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Non-invasive continuous versus intermittent oscillometric arterial pressure monitoring and maternal hypotension during cesarean delivery: a randomized controlled trial

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Maternal hypotension frequently occurs after spinal anesthesia for cesarean delivery. We investigated whether non-invasive continuous finger-cuff arterial pressure monitoring reduces hypotension compared with intermittent oscillometric monitoring. Women undergoing planned cesarean delivery (*n* = 151) were randomized to the treatment (finger-cuff monitoring with blinded intermittent oscillometric monitoring) or control group (intermittent oscillometric monitoring with blinded finger-cuff monitoring). Both groups received prophylactic phenylephrine. The primary outcome was the incidence of hypotension, defined as systolic arterial pressure (SAP) < 80% of baseline SAP, from spinal anesthesia to neonatal delivery. Secondary outcomes included area under the curve (AUC), time-weighted average (TWA), and duration of SAP < 80% and < 70% of baseline. Exploratory analyses using various mean arterial pressure thresholds were also performed. Maternal adverse outcomes, phenylephrine consumption, and neonatal outcomes were assessed. The incidence of hypotension did not differ between groups (50.7% vs. 58.1%; *P* = 0.358). The median AUC for SAP < 80% of baseline was similar (5.0 vs. 5.2 mmHg × min, *P* = 0.467), as was the median TWA SAP < 80% of baseline (0.19 vs. 0.17 mmHg, *P* = 0.617). Secondary outcomes were not significantly different. Continuous finger-cuff monitoring did not significantly reduce maternal hypotension; however, the observed effect trend suggests that larger-scale trials are required to definitively determine its clinical utility.

Keywords Arterial pressure, Cesarean delivery, Maternal hypotension, Post-spinal hypotension, Spinal anesthesia-mediated hypotension

Maternal hypotension frequently occurs following spinal anesthesia for cesarean delivery[1–3], which is most commonly defined as a systolic arterial pressure (SAP) < 80% of the baseline[4–6]. Accordingly, minimizing the incidence and severity of hypotension is paramount, as it is associated with adverse maternal and neonatal outcomes[7–10]. Although various thresholds for hypotension exist, SAP remains the primary parameter for guiding vasopressor titration in obstetric anesthesia[4,5]. Currently, prophylactic vasopressors are the mainstay for reducing post-spinal hypotension, requiring close arterial pressure monitoring for optimal titration[2,5,11]. However, invasive intra-arterial monitoring is generally not recommended for healthy pregnant women due to potential procedural complications[12,13]. Instead, intermittent oscillometric monitoring is standard[12,13], but this method may not provide timely data for effective intervention[14].

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Finger-cuff technology enables continuous non-invasive monitoring and provides real-time arterial pressure waveforms using a volume clamp technique[13,15–17]. Specifically, the Clearsight System (Edwards Lifesciences, Irvine, California, USA) is a commercially available device based on this technology[13]. While validation studies have demonstrated its accuracy and precision in various surgical settings[12,13,18,19], its clinical utility during cesarean delivery remains undetermined. Currently, although recent studies indicate that finger-cuff monitoring can reduce hypotension during non-cardiac surgery in non-obstetric patients[15,20,21], data regarding its application in obstetric patients are limited[12,22].

Therefore, we aimed to investigate whether finger-cuff non-invasive continuous arterial pressure monitoring could reduce maternal hypotension during cesarean delivery under spinal anesthesia. We hypothesized that the use of finger-cuff monitoring would help clinicians reduce the incidence and severity of maternal hypotension compared to standard intermittent oscillometric monitoring. Specifically, we assessed the extent of hypotension using the area under the curve (AUC), time-weighted average (TWA), and cumulative duration of SAP below 80% of baseline values. We also evaluated adverse maternal and neonatal outcomes.

Results

Of 189 women assessed, 154 patients were randomized (Fig. 1). The final analysis included 151 patients (treatment group: 77, control group: 74; Fig. 1). Three patients in the control group were excluded because their arterial pressure data were not recorded due to a technical failure of the data acquisition software (Vital Recorder). Consequently, these patients lacked the hemodynamic data required for primary and secondary outcome assessments. Baseline characteristics were comparable between the groups, except for age (Table 1).

Primary outcome

The incidence of maternal hypotension from spinal anesthesia completion to delivery did not differ between the groups (50.7% vs. 58.1% in the treatment and control groups, respectively; relative risk [95% confidence interval (CI)], 0.87 [0.65, 1.17]; $P = 0.358$; Table 2).

Secondary outcomes

The use of continuous finger-cuff monitoring did not reduce the AUC, TWA, or duration of systolic arterial pressure (SAP) < 80% of baseline SAP (Table 2). No significant differences were observed in the secondary outcomes when using the SAP threshold < 70% of baseline SAP. The sensitivity analysis, which utilized device-specific data for each group, yielded results consistent with the primary analysis (Supplementary Table S1). Although a numerical difference in the incidence of hypotension was observed (58.1% in the Control group vs. 46.9% in the Treatment group), this did not reach statistical significance ($P = 0.187$). Additionally, in our pre-specified exploratory analysis using mean arterial pressure (MAP) thresholds < 65, 60, and 55 mmHg, no significant differences were observed between the groups (Supplementary Table S2). These findings were consistent with those of the age-adjusted sensitivity analysis (Supplementary Table S3). In both best-case and worst-case scenarios, the results remained generally consistent with the primary analysis, demonstrating no

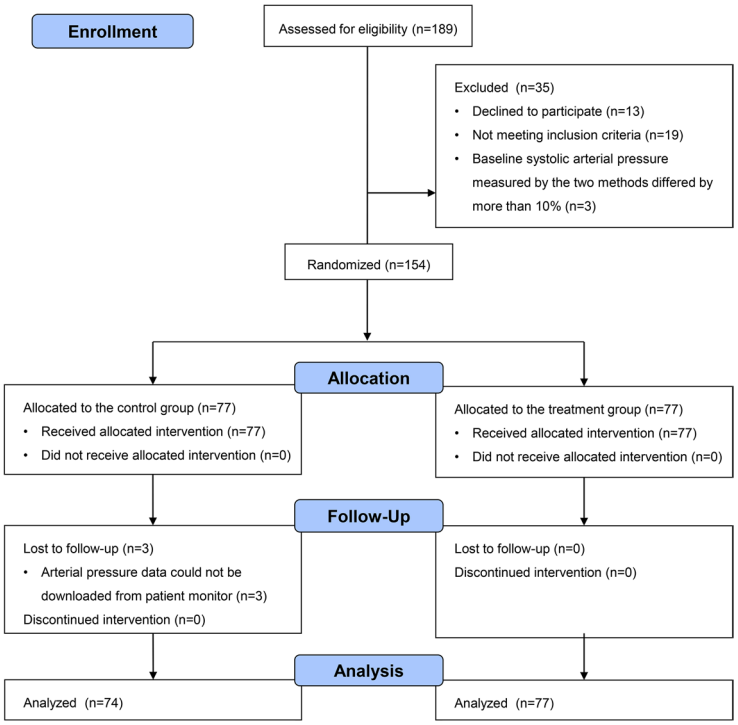

Fig. 1. CONSORT flow diagram of patient enrollment, randomization, allocation, and analysis.

Variables	Control ($n=74$)	Treatment ($n=77$)	Standardized difference
Age; yr	35 (33–38)	36 (34–40)	0.331
Height; cm	162.2 (158.7–166.1)	162.6 (159.8–164.6)	0.066
Weight; kg	68.8 (63.2–75.0)	68.0 (64.0–77.3)	0.159
Body mass index; $kg.m^{-2}$	26.4 (24.0–27.9)	26.1 (24.6–29.1)	0.135
Gestational age; weeks	38.4 (38.0–38.9)	38.4 (37.9–38.7)	−0.194
Baseline systolic arterial pressure; mmHg	119 (110–127)	117 (110–125)	−0.168
Baseline heart rate; bpm	82.5 (74–90)	83 (74–92)	0.069
Reasons for cesarean delivery			0.177
Maternal request	21 (28.4%)	27 (35.0%)	
Breech presentation of fetus	8 (10.8%)	8 (10.4%)	
Previous cesarean delivery	28 (37.8%)	28 (36.4%)	
Previous history of myomectomy	7 (9.5%)	7 (9.1%)	
Others	10 (13.5%)	7 (9.1%)	

Table 1. Patients' demographic and baseline data. Categorical data are presented as absolute numbers (percentages) and continuous data as medians (interquartile ranges). Absolute standardized difference > 0.32 was considered as imbalance between groups. Abbreviations: bpm, beat per minute.

Outcomes	Control ($n=74$)	Treatment ($n=77$)	Relative risk (95% CI)	Median difference (95% CI)[a]	*P* value[b, c]
Primary outcome					
Patients with ≥ 1 reading of hypotension (SAP < 80% of baseline), n	43 (58.1%)	39 (50.6%)	0.9 (0.7 to 1.2)		0.358
Secondary outcomes					
SAP < 80% of baseline					
Time-weighted average SAP < 80% of baseline, mmHg	0.17 (0–0.85)	0.19 (0–0.78)		0 (−0.1 to 0)	0.617
AUC SAP < 80% of baseline, mmHg × min	5.2 (0–24)	5.0 (0–18.2)		0 (−2.1 to 0)	0.467
Duration of SAP < 80% of baseline, min	1.3 (0–3)	1 (0–3)		0 (−0.3 to 0)	0.565
SAP < 70% of baseline					
Patients with ≥ 1 reading of severe hypotension (SAP < 70% of baseline SAP), n	13 (17.6%)	9 (11.7%)	0.7 (0.3 to 1.5)		0.306
Time-weighted average SAP < 70% of baseline, mmHg	0 (0–0.01)	0 (0–0)		0 (0 to 0)	0.094
AUC SAP < 70% of baseline, mmHg × min	0 (0–0.33)	0 (0–0)		0 (0 to 0)	0.095
Duration of SAP < 70% of baseline, min	0 (0–0)	0 (0–0)		0 (0 to 0)	0.312

Table 2. Primary and secondary outcomes of cesarean deliveries. All outcome variables were calculated using data from the completion of spinal anesthesia to delivery of the baby. Categorical data are presented as absolute numbers (percentages) and continuous data as medians (interquartile ranges). [a] Hodges–Lehmann Estimation was used to calculate the CI for median differences. [b] *P* value for the comparison between the control (intermittent oscillometric monitoring) and treatment (finger-cuff monitoring) groups. [c] Chi-square test was used to compare categorial variables, and Wilcoxon rank-sum test was used to compare medians. *CI* Confidence interval, *AUC* Area under the curve, *SAP* Systolic arterial pressure.

statistically significant difference between the groups. Although the best-case scenario for the TWA and AUC of SAP < 70% showed statistically significant differences ($P=0.032$ for both), these were influenced by the zero-inflated nature of the data ($n=90$ for both variables), where the imputation of extreme values shifted the rank-based comparison (Supplementary Tables S4 and S5). No significant differences were observed in the incidence of nausea, vomiting, or phenylephrine consumption (Table 3). Neonatal outcomes did not differ between the groups (Supplementary Table S6).

The median hypotension onset time did not differ between the groups (17.7 min vs. 14.2 min in the treatment and control groups, respectively; Log-rank test $P=0.321$; Fig. 2), and these results persisted after age adjustment ($P=0.278$).

Agreement between the finger-cuff and arm-cuff methods

From spinal anesthesia completion to delivery, Bland–Altman analysis showed a mean bias of 13.95 mmHg and 95% limits of agreement of −22.19 to 49.50 mmHg for 8,478 data pairs in 117 patients after applying the random-effects model for repeated measure data (Fig. 3). Bland–Altman plots are presented for baseline (Supplementary Fig. S1), immediately after anesthesia completion (Supplementary Fig. S2), 5 min after spinal anesthesia (Supplementary Fig. S3), and 1 min before delivery (Supplementary Fig. S4). The 95% CI was wide

Variables	Control ($n=74$)	Treatment ($n=77$)	Relative risk (95% CI)	Mean difference or median difference (95% CI)[a]	P value[b, c]
Nausea; n	9 (12.2%)	8 (10.4%)	0.9 (0.4 to 2.1)		0.731
Vomiting; n	1 (1.4%)	0	-		0.490
Symptomatic hypotension[d]; n	8 (10.8%)	8 (10.4%)	1.0 (0.4 to 2.4)		0.933
Dizziness; n	2 (2.7%)	4 (5.2%)	1.9 (0.4 to 10.2)		0.682
Breathlessness; n	4 (5.4%)	2 (2.6%)	0.5 (0.1 to 2.6)		0.436
Hypertension; n	2 (2.7%)	2 (2.6%)	1.0 (0.1 to 6.7)		0.968
Bradycardia[e]; n	6 (8.1%)	11 (14.3%)	1.8 (0.7 to 4.5)		0.230
Minimum SAP; mmHg	91 (81–98)	89 (80–101)		0 (−5 to 5)	0.994
Maximum SAP; mmHg	135 (126–148)	133 (122–143)		−4.2 (−9.9 to 1.5)	0.144
Minimum MAP; mmHg	67 (59–74)	65 (58–73)		−0.9 (−5.2 to 3.4)	0.684
Maximum MAP; mmHg	102 (92–111)	99 (92–105)		−3 (−7 to 1)	0.197
Minimum heart rate; bpm	52 (10)	54 (12)		1.5 (−2.4 to 5.3)	0.453
Cumulative phenylephrine consumption; µg	720 (500–900)	675 (400–925)		−50 (−150 to 75)	0.455
Rescue ephedrine use; n	0	1 (1.3%)	-		0.999
Rescue atropine use; n	0	0			-
Duration of surgery; min	60 (55–70)	60 (50–70)		0 (−5 to 5)	0.609
Spinal anesthesia to delivery; min	26 (22–31)	25 (21–27)		−1 (−4.9 to 1.0)	0.051
Total fluids during surgery; ml	700 (550–800)	650 (600–750)		0 (−50 to 50)	0.760

Table 3. Maternal outcomes. All outcome variables were calculated using data from the completion of spinal anesthesia to delivery of the baby. Categorical data are presented as absolute numbers (percentages), and continuous data as means (SD) or medians (interquartile ranges). [a] Hodges–Lehmann Estimation was used to calculate the CI for median differences. [b]P value for the comparison between the control (intermittent oscillometric monitoring) and treatment (finger-cuff monitoring) groups. [c] Chi-square test was used to compare distributions, and Wilcoxon rank-sum test or Student's t-test were used to compare medians or means. [d] Symptomatic hypotension was defined as hypotension plus nausea and/or vomiting. [e] Bradycardia was defined as a heart rate of < 50 bpm. Abbreviations: CI, confidence interval; SAP, systolic arterial pressure; MAP, mean arterial pressure.

in each Bland–Altman plot, and the agreement between the 2 methods appeared to be low[23]. Scatter and linear regression plots are presented in Supplementary Figures S5–S8.

Post-hoc sensitivity analysis

An age-adjusted sensitivity analysis was performed to address the slight age imbalance between groups. The statistical significance of the primary outcome remained unchanged ($P=0.279$; Supplementary Table S3). Secondary outcomes also showed no statistically significant differences after age adjustment (Supplementary Table S3).

Discussion

In this randomized controlled trial, finger-cuff continuous arterial pressure monitoring did not reduce the incidence of maternal hypotension compared to intermittent oscillometric monitoring in the context of prophylactic phenylephrine infusion. Furthermore, it did not decrease the extent of hypotension as measured by AUC, TWA, and duration across various thresholds. Notably, these findings contradict our initial expectations, and the observations reported in existing literature[12,15,20]. Several explanations may account for this discrepancy.

First, we quantified the incidence and extent of hypotension using oscillometric arterial pressure data, which is the established standard for obstetric patients[13], in both groups. Previous studies in non-obstetric settings have shown that finger-cuff continuous arterial pressure monitoring could reduce hypotension during non-cardiac surgery[15,20]. Notably, these trials utilized blood pressure data from the ClearSight system for their analyses[15,20]. This methodological difference may explain the discrepancy between our findings and those of previous studies[15,20]. Additionally, we used 1-minute intervals for oscillometric monitoring, whereas prior studies with 3–5-minute intervals[15,20], which could have influenced the results.

One potential limitation of our study design is that the exclusive use of oscillometric measurements for the primary outcome assessment might have masked the inherent advantages of continuous monitoring. To address this, we conducted a sensitivity analysis using the device-specific data that guided clinical interventions in each respective group (Supplementary Table S1). The results were generally consistent with our primary findings. However, a numerical difference in the incidence of hypotension was observed (58.1% in the Control group vs. 46.9% in the Treatment group). Given that our sample size was calculated to detect a 25% absolute reduction, the study was not powered to identify smaller between-group differences. These findings should therefore be interpreted with caution, and further large-scale, multicenter studies are required to provide a more definitive conclusion.

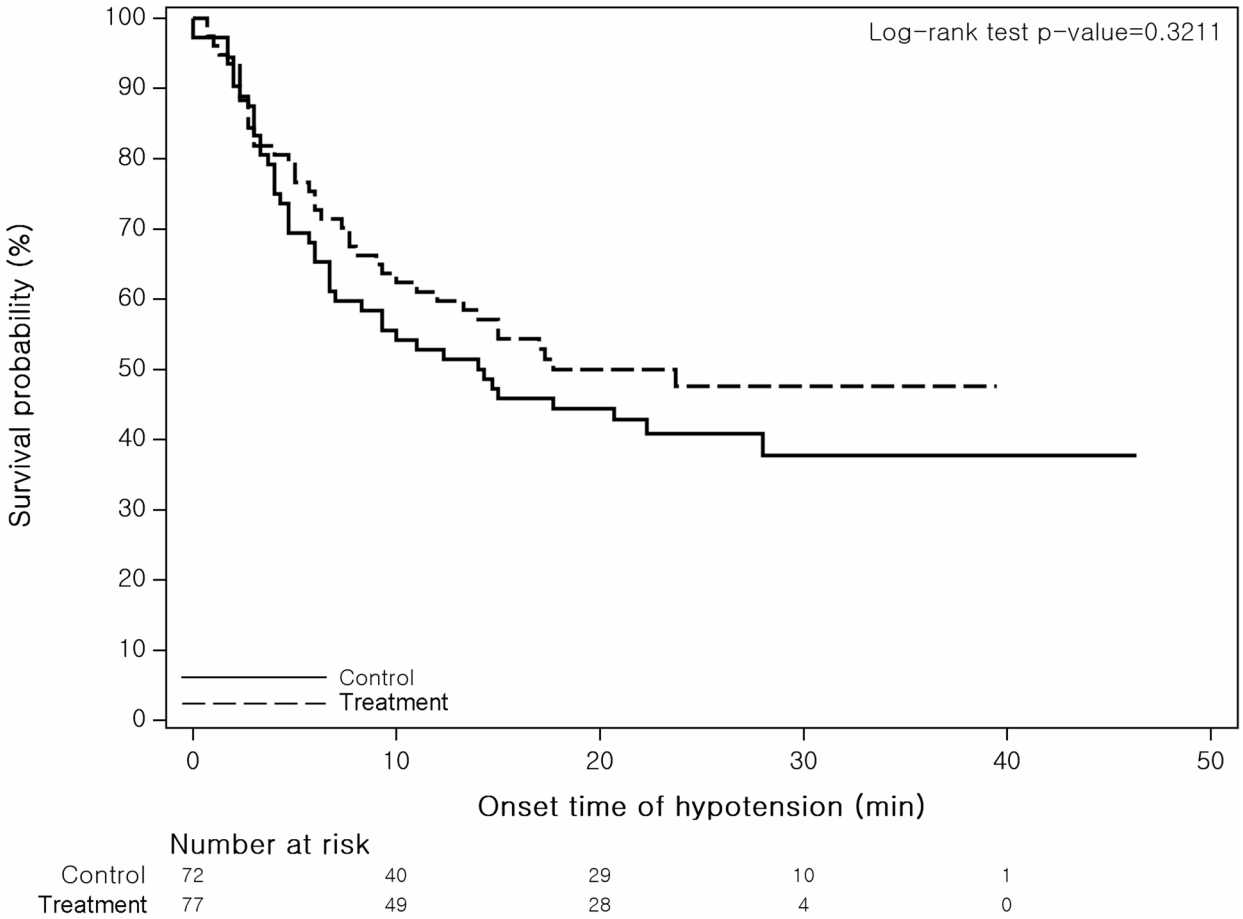

Fig. 2. Kaplan–Meier survival analysis for the time to the first hypotensive episode. The plot illustrates the cumulative probability of remaining free from hypotension from the completion of spinal anesthesia to delivery. The treatment group (continuous finger-cuff monitoring) is denoted by the dotted line, and the control group (intermittent oscillometric monitoring) by the solid black line. Hypotension was defined as a systolic arterial pressure (SAP) < 80% of the baseline value. The time to the first hypotensive episode was measured in minutes from the completion of spinal anesthesia (T0). No significant difference was observed between the two groups (log-rank test, $P = 0.321$).

Our analysis relied on oscillometric data, and the results were influenced by the concordance between the finger-cuff and oscillometric monitoring. A previous study reported reasonable agreement between the finger-cuff and invasive arterial pressure measurements during hemodynamically stable phases[24]. Conversely, our Bland-Altman analysis indicated limited agreement between finger-cuff and oscillometric monitoring during hemodynamically unstable phases after spinal anesthesia. Similarly, recent studies have indicated that finger-cuff methodology is not interchangeable with invasive monitoring[16,25]. Notably, even oscillometry showed limited agreement with the invasive 'gold standard' arterial catheterization method[15,24,26]. Since this study did not include invasive arterial catheterization as a reference, further research is needed to clarify the utility of finger-cuff technology in obstetric patients.

Second, we implemented a standardized hemodynamic management protocol using a phenylephrine infusion[5,6]. We chose this approach because the absence of a standardized protocol could potentially bias the results, as blinding of the study personnel was not feasible[12,15]. Previously, Juri et al. reported a reduced incidence of hypotension during cesarean delivery with finger-cuff compared to oscillometric monitoring (0% vs. 45%) [12]. However, the absence of hypotension in the finger-cuff group may have been influenced by a 4.8-fold higher phenylephrine consumption (7200 µg vs. 1500 µg) [12]. In contrast, phenylephrine consumption was comparable between the groups in our study, which may explain the lack of significant differences in the incidence and extent of hypotension.

Furthermore, we administered prophylactic phenylephrine to every mother, as recommended to prevent hypotension after spinal anesthesia[5]. Prophylactic phenylephrine likely contributed to the minimal extent of hypotension in both groups, thereby making it challenging to detect significant between-group differences. While the incidence of hypotension remained relatively high, its duration and severity were minimal, likely due to prophylactic phenylephrine infusion. Nonetheless, although a starting dose of 25 µg/min appears reasonable, our results suggest that higher doses may be needed to prevent hypotension more effectively.

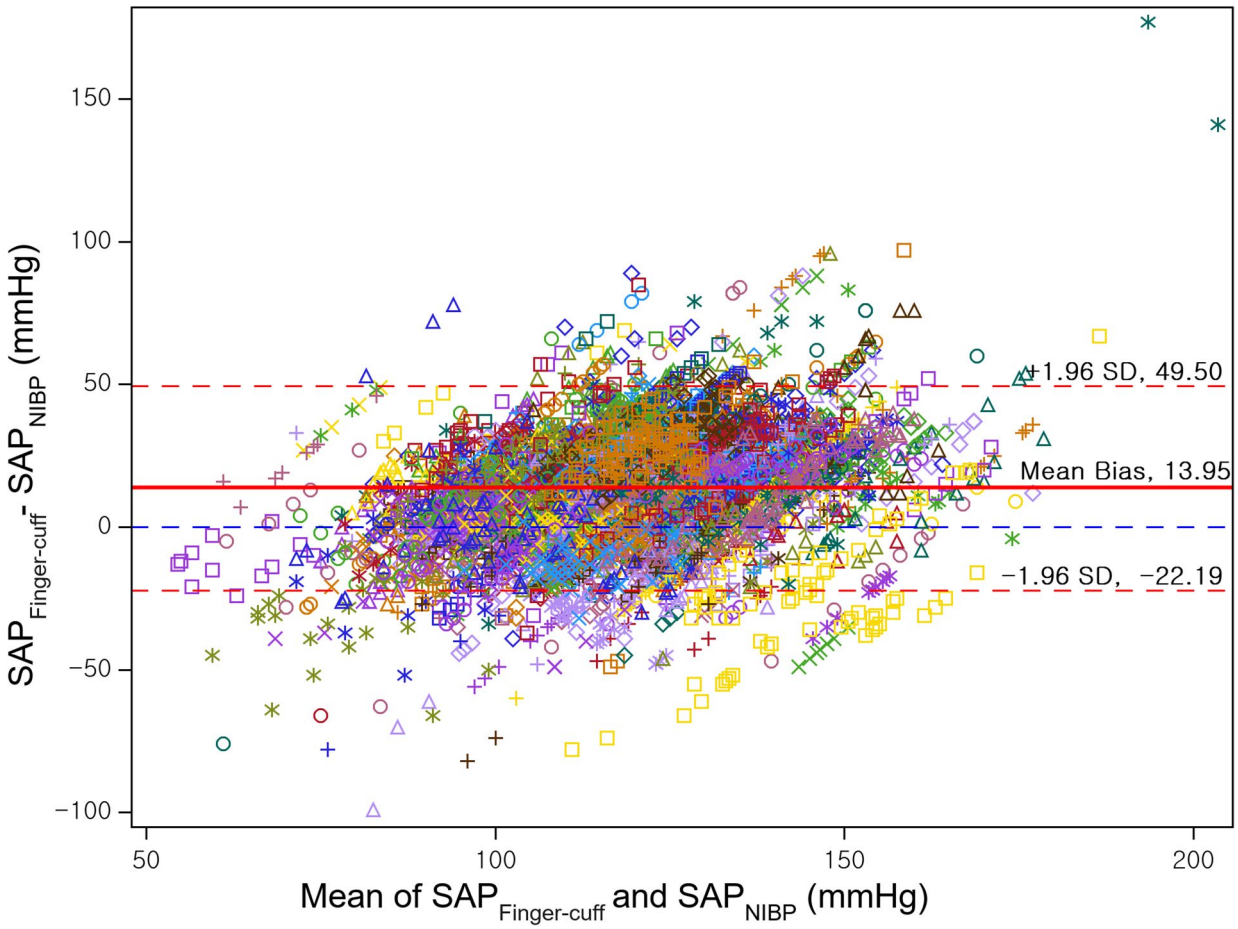

Fig. 3. Bland–Altman plot for assessing the agreement between finger-cuff and intermittent oscillometric monitoring. The plot assesses the agreement between systolic arterial pressure (SAP) measured with the finger-cuff and intermittent oscillometric monitoring for all measurements from the completion of spinal anesthesia to delivery. A total of 8,478 observations from 117 patients were analyzed with correction for repeated measures. The mean bias was 13.95 mmHg, and the 95% limits of agreement (defined as the mean difference ± 1.96 SD) ranged from − 22.19 to 49.50 mmHg. The within-subject variance was estimated using a random-effects model. *SAP* Systolic arterial pressure, *NIBP* Non-invasive blood pressure measured by an intermittent oscillometric cuff, *SD* Standard deviation.

Our data provide several insights into future research directions involving finger-cuff methodology. First, the continuous presentation of arterial waveforms has significant potential to improve hemodynamic management. Specifically, detecting a downward trend in finger-cuff waveforms could alert clinicians and facilitate timely interventions. Consequently, future studies incorporating early responses based on these real-time trends are required to explore the potential benefits of this technology. Second, within our phenylephrine infusion protocol, finger-cuff monitoring did not lead to earlier intervention. Since the effectiveness of this technology depends on the clinician response[15], close monitoring alone cannot prevent hypotension without appropriate treatment[27]. Future studies should explore earlier interventions and higher blood pressure thresholds to optimize the benefits of finger-cuff monitoring. Third, while our intervention protocol was primarily guided by SAP measurements, we incorporated MAP as a secondary parameter to provide a more comprehensive assessment of organ perfusion pressure[5]. Previous reports have shown good agreement between finger-cuff and intra-arterial MAP measurements[19,26,28]. However, our current observations regarding MAP-based outcomes are strictly exploratory. Accordingly, these analyses serve as supplementary evidence, and further research is needed to determine whether intervention guided by MAP could provide additional benefits in this population. Finally, this non-invasive technology should be explored as a supplementary tool rather than a replacement for reference methods, considering its suboptimal agreement with standard oscillometry during acute care conditions following spinal anesthesia.

This study has limitations. First, it lacked 'gold standard' invasive arterial catheterization measurements due to ethical concerns. Second, blinding of the attending anesthesiologist was not feasible due to the study's nature. Third, as a single-center trial, the results may have limited generalizability. Fourth, we included only healthy mothers with singleton pregnancies; consequently, results may differ in patients with cardiovascular diseases, preeclampsia, or multiple pregnancies. Fifth, we used a standardized prophylactic phenylephrine

infusion protocol, and results may differ with other management strategies. In particular, the phenylephrine dose used may have been insufficient to effectively prevent hypotension. Sixth, three patients in the control group were excluded from the final analysis due to technical recording errors. However, these cases represented only approximately 2% of the randomized cohort, and the data loss occurred independently of clinical variables. Furthermore, sensitivity analyses using best-case and worst-case scenario approaches confirmed that our primary findings remained robust across various assumptions. While minor statistical fluctuations were observed in some secondary parameters, these likely originated from the zero-inflated distribution of the data. Seventh, a methodological limitation of this study is the exclusion of patients who had a > 10% difference between finger-cuff and arm-cuff SAP at baseline. Although intended to ensure patient safety, this criterion may have introduced selection bias by excluding individuals with a large disparity between the two measurement methods. Such an approach could theoretically idealize the study population and weaken the external validity of our findings. However, since only a small fraction of the screened population (1.6%, 3/189) was excluded for this reason, the practical impact on our primary conclusions is likely limited. Furthermore, our data indicated that the agreement between methods was more acceptable at resting baseline compared to the intraoperative period (Supplementary Figure S1). Nonetheless, future studies should consider including such patients to better reflect real-world clinical variability.

Finally, and most importantly, our trial may have been underpowered to detect a smaller difference between the two monitoring methods. The initial sample size was powered to detect a 25% absolute reduction in hypotension—a threshold based on previous obstetric research[12,29] and considered clinically meaningful to justify a change in practice. However, the actual observed difference was 7.4% (58.1% vs. 50.7%), suggesting that the true effect size may be smaller than our pre-specified assumption. While this result is a statistically negative finding, it should not be interpreted as definitive evidence that continuous monitoring is ineffective. Instead, it suggests that the clinical benefit may be more subtle than initially hypothesized, particularly under contemporary anesthesia protocols using prophylactic phenylephrine. This creates the potential for a Type II error, where a significant difference might have been missed due to the current sample size. A large-scale multicenter study is required to definitively identify a subtle but clinically relevant 20% relative reduction. For instance, approximately 698 patients would be necessary to achieve 90% statistical power. Thus, while a 7.4% reduction may not currently warrant a change in clinical guidelines, our findings provide a critical foundation for future, adequately powered large-scale research.

In conclusion, under the sample size of this study, no statistically significant differences were observed between continuous finger-cuff and intermittent oscillometric monitoring in reducing the incidence of maternal hypotension. However, the observed effect trend is consistent with previous studies, suggesting that continuous monitoring may still offer potential benefits in hemodynamic management. Our findings underscore that further verification with larger-scale, adequately powered studies is required to provide a more definitive conclusion regarding the clinical utility of finger-cuff monitoring during cesarean delivery.

Methods

Study design

This randomized controlled trial was approved by the Institutional Review Board of Seoul National University Hospital, Seoul, Korea (reference number: 2010-093-1165; date of approval: January 25, 2021). The trial was registered prior to patient enrolment at ClinicalTrials.gov (identifier: NCT04752904; registration date: February 12, 2021; principal investigator: Sun-Kyung Park) and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants. This study was conducted from April 2021 to October 2022 at the Seoul National University Hospital and adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines[30].

Study participants

We included healthy adult pregnant women with singleton pregnancies ≥ 35 weeks of gestation who were scheduled for planned cesarean delivery under spinal anesthesia. The exclusion criteria were: (1) pre-existing or pregnancy-induced hypertension; (2) cardiovascular disease; (3) cerebrovascular disease; (4) known fetal anomaly; (5) any contraindication to neuraxial anesthesia; (6) any sign of labor onset; (7) body weight < 45 or > 90 kg; (8) height < 145 or > 180 cm; and (9) unwillingness to participate. The height and weight cutoffs were chosen to ensure a standardized spinal anesthesia protocol using a fixed dose of local anesthetics for all participants[6].

Randomization and blinding

Participants were randomized to a finger-cuff continuous non-invasive arterial pressure monitoring group (treatment group) or intermittent traditional oscillometric non-invasive arterial pressure monitoring group (control group) using a computer-generated randomization table. Group allocation was concealed in sequentially numbered sealed envelopes prepared by independent personnel not involved in the investigation. Only the attending anesthesiologist was allowed to open the envelope immediately before the induction of anesthesia. The patients, surgeons, and outcome assessors were blinded to the group allocation.

Study interventions

Each participant underwent arterial pressure monitoring using both continuous finger-cuff and intermittent oscillometric brachial cuff. In the treatment group, the finger-cuff continuous arterial waveforms and measurements were displayed on a patient monitor (IntelliVue AD85; Philips Healthcare, Amsterdam, Netherlands), and the attending anesthesiologist was blinded to the intermittent oscillometric arterial pressures.

In the control group, arterial pressure was measured at 1-minute intervals using standard upper-arm cuff oscillometry. The attending anesthesiologist was blinded to the finger-cuff arterial pressure readings.

Upon arrival in the operating room, standard monitoring was initiated, including pulse oximetry and electrocardiography. Intermittent blood pressure monitoring commenced at 1-min intervals using a sphygmomanometer with standard upper-arm cuffs (Comfort Care multi-patient use cuff, adult, Philips Healthcare, Amsterdam, Netherlands), which was connected to the patient monitor. Concurrently, continuous non-invasive blood pressure monitoring began using the ClearSight system (Edwards Lifesciences, Irvine, California, USA) with an appropriately sized finger-cuff on the contralateral middle finger. Before administering spinal anesthesia, baseline SAP was measured with the patient in the supine position. For the treatment group, baseline SAP was defined as the average SAP over three minutes using the ClearSight system. In the control group, baseline SAP was determined as the average of three consecutive measurements obtained via oscillometric arm cuffs. For safety reasons, if the baseline SAP values obtained by the finger-cuff and brachial-cuff methods differed by > 10%, the parturient was excluded from the study.

The heart reference sensor was placed at the level of the heart, and the ClearSight system was zeroed before commencing measurements. Continuous beat-to-beat finger-cuff arterial pressure measurements were automatically averaged over non-overlapping 20-s intervals, and the data were extracted from the ClearSight system. Intermittent oscillometric arterial pressure data were extracted from the Vital Recorder program, which automatically records data from patient monitors into a single case file[31].

Anesthetic management

All patients received standard spinal anesthesia. With the patient in the lateral decubitus position, we administered 9 mg of 0.5% hyperbaric bupivacaine with 10 μg of fentanyl intrathecally at the L3-4 or L4-5 intervertebral space using a 27G Sprotte spinal needle. During the spinal procedure, we co-loaded 500 ml of crystalloid (Plasma Solution A, HK Inno. N Corp., Cheongju, Korea). Lateral uterine displacement was applied after the spinal procedure to prevent maternal hypotension. Sensory blockade was assessed using cold swabs and pinprick tests at 1, 5, and 10 min after administering spinal anesthesia. Surgery commenced when the sensory level reached T6, as determined by a cold swab.

Arterial pressure management

Immediately after administering spinal anesthesia, a prophylactic phenylephrine infusion was commenced at an initial rate of 25 μg/min in both groups. The attending anesthesiologist titrated the phenylephrine infusion rate to maintain the SAP > 90% of baseline SAP. The infusion rate was titrated according to the following protocol.

1. SAP < 90% of baseline: infusion rate increased by 2.5 μg/min.
2. SAP < 80% of baseline: infusion rate increased by 5 μg/min.
3. SAP < 70% of baseline: infusion rate increased by 10 μg/min.
4. SAP < 80% of baseline for > 2 min: 100 μg of rescue phenylephrine was administered.
5. SAP < 80% of baseline for > 2 min after administration of 100 μg of phenylephrine: 5 mg of ephedrine was administered.
6. SAP baseline: rate decreased by 10 μg/min.
7. SAP baseline for > 2 min: the phenylephrine infusion was discontinued and reinitiated at 25 μg/min if the SBP was < 90% of baseline SAP.

We administered intravenous atropine (0.5 mg) in cases of bradycardia (defined as a heart rate [HR] < 50 bpm). Intravenous ondansetron 4 mg was administered to treat severe nausea and vomiting.

Outcomes

The primary outcome was the incidence of maternal hypotension, defined as an SAP < 80% of baseline SAP, from the completion of spinal anesthesia until delivery. To ensure a standardized methodology for comparison, oscillometric blood pressure data were used for the primary analysis in both groups, as this method is the established clinical standard for non-invasive blood pressure measurement[13,32]. Additionally, we performed a sensitivity analysis using finger-cuff data for the treatment group and oscillometric data for the control group. This approach was intended to reflect the actual clinical strategies employed in each group and to evaluate the robustness of the results across different analytical standards.

Secondary outcomes included the following: the amount of hypotension was quantified using the TWA, AUC, and cumulative duration of SAP < 80% of baseline. The amount of hypotension was further characterized using SAP < 70% of baseline SAP. Additionally, to evaluate the robustness of our results, we performed pre-planned exploratory analyses using various MAP-based thresholds: MAP < 65, 60, and 55 mmHg. The incidence of symptomatic hypotension (defined as hypotension plus nausea and/or vomiting), nausea, vomiting, dizziness, breathlessness, and hypertension (defined as SAP > 120% of baseline), and maximum and minimum SAP and MAP were assessed. We assessed the onset time of hypotension, phenylephrine consumption, incidence of bradycardia (defined as HR < 50 bpm), number of atropine uses, and minimum HR. Maternal outcomes were measured from the completion of spinal anesthesia until delivery. Neonatal outcomes included 1- and 5-min Apgar score, umbilical arterial pH, base excess, PO_2, and PCO_2, and the incidence of umbilical arterial pH < 7.2. Finally, the agreement between the two methods (ClearSight system and oscillometer) was assessed.

Sample size determination

In a previous study conducted at our institution[6], the incidence of hypotension was 62%. We considered an absolute reduction of 25% in hypotension incidence to be clinically significant. To detect a clinically significant

between-group difference of 25% with 80% power and 5% significance level, 70 patients per group were required (G* Power version 3.1.9.2). After accounting for a 10% dropout rate, a sample size of 77 patients per group was required.

Statistical analysis

The modified intention-to-treat principle was applied to all analyses. We calculated the standardized difference to evaluate the balance of baseline characteristics between groups. If the absolute standardized difference exceeded 0.32 (32%; $1.96 \times \sqrt{\frac{1}{74} + \frac{1}{77}}$), the baseline variable was considered different[33]. Continuous data were tested for normality using Q–Q plots. Normally distributed data were compared using the Student's *t*-test, non-parametric data using the Wilcoxon rank sum test, and categorical data using the chi-square or Fisher's exact test, as appropriate. The primary outcome was compared using the chi-square test. In a sensitivity analysis, adjustments were made for baseline variables with a standardized difference of > 0.32 using logistic regression for categorical data and analysis of covariance (ANCOVA) or non-parametric ANCOVA for continuous data. Hypotension's onset time was estimated using the Kaplan–Meier method and compared between the groups using the log-rank test. The Cox proportional hazard method was used to adjust for imbalanced baseline variables. The agreement between SAP from the finger-cuff and standard oscillometry was analyzed using the Bland–Altman plot, corrected for repeated measurements. The Bland–Altman plot for the overall dataset, from anesthesia completion to delivery, was plotted, and the results are presented as mean difference (± SD) and 95% limits of agreement[23,34]. The Bland–Altman plots were constructed separately for baseline, immediately after anesthesia completion, 5 min after anesthesia, and 1 min before delivery[35]. The within-subject variance was estimated using a random-effects model[36–38]. To identify proportional bias, linear regression using generalized estimating equation was conducted. To address the potential bias arising from the three missing data in the control group, we conducted a sensitivity analysis using best-case and worst-case scenario approaches. In the best-case scenario (favorable to the treatment group), the missing cases in the control group were assumed to have experienced hypotension, with TWA, AUC, and duration imputed with the maximum observed values. Conversely, in the worst-case scenario, these cases were assumed to have had no hypotension, with values imputed using the minimum observed values. Data were analyzed using SAS 9.4 Version (SAS Institute Inc., Cary, NC, USA), and a P value < 0.05 was considered statistically significant.

Data availability

Data supporting this study are available from the corresponding author upon reasonable request.

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Author contributions

YK and S-KP contributed to conceptualization, methodology, formal analysis, data curation, visualization, and investigation. HK and DYG curated the data. J-TK and SY contributed to methodology and investigation. S-KP supervised the project and performed project administration. YK and S-KP wrote the original draft. All authors reviewed and approved the final manuscript.

Declaration

Competing interests

The authors declare no competing interests.

Additional information

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