



Can Hypotension Episodes that were not Identified in the Non-Invasive Blood Pressure be Detected during Cesarean Section? A Randomized Controlled Trial

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Background: Neuraxial anesthesia is a commonly used technique for cesarean section (C/S) because of its simplicity, rapid onset of action, and the requirement of lower doses of anesthetic agents with the lack of uteroplacental transfer. However, this type of anesthesia often causes sudden onset of hypotension, and its pathogenesis is not yet clearly understood.

Aims: To evaluate the efficacy and necessity of continuous non-invasive arterial pressure (CNAP) by comparing it with non-invasive blood pressure (NIBP) in order to understand whether it has advantages over oscillometric technique for detection of hypotensive episodes in healthy pregnant women who underwent C/S under neuraxial anesthesia.

Study Design: A randomized controlled study.

Methods: This prospective study evaluated healthy pregnant women at term who were scheduled for elective C/S under spinal anesthesia. Subjects were randomly assigned into two groups to receive either CNAP and NIBP, or only NIBP. A 30% decrease in systolic blood

pressure from either baseline or the measured values in the first two minutes, or if the systolic blood pressure was less than 90 mmHg, is considered hypotension. Pre-, peri-, and postoperative specifications; newborn characteristics; and complications were recorded and compared.

Results: A total of 106 individuals were enrolled in the study, with 53 parturients in each group. They were equally distributed in both groups ($P > 0.05$). The oscillometric method failed to detect hypotension in 8 out of 29 pregnant women who were noted to be hypotensive with CNAP. The number of hypotension events detected was higher, and the time to detection of the first episode of hypotension was shorter in the CNAP group ($P > 0.05$). A total of four newborns required intensive care unit treatment, one of whom needed mechanical ventilator support, all born to mothers in the CNAP group ($P > 0.05$).

Conclusion: Continuous non-invasive arterial pressure in detecting hypotensive episodes does not provide an additional advantage to healthy pregnant women undergoing elective cesarean section.

INTRODUCTION

Neuraxial anesthesia is a commonly used technique for cesarean section (C/S) because of its simplicity, rapid onset of action, the requirement of lower doses of anesthetic agents with the advantage of absence of their uteroplacental transfer. However, this type of anesthesia often causes sudden onset of hypotension, and its pathogenesis is not yet clearly understood.¹ Peripheral venous dilatation and increased venous capacitance due to the sympathetic blockade, along with inferior vena cava compression by the gravid uterus cause a decrease in cardiac output as well as

reduction in cardiac preload, hence a hemodynamic compromise.² The most threatening effect of hypotension for pregnant women is uteroplacental perfusion depletion which might cause fetal hypoxia and acidosis if is not treated on time. Appropriate monitoring methods are necessary for providing beat-to-beat blood pressure monitoring in risky patients with comorbid conditions.³⁻⁵

The ideal arterial pressure monitor should be non-invasive, capable of continuous measurement, allow intra-arterial measurement, and offer the recognition of acute changes with minimal additional risk factors.⁶ Arterial cannulation is the gold standard method but may



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Received: March 29, 2022 Accepted: August 03, 2022 Available Online Date: September 09, 2022 • DOI: 10.4274/balkanmedj.galenos.2022.2022-3-130

Available at www.balkanmedicaljournal.org

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Cite this article as:

Ayhan A, Akovalı N, Camkiran Fırat A. Can Hypotension Episodes that were not Identified in the Non-Invasive Blood Pressure be Detected during Cesarean Section? A Randomized Controlled Trial. *Balkan Med J.*; 2022; 39(5):358-65.

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cause additional problems such as bleeding, infection, thrombosis, ischemia, and neuronal damage due to its invasive nature.^{7,8}

Continuous non-invasive arterial pressure (CNAP) measurement is a simple, accurate, and validated method of measuring continuous systolic, diastolic, and mean blood pressure and provides real-time estimates of arterial pressure comparable to invasive arterial monitoring under sedation, neuraxial anesthesia as well as general anesthesia.^{5,6,8-11} By just placing the sensor-cuff on the patient's finger, continuous display of arterial pressure and pressure waveform can be monitored. Identification of undetectable hypotension episodes by non-invasive blood pressure (NIBP) inspection supports the effectiveness of beat-to-beat blood CNAP for early intervention of hypotension and its consequences.

The reliability of CNAP during C/S under spinal anesthesia was previously evaluated, and those studies demonstrated variable results of CNAP as being either a better tool for hemodynamic management in pregnant women with potential benefits for the fetus or as an adjunct to the conventional technique to recognize fluctuating blood pressures.^{3,12} In this study, we aimed to test the hypothesis that CNAP will detect hypotensive episodes more frequently and earlier compared to NIBP in healthy pregnant women who underwent C/S under neuraxial anesthesia. We also evaluated the association between monitoring CNAP vs NIBP and outcomes as a secondary endpoint.

MATERIALS AND METHODS

This prospective study was approved by the local Institutional Review Board and Ethics Committee (project number: KA13/33), the subjects were clearly informed about the study, and their written informed consent was obtained.

Study Participants

The study group consisted of 106 pregnant women at term, who were scheduled for the elective (planned) C/S under spinal anesthesia in an academic tertiary care unit between February 2014 and February 2015. The exclusion criteria for the study were as follows: (1) emergency C/S; (2) simultaneous gynecological interventions with C/S such as myomectomy, tubal ligation, placental abnormalities, etc; (3) C/S that was performed in failure of labor to progress; (4) the presence of any systemic disease; (5) preeclampsia or eclampsia; (6) hypersensitivity to drugs that are used in C/S; (7) multiple pregnancies; (8) pregnancies with any intrauterine fetal pathology; and (9) cases with more than two missing consecutive NIBP readings.

Subjects were randomly assigned into 2 groups to receive either CNAP and NIBP or only NIBP. CNAP finger cuff (*Infinity*[®] *CNAP*[™], *Dräger*) was used by calibrating the device before the first measurement then calibration was repeated every 30 minutes. The basic working principle of CNAP is to keep the blood volume of the finger arteries constant by applying an exterior pressure to the vessel wall, which 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, as was detailed elsewhere.^{5,6,8-12}

In the CNAP group, the CNAP finger cuff and NIBP cuff were on the same arm of the patient while the intravenous catheter was on the contralateral side. In the control group, only oscillometric NIBP measurements were done in pregnant women similar to the study group without a CNAP. After intrathecal injection, systolic, diastolic, and mean blood pressures were measured and were recorded manually every minute on the CNAP monitor. The oscillometric NIBP measurements were set at the frequency of 3 minutes for the first 15 minutes, and at 5-minute intervals thereafter and were recorded manually.

Demographic and pregnancy-related characteristics (age, parity, gravidas of the pregnant women, weeks of gestation, and the type of fertilization (spontaneous or in vitro fertilization [IVF]) were recorded.

C/S and Neuraxial Anesthesia

All parturients underwent C/S after 8 hours of fasting period without any pharmacological premedication. They were monitored with 5 lead electrocardiograms and pulse oximetry in the operating theater. By providing the monitorization, a total of 1000 ml of Ringer's lactate infusion was given by an intravenous line with an 18-gauge cannula as preload/co-load. A 12.5 mg of hyperbaric bupivacaine was administered to all pregnant women in the left lateral decubitus position with a 26-gauge atraumatic spinal needle at the L3-4 or L4-5 interval. After the spinal injection, the patients were placed in the supine position, and the uterus was directed to the left side by using a support under the right hip. Oxygen was given to all the parturients at 3 lt/min by nasal cannula.

The block level was assessed by loss of sensitivity to cold. When it reached the T4 skin dermatome, the surgery was started. Motor block was determined and recorded using the modified Bromage scale (0= no block, 1= knee flexion possible, leg unable to lift, 2= ankle flexion and finger movements possible, unable to move the knee, 3= full motor block in the lower extremity). The sensitivity to cold was checked every 5 minutes and the maximum block level was recorded. Analgesia was evaluated using a visual analog scale score (0= no pain, 10= most severe pain). Time from intrathecal injection to delivery (block-delivery time), time from skin incision to delivery (skin-birth time), and time from uterine incision to delivery (uterus-delivery time) were recorded.

After the baby was born, the mother was sedated with midazolam 0.03 mg/kg so that the Ramsay sedation score was 2, and analgesia was provided with fentanyl 0.5 µg/kg if necessary. As the umbilical cord was clamped, 2 g of cephalosporin and 5 IU of oxytocin were administered intravenously, and 15 IU oxytocin in 1000 ml Ringer's lactate was infused in an hour.

Peri- and Postoperative Periods

Patients with a 30% decrease in systolic blood pressure from either baseline or the measured values in the first two minutes, or with a systolic blood pressure less than 90 mmHg; which is considered hypotension,¹³ were treated with a bolus of 200 ml Ringer's lactate solution. If blood pressure did not improve after 3 minutes, 5 mg intravenous ephedrine was administered.

A decrease in heart rate below 50 beats/min was considered bradycardia, and 0.5 mg intravenous atropine was administered when encountered.

The nausea-vomiting score was calculated as follows: the absence of nausea-0, nausea without vomiting-1, and vomiting-2 points.

Patient discomfort for NIBP cuff and CNAP cuff scored was as 0, 1, 2, and 3 for no discomfort, mild discomfort, moderate discomfort, and severe discomfort, respectively.

The amount of administered intravenous fluids and ephedrine during anesthesia, the umbilical artery blood gas values, and APGAR scores at the 1st minute, and at 5th minutes were also recorded.

Complications, i.e., postoperative fever, bleeding, need for a blood and blood product transfusion, aspiration, atelectasis, and postspinal headache were noted at the postoperative 24th and 48th hours. The length of hospital stay for the mother and baby, the requirement for intensive care unit, and/or mechanical ventilator were assessed separately.

Statistical Analysis

Sample Size Determination

According to the recommendations of the European Hypertension Society, 99 simultaneous measurements per case in 33 cases are required for the validity of new NIBP measuring devices.¹⁴ In our preliminary statistical evaluation considering the umbilical artery pH values based on the study of Vanderbilt University's "Power and Sample Size Program" to determine the number of patients, the inclusion of at least 29 patients was necessary for both groups for a power of 0.80, alpha 0.05, and a standard deviation of 0.04. In this direction, at least 40 participants were planned to be included in each group, considering the unforeseen technical problems.

Statistical Methods

The distribution of continuous variables was examined by using the Shapiro-Wilk test. Normally distributed variables were

documented as mean \pm SD and other continuous variables as median [min-max]. Categorical variables are shown with n (%).

Comparisons between the study and the control groups were performed with the *t*-test or the Mann-Whitney U test, depending on the distribution of the variables. The McNemar test was used for the calculation and comparison of hypotension that was detected by CNAP and NIBP groups. The time interval for the first episode of hypotension for both groups was compared with the Wilcoxon test. The statistical significance level was set to $p < 0.05$.

Software used for statistical analyses and calculations are IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.), The jamovi project [(2021), *jamovi*. (Version 1.8) Computer Software retrieved from <https://www.jamovi.org>], and R Core Team [(2021), *R: A Language and environment for statistical computing* (Version 4.0). Computer software retrieved from <https://cran.r-project.org>. R packages retrieved from MRAN snapshot 2021-04-01].

RESULTS

Initially, 110 pregnant women were assigned to the study, but 4 of them were excluded for various reasons, i.e., conversion to general anesthesia, CNAP calibration error and missing consecutive NIBP readings. Finally, a total of 106 individuals were enrolled, with 53 in each group.

Maternal and Newborn Characteristics

The maternal demographic characteristics and preoperative baseline parameters were statistically similar in both groups (Table 1).

There was no significant differences between the two groups in terms of anesthesia time to reach the T4 level, skin incision time, uterine incision time, and delivery time of the baby (Table 2). The amount of intravenous fluid given and ephedrine applied for treatments based on CNAP and NIBP measurements were also similar (Table 2). Moreover, no significant difference was observed concerning the postoperative adverse events between the two groups (Table 2). None of the mothers encountered fever,

TABLE 1. The Maternal Demographic Characteristics and Preoperative Baseline Parameters

Preoperative specifications	CNAP	NIBP	<i>P</i> value
Age (years) (mean \pm SD)	32.06 \pm 4.61	31.47 \pm 4.96	0.51
Body weight (kg) (mean \pm SD)	77.79 \pm 11.42	79.64 \pm 11.60	0.38
Gestational age (weeks) (mean \pm SD)	38.57 \pm 1.33	38.50 \pm 1.10	0.52
Gravidity; median (min - max)	1 (0-7)	2 (1-6)	0.17
Parity; median (min - max)	1 (0-2)	1 (0-3)	0.97
Spontaneous conception; <i>n</i> (%)	42 (79.2)	41 (77.4)	0.99
In vitro fertilization; <i>n</i> (%)	11 (20.8)	12 (22.6)	0.81

CNAP: Continuous non-invasive arterial pressure, NIBP: non-invasive blood pressure.

**P* values were calculated with chi-square, Mann-Whitney U test or *t*-test. SD: Standard deviation

aspiration, atelectasis, postspinal headache, or major bleeding that require transfusion of blood or blood products. Although one pregnant woman in the CNAP group reported severe discomfort, the parturients in both groups similarly tolerated their cuffs (Table 3).

Table 3 shows the APGAR scores of the newborn at the 1st, and 5th minute after delivery as well as the umbilical artery blood gas analyses at the time of birth. Similar results were observed, and no statistical difference was found (Table 3). A total of four neonates, all born to mothers in the CNAP group, were admitted to the neonatal intensive care unit and one also necessitating mechanical ventilator support. The reasons for NICU admission in these cases were respiratory distress (2 cases) and hypoglycemia (2) all appearing within one day after birth, the indication of C/S for those were being repeated C/S (scarred uterus) in two, breech presentation, and maternal fear of normal vaginal delivery (maternal request). Of note, no significant difference was found between the groups in terms of such complications ($P > 0.05$).

Determination of Hypotension

Systolic, diastolic, and mean arterial pressure values are given in Figures 1, 2, and 3, respectively.

TABLE 2. Perioperative Maternal Characteristics

Perioperative specifications	CNAP	NIBP	<i>P</i> value
Anesthesia time to reach T4 level (minutes) (mean ± SD)	4 ± 2.93	3.44 ± 2.51	0.22
Skin incision time (minutes) (mean ± SD)	7.60 ± 5.55	8.06 ± 5.61	0.25
Uterine incision time (minutes) (mean ± SD)	11.30 ± 6.42	11.17 ± 5.59	0.52
Time of birth (minutes) (mean ± SD)	13.43 ± 6.89	13.09 ± 5.89	0.67
Time to leave the operating theater (minutes) (mean ± SD)	46.85 ± 11.60	47.28 ± 10.06	0.21
Intraoperative fluid (ml) (mean ± SD)	1683.02 ± 581.5	1817.92 ± 91.8	0.18
Midazolam; <i>n</i> (%)	36 (67.9)	31 (58.5)	0.31
Fentanyl; <i>n</i> (%)	9 (17.0)	11 (20.8)	0.62
Bolus of 200 ml Ringer's lactate solution; <i>n</i> (%)	29 (54.7)	21 (39.6)	0.227
Ephedrine; <i>n</i> (%)	24 (45.3)	19 (35.8)	0.32
Amount of ephedrine used (mg) (mean ± SD)	5.42 ± 7.60	3.68 ± 5.73	0.27
Nausea; <i>n</i> (%)	21 (39.6)	17 (32.1)	0.42
Vomiting; <i>n</i> (%)	3 (5.6)	3 (5.6)	1
Length of hospitalization (days) (mean ± SD)	1.30 ± 0.54	1.17 ± 0.42	0.15
Cuff discomfort	CNAP(Finger Cuff) <i>n</i> (%)	NIBP (Arm Cuff) <i>n</i> (%)	
No sensitivity	39 (73.6)	35 (66.0)	
Mild	10 (18.9)	13 (24.5)	0.55
Moderate	3 (5.6)	5 (9.5)	
Severe	1 (1.9)	–	

CNAP: Continuous non-invasive arterial pressure, NIBP: non-invasive blood pressure.

**P* values were calculated with chi-square, Mann-Whitney U test or t-test.

SD: Standard deviation.

Hypotension detected by CNAP was not recognized by the oscillometric method in 8 of 29 (27.6%) pregnant women. Although the number of detected hypotension events was higher in the CNAP group, no statistically significant difference was found between the two groups in terms of hypotension determination ($P = 0.227$).

The time to detect the first episode of hypotension was found as 4.57 ± 2.29 minutes in the CNAP group, and 4.86 ± 2.59 minutes in the NIBP group. However, the time difference between the groups did not reach any statistical significance ($P = 0.75$).

DISCUSSION

This study aimed to investigate the efficacy and the necessity of CNAP by examining and comparing it with NIBP in order to see whether it has advantages over oscillometric technique for the detection of hypotensive episodes in healthy pregnant women who underwent cesarean section under neuraxial anesthesia. The results demonstrated that the reported rates of hypotension were higher, and the time to detect the first episode of hypotension was shorter in the CNAP group however without any statistically significant difference. Furthermore, clinical and biochemical analyses of newborns were within normal limits, and no major complications occurred in mothers after delivery in both groups.

Depending on the definition and research protocols, the incidence of hypotension after neuraxial anesthesia for C/S was reported between 30% and 100%.^{4,12,15} Hypotension may result in a reduction of the uterine blood flow that would potentially decrease the oxygen supply, and if followed by acidosis appear by the *deterioration* in both blood gas analyses and APGAR scores.^{12,16,17} Therefore, prophylactic measures, prevention, and treatment of hypotension deserve special attention.^{4,12,18-20} Exact blood pressure monitoring is critical, and continuous intra-arterial blood pressure measurement is accepted as the gold standard; however, the insertion of an arterial catheter can lead to complications, and careful consideration of advantages over disadvantages is necessary.^{8,21} Non-invasive intermittent oscillometric investigations via an upper arm cuff have become the ideal method in routine clinical practice, yet its accuracy is under debate.^{8,21,22} More than 20% of hypotensive episodes during surgery can be missed, and another 20% may be detected with a delay by NIBP that resulted in a disruption of urgent corresponding treatment.^{3,23} To date, no clinical guidelines for optimal NIBP cycle interval during C/S have been reported, and

measurement of this parameter within less than 1-minute interval is not always possible.

As an alternate approach that was previously evaluated and validated, CNAP evaluation allows the continuous beat-to-beat monitoring of blood pressure, and providing on time treatment in the setting of BP changes.^{3,5,6,9,10,12,21,24} However, there is uncertainty whether CNAP is either a better tool to have for hemodynamic management in pregnant women with potential benefits for the fetus or just as an adjunct to the conventional technique to recognize fluctuating blood pressures.^{3,12} Ilies et al.¹² showed significantly more hypotensive episodes and lower systolic arterial pressures with CNAP than with non-invasive arterial pressure (NIAP); moreover, the incidence of hypotension was 86%-91% with CNAP and 55%-63% with NIAP depending on its definition. On the other hand, CNAP overall readings were less often within the normal range during pre-fetal delivery periods with more likelihood for systolic hypotension, diastolic, and mean arterial hypertension when compared to NIBP, with

TABLE 3. Neonatal Characteristics

Characteristic	CNAP	NIBP	P value
APGAR score at 1 minute Median (min - max)	9 (4-10)	8 (3-10)	0.40
APGAR score at 5 minutes Median (min - max)	9 (8-10)	9 (6-10)	0.94
UA pH (mean ± SD)	7.36 ± 0.5	7.36 ± 0.6	0.78
UA pO ₂ (mean ± SD)	22.35 ± 7.57	22.8 ± 8.92	0.85
UA pCO ₂ (mean ± SD)	38.14 ± 7.41	37.3 ± 9.45	0.54
UA Lactate (mean ± SD)	1.73 ± 0.6	1.71 ± 0.5	0.75
Length of Hospitalization (days) (mean ± SD)	1.20 ± 0.54	1.17 ± 0.42	0.12

UA: umbilical artery; SD: standard deviation

*P values were calculated with Mann-Whitney U test or t-test.

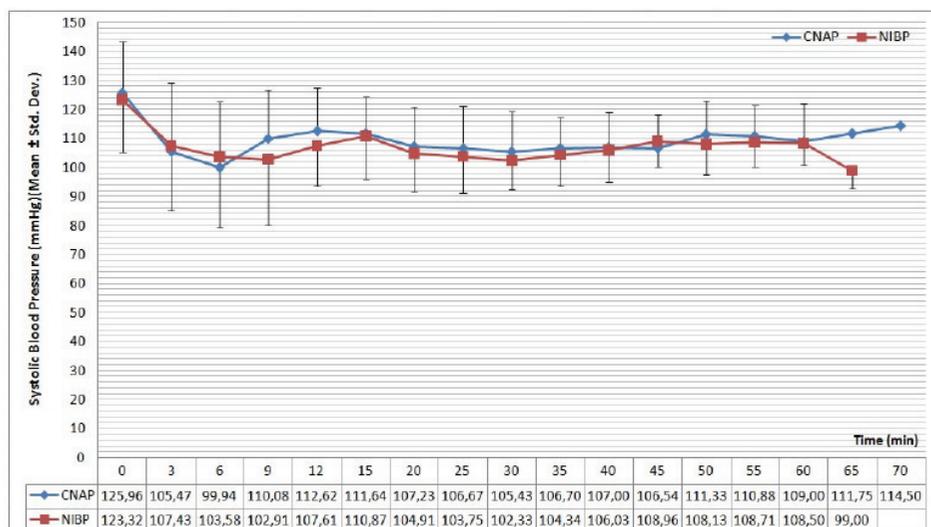


FIG. 1. Distribution of systolic blood pressure readings within the CNAP (Continuous non-invasive arterial pressure) and NIBP (Non-invasive blood pressure) groups during cesarean section.

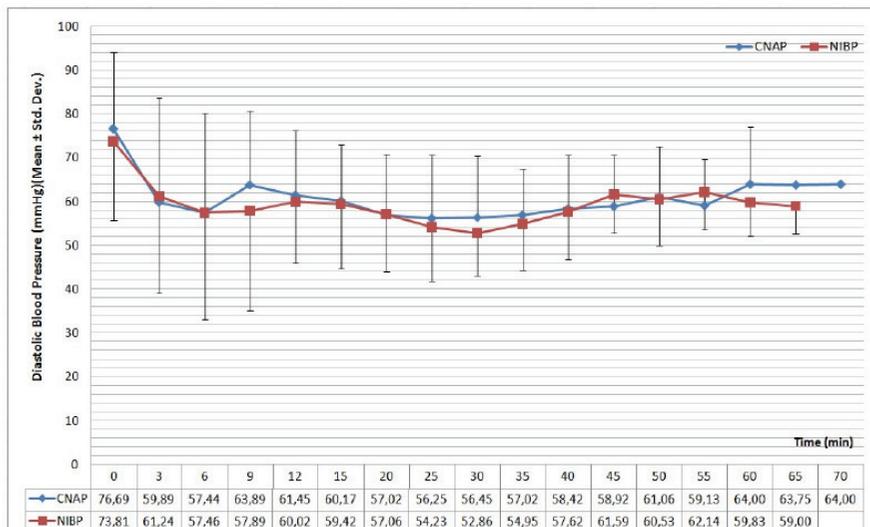


FIG. 2. Distribution of diastolic blood pressure readings within the CNAP (Continuous non-invasive arterial pressure) and NIBP (Non-invasive blood pressure) groups during cesarean section.

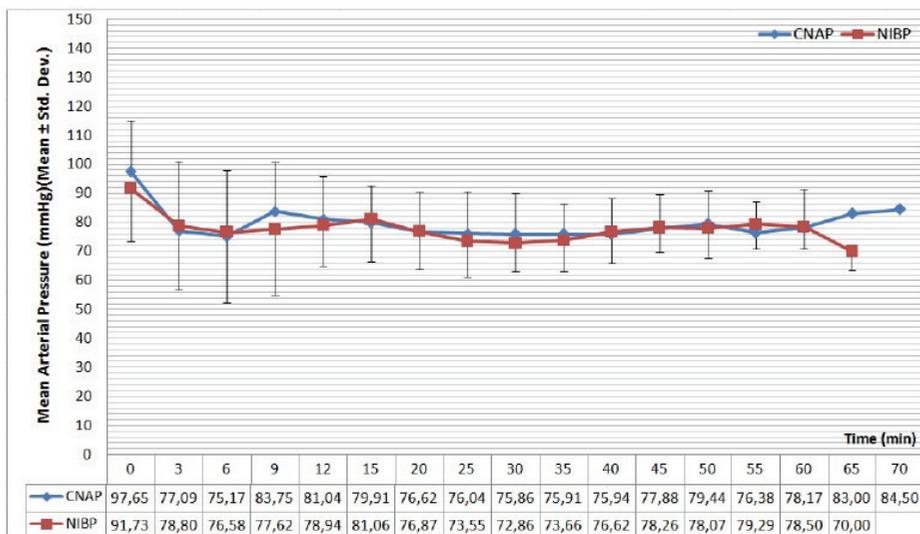


FIG. 3. Distribution of mean arterial pressure readings within the CNAP (Continuous non-invasive arterial pressure) and NIBP (Non-invasive blood pressure) groups during cesarean section.

persistently increased likelihood for systolic hypotension and diastolic hypertension during the post-fetal delivery periods.³ The same study also showed that the CNAP-based treated group had significantly lower use of oxytocin and lower estimated blood loss than the NIBP-based treatment group, but the differences in vasopressor use did not reach statistical significance.³

Our study supported our hypothesis. However, when it comes to the secondary endpoint, which was “the question of whether the episodes of hypotension detected by CNAP led to a change in the management of the patient?,” there was no statistical difference in intravenous fluid or ephedrine dose, although the number of detected hypotensive events were higher, and the time to detect the first episode of hypotension was shorter in the CNAP group. This data suggests that there is no consequence of measuring CNAP

compared to NIBP. However, our dataset is small to draw valid conclusions about the association between continuous monitoring and outcomes.

The influence of maternal hypotension on fetal outcomes during C/S is not yet clearly understood^{3,10,25} but can be potentially harmful; hence, close monitoring is strictly recommended when needed.^{3,11} Oxygen deficiency may result in progressive hypoxemia and hypercapnia, anaerobic glycolysis, and lactic and metabolic acidosis.²⁶ Umbilical cord blood gas analysis thresholds are still under debate. The morbidity and mortality may increase because of pathological fetal acidemia risk that is defined by umbilical artery pH level <7.0.^{25,27} Ilies et al.¹² showed that newborns of hypotensive mothers detected by CNAP demonstrated significantly lower umbilical vein pH compared

with those of normotensive mothers and suggested that the hypotensive periods have been missed by discontinuous NIAP at least at a 3-minute cycle.

In the present study, umbilical artery pH values were within normal limits in either group, and statistically similar results were identified; however, a total of four neonates required intensive care unit treatment, with one newborn needing mechanical ventilator support in the CNAP group. As was mentioned and presented previously, short-term and long-term consequences of newborns after maternal hypotension during C/S are unclear, and studies are needed to further understand the potential mechanisms focusing on such situations.¹²

CNAP and NIBP are known to be well-tolerated procedures. Although they did not document CNAP-related adverse events, Iliès et al.⁶ suggested that its long-term use may be associated with vascular occlusion, ischemia, and pain. Gupta et al.³ reported minimal skin changes in relation to finger cuffs that spontaneously resolved over time. A rotation of finger sensor cuffs among the fingers in order to decrease the pressure was recommended; however, they mentioned that the movement of the sensors may result in pressure changes.²⁸

Our study also evaluated discomfort related to the used cuffs in either CNAP or NIBP monitoring. More than 65% of the pregnant women reported “No sensitivity,” and only one patient claimed severe discomfort in the CNAP group. Although no statistically significant difference was found between the two groups, we want to emphasize the importance of selection for appropriate cuff size, close follow-up of the extremity and/or digits, and the comfort level of the patient.

This study has several limitations. First, the chosen interval of NIBP might be raised as a question; however, it was based on our center’s daily practice, and our research focused on understanding how much we need CNAP investigation in healthy pregnant women who undergo C/S in a routine clinical situation. Second, a 30% decrease in systolic blood pressure from either baseline or the measured values in the first two minutes (or if the systolic blood pressure was less than 90 mmHg) was considered hypotension.¹³ Setting the threshold values in the previous research focusing on a similar issue might reveal more hypotensive episodes,^{3,12} but as mentioned earlier, this study is based on the center’s routine clinical practice and the results are capable of answering the research question. Third, inter-arm and CNAP-NIBP readings’ differences might have a role in patient and operator-related bias. Also, it can be inferred that the CNAP tool may not be necessary for a healthy pregnant population, but its use could be beneficial and safer when compared to the application of an invasive arterial catheter in high-risk pregnant women with comorbidities that would undergo a surgical intervention under regional anesthesia, a question needs to be addressed in further research. Finally, although CNAP technology has been on the market for around a decade, it is still expensive for developing or underdeveloped countries.

The results of the present study demonstrated that CNAP detected hypotension in 27.6% of pregnant women which was not noted by the oscillometric method. Additionally, the time to detect the first episode of hypotension was shorter in the CNAP group. However, none of the above consequences were statistically or clinically significant in our current series of healthy parturients undergoing elective cesarean section.

Even if the NIBP measurements with the interval used in the authors’ daily practice missed detecting the hypotension captured by CNAP, none of these pregnant women required CNAP-measurement-based, and treatment-related events, and additionally gave birth to healthy neonates.

Ethics Committee Approval: This study was approved by Baskent University Institutional Review Board (project number KA13/33).

Informed Consent: Written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Author Contributions: Concept- A.A., N.K., A.C.F.; Design- A.A., N.K., A.C.F.; Data Collection or Processing- A.A., N.K., A.C.F.; Analysis or Interpretation- A.A., N.K., A.C.F.; Literature Search- A.A., A.C.F.; Writing- A.A.

Conflict of Interest: No conflict of interest was declared by the authors.

Funding: This study was supported by Başkent University Research Fund (project no: KA13/33).

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