Comparing oscillometric non-invasive and invasive intra-arterial blood pressure monitoring in term neonates under general anesthesia: A retrospective study

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Short running title: Blood pressure monitoring in neonates

a. What is already known about the topic

In adults, children, and infants, an acceptable correlation between oscillometric non-invasive and invasive intra-arterial blood pressure monitoring was confirmed within the normal range of blood pressure, but during hypotension and hypertension, the discrepancy between the two methods increases.

b. What new information this study adds

In term neonates, the mean blood pressure may be acceptable as an indicator for intraoperative hemodynamics rather than systolic or diastolic blood pressures. However, there was a large discrepancy in blood pressure measurements between the two methods during hypotension or hypertension.

Abstract

Background: Oscillometric non-invasive blood pressure and/or invasive intra-arterial blood pressure are commonly used to measure the systolic, diastolic, and mean components of blood pressure. Agreement between the two methods has been reported in adults, children, and infants, but rarely in neonates, especially under general anesthesia.

Aims: This retrospective study compared the agreement of each measured blood pressure value (oscillometric non-invasive or invasive intra-arterial blood pressure monitoring) in term neonates under general anesthesia.

Methods: Data were collected from neonates born at ≥36 weeks of gestation whose body weight was ≥2,500 g and who underwent abdominal or non-cardiac thoracic surgery with both oscillometric non-invasive and invasive intra-arterial blood pressure measurements from January 2015 to March 2020. The primary outcome was the agreement of systolic, diastolic, and mean blood pressure values between the two methods using Bland-Altman analysis.

Results: Paired blood pressure measurements (n=1193) from 67 cases were compared. In Bland-Altman analysis, bias (standard deviation), 95% limits of agreement, and percentage error were -9.3 (8.4), -26.1-7.6, and 26.9% for systolic; 1.6 (6.5), -11.3-14.6, and 38.7% for diastolic; and -1.3 (5.8), -13.0-10.3, and 26.9% for mean blood pressure, respectively. During low blood pressure (intra-arterial mean blood pressure ≤30 mmHg), the biases (standard deviation) of systolic, diastolic, and mean blood pressure were -11.4 (5.7), -0.7 (3.7), and -5.1 (4.2), whereas during high blood pressure (intra-arterial mean blood pressure ≥60 mmHg), the values were 0.1 (9.7), 5.6 (9.4), and 6.4 (7.4), respectively.

Conclusions: Based on the bias and percentage error, the mean blood pressure exhibited the most acceptable agreement between oscillometric non-invasive and invasive intra-arterial blood pressure monitoring in term neonates under general anesthesia. However, during hypertension or hypotension, there was a large discrepancy between the two methods.

Keywords: arterial blood pressure; hemodynamics; intraoperative care; neonate; oscillometric non-invasive blood pressure

Introduction

Blood pressure (BP) is an important factor to evaluate hemodynamics. BP values are characterized by systolic, diastolic, and mean components. Oscillometric non-invasive BP monitoring is the standard monitoring modality used in clinical settings.[1] In critically ill patients or during high-risk surgery, most anesthesiologists use invasive intra-arterial BP monitoring, which provides beat-to-beat information and allows easy arterial blood sampling. Intra-arterial BP measurement is considered the “gold standard” for BP monitoring.[2] However, the chosen values and methods used to assess hemodynamics depend on the individual anesthesiologist. Agreement between the two BP measurement methods has been reported in adults,[3-4] children,[5] and infants,[6] but rarely in neonates, especially under general anesthesia. Studies have demonstrated that an acceptable correlation between both methods has been confirmed within the normal BP range; however, during hypotension and hypertension, the discrepancy between the two methods increases.[3-5] We predicted that there would be similar findings in term neonates under general anesthesia. Therefore, this retrospective study assessed the agreement of each intraoperative BP measurement value, comparing the oscillometric non-invasive and invasive intra-arterial methods.

Methods

Study Design and Patients

This study was a single-center, retrospective study approved by the Nagoya University Hospital Ethics Committee (ref: 2019–0325). Information and an opt-out document for this observational study were available on our institution’s website. Written informed consent was not obtained due to the opt-out option provided during recruitment. The study included all neonatal patients who underwent abdominal or non-cardiac thoracic surgery from January 2015 to March 2020 and had both oscillometric non-invasive and invasive intra-arterial BP measurements. Patients with an American Society of Anesthesiologists physical status (ASA-PS) ≥4 or body weight <2,500 g, or those who were born preterm (<36 weeks gestational age) were excluded. Based on these criteria, 67 neonatal patients were identified.

Test Methods and Measurement

All BP measurements were automatically recorded in the anesthesia information management system (AIMS) (Life Scope TR BSM-9100 [Nihon Kohden, Tokyo, Japan], between 2015 and 2017; and IntelliVue MX800 [Philips, Andover, MA], between 2018 and 2020). For invasive intra-arterial BP, an intra-arterial line (Surflo I.V. catheter, 24G, 0.7 × 19.0 mm; Terumo Corporation, Tokyo, Japan) was inserted in the radial or dorsalis pedis artery, and the transducer (TruWave Disposable Pressure Transducer; Edwards Lifesciences, Irvine, CA) was usually placed at the mid-chest level. The intra-arterial BP measurement was recorded every 30 seconds in the AIMS. In contrast, the oscillometric non-invasive BP cuff (Neonatal Single-Patient NIBP Cuffs; Philips, Andover, MA) was placed on the upper arm or lower leg, and the cuff size was chosen according to the manufacturer’s recommendation. Non-invasive BP measurement intervals depended on the individual anesthesiologist. All data, including age, height, weight, sex, and ASA-PS, as well as intraoperative vital data (i.e. oscillometric non-invasive BP measurement, intra-arterial BP measurement, and heartrate) were acquired through the AIMS as a digital numerical value. The data were paired; in each method, the systolic, diastolic, and mean BP measurements were retrospectively collected for the same time point. Paired BP values which showed low pulse pressure (≤5 mmHg) or extreme values (i.e. 0 or 300) were excluded as they likely indicated damped values.

Outcome Measurements

The agreement of each paired BP value between the two methods (oscillometric non-invasive and invasive intra-arterial BP monitoring) was the primary outcome. The secondary outcome was the agreement of each value assessed during periods of high or low BP. Low BP was defined as an intra-arterial mean BP ≤30 mmHg,[6-7] and high BP was defined as an intra-arterial mean BP ≥60 mmHg. In addition, we assessed the tracking ability of each BP value (within two minutes) between both methods as the concordance rate.

Statistical Analyses

Baseline characteristics of the neonatal patients were compared using a Student's t-test, Mann-Whitney U test, or Fisher's exact test. Continuous data are expressed as the mean (standard deviation [SD]) or median (interquartile range [IQR] {range}), and categorical data as numbers (proportion, %). P<0.05 was considered statistically significant. As the primary outcome, the agreement of each paired BP value was evaluated using Bland-Altman analysis. This method provides the bias, percentage error ([2 SD of the bias]/[mean of the reference method]), and 95% limits of agreement.[8-9] A percentage error <±30% was the criterion for the acceptability of precision.[10] For the secondary outcome, the tracking ability was evaluated for both methods using four-quadrant plot analysis and presented as the concordance rate, which assesses the difference between consecutively obtained monitoring values for both the studied and reference technologies. The concordance rate was defined as the percentage of data points (obtained within two minutes) in the upper right or lower left quadrant of the four-quadrant plot.[11] As described in a previous BP monitoring study, we defined the exclusion zone as an area with <5 mmHg.[12] All statistical analyses were performed using R software version 3.5.1 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

The systolic, diastolic, and mean components of BP measurements from 1193 points in 67 cases were compared. Patient characteristics and BP data are summarized in Table 1. In Bland-Altman analyses, the bias (SD) and 95% limits of agreement were -9.3 (8.4) and -26.1-7.6 for systolic, 1.6 (6.5) and -11.3-14.6 for diastolic, and -1.3 (5.8) and -13.0-10.3 for mean BP, respectively. The percentage error was 26.9%, 38.7%, and 26.4% for systolic, diastolic, and mean BP, respectively (Table 2, Figure 1). During low BP (intra-arterial mean BP ≤30 mmHg, n=94), the biases (SD) of systolic, diastolic, and mean BP were -11.4 (5.7), -0.7 (3.7), and -5.1 (4.2), respectively; whereas during high BP (intra-arterial mean BP ≥60 mmHg, n=62), the values were 0.1 (9.7), 5.6 (9.4), and 6.4 (7.4), respectively (Table 2). In terms of the tracking ability determined by the four-quadrant plot analysis (n=143), the concordance rate was 87.1%, 74.2%, and 78.9% for systolic, diastolic, and mean BP, respectively (Figure 2).

Discussion

This observational study showed a lower bias and percentage error of the mean BP compared to systolic and diastolic BP. Therefore, mean BP measurement may be acceptable for intraoperative term neonatal hemodynamic management rather than systolic or diastolic BP. However, there was a large discrepancy in the mean BP measurement between oscillometric non-invasive and invasive intra-arterial monitoring methods when the BP was either high or low.

In our study, Bland-Altman analysis demonstrated that the agreement of mean BP between the oscillometric non-invasive and invasive intra-arterial methods was acceptable (percentage error <30%), and the absolute value of bias of the mean BP between the two methods was similar during high or low BP. Although the agreement of the systolic BP measurement was acceptable (percentage error <30%), there was a large bias between the two methods (except high BP). In contrast, although the diastolic BP had a small bias (especially during low BP), the percentage error was large (>30%).

During hypotension, the oscillometric non-invasive BP was higher than the invasive intra-arterial BP in each BP component. In contrast, during hypertension, the non-invasive BP was lower than the invasive intra-arterial BP. A discrepancy between BP measurements using the two methods leads to confusion and makes clinical decisions difficult. If invasive intra-arterial BP is the standard reference, the oscillometric non-invasive BP overestimates the BP during low BP. This is a serious weakness of oscillometric non-invasive BP. Referring only to oscillometric non-invasive BP for intraoperative hemodynamic management may cause a delay in intervention. Perioperative BP management affects various clinical prognosis parameters such as mortality, acute kidney injury, and myocardial injury in adults,[13] and encephalopathy in infants.[14] Therefore, according to our findings, we recommend that intra-arterial mean BP be used for intraoperative hemodynamic management, especially in neonatal patients with lower BP. In neonates, however, there is no clear definition of hypotension.[15] Therefore, the lack of a threshold for low BP delays intervention and may affect clinical outcomes. Further studies are needed to assess the thresholds for low BP that affect clinical outcomes with different references.

Wax et al. compared intraoperative oscillometric non-invasive and invasive intra-arterial BP measurements in adults and showed that non-invasive BP measurements tended to be higher than the intra-arterial BP measurements in patients with low BP, but lower than the intra-arterial BP measurements in patients with high BP.[3] Similarly, Agnes et al. compared oscillometric non-invasive BP with invasive intra-arterial BP in children with a median (IQR) age of 6 (5-11) months and demonstrated that non-invasive BP measurements were higher than the intra-arterial BP measurements during hypotension (mean intra-arterial BP ≤45 mmHg), while the bias (SD) of the systolic and mean BP were -13 (9) and -9 (5) mmHg, respectively.[4] Our study showed similar findings in term neonates.

Our study has several limitations. First, this study was a retrospective observational study. Each paired data were collected in different clinical situations, such as different positioning of the oscillometric non-invasive BP cuff or intra-arterial line, and more particularly, differences in the upper and lower limb and left and right BPs were not considered. Although further prospective trials are required to validate our findings, they may be applicable to the real-world population of term neonates in actual clinical settings. Second, data were collected from the AIMS of each patient who underwent abdominal or non-cardiac thoracic surgery at a single center, and thus, the sample size was too small to effectively compare the agreement between the two BP measurements. Therefore, the generalizability and bias of these findings remain debatable. Further studies with large sample sizes and multicenter trials in varying clinical situations are needed. Third, two measurement methods may indicate clinically relevant differences between actual and displayed pressure values, especially due to arterial waveform artifacts (e.g., underdamping and resonance phenomena). The oscillometric non-invasive BP cuff size and position also affect accuracy. In this study, the possibility of artifacts in BP measurements cannot be ruled out. However, we speculate that the mean BP is preferred over systolic BP because it may be less subject to error from damping.[16] Fourth, Bland-Altman and four-quadrant plot analyses were used to compare the agreement of both BP monitoring methods. Their criterion for the acceptability of precision (e.g. percentage error <30%) was mainly for cardiac output measurements, not for BP measurements. Thus, the optimal statistical method for comparing the agreement of BP monitoring methods has not been clarified. Finally, our neonatal data were collected during the first 28 days of life. Hemodynamics, such as BP, may differ between the time immediately after birth and 28 days of life. BP in neonates varies with gestational age and birth weight.[17] Hence, it is difficult to define normal BP and hypotension/hypertension in this population. Therefore, it is necessary to increase the sample size and analyze the agreement of the two BP measurements in various subgroups.

In conclusion, the mean BP, rather than systolic or diastolic BP, may be acceptable as an indicator for intraoperative term neonatal hemodynamics. However, there was a large discrepancy in BP measurements between the two methods during hypotension or hypertension. Further studies are needed to determine the appropriate BP measurement method during hypotension or hypertension.

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Conflict of interest

The authors declare no conflict of interest.

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and full-term neonates. *Pediatr Nephrol.* 2007;22:249-257.

Tables

Table 1

Patient characteristics and neonatal blood pressure data

Characteristic	Value
Age; days	2 (1-13 [0-27])
Sex; female	22 (33%)
Height; cm	49.0 (2.3)
Weight; kg	2.96 (0.4)
Surgical procedures	
Abdominal surgery	48 (72%)
Thoracic surgery	19 (28%)
Operation time; min	129 (97.5-180 [20-424])
Non-invasive SBP; mmHg	62.6 (11.4)
Non-invasive DBP; mmHg	33.6 (9.5)
Non-invasive mean BP; mmHg	44.2 (9.1)
Invasive intra-arterial SBP; mmHg	53.4 (11.4)
Invasive intra-arterial DBP; mmHg	35.2 (8.7)
Invasive intra-arterial mean BP; mmHg	42.8 (9.8)

Values are presented as the mean (standard deviation), median (interquartile range [range]), or number (proportion, %) of patients. BP, blood pressure; DBP diastolic blood pressure; SBP, systolic blood pressure.

Table 2

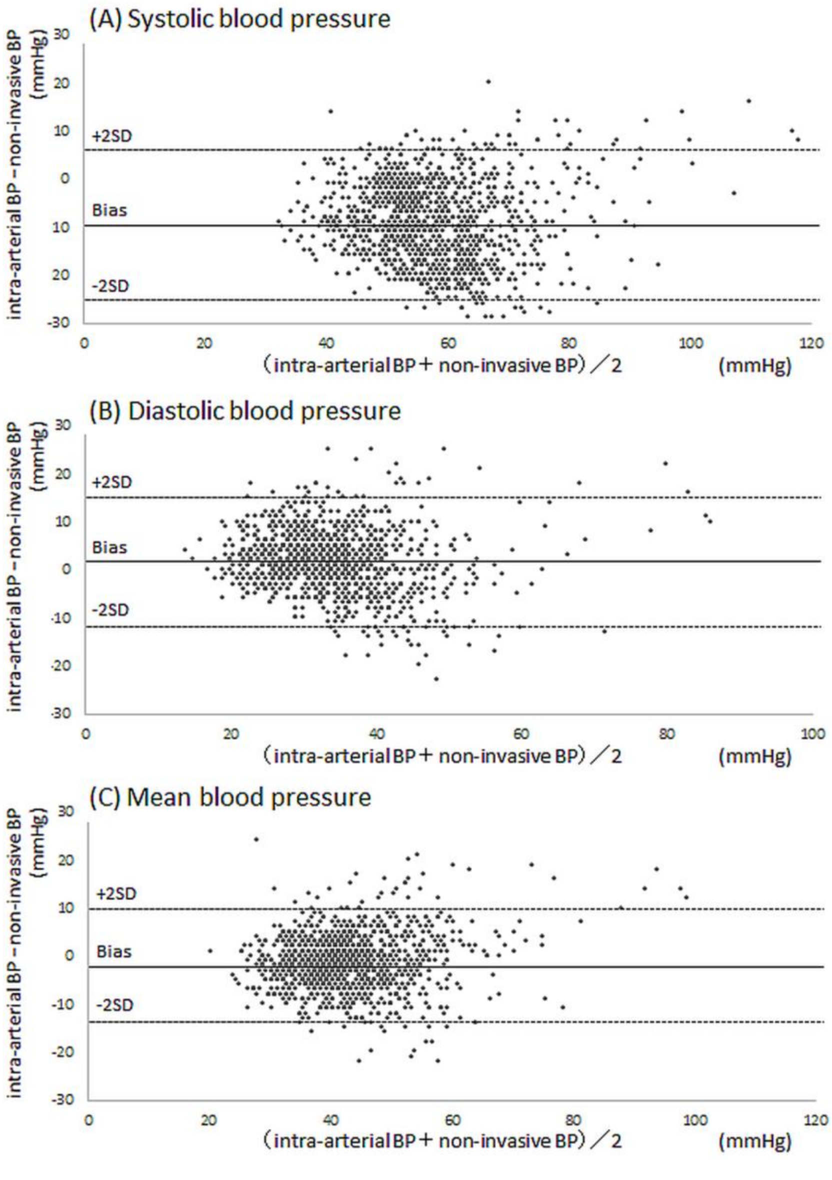
Agreement of blood pressure values between oscillometric non-invasive and invasive intra-arterial blood pressures

All data (n=1193)				
	Bias	SD	Percentage error	Correlation coefficient
Systolic	-9.3	8.4	26.9%	0.73
Diastolic	1.6	6.5	38.7%	0.75
Mean	-1.3	5.8	26.4%	0.81
Lower intra-arterial BP (intra-arterial mean BP ≤30 mmHg) (n=94)				
Systolic	-11.1	5.6	24.2%	0.36
Diastolic	-0.7	3.7	31.6%	0.53
Mean	-5.1	4.2	25.4%	0.43
Higher intra-arterial BP (intra-arterial mean BP ≥60 mmHg) (n=62)				
Systolic	0.1	9.7	23.3%	0.69
Diastolic	5.6	9.4	36.3%	0.71
Mean	6.4	7.4	23.5%	0.80

BP, blood pressure; SD, standard deviation.

Figure 1

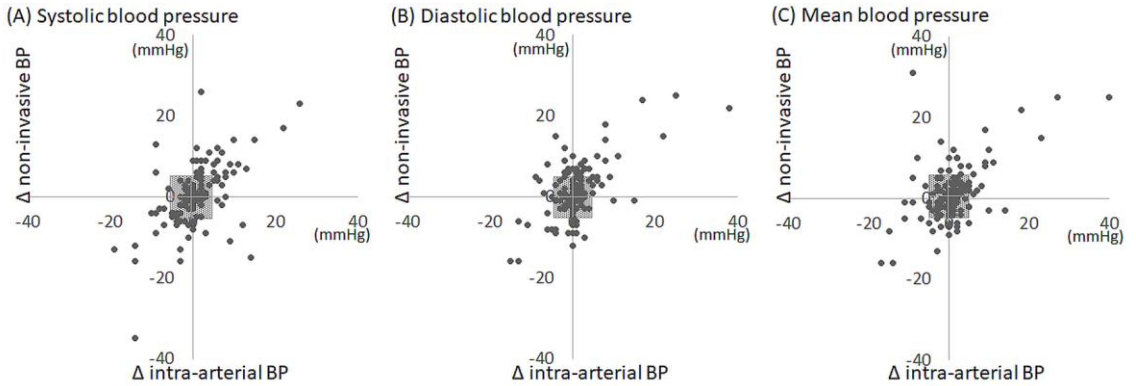
Bland-Altman analysis assessing the reliability of both the oscillometric non-invasive and invasive intra-arterial blood pressure measurement methods.



Bland-Altman analysis shows the mean bias (bold line) and 95% limits of agreement (dashed line). (A) Systolic, (B) diastolic, and (C) mean blood pressure. BP, blood pressure; SD, standard deviation.

Figure 2

Four-quadrant plot analysis for the tracking ability of two blood pressure monitoring methods.



Black points show the change of each paired blood pressure within two minutes (Δ intra-arterial BP: tracks the change of intra-arterial blood pressure; Δ non-invasive BP: tracks the change of non-invasive blood pressure). The exclusion zone is ≤5 mmHg. (A) Systolic, (B) diastolic, and (C) mean blood pressure. BP, blood pressure.