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ORIGINAL ARTICLE

Validation study of automated oscillometric measurement of the ankle-brachial index for lower arterial occlusive disease by comparison with computed tomography angiography

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The ankle-brachial index (ABI) determined by the oscillometric method has been shown to reliably detect peripheral arterial disease (PAD), with highly correlations with the Doppler method. However, most of these studies were shown in cohorts with a small number of PAD patients, and no imaging studies have been performed. The purpose of this study is to evaluate the diagnostic accuracy and optimal threshold of oscillometric ABI for detecting PAD using computed tomography angiography (CTA) as a gold standard in a cohort that consists mostly of PAD patients. This retrospective study included 108 consecutive patients with 216 limbs. ABI measured by an oscillometric device was compared with CTA. The diagnostic accuracy of oscillometric ABI to detect ⩾50% and ⩾75% stenosis confirmed by CTA and the optimal ABI cutoff values were evaluated using receiver operating characteristic (ROC) curve analysis. The oscillometric ABI could not be measured in nine limbs. The mean ABI was 0.72±0.31. The areas under the ROC curves (AUCs) for detecting ⩾50% and ⩾75% stenosis with oscillometric ABI were 0.919 and 0.918, respectively. The optimal ABI cutoff values to detect these levels of stenosis were 0.99 (sensitivity, 90%: specificity, 85%) and 0.87 (sensitivity, 84%: specificity, 89%), respectively. If patients with diabetes mellitus (DM) were analyzed separately, the AUC for detecting ⩾75% stenosis was 0.888. Oscillometric ABI had a high diagnostic accuracy to detect PAD using CTA as a gold standard. The diagnostic ability of ABI to detect PAD could be impaired by the presence of DM.
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INTRODUCTION

The ankle-brachial index (ABI) is a simple and noninvasive measure to assess the patency of the arteries of the lower extremity and can predict cardiovascular morbidity and mortality.[1,2] ABI obtained by Doppler ultrasonography is considered the gold standard; however, this approach is time consuming, requires trained observers and has an intra-observer variability of 10%, which precludes its routine use in general practice.[3]

Alternatively, automated oscillometric blood pressure devices have been developed for ABI measurement. This method reduces the measurement time, requires little observer training[4] and significantly increases the reproducibility of ABI estimates compared with the manual approach.[5] Several studies including a recent meta-analysis have evaluated the performance of the oscillometric method using the Doppler method as a reference standard. These studies demonstrated that the oscillometric method was accurate, as there was a high correlation between oscillometric and Doppler methods.[4–6] However, most of the subjects included in those studies were healthy individuals and only a small fraction had peripheral arterial disease (PAD). Furthermore, no imaging studies were carried out to define the severity of lesions based on anatomy. A recent statement from American Heart Association (AHA)[2] questioned the validity of the oscillometric ABI, especially in PAD patients in whom the oscillometric method tended to overestimate the actual ankle pressure and could not detect low pressure (<50 mm Hg).[7] Furthermore, the diagnostic performance of oscillometric ABI tended to decrease in patients with comorbidities such as diabetes mellitus (DM)[8] or renal failure that required hemodialysis.[9] Thus, a validation study of oscillometric ABI is mandatory in a cohort that includes a large number of PAD patients. The purpose of this study is to evaluate the diagnostic accuracy and optimal threshold of oscillometric ABI for detecting arterial occlusive disease using computed tomography angiography (CTA) as a gold standard in a cohort that consists mostly of PAD patients.

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METHODS

Study population

This retrospective study included 108 patients with 216 limbs. The patients were referred to our department based on a suspicion of PAD from June 2010 to December 2012. Patients who had a history of vascular surgery or endovascular treatment for PAD were excluded. Patient demographics are shown in Table 1. Informed consent was obtained from all participants. The institutional review board in our university approved this study.

ABI Measurements

The ABI measurements were obtained after the patients had rested for 15 min in the supine position in a room with a comfortable temperature (19–20 °C) and refrained from smoking, heavy exercise and drinking alcohol or caffeinated beverages for at least 2 h before the examination.

ABI was measured in all patients using an automated oscillometric device (form-III PWV/ABI, Omron Healthcare, Kyoto, Japan). The oscillometric cuffs were appropriately sized for arms and ankles. Systolic blood pressure was measured with the cuff placed on one arm and above the ankles in both legs using the modified oscillometric pressure-sensor method. Ankle pressures were measured over the dorsalis and posterior tibial arteries. The highest ankle pressure was used for calculating the ABI. All measurements using the oscillometric method were performed by the same investigator with 10 years of experience in ABI measurements.

CT angiography

All patients underwent CTA within 1 month before or after the ABI measurement. All examinations were performed with a dual-source 64-slice CT scanner (Somatom Definition; Siemens Medical Solutions, Erlangen, Germany). The CTA protocol consisted of plain, arterial and venous phases encompassing the abdomen and lower extremity. A total of 100–150 ml of nonionic-iodinated contrast medium was administered at a flow rate of 4 ml s^{-1}. Arterial phase scanning was performed using a bolus-tracking technique. The arterial phase data acquisition was initiated 6 s after the attenuation reached a predefined threshold of 120 Housenfield units. Delayed phase dual-energy CT scanning was performed with a standard delay of 70 s after the beginning of the contrast injection.

Analysis of the contrast-enhanced CT images was performed by a single radiologist with 10 years of experience in vascular imaging who was blinded to the patient's clinical symptom or ABI value. Axial images and maximum intensity projection (MIP) images were used for the evaluation of the stenosis. Stenosis of arteries were graded with a four-point scale (grade 1, 0–50%; grade 2, 50–75%; grade 3, 75–99%; grade 4, 100%) in each of the following arterial segments: aortoiliac, femoropopliteal and below the knee. Grading was performed by visual assessment, which has been commonly used in the past literatures.[10,11] There are commonly three main arteries below the knee (BTK arteries): anterior tibial, posterior tibial and peroneal. We used the artery with the least stenosis to grade all three BTK arteries together, according to the one straight line flow concept.

Table 1 Patient characteristics

Age (years)	71.2 ± 8.1
Female gender	14 (13%)
Symptom (n = 207 limbs)	
No symptom	45 (22%)
Intermittent claudication	153 (74%)
Critical limb ischemia	9 (4%)
Comorbidities (n = 108 patients)	
HT	95%
DM	54%
CAD	39%
CVD	26%
HD	16%
AF	10%

Abbreviations: AF, atrial fibrillation; CAD, cardiovascular disease; CVD, cerebrovascular disease; DM, diabetes mellitus; HD, hemodialysis; HT, hypertension.

Definition

Hypertension was defined as systolic blood pressure ⩾140 mm Hg and/or diastolic blood pressure ⩾90 mm Hg or ongoing medication therapy. DM was defined as HbA1c >6.5%, random plasma glucose >200 mg dl^{-1} or current treatment with oral hypoglycemic drugs or insulin injection. Coronary artery disease was defined as stable angina with documented coronary artery disease, history of percutaneous coronary intervention, history of coronary artery bypass graft surgery or previous myocardial infarction. Cerebrovascular disease was defined as a history of transient ischemic attack or stroke. Atrial fibrillation was diagnosed with an echocardiogram, which demonstrates the absence of P wave together with an irregular ventricular rate.

Parameters investigated

The following parameters were investigated: (1)diagnostic accuracy (sensitivity and specificity) of oscillometric ABI to detect ⩾50% and ⩾75% stenosis demonstrated in any lower extremity artery from the aortic bifurcation to the tibial arteries using CTA as a gold standard and (2) correlation of the ABI value and the severity of stenosis. The diagnostic accuracy was also evaluated with DM patients separately, in whom diagnostic accuracy of oscillometric ABI was reported to be lower than nonDM patients.[8]

Statistical analysis

Data are presented as the mean ± s.d. The diagnostic accuracy of oscillometric ABI was evaluated using receiver operating characteristic (ROC) curves. All statistical tests were performed using SPSS version 20 software (IBM, New York, NY, USA).

RESULTS

The oscillometric ABI value could not be measured in 9 out of 216 limbs: eight limbs due to diffuse calcification of the arterial wall and three limbs due to low blood pressure (two limbs had both of these conditions). These nine limbs were excluded from the analysis. There were 162 of 207 limbs (78%) that had at least one lesion with >50% stenosis. The mean ABI and mean systolic pressure of the brachial artery were 0.72 ± 0.31 mm Hg and 140 ± 18 mm Hg, respectively. Detailed ABI values according to the symptoms, stenosis grade are shown in Table 2.

Diagnostic accuracy (sensitivity and specificity) of oscillometric ABI.

When CTA was used as the gold standard to define ⩾50% and ⩾75% stenosis, the respective areas under the ROC curves (AUCs)

Table 2 Mean ABI values according to the symptoms and degree of stenosis

Symptom	*Number of limbs (%)*	*Median (minimum, maximum)*
No symptom	45 (22%)	1.03 ± 0.18
Intermittent claudication	153 (74%)	0.74 ± 0.22
Critical limb ischemia	9 (4%)	0.98 ± 0.54
Total	207	0.72 ± 0.31
Degree of stenosis		
Grade 1	45 (22%)	1.11 ± 0.19
Grade 2	28 (13%)	0.97 ± 0.20
Grade 3	70 (34%)	0.74 ± 0.19
Grade 4	64 (31%)	0.63 ± 0.17

Abbreviation: ABI, ankle-brachial index.
(Grade 1, 0–50%; Grade 2, 50–75%; Grade 3, 75–99%; Grade 4, 100%).

were 0.919 (95% confidence interval (CI): 0.880–0.959) and 0.918 (95% CI: 0.879–0.957) (Figure 1). A cutoff value of 0.99 was found to be optimal for detecting ⩾50% stenosis (sensitivity, 90%; specificity, 85%), whereas a cutoff value of 0.87 was optimal for detecting ⩾75% stenosis (sensitivity, 84%; specificity, 89%). If only patients with DM were analyzed separately, AUC for detecting ⩾75% stenosis was 0.888 (95% CI: 0.825–0.952) with an optimal cutoff value of 0.86 (sensitivity, 81%; specificity, 84%).

ABI value depending on the severity of stenosis.
With a greater stenosis of the artery in the lower extremity, the ABI value tended to become lower (Figure 2, Table 2).

DISCUSSION

Oscillometric ABI can be easily performed by clinical assistants and reduce the examination time, as compared with the Doppler method. Many investigators[4–6,12–14] have found that the oscillometric method is a useful tool for clinical assessment of PAD that can replace Doppler measurements in most clinical situations. However, other studies have found that oscillometry overestimates ankle pressure and is unreliable.[15,16] In those reports, a major problem was that the oscillometric method tended to give higher values than the Doppler method as it could not detect low ankle pressure (<50 mm Hg) compared with the Doppler method.[2,5,14] However, most of the studies only determined the correlation between Doppler and oscillometric ABI, without direct comparison with anatomical information. In the present study, a favorable diagnostic accuracy of oscillometric ABI for detecting ⩾50% and ⩾75% stenosis was demonstrated when CTA was used as a gold standard. The value of oscillometric ABI has been reported to be higher than Doppler ABI at low ankle pressure; however, the present results demonstrated the reliability of the oscillometric method compared with CTA in a cohort with a high prevalence of PAD. Guo *et al.*[17] compared oscillometric ABI with digital subtraction angiography and concluded that ABI was an accurate and reliable noninvasive alternative to conventional digital subtraction angiography for assessing lower extremity arteries. However, only 7% of the patients had PAD in that study, whereas 65% (134/207), 78% (162/207) of the limbs had ⩾75%, ⩾50% stenosis, respectively, in our study.

An ABI cutoff value of 0.99 was found to be optimal for detecting ⩾50% stenosis (sensitivity, 90%; specificity, 85%), whereas a cutoff value of 0.87 was optimal for detecting ⩾75% stenosis (sensitivity, 84%; specificity, 89%). Guo *et al.*[17] reported that 0.95 was the optimal cutoff value for detecting 50% stenosis. Clairotte *et al.*[8] found that the optimal cutoff value for detecting 50% stenosis was 1.02. Our optimal cutoff values are consistent with these previous studies. The recent statement from the AHA[2] recommended that subjects with an ABI between 0.91 and 1.00 should be considered ‘borderline’ because the risk of cardiovascular mortality might be slightly higher than normal. In total, 50% stenosis doesn’t necessarily impede the arterial flow, but it means atherosclerotic burden in the artery. From the point of cardiovascular event prevention, our optimal ABI cutoff of 0.99 for the detection of ⩾50% stenosis supports the AHA recommendation, with 1.00 as a threshold between normal and borderline.

When we separately analyzed patients with DM, the AUC for detecting ⩾75% was 0.888, inferior to that of the entire patient cohort (AUC, 0.918). Clairotte *et al.*[8] reported a lower diagnostic performance with a higher cutoff value of oscillometric ABI in diabetic patients. The reason for decreased diagnostic accuracy might be related to poor arterial compressibility resulting from stiffness and calcification, which may occur commonly in DM.[18,19] In the present study, eight of nine patients in whom ABI values could not be correctly measured had diffuse arterial calcification.

An interesting finding in the present study was that the optimal ABI cutoff value showed a tendency to decrease with increasing severity of stenosis in patients with PAD. Guo *et al.*[17] also reported this finding. However, it is difficult to predict the degree of stenosis based only on the ABI value, because not only the degree of stenosis but also the number of stenotic segments or amount of calcification in the arterial wall may affect the ABI value. Further study is required to resolve these issues.

This study has several potential limitations. All data were analyzed retrospectively at a single facility, which limits the power of the study. Most of the patients had intermittent claudication, and there were patients with critical limb ischemia (CLI). Iida *et al.*[20] reported that 43% of CLI patients had isolated BTK lesions. If the present study had included more CLI patients with isolated BTK lesions, the diagnostic performance of oscillometric ABI might have been lower. However, ABI would not be needed in CLI patients who have overt symptoms, such as ischemic color changes, ulcers or gangrene. The main use for

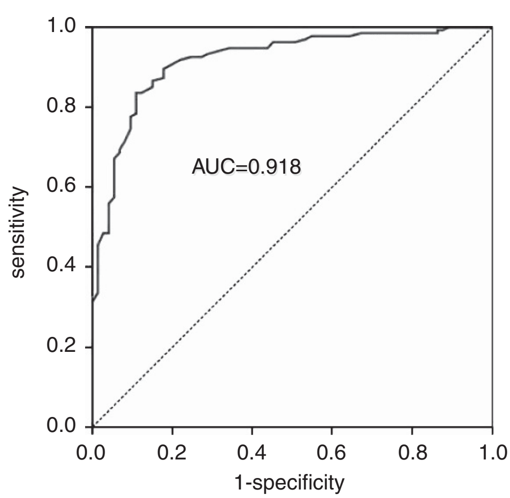

Figure 1 ROC curve of the ABI for diagnosing PAD when CTA was used as the gold standard for defining ⩾75% stenosis. A full color version of this figure is available at the *Hypertension Research* journal online.

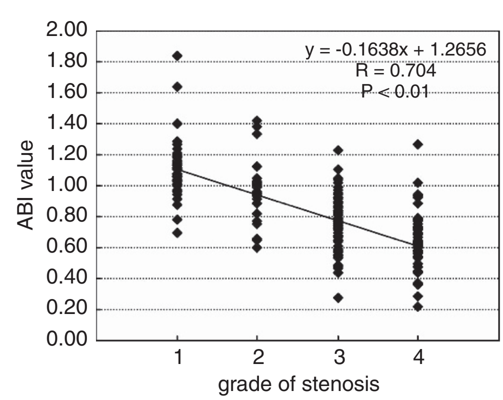

Figure 2 The relationship between the ABI and severity of the arterial stenosis in the lower extremity. (grade 1, 0–50% (*N*=45); grade 2, 50–75% (*N*=28); grade 3, 75–99% (*N*=70); grade 4, 100% (*N*=64)) *N*, number of limbs. A full color version of this figure is available at the *Hypertension Research* journal online.

ABI could be screening of patients with intermittent claudication or asymptomatic arterial stenosis, and the present results showed the usefulness of ABI in these types of patients.

In conclusion, oscillometric ABI measured in the present study, which included a large number of PAD patients, offered high diagnostic ability for lower arterial stenosis. The diagnostic ability of ABI may be impaired by the presence of DM.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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