Measurement error risk for finger-cuff blood pressure after aortic valve replacement are aortic valve area index and heart rate; FloTrac vs ClearSight

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Research Article

Keywords: Non-invasive blood pressure, Arterial pressure, Transcatheter aortic valve replacement, Error grid analysis.

Posted Date: March 18th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1460002/v1

Abstract

Purpose: The accuracy of ClearSight™ blood pressure measurements in patients with postaortic valve replacement may be inaccurate compared to intra-arterial pressure, the clinical risk of measurement discrepancy remains uncertain. This study aimed to determine the factors associated with errors in measurement.

Methods: From October 2020 to November 2021, we collected 881 pairs of intra-arterial/ClearSight blood pressure measurements from 30 adults who underwent transcatheter aortic valve replacement. The agreement of ClearSight blood pressure with intra-arterial pressure was compared, and the clinical risk was evaluated by classifying measurement errors into zones A (no risk) to E (dangerous risk) using error grid analysis.

Results: The bias and precision of ClearSight measurement were −4.88 ± 15.46 (mmHg) for systolic, 4.73 ± 8.95 (mmHg) for the mean and 9.53 ± 9.01 (mmHg) for the diastolic blood pressure. The proportions of measurement pairs in zones A were 88.0% for systolic BP and 71.2% for mean BP, respectively. Logistic regression analysis revealed that the risk of measurement error being outside zone A was heart rate [odds ratio, 1.24; 95% confidence interval, 1.15 to 1.35; p<0.001] for systolic and mean blood pressure, and aortic valve area index < 1.0 (cm_2. m^{-2}) [odds ratio, 1.62; 95% confidence interval, 1.21 to 2.16; p=0.02] for mean blood pressure.

Conclusion: These findings could help to identify patients of unsuitable for ClearSight blood pressure measurement. Our results demonstrate that the small aortic valve area index and low cardiac index are risk factors for measurement error.

Introduction

Intra-arterial pressure (IAP) monitoring is accepted and is a gold standard during general anesthesia in critically ill patients [1]. However, an alternative continuous blood pressure (BP) monitoring method to the IAP is the finger-cuff technology, ClearSight™ (Edwards Lifesciences, Irvine, CA, USA).

This is a method of measuring BP continuously, using the volume clamp/vascular unloading technique, in which the cuff pressure is quickly adjusted to maintain a constant blood vessel diameter in response to changes in blood volume in the finger artery, thereby equalizing the cuff pressure and finger artery BP [2]. ClearSight also shows a converted arterial waveform by utilizing the fact that there is almost no individual difference in the arterial waveform of the finger artery and brachial artery [3, 4].

In general, the error in the measurement of the mean arterial pressure during general anesthesia using ClearSight is considered to be overestimated by about 5 mmHg [3, 4]. This is because, measurement error is greater in elderly patients with significantly reduced arterial compliance [4]. Moreover, patients with low cardiac index (CI) and continuous phenylephrine administration, increase measurement error [3, 5–7].

Despite these known limitations, finger-cuff continuous BP measurement may be used in less risky non-cardiac surgeries because of its advantages of easy application and no complications.

The objectives of this study were to evaluate the accuracy of the finger-cuff method of BP measurement in post-TAVR patients by performing an error grid analysis and to determine factors associated with errors in measurement by using logistic regression analysis.

Methods

This prospective observational study was approved by the Institutional Ethics Committee of Hitachi General Hospital, Japan (Approval No. 2020-48) and registered in the Clinical Trials Registry (ref: UMIN000044953). Written informed consent was obtained from the patients. Patients aged over 65 years who underwent TAVR under general anesthesia from September 2020 to October 2021 were included. Patients with a diagnosis of peripheral artery disease, Raynaud's symptoms, emergency surgery and those who did not consent to the study were excluded. We performed standard monitoring during operation, including a 5-lead electrocardiogram, pulse oximeter and non-invasive intermittent BP measurement with the upper arm. Anesthesia was induced with propofol 1–2 $mg.kg^{-1}$ and fentanyl 0.05–0.1 $mg.kg^{-1}$. Tracheal intubation was facilitated by muscle relaxants. Ventilation was performed with a tidal volume of 7–8 $ml.kg^{-1}$ at ideal body weight and positive pressure ventilation of 5–10 cmH_2O. Inhaled oxygen fractions and respiratory rate were adjusted to maintain peripheral oxygen saturation above 96% and end-expiratory partial pressure of carbon dioxide between 35 and 45 mmHg. After induction of anesthesia, the IAP was measured at the radial artery through a catheter (Terumo arterial catheter, 22-gauge, 23 mm length; Terumo, Shibuya, Tokyo, Japan) and the FloTrac ^{TM} (Edwards Lifesciences) pressure transducer connected to a module (Life Scope TR, Nihon Kohden Co, Sinjuku, Tokyo, Japan) for direct BP measurement. The transducer was placed at the level of the right atrium. The IAP waveform was visually assessed by the attending anesthetist to ensure that there was no dumping. For non-invasive BP monitoring, the ClearSight finger-cuff was placed on the index or middle finger, ipsilateral to the IAP monitoring, with the correct size as recommended by the manufacturer. All patients had their IAP monitored using FloTrac with Vigileo™ (Edwards Lifesciences) platform and non-invasive finger-cuff BP monitoring was done using ClearSight with HemoSphere™ (Edwards Lifesciences) platform recorded at the same time intraoperatively. All haemodynamic data were automatically recorded using information management systems (PrimeGaia™, Nihon Kohden). After the prosthetic valve has been deployed, All patients were confirmed by transoesophageal echocardiography (TEE) to have no more than mild aortic regurgitation of the prosthetic valve and no paravalvular leakage. The ejection fraction (EF) was measured by the modified Simpson method and the aortic valve area index (AVAI) of the prosthetic aortic valve was also measured by TEE using the continuous equation, the formula is as follows;

$$AVAI\ (cm^2.m^{-2}) = CSA_{LVOT}\ (cm^2) \times V_{LVOT}\ (m.s^{-1})/V_{AV}\ (m.s^{-1})/BSA\ (m^2)$$

CSA_{LVOT}: cross-sectional area of left ventricular outflow tract

V_{LVOT}: blood flow velocity in the left ventricular outflow tract

V_{AV}: blood flow velocity in aortic valve

BSA: body surface area

After TEE measurement, minute by minute IAP and ClearSight arterial pressure (CSAP) measurement were recorded for 30 mins and cardiac index (CI) (CI_{IAP} and CI_{CSAP}) values were calculated by pulse contour method, which is the concept that the area of each arterial waveform corresponds to the stroke volume [8].

The sample size was calculated to be more than 646 pair data, based on the assumption that the two BP pair data to be compared would show a correlation coefficient of at least 0.8. Considering the deviation from the inclusion criteria, we decided to collect data from 30 patients. To assess the concordance of hemodynamic variables measured by IAP (reference method) and CSAP (test method), Bland–Altman analysis of repeated measurements was performed to calculate bias, precision, and limits of agreement [9, 10]. The percentage error was calculated as described by Critchley and Critchley [11]. A four-quadrant plot analysis was performed to evaluate the trend-tracking ability of the CSAP per minute with reference to the IAP [8]. The trend-tracking ability can be judged by the concordance rate, which is considered good if more than 92% of all values are in the upper right and lower left of the quadrant [11, 12]. The value in the center of the analysis table is set as the exclusion zone, which can be understood as the measurement point where the value did not change in the one-minute trend. The exclusion zone was set at 5 mmHg for BP data comparison [13, 14]. The error grid analyses were performed to compare the systolic and mean BPs of IAP and CSAP. The error grid analysis for arterial pressure can be performed to compare the clinical accuracy of BP estimates from a non-invasive measurement device with BP obtained with reference direct arterial pressure, reported by Saugel et al [15, 16]. The error between the gold standard and the test method was classified into five different clinical zones (from A to E) to assess the risk of leading to wrong intraoperative decisions [15]:

1. No risk (no difference in clinical actions between the test and gold standard methods).
2. Low risk (the values assessed by the test method and the gold standard differ, but the difference will probably lead to benign or no treatment)
3. Moderate risk (the values assessed by the test method and the gold standard differ, and the differences would lead to unnecessary treatment with moderate results that are not life-threatening to the patient)
4. Significant risk (the values assessed using the test method and the gold standard differ, and the difference leads to unnecessary treatment with serious non-life-threatening consequences for the patient).
5. Dangerous risk (the values assessed using the test method and the gold standard differ, and the difference leads to unnecessary treatment with life-threatening consequences for the patient).

In the error grid analysis, the test method can be considered to have the same clinical accuracy as the gold standard if the observed values that fall into the no risk category, i.e., zone A are 90% or more, zone B and C are within 5%, zone D is within 4%, and zone E is within 2% [15]. Logistic regression analysis was performed to explore potential confounding factors that could lead to errors in the IAP and CSAP being classified into a non-zone A category of clinical risk in the error grid analysis. The previously reported covariates included in the multivariate analysis were age, consecutive phenylephrine administration, coronary artery disease, hypertension, low CI and abnormal SVRI [5, 6, 17–19]. The patient population in this study was elderly and skewed by base hypertension and coronary artery disease immediately after valve replacement. After adjustment for patient background, AVAI, CI, and SVRI were selected as covariates. Statistical tests were two-tailed, and $p < 0.05$ was statistically significant. For statistical analysis, we used Matlab (The MathWorks Inc, Natick, MA, USA) and Stata/BE for Mac (Version 17.0; StataCorp, College Station, TX, USA).

Results

Eight hundred and 81 paired IAP and CSAP data from 30 patients undergoing TAVR were available for analysis; 19 paired data were excluded from the analysis due to loss of IAP data from blood sampling from arterial catheters.

Table 1 shows the patient background and the results of TEE measurements after aortic valve deployment. Figure 1 shows the agreement of the CSAP with the IAP as a reference. The bias and precision between the two methods were − 4.88 ± 15.46 for systolic BP, 4.73 ± 8.95 for mean BP, and 9.53 ± 9.01 for diastolic BP, respectively. The percentage errors were 24.9%, 22.6%, and 31.9% for systolic, mean, and diastolic BP, respectively. Table 2 shows a comparison of other hemodynamic parameters between FloTrac and ClearSight.

Table 1
Patient characteristics and intraoperative echocardiography measurements. Values are mean ± standard deviation or number and percentage.

	All patients (n = 30)
Age range (years)	78–91
Female (%)	53%
Height (cm)	152.3 ± 8.9
Body weight (kg)	53.8 ± 11.2
BSA (m^2)	1.48 ± 0.2
History of hypertension (%)	83%
History of coronary artery disease	53%
Administration of ephedrine (%)	60%
Administration of phenylephrine (%)	27%
TEE parameters (After prosthetic valve implantation)	
LVEF (%)	60.4 ± 6.1
LVDd	51.2 ± 5.9
LVDs	34.1 ± 5.6
$AVAI_{(C.E.)}$ (cm^2/m^2)	1.02 ± 0.2
PVL (mild/trivial/none)	11/0/19
AR (mild/trivial/none)	0/24/6

M, male; F, female; BSA, body surface area; TEE, transesophageal echocardiography, EF, ejection fraction; LVDd, left ventricular end-diastolic diameter; LVDs, left ventricular end-systolic diameter; AVAI, aortic valve area index calculated using the continuity equation; PVL, paravalvular leakage; AR, aortic regurgitation.

Table 2
Paired haemodynamics values (n = 881), their bias and lower and upper limits of agreement. Values are median ± standard deviation, number or percentage.

	FloTrac	ClearSight	Bias	LOA	PE
Heart rate	66.7 ± 13.1	66.4 ± 12.4	−0.24	−7.77 to 7.29	11.5
Cardiac index; $l.min^{-1}.m^{-2}$	2.78 ± 0.38	2.74 ± 0.35	−0.04	−0.55 to 0.47	18.8
SV; ml	55.7 ± 9.31	54.5 ± 7.56	−1.21	−25.8 to 23.4	45.1
SV variation; %	11.8 ± 4.22	15.2 ± 8.09	3.43	−14.3 to 21.1	153.2
SVRI; $dyne.sec.cm^{-5}.m^{-2}$	2634 ± 266	2718 ± 292	83.7	−739 to 906	31.9
SV, stroke volume; LOA, limits of agreement; PE, percentage error					

Figure 2 shows the results of the error grid analysis for the comparison of CSAP and IAP. The proportion of measurement pairs belonging to risk zones A– E was 88.0%, 11.4%, 0.4%, 0.1% and 0% for systolic BP and 71.2%, 28.0%, 0.8%, 0% and 0% for mean BP, respectively. Figure 3 shows the results of the four-quadrant plot analysis: the agreement between changes in CSAP and IAP measurements was 87.7% for systolic, 89.2% for mean and 89.7% for diastolic BP, respectively.

Based on previous reports, older age (> 65 years), lower CI (< 2.5 $l.min^{-1}$), lower EF, and abnormal SVRI have been identified as factors leading to measurement error [2, 3, 5–7]. Logistic regression analysis with the stepwise method was performed to identify independent predictors of measurement error not entered into zone A, which had a significant association recognized using univariate analysis (Table 3). The potential risk for clinically risky errors in systolic BP was heart rate [Odds ratio 1.24, (95%Conficence interval 1.15–1.35], p = 0.03. For mean BP, the potential risk was AVAI < 1.0 ($cm^2.m^{-2}$) [Odds ratio 1.62, (95%Conficence interval 1.21–2.16), p = 0.001], FloTrac calculated CI < 2,5 ($l.min^{-1}$) [Odds ratio 1.98, (95%Conficence interval 1.41–2.79), p < 0.001] and heart rate [Odds ratio 1.16, (95%Conficence interval 1.10 to 1.24), p < 0.001].

Table 3
Logistic regression analysis to identify the independent factors that IAP/CSAP measurement pairs out of Zone A.

Variables	Out of zone A (no risk)					
	Systolic arterial pressure			Mean arterial pressure		
	OR	95%CI	*p* value	OR	95%CI	*p* value
$AVAI_{(C.E.)}$ < 1.0	0.97	0.64 to 1.46	0.88	1.61	1.21 to 2.16	< 0.001*
$CI_{(FloTrac)}$ < 2.5	1.20	0.72 to 1.98	0.48	1.98	1.41 to 2.79	< 0.001*
HR	1.24	1.15 to 1.35	< 0.001*	1.16	1.10 to 1.24	< 0.001*

OR, adjusted odds ratio; $AVAI_{(C.E.)}$, aortic valve area index calculated using the continuity equation; CI, confidence interval; $CI_{(FloTrac)}$, cardiac index measured from FloTrac pulse contour method).
*Statistically significant.

Discussion

This prospective observational study evaluated the accuracy of non-invasive finger-cuff continuous arterial BP measurement by ClearSight using the volume clamp/vascular unloading method compared to direct arterial pressure measurement in patients who underwent TAVR. Bland–Altman analysis showed that the accuracy and precision of the finger-cuff technique after TAVR was good for mean BP, but not acceptable for systolic and diastolic BP (Fig. 1). It also did not reveal a good trend-tracking ability. Error grid analysis showed that more than 97% of the systolic BP measurements obtained from the finger-cuff technique were classified into no-risk or low-risk zones, but the mean BP measurements were well below the 90% criterion, indicating a risk of clinically inappropriate treatment (Fig. 2). Logistic regression analysis suggests that heart rate may contribute to measurement error in systolic BP and AVAI < 1.0 ($cm^2.m^{-2}$), CI < 2.5 ($l.min^{-1}$) and heart rate may contribute to measurement error in mean BP (Table 3).

This is the first study to evaluate the error predictors in the arterial pressure measurement performance of the ClearSight-HemoSphere platform in postaortic valve replacement patients using invasive arterial pressure measurement as the reference method. In general, there is a lack of data on the performance of finger-cuff BP measurement for continuous non-invasive monitoring in elderly patients after TAVR.

Several studies have compared non-invasive BP measurement with a finger-cuff to direct BP measurement with an invasive arterial catheter in a variety of patients, without an explicit focus on patients after valve replacement surgery [20–23]. Those studies have shown that the measurement accuracy of the finger-cuff method is reduced in hypertensive patients and the elderly because peripheral small arteries such as the fingertips may be occluded or stenotic secondary to the effect of hypertension [7, 24, 25]. In these patients, measurement by the finger-cuff method may be difficult even if there are no anatomical abnormalities. In addition, the volume clamp/vascular unloading method, which has a

measurement principle of repeating the pressurization and decompression of peripheral small arteries several hundred times per second, requires a certain degree of compliance in the small arteries of the target finger, and measurement is not possible in cases of suspected reduced elastance, such as with calcification or fingers with Raynaud's symptoms [2, 3].

In this study, the wide range of BP measurement errors was responsible for the lack of trend-following capability in BP changes. The systolic CSAP underestimated the IAP. This finding is consistent with previous studies [7, 24, 25]. In contrast, diastolic CSAP greatly overestimated IAP. Despite the good agreement in the Brand–Altman analysis of mean BP, the error grid analysis could make a difference in clinical decisions (Fig. 2). This may be related to the fact that CSAP tends to be higher than IAP in diastolic BP (Fig. 1). There are few reported error grid analyses performed in the past that suggested minimal clinical risk from the use of finger-cuff methods [7, 21]. Error grid analysis for arterial pressure is a relatively new methodology in BP measurement research and is not yet a regular validation protocol. However, the classification of clinical risk by this analysis may assist in the decision to use vasoactive, vasodilator or inotropic drugs during general anesthesia [7, 19, 21, 24–28].

According to the logistic regression analysis in this study, the clinical risk in ClearSight is considered AVAI < 1.0 ($cm^2.m^{-2}$) patients after aortic valve replacement. In addition, the increased heart rate and CI < 2.5 ($l.m^{-1}$) are also possible disadvantage in the use of finger-cuff devices. In some previous studies, age, history of hypertension and coronary artery disease, obesity and continuous phenylephrine administration were found to be associated with higher clinical risk by error grid analysis [7, 13–15, 19, 26]. In this study, the homogeneous patient group consisted of > 75 years of age heart failure patients, and the occurrence of hypertension and coronary artery disease were high. Hence, we did not include age, sex, or previous medical history as explanatory variables.

This study has several limitations. First, the error grid analysis used in this study is not a standard method for comparing two different devices. Therefore, this analysis needs to be further validated in the future. Second, since IAP and CSAP are measured in the ipsilateral upper extremity, the catheter inserted into the radial artery may be affecting the pulse wave transmitted to the peripheral finger and changing the mean BP. In general, the shape and absolute value of the arterial pressure waveform gradually changes as it moves from the brachial artery to the finger artery. Specifically, diastolic BP decreases in smaller arteries due to flow resistance [3, 4]. TAVR has the complication that part of the prosthetic valve can occlude a coronary artery, necessitating urgent coronary angiography. This is sometimes approached via an artery in the upper arm, making it difficult to fit the ClearSight system to the side of the upper limb that is not being monitored by the IAP.

The error grid analysis indicated that the differences between IAP and CAP for systolic and mean pressure post-TAVR patients were not acceptable. Increased heart rate was the significant factor for increased discrepancies between IAP and CAP for systolic and mean BP. Low AVAI and CI were the significant factors for increased discrepancies between IAP and CSAP for mean BP.

Declarations

The authors would like to thank Makoto Tanaka, MD, PhD (Department of Anesthesiology, University of Tsukuba, Japan) and the company Edwards Lifesciences (Irvine, CA, USA) for kindly providing all the facilities necessary for hemodynamic monitoring using the ClearSight and Swan-Ganz catheter systems. The manufacturer had no input in the design of the study or in the decision to submit the manuscript for publication.

Funding

No funding was received for the work.

Competing Interests

No external funding and no competing interests declared.

Author Contribution

Musashi Yahagi: study design, data collection, data analysis, writing up of the first draft of the paper.

Momoko Sasaki: data collection and revision of the paper.

Yuichi Yaguchi: revision of the paper and final approval of the version to be published.

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Figures

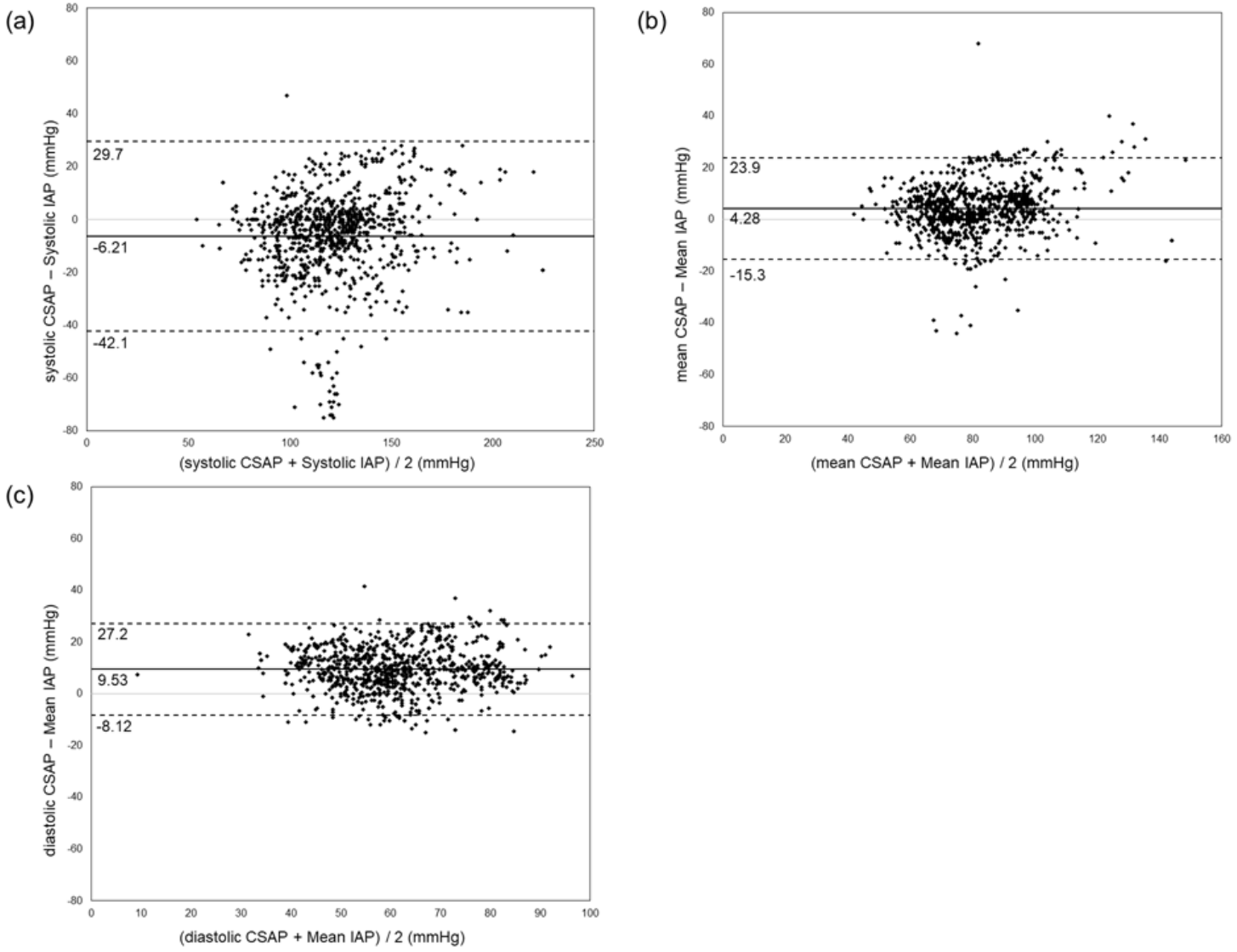

Figure 1

Bland–Altman analysis of 881 paired blood pressure measurements obtained by comparing intra-arterial pressure and ClearSight blood pressure during TAVR in 30 elderly patients. (a) shows systolic, (b) mean, and (c) diastolic blood pressure. The solid line shows the average bias and the dashed line shows the 95% limit of agreement

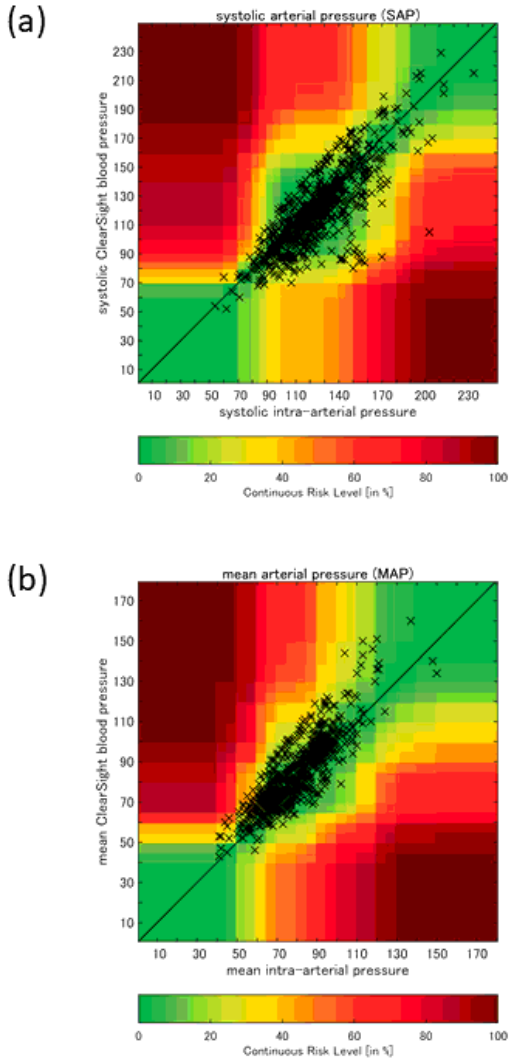

Figure 2

Error grid analysis showing the stratified clinical risk of intra-arterial pressure measured in the radial artery and in the ClearSight finger-cuff technology. (a) and (b) show systolic and mean blood pressures respectively. Pairs of measurements in the green areas lead to no risk for the patient. (a) Zone A includes 775 measurements (88.0%); (b) Zone A includes 627 measurements (71.2%)

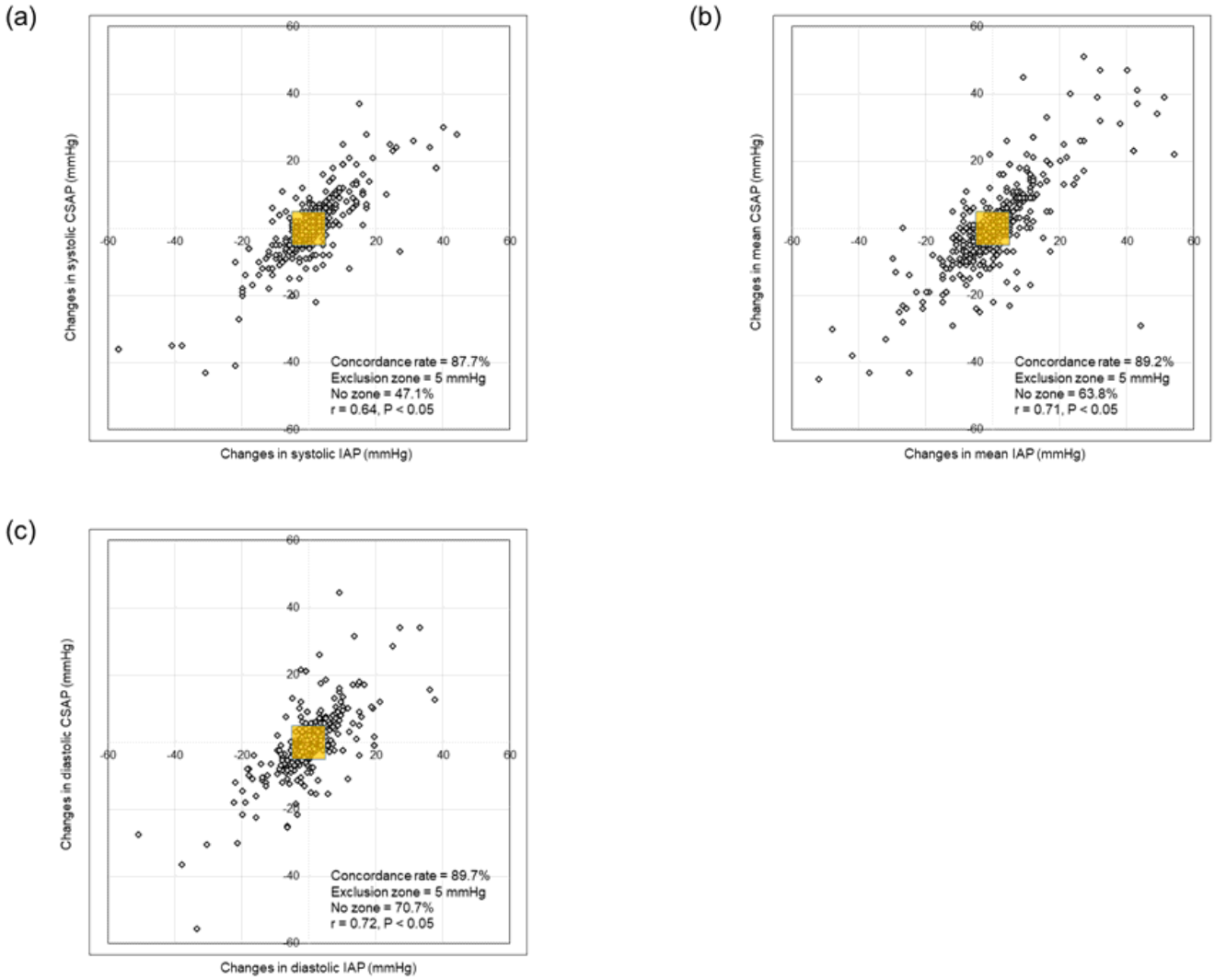

Figure 3

Four-quadrant plot analysis of the trend-tracking ability of ClearSight compared with IAP in concordance within the study observation period. (a) Systolic blood pressure, (b) mean blood pressure and (c) diastolic blood pressure was shown respectively. The central square is the exclusion zone (5 mmHg)