Noninvasive Blood Pressure Measurement Using the NICCI Monitor in Adolescents During Intraoperative Anesthetic Care

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Abstract

Background: The intermittent measurement of blood pressure (BP) remains the standard of care during anesthesia or procedural sedation. To improve the early identification of hemodynamic compromise, various noninvasive BP devices have been developed which provide a continuous BP reading. The current study evaluates the accuracy of a novel continuous BP device, the NICCI system, in adolescents weighing 40 - 80 kg.

Methods: During intraoperative anesthetic care, BP readings (systolic, diastolic, and mean) were captured from the arterial cannula and the NICCI device every second.

Results: The study cohort included 44 pediatric patients undergoing major orthopedic, cardiac, and neurosurgical procedures. A total of 383,126 pairs of systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) values from the arterial cannula and the NICCI device were analyzed. The absolute difference for SBP, DBP, and MAP values from the NICCI monitor and the arterial cannula were 10 ± 8, 9 ± 7, and 9 ± 7 mm Hg, respectively. The difference between the BP values from the NICCI and the arterial cannula was ≤ 10 mm Hg for 60% of the SBP readings, 67% of the DBP readings, and 56% of the MAP readings. Using Bland-Altman analysis, the bias was 2, 3, and 4 mm Hg for the SBP, DBP, and MAP.

Conclusions: Although there were technical limitations related to patient size that affected its ability to meet the strict accuracy criteria set by the American National Standards Institute/Association for the Advancement of Medical Instrumentation standards for noninvasive BP measurement (ANSI/AAMI SP10), the NICCI system provided a continuous noninvasive beat-to-beat BP measurement which was clinically relevant during a significant portion of intraoperative care.

Keywords: Continuous blood pressure monitoring; Invasive arterial pressure; Intraoperative monitoring; Pediatrics anesthesiology

Introduction

During anesthetic care, the standard of care mandates that blood pressure (BP) is measured either intermittently using an oscillometric noninvasive blood pressure monitoring (NIBP) device or continuously from an invasive intra-arterial cannula (AC). Evidence suggests that continuous BP monitoring is superior to intermittent NIBP monitoring and may improve outcomes, especially when caring for patients with severe comorbid conditions or during major surgical procedures where blood loss and hemodynamic compromise are expected [1]. It has been estimated that oscillometric NIBP devices, which may provide BP measurements every 3 - 5 min, miss up to 20% of hypotensive episodes, while an additional 20% of these episodes are only detected after a delay [2, 3]. Given the impact of hypotension on end-organ perfusion and postoperative outcomes, inaccuracies in BP readings may increase perioperative morbidity and mortality [3, 4]. Direct arterial cannulation and placement of an AC provide continuous beat-to-beat BP readings, thereby immediately demonstrating BP changes throughout the surgical procedure. However, placement of an AC may be associated with adverse effects, including bleeding, thrombophlebitis, thrombosis, embolism, ischemia, catheter-associated infection, pseudoaneurysm or fistula formation, and nerve injury [5-8].

To address and mitigate these concerns, recent advancements in monitoring technology have led to the development of noninvasive devices that provide continuous beat-to-beat BP readings with a display that resembles that seen with direct arterial cannulation. One such novel device is the NICCI BP device (Getinge/Pulsion Medical Systems, Feldkirchen, Germany) which uses infrared technology to measure BP continuously and display it in a waveform. This observational, single-center study prospectively compared systolic, diastolic, and mean arterial pressure readings from the AC with values

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Figure 1. The NICCI device with the calibrating noninvasive blood pressure cuff and finger cuffs in place. The inflation of the two finger cuffs is alternated to avoid pressure injury. The external pressure required to maintain blood flow within the fingers is measured using infrared technology which is converted into a continuous waveform on the monitor.

obtained from the NICCI noninvasive continuous BP monitor during intraoperative care in adolescent patients weighing 40 - 80 kg.

Materials and Methods

The study was approved by the Institutional Review Board of Nationwide Children's Hospital (Columbus, OH, USA), registered at Clinicaltrials.gov (NCT04373746) and was conducted in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration. After obtaining written informed consent from a parent or guardian and assent from patients ≥ 9 years of age, we enrolled patients weighing 40 - 80 kg undergoing various elective orthopedic, neurological, and cardiac surgeries requiring the placement of an AC. Patients with a history of peripheral neurologic disorders, vascular implants at the sites of NIBP measurement, patients in whom an AC could not be placed, and patients with pre-existing edema of the upper extremities were excluded.

The attending pediatric anesthesiologist determined the anesthetic induction and maintenance techniques based on the surgical procedure and the patient's status. After the induction of anesthesia, an AC was placed in the radial artery. After positioning for the surgical procedure, the NICCI sensor device was attached to the patient, with the calibrating NIBP cuff and finger cuff placed on the side opposite the radial AC (Fig. 1). The suitable size of the finger cuff was chosen according to the finger diameter. The NICCI monitor set-up and subsequent use followed the manufacturer recommendations, with a calibration time of every 30 min. The site of BP monitoring was at the level of the heart. BP readings, including systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were captured onto a laptop from the NICCI device and the AC for subsequent analysis. Data were down-

loaded from the laptop via ixTrend software to a standard Excel spreadsheet following the surgery. Data were subsequently manually reviewed, and incomplete and erroneous values such as those recorded during blood draw from the AC, AC transducer calibration, and periodic NICCI device calibration were excluded from the analysis.

Statistical analysis

The absolute difference of the SBP, DBP, and MAP values from the AC and NICCI device were calculated. Instead of the directional difference (positive or negative), the absolute difference was used to avoid affecting the data when calculating the mean and standard deviation (SD) of the differences. For instance, if the reading from the NICCI device was 5 mm Hg above or below the reading from the AC, a value of 5 mm Hg was used and not -5 mm Hg or +5 mm Hg. We also calculated the percentage of BP values from the NICCI device that were ≤ 5 mm Hg, ≤ 10 mm Hg, and > 10 mm Hg from the values obtained from the AC. Pearson's correlation coefficient was used to compare the SBP, DBP, and MAP values between the NICCI device and the AC values. Finally, Bland-Altman plots for repeated measures were used to determine the bias, precision, and 95% level of agreement between the values from the NICCI device and AC. Per standard statistical analysis practice, the actual value (-5 mm Hg or +5 mm Hg) was used to calculate the Bland-Altman analysis and develop a scatterplot of the difference between BP readings from the NICCI device and the AC. The NICCI minus the AC value was plotted on the vertical (y) axis against the average of the two BP readings (NICCI device and AC) on the horizontal (x) axis. Horizontal lines were drawn at the mean difference (blue line) and the 95% limits of agreement (mean difference ± 1.96 × SD) on either side of the mean difference line (red lines). All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) software for Windows, version 26.0. Armonk, New York, IBM Corporation.

Results

A total of 50 patients were enrolled in the study, but data from six patients were excluded from the analysis due to a downloading error or defective signal acquisition from the NICCI monitor, which interfered with recording of systolic or diastolic BP readings onto the laptop device. Data from a total of 44 patients (23 females and 21 males) were included in the final analysis. The demographic and clinical characteristics of the study cohort are summarized in Table 1. The mean (SD) age was 15 (2) years, mean (SD) weight was 56 (10) kg, and mean height was 162 (9) cm. Of the 44 patients, 40 were in the prone position, three in the supine position, and one in the lateral position. In all cases, the NICCI finger cuff sensor was placed on the opposite side of the AC. We analyzed a total of 383,126 pairs of SBP, DBP, and MAP values from the NICCI device and the AC. Table 2 summarizes the absolute difference, percentage of values that were ≤ 5 mm Hg, ≤ 10 mm Hg,

Table 1. Demographic and Clinical Characteristics of the Study Cohort

Patient and surgical characteristics	Data
Gender (female/male)	23/21
Age (years)	15 ± 2
Weight (kg)	56 ± 10
Height (cm)	162 ± 9
BMI (kg/m^2)	22 ± 4
Type of procedure	
Orthopedic	40
Cardiothoracic	2
Neurosurgical	2
Patient position	
Prone	40
Supine	3
Lateral	1
ASA Physical Classification	
I	8
II	22
III	13
IV	1

Data are presented as n (%), mean ± SD. SD: standard deviation; ASA: American Society of Anesthesiology; BMI: body mass index.

and more than more than 10 mm Hg from the actual BP value from the AC, and the correlation coefficients between the values. The difference between the BP values from the NICCI device and the AC was ≤ 5 mm Hg for 35% of the SBP readings, 39% of the DBP readings, and 31% of the MAP readings. The difference was ≤ 10 mm Hg for 60% of SBP readings, 67% of the DBP readings, and 56% of the MAP. Further, the difference was > 10 mm Hg for 40% of SBP readings, 33% DBP readings, and 44% of MAP. Pearson's correlation coefficient comparing the values obtained from the NICCI device with those from the AC showed a strong correlation for all BP readings including 0.60 for SBP, 0.55 for DBP, and 0.59 for MAP. Comparison of blood pressure readings from the AC and the NICCI monitor based on weight is summarized in Table 3. Table 4 summarizes the values for SBP less than or equal to 70

mm Hg versus greater than 70 mm Hg, and MAP less than or equal to 50 mm Hg versus greater than 50 mm Hg for both the AC and NICCI monitor. Table 5 and Figures 2 - 4 display the Bland-Altman analysis with the bias, precision, and 95% limits of agreement between the NICCI device and values from the AC for SBP, DBP, and MAP. The bias and precision were 2 and 13 mm Hg for SBP, 3 and 11 mm Hg for DBP, and 4 and 12 mm Hg for MAP.

Discussion

We investigated the accuracy and agreement between BP readings from the NICCI device and values obtained from a standard AC in adolescents weighing 40 - 80 kg, who were undergoing various inpatient orthopedic, cardiac, and neurological surgical procedures. To our knowledge, this study is the first to evaluate the performance of the NICCI monitor in the pediatric population. Although there were technical limitations that may have impacted accuracy, the NICCI system provided a continuous noninvasive BP reading within clinically useful parameters, defined as BP readings ≤ 10 mm Hg from the values obtained from the AC, approximately 60% of the time during intraoperative care. The NICCI technology is based on the Continuous Noninvasive Arterial Pressure (CNAP™, CN-Systems, Graz, Austria) technology, which was introduced to the market in 2006 [9, 10]. The NICCI device used for this study is a CE version with an investigational device exemption and is not currently available for commercial sale. Various modifications of the NICCI device have included an improved hardware design to facilitate the initial set-up and decrease application time. For example, the design of the novel hand device simulates the design of a standard computer mouse, thereby allowing easier application of the finger cuffs than the previously used wrist mount and double finger cuff system of the CNAP™ monitor. In imitation of the CNAP™ system, the NICCI device uses vascular unloading (volume clamping) technology to provide a continuous beat-to-beat noninvasive measurement of the BP and displays it as a continuous waveform [11, 12]. The absorption of infrared light that is shined through a finger is used to estimate the arterial volume within the vascular bed of the digit. The external pressure in the finger cuff is rapidly adjusted such that the arterial volume is "clamped" or maintained constant throughout the pressure-pulse cycle. Consequently, the cuff pressure waveform closely approximates the intra-arterial pressure waveform measured

Table 2. Comparison of Blood Pressure Readings From the AC and the NICCI Monitor

Parameter	Difference between AC and NICCI	Percentage of NICCI readings ≤ 5 mm Hg from AC value	Percentage of NICCI readings ≤ 10 mm Hg from AC value	Percentage of NICCI readings > 10 mm Hg from AC value	Correlation coefficient
SBP	10 ± 8	35%	60%	40%	0.60*
DBP	9 ± 7	39%	67%	33%	0.55*
MAP	9 ± 7	31%	56%	44%	0.59*

Data are displayed in mm Hg as the mean ± SD of absolute values or as percentages. Values are compared to those obtained from the AC. *Correlation is significant with a P value ≤ 0.01 (two-tailed). SD: standard deviation; SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure; AC: arterial cannula.

Table 3. Comparison of Blood Pressure Readings From the AC and the NICCI Monitor Based on Weight

Parameter	Difference between AC and NICCI	Percentage of NICCI readings ≤ 5 mm Hg from AC value	Percentage of NICCI readings ≤ 10 mm Hg from AC value	Percentage of NICCI readings > 10 mm Hg from AC value	Correlation coefficient
Patients weighing 40 - 60 kg					
SBP	10 ± 9	34%	60%	40%	0.70*
DBP	9 ± 8	39%	66%	34%	0.68*
MAP	9 ± 8	35%	63%	37%	0.81*
Patients weighing 60 - 80 kg					
SBP	10 ± 9	37%	62%	38%	0.64*
DBP	9 ± 8	41%	69%	31%	0.67*
MAP	8 ± 7	41%	70%	30%	0.56*

Data are displayed in mm Hg as the mean ± SD of absolute values or as percentages. Values are compared to those obtained from the AC. *Correlation is significant with a P value ≤ 0.01 (two-tailed). SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure; AC: arterial cannula.

Table 4. Comparison of SBP and MAP Readings From the AC and NICCI Monitor

Parameter	SBP ≤ 70 mm Hg		SBP > 70 mm Hg		MAP ≤ 50 mm Hg		MAP > 50 mm Hg	
	Percent of values	Mean ± SD	Percent of values	Mean ± SD	Percent of values	Mean ± SD	Percent of values	Mean ± SD
AC	3%	62 ± 6	97%	93 ± 12	2.3%	48 ± 3	97.7%	66 ± 8
NICCI	7%	62 ± 7	93%	97 ± 13	5.5%	45 ± 5	94.5%	72 ± 11

Data are displayed in mm Hg as the mean ± SD of absolute values or as percentages. Values are compared to those obtained from the AC. SD: standard deviation; SBP: systolic blood pressure; MAP: mean arterial pressure; AC: arterial cannula.

by a noninvasive BP cuff at the arm. The degree of external pressure required to maintain the intra-arterial volume constant is compared to the noninvasive BP measurement at the arm (brachial artery) and is converted to a beat-to-beat BP waveform displayed on the bedside monitor. Per the Penaz principle, photoplethysmography and closed-loop control of a pneumatic cuff are used to continuously adjust the cuff pressure to track the arterial pressure [13].

The NICCI device uses two-finger cuffs that are available in three different sizes (small, medium, large) with infrared light sensors to measure the counter-pressure required to maintain a stable blood flow and constant intra-arterial volume. The cuffs are placed on the second and third digits and can fit fingers varying in diameter from 13 to 28 mm. Inflation of the two cuffs is alternated to allow continued use of the

device while limiting the risk of potential ischemic injury from continuous inflation. Besides continuous BP monitoring, the NICCI monitor can be programmed to measure or calculate other hemodynamic parameters, including pulse rate, cardiac index, stroke volume index, stroke volume variation, pulse pressure variation, systemic vascular resistance, and cardiac power index.

Previous studies have demonstrated a clinically useful correlation of BP readings from the CNAP™ system in adult and pediatric patients in various clinical scenarios, including intraoperative care [3, 8-10, 14-16]. In the current study of patients weighing 40 - 80 kg, the NICCI device provided continuous noninvasive beat-to-beat BP measurements which were within clinically useful limits of values obtained from an AC during a significant portion of the intraoperative anesthetic care. However, the American National Standards Institute/Association for the Advancement of Medical Instrumentation standards for noninvasive BP measurement (ANSI/AAMI SP10) states that a clinically acceptable agreement is met by a mean difference (bias) of ± 5 mm Hg and a SD of 8 mm Hg [17]. Although the data for the current cohort of patients met these criteria for the bias for SBP, DBP, and MAP readings, the SD was well outside the recommended range.

Although the NICCI monitor functioned efficiently throughout the study, we would postulate that several factors may impact the device's accuracy (especially the ranges or precision noted) and explain why the BP readings did not meet the strict accuracy criteria. Most importantly, for the pur-
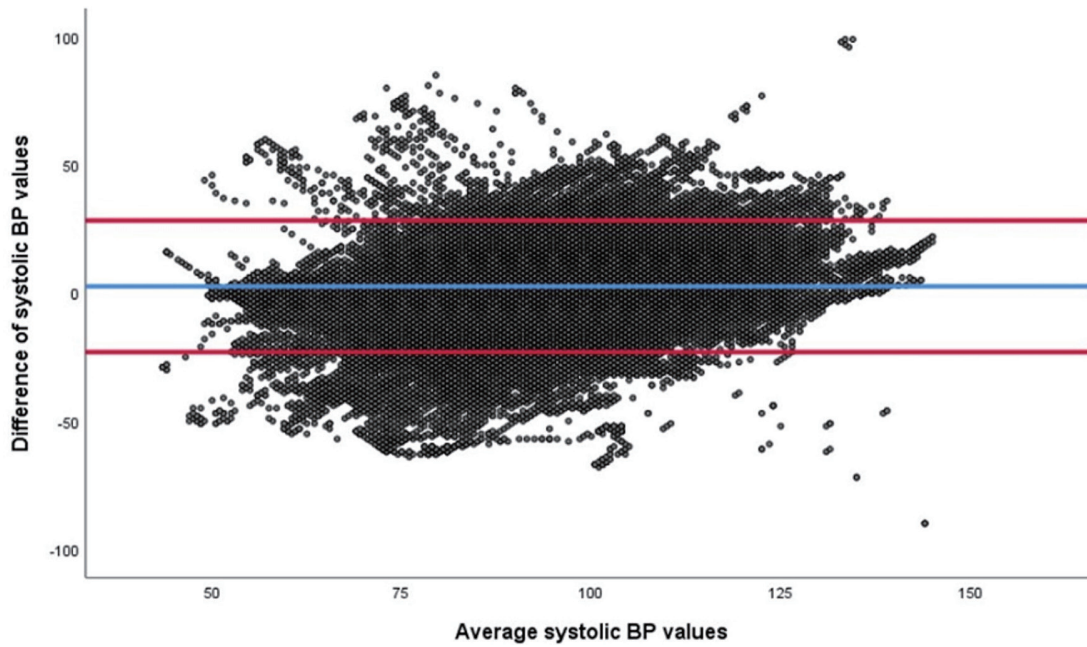
Table 5. Bland-Altman Analysis Comparing Blood Pressure Readings From the AC and NICCI Monitor

Parameter	Bias	Precision	95% level of agreement
SBP	2	13	-23 to +31
DBP	3	11	-19 to +26
MAP	4	12	-16 to +25

Data are presented in mm Hg rounded to the nearest whole integer. Values are compared to those obtained from an AC. SBP: systolic blood pressure; DBP: diastolic blood pressure; MAP: mean arterial pressure; AC: arterial cannula.

Figure 2. Bland-Altman analysis of the systolic blood pressure (SBP) from the arterial cannula (AC) and the NICCI device, both in mm Hg. The difference between the values (NICCI and AC) are plotted on the vertical axis and the average of the two values on the horizontal access. The red lines demonstrate the 95% limits of agreement (-23 to +31 mm Hg), and the blue line corresponds to the bias (2 mm Hg). BP: blood pressure.

poses of the study, the AC was considered the gold standard and the correct measure of BP. Although not evaluated in the current cohort of patients, variations in the accuracy of the

AC may result from very high dampening properties of the AC system, which can be caused by occlusion or compression of the catheter, arterial wall contact by the catheter tip,
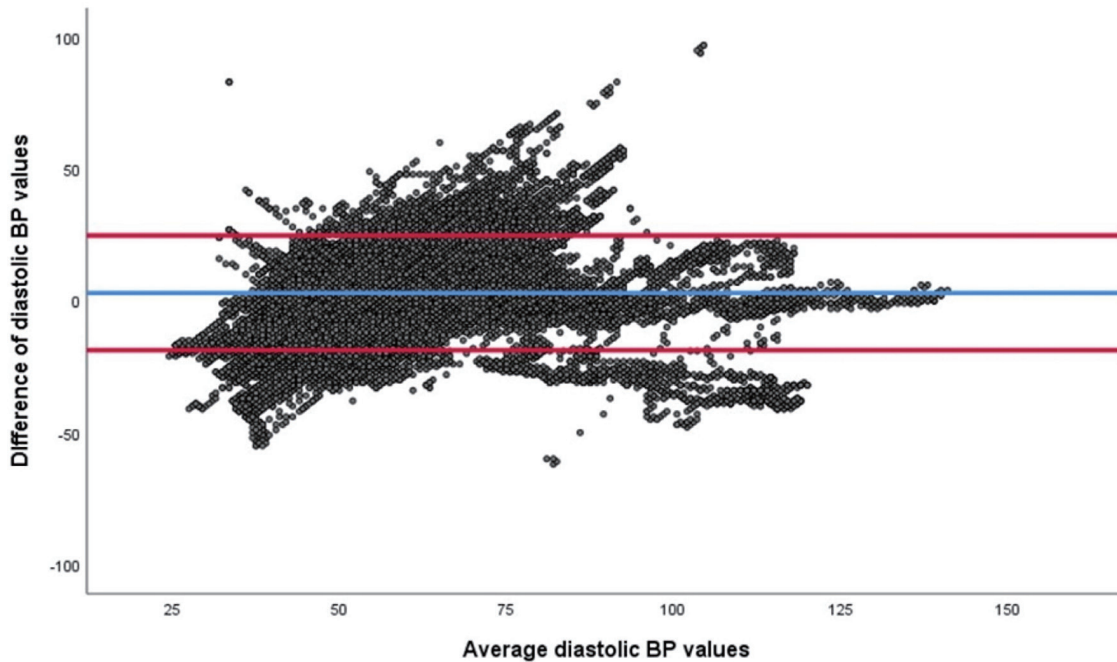

Figure 3. Bland-Altman analysis of the diastolic blood pressure (DBP) from the arterial cannula (AC) and the NICCI device, both in mm Hg. The difference between the values (NICCI and AC) are plotted on the vertical axis and the average of the two values on the horizontal access. The red lines demonstrate the 95% limits of agreement (-19 to +26 mm Hg), and the blue line corresponds to the bias (3 mm Hg). BP: blood pressure.
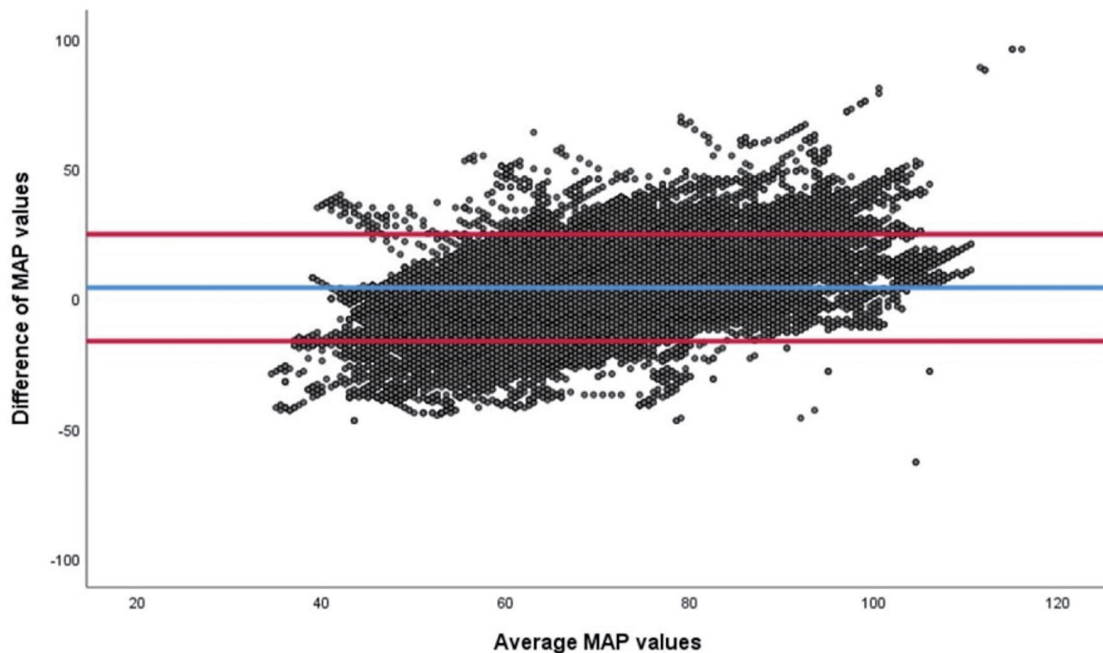
Figure 4. Bland-Altman analysis of the mean arterial pressure (MAP) from the arterial cannula (AC) and the NICCI device, both in mm Hg. The difference between the values (NICCI and AC) are plotted on the vertical axis and the average of the two values on the horizontal access. The red lines demonstrate the 95% limits of agreement (-16 to +25 mm Hg), and the blue line corresponds to the bias (4 mm Hg).

or air bubbles in the tubing system [18]. Furthermore, factors such as lack of or incorrect zero adjustments, wrong transducer position (above or below reference point), a defective transducer, and a very long or elastic tonometry tubing may result in inaccurate BP measurement from the AC [19]. Other factors that may impact the accuracy of the NICCI monitor include non-supine positioning of patients and problems with arm and finger cuffs which are not specifically manufactured for the pediatric population resulting in difficulty in creating effective fit given the varied dimensions and shape of the fingers, and minor positional changes due to movement of the patient or underlying artery in the subcutaneous space. Additionally, the placement of the NICCI monitor on the opposite arm to the AC could affect the accuracy of BP readings due to the inherent BP differences between the left and right arms. Furthermore, the NICCI value is calibrated against the arterial BP values at the brachial artery with the upper arm oscillometric measurements using a cuff placed above the elbow. In contrast, AC values represent arterial pressure values at the radial artery. As the arterial pressure measured varies based on the site along the same extremity, the values obtained from the two different sites may vary. Furthermore, the exposed hand and forearm of the study patients could be susceptible to the lower operating room temperatures compared to the core body temperature, thereby affecting the vascular tone, altering peripheral circulation, and directly affecting the NICCI sensor. The recalibration interval was 30 min according to the default settings of the NICCI device, which may have further impacted its accuracy in measuring BP. We observed that there were BP measurement inaccuracies during and immediately after recalibration of the NICCI monitor

until approximately 60 - 120 s post-calibration, during which time the BP readings drift back to a better estimation of the actual BP. The optimal recalibration interval during general anesthesia has not been investigated. Incomplete data sets or erroneous values such as those recorded during AC transducer calibration, blood draws from the AC, and periodic recalibration of the NICC were excluded from the analysis and may have increased the percentage of BP readings ≤ 10 mm Hg of the AC values. In the clinical setting, it may be helpful to have the values flash from the NICCI monitor flash during recalibration periods to alert the clinician of the potential for erroneous values during this time.

As accurate BP measurements play a significant role in managing the anesthetized patient, inaccurate values can lead to inappropriate interventions, significant complications, or even death. MAP serves as an essential parameter in ensuring the perfusion of vital organs, while SBP and DBP readings are used to accurately identify hypertension or hypotension, serving as indicators of changes in peripheral vascular resistance during surgery [20, 21]. When hemodynamic instability can be predicted, and arterial access is possible, intra-arterial BP measurement with placement of an AC remains the gold standard. At this time, a noninvasive device as such as the NICCI cannot replace invasive BP monitoring. The continuous information regarding BP changes provided by the NICCI device may be clinically more relevant and valuable than intermittent BP measurements obtained from an oscillometric device. Additional technological and equipment modifications including modifications in the algorithm to improve accuracy following intermittent monitor recalibration may increase the applicability of this technology in the perioperative arena.

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The authors have no financial relationships relevant to this article to disclose.

Conflict of Interest

The authors have no conflict of interest relevant to this article to disclose.

Informed Consent

Written informed consent for publication was obtained from all patients.

Author Contributions

Kwaku Owusu-Bediako helped with study design/conduct, patient recruitment, statistical analysis, data interpretation, manuscript preparation and editing. Joseph D. Tobias helped with study design/conduction, patient recruitment, statistical analysis, data interpretation, manuscript preparation and editing. Ismail Bekiroglu helped with study conduct, patient recruitment and manuscript preparation. Marcelino Murillo-Deluquez helped study conduct, patient recruitment and manuscript preparation. Julie Rice-Weimer helped study conduct, patient recruitment and manuscript preparation.

Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author.

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