

# Prevention of post-spinal anaesthesia hypotension in caesarean delivery using delayed supine positioning - A randomised controlled trial

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## ABSTRACT

**Background and Aims:** Maternal hypotension is a common and dangerous consequence after a subarachnoid block for a caesarean section. Combining pharmacological methods such as norepinephrine infusion, ondansetron and non-pharmacological methods in delayed supine positioning better impacts the maternal haemodynamic profile. The present study assessed the benefits and adverse effects of combining pharmacological and non-pharmacological methods in hypotension prophylaxis. **Methods:** This randomised controlled trial was conducted at Cairo University Hospital's obstetric theatre from January to October 2020. The study included 85 parturients who were randomised to two groups. Group Sitting was left seated for 2 min after injection, and Group Control was made to lie down in the supine position immediately after the subarachnoid block. Both groups received prophylactic intravenous norepinephrine infusion, in addition to an ondansetron bolus, before surgery. Patients' systolic blood pressure (SBP) from intrathecal injection until delivery of the foetus, was documented. **Results:** The Sitting group's SBP (122 (14) mmHg) till delivery was statistically higher than the Control group's readings (114 (10) mmHg) ( $P = 0.004$ ). The Sitting group's intraoperative SBP values were often greater than the Control group values. In addition, the Sitting group had a reduced hypotension incidence and a lower rate of ephedrine use than the other group, but bradycardia incidence was comparable between both groups. **Conclusion:** In elective caesarean delivery, combining pharmacological and non-pharmacological methods achieve better results regarding maternal hypotension, vasopressor consumption, nausea and vomiting, and foetal outcomes.

**Keywords:** Caesarean section, hypotension, norepinephrine, ondansetron, sitting, subarachnoid block, supine position

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## INTRODUCTION

After a subarachnoid block (SAB) for a caesarean section, maternal hypotension is a common consequence that may have major maternal and foetal concerns. Prophylaxis against maternal hypotension can be achieved in various ways, including fluid administration, pharmacological agents or patient positioning.<sup>[1-3]</sup> Even though fluid loading is preferable to non-loading methods in caesarean deliveries, all fluid-loading protocols do not significantly lower post-spinal hypotension (PSH) incidence.<sup>[2]</sup> Using vasopressors like ephedrine and phenylephrine might cause side effects such as foetal acidosis and reflex

bradycardia. As a result, combining vasopressor prophylaxis with non-pharmacological methods could help lessen the dose of vasopressors and negative effects.<sup>[1]</sup> Ondansetron is recognised as a safe and

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effective PSH prevention medicine with few adverse effects.<sup>[3]</sup> Techniques like head-down and head-up positions, sequential compression and leg wrapping devices, mechanical displacers or wedges, and operating table flexing or tilting are used to promote venous return or reverse aortocaval compression.<sup>[2]</sup>

Another aspect of positioning regimen is keeping the patient sitting for a short interval following the SAB to delay the block's onset. The slow neuraxial block's onset is supposed to enable the body to adapt to the sympathetic blockade, providing a better haemodynamic profile.<sup>[4]</sup> Maintaining the patient sitting after a subarachnoid block also prevents the local anaesthetic from spreading to the upper thoracic dermatomes, which is essential for avoiding PSH. In the supine position, gravity and the quick compression of the dural sac drive the cerebrospinal fluid (CSF) and the local anaesthetic solution towards the cranial direction. This posture also results in vena cava blockage and acute epidural venous plexus engorgement, resulting in excessively high block levels.<sup>[5]</sup> A few studies have evaluated the impact of delayed supine positioning on maternal haemodynamics after SAB anaesthesia.<sup>[6]</sup>

In the context of a multimodal strategy for preventing maternal hypotension, previous research has yet to assess the effects of sitting. Therefore, this research aims to examine the influence of a 2-min sitting position following SAB anaesthetic administration on maternal haemodynamics, when paired with prophylactic intravenous (IV) norepinephrine infusion and a preoperative bolus of ondansetron. We hypothesised that combining delayed supine posture following subarachnoid block anaesthetic with pharmacological prophylaxis might be superior to pharmacological prophylaxis alone in preserving maternal haemodynamic profile and appropriate block level.

## METHODS

This randomised controlled study was conducted from January to October 2020 after obtaining approval from the Research Ethical Committee, Faculty of Medicine Cairo University (vide approval number MD-85-2019, dated 14 September 2019). This study was carried out in accordance with the principles of the Declaration of Helsinki, 2013. The study was registered on [clinicaltrials.gov](https://clinicaltrials.gov) (vide registration number NCT04777123).

Before enrolment in the study, all subjects provided written informed consent for participation and use of the patient data for research and educational purposes. Inclusion criteria were parturients with full-term (above 37 weeks' gestation), singleton pregnancy, aged between 18 and 35 years, and scheduled for elective caesarean section under SAB anaesthesia. Exclusion criteria were foetal abnormalities, pregnancy-induced hypertensive disorder, contraindications to spinal anaesthesia, pre-existing hypertension, cardiac arrhythmias (i.e. sinus tachycardia and any rhythm apart from normal sinus rhythm), obese patients (body mass index [BMI] >35 kg/m<sup>2</sup>), valvular heart lesions, peripartum bleeding and impaired cardiac contractility (left ventricular ejection fraction <45%).

A statistician used an online random number generator to conduct randomisation. A research assistant who did not participate in the trial inserted sequentially numbered, opaque and sealed envelopes with patient codes. It was the responsibility of an anaesthesia resident who was not engaged in patient treatment to open the envelope.

Upon arrival, monitors were applied in the operation room (non-invasive blood pressure monitors, pulse oximeter and electrocardiogram) (GE Solar™ 8000i; GE Healthcare, Chicago, IL, USA). In the supine position, the baseline systolic blood pressure (SBP) was determined as the mean of three consecutive measurements at 2-min intervals, with a variance of <10%. All measurements were recorded before premedication and intravenous (IV) line insertion. Following peripheral IV 18-gauge line insertion, IV ondansetron (4 mg) and ranitidine (50 mg) were administered. SAB was obtained under complete asepsis in L4–L5 or L3–L4 interspace in a sitting position with a 25 G sharp bevelled needle. Subsequently, fentanyl (25 µg) and 0.5% hyperbaric bupivacaine (11 mg) were administered. The first (sitting) group was left seated for 2 min after injection, and the second (control) group lay down immediately after injection; both groups were put in a left lateral tilt with supine position lying down, and co-hydration was continued up to a total of 1.5 L of IV lactated Ringer's solution. Continued norepinephrine infusion was started in both groups in the form of IV 5 µg norepinephrine bolus [simultaneously with the injection of SAB anaesthetic], followed by norepinephrine fixed-rate infusion at an initial dosage of 0.05 µg/kg/min. Norepinephrine was prepared as 8 µg/mL and was delivered using a syringe pump. After

foetal delivery, oxytocin was administered as a bolus of 0.5 IU over 5 s and then by an infusion of 2.5 IU/h. Until delivery, the inspired air was supplemented with 3 L/min of oxygen using a nasal catheter.

In addition to a motor block, the effectiveness of the SAB was evaluated with sensation or using a pinprick test. PSH (defined as a reduction in SBP to less than 80% of the baseline value between intrathecal injection and the birth of the foetus) was treated with IV ephedrine (9 mg). Afterwards, IV ephedrine (15 mg) was used to treat severe PSH (defined as a drop in SBP <60% of the baseline value). Additional vasopressor bolus was administered if the patient's blood pressure did not react to the first dosage within 2 min. By discontinuing norepinephrine infusion, intraoperative hypertension (defined as SBP >120% of the baseline measurement) was controlled. The infusion was restarted when the patient's blood pressure returned to normal. Stopping the vasopressor infusion was used to treat intraoperative bradycardia (defined as a heart rate <55 bpm without hypotension between intrathecal injection and foetus delivery). If bradycardia was accompanied by hypotension (SBP less than 80% of the baseline value), the patient was treated with IV ephedrine (9 mg). If bradycardia continued following the above mentioned procedures or was not accompanied by hypotension, a bolus of IV atropine (0.5 mg) was administered.

Parturients with intraoperative blood loss >1000 mL, high spinal block patients (i.e. subarachnoid block anaesthesia where spinal denervation extends to the third or second thoracic dermatome and, in some cases, up to the cervical dermatome) and failed SAB cases (i.e., a sensory level below T4) were excluded from the analysis.

The primary outcome was the change in SBP, with parturient position as per the group allocation following SAB, when paired with prophylactic IV norepinephrine infusion and a preoperative bolus of IV ondansetron. Secondary outcomes included haemodynamic data (diastolic, mean, pulse pressure, heart rate). All start from the baseline reading (before giving SAB), including the following readings, until the first reading after the delivery of the foetus. PSH incidence (defined as the proportion of patients with declined SBP <80% of the baseline value) throughout the interval from intrathecal injection to the foetus delivery was assessed. During the interval between subarachnoid block and foetus delivery, severe PSH

incidence (defined as the proportion of patients with an SBP <60% of the baseline value) was also measured. The study also assessed post-delivery hypotension (the percentage of people whose SBP was less than 80% of what it was before the baby was delivered), and oxytocin was initiated. Reactive hypertension reported within 2 h (measured as an SBP more than 80% of the baseline value) was also assessed. Other parameters assessed included the SAB analgesia level and duration, vomiting and nausea during surgery, and norepinephrine and ephedrine intraoperative requirements. Other collected data included the amount of lost blood and the fluids consumed during surgery, time from SAB until delivery, and the interval between skin incision and foetus delivery. Umbilical blood gases, that is, bicarbonate ( $\text{HCO}_3^-$ ), partial pressure of oxygen ( $\text{pO}_2$ ), partial pressure of carbon dioxide ( $\text{pCO}_2$ ) and potential of hydrogen (pH), and the Appearance, Pulse, Grimace, Activity and Respiration (APGAR) score of neonates were measured at 1 and 5 min following delivery.

In a pilot trial including 15 subjects, we reported mean (standard deviation [SD]) SBP in the first 30 min following SAB in patients receiving pharmacological prophylaxis (IV norepinephrine infusion plus ondansetron) of 105 (17) mmHg. We used the 14.10.2 MedCalc Software (MedCalc Software, Ostend, Belgium) to determine the sample size that can detect a 10% difference in average SBP (i.e. 10.5 mmHg) between the two study cohorts. A minimal total number of 84 cases was required (42 in each group). Calculations were done using a study power of 80% and an alpha error of 0.05.

The Statistical Package for the Social Sciences (SPSS) software for Microsoft Windows (SPSS Inc., Chicago, IL, USA) was used for data analysis. Categorical data (incidence of hypotension, severe hypotension and bradycardia, incidence of nausea and vomiting) were presented as frequency (%) and analysed by Chi-square test. Continuous data (age, weight, BMI, time intervals, blood pressure, heart rates, total ephedrine and norepinephrine infusion) were tested for normality using the Shapiro–Wilk test and expressed as median (interquartile range) and mean (SD) as appropriate. Continuous data were analysed using Mann–Whitney (hypotensive episodes per mother, post-delivery hypotension episodes, duration of analgesia, amount of blood loss, urine output, APGAR score at 1 and 5 min, umbilical pH,

pO<sub>2</sub>, pCO<sub>2</sub>, HCO<sub>3</sub>) or unpaired *t*-test (age, weight, BMI, time intervals, blood pressures, heart rates, total ephedrine and norepinephrine consumption).

**RESULTS**

Ninety-eight women were screened for eligibility, and there were 43 females in the Control group and 42 females in the Sitting group in the final analysis [Figure 1]. Both groups' baseline haemodynamic characteristics and demographics were comparable [Table 1].

The Sitting group had a significantly higher BP than the control group (*P* = 0.004) [Table 2]. The Sitting group had higher intraoperative SBP measurements than the controls. SBP was generally maintained in the sitting group relative to the baseline reading; the intraoperative SBP readings in controls decreased than the baseline reading [Figure 2].

In addition, patients in the sitting group had ephedrine at a lower rate and elevated rates of hypertension, and lower incidence of severe hypotension than controls [Table 2].

**Table 1: Baseline haemodynamic features and demographic data**

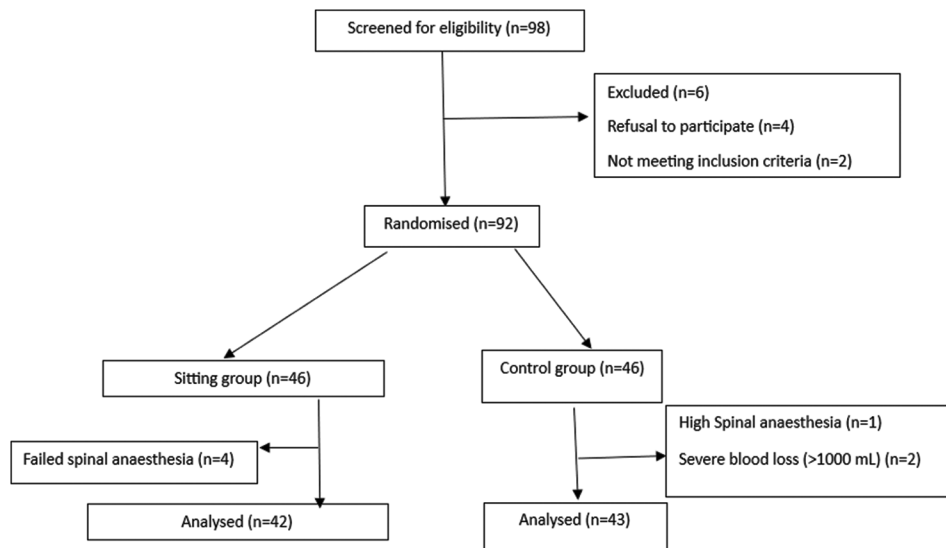
	Sitting group (n=42)	Control group (n=43)	P
Age (years)	28 (6)	28 (5)	0.644
Weight (kg)	78 (11)	77 (10)	0.695
Body mass index (kg/m <sup>2</sup> )	29 (3)	29 (4)	0.897
Time from spinal anaesthesia until delivery (min)	29 (5)	29 (8)	0.804
Time from incision until delivery (min)	21 (4)	21 (6)	0.719
Baseline systolic blood pressure (mmHg)	125 (10)	126 (10)	0.657
Baseline heart rate (bpm)	97 (13)	92 (14)	0.101

Data are expressed as mean (standard deviation). n=number of patients

**Table 2: Intraoperative maternal haemodynamics**

	Sitting group (n=42)	Control group (n=43)	Mean difference (95% confidence interval)	P
Incidence of hypotension	12 (29)	27 (63)	0.45 (0.35–0.57)	0.002
Hypotensive episodes per mother	0 (0, 1)	1 (0, 3)	1.13 (0.7–1.55)	<0.001
Incidence of severe hypotension	0	6	0.1 (0.01–0.18)	0.012
Incidence of post-delivery hypotension	9	23	0.07 (0.02–0.13)	0.002
Post-delivery hypotension episodes	0 (0, 1)	1 (0, 3)	0.79 (0.5–1.05)	<0.001
Total ephedrine (mg)	0 (0, 9)	30 (0, 45)	18.4 (12.4–24.3)	<0.001
Total norepinephrine infusion (µg)	207 (47)	200 (38)	203 (194–212)	0.450
Incidence of hypertension	11	2	0.14 (0.07–0.22)	0.006
Hypertension episodes per mother	0 (0, 1)	0 (0, 0)	0.48 (0.17–0.77)	0.007
Incidence of bradycardia	0	1	1.01 (–0.01 to 0.4)	0.320

Data are expressed as frequency, median (25, 75 quartiles) and mean (standard deviation)



**Figure 1: Patients' enrolment flowchart**

The intraoperative heart rate values of the two groups were similar. In both cohorts, the heart rate dropped from the baseline value (starting from 4 and 14 min following spinal anaesthesia in the Sitting and Control groups, respectively) [Figure 3]. Both groups had comparable bradycardia rates [Table 2].

Vomiting and nausea rates were reduced in the Sitting group compared to Controls. It was discovered that the Sitting group's analgesia lasted less time than it did in the Control group. Other maternal outcomes, including blood loss and urine output, were comparable in both cohorts [Table 3].

The Sitting group demonstrated a better neonatal APGAR score at 1 and 5 min and a better umbilical artery pH than the Control group. However, both groups were comparable regarding other umbilical artery blood gas parameters [Table 3].

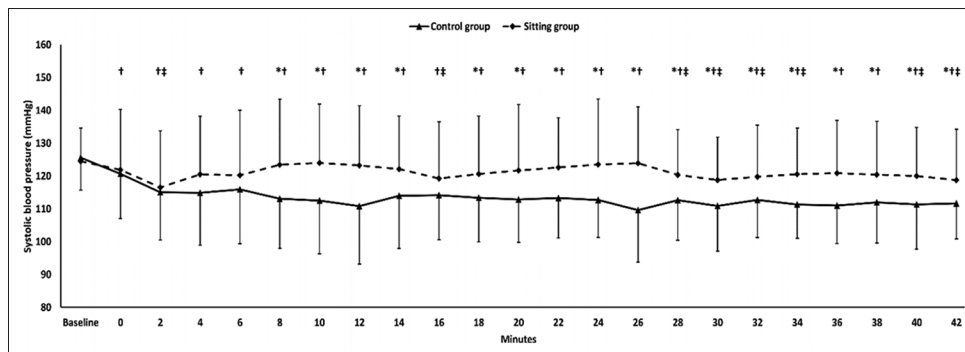
## DISCUSSION

The Sitting group's average SBP was significantly higher than that of the control group. In addition, the Sitting group had a reduced chance of hypotension with lower ephedrine consumption and an increased

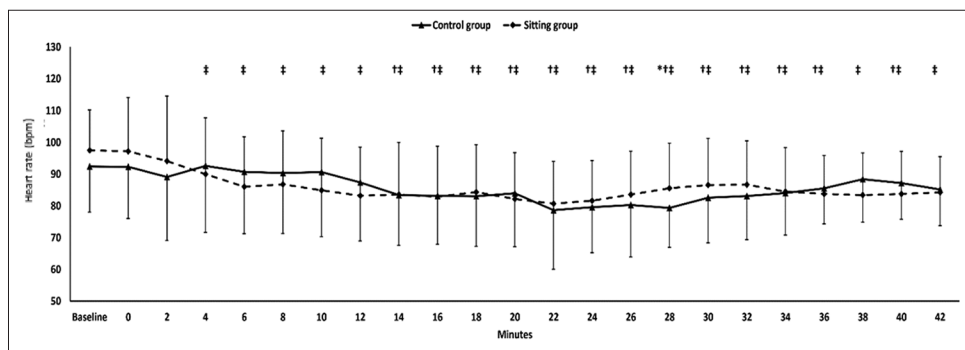
risk of hypertension. Regarding bradycardia, its incidence rates were comparable in both groups.

Vagal reflexes are more prevalent with the patient in sitting position. Also, uterine perfusion is greater in the lateral decubitus position, and when neuraxial anaesthesia is administered in the lateral position, epidural vein puncture is less likely due to reduced hydrostatic pressure.<sup>[7]</sup> Improved haemodynamics and lower demand for ephedrine were observed when the SAB was administered in the sitting position compared to the lateral position.<sup>[8,9]</sup>

Regarding haemodynamics, in contrast to our study, Kohler *et al.*<sup>[10]</sup> compared lying down immediately after the SAB to having patients sit upright for 3 min before lying down. They did not detect a variation regarding the total dose of ephedrine and the patient percentage requiring ephedrine for treating hypotension. These results might be partially attributed to the larger amount of hyperbaric bupivacaine used (0.5% hyperbaric bupivacaine, 2.8 mL) and the mild degree of lateral tilt used (10°), which has been linked to aortocaval compression.<sup>[10]</sup> In agreement with our study, El-Hakeem *et al.* observed that sitting for 5 min after less ephedrine and fluid requirements accompanied SAB



**Figure 2:** SBP. Markers are error bars, and means are the standard deviation. \*Implies significance between both cohorts, †indicates significance compared to the baseline reading in controls, ‡ indicates significance compared to baseline reading in the sitting group



**Figure 3:** Heart rate. \*Implies significance between both cohorts, †indicates significance compared to the baseline reading in controls, ‡ indicates significance compared to baseline reading in the sitting group

Table 3: Foetal and maternal outcomes

	Sitting group (n=42)	Control group (n=43)	Mean difference (95% confidence interval)	P
<b>Maternal outcomes</b>				
Duration of analgesia (min)	120 (90–128)	120 (120–150)	123 (117–128)	0.060
Blood loss (mL)	750 (500–900)	700 (500–800)	670 (621–723)	0.271
Urine output (mL)	300 (200–500)	200 (200–500)	333 (290–373)	0.132
Incidence of nausea	4	16	0.24 (0.14–0.33)	0.003
Incidence of vomiting	3	13	0.19 (0.1–0.27)	0.006
<b>Foetal outcomes</b>				
APGAR 1 min	7 (7–8)	7 (6–8)	7.36 (7.1–7.6)	0.021
APGAR 5 min	9 (9–10)	8 (8–9)	8.8 (8.6–9)	<0.001
<b>Umbilical artery blood gas parameters</b>				
pH	7.28 (7.22–7.32)	7.20 (7.18–7.29)	7.25 (7.24–7.26)	0.017
pCO <sub>2</sub> (mmHg)	42 (39–44)	45 (35–50)	43 (41.3–44.8)	0.117
pO <sub>2</sub> (mmHg)	23 (17–30)	23 (10–30)	21.5 (19.5–23.6)	0.979
HCO <sub>3</sub> (mmol/L)	20 (17–22)	18 (17–22)	19.8 (19.2–20.5)	0.184

Data are presented as frequency and median (25, 75 quartiles). APGAR=Appearance, Pulse, Grimace, Activity and Respiration, CI=confidence interval, pCO<sub>2</sub>=partial pressure of carbon dioxide, pH=potential of hydrogen, pO<sub>2</sub>=partial pressure of oxygen

administration without affecting SBP.<sup>[11]</sup> Moore *et al.* found that superior maternal haemodynamic profiles were observed on sitting for 2 min, where the seated time increased with an increase in bupivacaine dose.<sup>[6]</sup>

This study is limited to a single centre; patients with significant blood loss (>1000 mL) and those with pregnancy-related hypertensive disorders were excluded.

## CONCLUSION

Combining pharmacological (norepinephrine infusion and ondansetron) and non-pharmacological methods (sitting position) to prevent PSH will achieve better maternal hypotension, vasopressor consumption, nausea and vomiting, and foetal outcomes in mothers undergoing planned caesarean section.

### Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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