ORIGINAL ARTICLE

Combination of pulse volume recording (PVR) parameters and ankle–brachial index (ABI) improves diagnostic accuracy for peripheral arterial disease compared with ABI alone

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The ankle–brachial index (ABI) measurement is widely used as a screening tool to detect peripheral arterial disease (PAD). With the advent of the oscillometric ABI device incorporating a system for the measurement of pulse volume recording (PVR), not only ABI but also other parameters, such as the percentage of mean arterial pressure (%MAP) and the upstroke time (UT), can be obtained automatically. The purpose of the present study was to compare the diagnostic accuracy for PAD with ABI alone with that of a combination of ABI, %MAP and UT. This study included 108 consecutive patients on whom 216 limb measurements were performed. The sensitivity, specificity and positive and negative predictive values of ABI, %MAP, UT and their combination were evaluated and compared with CT angiography that was used as a gold standard for the detection of PAD. The diagnostic accuracy as well as the optimal cutoff values of %MAP and UT were evaluated using receiver operating characteristic (ROC) curve analysis. The combination of ABI, %MAP and UT achieved higher sensitivity, negative predictive value and accuracy than ABI alone, particularly for mild stenosis. The areas under the ROC curve for the detection of 50% stenosis with UT and %MAP were 0.798 and 0.916, respectively. The optimal UT and %MAP values to detect \geq 50% stenosis artery were 183 ms and 45%, respectively. The combination of ABI, %MAP and UT contributed to the improvement of the diagnostic accuracy for PAD. Consideration of the values of %MAP and UT in addition to ABI may have a significant impact on the detection of early PAD lesions. *Hypertension Research* (2016) **39**, 430–434; doi:10.1038/hr.2016.13; published online 25 February 2016

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INTRODUCTION

The ankle-brachial index (ABI) is broadly applied to detect peripheral arterial disease (PAD).^{1,2} The Doppler method has been a gold standard for obtaining ABI, but the automated oscillometric method, which can be performed rapidly by less trained observers, has been demonstrated to have comparable diagnostic ability to that of the Doppler method and has been adopted as the standard procedure at many vascular centers.^{3–5} In addition to its role in the detection of PAD, ABI has drawn attention as a useful prognostic marker for cardiovascular events. According to the recently published AHA (American Heart Association) guidelines for the measurement and interpretation of ABI, an abnormal ABI value is an indicator of atherosclerosis at other vascular sites, such as the carotid artery or coronary artery.¹ In the past, an ABI of < 0.90 and an ABI of > 1.40were considered to be abnormal values. However, because an ABI between 0.91 and 0.99, which may represent mild stenotic PAD, are associated with a 1.84-fold higher risk of cardiovascular mortality than the normal value, the AHA guidelines recommend that 0.91 ≦ABI \leq 0.99 should be classified as a borderline range so that mild stenosis

can be reliably detected to prevent cardiovascular mortality.1 Our previous study has shown that the cutoff value of oscillometric ABI is 0.99 for detecting \geq 50% stenosis with excellent diagnostic accuracy.5 However, 65% of the patients included in that study had \geq 75% stenosis, and the exact diagnostic accuracy for mild arterial stenosis between 50 and 75% remains unknown. A previous animal study investigating the relationship between the rate of stenosis and blood pressure (BP) in dogs has shown that a reduction in BP appears at 60% stenosis and that both the BP and flow start to decrease when the stenosis rate exceeds 80%.6 Given that ABI can detect only an arterial pressure drop, the diagnostic accuracy of ABI for mild stenosis may not be sufficient. Notably, Guo et al.7 have reported that the diagnostic accuracy of oscillometric ABI has a tendency to decrease with mildstenosis. Nakashima et al.8 have reported that 63% of patients with an ABI >0.90 have significant stenosis, as detected by angiography. To improve the diagnostic accuracy of ABI for PAD detection, particularly for mild arterial stenosis, an additional parameter should be combined with ABI.

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The formIII-PWV/ABI (Omron Healthcare, Kyoto, Japan), an automated oscillometric device, provides a system to analyze pulse volume recording (PVR) as well as ABI. Arterial inflow into the lower extremities is pulsatile, leading to measurable changes in lower limb volume with each cardiac cycle. PVR provides a method to evaluate the arterial pressure waveform profile via the use of a pneumoplethysmograph.⁹ In the case of PAD, the waveform of PVR becomes dampened, with its peak being delayed and diminished. In the past, PVR obtained by plethysmography has been shown to provide useful parameters for the detection of PAD, with a diagnostic accuracy of 95%.¹⁰ However, the subjective evaluation of the waveform can be strongly influenced by the experience of the observer, making it difficult to obtain reproducible results.^{10,11} To quantify the waveform objectively, two new parameters, the percentage of mean arterial pressure (%MAP) and the upstroke time (UT), have been introduced in the formIII-PWV/ABI oscillometric device. Recently, updated guidelines for noninvasive vascular function testing were published by the JCS (Japan Cardiology Society), and they introduce cutoff values of 45% for %MAP and 180 ms for UT for the detection of PAD.¹² However, to date, only small case studies have shown the diagnostic utility of these parameters for PAD detection.^{8,13} The purpose of this study was to assess the diagnostic accuracy of ABI, %MAP and UT in the detection of PAD and to clarify whether these new values can improve diagnostic accuracy for PAD compared with ABI alone.

METHODS

Patients who had been referred to our department between June 2010 and December 2012 were included in this retrospective study. Patients who had undergone vascular surgery or endovascular treatment for PAD were excluded. This patient cohort was identical to that of our previous study.⁵ Informed consent was obtained from all subjects. The study protocol was developed in accordance with the Declaration of Helsinki. The institutional review board of our university approved this retrospective study.

Measurement of ABI, %MAP and UT

ABI was measured with each patient in the supine position after at least 15 min of rest in a waiting room with a comfortable temperature. All measurements were performed using the form III-PWV/ABI. The form III-PWV/ABI is an automated oscillometric device designed to measure ABI using BP in all four limbs, as well as the %MAP and UT calculated from the PVR waves. Four oscillometric cuffs, which incorporated pressure sensors, were wrapped around both arms and ankles. Ankle pressures were measured over the dorsalis and posterior tibial arteries and used to calculate the ABI. The PVR waves were measured using pneumoplethysmography.14,15 To obtain PVR, the holding pressure of the cuffs was maintained at 54 mm Hg for the patients whose diastolic BP was above 62 mm Hg and at diastolic BP minus 8 mm Hg for the patients whose diastolic BP was below 62 mm Hg to minimize the influence of cuff pressure on hemodynamics. The waveforms were recorded and stored for 10 s. The transit time between the brachial and the ankle pulse waves was automatically determined and analyzed by the preloaded specialized software. The %MAP and the UT values were calculated for each beat of PVR, and the mean values were obtained from 10 s recordings. The %MAP is the value from the area of the waveform (P2) divided by the amplitude of the pulse (P1). This value was calculated with the following formula: %MAP = P2/P1 × 100 (%). The UT is the waveform upstroke time from the nadir to the peak. If one pulse interval was 25% shorter or longer than the previous beat interval, the beat was excluded because of the possibility of body movement or arrhythmia. If the number of pulses available for calculation was less than three, the %MAP and UT could not be calculated. A normal PVR has a rapid upstroke, a sharp systolic peak, a dicrotic notch and a downslope that bends toward the baseline (Figure 1). If hemodynamically significant stenosis is present, the volume of blood flow decreases, with the pulse wave being flattened (increment of the %MAP) and the UT being extended.



Figure 1 A case example of PVR measurement and CT angiography. (a) CT angiography shows total occlusion of right external iliac artery (EIA) and right popliteal artery. (b) Pulse waveforms. The waveforms of right leg is flattened with the dicrotic notch being disappeared as arterial flow decreases due to occlusion of right EIA and popliteal artery. The waveforms of left leg shows normal pattern. %MAP, percent mean arterial pressure; PVR, pulse volume recording; UT, upstroke time.

CT angiography (CTA) and image analysis

CTA was performed in all subjects within 1 month before or after the ABI measurements to confirm the presence, anatomical location and degree of stenosis. CTA was performed with a dual-source 64 slice CT scanner (Somatom Definition; Siemens Medical Solutions, Erlangen, Germany). Plain, arterial and venous phases were scanned, encompassing the abdomen and lower extremities. Arterial stenosis was graded with a 4-point scale (grade 1, 0–50%; grade 2, 50–75%; grade 3, 75–99%; grade 4, 100%) for each of the following arterial segments: aortoiliac, femoropopliteal and below the knee. The grading was performed by visual assessments of axial images and maximum intensity projection images, as shown in Figure 1. Grades 2–4 were diagnosed as PAD.

Definition of ABI, %MAP and UT

We defined the threshold of ABI as 0.99 because of a recent recommendation from the AHA that $0.91 \leq ABI \leq 0.99$ be classified as the borderline range.¹ According to the JCS 2013 guidelines, the cutoff values of %MAP and UT were defined as 45% and 180 ms, respectively.¹²

Investigated parameters

The following parameters were investigated: diagnostic accuracy sensitivity, specificity, positive predictive value, negative predictive value and accuracy of oscillometric ABI alone; %MAP alone; UT alone; the combination of %MAP and UT (%MAP $\geq 45\%$ or UT ≥ 180 ms); and the combination of ABI, %MAP and UT (ABI ≤ 0.99 or %MAP $\geq 45\%$ or UT ≥ 180 ms) compared with the reference diagnosis of PAD by CTA. The sensitivity of %MAP and UT depending on the degree of stenosis (grade 4, 100%; grade 3, 99-75%; grade 2, 75-50%; grade 1, 50-0%) was also evaluated. In addition, to determine whether %MAP and UT can improve the diagnostic accuracy of arterial stenosis in patients with borderline or normal ABI values, the sensitivities of %MAP and UT were evaluated separately in those patients. Continuous variables are presented as the mean \pm s.d. Discrete data are presented as counts and percentages. The significance of the differences of parameters was analyzed using the χ^2 test. The *P*-values of 0.05 were considered to be statistically significant. Receiver operating characteristics (ROC) analysis was used to determine the optimal cutoff points for both %MAP and UT.

RESULTS

A total of 108 patients were included in this study. The mean patient age was 71.2 ± 8 years. Patient baseline characteristics are shown in Table 1. ABI was obtained from 207 out of 216 limbs. Among the nine limbs with unsuccessful ABI measurements, eight limbs had total occlusion, indicating that measurement errors could arise from low BP. The mean ABI of the 207 limbs was 0.72 ± 0.31 . The mean pressure of the brachial artery was 140 ± 18 mm Hg. %MAP and UT were obtained from 210 out of 216 limbs. Among the six limbs with unsuccessful % MAP and UT measurements, five limbs had total occlusion. Overall, 13 limbs had measurement errors of either ABI or %MAP/UT that were excluded from the analysis. Table 2 summarizes the mean ABI, %MAP and UT values classified by the degree of stenosis.

Diagnostic accuracy of % MAP and UT

The areas under the ROC curves for detecting 50% stenosis with UT and %MAP were 0.798 and 0.916, respectively. The optimal UT and %MAP values to detect \geq 50% arterial stenosis were 183 ms and 45% (Figure 2).

Accuracy of ABI, %MAP, UT and the combination of ABI, %MAP and UT

Table 3 shows the accuracy of ABI, %MAP and UT; the combination of %MAP and UT; and the combination of ABI, %MAP and UT.

Table 1 Patient characteristics (n = 108)

Age (years)	71.2±8.1
Female gender, n (%)	14 (13)
<i>Symptom (</i> n <i>= 216 limbs)</i> No symptom	45 (21)
Intermittent claudication	160 (74)
Critical limb ischemia	11 (5)
Comorbidities	
HT	103 (95)
DM	58 (54)
CAD	42 (39)
CVD	28 (26)
HD	17 (16)
AF	11 (10)

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

The highest sensitivity of 98.1% was obtained with the combination of ABI, %MAP and UT; the highest specificity of 88.9% was obtained with %MAP; the highest positive predictive value of 96.3% was obtained with %MAP; the highest negative predictive value of 90.0% was obtained with the combination of ABI, %MAP, and UT; and the highest accuracy of 89.7% was obtained with the combination of ABI, %MAP and UT. In summary, the combination of ABI, %MAP and UT achieved the highest sensitivity, negative predictive value and accuracy among every combination, whereas %MAP achieved the highest specificity and positive predictive value.

The sensitivities of ABI alone and of the combination of ABI, % MAP and UT were compared according to the different grades of stenosis (Figure 3). The combination of the ABI, %MAP and UT achieved higher sensitivities than ABI alone for detecting all grades of stenosis, particularly for mild grade 2 stenosis, for which a statistically significant improvement was noted.

Figure 4 shows a comparison of the sensitivity of %MAP and UT with respect to the different grades of stenosis. The sensitivities of %MAP for grade 4, grade 3 and grade 2 stenosis were 97%, 81% and 50%, respectively, whereas the sensitivities of UT were 72%, 71% and 75%, respectively. From these results, %MAP achieved higher accuracy for detecting grade 3 and 4 stenosis than UT, whereas UT achieved higher accuracy for detecting mild grade 2 stenosis than %MAP.

Figure 5 shows the sensitivity of %MAP and UT for detecting PAD in the ABI ranges between 0.91 and 0.99 (N=25) and 1.00 and 1.40 (N=51). Sensitivities of 81.0% and 86.0% were obtained in an ABI range between 0.91 and 0.99, and 1.00 and 1.40, respectively. In addition, failure of ABI measurement was noted in nine limbs;

Table 2 ABI, %MAP and UT according to the degree of arterial stenosis

Degree of stenosis	Grade 4 (100%)	Grade 3 (75–99%)	Grade 2 (50–75%)	Grade 1 (0–50%)
Limbs (%)	61 (30)	69 (34)	28 (14)	45 (22)
ABI	0.63 ± 0.18	0.73 ± 0.18	0.97 ± 0.20	1.11 ± 0.19
%MAP	50 ± 4.59	48 ± 4.63	45 ± 4.29	40 ± 5.00
UT	213 ± 60.29	206 ± 48.55	204 ± 41.37	164 ± 24.64

Abbreviations: %MAP, percent mean arterial pressure; ABI, ankle-brachial index; UT, upstroke time.



Figure 2 Receiver operating characteristics (ROC) curves of %MAP (a) and UT (b). AUC, area under the ROC curve; %MAP, percent mean arterial pressure; UT, upstroke time. A full color version of this figure is available at the *Hypertension Research* journal online.

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	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
ABI alone	142/158 (89.9%)	38/45 (84.4%)	142/149 (95.3%)	38/54 (70.4%)	180/203 (88.7%)
%MAP alone	129/158 (81.6%)	40/45 (88.9%)	129/134 (96.3%)	40/69 (58.0%)	169/203 (83.3%)
UT alone	114/158 (72.2%)	33/45 (73.3%)	114/126 (90.5%)	33/77 (42.9%)	147/203 (72.4%)
Combination of %MAP and UT Combination of ABI, %MAP and UT	146/158 (92.4%) 155/158 (98.1%)	31/45 (68.9%) 27/45 (60.0%)	146/160 (91.3%) 155/173 (89.6%)	31/43 (72.1%) 27/30 (90.0%)	177/203 (87.2%) 182/203 (89.7%)

Table 3 Diagnostic ability of ABI, %MAP, UT and the combination of ABI, %MAP and UT

Abbreviations: %MAP, percent mean arterial pressure; ABI, ankle-brachial index; NPV, negative predictive value; PPV, positive predictive value; UT, upstroke time. Bold numbers represent the highest values in each statistical measure.



Figure 3 Comparison of sensitivity between ABI alone and the combination of ABI, %MAP and UT according to different grades of stenosis. The combination of the ABI, %MAP and UT shows higher sensitivities than ABI alone for detecting every grade of stenosis. ABI, ankle-brachial index; %MAP, percent mean arterial pressure; UT, upstroke time.



Figure 4 Comparison of the sensitivity between %MAP and UT according to different grades of stenosis. %MAP shows higher sensitivity for detecting grade 3 and 4 stenosis than UT, whereas UT shows higher sensitivity for detecting mild stenosis of grade 2 than %MAP. ABI, ankle-brachial index; %MAP, percent mean arterial pressure; UT, upstroke time.

however, in seven of these nine limbs, both %MAP and UT detected significant arterial stenosis.

DISCUSSION

The diagnostic ability of the oscillometric ABI for PAD detection has been evaluated in several previous studies, showing that oscillometric ABI can achieve comparable diagnostic ability to that of Doppler ABI, with its reproducibility being higher than that of Doppler ABI.^{3,4} In addition, when CTA or digital subtraction angiography is used as a reference, oscillometric ABI can also achieve excellent diagnostic ability for PAD.^{5,7} However, ABI can underestimate stenosis unless the stenosis does not reduce the BP of the lower limbs. Nakashima



Figure 5 Sensitivity of combination of %MAP and UT in the ABI range between 0.91 and 0.99, and between 1.00 and 1.40. ABI, ankle-brachial index; %MAP, percent mean arterial pressure; UT, upstroke time.

*et al.*⁸ have reported that 12 of 19 patients with an ABI > 0.90 had significant stenosis demonstrated by angiography. Guo *et al.*⁷ have reported that the areas under the ROC curve of oscillometric ABI for the detection of stenosis \geq 30, \geq 50 and \geq 70% were 0.786, 0.927 and 0.963, respectively, demonstrating that the diagnostic ability of ABI tends to be lower for mild stenosis. Furthermore, its diagnostic accuracy may be hampered in patients with calcified stiff arteries, because the pressure cuffs cannot compress the arteries. In contrast, PVR is based on air plethysmography and measures the segmental volume changes of the arteries, reflecting arterial pulsatility. Arterial calcifications do not have a significant impact on PVR evaluation compared with ABI measurement.^{11,16}

The utility of PVR measurements for the diagnosis of PAD has been reported previously.^{10,11} Kempczinski¹⁰ has reported that thigh PVR can correctly predict the presence or absence of aortoiliac disease in 95% of limbs. However, the major drawback of PVR is that the waveforms are subjectively evaluated by each observer, thus making it difficult to obtain reliable results unless the observer has sufficient experience and skill.

In the present study, ABI, %MAP and UT were automatically measured and calculated with the form III-PWV/ABI device for a short time, thus minimizing the observers' biases and enabling officebased diagnosis. We demonstrated that the combination of ABI, %MAP and UT improved the diagnostic accuracy for PAD beyond that of ABI alone, especially for mild stenosis. The sensitivity of the combination of ABI, %MAP and UT for the detection of mild stenosis was 93%, higher than the sensitivity of 64% of ABI alone. Given that mild stenosis can be a manifestation of systemic atherosclerosis progression, it is crucial to detect such early-stage PAD before patients experience cardiovascular events. Furthermore, in cases with border-line ABI values between 0.91 and 0.99, the combination of %MAP and UT achieved a sensitivity of 81% for the detection of PAD. Notably, among the nine limbs with ABI measurement failure, both %MAP and UT detected PAD in seven limbs. The addition of these new parameters may offer complementary values to oscillometric ABI to achieve a higher diagnostic accuracy for early PAD and eliminate measurement errors.

ROC analyses revealed that the areas under the ROC curve for detecting 50% stenosis with UT and %MAP were 0.798 and 0.916, respectively. From this result, higher diagnostic accuracy for PAD would be expected with %MAP than with UT. The optimal cutoff values for UT and %MAP in this study were 183 ms and 45%, respectively. These values were almost identical to the cutoff values recommended by the JCS guideline.¹² It is noteworthy that although the sensitivity of %MAP was higher than that of UT for the detection of moderate to severe stenosis, the sensitivity of UT was higher for mild stenosis. Nakashima et al.8 have reported that ankle UT can detect peripheral stiffness earlier than other parameters, such as ABI. Furthermore, Park et al.¹⁷ have reported that UT is strongly associated with coronary artery calcification scores, supporting that UT may be useful not only for the detection of peripheral stiffness and mild stenosis but also for the detection of coronary arterial disease. The efficacy of UT for the detection of comorbid diseases, such as coronary arterial disease or PVD, in PAD patients should be evaluated in the future. However, UT can be easily influenced by other factors, such as heart rate, aortic valve stenosis, aortic regurgitation and hypertension.¹⁸ In this study, patients with symptomatic aortic valve stenosis and aortic regurgitation were not included.

The following limitations of the present study should be noted. First, all data were analyzed retrospectively at a single facility, limiting the power of the study. Second, most of the patients recruited in this study had PAD. Therefore, the results of the study could not be applied to the general population. To evaluate the applicability of %MAP and UT as a vascular screening tool in the general population, further study is required on a larger cohort including both healthy volunteers and vascular patients.

In conclusion, the combination of ABI, %MAP and UT contributes to the improvement of the diagnostic accuracy for PAD, particularly for mild arterial stenosis. The consideration of %MAP and UT in addition to ABI may have a significant impact on the detection of early PAD lesions and the prevention of future cardiovascular events.

CONFLICT OF INTEREST

Tomoko Hashimoto is an employee of Omron Healthcare and has received >1 000 000 yen for her employment.

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