ORIGINAL ARTICLE

Accuracy of the CNAP^{TM} monitor, a noninvasive continuous blood pressure device, in providing beat-to-beat blood pressure measurements during bariatric surgery in severely obese adolescents and young adults

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Abstract

Background During perioperative care, the continuous measurement of blood pressure (BP) provides superior physiological monitoring compared to intermittent techniques, especially for patients with comorbid conditions such as severe obesity. The current study prospectively assesses the accuracy of a continuous, noninvasive BP device in severely obese adolescents and young adults.

Methods The technology evaluated was the CNAP Monitor 500, developed by CNSystems AG (Graz, Austria). The study cohort was composed of severely obese adolescents (body mass index ≥ 35 kg/m^2) undergoing a surgical weight loss procedure (robotically assisted or laparoscopic vertical sleeve gastrectomy or laparoscopic Roux-en-Y gastric bypass). Systolic (sBP), diastolic (dBP), and mean arterial (MAP) blood pressure readings were captured from an intraoperatively placed radial arterial cannula (AC) and the CNAP device at regular intervals (once per minute) during anesthetic care.

Results The study cohort consisted of 18 severely obese subjects undergoing weight loss surgery. A total of 2,159 pairs each of sBP, dBP, and MAP values obtained. The correlation coefficient between the AC and the CNAP device was 0.655, 0.667, and 0.783 for the sBP, dBP, and MAP, respectively. The CNAP values (sBP, dBP, MAP) were ≤ 5 mmHg from the AC values in 33, 40, and 41 % of the values, respectively. The difference was more than 10 mmHg (sBP, dBP, MAP) in 39, 28, and 25 % of the values, respectively. Using a Bland–Altman analysis, the precision and bias for the sBP, dBP, and MAP were 0.3 ± 14.2, -1.3 ± 9.5, and -0.6 ± 8.6 mmHg, respectively.

Conclusion When compared to previous studies in the adult population, the accuracy of the CNAP device in a cohort of severely obese adolescents undergoing weight loss surgery was slightly less than previously reported. The current data demonstrate a clinically useful trend of the CNAP device with arterial values in this challenging patient population in whom an arterial cannula may at times be difficult.

Keywords Dexmedetomidine · Fentanyl · Intranasal administration · Tympanostomy tube placement · Analgesia

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Introduction

Blood pressure (BP) measurement remains a standard of care during intraoperative anesthetic management as mandated by the American Society of Anesthesiologists. In the absence of significant comorbid conditions, BP is generally measured intermittently with a noninvasive, oscillometric blood pressure (NIBP) device. When continuous monitoring is necessary, an arterial cannula (AC) is placed. Although intermittent BP monitoring may be acceptable in specific clinical scenarios, continuous monitoring is preferable in patients with comorbid conditions. Severe obesity presents many anesthetic challenges including difficulties with the accurate use of NIBP devices and the potential for associated cardiac disease, even during

adolescence [1–3]. However, the placement of an AC may also be difficult or associated with complications [4–9].

One of the monitors that has been developed for continuous, noninvasive BP monitoring, the CNAP Monitor 500 (CNSystems Medizintechnik, Graz, Austria), provides beat-to-beat blood pressure readings. The clinical utility of the CNAP monitor has been described in the adult population in various clinical scenarios [10–13]. Two recent studies have suggested its utility in the pediatric population, including patients in the 20–40 kg range and those undergoing surgery in the prone position [14, 15]. The current study prospectively evaluates the utility and accuracy of this device in severely obese adolescents and young adults during weight loss surgery.

Methods

The study was approved by the Institutional Review Board of Nationwide Children's Hospital (Columbus, OH, USA). The study was registered on ClinicalTrials.gov (NCT01567371). Inclusion criteria included adolescent and young adult patients with severe obesity (BMI $\geq$ 35 kg/m^2) scheduled for weight loss surgery consisting of robotically assisted laparoscopic vertical sleeve gastrectomy ($n = 16$), laparoscopic vertical sleeve gastrectomy ($n = 1$), or laparoscopic Roux-en-Y gastric bypass ($n = 1$). Exclusion criteria included a history of peripheral neurological disorders, patients in whom an AC could not be placed, patients with vascular implants at the sites of NIBP measurement, and patients with preexisting edema or anatomical deformities of the upper extremities.

The CNAP Monitor 500 was developed and is marketed by CNSystems (Graz, Austria). It was CE-certified in December 2007. Following the induction of anesthesia, an AC was placed in a radial artery. The CNAP device was attached on the side opposite to AC. The CNAP monitor uses a cuff around two adjacent fingers on the side opposite the arm cuff. The finger cuffs are available in three manufacturer-ready sizes (small, medium, large) that can be used on fingers varying in diameter from 10 to 30 mm. To further define the effective use of the device, the blood pressure cuff was placed around the upper arm in 9 of the patients and around the forearm in the other 9 patients. Additional information regarding the device and its basic principles and previous clinical applications can be obtained from the company's website (www.cnsystems.at/en/products/cnap-monitor-500).

For the current study, the choice of the finger cuff was based on the patient's size and the dimensions of their fingers. Following placement and calibration, SBP, dBP, and MAP from the CNAP device and the AC were captured every minute for analysis. The readings were subsequently analyzed after the data were downloaded from the electronic medical record to a standard Excel spreadsheet. Erroneous values including those obtained during calibration of the AC or the CNAP device were subsequently excluded.

Statistical analysis and data presentation included a calculation of the absolute differences of the sBP, dBP, and MAP values of the AC and the CNAP device. To avoid biasing the data, the absolute, not directional, difference was used. For example, if the reading from the CNAP device was 10 mmHg above or below the reading from the AC, a value of 10 mmHg was used, not −10 or +10 mmHg. A nonpaired t test was used to compare the absolute differences of the first half of the study cohort (those with the BP cuff around the upper aspect of the arm) and the second half of the study cohort (those with the BP cuff around the forearm). A determination was also made of the percentage of values from the CNAP device that were $\leq$5 mmHg, 6–10 mmHg, and >10 mmHg from the AC values. A Pearson correlation coefficient was calculated comparing the sBP, dBP, and MAP values between the AC and the CNAP device. A Bland–Altman analysis was performed to determine the bias, precision, and 95 % level of agreement between the AC and the CNAP device.

Results

The initial study cohort included 21 patients; however, the finger cuff was expired in 1 patient, resulting in no data collection, and the data from 2 other patients were lost in the download to the electronic medical record system. Therefore, the final eligible study cohort was composed of 18 subjects ($n = 15$ females) who ranged in age from 14 to 23 years (17.6 ± 2.7 years) and in weight from 90.6 to 188.8 kg (126.8 ± 26.8 kg). The BMI ranged from 37.9 to 74.7 kg/m^2.

A total of 2,159 pairs of sBP, dBP, and MAP readings from the AC and the CNAP device were analyzed: 1,119 with the cuff on the upper aspect of the arm and 1,040 with the cuff on the forearm. Although statistical significance was noted, there was no clinical difference in the accuracy of the device (AC values versus CNAP values) when the cuff was on the forearm versus the upper aspect of the arm. The absolute differences for the sBP, dBP, and MAP between the AC and the CNAP device were 11.0 ± 9.0, 8.1 ± 5.2, and 7.7 ± 4.9 mmHg, respectively, when the cuff was on the lower aspect of the arm (forearm). The absolute difference for the sBP, dBP, and MAP between the AC and the CNAP device were 10.3 ± 9.7 mmHg ($p = 0.083$ versus forearm values), 7.5 ± 6.0 mmHg ($p = 0.0134$ versus forearm values), and 6.4 ± 4.7 mmHg ($p < 0.0001$ versus forearm values), respectively, when the

Table 1 Blood pressure measured by arterial cannula and CNAP monitor

	Percentage of CNAP values ≤5 mmHg from arterial cannula value (%)	Percentage of CNAP values that were 6–10 mmHg from the arterial cannula value (%)	Percentage of CNAP values that were >10 mmHg from the arterial cannula value (%)
sBP (mmHg)	33	28	39
dBP (mmHg)	40	32	28
MAP (mmHg)	41	34	25

Data are displayed as mean ± SD or absolute values

sBP systolic blood pressure, *dBP* diastolic blood pressure, *MAP* mean arterial pressure

Table 2 Results of Bland–Altman analysis for the cohort

Measurement	Bias	Precision	95 % level of agreement	Pearson correlation coefficient
Systolic BP	0.3	±14.2	−27.5 to +28.1	0.655
Diastolic BP	−1.3	±9.5	−20.0 to +17.3	0.667
Mean arterial pressure	−0.6	±8.6	−17.4 to +16.2	0.783

Bland–Altman data are listed in mmHg
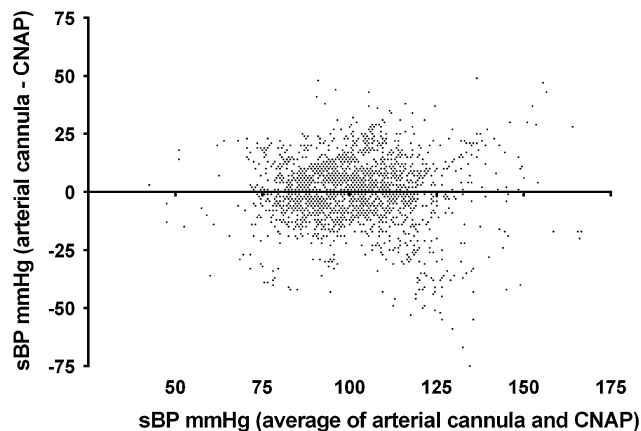
BP blood pressure

Fig. 1 Bland–Altman graph for systolic blood pressure. Difference (mmHg) between the arterial cannula and the CNAP device is listed on the *y*-axis. The average (mmHg) of the arterial cannula and the CNAP device is listed on the *x*-axis

cuff was on the upper aspect of the arm (around the biceps).

For the remainder of the results, the data are analyzed with the two groups considered as one. The number of CNAP values that were ≤5 mmHg, 6–10 mmHg, and >10 mmHg from the arterial cannula value are listed in Table 1. Results of the Bland–Altman and the Pearson correlation coefficient are outlined in Table 2. The Bland–
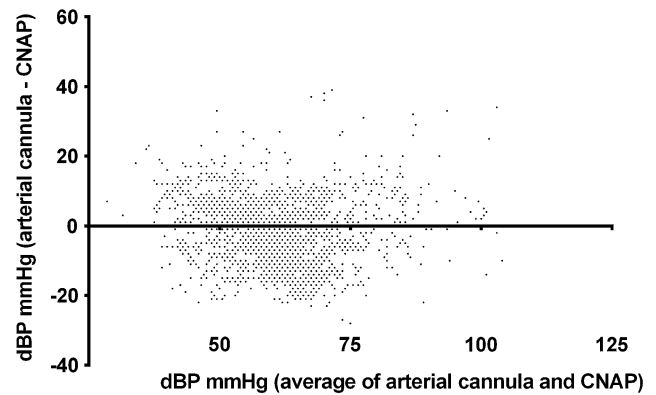

Fig. 2 Bland–Altman graph for diastolic blood pressure. Difference (mmHg) between the arterial cannula and the CNAP device is listed on the *y*-axis. The average (mmHg) of the arterial cannula and the CNAP device is listed on the *x*-axis
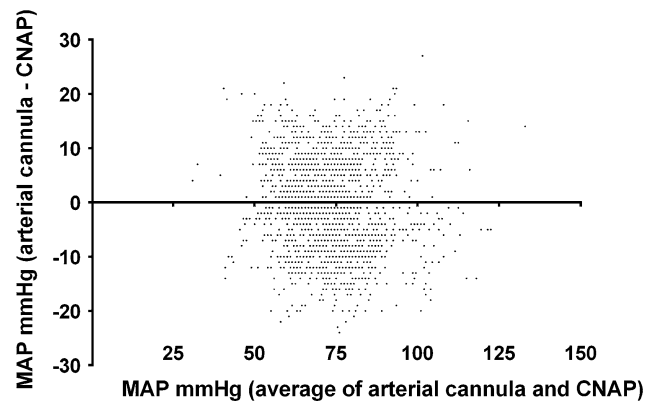

Fig. 3 Bland–Altman graph for mean arterial blood pressure. The difference (mmHg) between the arterial cannula and the CNAP device is listed on the *y*-axis. The average (mmHg) of the arterial cannula and the CNAP device is listed on the *x*-axis

Altman graphs for sBP, dBP, and MAP differences are demonstrated in Figs. 1, 2, and 3.

Discussion

The current study investigated the agreement between BP readings from the CNAP device and those obtained from an arterial cannula in severely obese adolescents and young adults during robotic, laparoscopic-assisted bariatric surgery. Although previously investigated in both the adult and pediatric populations, the current cohort is the first to evaluate the accuracy of the CNAP device in this challenging patient population. When determining the absolute difference of BP values obtained from the CNAP device and the AC, no clinically significant difference was noted when comparing the accuracy of the CNAP device with the cuff placed on the forearm versus

placement on the upper aspect of the arm. Given the difficulties with cuff placement on the upper aspect of the arm in severely obese patients, we evaluated the accuracy of the device when the cuff was placed on the forearm, as we have noted that this is a common clinical practice in this population. Although no clinically significant difference was noted, the device was more accurate with the cuff on the usual location (upper aspect of the arm).

As noted in our previous studies, the device provided a clinically useful trend of blood pressure throughout the surgical procedures. A high percentage of the sBP, dBP, and MAP readings were ≤5 mmHg from the value noted on the arterial cannula (33, 40, and 41 % of the values, respectively). Furthermore, 61 % of the sBP, 72 % of the dBP, and 75 % of the MAP values were ≤10 mmHg within the values from the AC. However, it must also be noted that approximately 30 % of the values deviated by more than 10 mmHg from the value obtained from the arterial cannula. As noted in our previous study and those performed in the adult population, the sBP measurement in the current study tended to be the least accurate. The accuracy of the CNAP device did not meet the standard of the Association for the Advancement of Medical Instrumentation for noninvasive BP measurement (ANSI/AAMI SP10), which states that a clinically acceptable agreement is met by a mean difference of ±5 mmHg and a standard deviation of 8 mmHg [16].

Previous studies in the adult population have demonstrated the efficacy and accuracy of the CNAP device in various clinical scenarios. Jeleazcov et al. [10] investigated the device in adult patients during major abdominal, cardiac, or neurosurgical procedures. In approximately 920,000 pairs of BP readings from 78 adults, the CNAP accuracy was +6.7, −5.6, and −1.6 mmHg for sBP, dBP, and MAP, respectively. Similar results were reported in 25 adult vascular surgery patients with a bias of +7.2, −7.5, and +1.8 mmHg for the sBP, dBP, and MAP respectively [11]. As in our study, both these studies show that the accuracy of the device is greater for MAP and dBP than for sBP values.

Several factors may have influenced the accuracy of the device in the current population, including the inherent differences in the adolescent and young adult arterial system when compared to older adults such as increased compliance or problems with the arm and finger cuffs that may be magnified in the severely obese population. In several cases, effective fit of the finger cuffs was problematic given the varied dimensions and shape of the fingers in the patients in the current cohort. Furthermore, despite the use of a larger cuff to ensure an effective fit on the arms of these patients, effective placement was problematic. An additional factor that may have skewed our results was the site of placement of the CNAP device (side opposite the AL in most cases) as well as the choice of the radial artery as a reference for invasive arterial pressure. CNAP values represent the arterial pressure values at the brachial artery because of the calibration with upper-arm oscillometric measurements. It is known that arterial pressure measured in different body regions differs significantly. Additional variation may have been the result of the study methodology whereby the data were collected from the electronic medical record. As such, it was not feasible to ensure that all erroneous values from the AC were excluded. These erroneous readings may be the result of dampening or overshoot of the waveform, inaccurate transducer height, or pressure variations during flushing of the cannula.

Limitations of the current study included that because of the large number of values obtained, the results were downloaded into a laptop computer for later analysis. As such, inaccuracies in the intraarterial BP measurement from dampening of the waveform or other technical errors could not be identified. Furthermore, there were a limited number of values at the extremes of the BP range and therefore it is difficult to draw firm conclusions regarding the accuracy of this device, especially during periods of hypotension (MAP ≤ 50 mmHg) or significant hypertension (MAP ≥ 110 mmHg).

Intraarterial BP measurement remains the gold standard in the operating room in cases where hemodynamic instability is anticipated. However, in various clinical scenarios, the continuous information of BP changes provided by the CNAP device may be useful. Such may include cases in which an AC cannot be placed, emergent situations when time is limited, cases of unpredicted patient instability, or when patient positioning makes arterial cannulation difficult. Additionally, there may be scenarios in which the risk–benefit profile does not warrant insertion of AC, even if continuous BP monitoring would be beneficial when compared to intermittent BP measurements. As the device involves the intermittent inflation of a cuff around the arm and fingers, it does not appear that there are any inherent risks to its use. The current study and previous studies have not reported any complications from its application. Future studies are needed in various clinical scenarios to more formally delineate the application of this new technology in the perioperative setting. Additional technological and equipment modifications may also be feasible to improve its accuracy in this challenging patient population.

Conflict of interest None.

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