

Vergleichbarkeit des oszillometrischen Messprinzips mit der manuellen Doppler-Methode bei der Bestimmung des Knöchel-Arm-Index

Der nachfolgende Artikel „Automated Oscillometric Determination of the Ankle–Brachial Index Provides Accuracy Necessary for Office Practice” wurde der Zeitschrift „Hypertension – Journal of the American Heart Association“ (Ausz. 2006/47, S. 35-38) entnommen. In der beschriebenen Studie wird die Vergleichbarkeit der Resultate von oszillometrischer Messmethode mit der Doppler-Methode belegt. Die im VascAssist verwendeten Blutdruckmessgeräte sind in Bezug auf Messprinzip und Messgenauigkeit gleichwertig mit dem in der Studie verwendeten Blutdruckmessgerät. Der Artikel ist in Englisch verfasst, im Folgenden haben wir den Abstract des Artikels ins Deutsche übertragen:

Abstract

Die Periphere Arterielle Verschlusskrankheit (PAVK) ist in der hausärztlichen Grundversorgung und bei Fachärzten nach wie vor unterdiagnostiziert. Die Feststellung einer PAVK wird in der ärztlichen Praxis erschwert durch die benötigten Spezialgeräte sowie durch den Zeitaufwand, der zur Durchführung der Knöchel-Arm-Index-Messung (Ankle-brachial index, ABI) benötigt wird. Wir untersuchten, ob die Genauigkeit der automatisierten ABI-Messung mit Hilfe der Oszillometrie vergleichbar ist mit dem Gold-Standard, der auf dem CW-Doppler basiert. Wir luden hierzu fortlaufend Patienten aus dem nichtinvasiven Gefäßzentrum unseres Universitätskrankenhauses zur Teilnahme an ABI-Messungen ein.

Von 205 Patienten nahmen 201 an der Studie teil, darunter 55 mit PAVK. Der ABI wurde mit Hilfe der automatischen oszillometrischen Methode sowie vergleichend mit Doppler-Ultraschall gemessen. Die Trendanalyse ergab einen Korrelationskoeffizienten von 0,78 im linken Bein und 0,78 im rechten Bein ($p = 0,01$ für beide Beine). Die mittlere ABI-Differenz zwischen beiden Methoden betrug $0,04 \pm 0,01$ (linkes Bein) und $0,06 \pm 0,01$ (rechtes Bein). Die Differenzen zwischen den Methoden folgten einer Normalverteilung. Die oszillometrische Bestimmung des ABI liefert somit eine genaue Bestimmung des Knöchel-Arm-Index in der ambulanten Patientenpopulation. Unsere Ergebnisse zeigen, dass die automatische oszillometrische Methode eine verlässliche und leichter beherrschbare Methode der ABI-Bestimmung darstellt, die die Schwelle zur Einführung dieses diagnostischen Tests in die klinische Praxis erniedrigt. (*Hypertension. 2006;47:35-38.*)

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Automated Oscillometric Determination of the Ankle–Brachial Index Provides Accuracy Necessary for Office Practice

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Abstract—Peripheral arterial disease (PAD) remains underdiagnosed by primary care and cardiovascular physicians. The office-based assessment of PAD is limited by the need for specialized equipment and the time required for performance of the ankle–brachial index (ABI). We explored whether the accuracy of automated ABI measurement by oscillometry compared favorably with the gold-standard method using continuous-wave Doppler ultrasound. Consecutive patients referred to our university hospital noninvasive vascular laboratory for ABI measurement were invited for participation. Of 205 patients, 201 participated, including 55 with PAD. The ABI was measured by automated oscillometry and Doppler ultrasound. The test of trends revealed a correlation coefficient of 0.78 in the left leg and 0.78 in the right leg ($P < 0.01$ for both). The mean ABI difference between methods was 0.04 ± 0.01 and 0.06 ± 0.01 , respectively, in the left and right legs. The differences between the methods followed a normal distribution. Oscillometric determination of the ABI provides an accurate determination of the ABI in an outpatient population. Our findings show automated oscillometry to be a reliable and easier method of ABI measurement, lowering the barrier to incorporation of this diagnostic test into clinical practice. (*Hypertension*. 2006;47:35-38.)

Key Words: vascular diseases ■ atherosclerosis

Peripheral arterial disease (PAD) remains the least recognized and treated form of atherosclerosis. It is present in 5 to 12 million Americans^{1,2} but is diagnosed in less than half of these patients.³ The diagnosis of PAD has important prognostic implications and requires institution of therapeutic lifestyle changes and medical therapy to reduce cardiovascular morbidity and mortality. One important reason that the diagnosis of PAD is made infrequently is the lack of an easy-to-perform diagnostic test.

The ankle–brachial index (ABI) is the ratio of the systolic pressure at the ankle compared with the brachial artery pressure. When the ABI is ≤ 0.9 , a diagnosis of PAD is made with up to a 90% accuracy.⁴ Measurement of the systolic pressure in both brachial arteries and pedal pulses is performed with a continuous-wave Doppler ultrasound. The greatest barrier to office-based ABI measurement is the time required for testing.⁵ A test that is automated, easy to perform, and less reliant on specialized skills may facilitate measurement of the ABI, increasing the diagnosis of PAD in susceptible populations. Oscillometric (automated) determination of blood pressure is approved for blood pressure measurement and is commonly available, reliable, and simple to use.⁶ Oscillometers measure the magnitude of the pressure vacillation in the limb as the cuff is deflated from suprasystolic pressures. As the pressure in the cuff decreases and

approaches systolic blood pressure, oscillation rapidly increases and eventually reaches a peak after which decrease of the cuff pressure causes the oscillation to decrease. Systolic blood pressure is calculated when the oscillation increases rapidly and the diastolic pressure when the oscillation decreases rapidly. Accordingly, we compared the automated, oscillometric measurement of the ABI to the Doppler ultrasound measurement of the ABI to determine whether there is a simple, fast, and accurate method suitable for common use in the office.

Methods

Patient Selection

All of the men and women aged 18 years or older referred to the Brigham and Women's Noninvasive Vascular Laboratory between May 1 and August 20, 2004, for evaluation of PAD were asked to participate. Subjects were excluded if they were unable to consent. Each subject provided written, informed consent. This study was approved by the Human Research Committee of Brigham and Women's Hospital.

Study Procedures

Demographic information was acquired after consent was obtained. Doppler pressure measurements and automated oscillometric pressure measurements were performed using sphygmomanometric cuffs that were appropriately sized to the diameter of the arms and ankles. The subject rested supine for 10 minutes before measuring pressures.

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Doppler pressure measurements were made with a commercially available machine (Parks Medical Electronics, Inc). A cuff was inflated to suprasystolic pressure and deflated slowly until a flow signal was detected by Doppler over the dorsalis pedis and posterior tibial arteries, indicating the systolic pressure at the ankle. Brachial artery systolic pressure was determined similarly. The ABI for each extremity was calculated as the higher of the 2 pedal pressures divided by the higher of the 2 arm pressures. Oscillometric measurements were made using a standard automated blood pressure cuff system (Cas 740, Cas Medical Systems, Inc). This model has a reported accuracy to within 5 mm Hg and a SD of ≤ 8 mm Hg.⁷ Hospital standard calibration of the device was performed just before study initiation and halfway (4 weeks) through recruitment by the hospital Biomedical Engineering department. Using a cuff sized for the arm, blood pressures were obtained in both arms and ankles. ABI was calculated as the quotient of the ankle pressure and the higher of the 2 arm pressures after both sets of measurements were made. Subjects with incompressible ankle arteries ($ABI \geq 1.4$) were excluded.

Statistics

Demographic variables are presented as mean \pm SD and computed measures as mean \pm SE. Correlation between measures was determined by linear regression adjusted for demographic variables. For each method of measurement, agreement between standard ABI measurements and oscillometric measurements was investigated using the Bland and Altman method. A correlation analysis between the difference of the two methods was performed to see whether these measures varied systematically over the range of ABI. Sensitivity, specificity, positive predictive value, and negative predictive of the oscillometric measurements to predict an abnormal ABI of <0.9 were determined using the Doppler ultrasound ABI measurement as the gold standard. Kolmogorov–Smirnov analysis was performed to determine normality of differences between both measures. To avoid the effect of interrelated measures within each subject, we analyzed each leg separately, thus making each leg an independent observation.

Results

Of the 205 subjects that were approached, 201 participated. The subjects were typical of those referred to a vascular laboratory. Subjects mean age was 66 ± 11 years, 53% were female, 78% were white, and 36% had diabetes mellitus. Twenty-eight subjects (14%) were excluded from the analysis because of lower extremity vascular calcification artifact,

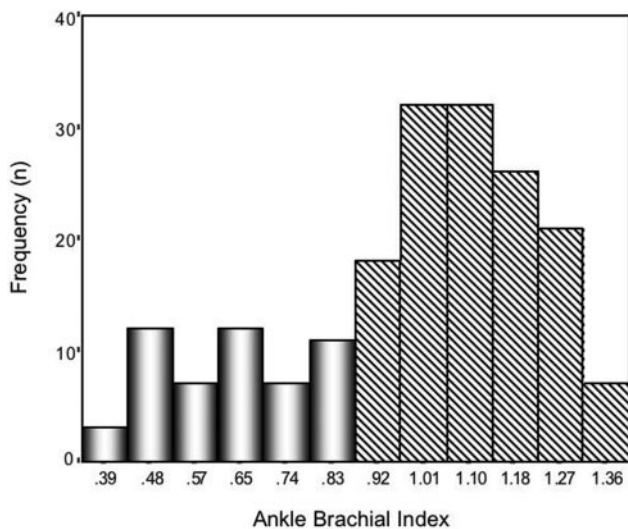


Figure 1. Distribution of ABI across the enrolled population. Patients with an abnormal ABI represented 32% of the cohort.

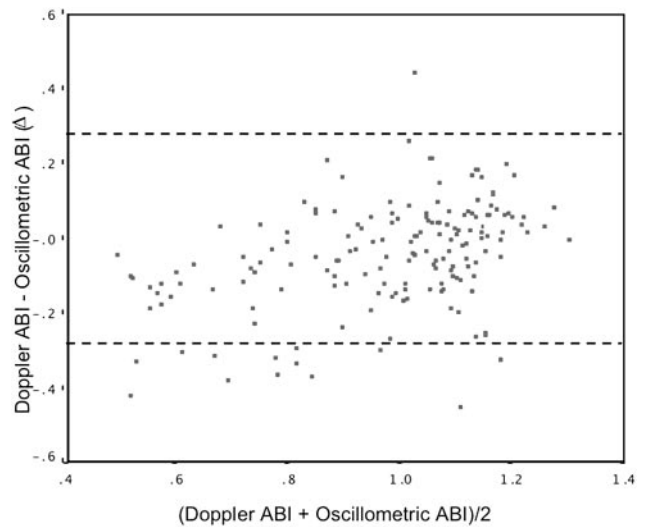


Figure 2. Bland–Altman plot of average difference between the 2 measures across the average ABI for the population.

leaving 173 evaluable subjects. Vascular calcification prevents compression of the artery, thus artificially raising the detection of flow by Doppler ultrasound well beyond normal. Of the remaining subjects, 55 had an abnormal ABI (<0.9), and 118 had a normal ABI ($0.9–1.39$) (Figure 1). The oscillometric determination of blood pressure reliably measured arm systolic blood pressure, differing by a mean of 2.8 ± 13.6 mm Hg from Doppler ultrasound determination of arm systolic blood pressure.

There was a strong association between types of measurement in each leg tested separately (Figure 2). A test of trends revealed a β coefficient of 0.78 in the left leg (Figure 3) and 0.78 in the right leg ($P < 0.01$ for both). Diabetes, end-stage renal disease, age, sex, and race did not impact on the association. The mean difference between the methods was 0.04 ± 0.01 in the left leg and 0.06 ± 0.01 in the right leg. The

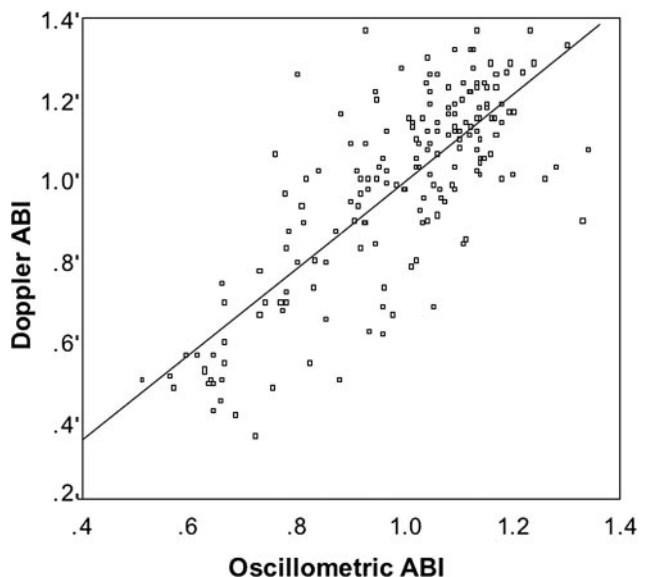


Figure 3. Scatter plot of automated oscillometric and Doppler ultrasound determination of ABI. The mean difference between the 2 methods was 0.04 ± 0.01 .

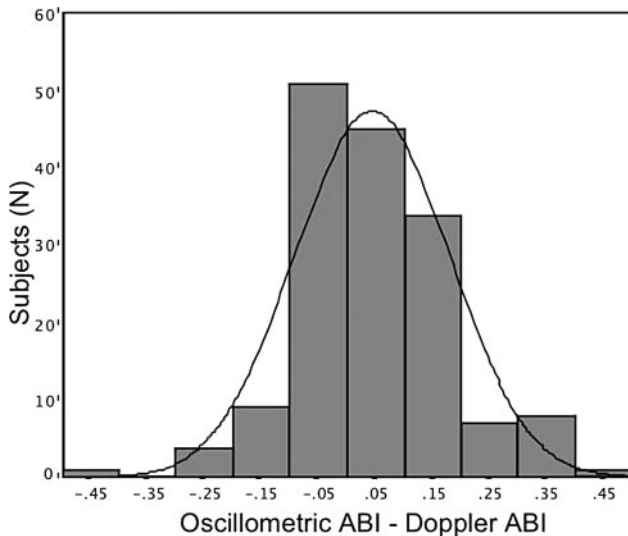


Figure 4. Nomogram demonstrating the differences between the 2 measures demonstrating a normal distribution of differences (Komogorov-Smirnov Z *P* value is not significant.)

differences between the 2 measures followed a normal distribution ($P=0.2$; Figure 4). The 95% CI for the difference of the means suggests a slightly higher ABI for the oscillometric measure (0.02 to 0.06 for the left leg and 0.04 to 0.09 for the right leg).

Assuming that the Doppler measurement is the gold standard, the automated, oscillometric measurement had a sensitivity of 88%, specificity of 85%, positive predictive power of 65%, and negative predictive power of 96% in the left leg. Similarly, a sensitivity of 73%, specificity of 95%, positive predictive value of 88%, and negative predictive value of 88% was noted in the right leg.

Discussion

One of the most important barriers to the reduction of cardiovascular morbidity and mortality in patients with PAD is disease recognition. PAD is commonly not diagnosed by primary care and specialty medical services for a number of reasons, an important one of which is the need to perform a time-intensive diagnostic test.^{3,8} Doppler ultrasound measurement of the ABI requires specialized equipment, training, and 10 to 15 minutes to perform. These constraints limit the use of this measurement in primary care and specialty offices. A simple, faster, accurate method should facilitate the diagnosis of PAD in the office setting by increasing the number of ABI tests performed.

We used an automated, oscillometric blood pressure cuff to determine blood pressures in all 4 extremities. This method has met the US Food and Drug Administration standard⁹ for blood pressure determination previously. Our goal was to use a technology that met the standards for reproducibility, that is, <5 mm Hg. In our hands, oscillometry and Doppler ultrasound determination of blood pressure were very similar, <3 mm Hg apart. In fact, the difference between the 2 measures was similar to that seen when obtaining repeat ambulatory blood pressure¹⁰ or performing the ABI.¹¹ Not surprisingly, Doppler ultrasound determination of the ABI

and oscillometric-based ABI were quite similar, showing a strong association between the 2 methods. Other studies have evaluated oscillometry in the determination of the ABI.¹²⁻¹⁷ In comparison to the other studies, our study is the largest, avoids the problem of interrelated outcomes by including only 1 leg in the determination of accuracy, and represents the outpatient population seen in a typical vascular laboratory. Oscillometry yielded modestly higher ABI values over the entire range of measurements. Several factors may contribute to this finding. First, blood pressure taken just above the ankle may be higher because of reflected arterial pressure waves, which increase in importance as one moves proximally in the lower extremities. Second, taking blood pressure 6 inches more proximally may avoid arterial occlusive disease present between the cuff and the 2 pedal pulses. Because of the higher pressures by oscillometry, the negative predictive value of the oscillometry is quite high. Thus, if used in practice, a normal ABI (>0.9) by oscillometry should exclude the possibility of peripheral arterial disease. Some oscillometers, including the one used in this study, cannot determine blood pressure below a low threshold, such as 30 mm Hg. This might serve to artificially lower the ABI in patients with severe PAD. However, in a real-world situation, despite an inaccurately low ABI value, the clinician would still be able to diagnose PAD, start risk factor modification at secondary prevention levels, and inquire about leg-specific symptoms.

Automated, oscillometric sphygmomanometry is commonplace in clinical practice, requires little training, and requires 1 minute to measure limb blood pressure. Recent evidence suggest that measuring the ABI in patients above the age of 70 or above the age of 50 in patients with diabetes or smokers should yield a positive rate of $\approx 30\%$.³ In unselected patients above the age of 65, disease prevalence approaches 20%.¹⁸ Because the ABI changes ≈ 0.02 per year,¹⁹ we would suggest test repetition in at risk populations every 5 years. Diagnosis of PAD changes medical recommendations, requiring the institution of antiplatelet therapy, risk factor modification, and a directed examination of the lower extremities. Thus, oscillometric determination of the ABI would allow for greater office-based diagnosis of PAD.

Perspectives

Peripheral arterial disease is present in as many as 20% of the Medicare population¹⁸ but diagnosed in <50% of the patients with the disease.³ Because of the attendant risk of cardiovascular morbidity and mortality, making the diagnosis of PAD may impact significantly on patient outcomes. An important barrier to diagnosis is the lack of an easy, office-based method. This investigation demonstrates that automated, oscillometric determination of the ABI correlates well with Doppler ultrasound measurement of the ABI. Because of the decreased time and training required for ABI determination, the barriers to ABI measurement are lowered, enhancing the possibility of PAD diagnosis.

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