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ORIGINAL ARTICLE

Validity of the augmentation index and pulse pressure amplification as determined by the SphygmoCor XCEL device: a comparison with invasive measurements

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Augmentation index (AIx) and pulse pressure (PP) amplification can be determined by the SphygmoCor XCEL device in an operator-independent manner. This study aimed to examine its validity against invasive measurements. Simultaneous recordings of central aortic pressure waveforms were performed with oscillometric and high-fidelity invasive methods in 35 patients who underwent coronary arteriography. Brachial blood pressure was also recorded using the two methods. AIx for the aortic pressure waveform was defined as the ratio of augmentation pressure to PP. PP amplification was defined as the ratio of brachial PP to aortic PP. The differences between the invasive and oscillometric measurements were −7.7 ± 12.7% for AIx and 0.17 ± 0.14 for PP amplification (mean ± s.d.). Strong correlations between the invasive and oscillometric measurements were found in both indices (AIx: $r = 0.75$; PP amplification: $r = 0.80$; both $P < 0.001$). The Bland–Altman plot showed a proportional bias of PP amplification, but not of AIx (AIx: $r = -0.21$, $P = 0.23$; PP amplification: $r = -0.61$; $P < 0.001$). In conclusion, estimated AIx may be reliable considering the high correlation between the invasive and noninvasive values and the lack of proportional bias against invasive assessment. However, a substantial underestimation and a large scatter of estimated AIx were also observed. Further studies using the device to investigate associations with target organ damage or prognoses are needed to clarify its clinical validity.
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Keywords: augmentation index; invasive measurement; pulse pressure amplification; oscillometric method; validation study

INTRODUCTION

Central and peripheral blood pressure (BP) waveforms differ in shape and amplitude because of various physiological factors. Central pressures,[1,2] augmentation index (AIx)[3,4] and BP amplification[5] have been reported to provide additional information regarding cardiovascular risk stratification. Numerous noninvasive devices that estimate these parameters have been developed for clinical use. The SphygmoCor tonometer-based device (AtCor Medical, Sydney, Australia) is the most widely used device for clinical studies;[6] however, its operator dependence has limited its use in daily clinical practice.

New devices have been developed to estimate central hemodynamic indices in an operator-independent manner.[7] The SphygmoCor XCEL (AtCor Medical) is a brachial-cuff-based oscillometric device that provides such indices by automatically applying a transfer function to estimate the aortic waveform. We previously reported the validity of this device in measuring central aortic BP compared with invasive measurements.[8] Moreover, some studies have compared the AIx values estimated by this device with those estimated by the SphygmoCor tonometer-based device but not with those made by an invasive catheter.[9–11] Studies have not examined the validity of this device for BP amplification determination. This study, therefore, aimed to investigate the validity of the SphygmoCor XCEL device in measuring AIx and BP amplification by comparing the results with reference values obtained by a high-fidelity invasive catheter.

METHODS

We used data from the invasive validation study of the SphygmoCor XCEL device.[8]

Patients

Forty-seven patients undergoing elective coronary angiography for coronary artery disease assessment at our institution were included. Subjects with moderate or severe valvular heart diseases ($n = 1$) or exhibiting a difference of >5 mm Hg between the left and right brachial systolic BP (SBP) ($n = 7$) were excluded at the screening process.[12] We further excluded subjects with arrhythmias during pulse recordings ($n = 3$) or with insufficient AIx measurements using the SphygmoCor XCEL device ($n = 1$). Thirty-five subjects were included in the final analysis (13 women) in accordance with the European Society of Hypertension International Protocol for the validation of BP measuring devices in adults.[13] This study was approved by our regional ethics committee, and all participants provided written informed consent. Patients were considered hypertensive if they exhibited brachial SBP ⩾140 mm Hg or brachial diastolic BP (DBP) ⩾90 mm Hg or used antihypertensive drugs.

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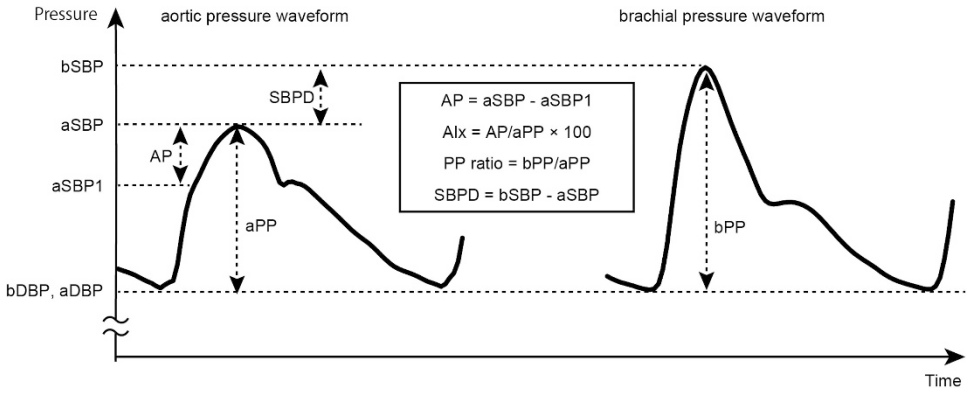

Figure 1 Schematics of the aortic and brachial arterial pressure waveforms. aSBP1 and aSBP indicate the values of the early systolic shoulder pressure and the systolic peak pressure, respectively. Abbreviations: a, aortic; AIx, augmentation index; AP, augmentation pressure; b, brachial; DBP, diastolic blood pressure; PP, pulse pressure; SBP, systolic blood pressure; SBPD, SBP difference.

Table 1 Baseline clinical characteristics of the study population

Characteristics	*Value*
Age, years	68.8 ± 13.6
Female	13 (37.1%)
Height, cm	161.0 ± 10.3
Weight, kg	63.7 ± 13.2
Body mass index, kg m^{-2}	24.4 ± 3.5
Heart rate, b.p.m.	68.2 ± 12.2
Clinical diagnosis	
Hypertension	27 (77.1%)
Diabetes mellitus	9 (25.7%)
Coronary artery disease	29 (82.9%)
Medications	
Vasoactive drugs	27 (77.1%)
Renin–angiotensin system inhibitors	15 (42.9%)
Beta blockers	13 (37.1%)
Calcium-channel blockers	18 (51.4%)
Nitrates	8 (22.9%)
Antidiabetic drugs	5 (14.3%)

All values are expressed as mean ± s.d. or *n* (%).
Vasoactive drugs include renin–angiotensin system inhibitors, beta blockers, calcium-channel blockers and nitrates.

Table 2 Blood pressure values of the study population

Variable	*Invasive catheter*	*SphygmoCor XCEL*
Central aortic blood pressure		
SBP	124.3 ± 22.6	120.2 ± 15.9*
DBP	64.5 ± 11.4	77.8 ± 10.8**
PP	59.8 ± 21.5	42.0 ± 13.6**
Brachial blood pressure		
SBP	133.2 ± 21.1	132.8 ± 17.0
DBP	65.2 ± 10.8	77.0 ± 10.5**
PP	68.0 ± 18.5	55.8 ± 14.4**

Abbreviations: DBP, diastolic blood pressure; PP, pulse pressure; SBP, systolic blood pressure.
Blood pressure values are given in mmHg, and expressed as mean ± s.d.
The comparison was performed between corresponding parameters measured with an invasive catheter and the SphygmoCor XCEL.
*P<0.05, **P<0.001.

Patients with fasting blood glucose levels ⩾126 mg dl^{-1} with HbA1c ⩾6.5% or those who used hypoglycemic agents or insulin were considered as having diabetes mellitus. Patients who exhibited stenosis of >50% in a major epicardial coronary artery or those who underwent prior percutaneous coronary intervention were considered as having coronary artery disease.

Measurement of hemodynamic indices

Hemodynamic indices were evaluated as previously described.[8] Briefly, measurements were performed in the supine position on the catheterization table using a high-fidelity pressure wire (diameter 0.014″, Certus or Aeris, St Jude Medical (St Paul, MN, USA)) for the invasive assessment and the SphygmoCor XCEL device for the noninvasive assessment. The invasive catheter was placed via a radial artery, which was chosen based on Allen's test (right arm, 62.3%; left arm, 37.1%), and a properly sized cuff, according to the manufacturer's instructions, was fitted on the contralateral brachium. Under radiographic guidance, the invasive catheter digitally recorded central aortic and brachial pressure waveforms at 100 Hz for 30–60 s. Simultaneously, three repeated measurements were obtained by the SphygmoCor XCEL device, which were averaged to determine the noninvasive homodynamic indices. Brachial SBP and DBP were used for calibration. Regular medications were not withheld for this study; however, vasoactive drugs were not administered during the measurement.

AIx was defined for a central aortic pressure waveform as the ratio of augmentation pressure (AP) to pulse pressure (PP) (Figure 1). For invasive assessments, inflection points were obtained by a mathematical algorithm using multidimensional derivatives of the original pressure pulse waveforms.[14] Noninvasive AP and AIx were determined automatically using the SphygomoCor XCEL software.

BP amplification was assessed with the PP ratio and the SBP difference. The PP ratio was defined as the ratio of brachial PP to aortic PP, and the SBP difference was defined as the difference between brachial SBP and aortic SBP (Figure 1). Aortic and brachial pressure waveforms were used to determine these indices in invasive measurements. The SphygmoCor XCEL device provided both aortic and brachial BP values for noninvasive assessment.

Statistical analysis

All data were analyzed using the STATA 14.2 software (College Station, TX, USA). All continuous values were expressed as mean ± s.d., and categorical variables were reported as percentages. The measurements between the SphygmoCor XCEL device and the invasive catheter were compared using the paired sample *t*-test and the Bland–Altman analysis. Pearson's linear correlation test was used to analyze the correlations between the hemodynamic indices of the paired invasive and noninvasive measurements. All *P*-values were two-tailed, and *P*-values <0.05 were considered to be statistically significant.

Table 3 Difference between the hemodynamic indices measured with the SphygmoCor XCEL and those with an invasive catheter

Variable	*Invasive catheter*	*SphygmoCor XCEL*	*Mean difference*	*s.d. of the difference*
Augmentation parameters				
AIx (%)	31.9±19.3	24.2±16.8*	−7.7	12.7
AP (mm Hg)	20.8±15.8	11.3±9.7*	−9.5	9.4
Amplification parameters				
PP ratio	1.19±0.24	1.36±0.15*	0.17	0.14
SBPD (mm Hg)	8.9±6.2	12.6±3.4*	3.7	5.4

Abbreviations: AIx, augmentation index; AP, augmentation pressure; PP, pulse pressure; SBPD, systolic blood pressure difference; s.d., standard deviation.
All values are expressed as mean±s.d.
The comparison was performed between corresponding parameters measured with an invasive catheter and the SphygmoCor XCEL.
*$P<0.001$.

RESULTS

Baseline clinical and BP characteristics of the 35 enrolled subjects are presented in Tables 1 and 2, respectively. The mean age of the subjects was 68.8±13.6 years (range, 23–88 years), and 37.1% (13/35) of the participants were females. As this study included subjects who underwent coronary angiography, most of the participants had coronary artery disease (82.9%) and risk factors such as hypertension (77.1%). Thus, 77.1% of the subjects were prescribed vasoactive drugs. As we previously described,[8] the SphygmoCor XCEL device slightly underestimated aortic SBP (4.1 mm Hg) and moderately underestimated aortic and brachial PP because of the overestimation of both DBPs (see Table 2).

Comparison between the SphygmoCor XCEL-derived and invasive catheter-derived augmentation parameters

The SphygmoCor XCEL device underestimated AIx (−7.7±12.7%) and AP (−9.5±9.4 mm Hg) (Table 3). Scatter plots and Bland–Altman plots of noninvasive *vs.* invasive measurements are shown in Figure 2. Strong correlations were found in these parameters

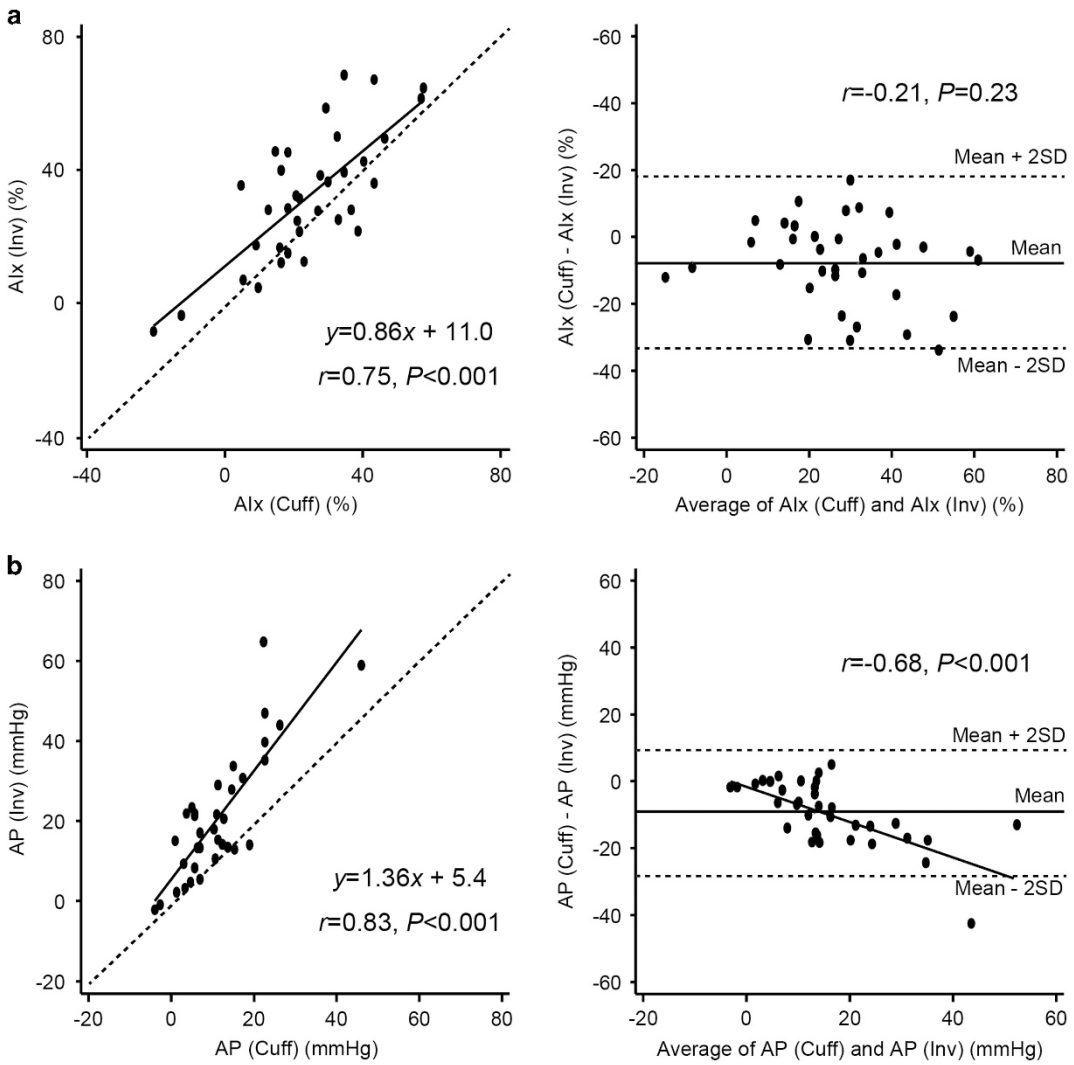

Figure 2 Scatter plots and Bland–Altman plots of AIx (**a**) and AP (**b**) measured using an invasive catheter *vs.* using the SphygmoCor XCEL device. In the scatter plots, the dotted lines indicate the identity line. The regression lines are shown as solid lines. In the Bland–Altman plots, the solid horizontal lines indicate the mean value and the dotted lines indicate the ±2s.d. values. The mean and the s.d. of the differences are provided in Table 3. Abbreviations: AIx, augmentation index; AP, augmentation pressure; Cuff, measured with the SphygmoCor XCEL device; Inv, measured with an invasive catheter; s.d., standard deviation.

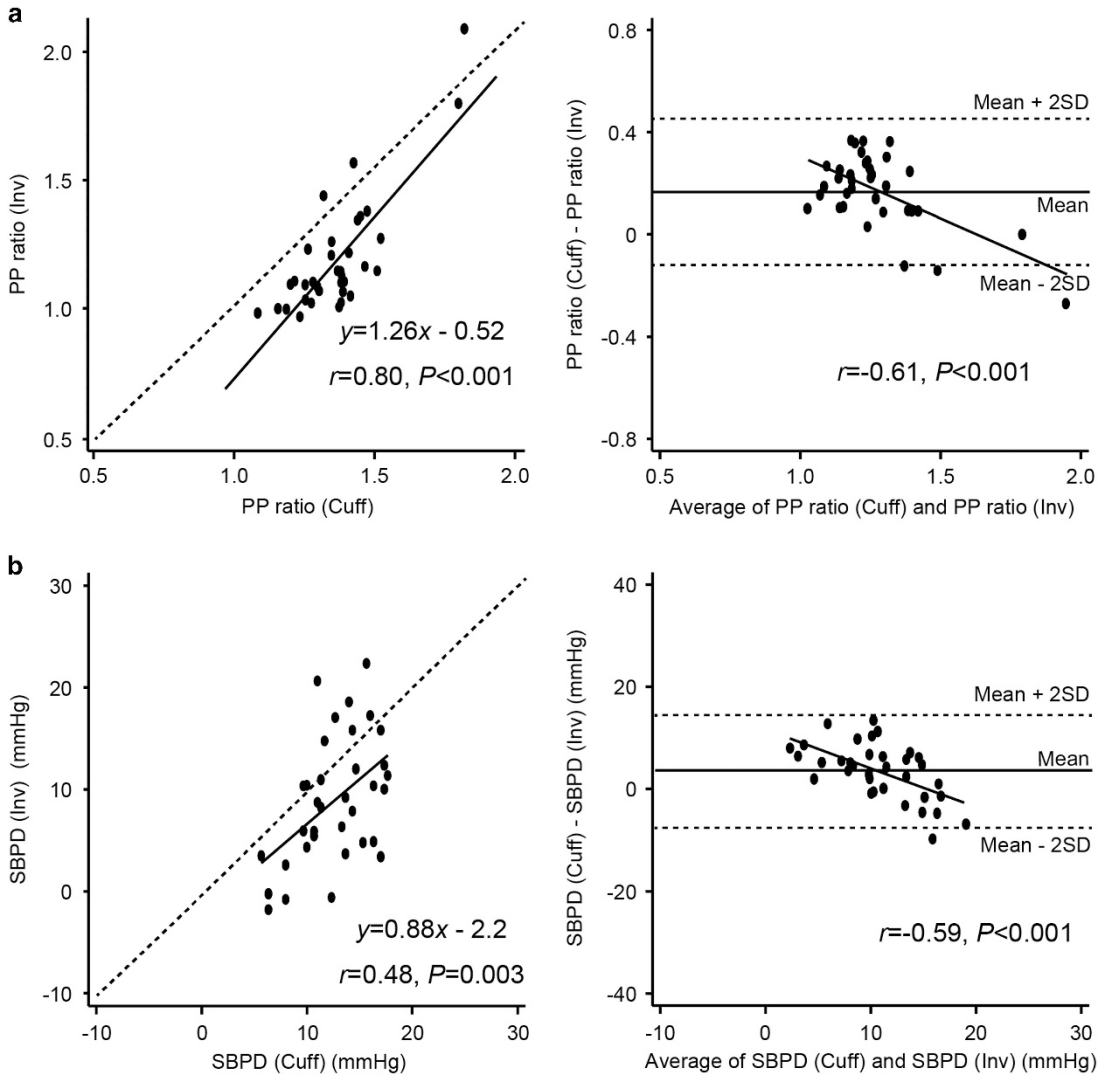

Figure 3 Scatter plots and Bland–Altman plots of the PP ratio (**a**) and SBPD (**b**) measured using an invasive catheter *vs.* using the SphygmoCor XCEL device. In the scatter plots, the dotted lines indicate the identity line. The regression lines are shown as solid lines. In the Bland–Altman plots, the solid horizontal lines indicate the mean value and the dotted lines indicate the ±2s.d. values. The mean and the s.d. of the differences are provided in Table 3. Abbreviations: Cuff, measured with the SphygmoCor XCEL device; Inv, measured with an invasive catheter; PP, pulse pressure; SBPD, systolic blood pressure difference; s.d., standard deviation.

(AIx: $r=0.75$; AP: $r=0.83$; both $P<0.001$); however, the slopes were slightly distant from 1.0 (AIx: slope = 0.86; AP: slope = 1.36). Based on the Bland–Altman plot, there was no evidence of systematic bias regarding AIx ($r=-0.21$; $P=0.23$); however, a significant bias toward lower AP values in the cuff-based device at the higher range was noted ($r=-0.68$; $P<0.001$).

Comparison between the SphygmoCor XCEL-derived and invasive catheter-derived amplification parameters

The SphygmoCor XCEL device overestimated the PP ratio (0.17 ± 0.14; $P<0.001$) and the SBP difference (3.7 ± 5.4 mm Hg; $P<0.001$). Scatter plots and Bland–Altman plots of noninvasive *vs.* invasive measurements are shown in Figure 3a, and strong correlation was found in the PP ratio between noninvasive and invasive measurements ($r=0.80$; $P<0.001$); however, the slopes were slightly distant from 1.0 (slope = 1.26). The correlation between the noninvasive and invasive values of the SBP difference was significant but moderate ($r=0.48$; $P=0.003$). A slight slope difference from 1.0 was noted (slope = 0.88). A significant proportional bias was found in both indices based on the Bland–Altman plot, that is, toward lower values in the cuff-based device at the higher range (PP ratio: $r=-0.61$, SBP difference: $r=-0.59$; both $P<0.001$).

DISCUSSION

To the best of our knowledge, this is the first study to validate the SphygmoCor XCEL device for measuring augmentation and amplification parameters against well-established invasive techniques. This device underestimated augmentation parameters and overestimated amplification parameters. However, we found significant and strong correlations between values derived from the invasive catheter and the SphygmoCor XCEL device regarding augmentation parameters and the PP ratio.

The observed underestimation of AIx estimated by the brachial-cuff-based device was similar to previous reports comparing the AIx values estimated by carotid or radial tonometry with those measured by an invasive method.[15,16] In addition, three previous studies

consistently reported that there was no significant difference between the mean values of AIx derived from the SphygmoCor XCEL device and those derived from the SphygmoCor tonometry device,[9–11] which leads us to believe that systemic underestimation is a common problem of noninvasive methods but is not a brachial-cuff-based device-specific problem. However, we also found that the scatter of the estimated and invasively measured AIx differences was substantially large (s.d. of the difference = 12.7%), which indicates the presence of a device-specific problem. Identification of the systolic inflection point might be difficult for brachial-cuff-based methods in some cases.

The high correlation between estimated and invasively measured values and no evidence of a proportional bias in estimated values in the Bland–Altman plots support the reliability of estimated AIx, but not AP. In addition, the slope of the regression line between the invasive and brachial-derived AIx was relatively close to 1.0 (the slope = 0.86) when compared with the slopes in the validation studies of the SphygmoCor XCEL device against the SphygmoCor tonometry device (the slope = 0.62[9] and 0.6[11]). Because invasive assessment, not the tonometry device, is the gold standard reference measurement, we believe that there is little systemic bias in the estimated AIx by the SphygmoCor XCEL device. However, it may be of some concern when comparing the brachial-cuff-derived values to existing values obtained with the SphygmoCor tonometry-based device, which has been most commonly used in clinical studies.[6]

The amplification parameter overestimation was mainly due to the underestimation of estimated aortic SBP. Despite the overestimation, the PP ratio estimated by the SphygmoCor XCEL device showed a strong correlation with the invasive PP ratio. Meanwhile, the correlation of the SBP difference was weaker than that of the PP ratio but was similar to that in a previous study comparing amplification parameters derived from tonometry methods with those derived from invasive measurements.[17] This might be clinically essential because some studies showed that the PP ratio, but not the SBP difference, was useful for risk stratification.[18,19] Furthermore, the accuracy of the estimated aortic SBP value is largely affected by the brachial BP calibration,[8,20–23] leading to an SBP difference error.[24] However, the PP ratio is poorly influenced by the calibration,[25] which could be the strength of this index in risk prediction.[26] The stronger correlation with invasive measurements in this study also suggests the superiority of the PP ratio to the SBP difference when using the SphygmoCor XCEL device as an amplification parameter.

However, a proportional bias in the PP ratio and the SBP difference based on the Bland–Altman plots may raise some concern regarding the reliability of the estimated values. Considering the lack of evidence of proportional bias in AIx, the estimated AIx by the SphygmoCor XCEL device may be more reliable than the estimated amplification parameters, although further investigation is needed to clarify its clinical utility.

Our findings must be interpreted within the context of the strengths and limitations of our study. A major strength of this study was that we validated the SphygmoCor XCEL device in the estimation of augmentation parameters by identifying the inflection point using a micromanometer-tipped catheter, as recommended in the very recently published consensus statement on protocol standardization.[27] Although this study was conducted before the statement was published, this study met most of the validation protocol's requirements. In addition, the simultaneous measurement of aortic and brachial BP via invasive methods allowed us to compare the values of amplification parameters derived from invasive and noninvasive methods. Conversely, there are some limitations to this study. First, this study does not meet some of the requirements outlined by the statement. For example, the sample size might be considered small. However, the statement recommended that the appropriate sample size for special groups, such as this study, should be defined after a successful study in the general population.[27] Since an early validation study of the SphygmoCor XCEL device against a tonometric method included 30 subjects,[9] we considered the sample size of this study to be acceptable. Second, the high prevalence of subjects that took vasoactive drugs may have affected the accuracy of the noninvasively estimated aortic pressure waveform. Third, it remains unknown whether our findings are applicable to the general population because we included only high-risk patients who were undergoing coronary angiography. Finally, noninvasive measurements were performed in the arm not used for invasive measurements. However, Hwang *et al.*[10] reported that the SphygmoCor XCEL measurements were not affected by the body side.

In conclusion, we demonstrated the validity of the SphygmoCor XCEL device in measuring the augmentation and amplification parameters against invasive measurements. The high correlation between the invasive and noninvasive values and the lack of evidence of proportional bias against invasive assessment suggest that AIx measurements are more reliable than the AP and amplification parameters. However, a substantial underestimation and a large scatter of estimated AIx were also observed. Although the SphygmoCor XCEL device has a potential for widespread use in daily clinical practice because of the operator-independent feature, further studies investigating the device in association with target organ damage or prognoses are needed to clarify its clinical validity.

CONFLICT OF INTEREST

SO received lecture fees from Otsuka Pharmaceutical (Tokyo, Japan), Takeda Pharmaceutical (Osaka, Japan) and MSD (Tokyo, Japan). SO received a research grant from the Daiwa Securities Health Foundation (Tokyo, Japan) and the Kashiwado Memorial Foundation (Chiba, Japan). YK received lecture fees from Daiichi-Sankyo (Tokyo, Japan), Takeda Pharmaceutical (Osaka, Japan), Bayer Yakuhin (Osaka, Japan) and Boehringer Ingelheim (Ingelheim, Germany). YK received research grants from Boehringer Ingelheim (Ingelheim, Germany), Pfizer (New York, USA), Otsuka Pharmaceutical (Tokyo, Japan), Takeda Pharmaceutical (Osaka, Japan), Mitsubishi Tanabe Pharma (Osaka, Japan), Sumitomo Dainippon Pharma (Osaka, Japan), Astellas Pharma (Tokyo, Japan), St Jude Medical (St. Paul, USA), Abbott Vascular Japan (Tokyo, Japan) and Daiichi-Sankyo (Tokyo, Japan). The remaining authors declare no conflict of interest.

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