Research Reports in Clinical Cardiology

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ORIGINAL RESEARCH

Central aortic blood pressure and augmentation index: comparison between Vasotens® and SphygmoCor® technology

This article was published in the following Dove Press journal:
Research Reports in Clinical Cardiology
14 May 2012
Number of times this article has been viewed

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Introduction: The aim of this study is the comparison of Vasotens® technology as used in a device with an oscillometric method of blood pressure measurement (BPLab, Petr Telegin Ltd, Nizhny Novgorod, Russian Federation) against the validated tonometric system (SphygmoCor®, AtCor Medical Pty Ltd, West Ryde, Australia).

Methods: The examinations were carried out in two medical centers. Exclusion criteria included atrial fibrillation, severe cardiac anomalies, heart failure, arrhythmia, decompensated diabetes, the presence of an artificial pacemaker, pregnancy, and BMI > 30. Overall, 160 patients and healthy volunteers were examined. Central aortic systolic blood pressure (aSBP) and augmentation index (aAIx) were obtained by means of applanation tonometry and the oscillometric method was compared.

Results: aSBP and aAIx measured using the BPLab device equates significantly with the same parameters measured by SphygmoCor.

Conclusion: This finding allows the recommendation of Vasotens technology, which can be used with the 24-hour BPLab monitoring system for wide clinical use.

Keywords: central aortic blood pressure, augmentation index, validation, Vasotens®, BPLab®

Introduction

The sphygmomanometric methods of blood pressure (BP) measurement have been used worldwide for over a century. It is well-known that systolic and diastolic BP measured over the brachial artery are both prognostically important and have therapeutical applications. However, nowadays it is also important to evaluate other vascular parameters.

For example, results of the CAFE study showed that brachial BP is not always a good surrogate for the efficacy estimation of BP-lowering drugs on arterial hemodynamics.[1] It is now clear that many factors determine the relationship between brachial and aortic systolic BP (aSBP),[2] and the latter should more accurately predict cardiovascular outcomes.[1,3,5]

There is substantial evidence that the augmentation index (AIx) independently predicts cardiovascular morbidity and mortality in a variety of populations, as confirmed by recent meta-analysis studies.[6,7] AIx correlates with the left ventricular mass in normotensive as well as in hypertensive patients.[8] It has been shown that both elevated aSBP and AIx are independent predictors of mortality in various patients.[8] With the absence of arterial occlusive lesions, diastolic arterial BP in the brachial artery, as well

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as in the aorta, are practically the same. Consequently, a study of aSBP and AIx are of primary importance for our validation procedure.

The gold standard is a direct measurement of aSBP by using a transducer introduced into the aortic root at the time of cardiac catheterization, but being invasive, it is unsuitable for routine clinical practice. An alternative approach is an analysis of the peripheral arterial waveform obtained by oscillometry or tonometry and assessment of the central aortic pressure parameters using the so-called "transfer function" (TF) applied in some hemodynamic models.[9–12]

It is a well-known fact that the validated generalized TF of the radial artery can be obtained by SphygmoCor® (AtCor Medical Pty Ltd, West Ryde, Australia). As for the TF of the brachial artery, it can be put into practice by means of Vasotens® technology (Petr Telegin Ltd, Nizhny Novgorod, Russian Federation). The study of reproducibility and repeatability of aSPB and AIx obtained by means of Vasotens® technology has been published recently.[13] The aim of our study is the validation of this technology used in a device with an oscillometric method (Vasotens® technology in BPLab system) compared to a validated tonometric technology system (SphygmoCor).

Methods

Study population

The examinations were carried out in two medical centers, at the Cardiology Research Complex, Moscow, Russia and at the Therapy Research Institute, Novosibirsk, Russia. The validation protocol was authorized by the local ethics committee.

Exclusion criteria included atrial fibrillation, severe cardiac anomalies, heart failure, arrhythmia, presence of an artificial pacemaker, decompensated diabetes, pregnancy, and BMI > 30. Overall, 160 patients and healthy volunteers were included in this study, 73 female and 87 male. The mean age was 53 ± 11 (range 18–81) years. Medical treatment was not withheld for these measurements. The mean values of BP were 129 ± 15 mmHg and 78 ± 12 mmHg for systolic and diastolic BP, respectively. For detailed baseline characteristics, refer to Table 1.

Table 1 Baseline characteristics in the 'validation' group

Characteristics	Value
Male/female	87 (54.4%)/73 (45.6%)
Hypertension	78 (48.75%)
Smoker	34 (21.25%)
Previous myocardial infarction or stroke	7 (4.4%)
LVH	69 (43.2%)
Carotid plaque	45 (28.2%)
Renal disease	16 (10%)
Age (years)	53 (11)
Height (cm)	169.2 (8.4)
Weight (kg)	84 (14.5)
BMI	28.4 (3)
SBP (mmHg)	129 (15)
DBP (mmHg)	78 (12)
Heart rate (bpm)	71.2 (9.8)
SBP 0–99 (mmHg)	6 (3.75%)
SBP 100–129 (mmHg)	83 (51.9%)
SBP 130–159 (mmHg)	64 (40%)
SBP 160–179 (mmHg)	7 (4.4%)

Note: Values are numbers (and percentage) or means (and standard deviations).
Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; LVH, left ventricular hypertrophy; SBP, systolic blood pressure.

Investigation method

All measurements were performed during clinical routines by trained medical examiners. A number of aspects of the international recommendations for the measurement of arterial stiffness were taken into consideration. The measurements took place at a comfortable room temperature, while avoiding external stress influences. The conditions included a minimal resting period of 10 minutes. The consecutive recording of the pulse waves was obtained by two devices and was carried out in random order on the left arm. Usually, at least three iterations were performed in each session; median values were used.

SphygmoCor

The peripheral pulse pressure curve was registered at the radial artery by means of applanation tonometry (SphygmoCor) and simultaneously recorded into a personal computer. The quality of the recording could be controlled by using the provided operator index. In all of the recordings, its level exceeded 90%. The pulse pressure levels, which are necessary for device calibration, were obtained by two means:

A. measuring upper arm BP with the oscillometric method using a clinically validated Omron HEM 750;
B. measuring upper arm BP by BPLab which also correlates to the A/A class of accuracy.[13]

The SphygmoCor personal computer software calculates the aortic pulse wave using a TF. This transformation

provides us with the first parameters under investigation: aSBP and aortic pulse pressure (aPP). A characteristic point of the pressure curve, the inflection point, is identified within the time domain, indicating the arrival of the reflected wave in the ascending aorta. The BP at this point of time is called "inflection pressure". The difference between aSBP and inflection pressure is called "augmentation pressure" (AP). The aAIx is then calculated by AP/aPP × 100. In addition, the SphygmoCor device allows us to automatically estimate the peripheral AIx (pAIx) derived from the radial artery.

Vasotens

Vasotens technology is an innovative method used for the determination of aSBP and AIx based on oscillometric BP measurements with a regular cuff by the BPLab device.[14] The technology was developed by Petr Telegin Ltd. This method consists of assessing pulse waves at the brachial artery. The recordings are made by using a conventional BP cuff for adults. In measuring BP, the pressure pulsations in the cuff are registered during a step-by-step deflation.

The sampling rate of the device is 100 Hz. After digitalization, the signal processing is performed using a special mathematical algorithm, which is based on a specially developed TF. Amplitude and phase characteristics of the Vasotens TF are illustrated in Figure 1A. Determination of aSBP and AIx were carried out in the same way as in SphygmoCor (see Figure 1A–D). The amplitude of all signals recorded when the pressure in the cuff exceeded the systolic BP was used for waveform averaging (Figure 1B). Quality control method consists of visual assessment of the curves in the Vasotens clinical report screen.

Statistics

All data are shown as the mean and standard deviation. Furthermore, the data were analyzed using the Bland–Altman method. This was mainly helpful to represent the data graphically and to analyze the reproducibility of measurements according to different methods of BP calibration. Microsoft Excel software was used for the analysis (Microsoft, Redmond, WA).

Results

Statistics of the hemodynamic measurements are summarized in Table 2.

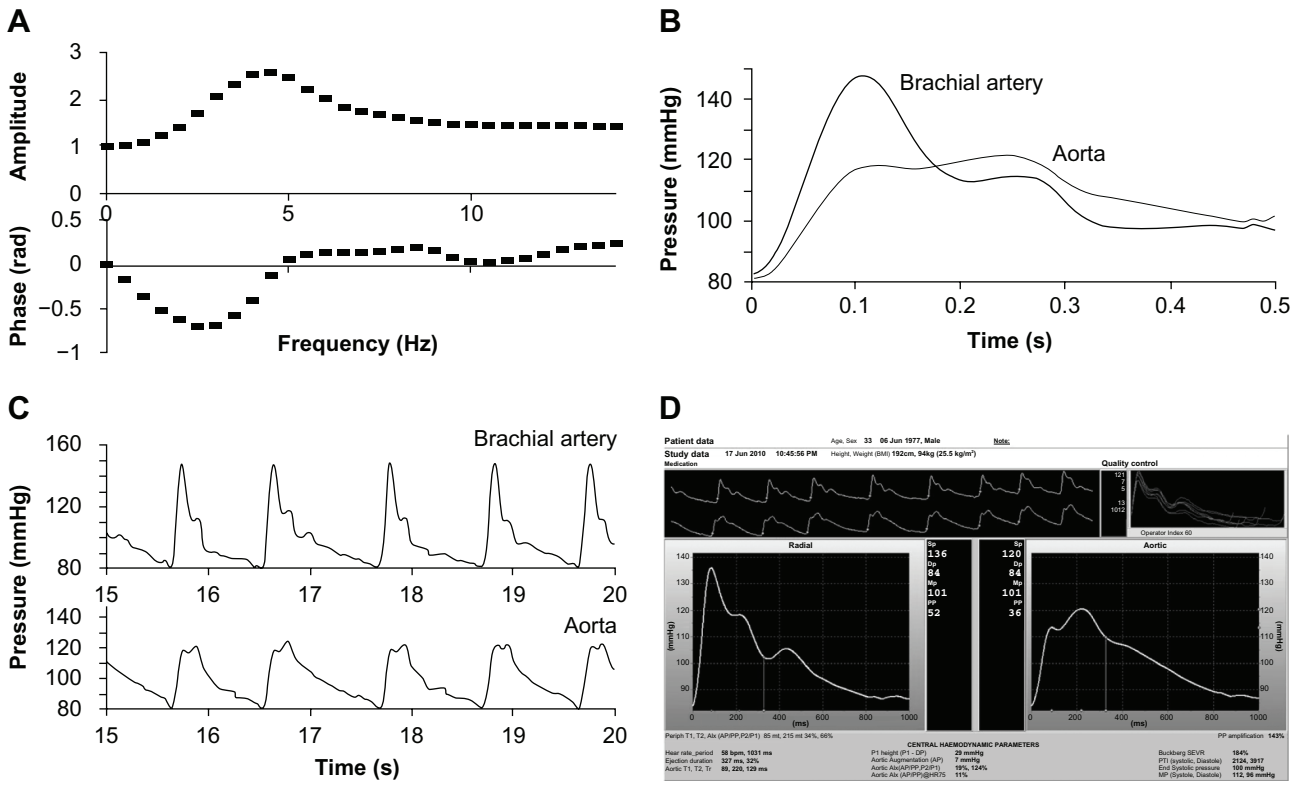

Figure 1 (**A**) Characteristics of transfer function used in Vasotens® technology; (**B**) averaged waveforms of brachial artery and aortic pulse in BPLab® device with Vasotens® technology; (**C**) sphygmograms obtained by the BPLab® device with Vasotens® technology; (**D**) display screen of SphygmoCor® software during examination of the same volunteer.

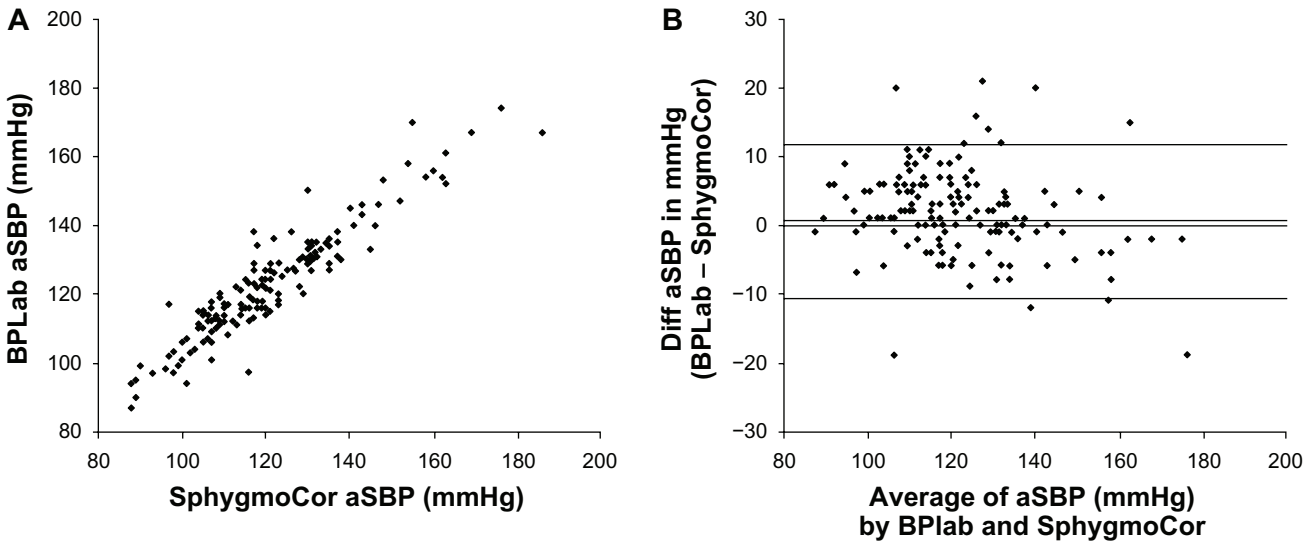

Figure 2 (**A**) Relationship between SphygmoCor and BPLab aortal systolic blood pressure (aSBP) when the pulse pressure level was calibrated in SphygmoCor by Omron HEM 750; (**B**) Bland–Altman analysis of the same aSBP data.

aSBP

During initial processing, the regression relationships of aSBP were considerably spread out (Figure 2). However it should be noted that the same scatter has been found in systolic BP and diastolic BP as measured by the BPLab and Omron devices (Figure 3). This can be explained by objective differences that are related to the difference in BP measurement algorithms, along with nonsimultaneous pressure measurement. Consequently, we have used the measurement results of BPLab as calibration values for SphygmoCor. As a result, the correlation of measurements by the two devices has improved – the correlation coefficient has increased from 0.939 to 0.988 and the deviation from the regression function "$y = x$" line has also decreased (Figure 4).

pAIx

pAIx for the brachial artery as measured by the BPLab device resulted in fairly similar measurements as for the radial artery by the SphygmoCor device ($r = 0.803$). Since these records on the two devices were obtained from different points, the absolute and mean values did not match (Table 2). Therefore, we only graphically present AIx regression (Figure 5).

Table 2 Mean values compared

Rate	BPLab	SphygmoCor	Correlation coefficient
pAIx (%)	−14.90	−18.78	0.803
aAIx (%)	26.07	26.84	0.740
aSBP (mmHg) (A)	122.5	122.0	0.939
aSBP (mmHg) (B)	122.5	121.2	0.988

Notes: (A) when pulse pressure level was calibrated in SphygmoCor by Omron HEM 750; (B) when pulse pressure level was calibrated in SphygmoCor by BPLab.
Abbreviations: pAIx, peripheral augmentation index; aAIx, aortic augmentation index; aSPB, aortic systolic blood pressure.

Central AIx

Central (aortic) AIx (aAIx) obtained from measurements from the two devices also showed good statistically significant correlation, although less impressive than for pAIx (Figure 6A and B).

In 16% of the cases, automatic analysis did not allow detection of what was required for AIx estimation characteristic points on the calculated aortic pressure curve.

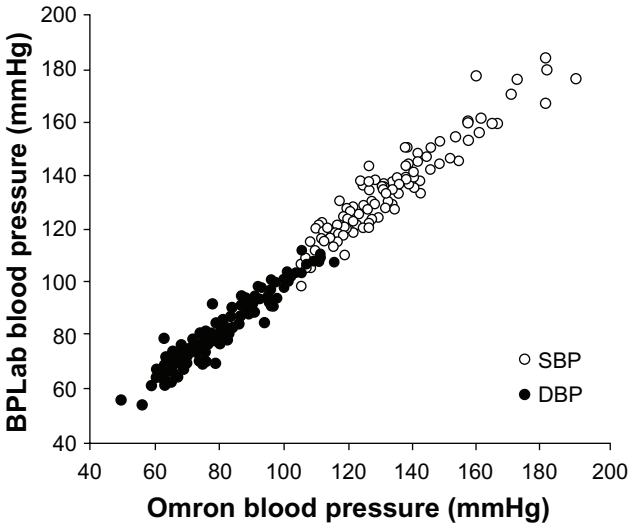

Figure 3 Relationship between BPLab and Omron HEM 750 systolic and diastolic blood pressure (SBP, DPB).

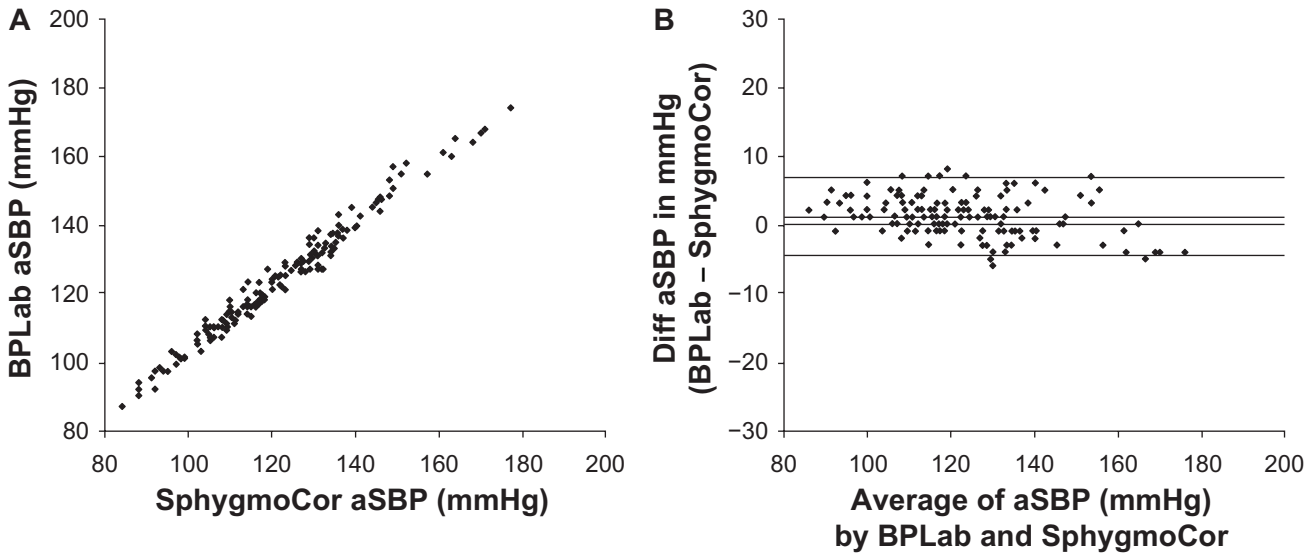

Figure 4 (**A**) Relationship between SphygmoCor and BPLab aortal systolic blood pressure (aSBP) when the pulse pressure level was calibrated in SphygmoCor by BPLab; (**B**) Bland–Altman analysis of the same aSBP data.

In those cases where for undetermined reasons, the central hemodynamics could not be determined by the TF, Vasotens technology offers an alternative regression method, which uses common to all patients' regression of peripheral and central parameters values. These relationships were found in the preliminary validation process by means of regression analysis of brachial values measured by BPLab and central values measured by SphygmoCor. In particular, the aAIx linear regression relationship is aAIx = 0.536 (pAIx + 65.9).

The regression and Bland–Altman diagram of which this alternative method is shown in Figure 6C and D have similar forms to the analogous results obtained by a TF. The correlation coefficient in both cases has the same value ($r = 0.74$).

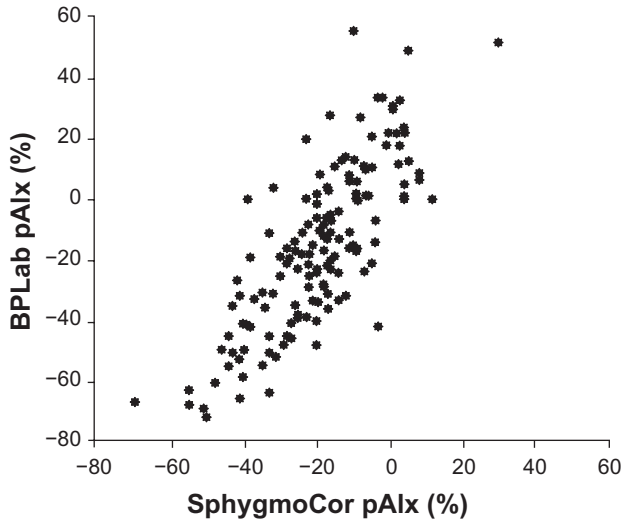

Figure 5 Relationship between SphygmoCor and BPLab peripheral augmentation index (pAIx).

Discussion

The aim of this study was the analysis of the clinical suitability of the Vasotens technology algorithm. The aSBP and the aAIx parameters obtained by Vasotens were compared with the corresponding parameters of SphygmoCor, which served as the reference device. As seen from the research, there is a satisfactory agreement between the two methods.

Similar agreement can be found in other studies that examined the oscillometric method of pulse wave analysis in comparison with common methods. Wassertheurer et al showed sufficient accuracy of the aSBP and augmentation pressure obtained by oscillometry in comparison with the tonometric method.[15] The studies conducted by Baulmann et al showed similar results in comparison with tonometric and piezo-electronic methods.[16] In addition, sufficient reproducibility and repeatability of pulse wave analysis made by oscillometric method were shown in other studies.[13,17]

Undoubtedly, only aortic catheterization can give a final result of clinical validation. Further invasive comparisons should be performed to provide actual evidence.

Though the abovementioned comparisons are to be carried out in the future, the ease of clinical application provided by the oscillometric method and its agreement with the reference method allows for the recommendation of

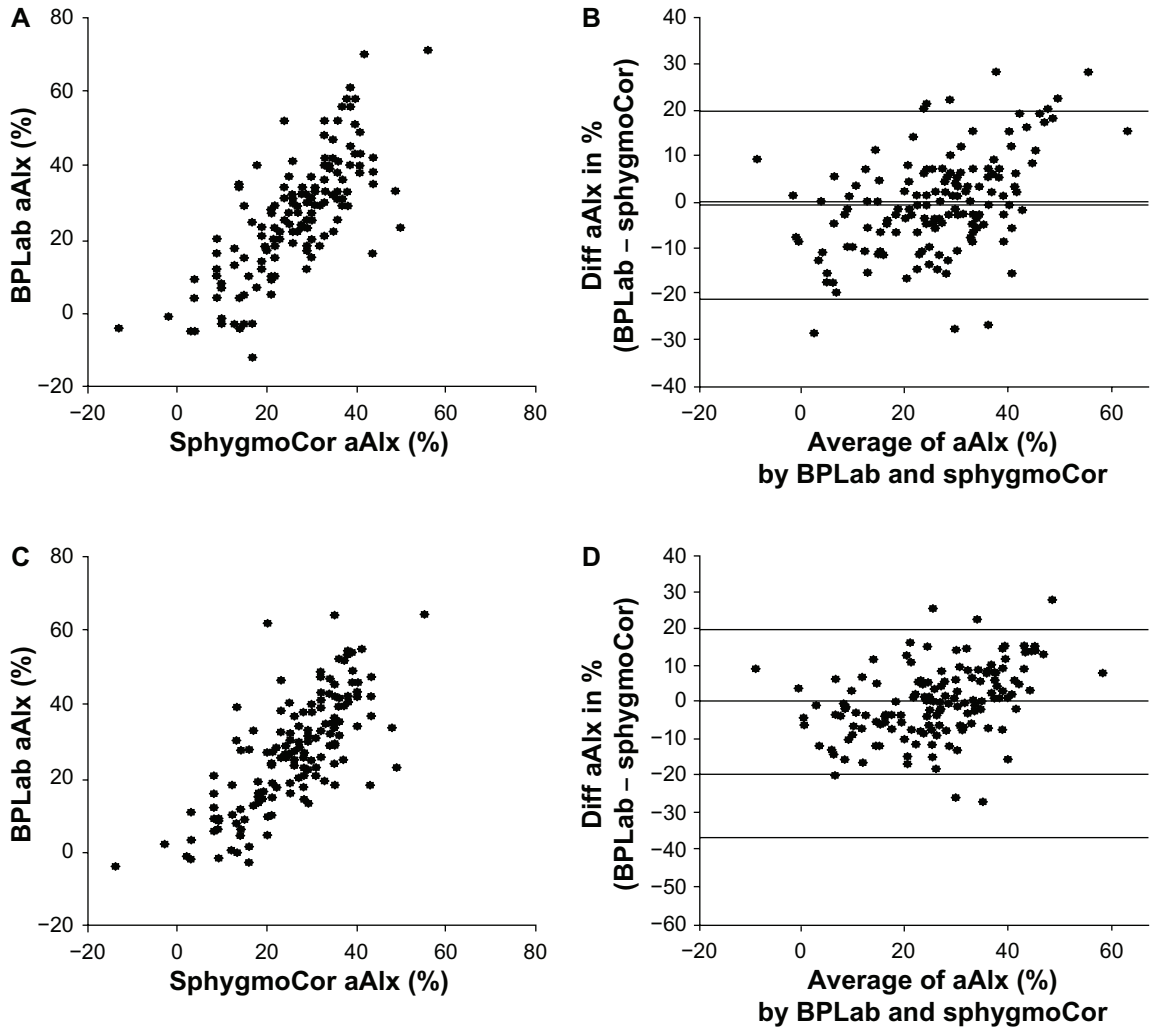

Figure 6 (**A**) Relationship between SphygmoCor and BPLab aortal augmentation index (aAIx); (**B**) Bland–Altman analysis of the same aAIx data; (**C**) Relationship between SphygmoCor aAIx and BPLab aAIx obtained by the alternative method; (**D**) Bland–Altman analysis of the same data as in Figure 6C.

24-hour BPLab monitoring system with Vasotens technology for clinical use. An additional advantage of this system is the ability to observe the studied parameters in men and women during a 24-hour (or longer) period.

Disclosure

The authors report no conflicts of interest in this work.

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