to be in agreement with the standard Doppler method and is effective in the detection of PAD defined by a pathological ABI less than 0.90 in routine clinical examinations in asymptomatic subjects. Subjects with a pathological Doppler test are classified accurately by the new method (97% accuracy and 87% concordance). This result is in line with a study performed to compare an automatic oscillometric blood pressure device with the standard Doppler method in the postoperative surveillance of infra-inguinal bypasses by ABI [14] and with our previous study in cardiovascular patients [11]. Sensitivity (92%), specificity (98%) and accuracy (97%) are higher here than in our previous study in cardiovascular patients (76, 95 and 89%, respectively). This underlines the value of this method for detecting unknown PAD in middle-aged subjects not consulting for cardiovascular reasons.

Perspectives

This new method for determining ABI in the routine detection of moderate PAD appears to be effective. It seems of particular value in ruling out significant PAD, given its excellent specificity and negative predictive value. It seems useful for general or preventive medicine physicians who are not trained in using the Doppler probe. Furthermore, it
would be of value if automatic devices devoted to measuring blood pressure (particularly low blood pressure) in the lower limbs could be developed by manufacturers, particularly in terms of cuffs and algorithms. In fact, the value of automatic ABI measurement lies in its capacity to easily detect patients with PAD who would probably not have been diagnosed in real medical practice. The subjects who are at high risk of cardiovascular events (also identified as such by other methods, such as risk factor scores) [15] will need further appropriate investigations (Doppler, Echo-Doppler, etc.) to assess the focal lesions precisely and appropriate interventions.

Limitations

As the aim of this study was to test the accuracy and feasibility of the automatic method for detecting pathological indexes in preventive medicine, the two measurement methods (automatic and Doppler) were not used in all subjects but only in a large subgroup (n = 196). A recent paper [16] pointed out somewhat less inter-observer reproducibility between automatic measures of ABI than between Doppler measures (in an analysis of limbs) in a short series of 50 tests done by vascular physicians. This result shows that the automatic method is perhaps less reproducible than Doppler method and somewhat less precise in assessing the severity of PAD, but in practice, for general physicians, the most important factor is whether the method is able to detect patients with an abnormal index in routine examinations. Our results in routine examinations performed by preventive medicine physicians at work support the accuracy of the automatic method for this purpose.

Conclusion

The use of a commercially available automatic blood pressure device for determining ABI in preventive medicine appears feasible, easy, quick and precise in detecting normal or abnormal ratios. It will provide a practical and cost-effective tool that enables preventive medicine or general physicians not trained in the Doppler method to assess ABI more systematically in any routine medical consultation in adults, to detect PAD, to make a more complete local assessment and to assess global cardiovascular risk.

References