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ORIGINAL RESEARCH

Comparison between intra-arterial and two non-invasive blood pressure measuring systems: a cross-sectional analytic study employing Bland–Altman and error grid analyses

Appendix

Table AI: Statistical procedures

Analysis	Data	Software
Descriptive statistics Shapiro–Wilk test for normal distribution F-test for equal variances	Continuous (numeric) data	MedCalc® Statistical Software version 20.115 (MedCalc Software Ltd., Ostend, Belgium; 2022 https://www.medcalc.org)
Histograms of blood pressure measurement differences	*SAP*: Invasive-BP – OscNIBP Invasive-BP – US-NIBP OscNIBP – US-NIBP *MAP:* Invasive-BP – OscNIBP	
Bland–Altman analysis Mountain plots*	*SAP:* Invasive-BP vs. OscNIBP Invasive-BP vs. US-NIBP OscNIBP vs. US-NIBP *MAP:* Invasive-BP vs. OscNIBP	
Paired t-test Alternatively: Wilcoxon signed-rank test for non-normally distributed data	Systolic blood pressure: Zone A vs. Zone B in the error grids	
Least squares multiple regression†	*Dependent variable:* SAP differences *Independent variables tested:* Invasive-BP Systems A, B, C, D Invasive-BP natural frequency Invasive-BP damping ratio Age, BMI, heart rate Vasopressor usage	
Error grid analysis[12]	SAP *Reference:* US-NIBP *Test:* Invasive-BP MAP *Reference:* OscNIBP *Test:* Invasive-BP	Compiled MATLAB program (The MathWorks Inc., Natick, USA), written by Oliver Grothe and Anika Kaplan as a supplement to the publication by Grothe et al.[30]
Preiss–Fisher procedure‡	Bland–Altman data	Bland–Altman F-P Checker https://docs.google.com/spreadsheets/d/1OZEXCD9SOd_0-ZX5jc976eOdgjKkDjoQ34WJhj2lsfs/edit#gid=0

* Folded empirical cumulative distribution plots (*see Supplementary file*).[18]
† Backward entry.
‡ Procedure to check whether the measurement range is sufficiently wide for a reliable Bland–Altman analysis.[16]
BMI – body mass index, invasive-BP – intra-arterial blood pressure, MAP – mean arterial pressure, OscNIBP – oscillometrically measured arterial pressure, SAP – systolic arterial pressure, US-NIBP – systolic arterial pressure (ultrasound method), Zones A and B – error grid zones

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Supplementary file 1

Table SI: Recommended cuff sizes for accurate non-invasive measurement of blood pressure[1]

Arm circumference (cm)	Recommended cuff size (cm)
22–26	12 × 22 (small adult)
27–34	16 × 30 (adult)
35–44	16 × 36 (large adult)
45–52	16 × 42 (adult thigh)

Order of the arterial blood pressure measurements

Three intra-arterial blood pressure (IABP) and heart rate (HR) measurements were interspersed with pre-randomised OscNIBP and US-NIBP measurements.

The order was as follows:

1. Record the first IABP (systolic, mean, diastolic) and HR from the monitor screen.
2. Measure and record the OscNIBP or the US-NIBP systolic blood pressure according to randomisation.
3. Record the second IABP and HR.
4. Measure and record the OscNIBP or US-NIBP systolic pressure according to the pre-randomised order.
5. Record the third IABP and HR.

Each patient's IABPs and HR were taken as the averages of the three measurements.

The Preiss–Fisher procedure

It is generally accepted that Bland–Altman analysis is the preferred method for determining whether two methods of measurement are equivalent rather than the correlation coefficient. In 2008, Preiss and Fisher pointed out that Bland–Altman analysis of a narrow data range can give rise to spurious small bias and good precision.[2] They suggested randomising the paired measurements repeatedly and determining some measure of precision with each randomisation. If more than 5% of the randomly paired measurements result in good precision, then the original precision may well have resulted by chance.

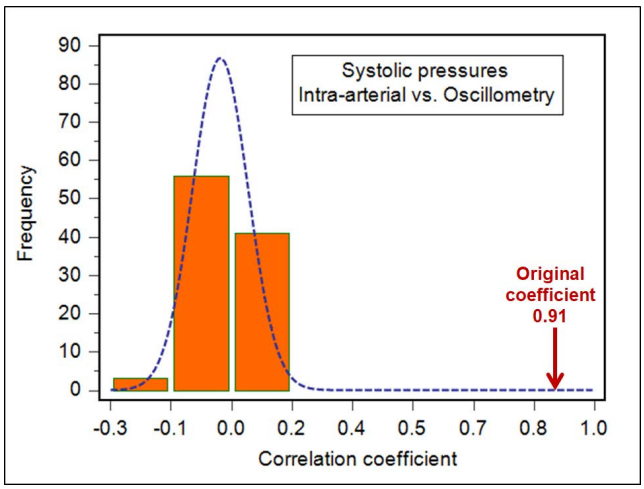


Figure S1: Graphic illustration of the result of a Preiss–Fisher test

In their publication, they employed the standard deviation of the mean differences as a measure of precision and provided a link to a website for conducting their procedure. The procedure has recently been updated and now uses the correlation coefficient between the two sets of measurement as the measure of precision (https://docs.google.com/spreadsheets/d/1OZEXCD9SOd_0-ZX5jc976eOdgjKkDjoQ34WJhj2lsfs/edit#gid=0).[1]

Figure S1 is an example of the procedure. The distribution of the correlation coefficients from 100 randomised pairs is displayed along with the original coefficient; 95% of the coefficients (i.e. within ± 2 × standard deviations) do not include the original coefficient of 0.91. Thus, it can be concluded that the range of the paired measurements was adequate for a reliable Bland–Altman analysis. Table SII depicts the results of the Preiss–Fisher procedures for each Bland–Altman analysis that we conducted in this study.

The original Pearson product-moment correlation coefficient between 195 pairs of systolic pressure measurements was 0.91 (arrow). Random reshuffling of the paired measurements 100 times resulted in 100 mismatched pairs and 100 correlation coefficients. The distribution of the correlation coefficients is illustrated in the figure.

Table SII: Results of the modified Preiss–Fisher procedure for determining whether the data range is acceptable for a reliable Bland–Altman analysis

Comparison	*n*	Original R	Mean mismatched R	From -2 × SD to + 2 × SD	Result
SAP: OscNIBP vs. US-NIBP	195	0.981	0.014	-0.014 to 0.171	Acceptable range
SAP: IABP vs. US-NIBP	195	0.930	-0.013	-0.149 to 0.130	Acceptable range
SAP: IABP vs. OscNIBP	195	0.912	0.009	-0.122 to 0.142	Acceptable range
MAP: OscNIBP vs. IABP	194	0.893	0.010	-0.128 to 0.148	Acceptable range

APB – intra-arterial blood pressure, MAP – mean arterial pressure, *n* – number of paired measurements, OscNIBP – oscillometric non-invasive blood pressure measurement, R – Pearson product-moment correlation coefficient, SAP – systolic arterial pressure, SD – standard deviation, US-NIBP – non-invasive blood pressure measurement by ultrasound

Interpretation: the original coefficient is not included within the range of two standard deviations from the mean value, an indication that the range of systolic pressure measurements was adequate for a reliable Bland–Altman analysis (mean mismatched coefficient -0.005; ± 2 standard deviations -0.155 to 0.144).

Explanation of folded empirical cumulative distribution plots (mountain plots)

A mountain plot is created as follows:[3]

1. Rank the differences between measurement methods from smallest to greatest.
2. Compute a percentile for each ranked difference:

$$percentile = rank * \left(\frac{100}{N+1}\right)$$

3. To obtain a folded plot, convert every percentile greater than 50 to:

$$Percentile = 100 - percentile$$

These percentiles are then plotted on the ordinate versus the differences between the methods on the abscissa.

The mountain plot provides information about the distribution of the differences between the measurement methods. If two measurement methods are unbiased with respect to each other, the mountain plot will be centred over zero. Long tails in the plot reflect large differences between the methods.

Krouwer et al.[3] point out its advantages:

- It is easier to find the central 95% of the data.
- It is easier to estimate percentiles for large differences (e.g. percentiles greater than 95%).
- Unlike a histogram, the plot shape is not a function of the intervals.
- Comparing different distributions is easier.
- The plot is easier to interpret than a standard empirical cumulative distribution plot.

Figures S2A to S2D show Bland–Altman graphs where the differences between measurements are expressed as percentage differences.

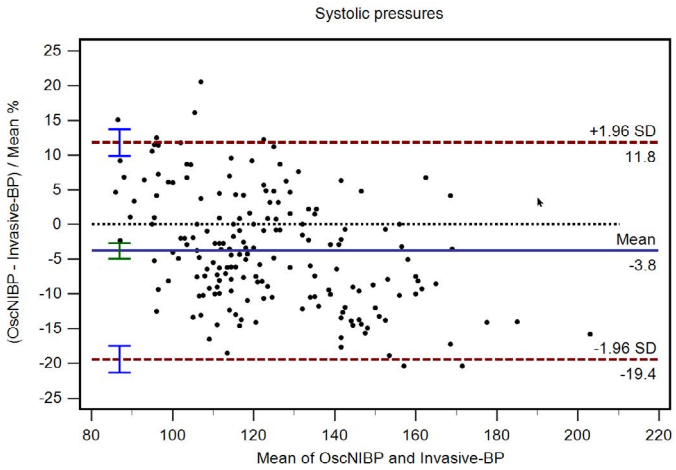


Figure S2A: Systolic pressures, invasive-BP versus OscNIBP with differences expressed as percentages

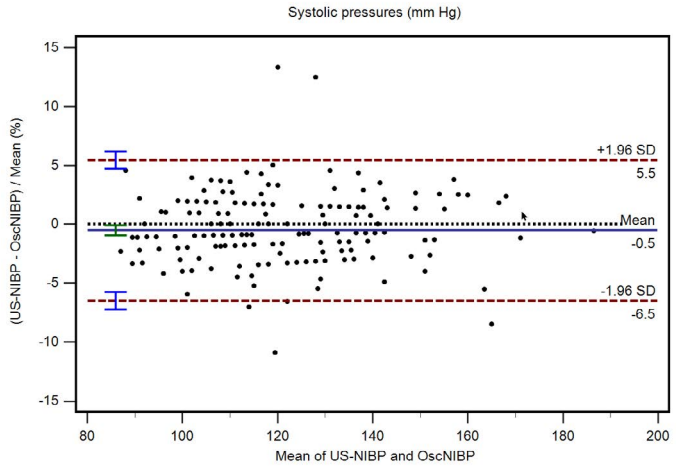


Figure S2B: Systolic pressures, invasive-BP versus US-NIBP with differences expressed as percentages

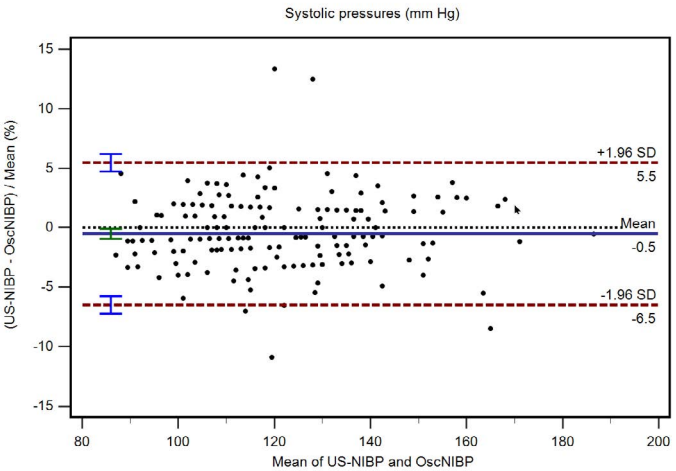


Figure S2C: Systolic pressures, OscNIBP versus US-NIBP with differences expressed as percentages

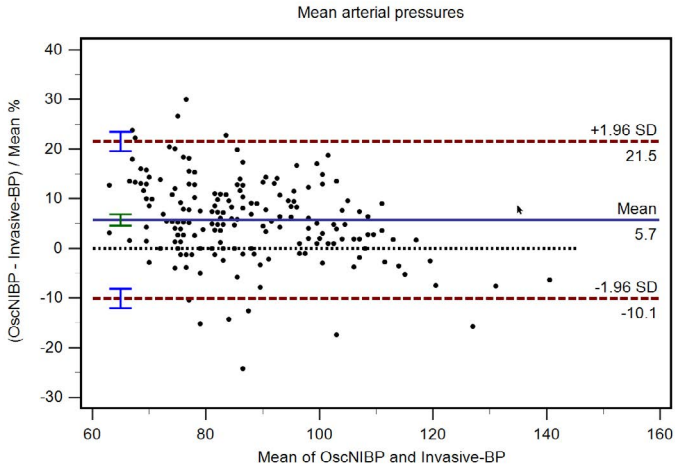


Figure S2D: Mean arterial pressures, OscNIBP versus invasive-BP with differences expressed as percentages

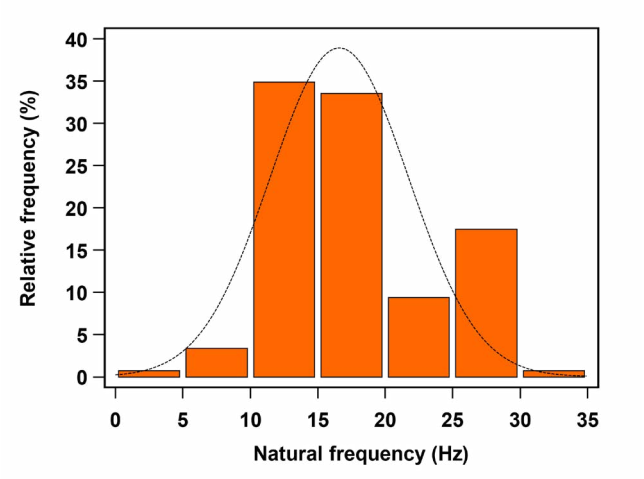
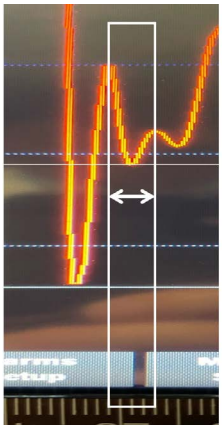


Figure S5: Histogram of the distribution of 163 measured natural frequencies (f_n)



$$f_n = \frac{(trace\ speed\ in\ mm.s^{-1})}{(peak\ to\ peak\ distance\ \ in\ mm)}$$

$$Natural\ frequency\ (f_n) = \frac{50}{4}$$

= 12.5 Hz

Figure S3: Illustration of the determination of the natural frequency (fn) of an intra-arterial blood pressure measuring system from a monitor screen photograph of a rapid flush test

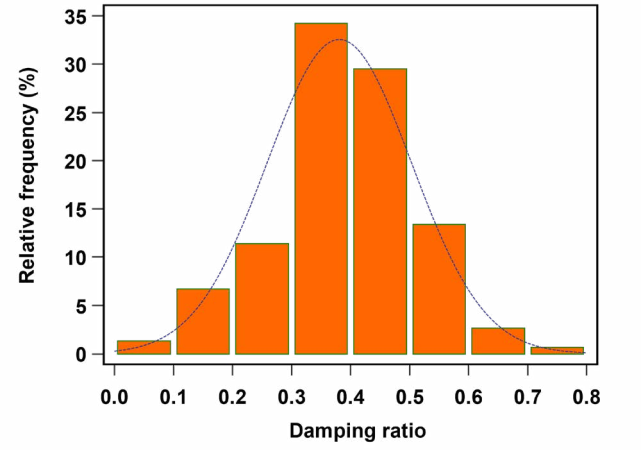


Figure S6: Histogram of the distribution of 152 measured damping ratios (ζ)

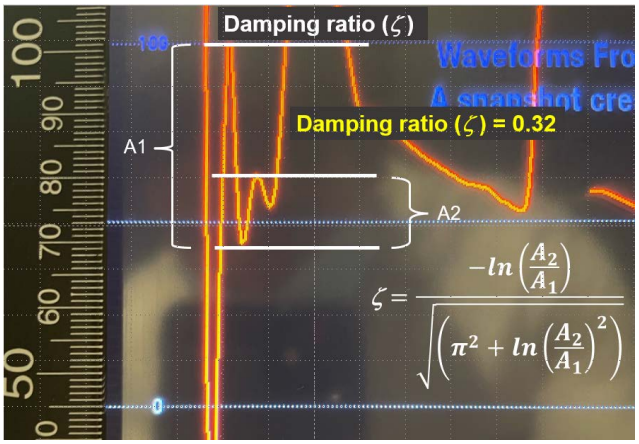


Figure S4: Illustration of the determination of the damping ratio (ζ) of an intra-arterial blood pressure measuring system from a monitor screen photograph of a rapid flush test

Table SIII: Results of multiple regression

Dependent Y	**Difference between systolic IABP and US-NIBP**

Least squares multiple regression

Method	**Backward**
Enter variable if $p <$	0.05
Remove variable if $p >$	0.1
Sample size	149
Coefficient of determination R^2	0.07774
R^2-adjusted	0.05865
Multiple correlation coefficient	0.2788
Residual standard deviation	8.5646

Regression equation

Independent variables	**Coefficient**	**Std. error**	**t**	***p***	$r_{partial}$	$r_{semipartial}$
(Constant)	15.3613					
System A	3.9371	2.0940	1.880	0.0621	0.1543	0.1499
f_n	-0.3007	0.1399	-2.149	0.0333	-0.1757	0.1714
ζ	-12.1000	5.8118	-2.082	0.0391	-0.1704	0.1660
Variables not included in the model						
System D[a]						
Age						
BMI						
Vasopr						
System B						
System C						
HR						

[a] Excluded because of multicollinearity (VIF > 10^4).

Analysis of variance

Source	**DF**	**Sum of squares**	**Mean square**
Regression	3	896.4917	298.8306
Residual	145	10636.0989	73.3524
F-ratio	4.0739		
Significance level	$p = 0.0082$		

Residuals

Shapiro–Wilk test for normal distribution	**W = 0.9954 accept normality ($p = 0.9252$)**

Table SIII (continued)

Zero-order and simple correlation coefficients

Variable	**IABP-OscNIBP difference**	f_n	ζ
f_n	-0.1751		
ζ	-0.1293	-0.1241	
System A	0.1605	-0.1561	0.1121

BMI – body mass index, HR – heart rate, IABP intra-arterial blood pressure, OscNIBP – oscillometric non-invasive blood pressure measurement, US-NIBP– non-invasive blood pressure measurement by ultrasound, f_n – natural frequency, ζ – damping ratio

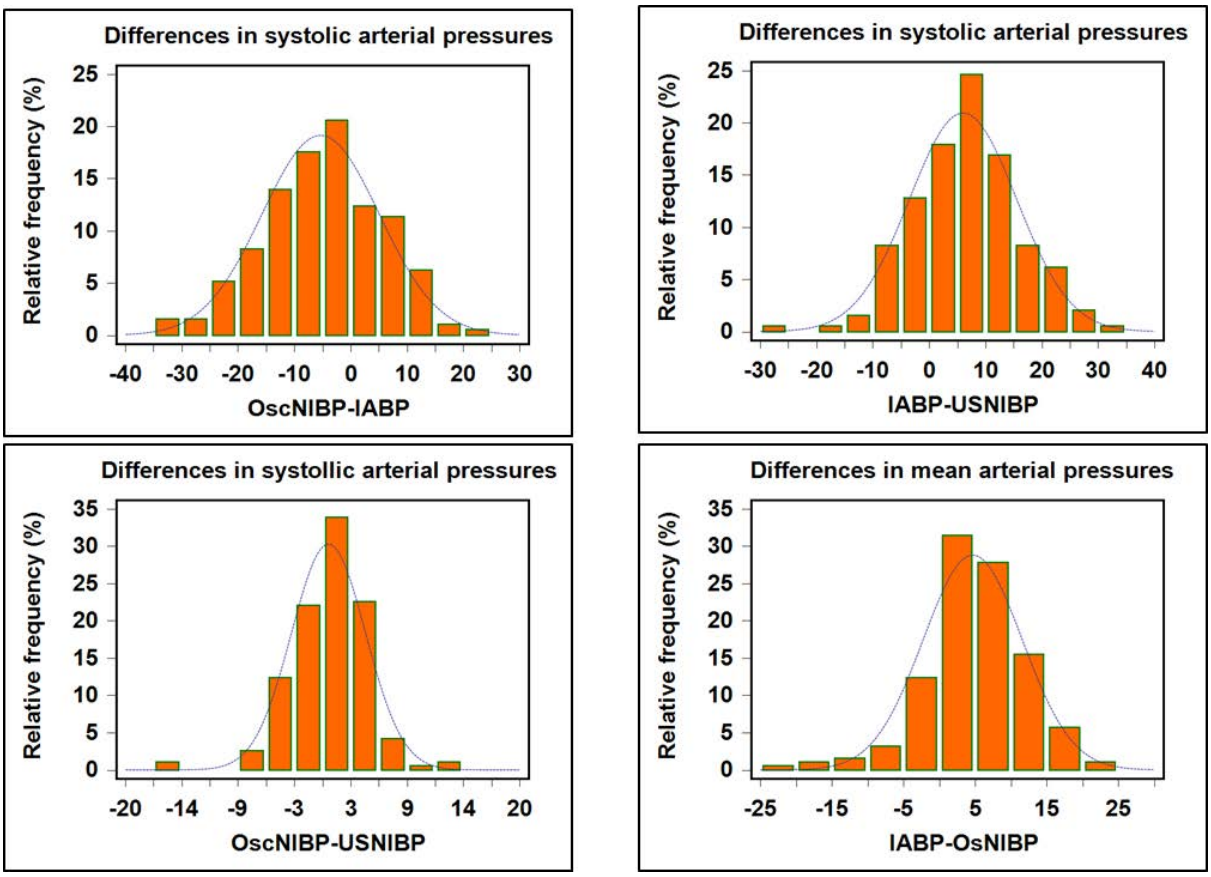


Figure S7: Histograms of the differences in pressure measurements

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2. Preiss D, Fisher J. A measure of confidence in Bland–Altman analysis for the interchangeability of two methods of measurement. J Clin Monit Comput. 2008;22(4):257-9. https://doi.org/10.1007/s10877-008-9127-y.
3. Krouwer JS, Monti KL. A simple, graphical method to evaluate laboratory assays. Eur J Clin Chem Clin Biochem. 1995;33(8):525-7.

Checklist for reporting Bland-Altman analyses[1]

	Checklist item	Compliance in manuscript
1	Pre-established acceptable limits of agreement	Set to 5 mmHg[2]
2	Description of the data structure (detailed description of who performed the measurements and how)	A detailed description thereof is in the methods section
3	Estimation of repeatability of measurements if possible (mean of differences between replicates and respective standard deviations)	Replicates of IABP were performed. A single investigator performed the measurements
4	Plot of the data and visual inspection for normality absence of trend and constant variance across the measurement range (e.g. histogram scatter plot)	Histograms of the differences indicated approximately normal distributions (figures in supplemental file). Scatterplots are depicted in the error grids. Trends are indicated by the slope of the linear regression equation of the differences (dependent variable) versus the mean of the measurements (independent variable) (Table 2)
5	Transformation of the data (e.g. ratio log) according to 4) if necessary	Not applicable as data were judged to be approximately normally distributed.
6	Plotting and numerically reporting the mean of the differences (bias)	Bland-Altman plots of differences vs. means of measurements in Figure 1) Results of the Bland-Altman analyses presented in Table 2.
7	Estimation of the precision i.e. standard deviation of the differences or 95% confidence interval for the mean difference	95% Confidence intervals of the means of the differences in Figure 1 and Table 2)
8	Plotting and numerically reporting the BA LoA	LoA are displayed In the Bland-Altman plots (Figure 1) and reported in Table 2)
9	Estimation of the precision of the BA LoA by means of 95% confidence intervals	95% CI's of the LoA are displayed in the BA plots (Figure 1) and reported in Table 2)
10	Indication of whether the measurement range is sufficiently wide (e.g. apply the Preiss-Fisher procedure[3]	Preiss–Fisher procedure appllied for each BA analysis. Results are reported in the Supplementary file
11	Between- and within-subject variance or stating that the confidence intervals of the BA LoA were derived by taking the data structure into account.	Medcalc® software calculates the 95% CI's of the LoA according to the method of Bland & Altman[4]
12	Software package or computing processes used	Bland-Altman Analysis: MedCalc® Statistical Software version 20.110 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2022) Preiss-Fisher procedure[3] https://docs.google.com/spreadsheets/d/1OZEXCD9SOd_0-ZX5jc976eOdgjKkDjoQ34WJhj2lsfs/edit#gid=0
13	Distributional assumptions made (e.g. normal istribution of the differences)	Normal distributions assumed
14	Sample size considerations	Described in the Methods section
15	Correct representation of the x-axis	Mean of the two measurements
16	Upfront declaration of conflicts of interest	There were no conflicts of interest

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1. Gerke O. Reporting Standards for a Bland-Altman Agreement Analysis: A Review of Methodological Reviews. Diagnostics (Basel) 2020;10(5):334.
2. Stergiou GS, Alpert B, Mieke S, Asmar R, Atkins N, Eckert S, et al. A universal standard for the validation of blood pressure measuring devices: Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement. J Hypertens 2018;36(3):472-8.
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Supplementary file 2

To access the Error Grid visit https://www.sajaa.co.za/index.php/sajaa/article/view/3105

Saugel and colleagues proposed error grid analysis as a method to estimate the clinical importance of differences between two methods of arterial blood pressure measurement, in addition to Bland-Altman analysis.[1] First applied to blood glucose and to haemogloblin measurements, error grid analysis involves creation of a scattergram whereby a "test" method is plotted against a reference method. Zones are defined that demarcate acceptable and unacceptable errors. At least 90% of the measurements should be included in the "acceptable" zone and none in the "unacceptable" zones. This spreadsheet enables the clinician to plot the two measurements on the error grid of Saugel et al. in order to evaluate the clinical importance of a difference in measurements.

The various zones are defined as follows:

*"**Zone A:** No risk (ie, no difference in clinical action between the reference and test method)*

***Zone B:** Low risk (ie, test method values that deviate from the reference but would probably lead to benign or no treatment)*

***Zone C:** Moderate risk (ie, test method values that deviate from the reference and would eventually lead to unnecessary treatment with moderate non–lifethreatening consequences for the patient)*

***Zone D:** Significant risk (ie, test method values that deviate from the reference and would lead to unnecessary treatment with severe non–life-threatening consequences for the patient)*

***Zone E.** Dangerous risk (ie, test method values that deviate from the reference and would lead to unnecessary treatment with life-threatening consequences for the patient)."*

Saugel et al. suggest that for clinically acceptable agreement between a "test" method and a "reference" method of blood pressure measurement, the proportions of the paired measurements within the various zones of the scattergram, should be 90%, 5%, 4%, 2% and 0% for zones A, B, C, D, and E respectfully.

JF Coetzee

November 2022

Reference:

1. Saugel B, Grothe O, Nicklas JY. Error grid analysis for arterial pressure method comparison studies. Anesthesia & Analgesia. 2018 Apr 1;126(4):1177-85.