

Invasive validation of a new oscillometric device (Arteriograph) for measuring augmentation index, central blood pressure and aortic pulse wave velocity

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Background The importance of measuring aortic pulse wave velocity (PWV_{ao}), aortic augmentation index (Aix) and central systolic blood pressure (SBP_{ao}) has been shown under different clinical conditions; however, information on these parameters is hard to obtain. The aim of this study was to evaluate the accuracy of a new, easily applicable oscillometric device (Arteriograph), determining these parameters simultaneously, against invasive measurements.

Methods Aortic Aix, SBP_{ao} and PWV_{ao} were measured invasively during cardiac catheterization in 16, 55 and 22 cases, respectively, and compared with the values measured by the Arteriograph.

Results We found strong correlation between the invasively measured aortic Aix and the oscillometrically measured brachial Aix on either beat-to-beat or mean value per patient basis ($r = 0.9$, $P < 0.001$; $r = 0.94$, $P < 0.001$), which allowed the noninvasive calculation of the aortic Aix without using generalized transfer function. Similarly strong correlation ($r = 0.95$, $P < 0.001$) was found between the invasively measured and the noninvasively calculated central SBP_{ao}; furthermore, the BHS assessment of the paired differences fulfilled the 'B' grading. The PWV_{ao} values measured invasively and by Arteriograph were 9.41 ± 1.8 m/s and 9.46 ± 1.8 m/s, respectively (mean \pm SD); furthermore, the Pearson's correlation was 0.91 ($P < 0.001$). The limits of

agreement were 11.4% for aortic Aix and 1.59 m/s for PWV_{ao}.

Conclusion Aix, SBP_{ao} and PWV_{ao}, measured oscillometrically, showed strong correlation with the invasively obtained values. The observed limits of agreement are encouragingly low for accepting the method for clinical use. Our results suggest that the PWV_{ao} values, measured by Arteriograph, are close to the true aortic PWV, determined invasively. *J Hypertens* 28:000–000 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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Keywords: arterial stiffness, Arteriograph, augmentation index, invasive measurement, oscillometric method, pulse wave velocity, validation

Abbreviations: Aix-ao, aortic augmentation index; Aix-br, brachial augmentation index; BP, blood pressure; CAS, coronary artery stenosis; c-f PWV, carotid–femoral pulse wave velocity; GTF, generalized transfer function; Jug-Sy, Jugulum–Symphysis; PWV_{ao}, aortic pulse wave velocity; RT, return time; SBP_{ao}, central systolic blood pressure

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Introduction

The importance of the parameters (aortic pulse wave velocity, PWV_{ao}; aortic augmentation index, Aix; central systolic blood pressure, SBP_{ao}) describing the arterial function (stiffness) has been shown on different groups of patients: end-stage renal disease [1–3], coronary artery disease [4,5], hypertension [6,7], diabetes [8]) and, on general, apparently healthy population [9]. Based on these results, the evaluation of arterial stiffness was included in the 2007 ESH/ESC guidelines for the management of arterial hypertension, both in evaluating organ damage and in the cardiovascular risk calculation of patients with hypertension [10].

However, the examination of the above-mentioned parameters has not become part of the daily routine in clinical work so far [10]. A possible cause may be that the methods used did not allow to determine these parameters at the same time, were fairly complicated

and time-consuming and trained professionals were required to properly complete the measurements. Furthermore, some theoretical problems exist, linked to the principles of the most commonly used methods of describing the arterial function.

The new instrument, using an oscillometric, occlusive technique (Arteriograph), seems to offer a solution for the above-mentioned difficulties. Aortic PWV, Aix, SBP_{ao} and peripheral BP can be measured simultaneously using a simple upper arm cuff, and the procedure takes only 2–3 min. The detailed description of the device can be found in Materials and Methods.

So far, four studies have compared the Arteriograph with applanation tonometry and to the piezoelectric method [11–14].

These comparative studies for validation purposes determined that the aortic PWV by the carotid–femoral

technique, referred to as ‘gold standard’, cannot be considered identical to the true aortic PWV. On the contrary, Segers *et al.* [15] validated the operation principle of the Arteriograph (completely occluded brachial artery, stop flow) by an elegant mathematical model. They found that the time interval between the early and late systolic peaks, used by the Arteriograph to determine aortic PWV, shows a very strong ($R^2 = 0.9739$) linear correlation with the change of the aortic stiffness, namely with the true aortic PWV.

Based on the above-mentioned facts, the aim of our study was the complex and invasive validation of the hemodynamic parameters, measured by the new, oscillometric device. Our work was carried out in the Hemodynamic Laboratory of the Heart Institute of PTE (University of Pécs, Medical School, Hungary) and in the Hemodynamic Laboratory of University of Rome ‘La Sapienza’, Polo Pontino, (Italy).

Methods

Description of the Arteriograph device

The novelty of the Arteriograph (TensioMed Kft., Budapest, Hungary, www.tensio-med.com) device is that a simple upper arm cuff is used as a sensor, but in a very special condition: the cuff is pressurized at least 35 mmHg over the actual systolic pressure (S_{35}). By creating this stop-flow condition a small diaphragm will develop in the brachial artery at the level of the upper edge of the overpressurized cuff. As the central pressure changes, early (direct) systolic wave (P_1), late (reflected) systolic wave (P_2) and diastolic wave(s) (P_3) will reach this point and cause a beat on the membrane like a drumstick. Because the upper arm tissues are practically incompressible, the energy propagates and reaches the skin/overpressurized cuff edge, where it causes a very small volume/pressure change in the cuff. These very small suprasystolic pressure changes are recorded by a high-fidelity pressure sensor in the device. In this situation the conduit arteries (subclavian, axillary, brachial) act like a cannula to transfer the central pressure changes to the edge-position sensor (similar to the central pressure measurement during cardiac catheterization). It is worth mentioning that in this setup (stop-flow, occluded artery) the local influence of the characteristics of the wall of the brachial artery is practically eliminated, due to the fact that the arterial wall does not move beneath the cuff, and so the received curves are pure pressure waves.

The Arteriograph first measures the actual systolic and diastolic blood pressures (BPs) oscillometrically, then the device decompresses the cuff. In a few seconds the device starts inflating the cuff again, first to the actually measured diastolic pressure, then to the suprasystolic (actually measured systolic +35 mmHg) pressure, and records the signals for 8 s (optionally up to 10) at both cuff pressure levels. All of the signals received by the device are transmitted wireless to a notebook or desktop PC.

The data analysis is performed by the software (version 1.10.0.1) designed for this purpose. The software of the device determines the augmentation index by using the formula:

$$Aix (\%) = \frac{P_2 - P_1}{PP} \times 100$$

where P_1 is the amplitude of the first (direct) wave, P_2 is the amplitude of the late (reflected) systolic wave and PP is the pulse pressure.

To determine PWV_{ao}, the Arteriograph uses the physiological behavior of the wave reflection, namely that the ejected direct (first systolic) pulse wave is reflected back mostly from the aortic bifurcation. The device measures the time interval between the peaks of the direct (first) and reflected (late) systolic wave (return time – RT). For both the invasive and noninvasive PWV_{ao} calculation, the distance from sternal notch to the upper edge of the pubic bone (Jugulum-Symphysis = ‘Jug – Sy’) is used because this provides the nearest value of the true aortic length [16]. Care was taken to avoid the overestimation of the distance by measuring on the body surface. Instead, parallel, straight-line distance was measured between these anatomical points. The PWV_{ao} was calculated by using the formula:

$$PWV_{ao} \left(\frac{m}{s} \right) = \frac{Jug - Sy (m)}{RT/2 (s)}$$

The calculation of the central SBP in the Arteriograph was based on the relationship between the brachial and central SBP on the basis of the late systolic wave amplitude. The BP measuring algorithm in the device has been validated [17].

Description of the simultaneous, comparative measurements

Invasive measurements

Our studies were performed on patients who underwent routine coronary angiography. Taking into consideration that the frequencies of changes in the pulse pressure waves (early and late systolic waves) are below 20 Hz, standard (5 French), fluid-filled, pigtail catheters were used to record pulse pressure wave signals, by which the pressure changes in this frequency range could be recorded acceptably. In the case of single-catheter measurements, for the recordings and printout of the aortic pressure pulses, we used Marquette Maclab 5000 hemodynamic recording system. The pressure curves were printed out at 100 mm/s paper speed. For measurements with two catheters, the invasive pressure signals and noninvasive oscillometric curves from Arteriograph were fed to Biopack MP100 system (BIOPAC Systems, Inc., Goleta, California, USA) using AcqKnowledge 3.7.2 software to analyze the synchronized data with 1000 Hz sampling rate on identical heart cycles.

Intra-aortic (Aix-ao) versus Arteriograph-measured brachial (Aix-br) augmentation index

In 16 cases, we measured the Aix-ao with an intra-aortic cannula positioned into the aortic root and the Aix-br with Arteriograph simultaneously on identical heart cycles. Altogether 154 identical pulse waves were compared in the range of the Aix-ao from -13.0 to 58.9% . The Aix-ao values were calculated by visual measurements and by automatic, mathematical algorithm, using second derivatives.

Invasively measured versus Arteriograph-calculated central systolic blood pressure

In 55 cases, simultaneous invasive (in the aortic root) and noninvasive measurements were performed to compare the central SBPao values obtained by these two different methods. The Arteriograph calculates the central SBPao on the basis of the brachial SBP and the pulse pressure curve, measured together in the same process on the upper arm.

Comparison of the invasively measured true aortic pulse wave velocity between the aortic root and bifurcation and the Arteriograph-measured aortic pulse wave velocity

In 22 cases, the invasively and noninvasively measured PWVao values were compared. In 13 cases, the PWVao was determined with one catheter by pulling it back from the aortic root to the bifurcation under X-ray control, and the transit time of the pulse wave was measured using ECG gating. In nine cases, we used two catheters (inserted from radial and femoral artery) positioned to the aortic root and to the aortic bifurcation. The transit time of the pulse wave between these two points was measured simultaneously on identical heart cycles. The foot of the waves was determined manually by two independent observers in all of the measurements using tangent intersecting algorithm, but in cases, where two catheters were installed beyond visual control, we used automatic, software-based (first derivative) determination of the foot of the waves as well. In these cases the mean of the two manually and the one automatically obtained values were used for further analysis. When determining the foot of the aortic pulse wave manually, the mean of the values obtained by two observers was used for statistical calculation.

The studies were approved by local ethics committees. All of the patients gave written consent to the examination.

Statistical analysis

First, descriptive statistics were calculated for both the invasively and noninvasively (Arteriograph) measured parameters (Table 1). Bland–Altman analysis [18] was performed to assess the comparability of the two methods (differences were calculated as invasive value – noninvasive value). Linear regression analysis was also carried out to define the relationship and correlation coefficients

Table 1 Participants characteristics and descriptive statistics

Variable	Aix (<i>n</i> = 16)	PWV (<i>n</i> = 22)	SBPao (<i>n</i> = 55)
Age (years)	56 ± 10	62 ± 8	66 ± 9
Men, <i>n</i> (%)	8 (50)	12 (55)	43 (74)
Weight (kg)	82 ± 14	82 ± 13	78 ± 14
Height (cm)	170 ± 10	169 ± 9	168 ± 7
SBP (mmHg)	150 ± 27	152 ± 25	154 ± 24
DBP (mmHg)	88 ± 15	87 ± 14	93 ± 12
Hypertensive, ^a <i>n</i> (%)	10 (63)	16 (73)	43 (74)
HR (beats/min)	77 ± 14	68 ± 11	71 ± 12
PP	62 ± 16	65 ± 17	61 ± 15

Aix, aortic augmentation index; DBP, diastolic blood pressure; HR, heart rate; PP, pulse pressure; PWV, pulse wave velocity; SBP, systolic blood pressure; values are mean ± SD. ^aIf SBP is over 140 mmHg.

between the invasive and noninvasive variables. Continuous variables are indicated as mean and standard deviation (SD), and categorical variables as percentages.

A probability of less than 5% (two-tailed) was taken as indicative of statistical significance. Calculations were made using SPSS 15 statistical package (SPSS Inc., Chicago, Illinois, USA).

Results

Comparison of intra-aortic (Aix-ao) and Arteriograph-measured brachial (Aix-br) augmentation index

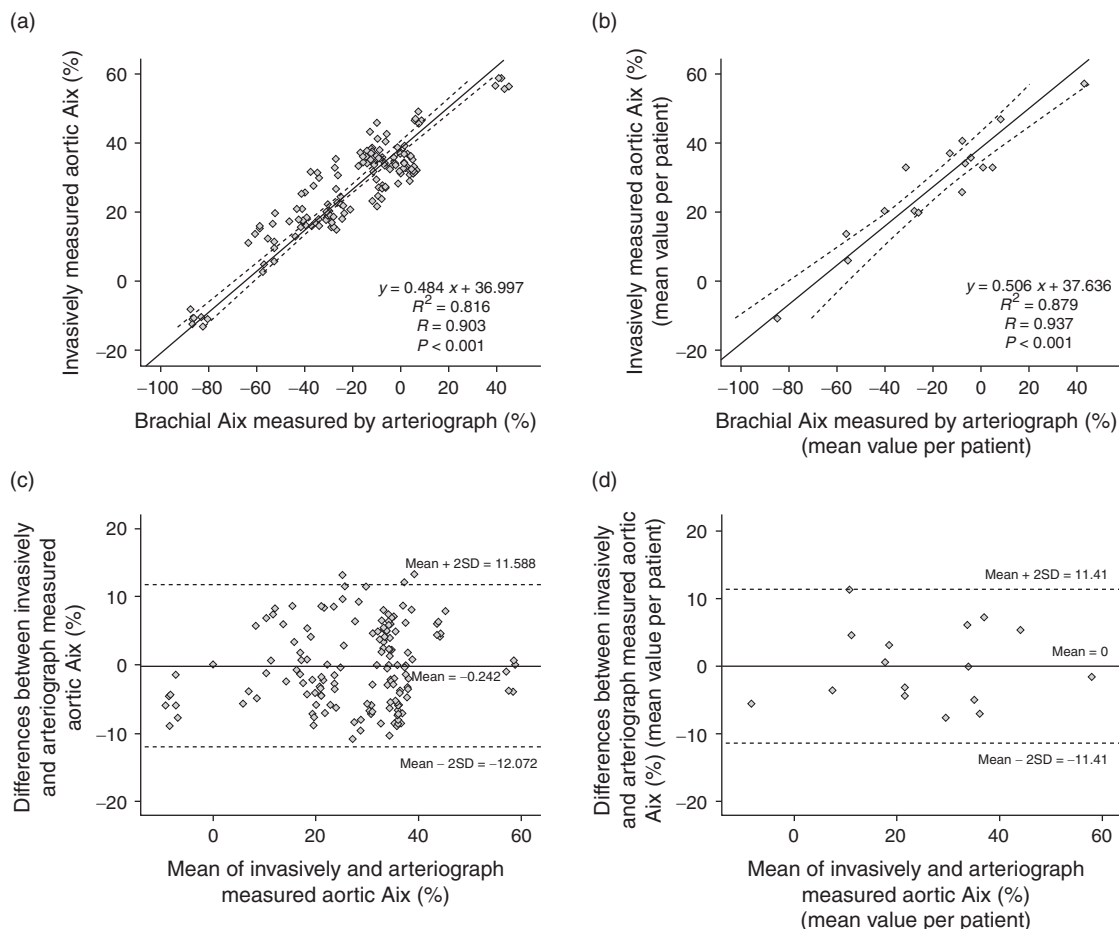
A strong, linear and significant correlation was found between the invasively recorded aortic and Arteriograph-measured brachial Aix on both identical beat to beat and average Aix per patient basis, with $R=0.9$ ($P<0.001$) and $R=0.94$ ($P<0.001$), respectively (Fig. 1a and b). Equally strong correlations ($R=0.9$ for beat to beat and 0.95 for mean value per patient) were found if automatic, second-derivative-based determination was used to assess the invasively measured aortic Aix.

The range of the aortic Aix varied between -13.0 and 58.9% in the studied group, which practically covers a wide range of the possible values. The observed very strong linear correlation between Aix-ao and Aix-br, especially in the averaged Aix values/patient group, allowed us to calculate the aortic Aix from the brachial Aix in the Arteriograph software using the regression equation $y = 0.5062x + 37.636$. By using this formula the invasively recorded and Arteriograph-calculated aortic Aix had become comparable with Bland–Altman plot, because of the same dimensions. Bland–Altman comparisons showed acceptable accuracy; that is, more than 95% of the differences were within +2SD and the mean differences between the methods were only 0.0% (mean values per patients) and -0.2% (beat to beat). The limits of agreement for the beat-to-beat comparison were 11.6% (mean + 2SD) and -12.1% (mean – 2SD) (Fig. 1c and d).

Invasively measured versus Arteriograph-calculated central systolic BP

Very strong and significant correlation ($R=0.95$; $P<0.001$) was found between the invasively measured

Fig. 1



Comparison of intra-aortic and Arteriograph-measured brachial augmentation index. (a) Relationship between brachial Aix measured by Arteriograph and invasively measured aortic Aix (beat-to-beat basis). (b) Relationship between brachial Aix measured by Arteriograph and invasively measured aortic Aix (mean value per patient). (c) Bland-Altman analysis of mean values and differences for aortic Aix measured invasively and by Arteriograph (beat-to-beat basis). (d) Bland-Altman analysis of mean values and differences for aortic Aix measured invasively and by Arteriograph (mean value per patient). Aix, aortic augmentation index.

and the Arteriograph-calculated SBPao (Fig. 2a). The mean SBPao of the 55 patients was $158.1 (\pm 26.4)$ mmHg for the invasive and $158.6 (\pm 26.9)$ mmHg for the oscillometric measurements with no significant difference found between them ($P = 0.63$; paired t -test). As shown by the Bland-Altman plot (Fig. 2b), more than 90% of the paired readings were inside the 2SD range and the mean difference was merely 0.56 mmHg between the methods. The limits of agreement were about ± 17 mmHg; however, 91% of the paired comparisons were within 15 mmHg, 82% within 10 mmHg and 60% within 5 mmHg of differences (Fig. 2c), which fulfils the 'B' grade of the BHS criteria for the evaluation of the BP measuring devices [19].

Comparison of the aortic pulse wave velocity measured invasively and with oscillometric Arteriograph device

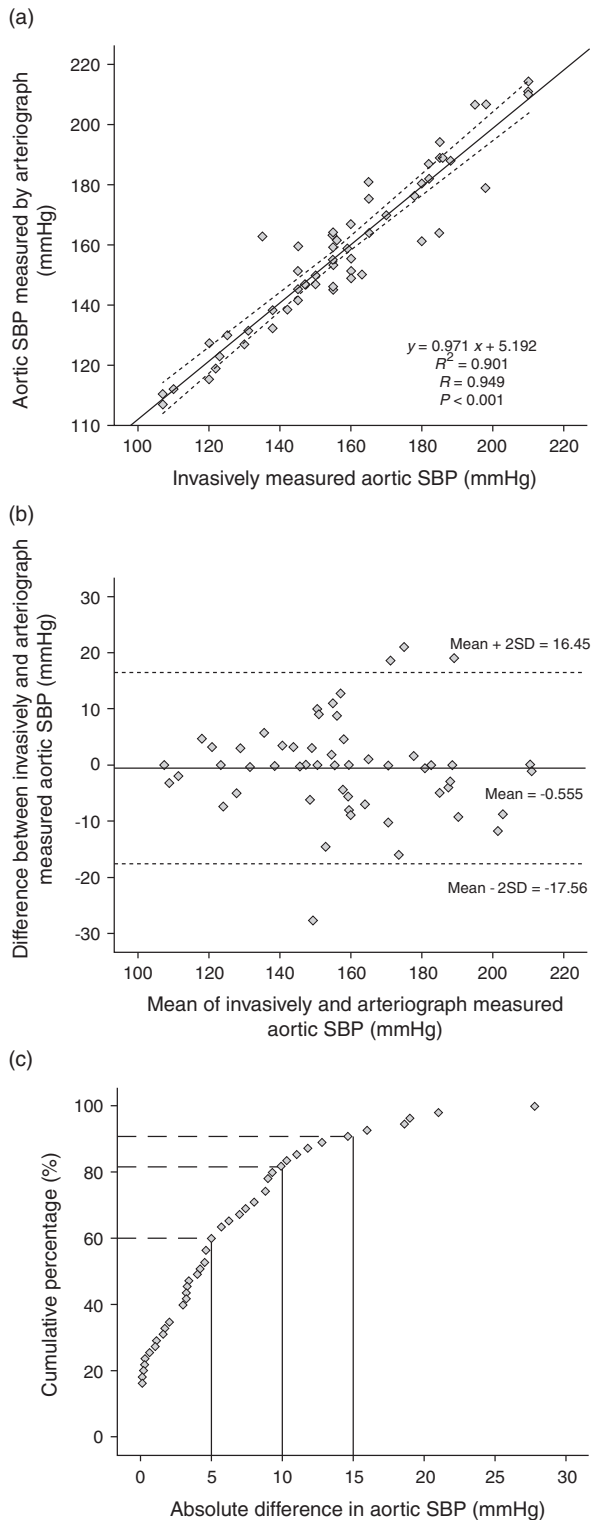
The mean of the PWVao values measured invasively versus Arteriograph was 9.41 ± 1.8 m/s and 9.46 ± 1.8 m/s,

respectively, and the difference between the PWVao values was not significant ($P = 0.77$). The Pearson's correlation coefficient between the invasively and non-invasively measured PWVao proved to be $R = 0.91$ ($P < 0.001$) (Fig. 3a). Using the Bland-Altman plot (Fig. 3a) most of the differences (90.9%) were within the mean $\pm 2SD$ range and the limits of agreement were 1.49 and -1.59 m/s. There was no systematic trend in the differences between the two methods, that is the accuracy was approximately the same across the whole PWVao range. Accordingly, regression analysis yielded not significant results ($P = 0.83$, the slope of the regression line did not differ significantly from 0).

Discussion

The most important result of our study is the strong, significant correlation between the invasively and oscillometrically measured (calculated) aortic Aix, central SBP and aortic PWV values.

Fig. 2



Invasively measured aortic SBP versus central SBP calculated by the Arteriograph device. (a) Relationship between invasively measured and Arteriograph-calculated aortic SBP. (b) Bland–Altman analysis of mean values and differences. (c) Cumulative percentage of absolute difference in central aortic systolic pressure. British Hypertension Society criteria level ‘B’. SBP, systolic blood pressure.

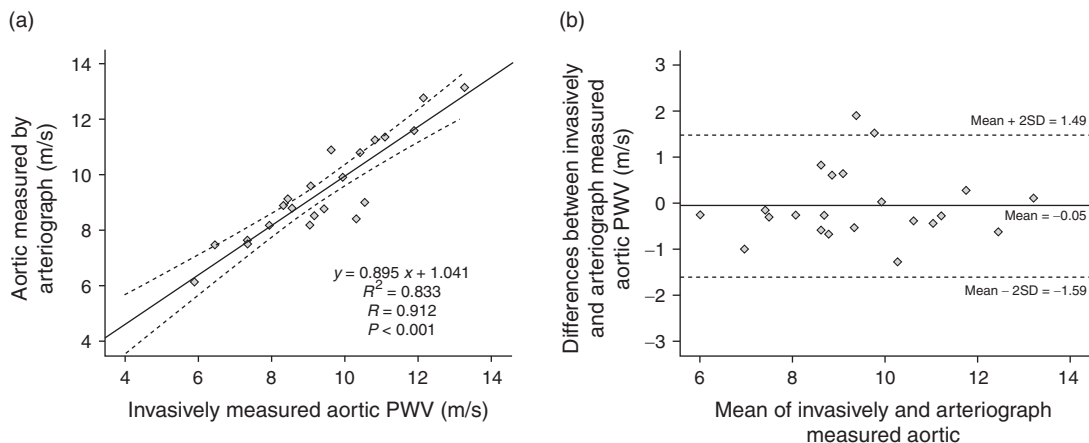
The observed strong linear correlation between the invasively measured Aix-ao and the Aix-br measured by Arteriograph on the brachial artery allows the determination of the central (aortic) Aix with a satisfactory level of accuracy for the clinical routine, without using the special mathematical method, the highly controversial generalized transfer function (GTF) [20–22]. This is supported by the fact that the limits of agreement of the compared techniques proved with be only 11%.

Despite the strong correlation, discovered during the comparison of the central (aortic) and the noninvasively measured SBP value, using the Bland–Altman plot the 2SD range turned out to be approximately ± 17 mmHg wide. Because of the current lack of methods judging the acceptable thresholds of the limits of agreement, we used the classification of the British Hypertension Society [19]. The Arteriograph reached grade B, which is considered acceptable for clinical use. Earlier Hope *et al.* [21] also compared the invasively measured central SBP values with the noninvasively calculated aortic SBP values, which were reconstructed by GTF of the radial pulse wave. In their study involving a similar number of participants to ours, the BHS classification resulted in D grade. Furthermore, the authors observed that the calculated SBPao values from radial pulse overestimated the invasively measured central SBP in low pressure ranges whereas they underestimated it in high ranges. In our findings the differences did not show systematic deviation from the mean value. This might be caused by the fact that the Arteriograph does not use transfer function, and it determines the central BP from the brachial BP and Aix-br based on the strong correlation between the brachial and central Aix. The usefulness of the direct analysis (without GTF) of the peripheral (radial) pulse wave is supported by the most recent article of Hickson *et al.* [23], where they proved a strong relation between the SBPao value, calculated from the late systolic peak on the peripheral pulse pressure curve, and the invasively measured central SBP ($R = 0.92$).

Furthermore, another reason why the oscillometric, occlusive technique provided more accurate results than the radial applanation tonometry for assessing SBPao, may be the fundamental difference in the measuring methods. During applanation tonometry the flow is maintained throughout the entire cardiac cycle and in the compressed artery, applanated by the tonometer, the shape of the pulse curve is influenced by the Bernoulli effect. In contrast to this, in case of the Arteriograph, which utilizes the occlusive method (suprasystolic pressure, stop flow in the brachial artery), there is no flow in the artery at all, and consequently pulse pressure waves can be recorded without the influence of the Bernoulli effect.

The importance of the stop flow, caused by the occlusion, to detect a clear, pronounced late systolic wave, which is

Fig. 3



Comparison of the aortic pulse wave velocity between the aortic root and bifurcation, measured invasively with intra-aortic catheter and with oscillometric Arteriograph device. (a) Relationship between invasively measured aortic PWV (mean of manually and automatically obtained values) and aortic PWV measured by Arteriograph. (b) Bland–Altman analysis of mean values and differences. PWV, pulse wave velocity.

essential to determine Aix and consequently SBPao, was proven by Segers *et al.* [15] by a mathematical circulatory model.

The question arises: if the assessment of SBPao is less accurate with using GTF (D grading) than without it (B grading), why was a strong correlation observed between the aortic Aix reconstructed by GTF and the Aix, measured directly on the brachial artery in the study of Baulmann *et al.* [11]? The most probable reason for this is that while in the case of Aix calculation only ratios have to be examined, in the case of SBP determination absolute pressure values are necessary.

The most important result of the present study is the significant correlation between the invasively measured true aortic PWV and the oscillometrically determined PWVao with limits of agreement acceptable for clinical practice. These results are better than the correlations found in earlier studies where PWVao values, determined by the Arteriograph, were compared with noninvasively measured carotid–femoral PWVs recorded by applanation tonometry (SphygmoCor) and by a piezoelectric (Complior) device [11–13]. In contrast with these results in a recently published prospective study, among patients on maintenance hemodialysis the authors found poor agreement between Arteriograph PWVao and carotid–femoral pulse wave velocity (c-f PWV) assessed by applanation tonometry (PulsePen) [14].

One of the main reasons for the high level of conformity between the PWVao, measured by Arteriograph and the invasively obtained measurements, may be the fact that by this method we could find values closer to the true aortic PWV than with c-f PWV measurement because the time interval between two systolic pulse peaks during

brachial stop-flow condition reflects the time difference between the direct and the reflected aortic waves; consequently, only the aorta is represented as a vessel during the measurement. In the case of the c-f PWV determination, the transit time is influenced by arteries with different PWVs, such as carotid, iliac and femoral arteries. Furthermore, the opposite direction of wave propagation in the case of Complior and the beat-to-beat variability of the isovolumetric contraction time during ECG gating for sequential measurement by SphygmoCor may also decrease the accuracy of measuring true PWVao [11]. The above-mentioned circumstances might result in the fact that the PWV variance and repeatability measured by c-f PWV method – considered to be the ‘gold standard’ so far – turned out to be much worse compared with Arteriograph [11,13]. According to the Bland–Altman article [18], if the old method has larger variance it cannot be considered as gold standard.

The association between c-f PWV and the aortic PWV has only been discussed by two publications so far. The latest article compared the invasively measured aortic PWV to the c-f PWV measured by the SphygmoCor device [24]. Unfortunately, the measurements were not performed at the same time; the invasive measurements predated the noninvasive ones by one day. The Spearman’s correlation between the two methods was in the range of 0.73–0.77, depending on the distance used for the calculations. In the other study, a more favorable setup was used concerning the accuracy and comparability as invasive and c-f PWV (Complior) measurements were performed simultaneously in a group of patients with coronary artery stenosis (CAS) as well as in CAS-negative participants [25]. The overall Spearman’s correlation was 0.7, which was similar to the findings of the previous study, although

a significant difference was observed between the two groups (CAS positive, $R = 0.74$; CAS negative, $R = 0.46$). Based on these findings, the authors concluded that the invasively measured aortic PWV and the c-f PWV should not be used interchangeably.

The surprisingly high agreement between the oscillometrically and the invasively measured PWVao may provide data for answering the several decades old question about the reflection site of the aortic pulse wave [26–28]. The unique setup in our study using two aortic catheters positioned into the root and to the bifurcation allowed us to measure identical heart cycles and to eliminate completely the errors caused by the varying isovolumetric contraction time during ECG-gated sequential pulse wave recording.

The observed strong correlation ($R = 0.9$; $P < 0.001$) for the nine patients, examined in this arrangement, proves that the propagation time from the aortic root (arch) to the bifurcation and the time between the peaks of direct and reflected waves, recorded by Arteriograph, are basically identical. According to these findings we can conclude that the forward wave is reflected with a high probability from the area of the bifurcation. This finding is corroborated by our further and by other authors' sequential measurements using one catheter, because the transit time of the aortic pulse wave was found to be in the same range [24,25].

However, our study has several limitations. For the measurements instead of micromanometer-tip catheters we used fluid-filled catheters. Considering the fact that the useful frequency components for characterizing the actual pulse pressure wave with sufficient resolution do not surpass 20 Hz, and well designed fluid-filled catheter systems can transmit this frequency, we were able to record the aortic pulse pressure curves with sufficient quality. This opinion is supported by the most recently presented paper by Wassertheurer *et al.* [29], which proves that with modern sensor systems a tip-catheter-like level of accuracy can be achieved. The size of our studied population was relatively small; however, in the case of invasive examinations this magnitude could be acceptable considering its power of evidence. The majority of our patients suffered from hypertension, which, according to our point of view, did not alter our findings; furthermore, at the central SBPao comparison examination it was especially advantageous that we were able to validate the Arteriograph even in a range with high central systolic pressure values (200 mmHg).

Finally, we can conclude that the parameters (Aix, SBPao and PWVao) measured by Arteriograph, using oscillometric occlusive method, showed considerably strong agreement and correlation with the values recorded with invasive measurements and the observed limits of agreement would be acceptable for the clinical routine. Our results suggest that the PWVao values, measured by

Arteriograph, are close to the true aortic PWV, determined invasively.

Acknowledgements

There are no conflicts of interest.

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