Original Contribution

Accuracy of the CNAP monitor, a noninvasive continuous blood pressure device, in providing beat-to-beat blood pressure readings in the prone position

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ABSTRACT

Study Objective: To assess the accuracy of a noninvasive continuous blood pressure (BP) monitor in patients who are positioned prone in the operating room.

Design: Prospective study.

Setting: Operating room at a children's hospital.

Patients: 20 pediatric patients, aged 1.38 ± 2 years, and 63.7 ± 18.8 kg, scheduled for surgery in the prone position, and for which arterial catheter placement was planned.

Interventions: Measurements were recorded with an arterial line (AL) and a new noninvasive continuous BP monitor.

Measurements: Systolic (SBP), diastolic (DBP), and mean arterial (MAP) pressure readings were captured from an arterial cannula and the CNAP device every minute during anesthesia.

Main Results: The study cohort consisted of analysis of 4104 pairs of SBP, DBP, and MAP values, which showed an absolute difference between the AL and CNAP device readings of 7.9 ± 6.3 mmHg for SBP, 5.3 ± 4.3 mmHg for DBP, and 4.6 ± 3.9 mmHg for MAP. Bland-Altman analysis of MAP values showed a bias of 0.26 mmHg, an absolute difference between the AL and CNAP device readings of 7.9 ± 6.3 mmHg for SBP, 5.3 ± 4.3 mmHg for DBP, and 4.6 ± 3.9 mmHg for MAP.

Conclusions: During prone positioning, the CNAP monitor provided clinically acceptable accuracy for MAP values, similar to those reported in adults in the supine position.

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Data are means ± SD or absolute values.

BMI = body mass index.

without the drawbacks of an invasive arterial catheter. It may also be useful in the event of unanticipated hemodynamic instability in a patient without intra-arterial access, or failure of access during the course of the surgical procedure. Use of the CNAP monitor has been described in the adult population in various clinical scenarios [13-16]. The current study prospectively evaluated the accuracy of the CNAP device in pediatric patients who were placed in the prone position. The prone position is frequently required in the operating room (OR) for various surgical procedures including major orthopedic surgery. During such procedures, there are many challenges for intraoperative anesthetic care, including the various factors that may lead to hemodynamic instability such as rapid blood loss [17,18].

2. Materials and methods

The study was approved by the Institutional Review Board of Nationwide Children’s Hospital (Columbus, OH, USA) and was registered on ClinicalTrials.gov (NCT01356082). Inclusion criteria included patients weighing more than 40 kg, who were undergoing surgical procedures in the prone position for which placement of an intra-arterial catheter was planned as part of intraoperative anesthetic care. An inclusion weight of 40 kg was chosen; greater variability in patient size would have required a larger patient cohort, which was outside the scope of this study. Exclusion criteria included patients with a history of a peripheral neurologic or neuropathic disorder, patients in whom an invasive arterial cannula could not be placed, patients with vascular implants at the sites of noninvasive BP measurement (fingers and upper arm of the examined arm), and patients with preexisting edema of the upper extremities.

The technology evaluated in this study was the CNAP Monitor 500 (software version 3.5), which was developed by CNSystems AG, Graz, Austria, and which received FDA approval in October, 2008.

Following induction of anesthesia, an invasive arterial cannula was placed in a radial artery. After prone positioning, the CNAP device was attached to the patient, with the calibrating noninvasive BP (NIBP) cuff placed on the same side as the arterial cannula and the finger cuff on the opposite side, as recommended by the manufacturer. The site of monitoring in all cases was at the level of the heart. The CNAP monitor was set to obtain single beat detection from the infrared sensor located in the finger cuff. The CNAP monitor self-calibrated every 30 minutes. Systolic (SBP), diastolic (DBP), and mean arterial pressure (MAP) values from the CNAP device and the arterial cannula were captured every minute for analysis. Following the case, the readings were analyzed after the data were downloaded from the laptop to a standard Excel spreadsheet (Microsoft, Redmond, WA, USA). Incomplete data sets or erroneous values obtained during AL access or calibration of the arterial cannula or the CNAP device were excluded from the analysis.

Statistical analysis and data presentation included a Bland-Altman analysis of pooled MAP measurements. The mean difference in SBP, DBP, and MAP values of the two devices using absolute rather than directional differences also was calculated. For example, if the CNAP device was 10 mmHg above or below the reading from the arterial cannula, a value of 10 mmHg was used, not -10 mmHg or +10 mmHg. The percentage error was calculated and finally a determination was made of the percentage of values from the CNAP device that were ± 5 mmHg and ± 10 mmHg within the arterial cannula values. A subgroup analysis was performed to determine the accuracy of the device for measurements with a MAP < 60 mmHg.

3. Results

The study cohort included 20 patients undergoing surgery in the prone position. Demographic data are listed in Table 1. Surgical procedures included posterior spinal fusion for scoliosis (n = 17), lumbar/thoracic laminectomy for spine bifida and disc herniation (n = 18), and cervical laminectomy/laminoplasty for Chiari malformation (n = 19). Duration of surgery was 4.9 ± 1.9 hours. There were no complications associated with either arterial catheter placement or CNAP monitoring such as damage or change to the skin of the finger or arm site where the CNAP cuff was placed. A total of 4104 pairs of SBP, DBP, and MAP values from the arterial cannula and the CNAP device were analyzed. The absolute differences between the readings were 7.9 ± 6.3 mmHg for SBP, 5.3 ± 4.3 mmHg for DBP, and 4.6 ± 3.9 mmHg for MAP [Table 2].

A Bland-Altman analysis of MAP measurements showed a bias of 0.26 mmHg, with upper and lower limits of agreement of 12.18 mmHg and -11.67 mmHg, respectively [Fig. 1]. The percentage error of CNAP measurement of SBP, DBP and MAP readings was 8.6 ± 7.0, 9.8 ± 8.0 and 7.1 ± 6.4, respectively. The reading from the CNAP was ≤ 5 mmHg from the arterial cannula value in 67% of MAP readings, 59% of DBP readings, and 43% of SBP measurements. The percentage difference was ≤ 10 mmHg for 94% of MAP readings, 90% of DBP readings, and 73% of SBP readings. Mean arterial pressure was < 60 mmHg in 813 measurements [Fig. 2]. In this subgroup, CNAP measurement of SBP was less accurate, for DBP it was more accurate, while MAP values were equivalent, when compared with the group of measurements with an MAP ≥ 60 mmHg [Table 3].

4. Discussion

The current study investigated the agreement between BP readings from the CNAP device and those obtained from an arterial cannula while patients were placed prone. When determining the

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient demographics of the study cohort</th>
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<tbody>
<tr>
<td>Patients (n)</td>
<td>Age (yrs)</td>
</tr>
<tr>
<td>20</td>
<td>13.8 ± 2</td>
</tr>
</tbody>
</table>

| Data are means ± SD or absolute values. |

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Blood pressure measured by arterial line (AL) and CNAP monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>AL-CNAP</td>
<td>% CNAP ± 5 mmHg of AL</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>93.4 (12.6)</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>54.8 (7.0)</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>66.6 (8.5)</td>
</tr>
</tbody>
</table>

| Data are means (SD) or absolute values. |

| CNAP = noninvasive continuous blood pressure monitor (CNAP Monitor 500; CNSystems AG, Graz, Austria), SBP-systolic blood pressure, DBP-diastolic blood pressure, MAP= mean arterial pressure. |
absolute difference between the device and the BP from the arterial cannula, the accuracy of the MAP values was greatest, with a mean absolute difference of 4.6 mmHg. In addition, 67% of MAP values were within 5 mmHg, and 94% were within 10 mmHg, of the values obtained from the intra-arterial cannula. According to the Association for the Advancement of Medical Instrumentation standards for noninvasive blood pressure measurement (ANSI/AAMI SP10), clinically acceptable agreement is met by a mean difference of ± 5 mmHg and a standard deviation of 8 mmHg [19]. Although we have used this standard as guidance to assess our results, its validity has not been confirmed for finger cuff devices. Furthermore, the standard recommends central arterial pressure monitoring to be used as a reference.

In the current cohort of patients, these strict criteria were met only by the MAP. Although the DBP readings were close to these standards, the SBP measurements were the least accurate. The greater accuracy of the MAP measurements when compared with SBP and DBP readings has been described in previous studies.

Jeleazcov et al investigated the accuracy of the CNAP device in 88 adult patients undergoing major abdominal, cardiac, and neurosurgical procedures [13]. Approximately 920,000 pairs of BP readings from the arterial cannula and the CNAP device were analyzed. They reported a bias of +6.7 mmHg, -5.6 mmHg, and -1.6 mmHg for SBP, DBP, and MAP, respectively. Similar values were reported in 25 adult vascular surgery patients, with a bias of +7.2 mmHg, -7.5 mmHg, and +1.8 mmHg for SBP, DBP and MAP, respectively [14]. In both of these studies and our own, the CNAP device most accurately measured MAP.

In contrast, after analyzing 520,000 paired measurements in 100 adult patients, Hahn and colleagues found no clinically acceptable accuracy for MAP values with the CNAP device [15]. Although the bias for the MAP values was -3.1 mmHg, the limits of agreement were -21.6 to 15.4 mmHg. The accuracy of the device may also be lower during various aspects of anesthetic care (induction) or periods of hypotension [16]. In a study of 16,800 paired pressure readings from 85 adult patients, there was reduced accuracy of the CNAP monitor during anesthetic induction and hypotensive periods. The bias (precision) of MAP readings was -10.2 (11.3) mmHg during induction of anesthesia compared with -4.3 (6.8) mmHg during maintenance anesthesia [16]. Accuracy was even less when a subset of the data was analyzed when MAP was < 70 mmHg. In our study, a subgroup analysis of measurements when MAP was < 60 mmHg showed no clinically significant difference in the accuracy of the device.

The limitations of our study included a small cohort size of a specific population. In addition, as an investigator was not in the OR during all data collection, it was difficult to retrospectively identify all times when data collection was erroneous due to arterial catheter access or recalibration of devices. This situation may have led to inclusion of erroneous data and an underestimation of accuracy. Furthermore, we did not routinely perform a test for over or underdamping of the arterial pressure transducing system.

Where hemodynamic instability can be predicted and arterial access is possible, intra-arterial BP measurement remains the gold standard. However, in various clinical scenarios, continuous information on BP changes provided by the CNAP device may be useful. These may include cases where an arterial cannula cannot be placed, in emergent situations when time is limited, in cases of unpredicted patient instability, or when patient positioning renders arterial cannulation difficult. As was noted in the current and previous

Fig. 1. Bland-Altman analysis of the differences of the mean arterial pressure (MAP) reading from the arterial cannula and the continuous noninvasive arterial pressure monitor (CNAP Monitor 500; CNSystems Medizintechnik AG, Graz, Austria), plotted on the y-axis versus the average of the two values plotted on the x-axis. All values are expressed in mmHg. AL = arterial line.

Fig. 2. Bland-Altman analysis: difference versus average of continuous noninvasive arterial pressure monitor (CNAP Monitor 500; CNSystems Medizintechnik AG, Graz, Austria) and arterial catheter mean arterial pressure (MAP) measurements for the subgroup whose MAP value was < 60 mmHg.

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Table 3
Accuracy of CNAP measurements when mean arterial pressure (MAP) is less than 60 mmHg.

<table>
<thead>
<tr>
<th>MAP (mmHg)</th>
<th>SBP (mmHg)</th>
<th>DBP (mmHg)</th>
<th>MAP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAP &lt; 60</td>
<td>8.5 ± 6.1</td>
<td>4.6 ± 4.0</td>
<td>4.5 ± 4.3</td>
</tr>
<tr>
<td>MAP ≥ 60</td>
<td>7.7 ± 6.3</td>
<td>5.4 ± 4.3</td>
<td>4.7 ± 3.8</td>
</tr>
</tbody>
</table>

CNAP = noninvasive continuous blood pressure monitor (CNAP Monitor 500, CNSystems AG, Graz, Austria), AL = arterial line, SBP = systolic blood pressure, DBP = diastolic blood pressure.

* P < 0.01 vs MAP ≥ 60 mmHg.
† P = NS vs MAP ≥ 60 mmHg.

studies, accuracy of MAP values was greater than that achieved for either SBP or DBP. Future studies are needed in various clinical scenarios to more formally delineate the application of this new technology in the perioperative setting.

References


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