OBSTETRICS

Detection of hypotension during Caesarean section with continuous non-invasive arterial pressure device or intermittent oscillometric arterial pressure measurement

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Editor’s key points

- Hypotension after spinal anaesthesia during Caesarean section is common.
- Significantly more hypotensive episodes and lower APs were detected using a continuous device.
- Newborns of hypotensive mothers detected by CNAP demonstrated significantly lower umbilical vein pH compared with those of normotensive mothers.
- All children of mothers with a systolic AP above 100 mm Hg measured by CNAP had an umbilical vein pH above 7.3.

Background. The intensified use of spinal anaesthesia (SPA) for Caesarean section significantly contributed to a decreased maternal mortality and morbidity. Nevertheless, one of the major side-effects is hypotension after SPA with potential negative effects on the fetus. Owing to discontinuous oscillometric measurements (non-invasive arterial pressure, NIAP), hypotensive episodes may be missed. Recently, a continuous NIAP measurement device (CNAP) with acceptable agreement with the mean invasive AP was introduced. We hypothesized that CNAP detects hypotensive episodes more reliably compared with NIAP measurements.

Methods. A total of 65 women undergoing Caesarean section under SPA were included in the study analysis. A total of 888 NIAP measurements obtained at 3 min cycles, starting from before SPA and continued until delivery, were analysed.

Results. When averaged over all cycles, the lowest systolic AP identified by CNAP in each cycle [105 mm Hg, (24.4)] was significantly lower ($P<0.001$) than the average of the individual corresponding single NIAP measurements [126 mm Hg (22.1)] and highest CNAP average [126 mm Hg (24.5)]. Hypotension (systolic AP <100 mm Hg) was detected in 39% of all cycles with CNAP and in 9% with NIAP. Hypotension was detected in 91% of the patients based on CNAP and in 55% based on NIAP. Fetal acidosis defined by an umbilical vein pH under 7.25 did not occur when the lowest systolic AP measured by CNAP was above 100 mm Hg.

Conclusions. The CNAP device detected more hypotensive episodes after SPA and significantly lower AP compared with NIAP. AP monitoring based on CNAP may improve haemodynamic management in this patient population with potential benefit for the fetus.

Keywords: anaesthesia, obstetric; arterial pressure, hypotension; complications, hypotension; measurement techniques, plethysmography

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The intensified use of spinal anaesthesia (SPA) compared with general anaesthesia for Caesarean section significantly decreased maternal deaths and morbidity in the western world. Nevertheless, hypotension due to sympatholysis in the course of SPA remains a common side-effect of the neuraxial block. The incidence of hypotension is described as up to 95%. Besides hypotension, other common side-effects related to hypotension are maternal nausea, vomiting, and dizziness with incidences of around 25%. The impact of hypotension on fetal outcome is still unclear. Because of the potential harm to the fetus and the dependency of fetal oxygenation on maternal arterial pressure (AP), it has been strongly recommended to closely monitor mother’s AP and to immediately treat hypotension. Usually, if AP needs to be monitored very precisely, an arterial line has to be inserted. This has not become an accepted procedure in clinical routine because of side-effects of such catheters and time-consuming aspects. Thus, AP is monitored discontinuously via an upper arm cuff device. There are a number of studies stressing that more than 20% of all hypotensive episodes during surgery are missed by non-invasive AP (NIAP) readings and another 20% are detected with delay, thus, immediate treatment is postponed. Rout and Rocke reported an incidence of hypotension of 51% already 3 min after application of SPA. These episodes probably would only be detected with delay by NIAP measurement compared with a beat-to-beat technique. Actually, there is no common approach or standard regarding the
optimal NIAP cycle during Caesarean section. NIAP cycles from around 20–30 s to 5 min are used initially, depending more on individual practice than on evidence-based guidelines.

Recently, a monitor for continuous non-invasive AP monitoring (CNAP™ Monitor 500, CNSystems Medizintechnik AG, Graz, Austria) using the volume-clamped method first described by Pénaz and colleagues was introduced. The monitor was evaluated during general anaesthesia and showed acceptable agreement with invasive AP measurements. The aim of this study was to investigate if the CNAP device is more reliable in terms of detection of hypotensive episodes compared with a conventional intermittent oscillometric AP measurement device during Caesarean section under SPA.

Methods
The study was registered at clinicaltrials.gov (Identifier: NCT 01157520). After approval by the ethics committee of the medical faculty of the Christian Albrechts University, Kiel, Germany, and obtaining written informed consent, 80 women undergoing elective Caesarean section under SPA were included into the study. Inclusion criteria were a pregnancy week above 30 and planned SPA. Exclusion criteria were age <18 yr, cardiac arrhythmia, vascular pathologies of the upper limbs (recent vascular surgery, Raynaud’s disease, vascular stenosis), contraindication for SPA, and emergency cases.

After admission to the operating theatre, patients were monitored using a five-lead ECG, oscillometric AP measurement, and pulse oximetry. A volume preload with 500 ml of hydroxyethyl starch (Volulyte 6% 130/0.4, Fresenius Kabi AG) was infused after application of a peripheral venous catheter. The CNAP (CNAP™ Monitor 500, CNSystems Medizintechnik AG) device was calibrated before the first measurement, thereafter calibration was repeated every 30 min. The time interval for the oscillometric measurements was set to 3 min. CNAP monitor and the oscillometric measurement were timely synchronized and values were registered continuously online. We placed the CNAP finger cuff together with the NIAP cuff on the same arm. On the contralateral arm, the i.v. catheter was placed. CNAP monitor values were blinded for the anaesthesiologist, so that treatment of hypotension was based on NIAP values obtained by the clinician. Baseline NIAP was defined as the first measurement achieved in the operating theatre. Baseline CNAP was averaged from the first 100 beats after CNAP was calibrated. SPA was performed in the sitting position using a 24 G Sprotte cannula, and 10–12.5 mg hyperbaric bupivacaine was injected. After application of bupivacaine, patients were brought into the gynaecological position, supine with the legs up in leg holders at ~30° and the table tilted to the left side. The spread of the sensoric block was tested and defined by a total loss of cold sensation using a cold spray. The management of hypotension was as follows: (i) at a systolic NIAP under 100 mm Hg 0.5 ml Akrinor corresponding to caferdine 50 mg and theodrenaline 2.5 mg (Akrinor®, AWD Pharma GmbH & Co KG, Radebeul, Germany) effect on AP approximately comparable with 10 mg ephedrine, and 5 μg of norepinephrine was administered and repeated until normotension. (ii) If more than caferdine 200 mg/theodrenaline 10 mg were needed due to persistent hypotension, a second colloid load with 500 ml hydroxyethyl starch (Volulyte 6% 130/0.4, Fresenius Kabi AG) was rapidly administered. The mechanisms of the action of Akrinor are mostly based on a direct β-mimetic effect, resulting in a moderate increase in inotropy and stroke volume with minor chronotropic effects in humans. The second pharmacological effect is an increase in the tonus of venous capacity vessels. Birthweight, maternal blood loss measured by a scaled reservoir of a suction device, Apgar score after 1, 5, and 10 min, and first umbilical vein blood gas analyses at birth were noted for all newborns.

The CNAP system consists of a double finger cuff, a pressure transducer mounted on the forearm, and an upper arm oscillometric cuff for calibration. The principle of CNAP is to keep the blood volume of the finger arteries constant by applying an exterior pressure to the vessel wall. This is done by an electronic system controlling the pressure inside a cuff around the finger. The pressure in the cuff, which is needed to keep the volume constant during arterial pulsation, corresponds to the AP. This ‘volume clamped method’ was originally developed by Pénaz and colleagues in the early 1970s, who used an infrared transmission plethysmograph for the detection of the blood volume and an electro-pneumatic servo control for the cuff pressure adjustment. We used the middle finger and the index for the finger cuffs. The system can be pre-set to average 5, 10, or 20 beats. For this investigation, all CNAP values were presented as a moving median over the last 10 beats. The device has been evaluated recently showing good agreement compared with invasive AP measurements.

Statistical analysis was performed using the Graph Pad software (Prism Version 5, Graph Pad Software, San Diego, CA, USA). Hypotension was defined as a systolic AP below 100 mm Hg, a decrease in the initial systolic AP of 20% from baseline, or both. NIAP baseline was defined as the first obtained NIAP in the sitting position. CNAP baseline was obtained by averaging the first 100 beats after calibration. For comparison of CNAP and oscillometric measurements, we compared cycles of 3 min. The measurement cycle started when the oscillometric cuff began to inflate. The analysed measurement period began when the patients had the standard monitoring established and the colloid infusion was started. It included spinal puncture, supine with 20° left tilt and legs up, disinfection, incision, and delivery of the baby. For all data sets, a Gaussian distribution was tested using the Kolmogorov–Smirnov test. The mean AP records for the highest and lowest CNAP per cycle and the correspondent single NIAP were compared using Student’s t-test. Non-parametric data were compared using the Mann–Whitney test. Comparison of hypotensive periods detected by both devices and number of acidosis was done using Fisher’s exact test. AP comparison between the
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After IRB approval and written informed consent, 80 patients were enrolled into the study. Six patients showed excessive movement of the fingers due to distinct anxiety. To avoid bias on the measurement of the CNAP based on finger cuff pressure recording, these patients were excluded from the study. We further excluded seven additional patients due to technical problems with data recording. CNAP data recording was performed using a data stick. For these seven patients, the data stick did not record all AP values. This error affected only AP data collection but not AP monitoring. For two newborns, we could not obtain full blood gas analysis. Thus, we compared 888 intervals from 65 patients, with a mean time of data acquisition of 41 min per patient, respectively.

Patient characteristic data are shown in Table 1. The baseline NIAP was 137 (22.6) mm Hg and CNAP 127.5 (19.7) mm Hg. According to the Bland–Altman comparison, the mean NIAP was 137 (22.6) mm Hg and CNAP 127.5 (19.7) mm Hg, respectively. For CNAP, six patients were allocated with one indicated by NIAP. Table 2 shows characteristics patients with a systolic AP below 100 mm Hg compared with normotensive or normotensive mothers nor depending on the AP measuring technique.

Figure 2 shows the systolic AP obtained by both devices. For CNAP, both the highest and lowest systolic pressures during one cycle were identified. The mean maximal systolic AP for all 888 cycles measured with CNAP was 125.8 (24.5) mm Hg, and the mean minimal AP was 104.7 (23.4) mm Hg for the NIAP measurement. For the averaged values, maximal systolic CNAP and systolic NIAP were almost identical. Maximal systolic CNAP was significantly higher than the lowest systolic CNAP (P<0.0001). The lowest systolic CNAP was significantly lower compared with systolic NIAP (P<0.0001).

Figure 3 shows the number of hypotensive episodes defined by a systolic AP below 100 mm Hg detected by both devices. From 888 cycles, hypotension was detected in 345 (39%) by CNAP and in 77 (9%) by NIAP (P<0.0001). From 65 patients, hypotension (sys AP <100 mm Hg) was detected in 59 (91%) by CNAP and in 36 (55%) by NIAP (P>0.05).

Table 1 Patient characteristic data, n=65. Data are mean (sd), mean (range) for age, or absolute numbers

| ASA, I/II/III | 33/25/7 |
| Weight (kg) | 83 (19) |
| Height (cm) | 167 (9) |
| Age (yr) | 34 (22–41) |
| Gestational age (weeks) | 37 (30–40) |

Table 2 Birthweight, pH, Apgar after 1, 5, and 10 min and maternal blood loss, and number per group as mean (sd) or absolute number for the lowest systolic AP detected by CNAP and NIAP under and over 100 mm Hg. *P<0.03 within CNAP or NIAP

<table>
<thead>
<tr>
<th></th>
<th>CNAP sys &gt;100 mm Hg</th>
<th>CNAP sys &lt;100 mm Hg</th>
<th>NIAP sys &gt;100 mm Hg</th>
<th>NIAP sys &lt;100 mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight (g)</td>
<td>3346 (367)</td>
<td>3280 (516)</td>
<td>3261 (448)</td>
<td>3306 (547)</td>
</tr>
<tr>
<td>pH</td>
<td>7.35 (0.02)</td>
<td>7.30 (0.06)*</td>
<td>7.32 (0.04)</td>
<td>7.29 (0.06)*</td>
</tr>
<tr>
<td>Apgar 1 min</td>
<td>8.0 (1.8)</td>
<td>8.6 (1.2)</td>
<td>8.5 (1.3)</td>
<td>8.6 (1.3)</td>
</tr>
<tr>
<td>Apgar 5 min</td>
<td>8.8 (1.3)</td>
<td>9.4 (0.8)</td>
<td>9.3 (0.9)</td>
<td>9.4 (0.8)</td>
</tr>
<tr>
<td>Apgar 10 min</td>
<td>9.5 (0.8)</td>
<td>9.7 (0.6)</td>
<td>9.6 (0.6)</td>
<td>9.7 (0.6)</td>
</tr>
<tr>
<td>Maternal blood loss (ml)</td>
<td>333 (125)</td>
<td>492 (154)*</td>
<td>467 (164)</td>
<td>486 (154)</td>
</tr>
<tr>
<td>n</td>
<td>6</td>
<td>59</td>
<td>29</td>
<td>36</td>
</tr>
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</table>
Figure 4 shows the number of hypotensive episodes defined by a decrease in systolic AP of more than 20% from baseline detected by both devices. In 888 cycles, CNAP detected 376 (42%) episodes compared with 208 (23%) detected by NIAP ($P < 0.001$). From 65 patients, hypotension (decrease of systolic AP $>20\%$ from baseline) was detected in 56 (86%) women by CNAP and in 44 (68%) parturients by NIAP ($P > 0.05$).

**Discussion**

We investigated the feasibility of a non-invasive continuous AP device for detection of hypotension during SPA for Caesarean section and compared it with the routine haemodynamic monitoring, intermittent oscillometric measurements. The main findings of our prospective, controlled clinical trial are as follows: (i) significantly more hypotensive episodes were
detected using a continuous device; (ii) CNAP detected lower systolic APs than NIAP; (iii) the incidence of hypotension (sys AP < 100 mm Hg) was 91% with CNAP and 55% with NIAP and for hypotension defined as a decrease in systolic AP of more than 20% from baseline 86% with CNAP and 63% with NIAP; (iv) newborns of hypotensive mothers detected by CNAP demonstrated significantly lower umbilical vein pH compared with those of normotensive mothers. In contrast to NIAP, all children of mothers with a systolic AP above 100 mm Hg measured by CNAP had an umbilical vein pH above 7.3.

Much attention has been spent on prevention and treatment of hypotension after SPA for Caesarean section in the past decades.\textsuperscript{4, 5, 19, 20} Hypotension causes maternal side-effects such as unconsciousness, dizziness, nausea, and vomiting. The potential fetal side-effects are caused by a reduction in the uterine blood flow with consequent reduced oxygen supply and acidosis reflected by impaired blood gas analyses and impaired Apgar scores.\textsuperscript{7, 21} The incidence of hypotension reported ranges from 30% to 100% depending on the definition of hypotension and study design.\textsuperscript{4, 22} Therefore, much effort has been spent on prophylactic measures and immediate treatment of hypotension after spinal block during Caesarean section. The incidence of hypotension could be reduced by some degree but is still present in an unacceptable high incidence.\textsuperscript{4} Although our clinical routine includes volume preload with colloids and rapid application of vasoressors, hypotension occurred in 55–91% of our patients depending on the definition of hypotension and the measuring technique.

The defined interval of NIAP measurements may be crucial for the detection of hypotensive episodes and for the aim of this trial. There is no evidence or clinical guideline on the optimal NIAP cycle. In our country, intervals between

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**Fig 3** Incidence of hypotension defined by a systolic AP below 100 mm Hg detected by CNAP or NIAP in (a) all patients and (a) all intervals. *P*<0.0001 vs CNAP.

**Fig 4** Incidence of hypotension defined by a decrease in the baseline systolic AP of more than 20% detected by CNAP or NIAP in (a) all patients and (a) all intervals. *P*<0.0001 vs CNAP.
With a systolic AP below 100 mm Hg. One reason is the definition of the baseline value as we saw many patients with systolic pressures above 140 mm Hg due to anxiety. A second reason is the distribution of acidic babies, being four to the normotensive and only one to the hypotensive group when measured with NIAP. With CNAP, at least four from five were allocated to the hypotensive group based on the 20% decrease definition. Therefore, we would recommend treatment of hypotension based on a systolic pressure below 100 mm Hg for both measuring methods.

The accuracy of non-invasive continuous AP devices may be questioned. In terms of the CNAP system, comparison with continuous invasive AP recording showed good agreement with the gold standard of invasive measurements and probably more important, a reliable detection of fast AP changes and hypotension periods during abdominal, neurosurgical, and cardiac surgical procedures. There is evidence that the correlation between NIAP and invasive AP (IAP) itself is only moderate in some conditions. The influence of different IAP levels on NIAP compared with IAP was shown by Manios and colleagues during acute stroke. NIAP underestimated systolic IAP up to 19.8 mm Hg. On the other hand, the systematic bias between IAP and NIAP measurement is also considered by the AAMI standard. A meta-analysis reported absolute differences of 0.68–13.4 and 0.8–18 mm Hg for systolic AP and diastolic AP, respectively. We intentionally did not focus on the difference between IAP and NIAP or CNAP, respectively, as our data are only based on the clinical standard NIAP. Nevertheless, the CNAP monitor is calibrated based on an oscillometric upper arm measurement. Hence, agreement to invasive measurements might not be the issue for Caesarean section, where the standard AP monitoring is equal to the calibration reference of CNAP. The more important issue is the beat-to-beat pressure probably allowing faster detection and treatment of hypotension.

As a limitation for the use of finger-cuff-based monitoring systems, anxious patients with excessive movement of the hand and fingers may hinder appropriate measurements. Likewise, we had to exclude six out of 80 patients (7.5%). In clinical practice, this rate seems rather high as we excluded every patient unable to keep her fingers still in order to reduce bias. We assume that at least half of these patients could have been measured accurately in clinical routine. The defined NIAP interval was based on practical considerations. Nevertheless, the chosen interval of 3 min may be rather long and the difference between CNAP and NIAP may have been smaller if compared at a shorter cycle. Our results support the daily practice of many departments which use shorter NIAP intervals for the first 5 min after SPA. No intervention was defined based on continuous monitoring, thus no comparison of women’s or fetal outcome based on different interventions could be performed. Further studies are needed to investigate whether haemodynamic interventions based on continuous AP monitoring improve outcome in these groups of patients.
In conclusion, our data indicate that discontinuous AP monitoring every minute in patients under SPA for Caesarean section failed to detect hypotensive episodes in a considerable number of events. The continuous device demonstrated detection of a significantly higher proportion of patients with hypotension, and detected lower umbilical vein pH implicating that a continuous system would lead to more precise detection of hypotension. When using an oscillometric device, an interval of 3 min seems inadequate and therefore cycles of 1 min or less should be used. Interventions based on continuous AP readings might improve outcome of mother and child.

Declaration of interest
R.H. has received an unrestricted grant from CNSystems, Graz, Austria. C.I. received travel fees from CNSystems. There was no additional payment depending on the results of the study. Monitoring, equipment, and medication used within the study were those routinely used for anaesthesia in our hospital. The CNAP™ Monitor was supplied by CNSystems, Graz, Austria.

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