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Research Article

A new modality for improving the efficacy of intrathecal injection for cesarean section

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Abstract *Background:* Intrauterine resuscitation (IUR) is to improve O2 delivery to the placenta and umbilical blood flow, for reversal of foetal hypoxia and acidosis. We evaluated whether maintaining a lateral position after an intrathecal injection of a relatively low dose of hyperbaric bupivacaine and high dose of fentanyl improving the efficacy of spinal anaesthesia, IUR and preventing hypotension during cesarean delivery.

Methods: One hundred and seventy two healthy women undergoing elective cesarean delivery were enrolled in a double blind prospective randomized study. Spinal anesthesia was conducted in the right lateral position which maintained for 6 min for all the patients participated in the study, and then the subjects were turned supine. Patients were randomly allocated to two groups: low-dose spinal bupivacaine (LD) group ($n = 86$) patients received 6 mg of hyperbaric bupivacaine 0.5% and 15 μg of fentanyl, high-dose spinal bupivacaine (HD) group ($n = 86$) patients received 10 mg of hyperbaric bupivacaine and 15 μg of fentanyl. The incidence of hypotension and nausea, ephedrine requirement, maximal block height, and Apgar score at 1 and 5 min.

Results: The authors found significant decrease in MAP in the group that was given the high dose of bupivacaine the incidence of hypotension was 80% but the LD spinal bupivacaine group was hemodynamically stable. The lowest blood pressure, boluses of inj. ephedrine used, or nausea were more significant in the HD group than in LD group. Onset of hypotension was more rapid (8 ± 3 vs. 16 ± 6 min, $P < 0.001$), and the sensory block level was more cephalad in HD group than in LD group (T2 [C8–T5] vs. T4 [T1–T6], $P = 0.001$). Apgar scores did not differ between the groups.

Conclusion: Maintaining the lateral position for 6 min after an intrathecal injection of a relatively

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low dose of hyperbaric bupivacaine and high dose of fentanyl resulted in improving the efficacy of spinal anaesthesia, IUR by more gradual and higher cephalad sensory block, without an increase in the incidence of maternal hypotension.

1. Introduction

In routine obstetric practice for the sake of intrauterine resuscitation (IUR) parturients are usually kept in the lateral position but they have to be placed supine for caesarean section. The syndrome of "Supine hypotension" presents an enigmatic challenge to an obstetric anesthesiologist who is actively involved in IUR especially during establishment of regional anaesthesia for caesarean delivery of foetus [1].

It may be possible to reduce maternal hypotension if the simultaneous effects of sympathetic block by spinal anesthesia and aortocaval compression by the gravid uterus in the supine position were avoided [2]. Therefore a need for uterine displacement device was felt. Various devices were tried such as a 15° wedge [3], inflatable wedge [4,5] and left lateral table tilt positions of various angles [6]. However, this methods cannot completely abolish hypotension. It was noted that initial position of the patient just after placement of spinal block affect the maximum height of block attained and thus degree of hypotension [1].

Hypotension during cesarean delivery generally occurs around 6 min after intrathecal injection [7–9] however, delayed supine positioning from sitting as a new mode for intrathecal injection was the aim of many authors researches of obstetric anesthesia. They reported that the characteristics of block spread differ somewhat and an insufficient sensory block by hyperbaric anesthetics which may resulting from delayed supine positioning from sitting position [2,9,10].

As sensory block height was more predictable and hemodynamics stablity after administered intrathecal injection in the left lateral position with Oxford position [11], this opened the way for investigation to the lateral position for a period of 6 min after an intrathecal injection, the authors reported a more gradual and higher satisfactory cephalad sensory block, without hemodynamics stablity with an increase in ephedrine requirement [2] but we could not find in this studies, authors comments on the influence of different injected intrathecal doses of hyperbaric bupivacaine, with a same parturient position, in maternal hypotension and IUR.

Therefore, our new modality in maintaining a lateral position for 6 min after an intrathecal injection of a relatively low dose of hyperbaric bupivacaine and high dose of fentanyl would be helpful for improving the efficacy of spinal anaesthesia, IUR and preventing hypotension during cesarean delivery.

2. Materials and methods

A double-blind prospective randomized study enrolled, 172 ASA physical status I and II full-term gestation participants women who were scheduled to undergo non-emergent lower segment caesarian section. Females of age between 20 and 35 yrs having a height of 160–170 cm and weight of 70–80 kg were included after approval by the Hospital ethical committee and the written informed consent. Parturients with preexisting hypertension, preeclampsia, cardiovascular disease, diabetes, obesity, or multiple pregnancies were excluded.

Electrocardiography and pulse oximetry were monitored. The cuff of an automated noninvasive blood pressure (BP) device was attached to the right arm, and maximum abdominal circumference was measured. Intravenous access was prepared with an 18-gauge cannula in the left forearm. Oxygen (5 L/min) via a facial mask was applied to all patients from the beginning of spinal anesthesia. After a 5-min rest, BP and heart rate were measured three times at 1-min intervals in the wedged supine position. The average value of the second and third mean BP values was recorded as the baseline value [10,12]. Each patient received 1000 mL of lactated Ringer's solution and 500 mL of Hetastarch 6% (Voluven®, Fresenius, France), and spinal anesthesia was induced in the right lateral decubitus position. A 25-gauge spinal needle was inserted under strict aseptic conditions at the L3-4 interspace after clear cerebrospinal fluid appeared.

Using sealed envelopes, patients were randomly allocated to two groups: HD group, patients received 10 mg of hyperbaric bupivacaine 0.5% (Marcaine®, AstraZeneca, Södertälje, Sweden) and 15 μg of fentanyl and LD group patients, received 6 mg of hyperbaric bupivacaine and 15 μg of fentanyl. The lateral position was maintained for 6 min for all the patients participated in the study, and then the subjects were turned supine. To displace the uterus to the left, an air balloon (1500 mL) was inserted under the right upper buttock in the supine position in both groups.

The intrathecal injections were prepared by an anaesthesiologist who was not involved in any other aspect of the study. All syringes were identical and had similar volumes. The investigator who administered the drug, the anaesthesiologist who performed the intrathecal injections and the patients, were unaware of the group allocated and the drug that was received by the patient. After this, all hypotension measurements and treatments were made by another observer who was blinded to the patient group.

The sensory block level was assessed separately on each side (right vs. left) using a pinprick test at 2-min intervals for 20 min. The times from intrathecal injection to achieving the loss of sensory stimulation at the T6 level and to achieving the highest sensory level blocked were checked. BP and heart rate were evaluated every min until delivery. Ephedrine was administered in increments of 5 mg at 2-min intervals [2,11] intravenously to treat hypotension which defined as a decrease in mean BP by $\geqslant 20\%$ from baseline. If the BP decreased $> 30\%$ (severe hypotension). In addition, as per our routine praxis, when patients felt nauseated or vomiting the same treatment was initiated regardless of the arterial blood pressure values obtained at that time. The incidence of nausea and vom-

iting during the intraoperative period was recorded. The time from completion of spinal induction to delivery and the time from skin incision to delivery were recorded. Neonates were evaluated by Apgar score at 1 min and 5 min after birth, and an umbilical arterial blood gas analysis was conducted.

2.1. Statistical analysis

The results of previous studies [1,2,9,13] had indicated that a sample size of a minimum 43 subjects in each group would yield 80% power analysis, a significance level of 0.05 and demonstrate a 50% absolute difference in ephedrine requirements (8 vs. 14.5 mg or 6 vs. 12 mg) between two groups (common SD, 9.2 mg) of patients in different positions. Based on these findings we decided to recruit 180 parturients which a relatively large sample size in contrast to previous studies, may have allowed for greater elucidation of differences comparing two different doses hyperbaric bupivacaine with the same position.

Statistical analysis was performed using the unpaired Student's *t*-test or rank-sum test, and the chi-square or Fisher's exact test, as appropriate. Significance was indicated by $P < 0.05$.

3. Results

The patient flow diagram is illustrated in Fig. 1 showed that one hundred eighty parturients were evaluated for eligibility. Eight parturients were excluded. Two patients because of refusal, two patients for emergent delivery, two patients for inadequate block at the first trial, and two patients for hypertension at baseline. The remaining 172 parturients (86 per group) finished the study.

No significant differences in age, body weight, height, body mass index, or abdominal circumference were observed between the groups (Table 1).

The incidence of hypotension were statistically significant between the two groups ($P = 0.004$ and $P = 0.55$ respectively). Preoperative BP and the lowest BP were similar in LD group, but were statistically significant in HD group. The time from the spinal injection to the lowest BP was significantly longer in LD group compared with HD group (16 ± 6 vs. 8 ± 3 min, respectively, $P < 0.001$). The total amount of ephedrine were statistically highly significant in HD group ($P = 0.004$), and not used in LD group. The incidence of nausea and vomiting was highly significant in HD group ($P = 0.001$) and 32 parturients (37%) were given ephedrine because of nausea and vomiting (Table 2).

The sensory block characteristics are summarized in (Table 3). Initially, the spread of sensory block was significantly delayed in LD group compared with HD group ($P = 0.001$); however, the final sensory block level was higher in HD group ($P = 0.001$). No discrepancy in the highest sensory block level was observed between the right and left sides in either groups. No one in LD group while 42 subjects in HD group achieved sensory block at a level higher than T2 (0% vs. 49%, respectively) ($P = 0.001$).

The time from spinal injection to delivery was delayed in LD group, but the time from skin incision to delivery was comparable between the groups (Table 3). All neonates had similar Apgar scores at 1 and 5 min. The umbilical arterial pH was slightly lower ($P < 0.001$) and PCO_2 was higher in HD group than in LD group ($P < 0.002$), but all values were within normal limits (Table 4).

4. Discussion

Hypotension during cesarean delivery is very common, particularly under spinal anesthesia. However, fewer studies have evaluated the role of IUR by maneuvers and drugs for

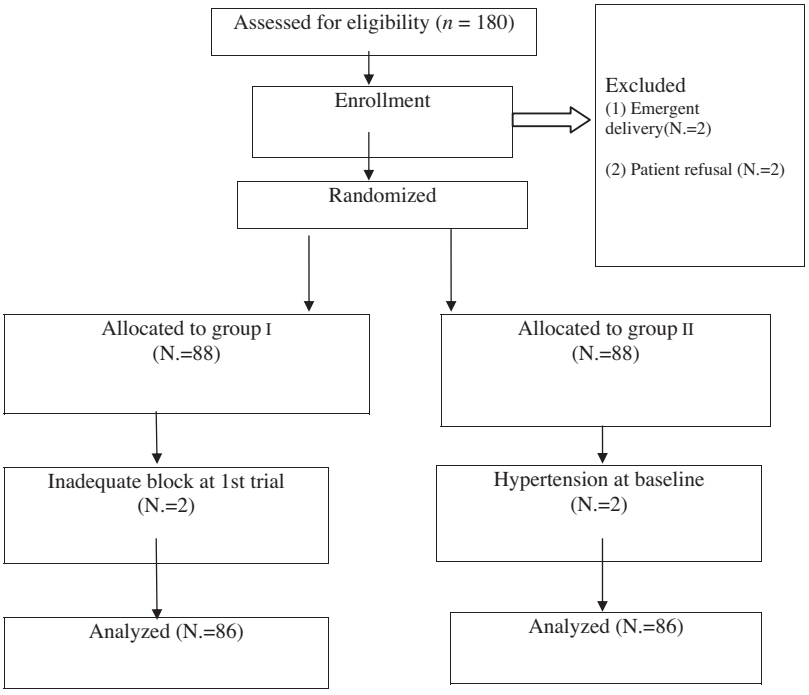

Figure 1 Trial profile.

Table 1 Demographic data.

	HD group (*N.* = 86)	LD group (*N.* = 86)
Age (yr)	34 (8)	35 (6)
Height (cm)	171 (10)	172 (11)
Weight (kg)	80 (18)	78 (20)
Body mass index (kg/m^2)	29 (20)	28 (10)
Abdominal circumference (cm)	105 (15)	100 (14)

Values are mean (SD).

improvement of foetal wellbeing [1]. Authors failed to identify any impact of maternal hypotension on perinatal infant outcome but stated that fetal acidosis have been associated with large doses of ephedrine in a retrospective study of 919 cesarean deliveries under spinal or epidural anesthesia, 47% of the parturients experienced a drop of >30% in mean BP compared with preoperative BP, but they implied that aggressive treatment for a mild decrease in BP is not essential for ensuring neonatal outcome during elective cesarean delivery [2,13,14].

However another study stated that healthy women receiving a very small-dose anesthetic solution of hyperbaric bupivacaine and sufentanil as part of a CSE technique in the sitting position, received less ephedrine but required more epidural supplementation, whereas the neonates had higher umbilical artery pH values as compared with those whose mothers had received the block in the lateral decubitus position [9].

Also, in a recent study when two different positions were compared in a prospective randomized manner following spinal anaesthesia demonstrated that maintaining a lateral position for 6 min after an intrathecal injection of hyperbaric bupivacaine delayed the spread of sensory block and the onset of hypotension during elective cesarean delivery and this was maximal decrease in BP due to sympathetic block which gen-

Table 2 Hemodynamic data of parturients.

	HD group (*N.* = 86)	LD group (*N.* = 86)	*P*-value
Baseline mean blood pressure (mmHg)	75 (15)	74 (14)	0.55
Lowest blood pressure after spinal anesthesia (mmHg)	55 (9)	73 (15)	0.004
Time from injection to the lowest blood pressure (min)	(3)8	16 (6)	0.001
Incidence of hypotension[a] (*N.*)	69 (80%)	0	0.001
Incidence of severe hypotension[b] (N.)	42 (49%)	0	0.002
Ephedrine requirement (mg)	15 (12)	0	0.004
Nausea/vomiting after spinal anesthesia (N.)	32 (37%)	0	0.001

Data are expressed as mean (SD) or as number (%). Hypotension (a): mean blood pressure < 80% of the baseline value, severe hypotension (b) <70% of baseline.

Table 3 Spinal anesthesia characteristics.

	HD group (*N.* = 86)	LD group (*N.* = 86)	*P*-value
Time to T6 sensory block (min)			
Left side	5.9 (1.8)	12.3 (2.5)	0.001
Right side	5.8 (1.9)	8.5 (1.7)	0.016
Highest sensory block level			
Left side	T2 (C8–T5)	T4 (T1–T6)	0.001
Right side	T2 (C8-T5)	T4 (T1–T6)	0.001
N. of patients sensory block >T2	42 (49%)		0.001
Time from injection to delivery (min)	21.5 (6.4)	27.0 (5.8)	0.016
Time from skin incision to delivery (min)	4.9 (1.3)	5.0 (1.2)	0.75

Data are expressed as mean (SD or range) or as number (%).

Table 4 Neonatal outcome: Apgar scores and umbilical artery gas analysis.

	HD group (*N.* = 86)	LD group (*N.* = 86)	*P*-value
Apgar score at 1 min	8 (7–9)	8 (7–9)	0.97
Apgar score at 5 min	9 (8–10)	9 (8–10)	0.66
Umbilical artery pH	7.28 (0.03)	7.30 (0.03)	0.001
PCO_2 (mmHg)	54.2 (5.8)	50.1 (4.6)	0.002
BE (mmol/L)	−2.7 (1.6)	−2.6 (1.5)	0.77
PO_2 (mmHg)	18.9 (4.2)	20.6 (5.2)	0.15

BE: Base excess. Data are expressed as median (range) or mean (SD).

erally occurs at about 6 min or later after intrathecal injection but the delay did not influence the incidence of maternal hypotension, intrauterine resuscitation or the ephedrine requirement [2].

As there were inconsistencies in the IUR results we have also noted a more conflict between authors when comparing two different positions after intrathecal injection of a same hyperbaric bupivacaine dose and this clear from the research of Coppejans et al. [9] and Kohler et al. [7] who compared the incidence of hypotension with parturients in the lateral and sitting positions during combined spinal–epidural anesthesia when a delay of up to 3 min was allowed to insert the epidural catheter before supine positioning, the former found that there was no difference in the incidence of hypotension, although the degree of hypotension was less severe in the sitting group and the latter found that 3 min of sitting before supine positioning could reduce the incidence of hypotension and failed to show a reduction.

This inconsistency was imperative for further study based on data obtained from Hwang et al. [2] and we demonstrated this study to compare the relative efficacy of two different intrathecal doses of hyperbaric bupivacaine and high dose of fentanyl in a prospective randomized manner following spinal anaesthesia during maintaining a lateral position for 6 min in improving the efficacy of spinal anaesthesia, IUR by more gradual and higher cephalad sensory block, without an increase in the incidence of maternal hypotension and decreased the ephedrine requirement.

Bryson et al. [15] investigated the dose effect of intrathecal bupivacaine during cesarean delivery and found that 4.5 and 12 mg of bupivacaine yielded similar sensory blocks. A relatively high-dose spinal anaesthesia (14 mg) was done by Cooper et al. [16] but they recommended phenylephrine infusion regimen to minimizine hypotension and nausea.

Therefore, our study was designed to administered 10 mg in HD group and 6 mg in LD group of bupivacaine and 15 μg of fentanyl for spinal anesthesia with maintaining the lateral position for 6 min. Although fentanyl was added, doses of bupivacaine is a relatively small dose compared with doses of 12–14 mg used in other studies [7,11,10,14,17]. The subjects height was considered in our estimation for the intrathecal bupivacaine dose on the basis of data obtained from studies done by Coppejans et al. [9] and Rucklidge et al. [18] who reported that 6.6 mg of bupivacaine with 10 μg of sufentanil produced maximal spread of the sensory block at T6 in parturients taller than ours (167 vs. 161 cm).

Contrary to our results Ben David et al. [19] found that with low-dose bupivacaine plus fentanyl, 8 out of 16 patients noted transient pain or pressure with stretching of the incision and/or with uterine fundal pressure at delivery but in our study with maintenance of a lateral position in LD group, the spread of the sensory block initially progressed more slowly and no sensory block level was lower than T6, but a higher maximum sensory block level and shorter time from injection to the lowest BP were achieved with larger dose of intrathecal bupivacaine in HD group than in LD group (T2 vs. T4) (8 ± 3 vs. 16 ± 6 min, $P < 0.001$) deduced that to more cephalad spread of the sensory block. The spread of the sensory block might have been limited using the Oxford position (inflated bag under the shoulder) [17].

In our study, 80% of all subjects in HD group experienced a BP decrease of >20% from baseline, and 49% of subjects experienced a decrease of >30% in the same group but subjects in LD group were hemodynamically stable all over the procedure. A higher level of sensory block with larger dose of intrathecal bupivacaine group may mask the possible protective effect of lateral positioning against hypotension as corresponding to our results as 42 subjects in HD group was achieved sensory block at a level higher than T2 while no one in LD group (49% vs. 0%, respectively) ($P = 0.001$). The time from spinal injection to maximal decrease of BP was prolonged to 16 min in the LD group, suggesting that a dose of 6 mg of bupivacaine may be required to avoid the simultaneous effect of sympathetic block by spinal anesthetics and caval compression by a gravid uterus.

Our study demonstrated a large decrease in MAP ($P = 0.004$), which changes were immediate monitored within less than 2 min. To counteract these prominent and immediate changes, vasopressor was given, and our choice of vasopressor based on that ephedrine which, mainly acts as a β-agonist, would further increase cardiac output and this extra option than phenylephrine which is an α-agonist, can counteracts the vasodilatory effect only [20]. However, ephedrine and phenylephrine are standard drugs for maintaining maternal BP during cesarean delivery we use ephedrine sharply with the incidence of hypotension it also reflected the severity of the hypotension. Dose of ephedrine required was stated to be the primary outcome because it more sensitive marker and used only according to a decrease in BP, and our cutoff value was >30% of baseline, instead of >20% of baseline as in the previous studies [1,2,9,21]. However, as early administration of vasopressors can prevent or treat nausea during cesarean delivery, may be the delayed administration of ephedrine might have affected the incidence and severity of maternal nausea in this study which was thirty two parturients (37%), only in HD group.

No short-term complications in neonates were observed in our study. The effect of intrauterine resuscitation on neonatal well being was assessed by Apgar scoring at 1 min and 5 min interval which was found statistically similar ($p = 0.97$and $p = 0.66$ at 1 and 5 min respectively. Also, our modality was effective between LD group which showed blood pressure stability associated with significant IUR obtained from results of the umbilical arterial Ph which was slightly higher ($P < 0.001$) and lower PCO_2 ($P < 0.002$), but all values were within normal limits and this data were based on a proximity of the time from completion of spinal induction to delivery and the time from skin incision to delivery between the groups ($P = 0.016$ and $P = 0.75$).

Some limitations of this study should be noted. First, although no major complications were observed and no parturient required conversion to general anesthesia, we did not assess the parturients' satisfaction. Second, when testing the anesthetic level, we only checked the pain sensation (pinprick test) and did not check the sympathetic level (i.e., cold test), which may have more of a relationship with hypotension. However, we assumed that both would have a close correlation. Third, we did not measure or describe the detailed body type, such as the relative size of the hips or shoulders, which might have affected the spread of local anesthetics while the subjects were in the lateral position. Fourth, the correlation between the dose of the intrathecal injections and the duration of spinal anesthesia and postoperative analgesia it was out of our study scopes.

we can recommend maintaining the lateral position for 6 min after after spinal injection of low dose of hyperbaric bupivacaine as a method for reducing maternal hypotension and IUR on the basis of attempts which contrary to our study results, and were done by, Nair et al. [22] and Jeon et al. [23] they stated that a longer stay in the lateral position increases the risk for unilateral block, which can be induced when the patient is positioned laterally for 10–15 min after low dose administration of spinal anesthetic and our results showed that no left–right discrepancy was observed in either group after achieving the maximal block height also, initial spread of the sensory block was more rapid on the right in HD group.

So we recommend further study regarding prolonged maintaining the lateral position after spinal injection with standard local anesthetics doses, which would thereby reduce the incidence of maternal hypotension, improving the efficacy of spinal anaesthesia and intrauterine resuscitation.

5. Conclusions

Maintaining the lateral position for 6 min after an intrathecal injection of a relatively low dose of hyperbaric bupivacaine and high dose of fentanyl reduce the incidence or severity of maternal hypotension, delayed the onset of hypotension and did not induce a higher level of sensory block during spinal anesthesia for elective cesarean delivery and so improving the efficacy of spinal anaesthesia and intrauterine resuscitation.

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