

Measurement Accuracy of a Stand-Alone Oscillometric Central Blood Pressure Monitor: A Validation Report for Microlife WatchBP Office Central

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BACKGROUND

The superiority of prognostic value of blood pressure (BP) measured at central aorta (CBP) over conventional brachial BP measured by cuff-based BP monitors has reignited the development of new non-invasive techniques for estimating CBP. The present study validated the accuracy of CBP measured by a newly developed stand-alone CBP monitor.

METHODS

The CBP monitor provided readings of brachial systolic BP (SBP), brachial diastolic BP (DBP), central SBP, and central pulse pressure (PP). Brachial PP and central DBP were calculated from the relevant readings. The accuracy of the brachial and central SBP, PP, and DBP was validated against the simultaneously recorded invasively measured central aortic SBP, PP, and DBP, according to the invasive standard requirements for the noninvasive brachial BP monitors from the Association for the Advancement of Medical Instrumentation (AAMI) in 85 subjects (255 measurements; age range, 30–93 years).

RESULTS

The mean differences of cuff BP with reference to the invasively measured central SBP, PP, and DBP were -2.6 ± 9.0 , -8.6 ± 11.2 , and 6.1 ± 7.0 mm Hg, respectively, with the former two being obviously underestimated at high CBP and overestimated at low CBP. In contrast, the corresponding differences for the central SBP, PP, and DBP measured by the CBP monitor were -0.6 ± 5.5 , -0.4 ± 7.0 , and -0.2 ± 6.5 mm Hg, respectively, without obvious systematic bias. The distribution of measurement errors for central SBP, PP, and DBP surpassed the AAMI criteria.

CONCLUSION

Central SBP, PP, and DBP can be measured accurately by a stand-alone automatic BP monitor.

Keywords: blood pressure; central pulse pressure; hypertension; oscillometric signals; pressure wave reflection; pulse volume plethysmography; pulse wave analysis.

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The blood pressure (BP) amplification from central aorta to peripheral arteries, which varies substantially between subjects, causes conceivable discrepancy between central BP (CBP) and BP recorded at a person's upper arm.^{1–6} Although mean BP and diastolic BP (DBP) are relatively constant in the conduit arteries, systolic BP (SBP) and pulse pressure (PP) measured from peripheral arteries are usually higher than those measured at the origin of the arterial tree, namely, the aortic root.^{3,7} CBP can be estimated noninvasively, mainly by using the technique of applanation tonometry.^{3,8,9}

Thereafter, it has been shown that the noninvasively measured CBP and the conventional brachial BP respond to anti-hypertensive medications differently.^{10,11} Furthermore, the superior prognostic value of CBP over conventional brachial BP demonstrated in previous studies^{12–14} has reignited the development of more convenient noninvasive methods for CBP measurements, including tonometry-based¹⁵ and brachial cuff-based techniques.^{16,17}

We have developed and validated a novel oscillometric method to estimate central SBP and PP.^{16,18,19} Noninvasively

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measured central SBP and PP can be estimated according to separate multivariate regression equations with parameters derived from off-line analysis of the acquired brachial pulse volume plethysmography (PVP) waveforms calibrated to the noninvasive brachial SBP and DBP.^{16,19} This PVP waveform analysis method has the potential to be built into any stand-alone noninvasive BP monitors to offer simultaneous readings of CBP and brachial BP for ambulatory and home applications. To date, there has been no report for such a stand-alone CBP monitor validated against international standards.^{20–22} In fact, there have been no international standards for the validation of the CBP monitors. Thus, the purpose of the present study was to validate the accuracy of a newly developed stand-alone CBP monitor incorporated with the PVP method, according to the invasive standard requirements for the noninvasive brachial BP monitors from the Association for the Advancement of Medical Instrumentation (AAMI).²⁰

METHODS

Study population

The study protocol was approved by the Institutional Review Board at Taipei Veterans General Hospital, Taiwan, and adhered to the principles of the Declaration of Helsinki. Written informed consents were obtained from all patients before the study.

All study subjects enrolled in this study were selected consecutively from those scheduled to undergo diagnostic cardiac catheterization and/or coronary angioplasty. Patients who had acute coronary syndrome, peripheral arterial disease, rhythms other than normal sinus rhythm, or pressure differences >3 mm Hg between left and right arms, had been excluded from the studies. The study population was divided into 2 independent groups, the generation group ($n = 56$; age range, 34–89 years) and the validation group ($n = 85$; age range, 30–93 years) with characteristics given in Table 1.

The techniques of estimating central SBP and PP separately using the PVP waveform analysis method have been built into a commonly used noninvasive BP monitor (WatchBP Office; Microlife AG, Widnau, Switzerland) as the prototype CBP monitor. The accuracy of the noninvasive brachial BP measured by the prototype CBP monitor has passed the requirements suggested by European Society of Hypertension International Protocol.²³ First, we refined the algorithms for identification of the characteristic points on the PVP waveforms recorded within the prototype CBP monitor and recalibrated the prediction equations for central SBP and PP, using 191 measurements from 56 subjects in the generation group. Central DBP was simply the subtraction of central PP from central SBP. The final algorithms and prediction equations were then incorporated into the prototype CBP monitor. Thereafter, the accuracy of CBP obtained from this final version prototype CBP monitor was examined in the validation group.

The recruitment of subjects in validation group strictly adhered to the published international standards.^{20–22} Of the 95 subjects who entered the study, 10 were unable to successfully complete it (4 because of frequent atrial ectopic beats and 6 because of catheter damping). The remaining 85 subjects and 255 measurements formed the basis of this report.

The ranges and means of the subjects' characteristics in the validation group are shown in Table 1 and Table S1 (online supplementary data). Participants were ≥ 18 years old, 30.6% were women, and 12.9% were age >80 years old. Based on invasive measurements, the central SBP was >160 mm Hg in 18.8% and <100 mm Hg in 10.6% of subjects, and the central DBP was >85 mm Hg in 16.5% and <70 mm Hg in 63.5% (Table S1).

Study protocol

When subjects arrived in the catheterization laboratory, their height, weight, and left upper arm circumference were measured. All routine medications were continued at the time of the procedure. After local injection of 2–3 mL of 1% lidocaine and successful placement of a 6F arterial sheath in the right radial artery, 2.5 mg pf verapamil was administered intra-arterially to prevent vasospasm during the catheterization. Heparin (5,000 U) was administered intravenously after insertion of the arterial catheter. Intravenous atropine and/or sublingual nitroglycerin were given to all subjects before angiography.

The appropriate-size BP cuff was selected according to the manufacturer's direction and was placed on the subject's upper left arm with its lower edge 2.5 cm above the antecubital fossa. Before diagnostic catheterization, a large-lumen 6F arterial catheter was advanced to the ascending aorta via the right radial artery and placed 2 cm above the aortic valve under fluoroscopic guidance. We positioned the distal end of the catheter away from the walls of the aorta and perpendicular to the direction of blood flow to avoid the elevation of pressure readings resulting from kinetic energy transfer.

All direct pressure measurements were obtained with subjects in the supine position during the process of automatic pressure measurement with the CBP monitor, with the left arm positioned at midchest level. The simultaneous direct pressure recording and the automatic pressure measurement were repeated after diagnostic coronary angiography and finally after left ventriculography, with a total of 3 measurements for each participant in the validation group.

Automatic CBP monitor and automatic pressure measurement

The prototype automatic CBP monitor was built from a validated oscillometric arm BP monitor (WatchBP Office; Microlife AG, Widnau, Switzerland) to perform PVP and instant PVP waveform analysis for the estimation of central SBP and PP. The CBP monitor incorporated a microcontroller MSP430F4617 (Texas Instruments, Dallas, USA), a pressure transducer, a 12-bit analog-to-digital converter, a flash memory, and a digital-to-analog converter to acquire and store the continuous PVP signals.

The pressure transducer (MP3V5050; Freescale Semiconductor, Texas, USA) had a linear range of 0 to 300 mm Hg for acquiring oscillometric signals of cuff pressure. An instrumentational amplifier was seated behind the pressure transducer for reducing common mode signal and amplifying oscillometric signals. A band-pass filter was used to minimize the effect of baseline shift, with the cutoff frequency set at 0.5 to 30 Hz. A 12-bit analog-to-digital converter with a sampling rate of 256 Hz was used to digitize the continuous pressure

Table 1. Characteristics of Study Subjects

Characteristics	Generation group (n = 56)	Validation group (n = 85)
Male sex	66.1%	69.4%
Age (years)	65.5 ± 13.7 (34–89)	64.8 ± 13.6 (30–93)
Age >80 years	21.4%	12.9%
Height (cm)	162.4 ± 10.5 (141–183)	163.8 ± 7.8 (144–178)
Weight (kg)	68.8 ± 13.1 (49–105)	68.1 ± 11.7 (46–103)
Waist circumference (cm)	87.7 ± 10.9 (62–115)	87.7 ± 10.7 (64–105)
Left arm circumference (cm)	30.3 ± 2.8 (26–39)	29.9 ± 2.7 (25–39)
Body mass index (kg/m ²)	26.1 ± 4.2 (17.5–38.1)	25.4 ± 3.6 (17.8–34.6)
Left ventricular ejection fraction (%)	52.5 ± 11.4 (17–68)	53.1 ± 9.1 (25–75)
Smoking	17.9%	11.8%
Clinical diagnosis		
Hypertension	71.4%	52.9%
Type 2 diabetes mellitus	37.5	24.7%
Dyslipidemia	53.6%	37.7%
Coronary artery disease	66.1%	63.5%
Chronic renal failure	8.9%	3.5%
Medications		
α-blockers	17.9%	10.6%
β-blockers	55.4%	42.4%
Calcium channel blockers	25%	42.4%
Angiotensin-converting enzyme inhibitors	12.5%	5.9%
Angiotensin receptor blockers	37.5%	27.1%
Diuretics	35.7%	28.2%
Antiplatelet agents	71.4%	68.2%
Statins	51.8%	45.9%
Recruitment BPs (mm Hg)		
Aortic SBP	141 ± 27 (83–200)	135 ± 22 (83–197)
Aortic mean BP	99 ± 14 (68–132)	97 ± 12 (64–134)
Aortic DBP	68 ± 12 (44–107)	70 ± 12 (41–109)
Aortic PP	73 ± 26 (24–133)	64 ± 23 (20–132)
Noninvasive aortic SBP	141 ± 25 (81–194)	134 ± 20 (86–190)
Noninvasive aortic DBP	69 ± 13 (43–102)	70 ± 10 (43–102)
Noninvasive aortic PP	73 ± 25 (28–126)	64 ± 21 (28–126)
Noninvasive brachial SBP	138 ± 23 (91–196)	132 ± 18 (96–195)
Noninvasive brachial DBP	76 ± 11 (53–113)	76 ± 10 (48–113)
Noninvasive brachial PP	62 ± 20 (24–107)	56 ± 16 (22–104)
Baseline heart rate (beats/min)	69 ± 10 (45–95)	69 ± 12 (46–103)

Abbreviations: BP, blood pressure; DBP, diastolic BP; PP, pulse pressure; SBP, systolic BP.

Except where given as percentages of subjects, values represent means ± SDs, with ranges in parentheses.

signals. To accurately maintain the cuff pressure at 60 mm Hg, an air pump and an electrical controlled linear valve were used to adjust the inflating and deflating rate, respectively. The PVP waveform analysis algorithm was implemented in C programming language using Borland C++ Builder 6.0.

This prototype CBP monitor was customized to measure brachial SBP and DBP and then perform PVP at a cuff pressure of 60 mm Hg. The PVP waveform was then calibrated to the brachial SBP and DBP and used for estimating central SBP and PP.^{16,19} The prediction equation for central PP measurements was produced by adopting the same theoretic framework for central SBP¹⁹ (see methods of supplementary data online for details). The values of brachial SBP and DBP and central SBP and PP displayed on the CBP monitor were the means of 2 recordings separated by 1 minute. Brachial PP was calculated as brachial SBP minus brachial DBP. Central DBP was calculated as central SBP minus central PP.

Direct pressure measurement

Invasive CBP was measured from the ascending aorta using a fluid-filled catheter system attached to Siemens-approved transducers with a resistance of 200 to 3,000 Ω and an equivalent pressure sensitivity of 5 $\mu\text{V}/\text{V}/\text{mm Hg} \pm 10\%$.

To maximize the fidelity of the catheter-transducer systems, we thoroughly flushed the catheters outside the duration of pressure recording and avoided any unnecessary connections between the catheter and transducer.²⁴ The frequency range of our catheterization laboratory amplifier is 0 to 400 Hz for pressure measurement (-50 to 400 mm Hg) with the accuracy of ± 1 mm Hg or $\pm 3\%$ exclusive of transducer.¹⁶ The routinely checked natural frequency and damping coefficients of the system were 30 Hz (21–41 Hz) and 0.2 (0.14–0.41), respectively, which surpassed the recommended guidelines.^{20,25} The pressure transducers had been warmed for a minimum of 30 minutes before calibration and use. Each transducer was calibrated against mercury immediately before pressure measurement, with the zero reference level for pressure measurement set at midchest height, which was also used for balancing. Both calibration and balancing were checked before each measurement was performed. During all automated BP measurements with the CBP monitor, pressure tracings were recorded simultaneously and continuously with recording of zero reference at the end of each pressure segment to check for and correct any measurable pressure drift.

Data analysis

The invasively recorded central aortic pressure signals were analyzed off-line using custom-designed software developed on a commercial software package (Matlab, version 7.0; The MathWorks, Massachusetts, USA). All processed individual signals were subjected to fully automatic batch analysis to avoid inter- and intraobserver variations. The invasively measured central SBP, DBP, and PP were determined from the highest readings, the lowest readings, and the amplitudes of all central aortic pressure waveforms recorded during the whole process of automatic pressure measurement with the prototype CBP monitor. Pressure measurements recorded during and after isolated premature

beats were excluded from analysis; multiple premature beats during a single period resulted in removal of the patient from the protocol. The mean values for invasive CBP (± 1 SD) represented the range of variation for the invasive reference CBP,²⁰ which served as the basis for comparison with indirect measurements.²⁰ All measurements were obtained from the tracings by one experienced observer blinded to the indirect readings and the clinical status of the patients.

Assessment of magnitude of errors

Shown in Tables 2 and 3, *band error* was determined according to the suggestion of AAMI SP10 (2009), the error used for comparison with the predefined criteria, 5 ± 8 mm Hg.²⁰ In brief, band error was the extent to which estimated BP fell outside the range of variation of invasively measured CBP, as mentioned above. *Absolute error*, presented in Table 2 represented the absolute value of difference between estimated CBP and measured range of variation of CBP. *Relative error*, shown in Table 2, was similarly defined as absolute error, but was expressed as a percentage of the simultaneous direct measurement. The values for *overestimation* or *underestimation*, in Table 2, reflect the mean overestimation or underestimation of the difference between estimated CBP and measured mean CBP, displaying the tendency of the automatic CBP monitor to overestimate or underestimate direct readings. Table 2 also provides Pearson's correlation coefficients for comparisons between indirect and direct BP recordings.

Statistical analyses

We tested the normality of all the BP parameters using the Shapiro-Wilk test. Because of the strict recruiting requirement of AAMI²⁰ aiming to enroll representative as described in Study population, all BP parameters were therefore normally distributed. Data are presented as means \pm SDs. Agreements between the paired measurements were examined using the paired-samples *t* test and the Bland-Altman analysis. Statistical significance was declared at the 2-tailed $P < 0.05$ level.

RESULTS

Recruitment of Study Subjects

Overall, 56 and 85 subjects were included in the generation and validation groups, respectively. As shown in Table 1, the age distribution and associated comorbidity represented a study population with a wide variety of clinical characteristics. Table S1 (online supplementary table) details the fulfillment of specific requirements of AAMI SP10²⁰ and the relative distribution of invasively measured CBP, which consisted of the widely scattered BP readings during measurements.

Validation Results with Reference to Invasively Measured CBP

Table 2 provides the magnitude of observed errors and correlation coefficients. The band errors for central SBP, PP, and DBP measurements were -0.4 ± 3.0 , -0.4 ± 5.2 , and 0.5 ± 4.2 mm Hg, respectively. In contrast, the band errors

Table 2. Magnitude of Error and Correlation Between Estimated and Measured CBP (255 Measurements)

	SBP	PP	DBP
Band error (mm Hg) ^a			
Range	-8.6 to 14.9	-14.1 to 20.1	-19.2 to 15.3
Mean ± SD	-0.4 ± 3.0	-0.4 ± 5.2	0.5 ± 4.2
Absolute error (mm Hg) ^b			
Range	0.0–19.5	0.0–22.7	0.0–20.6
Mean ± SD	4.3 ± 3.5	5.5 ± 4.3	5 ± 4.2
Relative error (%) ^c			
Range	0.0–19.2	0.0–70.3	0.0–33.7
Mean ± SD	3.3 ± 2.9	10.2 ± 11.1	7.2 ± 6.4
Overestimation or underestimation (mm Hg) ^d			
Range	-12.9 to 19.5	-16.1 to 22.7	-20.6 to 20.0
Mean ± SD	-0.6 ± 5.5	-0.4 ± 7.0	-0.2 ± 6.5
Correlation between measured and estimated CBP	0.97	0.95	0.83

^aDetermined according to the suggestion of AAMI SP10²⁰; the error is the extent to which estimated CBP fell outside the range of the mean measured CBP ± SD.

^bAbsolute value of difference between estimated and measured CBP.

^cAbsolute error × 100%/measured CBP.

^dDifference between estimated and measured CBP.

Abbreviations: CBP, central blood pressure; DBP, diastolic blood pressure; PP, pulse pressure; SBP, systolic blood pressure. All calculations for errors are derived from estimated CBP minus measured CBP.

Table 3. Distributions of the Absolute Value of Band Error for Comparison Between Calculated and Measured Central BP

	<5mm Hg		<10mm Hg		<15mm Hg	
	No.	%	No.	%	No.	%
Central SBP	225	88.2	252	98.8	255	100
Central PP	177	69.4	235	92.2	252	98.8
Central DBP	212	83.1	240	94.1	252	98.8

Values represent numbers and percentages of measurements ($n = 255$).

Abbreviations: BP, blood pressure; DBP, diastolic BP; PP, pulse pressure; SBP, systolic BP.

for cuff SBP, PP, and DBP were -2.0 ± 6.0 , -7.5 ± 9.7 , and 3.3 ± 5.4 mm Hg, respectively.

Table 3 shows the distributions of measurement errors within the ranges of <5, <10, and <15 mm Hg, which clearly surpassed all recommended standards including AAMI SP10,²⁰ British Hypertension Society protocol grade A,²² and European Society of Hypertension International Protocol 2010.²¹

Bland-Altman analyses for the noninvasive brachial and central SBP, PP, and DBP are shown in Figure 1, 2 and 3. The mean differences between noninvasive and invasive central SBP, PP, and DBP (with SDs) were -0.6 ± 5.5 , -0.4 ± 7.0 , and -0.2 ± 6.5 mm Hg, respectively, well within the 5 ± 8 mm Hg defined by AAMI SP10.²⁰ No remarkable systematic drift was observed. In contrast, the noninvasive brachial SBP slightly underestimated invasive central SBP but with large scattering and an obvious systematic bias proportional to magnitudes of measured values (Figure 1), the noninvasive brachial PP markedly underestimated invasive central PP

with large scattering and an obvious proportional systematic bias (Figure 2), and the noninvasive brachial DBP substantially overestimated invasive central DBP but with acceptable scattering and a slight systematic drift (Figure 3).

The comparisons of measurement accuracy between cuff brachial BP and noninvasive CBP measured by the CBP monitor are presented in Figure 4. The band errors for noninvasive CBP with reference to the invasive CBP were close to zero and were significantly smaller than those of the corresponding cuff BP (all $P < 0.001$ for SBP, PP, and DBP).

DISCUSSION

The present study is the first to report the validation results of a newly developed stand-alone CBP monitor against currently available international standards with reference to invasively measured CBP. The measurement accuracy of the CBP monitor has clearly surpassed all requirements of the international standards.^{20–22}

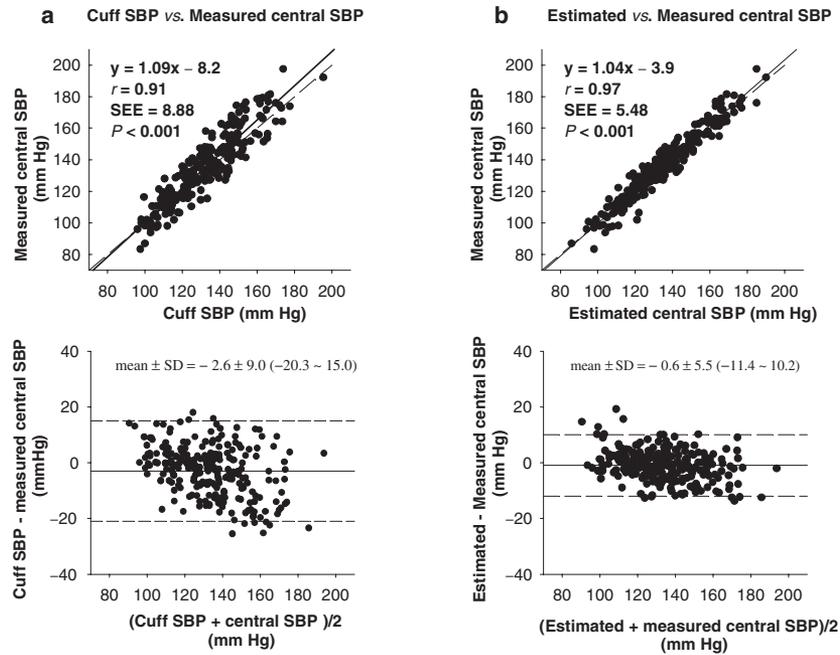


Figure 1. Bland-Altman analyses (255 measurements). (a) Agreement between cuff SBP and measured central aortic SBP. (b) Agreement between estimated and measured central aortic SBP. Dashed lines of lower panels indicate boundaries of 2 SDs of the differences; dashed lines of upper panels, lines of identity. Abbreviation: SEE, Standard Error of the Estimate.

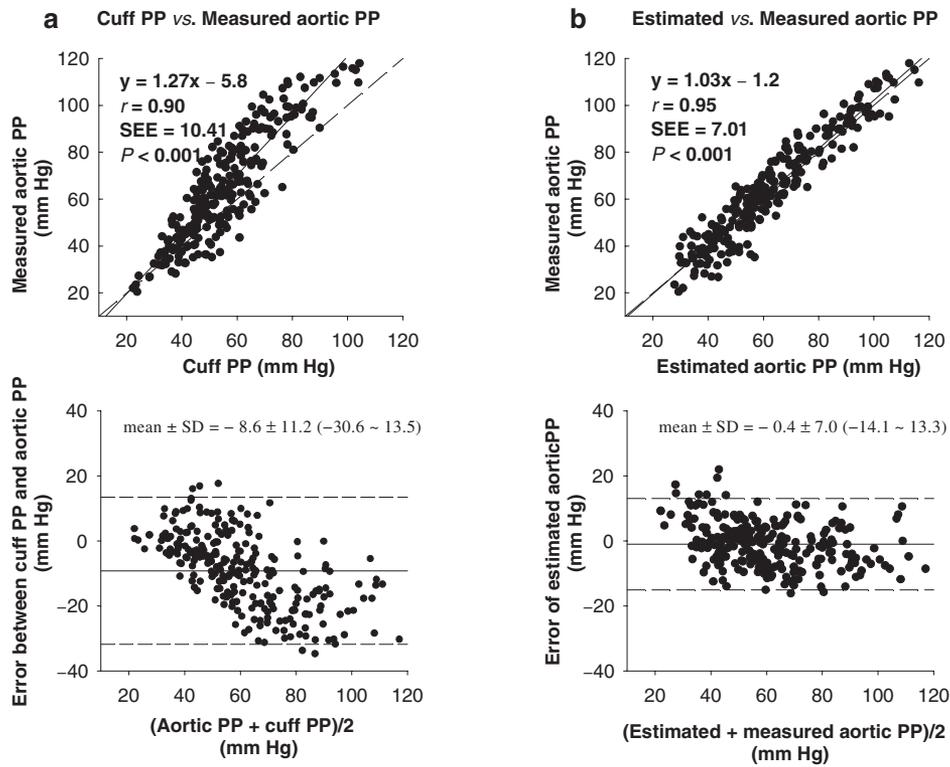


Figure 2. Bland-Altman analyses (255 measurements). (a) Agreement between cuff pulse pressure (PP) and measured central aortic PP. (b) Agreement between estimated and measured central aortic PP. Dashed lines of lower panels indicate boundaries of 2 SDs of the differences; dashed lines of upper panels, lines of identity. Abbreviation: SEE, Standard Error of the Estimate.

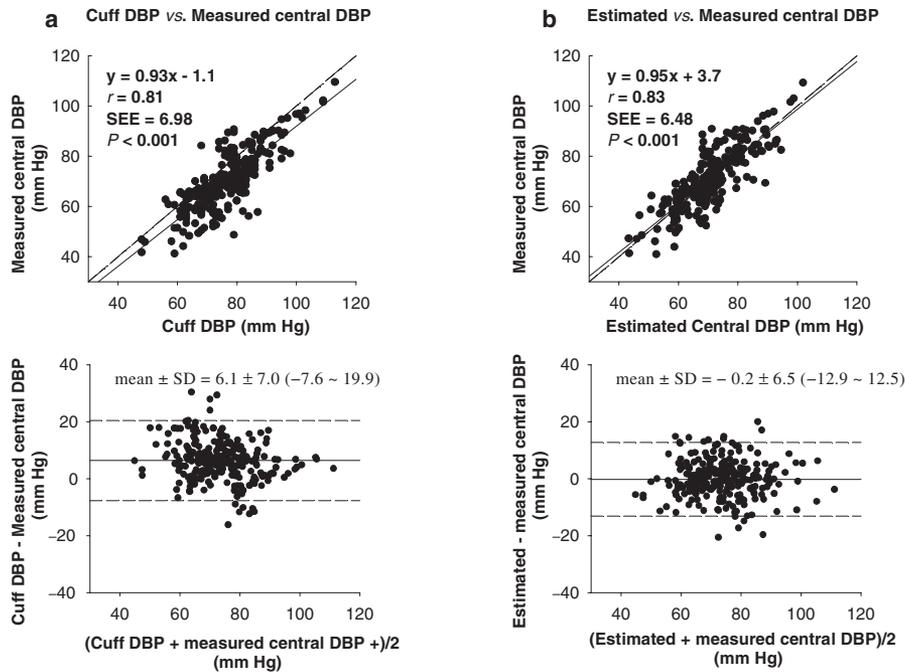


Figure 3. Bland-Altman analysis (255 measurements). (a) Agreement between cuff diastolic pressure (DBP) and measured central aortic DBP. (b) Agreement between estimated and measured central aortic DBP. Dashed lines of lower panels indicate boundaries of 2 SDs of the differences; dashed lines of upper panels, lines of identity. Abbreviation: SEE, Standard Error of the Estimate.

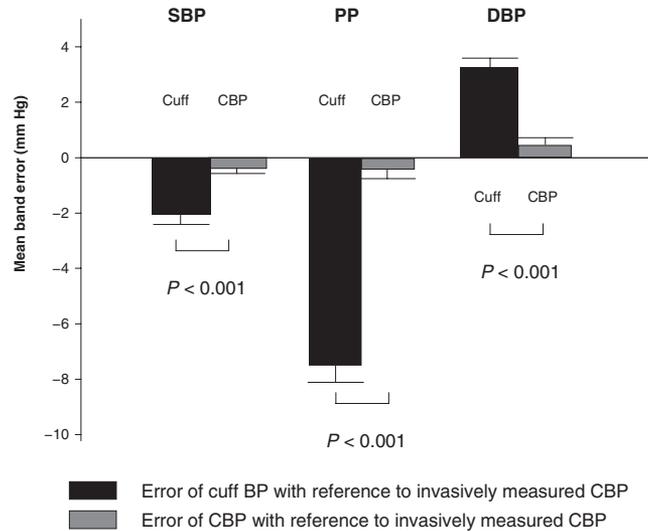


Figure 4. Mean band errors for determination of central aortic systolic blood pressure (BP) (SBP), pulse pressure (PP), and diastolic BP (DBP) of the brachial BP (cuff BP) or central BP (CBP) measured with the stand-alone CBP monitor. Error bars denote SEs of means.

With the advent of CBP monitors and their availability on the market, challenges to validate these devices are expected. The first challenge is the choice of reference standard. For automatic brachial BP monitors, the well-accepted reference standard is the auscultatory method. As for the CBP monitors, true reference standard for the CBP measurements should still be the invasive BP measured at the ascending aorta rather than measurements obtained with other widely used devices, because of their large systematic and random errors shown in a recent meta-analysis.²⁶ Therefore, we chose the invasive BP as a “true

reference standard” and adhered to AAMI’s suggestions by using either a fluid-filled catheter or an external pressure transducer with tip in situ.²⁰ We have demonstrated that central aortic SBP and DBP are mainly determined from the low frequency components of the pressure waveforms recorded using either a high-fidelity catheter-tip or a fluid-filled catheter (see online supplementary data, Figure S1).²⁷ Therefore in the present validation study, we used the fluid-filled catheter instead of the high-fidelity pressure catheter to invasively measure CBP, because the high-frequency waveform details were of less concern.

AAMI requires a total of 85 subjects with 255 measurements (3 for each) in the noninvasive validation studies.²⁸ For the invasive validation study, AAMI SP10 requires recruitment of ≥ 15 subjects with a minimum of 150 paired observations and a maximum of 10 paired measurements per subject.²⁰ The efforts of the present study represent the most rigorous approach; subjects were recruited according to the recommendations for noninvasive validation, and all requirements for the invasive reference standard were also fulfilled.²⁰

According to AAMI SP10,²⁰ error determination, with the intra-arterial BP used as the reference standard, is different from the conventional method of calculating mean differences between paired measurements. The measurement error is determined by first calculating the range of variation of the invasive BP and then analyzing the differences outside the above range. The calculations produce the “band error,” which should be compared with the predefined criterion of 5 ± 8 mm Hg.²⁰

Early validation data that compared the cuff BP measured by the indirect auscultatory method with the directly measured intra-arterial BP have revealed substantial discrepancies between the two measurements.^{29,30} The large systematic and random errors for the indirect auscultatory method disclosed in the official AAMI document²⁰ have not precluded its use as a current standard for validating automatic BP monitors and clinical decision making. Therefore, for directly comparison with the intra-arterial BP, current noninvasive BP monitors may also give BP values with similarly large systematic and random errors, even when they have passed the requirements of international validation protocols. The influence of such inaccuracy may have manifestly been ignored. The results of the present study confirm the variable magnitude of underestimation or overestimation of cuff BP at different ranges of the invasive CBP and dispute the use of cuff BP measurements as surrogates for CBP.

SBP Measurements

Current CBP estimating techniques^{8,15,17,31–33} usually focus on central SBP. All methods require calibration of the noninvasively derived pressure waveforms using the cuff SBP and DBP or cuff mean BP and DBP. The errors of the cuff BP would invariably be transferred to the estimated central SBP.³⁴ To adjust the underestimation of cuff SBP, Takazawa *et al.* used a regression equation implemented in a radial tonometric device (HEM-9000AI, Omron Healthcare, Kyoto, Japan) for the estimation of central SBP from a peripheral late systolic shoulder (SBP2).³²

We compared the present validation results with those of a recently proposed brachial-cuff based method, which uses a transfer function like algorithm (ARCSolver¹⁷); this comparison indicated that the current CBP monitor has better agreement with the invasively measured CBP (mean difference, -0.6 ± 5.5 vs. -3.0 ± 9.5 mm Hg for central SBP and -0.2 ± 6.5 vs. 7.6 ± 7.1 mm Hg for central DBP). A large difference between the cuff BP and the invasive CBP in the ARCSolver algorithm validation

study (mean difference, -8.8 ± 10.4 mm Hg for SBP and 6.7 ± 7.3 mm Hg for DBP) may have caused a large calibration error.¹⁷ In contrast, our PVP waveform analysis method may partly account for the calibration error by using the noninvasively calibrated PVP waveforms to generate the multivariate prediction models.¹⁶ In addition, the performance of the current CBP monitor in measuring cuff BP has been strictly validated (mean difference from the invasive CBP, -2.6 ± 9.0 mm Hg for SBP and 6.1 ± 7.0 mm Hg for DBP).

DBP Measurements

DBP is critical for the coronary perfusion and is important in the diagnosis of isolated systolic hypertension³⁵ and understanding of the J-curve phenomenon.^{36–39} Invasive brachial DBP is usually equal to invasive central DBP.⁶ However, current oscillometric BP monitors consistently overestimate DBP and may invalidate the use of DBP as an effective parameter in the classification of hypertension subtypes, selection of adequate antihypertensive medications, and assessment of myocardial ischemia.³⁶ The auscultatory method was introduced more than 100 years ago. Until now, the PVP method may have the potential to improve the accuracy of noninvasive DBP measurement by obtaining more accurate central SBP and PP.

In conclusion, the present validation study suggested that central SBP, PP, and DBP can be measured accurately by a stand-alone automatic BP monitor. The prognostic values of these CBP estimates should be further investigated.

Limitations of the Present Study

Our study population consisted of adult patients (age range, 30–93 years) referred for evaluation of coronary anatomy and/or angioplasty, and this population may differ from the general population in the sex distribution and in the prevalence of underlying medical comorbidity. However, our population may more appropriately represent persons in whom BP determinations are most often needed. Moreover, we used the fluid-filled systems for the invasive CBP measurements rather than micromanometer-tipped catheters. Given the documented frequency response of our system with carefully performed pressure recording procedures, the differences of the measured CBP between these two methods might be negligible.

SUPPLEMENTARY MATERIAL

Supplementary materials are available at the American Journal of Hypertension online (http://www.oxfordjournals.org/our_journals/ajh/). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

DISCLOSURE

MicroLife and National Yang-Ming University have signed a contract for transfer of the noninvasive CBP technique. The contract of technology transfer includes research funding for conducting the validation study.

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