

Validation of the integration of technology that measures additional “vascular” indices into an ambulatory blood pressure monitoring system

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Background: The objective of this study was to validate the novel integration of oscillometric (Vasotens®) technology into a BPLab® ambulatory blood pressure (BP) monitoring system to measure central BP, the aortic augmentation index, and pulse wave velocity (PWV) compared with the recommended and widely accepted tonometric method.

Methods: The ARTERY Society guidelines for comparison of PWV measurement techniques were used as the basis for recruitment of 99 individuals (mean age 44±19 years, 52 males). The standard for comparison was the conventional “classic” SphygmoCor device.

Results: Accordance of the two methods was satisfactory ($r=0.98$, mean difference of 2.9 ± 3.5 mmHg for central systolic BP; $r=0.98$, mean difference of -1.1 ± 2.3 mmHg for central diastolic BP; $r=0.83$, mean difference of $-2.6\pm13\%$ for aortic augmentation index; $r=0.85$, mean difference of 0.69 ± 1.4 for PWV).

Conclusion: The performance of Vasotens algorithms using an oscillometric ambulatory BP monitoring system is feasible for accurate diagnosis, risk assessment, and evaluation of the effects of antihypertensive drugs.

Keywords: validation study, ambulatory, 24-hour, monitoring, arterial stiffness, pulse wave velocity, augmentation index, central blood pressure

Introduction

The past decade has been characterized by increases in the prognostic value of ambulatory blood pressure monitoring (ABPM) and the role of ABPM in the diagnosis and management of hypertension. ABPM shows several advantages over conventional non-time-specific single blood pressure (BP) measurements, especially in routine clinical practice, such as improved accuracy, reduced observer error, elimination of office-induced pressor effects on BP, and offering a more standardized measurement technique using an automated oscillometric sphygmomanometer.¹⁻³ ABPM devices measure not only systolic BP and diastolic BP but also mean BP and pulse pressure. Recently, ABPM monitors measure or calculate other parameters that provide information about vascular wall properties have been developed. Several oscillometric ABPM systems, for example, the BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia), use specific algorithms to perform pulse wave analyses based on 24-hour recordings of ABPM data and to calculate central BP.⁴⁻⁷

The central BP waveform is a composite of the forward pressure wave produced by left ventricular contraction and a reflected wave.⁸ Thus, the BP in the ascending aorta represents the actual pressure imposed on the heart, the large arteries, the brain, and the kidneys. The effect of wave reflection on the aortic systolic pressure peak can

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be described as an augmentation and can be estimated using the augmentation index. In principle, the augmentation index can be measured by calculating the quotient of the pressure peaks of the initial and reflected waves.

The central and brachial BP values are different because of superimposition and divergence of incoming and reflected waves along the arterial tree. Calculation of central BP in patients with hypertension has received increasing interest because central and brachial BP values were compared with respect to their predictive value for cardiovascular events and their utility for evaluation of the differential effects of antihypertensive drugs.¹ Some studies have shown that the central BP and augmentation index are independent predictors of mortality in several populations.^{9,10} Central BP and augmentation index measurements are recommended for routine clinical use in cases of isolated systolic hypertension among the young. In some of these individuals, central BP may be normal, while systolic BP at the brachial level may be elevated due to strong amplification of the central pressure wave.^{1,11}

It is well known that wave reflection and stiffening of the aorta are crucial factors that mediate the increases in isolated systolic hypertension and pulse pressure accompanying aging.¹² Aortic stiffening results in increased propagation velocity of the pressure wave along the arterial tree (ie, increased pulse wave velocity [PWV]), which is associated with arterial distensibility.⁸ Thus, the PWV can be used as a measure of aortic stiffness.¹³ The PWV is increasingly being used in population studies. It has been demonstrated that the PWV has greater predictive value than traditional risk factors, such as the SCORE (Systematic COronary Risk Evaluation) and Framingham risk scores.^{14,15} PWV measurements are recommended by the European Society of Hypertension for the management of hypertension. A substantial proportion of patients with classifications of intermediate risk may be reclassified into categories of higher or lower cardiovascular risk when the PWV, used as a measure of arterial stiffness, exceeds 10 meters per second.¹

In recent years, several methods, such as applanation tonometry and transfer functions, have been developed to estimate central BP and the augmentation index.¹³ When used with sequential electrocardiography-gated carotid and femoral artery tonometry via the SphygmoCor device, (software version 9; AtCor Medical, Sydney, Australia), the PWV can be measured noninvasively in parallel with central BP and the augmentation index. Carotid-femoral PWV, as measured by applanation tonometry, is presently considered to be the gold standard for noninvasive assessment of arterial

stiffness and for validation of noninvasive hemodynamic measurement devices, such as ABPM monitors that include additional features estimating vascular wall properties.¹³ In 2010, the ARTERY Society published widely recognized guidelines for the design of high-quality studies validating noninvasive hemodynamic measurement devices.¹⁶ Thus, the objective of our study was to validate the novel integration of oscillometric (Vasotens) technology into a BPLab ABPM system to measure central BP, the aortic augmentation index, and the PWV compared with the recommended and widely accepted tonometric method according to these guidelines.

Materials and methods

Recruitment of participants

We used the guidelines of the ARTERY Society for comparisons between PWV techniques as the basis for our study comparing the measurements of central BP and the augmentation index using different devices.¹⁶ The individuals recruited for the study were equally distributed across three age ranges (ie, 18–30 years, 30–60 years, and older than 60 years). At least 25 individuals were included in each age range, and each range included a minimum of 40% men and 40% women. Participants were excluded if they were under the age of 18 years, were pacemaker-dependent, were not in sinus rhythm, were pregnant, had a body mass index higher than 30 kg/m², had known carotid or femoral artery stenosis, or the pulse at the site of measurement was impalpable. The study was approved by the local ethics committee.

Measurements

To ensure hemodynamic stability, the measurements were performed in the supine position after the participants had been resting in this position for a minimum of 15 minutes. All subjects were familiarized with the environment, the procedure, and the devices. Central BP, augmentation index, and PWV measurements were recorded in triplicate using each device. These three recordings from each device were averaged to produce a single value for each individual from each device.

The standard for comparison of the PWV measurements was the measurement of carotid-femoral PWV using a conventional or “classic” SphygmoCor device (AtCor Medical), which allows for sequential recording of the pulses at the carotid and femoral sites via applanation tonometry. These two signals are gated using the QRS complex from a simultaneously recorded electrocardiogram. The BP value entered into the SphygmoCor device for calibration of the pulse waves was measured using a BPLab device; this

device is known to display an accuracy of class A/A.¹⁷ The augmentation index was then initially determined using SphygmoCor software by calculating the central BP by a transfer function.¹⁸ Two investigators performed this protocol, and restricted themselves to the use of a single device for each subject but alternated the device they used between subjects. The investigators were blind to the results obtained from the alternate device. The order of measurements for two sequential subjects was as follows.

Subject 1

First measurement, SphygmoCor, observer A; second measurement, BPLab, observer B; third measurement, SphygmoCor, observer A; fourth measurement, BPLab, observer B; fifth measurement, SphygmoCor, observer A; and sixth measurement, BPLab, observer B.

Subject 2

First measurement, BPLab, observer A; second measurement, SphygmoCor, observer B; third measurement, BPLab, observer A; fourth measurement, SphygmoCor, observer B; fifth measurement, BPLab, observer A; sixth measurement, SphygmoCor, observer B.

Vasotens technology

Vasotens technology involves an innovative method of pulse wave analysis based on oscillometric blood pressure measurements from the BPLab ABPM system (OOO Petr Telegin Company). The principle of the oscillometric method is based on plethysmography, where changes in the pulsatile pressure in the brachial artery are recorded. The recordings are performed in the supine position using a conventional brachial BP cuff for adults. During BP measurement, the pressure waveforms in the cuff are recorded, digitalized, and stored in the device while performing step-by-step deflation.

Thereafter, an aortic pulse wave is generated using a generalized transfer function that utilizes a modification in a certain frequency range within the acquired pulse signal to derive the aortic pressure wave. The modulus and phase characteristics of the Vasotens transfer function have been published previously.¹⁹ The difference in time between the first wave and the second wave (ie, the reflected wave) correlates to the distance, according to the manufacturer's instructions, and the resulting PWV is expressed as meters per second. The principle of PWV measurement using Vasotens technology has also been described previously.^{7,20}

Statistical analysis

The statistical analysis was performed using Microsoft Excel software (Redmond, WA, USA). All results are presented as the mean \pm standard deviation (SD) unless otherwise stated. We used Pearson correlations and the Bland–Altman method for analyses.²¹ The *R* coefficient was calculated for assessment of bias. The accuracy of the test device was determined based on both the mean difference from the reference and the standard deviation of this difference. For example, we considered the accuracy of the PWV measurements to be excellent when the mean difference was ≤ 0.5 meters per second and the SD was < 0.8 meters per second; the accuracy was considered to be acceptable when the mean difference was < 1.0 meters per second and the SD was ≤ 1.5 meters per second; and the accuracy was considered to be poor when the mean difference was > 1.0 meters per second or the SD was > 1.5 meters per second.¹⁶ To assess the accuracy of the BP measurements, we used the mean difference and SD thresholds recommended in international protocols.^{22–24}

Results

Parameters of the study population

Ninety-nine individuals (including 52 males) of mean age 44 ± 19 (18–77) years were recruited. They were evenly distributed across the three designated age groups, and were balanced with respect to sex (Table 1). Thus, this necessary condition for validation of noninvasive hemodynamic measurement devices according to the guidelines of the ARTERY Society protocol was satisfied. Table 1 also includes the results of the measurements and comparison measurements for the entire group of study participants and each of the three age groups of participants.

Central BP

Across the study population, central systolic BP measured using the SphygmoCor device was 120 ± 14 mmHg, and the central systolic BP calculated using the Vasotens device was 123 ± 14 mmHg. The correlation between central SBP values measured using these two methods was significant ($r=0.98$, $P<0.0001$). The Bland–Altman plot of these data, as shown in Figure 1, indicates excellent agreement (mean difference 2.9 ± 3.5 mmHg) and no systematic bias. The central DBP values measured using the tonometer-based and one-cuff-based approaches were 68 ± 11 mmHg and 67 ± 11 mmHg, respectively. The correlation between these central DBP values was significant ($r=0.98$, $P<0.0001$). The Bland–Altman plot of these central diastolic BP data,

Table I Demographics and results of measurements compared for the entire group of study participants and each of the three age groups of study participants

Parameter	All participants	18–30 years	30–60 years	>60 years
Demographics				
n	99	34	33	32
Age, years	44±19	25±2	44±11	69±6
Male, n (%)	52 (53)	19 (56)	17 (52)	16 (50)
Height, m	1.7±0.1	1.6±0.2	1.7±0.1	1.7±0.1
Weight, kg	67±13	67±12	67±12	68±10
BMI, kg/m ²	23±3	22±3	23±3	25±3
SBP, mmHg	129±20	121±12	130±22	138±20
DBP, mmHg	76±11	73±10	79±12	76±10
SphygmoCor measurements				
SBPao, mean (SD), mmHg	120±14	116±5	119±14	123±15
DBPao, mean (SD), mmHg	68±11	65±3	69±9	70±12
Alx, mean (SD), %	11±11	2±8	10±11	12±11
PWV, mean (SD), m/sec	7.03±1.88	6.5±0.9	7.9±1.7	8.2±2.1
BPLab®-Vasotens® measurements				
SBPao, mean (SD), mmHg	123±14	117±5	119±15	126±16
DBPao, mean (SD), mmHg	67±11	66±3	69±11	71±13
Alx, mean (SD), %	13±12	3±11	9±14	14±15
PWV, mean (SD), m/sec	7.7±1.41	6.5±0.9	7.8±1.8	8.2±2.1
Comparison of BPLab®-Vasotens® with SphygmoCor				
SBPao, mean difference (SD), mmHg	2.9 (3.5)	−0.9 (1.2)	2.0 (3.9)	4.5 (5.1)
DBPao, mean difference (SD), mmHg	−1.1 (2.3)	0.2 (1.2)	−2.1 (1.3)	4.1 (2.2)
Alx, mean difference (SD), %	−2.6 (13)	−0.3 (6)	1.1 (4)	−2.9 (8)
PWV, mean difference (SD), m/sec	0.7 (1.4)	0.01 (0.2)	−0.05 (0.9)	0.8 (1.5)

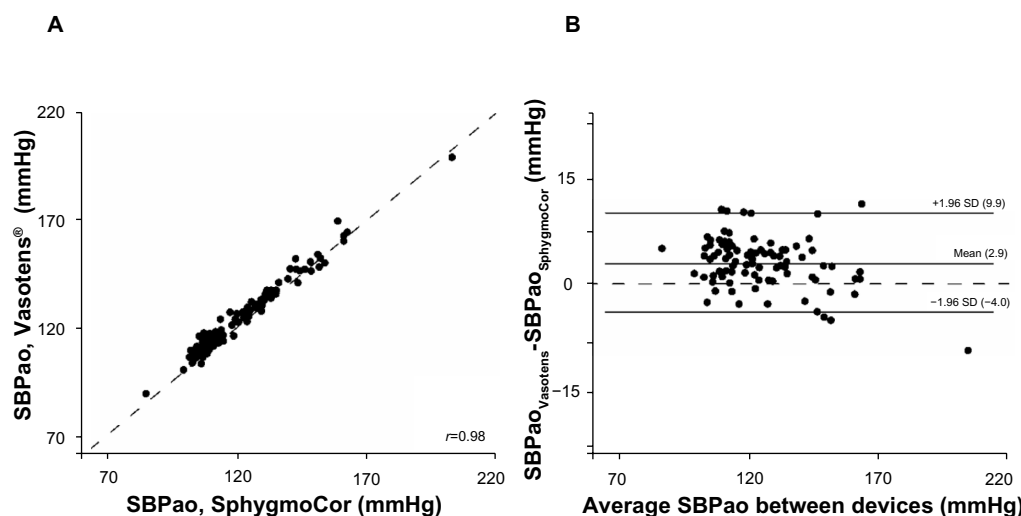
Notes: BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia); SphygmoCor device (software version 9; AtCor Medical, Sydney, Australia).

Abbreviations: SD, standard deviation; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; SBPao, central SBP; DBPao, central DBP; Alx, augmentation index; PWV, pulse wave velocity.

as shown in Figure 2, shows excellent agreement (mean difference of -1.1 ± 2.3 mmHg) and no systematic bias.

The mean aortic augmentation index values obtained using the SphygmoCor and Vasotens devices were $11\%\pm11\%$ and $13\%\pm12\%$, respectively. The correlation between the

aortic augmentation index values measured using these two methods was significant ($r=0.83$, $P<0.001$). The Bland–Altman plot of the aortic augmentation index values, as shown in Figure 3, shows good agreement (mean difference $-2.6\%\pm13\%$) and no systematic bias.

**Figure 1** Scatter plot containing the regression line (A) and Bland–Altman plot (B) comparing the SphygmoCor and Vasotens methods.

Notes: BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia); SphygmoCor device (software version 9; AtCor Medical, Sydney, Australia).

Abbreviations: SBPao, aortic systolic blood pressure; SD, standard deviation.

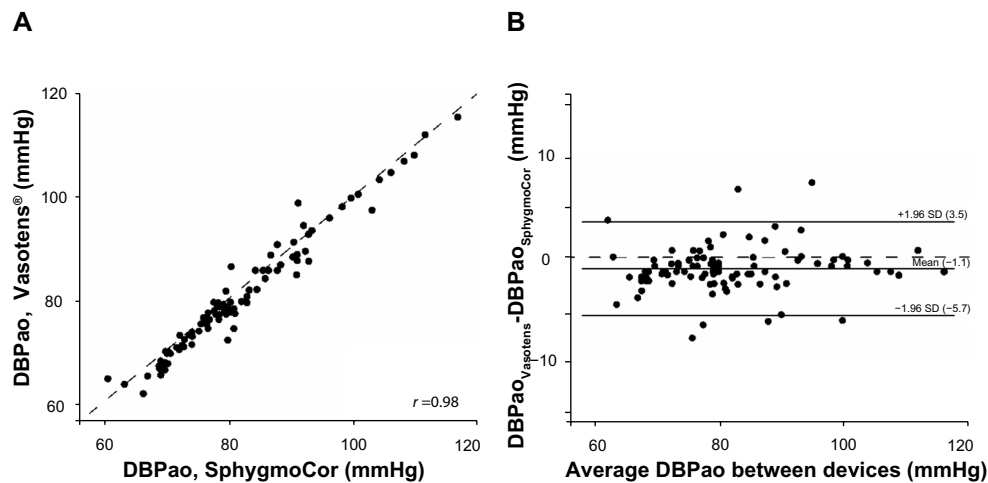


Figure 2 Scatter plot containing the regression line (A) and Bland–Altman plot (B) comparing the SphygmoCor and Vasotens methods.

Notes: BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia); SphygmoCor device (software version 9; AtCor Medical, Sydney, Australia).

Abbreviations: DBPao, aortic diastolic blood pressure; SD, standard deviation.

Pulse wave velocity

The mean aortic PWV measured by applanation tonometry was 7.03 ± 1.88 meters per second and that using the one-cuff-based approach was 7.72 ± 1.41 meters per second. The correlation between the PWV values measured using these two methods was significant ($r=0.85$, $P<0.001$). The Bland–Altman plot of these PWV data, as shown in Figure 4, shows a mean difference of 0.69 ± 1.4 . According to the guidelines of the ARTERY Society, the accuracy of the Vasotens technology was “acceptable” (ie, the mean difference was less than 1.0 ± 1.5 meters per second).

Discussion

This study sought to validate a method of collecting additional “vascular” indices (ie, the central BP, the augmentation index, and the PWV) using the novel Vasotens technology

and integration of these indices into the BPLab oscillometric ABPM system, which uses an original pulse wave analysis algorithm based on plethysmography. As recommended in the ARTERY Society guidelines, the tonometer-based assessment of these indices was chosen as the reference standard because this parameter has been used in the clinic setting and in large population studies.^{16,18,25–27} Thus, the equivalence of these data is a necessary requirement for oscillometric one-site-based measurements to be meaningful and useful for accurate diagnosis, risk assessment, and evaluation of the effects of antihypertensive drugs.

Other investigators have previously demonstrated that the brachial waveforms acquired using normal blood pressure cuffs can be used to calculate central BP.^{28,29} Our results also support the hypothesis that a generalized mathematical transfer function can be used to calculate central BP based

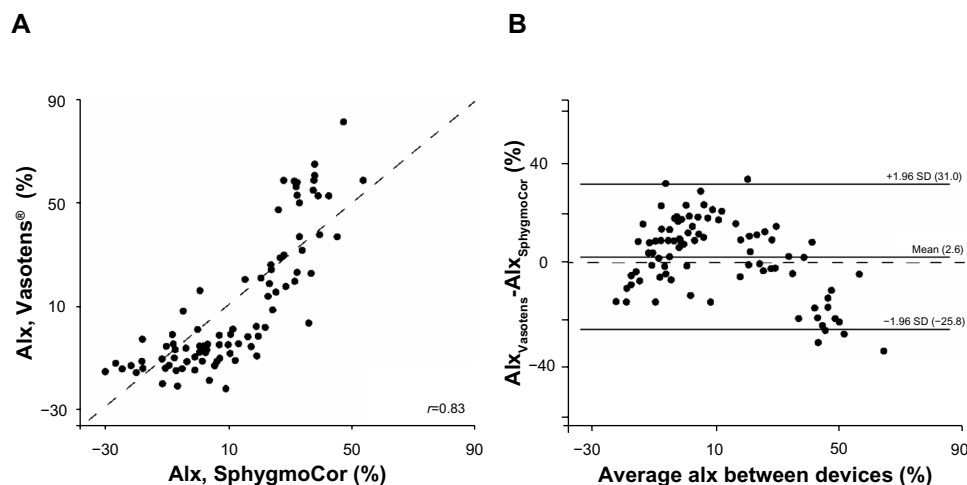


Figure 3 Scatter plot containing the regression line (A) and Bland–Altman plot (B) comparing the SphygmoCor and Vasotens methods.

Notes: BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia); SphygmoCor device (software version 9; AtCor Medical, Sydney, Australia).

Abbreviations: Alx, augmentation index; SD, standard deviation.

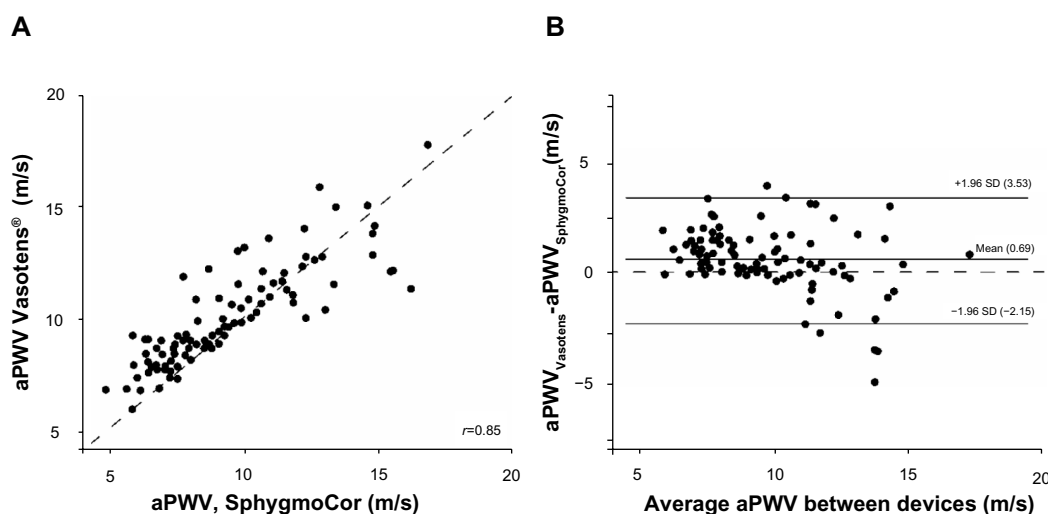


Figure 4 Scatter plot containing the regression line (A) and Bland–Altman plot (B) comparing the SphygmoCor and Vasotens methods.

Notes: BPLab® with Vasotens® technology (OOO Petr Telegin, Nizhny Novgorod, Russia); SphygmoCor device (software version 9; AtCor Medical, Sydney, Australia).

Abbreviations: aPWV, aortic pulse wave velocity; SD, standard deviation.

on peripheral waveforms.³⁰ Our findings revealed levels of performance that are similar to those described in previous studies of oscillometric sphygmomanometers.³¹ The mean difference and SD for central systolic BP were 2.9 and 3.5, respectively, which were far below the thresholds of ± 5 (SD 8) mmHg for the mean difference and SD that are defining the highest levels of accuracy of conventional blood pressure measurements.^{22–24} The mean difference and SD for central diastolic BP were even lower.

The augmentation index values determined in our study were within the ranges that have been published for the SphygmoCor device, and the results of our comparisons of the aortic augmentation index measurements revealed sufficient accuracy.

The ability to obtain the data required to calculate PWV values using brachial waveforms acquired from a regular BP cuff has also been demonstrated previously.^{4–7} The accuracy of measurements produced using the Vasotens technology was “acceptable” according to the guidelines of the ARTERY Society, which were used as the basis of our study protocol.¹⁶ Despite the wider range of PWV values compared with that reported in invasive and noninvasive validation studies, we obtained similar correlation coefficients, mean differences, and SDs.^{4,6,7}

For comparison of measurements between the different age groups, acceptable accuracy was detected for the entire group of study participants as well as for each of the three age groups.

There were limitations associated with this study. The aforementioned limits (± 5 [SD 8] mmHg) recommended to define the levels of accuracy of BP measurements were designed to validate BP measurement devices for

brachial BP but not for central BP. There is a need to develop formal recommendations to validate central BP measurements.

A further advantage of the Vasotens method that should be noted is its ability to collect 24-hour profiles of “vascular” indices. In fact, putative approaches to analyze 24-hour profile PWV data have already been proposed, and studies of the correlation between target organ damage in hypertension and the repeatability of the indices recorded using these approaches have been performed.^{7,32,33}

Conclusion

Our study revealed satisfactory accordance between the two methods. Thus, the performance of Vasotens algorithms using the oscillometric ABPM system represents a feasible approach to provide accurate diagnosis, risk assessment, and evaluation of the effects of antihypertensive drugs.

Disclosure

The authors have no conflicts of interest to report in this work.

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