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Comparision of fixed dose/calculated dose according to height & weight of hyperbaric Bupivacaine for elective cesarean section of parturients in tertiary care hospital

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Abstract
Background: Spinal anesthesia is the preferred anesthetic technique for cesarean deliveries. But there is a dosage dilemma regarding block to the desired level and preventing hypotension.
We aim to study effects of fixed dose with height and weight adjusted dose of intrathecal 0.5% hyperbaric bupivacaine during elective cesarean section.
Methods: Eighty-eight singleton term parturients were enrolled and divided into two groups,
Group FD (Fixed Dose) and CD (Calculated Dose) in this prospective, double-blind, randomized controlled trial. Group FD received 2.0 ml and
CD received a height and weight adjusted calculated dose based on Harten's chart. Hemodynamic changes, onset time to sensory block to T_6, maximum block in 20 minutes, and adverse effects were compared.
Results: There was a significant reduction in median drug dosage of 10 mg in FD versus 8 mg in CD group. The mean onset time of spinal block to T_6 in group FD of 2 minutes was faster than Group CD 4 minutes. The spinal block extended above T_4 in the larger number of parturients 23 (52%) in Group FD than in three (6.8%) in group CD ($p<0.05$).
Significantly larger number 20 (45.45%) in group FD developed hypotension than seven (15.9%) in Group CD. Bradycardia and vomiting were also found in group FD.
Conclusions: The calculated dose provided the desired level of the spinal block and also restricted spinal block level with a distinct advantage of less hypotension.

Keywords: Bupivacaine, calculated dose, cesarean section, Fixed Dose, Harten chart, Spinal anesthesia

Introduction
Spinal anesthesia with hyperbaric bupivacaine is the preferred anesthetic technique for cesarean deliveries [1]. The incidence of hypotension following spinal anesthesia for cesarean section is high with trials reporting as high as 80%. [2]. Untreated severe hypotension can pose serious risks to both mother (maternal nausea, vomiting, pulmonary aspiration, apnoea, unconsciousness or even cardiac arrest) and baby (impaired placental perfusion leading to hypoxia, fetal acidosis and neurological injury) [3]. The preventive measures decrease the incidence and severity of adverse effects rather than treating hypotension once it is established, however, there is no established ideal technique.
Strategies currently used to minimize hypotension include-preloading/co-loading of fluids (crystalloids/colloids) [4-6], a maternal position with manual uterine displacement, table tilt 15-20º, use of vasopressors [7], use of prophylactic ondansentron [8], and physical interventions like leg compression.
Studies have also been done by reducing the dose of a local anesthetic agent which is required for producing adequate blockade, yet maintain hemodynamic stability. However, dose selection for the single-injection spinal anesthesia is one of the major difficulties [9]. The dose adjustment study is based on a population whose body built differs from that of our population but still, we used it to compare the effects on the ground of hemodynamics, block characteristics and adverse effects.

Methods

Sample size calculation

It was done based on the previous study of Subedi A *et al.* [10] taking 95% confidence interval and of power of 80%. A total of 88 parturients enrolled in study

Inclusion Criteria's

Parturients of singleton term gestation, American Society of Anesthesiologists physical status (ASA-PS) class II planned for the elective cesarean section and the combination of height and weight falling in Harten's chart were included.

Exclusion criteria's

Patients with contraindication to spinal anesthesia, pre-existing and pregnancy-induced hypertension, cardio-respiratory illnesses and patients not falling in inclusion criteria were excluded.

The objectives of this study were to compare hemodynamics (SBP, MAP, and HR), time to T_6 sensory blockade, extent of sensory blockade at 20 mins, time to complete motor blockade and incidence of adverse effects (hypotension, bradycardia, vomiting) between the groups.

A written informed consent was obtained from the each parturient meeting the inclusion criteria for enrollment in the study. Height and weight of the parturient were noted as well as her anesthetic evaluation was done a day before the surgery. Patient fasted for 6 hours before the surgery [11]. The patient was allocated randomly to one of the following two groups using sealed opaque envelope method by odd & even numbers.

1. **Group FD** (Fixed dose Group): fixed dose of 2.0 ml 0.5% heavy bupivacaine.
2. **Group CD** (Calculated dose Group): 0.5% heavy bupivacaine, volume calculated according to height and weight from the mentioned Harten's chart [12].

Baseline non-invasive blood pressure, heart rate, and oxygen saturation were measured in the waiting room. Intravenous access was achieved with an 18 Gauge intravenous cannula in either of the hands after consent. The parturient was pre-loaded with 10 ml/kg of Ringer's lactate 30 minutes before the performance of spinal anesthesia. Patient was pre-medicated with injection metoclopramide 10 mg and injection ranitidine 50 mg intravenously simultaneously while being preloaded. The subarachnoid block was performed by a blinded anesthesia researcher who was well instructed in the study and the data was collected by the researcher. Both the parturient and the researchers were kept blinded. Under all aseptic technique in sitting position after proper cleaning and draping in the straight operating table, 25 Gauge Quincke's spinal needle was used for subarachnoid block in L4-L5 or L3-L4 level. With full aseptic & Antiseptic precautions after the free flow of cerebrospinal fluid the study drug 0.5% heavy bupivacaine was injected by the blinded anesthesia provider using, 2 ml syringe at a speed of 0.2 ml/sec. The patient was immediately placed back to the supine position with a left lateral tilt with a wedge (folded towel) beneath the right pelvic region to prevent aortocaval compression. Oxygen supplementation was given via nasal prong at 2 liters per minute from the beginning of the procedure. For the assessment of sensory neural blockade, pin prick test with 27-gauge blunt needle

Sensory and motor assessment were done at 1 minute following the spinal block and every min thereafter until complete (Grade 3) motor blockade and T_6 level of sensory block were achieved. If the sensory blockade was inadequate even after 10 minutes, the table was positioned in 10-degrees head down tilt and repositioned back to horizontal after sensory block at the T_6 level or for next 10 minutes whichever was earlier. Cases requiring head down was noted. The surgery was allowed to commence once T_6 sensory and grade 3 motor block was achieved. If the desired level of sensory block was not achieved even after 20 minutes of spinal anesthesia, then the case was performed under general anesthesia. Those cases were noted and included in the study. The maximum height of sensory block achieved in 20 minutes was also noted. Patients complaining of intolerable intraoperative pain and demanding for analgesia were treated with a 0.3 mg/kg intravenous bolus dose of ketamine before delivery of baby and fentanyl 0.5 mcg/kg alliquotes after delivery of the baby. If the pain still persisted, conversion to general anesthesia with a tracheal intubation was done. HR, SBP, and MAP were measured in every 2 minutes for 20 minutes following spinal anesthesia, then every 5 minutes after that. Hypotension was defined as a decrease in noninvasive mean arterial pressure (MAP) > 20% of baseline or mean arterial pressure (MAP) < 60 mmHg (whichever was lower) and was treated with intravenous Ringer's lactate (5 ml/kg); if hypotension was not corrected, mephentermine 6 mg intravenously in increment doses was given. Bradycardia was defined as heart rate < 20% of baseline or < 60 beats/minute (whichever was lower) and was treated with atropine 0.6 mg intravenously. If the patient complained of nausea or vomiting, the cause was ruled out first. If the cause was hypotension, it was treated as mentioned above. If the patient still complained of nausea or vomiting, ondansetron 0.1 mg/kg was given intravenously. Any complications were managed according to standard hospital protocols. After delivery of the baby, oxytocin 5 units was given intravenously as a slow bolus.

Statistical Analysis

Collected data were analyzed by means of statistical software SPSS 20.0 with appropriate tests. All data were tested for normal distribution using Kolmogorov-Smirnov test. Continuous variables- age, height, weight, SBP, MAP, HR were analyzed by the student's t-test. Categorical data - ASA, parity, adverse effects were analyzed with Pearson Chi-square test. Skewed data such as Bupivacaine dosage, time to sensory block T_6, maximum block height, time to motor block Bromage-III, dose of mephentermine consumed were analyzed by Mann-Whitney U test. A p value of < 0.05 was considered statistically significant. (S). $P<0.001$ is Highly Significant (HS).

Results

A total of 88 parturient who met the inclusion criteria were included in the study. Detail is shown in the figure 1 below.

Table 1: Demographics parameters

Parameter	Gr FD (n=44)	Gr CD (n=44)	P value	Inference
Age(yrs)	25.2+/-2.3	24.5+/-2.8	>0.05	NS
Height(cm)	156.1 +/- 2.4	155.2+/-2.6	>0.05	NS
Weight(kg)	55.8+/-2.2	56.2+/-3.1	>0.05	NS
ASA gr.l/ll	34/10	32/12	>0.05	NS
Duration of surgery (mins)	34.4+/-2.8	32.8+/-2.4	>0.05	NS

Table 2: Baseline Hemodynamic parameters

Haemodynamics	Gr. FD(n=44)	Gr CD (n=44)	P value	Inference
SBP /DBP (mm of Hg)	(122.2+/-2.4)/ (80+/-2.2)	(124.2+/-2.2)/(81.4+/-2.1)	>0.05	NS
MAP (mm of Hg)	84.4+/-2.1	83.8+/-2.4	>0.05	NS
HR (/ min)	78.2+/-1.6	77.2+/-1.9	>0.05	NS

The mean baseline MAP, SBP, HR and other parameters like mean duration of surgery, mean blood loss and median consumption of fluids were comparable between the groups. The difference between baselines SBP and minimum SBP 17.93±3.91mm of Hg in group FD and 15.97±2.51in Group CD were also comparable.

Table 3: Sensorimotor characteristics

Parameter	Group FD(n=44)	Group CD(n=44)	P value	Inference
Bupivacaine dose in ml (mg)	2 ml (10 mg)	1.6+/-0.2 ml (8+/-1 mg)	<0.001	HS
Time to sensory block at T_4 (mins)	2	4	<0.001	HS
Highest sensory level at 20 mins	T_3-4	T_4-5	<0.001	HS
Level achieved above T_4	8(17.6%)	-	<0.001	HS
Requirements of 10 degree head low position	--	2(4.4%)	<0.001	HS
Requirement of rescue Ketmine	1(2.2%)	2(4.4%)	<0.05	S
Requirement of rescue fentanyl	1(2.2%)	1(2.2%)	>0.05	NS
Conversion to n General anaesthesia	-	-	-	NS

Values are *mean± SD, **number (percentage The mean dosage of 0.5% Hyperbaric Bupivacaine was significantly low of 8 in CD group in comparison to 10 mg in FD group. The mean time to reach T_6 sensory block 2 minutes in Group FD was much early in comparison to 4 minutes in Group CD. The mean maximum sensory level achieved in 20 minutes T_3-T_4 in Group FD was also significant in comparison to T_4-5. The maximum sensory level achieved in Group FD was T_4 and in Group CD was T_6 15 parturient (34%) in group FD and 3 (7%) in Group CD attained a level of sensory block T_4. The values are statistically significant with p-value <0.05. The mean time to motor blockage Bromage-III was relatively early 4 minutes in Group FD in comparison to 6 minutes in Group CD with a p-value of <0.05. Two parturient (4.4%) in Group CD needed head down position in order to get the desired level of sensory block. One parturient (2.2%) in both groups required supplementary analgesia.

** None of the cases were converted to General Anesthesia in either groups.

Adverse reactions

Hypotension in 20 parturient (45%) was significant in Group FD in comparison to 7 parturient (16%) in Group CD with a p-value of 0.003. Bradycardia in 3 (6.8%) and Vomiting in 2 (4.5%) were also noted in Group FD parturient.

Bradycardia in 3 (6.8%) and Vomiting in 2 (4.5%) were also noted in Group FD parturient. The mean dose of mephentermine consumed 12 mg in Group FD was statistically significant in comparison to 6 mg in Group CD.

Discussions

The dose of local anesthetic is reduced by about one-third in pregnant compared to non-pregnant lady for a variety of reasons. Till date, several studies have been conducted to establish the minimal but adequate dose of intrathecal bupivacaine for a cesarean section to limit the adverse effects related to spinal anesthesia but none have quoted for an absolute value.

Bupivacaine dosage

There was a significant reduction in Bupivacaine dosage. A survey of UK practice13 showed that the mean (SD) volume of bupivacaine 0.5% usually given is 2.57 ml with a fixed dosage scheme, whereas a median [range] dose of 2.34 [1.2-3.0] ml in a variable dose scheme. Our findings were comparable to study conducted by Harten *et al.* [12], where the fixed dose was 2.0 ml (10 mg) and the mean dose received in the dose adjusted group was 1.6 ml (8 mg), Asian women are usually shorter in height than European women [14]. Nagata *et al.* [15] found that 8 mg of 0.5% Hyperbaric Bupivacaine was adequate for cesarean section in Japanese parturient. Subedi A *et al.* [10] used a fixed dose of 2.2 ml (11 mg) and the median dose in the adjusted group was 1.8 ml (9 mg), 9 (8-9.5 [7.5-10]) mg, p-value: 0.001 in Nepalese parturient.

Hemodynamics: With higher doses, the level of block attained is higher so are the chances of adverse cardiac consequences more with it. The combined effects of sympathetic inactivity and vagal overactivity, anesthesia of cardio accelerator fibers, activation of cardiovascular reflexes lead to decreased cardiac output and systemic vascular resistance finally causing adverse effects like hypotension and bradycardia [16]. There is a decrease in arterial pressures, including systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure during pregnancy. DBP and mean arterial pressure decrease more than SBP during the pregnancy [17]. The difference

between baseline MAP and minimum MAP 17.60±4.66 mm of Hg in group FD and 14.5±2.98 in Group CD was significant. 52% of parturient in the fixed-dose group have gained a sensory block above T_4. So, the significant difference in the MAP in fixed-dose group can be explained to be a part of this.

Harten *et al.* [12] and Subedi *et al.* [10]: Both found a significant difference between baseline and minimum mean arterial pressure (mmHg) 35.0 ±16.4 as compared to 28.0 ±13.5 and 96.5 ± 6.74 mm Hg as compared to 101.6 ± 6 mm between fixed and adjusted dose groups respectively. Block characteristics A T_6 level of the sensory blockade is usually sufficient for cesarean section18. The volume of drug is one of the determinants of a local anesthetic spread in SAB [19]. Greater the volume greater is the level of sensory block. Thus, in FD group the onset of sensory block was early but the level of block was not confined to the desired one. The spread was more cephalad up to T_2. Though, the onset of sensory block was relatively slower in CD group the desired level of block was relatively confined.

Two parturient in Group CD needed 10º head down position in order to get the desired level of the block, while none was needed in Group FD. One parturient in each group complained of pain during intraoperative period and was given supplementary analgesia. Subedi *et al.* [10] found that the median onset time for the target spinal block of T_5 was significantly (p=0.01) prolonged in Adjusted dose group than in Fixed dose group (6 minutes vs. 4 minutes). In Group FD, the maximum block level extended above T_3 in 12 (24%) patients while it did so in one (2%) patient in Group AD. Six (12%) patients in Group AD required a head -down tilt after 10 minutes of intrathecal injection to attain T_5 block height as compared to one patient in the Fixed Group. Although there were no significant differences between the groups in the quality of intraoperative anesthesia, 4 (8%) parturient required supplementary analgesia with IV ketamine in Group AD patients. However, none of the patients in either groups required conversion to GA. Harten *et al.* [12] also found that the onset of the sensory block was faster with the fixed-dose than with the adjusted dose (p = 0.02). Five patients in the Adjusted-Dose Group and no patients in the Fixed-Dose Group required head-down tilt. No patients in either group required conversion to general anesthesia.

Nagata *et al.* [15] found that ten minutes after the spinal anesthesia, in 79% of 8 mg group and in 88% of 10 mg group, sensory block level reached T_4. The result of our study correlates with the results of above studies and support that calculated drug doses are sufficient enough to achieve the desired level of sensory block and providing good quality of intraoperative anesthesia and analgesia whereas with fixed doses the level of block achieved is much higher than the desired one. The median time to motor blockage, Bromage-III in Group FD was 4 minutes, 4 minutes. In comparison to 6 minutes, 6 minutes in Group CD.

Adverse effects

Hypotension in 20 parturient (45%) was significant in Group FD in comparison to 7 parturient (16%) in Group CD. High level of spinal block is a potential risk factor for the intraoperative hypotension20. Correlating the hypotensive episodes with the level of block attained we found that all 20 parturient in group FD had block height $\geq T_4$ (8-T_2, 10-T_3, 2-T_4). Similarly, in Group CD out of 7, 6 parturient had block height $\geq T_4$ (2-T_3, 4-T_4, 1-T_5. Greater the level of the sensory block, more pronounced are these effects. Greater the incidence of hypotension, greater is the use of vasopressor (mephentermine).

Bradycardia in three (6.8%) and vomiting in two (4.5%) were also noted in Group FD parturient but they were comparable. The incidence of vomiting in the fixeddose group of our study could be attributed to the greater reduction in arterial blood pressure in the fixed-dose intrathecal block [21].

Harten *et al.* [12] found that the incidence of hypotension after spinal anesthesia was 71.7% in the Fixed-Dose Group and 50.0% in the Adjusted Dose Group (p = 0.035). More patients in the Fixed-Dose Group were given ephedrine (79.5% vs 56.8%, p = 0.02), and a larger median dose was administered (9 mg vs. 6 mg, p = 0.042. The percentage of patients in the Fixed-Dose Group who vomited was 17.9%, compared to 4.5% in the Adjusted Dose Group (p = 0.052).

Subedi A *et al.* [10] found that a significantly (p < 0.01) large number of patients in Group FD [32 (6%)] had hypotension than in Group AD [15 (30%)]. The vasopressor requirement was more in the FD group (9 mg versus 6 mg in the AD group; p = 0.003). Nausea and vomiting were more frequent in Group FD than in Group AD. One patient in the fixed-dose group developed a very high block above T1 and had difficulty in breathing. The incidence of bradycardia and shivering was similar in patients of both the groups.

AM *et al.* [2] Ozoagu [2] found that patients in the fixed-dose group had lower intraoperative mean arterial pressure (p=0.001), higher incidence of hypotension (62.9% vs 28.6% with p<0.001), and so needed more ephedrine (62.9% vs 28.6%), and more patients reported nausea (15.7% vs 2.9% at p=0.009) but there was no vomiting in either group.

Nagata E *et al.* [15] found that hypotension occurred in 19 parturient (7 in 8 mg group and 12 in 10 mg group). The incidence of hypotension was significantly lower in 8 mg group (37%) than in 10 mg group (71%).

C. Arzola, *et al.* [23] found that in a Lower dose (LD) group exhibited a lower risk of hypotension (RR¼0.78, 95% CI¼0.65-0.93) and nausea/vomiting (RR¼0.71, 95% CI¼0.55-0.93).

Conclusion

In nutshell, the calculated dose of spinal bupiivacaine by usage of Harten chart, Provided adequate level of sensory & motor blockage, and less hemodynamic changes than fixed dose of intrathecal bupivacaine in partirients for LSCS.

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