ORIGINAL ARTICLE

Accuracy of the CNAP™ monitor, a noninvasive continuous blood pressure device, in providing beat-to-beat blood pressure readings in pediatric patients weighing 20–40 kilograms

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Keywords
arterial blood pressure; blood pressure monitors; pediatrics

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Section Editor: Greg Hammer

Accepted 11 March 2013
doi:10.1111/pan.12173

Summary

Background: During perioperative care, the continuous measurement of blood pressure (BP) provides superior physiologic monitoring to intermittent techniques. However, such monitoring requires placement of an intraarterial catheter, which may be time-consuming or associated with adverse events and technical difficulty. A noninvasive, continuous BP monitoring device has been studied in the adult population. This study prospectively assesses its accuracy in pediatric patients, weighing 20–40 kg.

Methods: The technology evaluated is the CNAP™ Monitor 500, developed by CNSSystems AG (Graz, Austria). The study cohort included pediatric patients weighing between 20 and 40 kg, scheduled for surgery for which arterial line (AL) placement was planned. Systolic (sBP), diastolic (dBP), and mean arterial (MAP) blood pressure readings were captured from the AL and the CNAP™ device every minute during anesthetic care.

Results: The study cohort consisted of 20 patients (11 weighing between 30 and 40 kg and 9 weighing between 20 and 29.9 kg) with a mean age of 9.8 ± 3.4 years (range, 6–16 years) and weight of 29.8 ± 6.1 kg (range, 20.9–38.7 kg). There were a total of 1076 pairs each of sBP, dBP, and MAP values in the 20–29.9 kg group. The absolute difference between the sBP, dBP, and MAP was 9.8 ± 8.5, 6.8 ± 5.3, and 6.7 ± 6.2 mmHg, respectively. The correlation coefficient between the AL and the CNAP™ device was 0.48, 0.60, and 0.64 for the sBP, dBP, and MAP, respectively. The CNAP™ values (sBP, dBP, MAP) were ≤ 5 mmHg from the AL values in 38.6%, 48.5%, and 55.0% of the values, respectively. In the 30–40 kg group, there were a total of 2737 pairs of sBP, dBP, and MAP values. The absolute difference between the sBP, dBP, and MAP was 11.5 ± 9.3, 7.5 ± 5.3, and 7.9 ± 6.6 mmHg, respectively. The correlation coefficient between the arterial cannula and the CNAP™ device was 0.48, 0.45, and 0.51 for the sBP, dBP, and MAP, respectively. CNAP™ readings were ≤ 5 mmHg from the AL values (sBP, dBP, MAP) in 29.0%, 41.9%, and 40.5% of the values, respectively.

Conclusion: Although some variation in its accuracy was noted, the CNAP™ device provides a noninvasive and continuous blood pressure reading which appears to be within clinically useful limits. It may be that modification of the finger cuffs is needed to improve its absolute accuracy as our clinical experience demonstrated that achieving an effective fit with the cuffs was at times difficult.
Introduction

Blood pressure (BP) measurement remains a standard of care during intraoperative anesthetic management. During perioperative care, BP is measured either intermittently with a noninvasive, oscillometric blood pressure (NIBP) device or continuously from an invasive arterial cannula or line (AL). Although intermittent BP monitoring may be acceptable in specific clinical scenarios, continuous monitoring is preferable in patients with comorbid conditions and during major surgical procedures where hemodynamic changes or blood loss can be expected. During intraoperative anesthetic care, intermittent BP monitoring may miss up to 20% of hypertensive episodes while delays in detection have been noted in an additional 20% (1). These hypertensive episodes may be associated with adverse outcomes during the perioperative period (2,3). In specific clinical scenarios, excessive or repeated pressure from NIBP devices may cause nerve and skin damage (4–6). By comparison, placement of an invasive AL may be time-consuming or even rarely impossible in specific clinical scenarios or patient population. Additionally, associated complications of AL placement may include arterial occlusion (13%), hematoma formation (12%), blood loss due to unintended disconnection, infections, sensory disturbance, necrosis, and fistula formation (7–12).

A newly developed monitor for continuous noninvasive BP monitoring (CNAP™ Monitor 500; CNSystems Medizintechnik AG, Graz, Austria) provides beat-to-beat pressure readings. Use of the CNAP™ monitor has been described in the adult population in various clinical scenarios (13–16). To date, there are no data regarding use of this device in patients weighing 20–40 kg. The current study prospectively evaluates the accuracy of the CNAP™ device in the pediatric population.

Methods

The study was approved by the Institutional Review Board of Nationwide Children’s Hospital (Columbus, Ohio). The study was registered at ClinicalTrials.gov (NCT01356082). Inclusion criteria included patients weighing between 20 and 40 kg undergoing surgical procedures, which required placement of an intraarterial catheter. Exclusion criteria included a history of peripheral neurologic disorders, patients in whom an AL could not be placed, patients with vascular implants at the sites of NIBP measurement, and patients with preexisting edema of the upper extremities.

The technology evaluated in this study was the CNAP™ Monitor 500, developed by CNSystems AG, Graz, Austria, and CE-certified in December 2007. Following the induction of anesthesia, an AL was placed in a radial artery. In all except one patient, the CNAP™ device was attached on the side opposite to AL. The CNAP™ Monitor uses a cuff around two adjacent fingers on the same side as the arm cuff. The finger cuffs are available in three manufacturer ready sizes (small, medium, and large), which can be used on fingers varying in diameter from 10 to 30 mm. More information regarding the device and its basic principles can be obtained from the company’s website (http://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 AL were captured every minute for analysis. The readings were subsequently analyzed after the data were downloaded from the laptop to a standard excel spreadsheet. Erroneous values including those obtained during calibration of the AL or the CNAP™ device were excluded.

Statistical analysis and data presentation included a calculation of the absolute difference of the sBP, dBP, and MAP values of the two devices. To avoid biasing the data, the absolute not directional difference was used. For example, if the reading from CNAP™ device was 10 mmHg above or below the reading from the AL, a value of 10 mmHg was used, not −10 or +10 mmHg. Additionally, a determination was made of the percentage of values from the CNAP™ device that were ≤5 mmHg and more than 10 mmHg from the AL values. A Pearson’s correlation coefficient was calculated comparing the sBP, dBP, and MAP values between the AL and the CNAP™ device. A Bland–Altman analysis with multiple measurements per subject was performed to determine the bias and 95% level of agreement for the two weight groups. The true value varies in each subject model was used. Statistical analyses were performed using MedCalc for Windows, version 12.4.0.0 (MedCalc Software, Mariakerke, Belgium).

Results

The study cohort included 20 patients, 11 weighing between 30 and 40 kg, and 9 weighing between 20 and 29.9 kg. Patient demographics and information related to device placement are listed in Tables 1 and 2. The surgical procedures included major orthopedic surgery such as spinal fusion (n = 9), surgery for congenital heart disease (n = 7), and neurosurgical procedures (n = 4). A total of 3813 pairs of sBP, dBP, and MAP from the AL and the CNAP™ device were analyzed, which included 1076 pairs in the 20–29.9 kg group and 2737 pairs in the 30–40 kg group.
For the 20–29.9 kg group, the absolute difference and the correlation coefficient between the readings from CNAP™ device and the AL are noted in Table 3. The difference between the values from the CNAP™ device and the AL was more than 10 mmHg for 35.7% of the sBP readings, 22.8% of the dBP readings, and 18.1% of the MAP readings. For the 30–40 kg group, the absolute difference and the correlation coefficient between the readings from CNAP™ device and AL values are noted in Table 4. The difference was more than 10 mmHg (sBP, dBP, MAP) in 44.9%, 26.1%, and 26.9% of the values, respectively. The results of the Bland–Altman analysis with the bias and 95% level of agreement for both groups are outlined in Table 5.

As noted above, the device has three sizes of finger cuffs that may be used based on the size of the patient’s fingers. In 18 patients, the small sized cuff was used and in two, the medium sized finger cuff was used. The absolute differences in the sBP, dBP, and MAP when using the small and the medium sized finger cuffs are outlined in Table 6.

### Discussion

The current study investigated the agreement between BP readings from the CNAP™ device and those obtained from an AL in pediatric patients weighing from 20 to 40 kg. Although previously investigated in the adult population, the current study is the first to investigate the accuracy of the CNAP™ device in the pediatric population. When determining the absolute difference of BP values obtained from the CNAP™ device and the AL, the accuracy of the dBP values and the MAP values from the CNAP™ device and AL values are noted in Table 4. The difference was more than 10 mmHg (sBP, dBP, MAP) in 44.9%, 26.1%, and 26.9% of the values, respectively. The results of the Bland–Altman analysis with the bias and 95% level of agreement for both groups are outlined in Table 5.

As noted above, the device has three sizes of finger cuffs that may be used based on the size of the patient’s fingers. In 18 patients, the small sized cuff was used and in two, the medium sized finger cuff was used. The absolute differences in the sBP, dBP, and MAP when using the small and the medium sized finger cuffs are outlined in Table 6.

### Table 1: Patient demographics of the study cohort

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of patients</th>
<th>Age (years)</th>
<th>Weight (kilograms)</th>
<th>Male - Female</th>
<th>ASA status (1 – 2 – 3 – 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–29.9 kg</td>
<td>9</td>
<td>7.7 ± 1.2</td>
<td>24.0 ± 2.9</td>
<td>7–2</td>
<td>0 – 3 – 4 – 2</td>
</tr>
<tr>
<td>30–40 kg</td>
<td>11</td>
<td>12.5 ± 2.7</td>
<td>34.5 ± 2.8</td>
<td>5–6</td>
<td>0 – 2 – 3 – 1</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>10.4 ± 3.2</td>
<td>29.8 ± 6.1 (range, 20.9–38.7)</td>
<td>12–8</td>
<td>0 – 5 – 12 – 3</td>
</tr>
</tbody>
</table>

Data are displayed as the mean ± SD or absolute values.

ASA, American Society of Anesthesiologists’ classification.

### Table 2: Patient positioning and device placement

<table>
<thead>
<tr>
<th>Group</th>
<th>Number</th>
<th>Patient position</th>
<th>Cuff position in relationship to AL</th>
<th>Cuff orientation</th>
<th>CNAP™ finger size</th>
</tr>
</thead>
<tbody>
<tr>
<td>20–29.9 kg</td>
<td>9</td>
<td>Supine – Prone – Lateral</td>
<td>Same side 0</td>
<td>Standard 8</td>
<td>Small – Middle – Large</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Opposite side 9</td>
<td>Reverse 1</td>
<td></td>
</tr>
<tr>
<td>30–40 kg</td>
<td>11</td>
<td></td>
<td>Same side 1</td>
<td>Standard 5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Opposite side 10</td>
<td>Reverse 6</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td></td>
<td>Same side 1</td>
<td>Standard 13</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Opposite side 19</td>
<td>Reverse 7</td>
<td></td>
</tr>
</tbody>
</table>

AL, arterial line or cannula.

### Table 3: Blood pressure measured by arterial line and CNAP™ monitor in the 20–29.9 kg group

<table>
<thead>
<tr>
<th></th>
<th>Percentage of CNAP™ values ≤ 5 mmHg from AL value</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>sBP (mmHg)</td>
<td>9.8 ± 8.5</td>
<td>38.6</td>
</tr>
<tr>
<td>dBP (mmHg)</td>
<td>6.8 ± 5.3</td>
<td>48.5</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>6.7 ± 6.2</td>
<td>55.0</td>
</tr>
</tbody>
</table>

Data are displayed as mean ± SD of absolute values.

AL, arterial line; sBP, systolic blood pressure; dBP, diastolic blood pressure; MAP, mean arterial pressure.
deviation) was generally not. The accuracy was slightly within these standards although the precision (standard
lar to the bias of the Bland
values, but rather a mean difference which is more simi-

20 although dBP and MAP values from patients weighing
the differences, no group could meet these strict criteria, although dBP and MAP values from patients weighing
20–29.9 kg were close to these standards. However, by
conventional standards, the ANSI does not use absolute
values, but rather a mean difference which is more similar
to the bias of the Bland–Altman analysis (Table 5). If this assessment is used, the bias of the monitor was
within these standards although the precision (standard
development) was generally not. The accuracy was slightly
less in the 30–40 kg patients (Tables 3–5). Additionally,
we noted that the accuracy of the device was slightly
greater with the use of the small versus the medium sized
finger cuff; however, although there were a large number of
BP values, the medium cuff was used in only two
patients which make a true analysis difficult.

As noted in our previous study and those performed
in the adult population, the sBP measurement in the current study was the least accurate when compared to the
AL values (18). In our previous study, 4104 pairs of BP
values from the AL and CNAP™ device were collected
from 20 adolescents weighing more than 40 kg undergoing
surgery in the prone position (18). The absolute
differences were 7.9 ± 6.3 mmHg for sBP, 5.3 ± 4.3
mmHg for dBP, and 4.6 ± 3.9 mmHg for MAP, respectively.

Previous studies in the adult population have demonstrated the efficacy and accuracy of the CNAP™ device
in various clinical scenarios. Jeleazcov et al. investigated
the device in 78 adults during major abdominal, cardiac,
or neurosurgical procedures. In approximately 920 000
pairs of BP readings from the AL and the CNAP™ device,
the authors reported that the CNAP™ accuracy was +6.7 mmHg, −5.6 mmHg, and −1.6 mmHg for sBP, dBP, and MAP, respectively (13). Similar results
were reported in 25 adult vascular surgery patients with
a bias of +7.2 mmHg, −7.5 mmHg, and +1.8 mmHg for
the sBP, dBP, and MAP, respectively (14). As in our
study, both of these studies show that the accuracy of
the device is greater for MAP and dBP than for sBP
values.

After analyzing approximately 524 900 paired mea-
surements in 100 adult patients, Hahn and colleagues
concluded that they found clinically acceptable agree-
ment between CNAP™ and AL values, although the
correlation did not meet the strict AAMI standards (15).
Another subsequent study of 16 800 paired pressure
readings from 85 adult patients questioned the accuracy
of the CNAP™ in various situations including during
induction of anesthesia and periods of hypotension (16).

Several factors made use of this device more chal-
enging in our current cohort of patients including inherent
differences in the pediatric arterial system when com-
pared to adults such as increased compliance, nonsupine
positioning of patients, and problems with the arm and
finger cuffs which are not specifically manufactured for
the pediatric population. In several cases, effective fit of
the finger cuffs was problematic given the varied dimen-
sions and shape of the fingers in the patients in the
current cohort. An additional factor which 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

The accuracy of the CNAP™ monitor was generally not. The accuracy was slightly within these standards although the precision (standard deviation) was generally not. The accuracy was slightly lower in the 30–40 kg patients (Tables 3–5). Additionally, we noted that the accuracy of the device was slightly greater with the use of the small versus the medium sized finger cuff; however, although there were a large number of BP values, the medium cuff was used in only two patients which make a true analysis difficult.

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After analyzing approximately 524 900 paired measurements in 100 adult patients, Hahn and colleagues concluded that they found clinically acceptable agreement between CNAP™ and AL values, although the correlation did not meet the strict AAMI standards (15). Another subsequent study of 16 800 paired pressure readings from 85 adult patients questioned the accuracy of the CNAP™ in various situations including during induction of anesthesia and periods of hypotension (16).

Several factors made use of this device more challenging in our current cohort of patients including inherent differences in the pediatric arterial system when compared to adults such as increased compliance, nonsupine positioning of patients, and problems with the arm and finger cuffs which are not specifically manufactured for the pediatric 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. An additional factor which 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

### Table 4 Blood pressure measured by arterial line and CNAP™ monitor in the 30–40 kg group

<table>
<thead>
<tr>
<th>Difference between AL and CNAP™ values</th>
<th>Percentage of CNAP™ values</th>
<th>Correlation coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>sBP (mmHg)</td>
<td>11.5 ± 9.3</td>
<td>29.0</td>
</tr>
<tr>
<td>dBP (mmHg)</td>
<td>7.5 ± 5.3</td>
<td>41.9</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>7.9 ± 6.6</td>
<td>40.5</td>
</tr>
</tbody>
</table>

Data are displayed as mean ± SD of absolute values.

<table>
<thead>
<tr>
<th>Bias</th>
<th>95% level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td>−26 to +27</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>−19 to +16</td>
</tr>
<tr>
<td>Mean arterial pressure</td>
<td>−18 to +19</td>
</tr>
</tbody>
</table>

### Table 5 Results of the Bland–Altman analysis for the two weight groups

<table>
<thead>
<tr>
<th>Weight group (20–29.9 kg)</th>
<th>Bias</th>
<th>95% level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td>1</td>
<td>−26 to +27</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>−2</td>
<td>−19 to +16</td>
</tr>
<tr>
<td>Mean arterial pressure</td>
<td>0</td>
<td>−18 to +19</td>
</tr>
</tbody>
</table>

### Table 6 Blood pressure measured by arterial line and CNAP™ monitor using a small or medium finger cuff

<table>
<thead>
<tr>
<th>Small cuff group (n = 18 3073 pairs)</th>
<th>Bias</th>
<th>95% level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>sBP (mmHg)</td>
<td>10.6 ± 9.1</td>
<td>−26 to +27</td>
</tr>
<tr>
<td>dBP (mmHg)</td>
<td>7.4 ± 5.4</td>
<td>−19 to +16</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>7.2 ± 5.9</td>
<td>−18 to +19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Middle cuff group (n = 2739 pairs)</th>
<th>Bias</th>
<th>95% level of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>sBP (mmHg)</td>
<td>12.6 ± 8.9</td>
<td>−26 to +27</td>
</tr>
<tr>
<td>dBP (mmHg)</td>
<td>6.5 ± 4.8</td>
<td>−19 to +16</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>8.7 ± 6.3</td>
<td>−18 to +19</td>
</tr>
</tbody>
</table>

P-value: P < 0.0001 *

*Statistically different values between the two groups.

Data are displayed as mean ± SD of absolute values.

AL, arterial line; sBP, systolic blood pressure; dBP, diastolic blood pressure; MAP, mean arterial pressure.
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 which may partly explain the variation noted in the current study.

When hemodynamic instability can be predicted and arterial access is possible, intraarterial BP measurement remains the gold standard. However, in various clinical scenarios, the continuous information on BP changes provided by the CNAP™ device may be useful. These may include cases where an AL cannot be placed, in emergent situations when time is limited, in cases of unpredicted patient instability, or when patient positioning makes arterial cannulation difficult. Additionally, there may be scenarios where the risk-benefit profile does not warrant insertion of AL, even if continuous BP monitoring would be beneficial when compared to intermittent BP measurements. Future studies are needed in various clinical scenarios to more formally delineate the application of this new technology in the perioperative setting. Furthermore, it must be recognized that this technology was not developed for use outside of adult-sized patients. Additional technological and equipment modifications may also be feasible to improve its accuracy in the pediatric population.

Acknowledgments

This research was carried out without funding.

Conflict of interest

No author has a conflict of interest with regard to any device employed in this study. The CNAP™ monitor used for the study was supplied free of charge by the company (CNSystems AG, Graz, Austria).

References