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Effect of 0.5% hyperbaric bupivacaine dose adjusted by height versus height and weight for spinal anaesthesia in a caesarean section- a study

Dr. Joseph Lalhrauitluanga[1], Dr. Takhelmayum Hemjit Singh[2], Dr. Nongthombam Ratan singh[3], Dr. Cherajlaxmi Angom[1], Dr. Andrea Nongsiej[1]

[1] PGT, [2] Associate Professor, [3] Professor

Department of Anaesthesiology, Regional Institute of Medical Sciences, Lamphelpat, Imphal West, Manipur, India. PIN- 795004

***Corresponding Author:**
Dr. Takhelmayum Hemjit Singh

Department of Anaesthesiology, Regional Institute of Medical Sciences, Lamphelpat, Imphal West, Manipur, India. PIN- 795004

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Abstract

Background

Spinal anaesthesia is the preferred anaesthetic technique for caesarean section with various doses of local anaesthetic tried by different workers. The present study was carried out to assess the block characteristics of 0.5% hyperbaric bupivacaine dose adjusted either according to the height of the patient or dose adjusted according to the height and weight using Harten chart or a fixed dose of 10mg.

Materials and methods

The study was a prospective, randomized, double blinded and controlled one in which 135 patients only of the indigenous population of Manipur with ASA grade I and II, with singleton pregnancy between 18-40 years of age, who were scheduled to undergo elective caesarean section under spinal anaesthesia were randomly allocated into three groups to receive 0.5% inj hyperbaric bupivacaine as Group A (dose adjusted according to height), Group B (dose adjusted according to height and weight using Harten chart) and Group C (fixed dose group). The heart rate, blood pressure intraoperatively, sensory onset time, time to reach T_{10} sensory block, maximum sensory block level, time to peak sensory block level, time to adequate block level, time to achieve Modified Bromage Scale of 3, time to two segment regression, duration of surgery, time to first analgesic rescue, need for supplementary analgesia, APGAR score at 1 and 5 minutes, incidence of hypotension, bradycardia, nausea, vomiting, shivering, etc were noted and analysed.

Results

The incidence of hypotension was significantly less ((P value of 0.03) in the height and weight adjusted group (20 patients or 44%) as compared to the height alone group (31 patients or 68%) and the fixed dose group (30 patients or 66%). There were no significant differences in the mean heart rate, sensory onset time, maximum sensory block level, time to peak sensory block level and other recorded parameters in all the three groups.

Conclusion

The dose of 0.5% hyperbaric bupivacaine calculated according to the height and weight of the patient using Harten chart improves the quality of spinal anaesthesia without compromising motor and sensory blockade.

Keywords: Spinal Anaesthesia, Dose, Hyperbaric Bupivacaine, Height and Weight, Harten Chart

INTRODUCTION

The primary objective of spinal anaesthesia technique is to provide effective surgical anaesthesia with minimal maternal and neonatal side effect, and spinal anaesthesia with bupivacaine is the preferred anaesthetic technique in caesarean section. Bupivacaine is a long-acting anaesthetic agent of the amide type with an onset time of less than 15 minutes and duration of action of 2-3 hours.

Various doses of local anaesthetic have been tried by various workers in spinal anaesthesia.[1] The use of low dose local anaesthetic or addition of fentanyl to low dose bupivacaine reduces the incidence of adverse effects such as hypotension, nausea and vomiting, but compromises the adequacy and requires supplementary analgesia or conversion to general anaesthesia.[2] On the other hand, the use of higher doses of local anaesthetic results in higher incidence of hypotension due to the enhanced segmental blockade.[3] Moreover, in order to achieve a pain free experience at caesarean section, it has been suggested that a block at T_4 to pinprick and light touch at T_6, is required.[4] The conventional dose of bupivacaine in spinal anaesthesia ranged from 5- 20 mg; however nowadays, the cut off dose is considered as >8mg or $\leq$ 8mg.[5]

The dose of local anaesthetic has been studied on various parameters like height [6]and height and weight[7], etc. and has been shown to limit the spread of spinal anaesthesia in Caucasian population, reducing the unwanted effects of spinal anaesthesia than from those who are given a fixed dose of bupivacaine.

Hence, this randomized double blinded study was aimed at evaluating the effect of intrathecal bupivacaine dose adjusted and based on height alone versus height and weight in the indigenous parturient, where height and weight are comparatively lower than the Caucasians, scheduled to undergo elective caesarean section under spinal anaesthesia.

MATERIALS AND METHODS

The study was a randomized, controlled, double-blinded one conducted at a tertiary care centre, Imphal, Manipur during two years period starting from September 2018 to August 2020. With due approval from Institutional Ethical Committee and written informed consent from parturient of only indigenous population of Manipur, of American Society of Anaesthesiologists (ASA) physical status I or II, with singleton pregnancy, of 18- 40 years of age scheduled to undergo elective caesarean section under spinal anaesthesia were enrolled. Parturient refusing regional anaesthesia, history of allergy to study drugs, ppregnancy iinduced hhypertension, ccardiovascular co- morbidities, central nervous system disease, bleeding tendency, local site infection, weight <50 kg or > 110 kg, height <140 cm and >180 cm, uncooperative, cardiac, respiratory diseases and spinal deformities patients were excluded from the study.

Sample size was calculated based on the previous study [8] for an α value of 0.05 and power (1-β) value of 80% as 43 per group, rounded to 45, assuming a 5% drop out rate. The 135 parturient were assigned into three groups of 45 each based on computer generated randomization viz: **Group A:** received 0.5% hyperbaric bupivacaine dose calculated according to the height of the patient at a dose of 0.06 mg/ cm in L_{2-3} intrathecal space,[6] **Group B:** received 0.5% hyperbaric bupivacaine dose calculated according to the height and weight of the patient in L_{2-3} intrathecal space[7]and **Group C**: received fixed dose (10mg) of 0.5% hyperbaric bupivacaine.

Preoperative assessment was done a day prior to the scheduled day of surgery and the parturient were asked to take tab. ranitidine 150 mg orally the night before the surgery. On the day of surgery, inj. metoclopramide and inj. ranitidine 50 mg were given intravenously in the morning of surgery in the pre anaesthetic room and intravenous assess was established to start the maintenance fluids. At the operation theatre, monitoring of heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SPO_2) and electro- cardiogram (ECG) were started. All the patients received Ringers Lactate solution 10 ml per kg. as preloading solution within 30 minutes of subarachnoid block. In the lateral position, the skin over the desired site for spinal block was infiltrated with local anaesthetic (2% lignocaine, 1 ml) under strict aseptic and antiseptic precaution and dural puncture was performed in the L_2-L_3 interspace through a 25 G Quincke needle. After confirming the intrathecal space with free flow of cerebrospinal fluid, spinal anaesthesia was performed with the calculated dosage of 0.5% hyperbaric bupivacaine with either of the two calculated doses depending on the group. The patient was immediately made supine with a left lateral uterine tilt with a wedge. The operative

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procedure commenced only when a sensory block of T_6 was achieved within 8 minutes. In case of inadequate block not achieved within 8 minutes, a 10^0 head down manipulation of the table will be positioned to attain the desired block level or a supplementation of bolus of inj. Ketamine 0.5 mg/kg iv. as up to 1 mg/ kg of Ketamine is not harmful to the fetus.[9] If these measures failed, general anaesthesia will be administered. The study drug was prepared by another person not involved in the study and were also blinded to both the investigator and the patients.

Hypotension, defined as fall in the systolic blood pressure (SBP) more than 20% of the baseline blood pressure or absolute value less than 100 mm Hg. was treated with fluids (100 ml of Ringers Lactate) or with intravenous mephentermine in increments of 3 mg. as and when required. Bradycardia (heart rate-HR<50 bpm) was treated with injection atropine 0.3–0.6 mg intravenous. Time of analgesia at T_{10} dermatome i.e. time interval from the local anaesthetic drug administration and the onset of cutaneous analgesia at T_{10} was assessed using a midline pinprick bilaterally every minute, till complete loss of cutaneous sensation at T_6, at which point the surgical procedure commenced along with the APGAR score being noted at 1 minute and 5 minutes. The maximum analgesic dermatome achieved, ttime to peak sensory block level (TPSBL), ttime to two segment regression (TTSR), time to first analgesic rescue(TFAR) and supplementary analgesics requirements were assessed and noted. The adequacy of effectiveness of pain relief was assessed by VAS.[10] The hemodynamics parameters and details of any other adverse effects (if any) were also recorded.

The data collected was summarized using descriptive statistics like percentage, mean, etc. Statistical analysis of the data obtained was done using Windows based statistical package for social sciences [SPSS] Version 21.0 (Armonk, NY: IBM Corp.) by using the students 't' test for continuous data, Chi square test for categorical data and ANOVA test for more than two independent variables. $P \leq 0.05$, was considered as statistically significant.

RESULTS AND OBSERVATIONS

The study protocol was completed in all the enrolled 135 patients. The demographic parameter such as age, ASA, height and weight were comparable in all the three groups and did not affect the study outcome, as shown in table 1.

Table 1 : Demographic Profile of the three study groups (N=135)

Parameters	*Group A (N=45)*	*Group B (N=45)*	*Group C (N=45)*	*P value*
Age (Years)	29.42±5.57	30.04±6.34	29.29±5.64	0.80
ASA Grading (I:II)	37:8	39:6	39:6	0.79
Height (cm)	157.80±4.34	156.67±4.14	157.53±4.75	0.44
Weight (kg)	59.07±4.83	61.64±7.12	59.93±5.62	0.08

P<0.05 is significant

The heart rate did not fluctuate much from the baseline value in all the three groups at different time points except significant readings were observed at 30th and 45th minutes between groups B and C(shown in figure 1)

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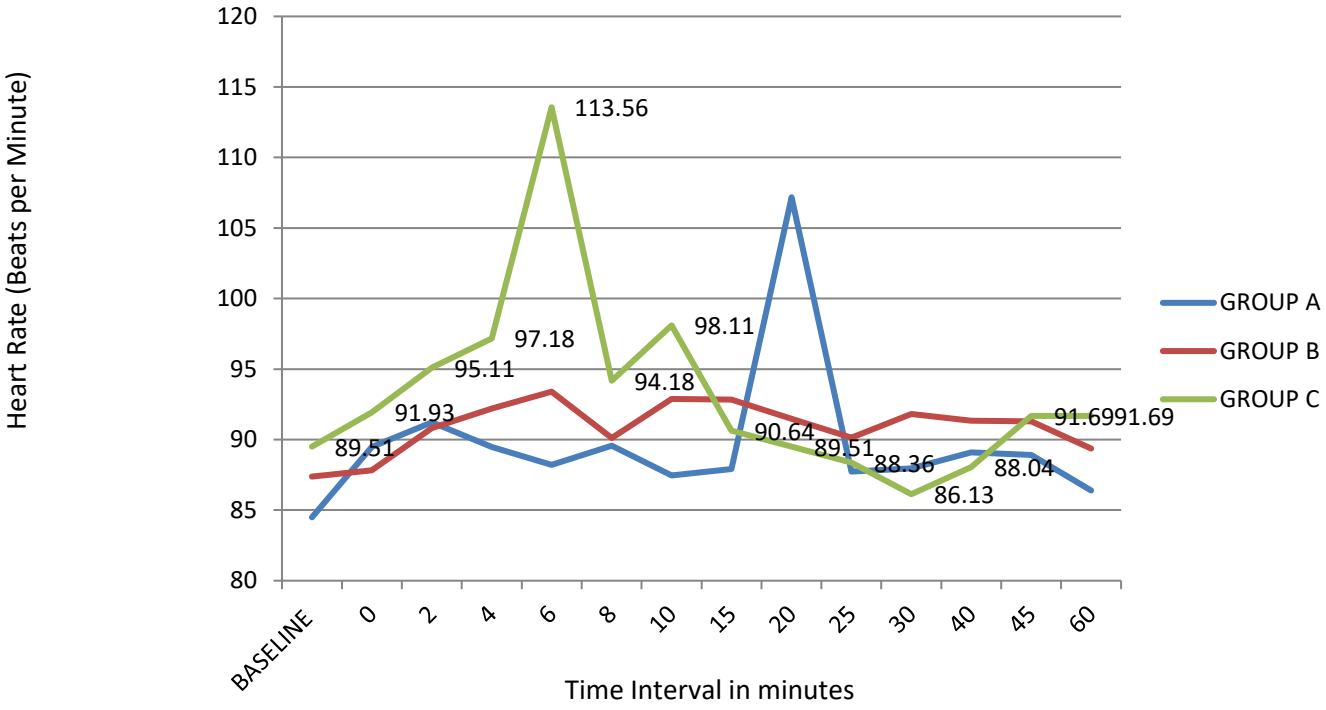
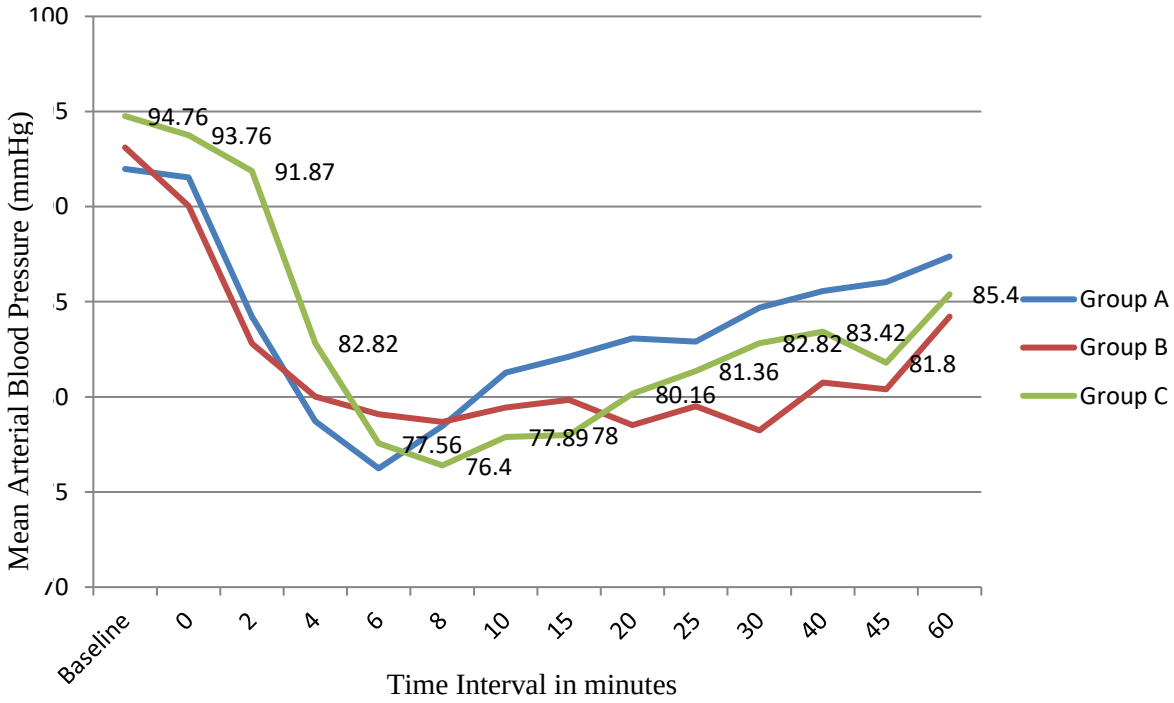
Figure 1 :Heart rate variation between the three groups



The mean arterial pressure in the three groups falls to a maximum at around 6th minutes and rose slowly thereafter to approach its baseline value, but the fall was more in group C as compared to other groups (shown in figure 2). Significant fall was observed at 15th, 30th and 45th minutes in group B & C as compared to group A.

Figure 2: Mean Arterial Pressure at various time points between the three groups.



The block characteristics with sensory onset time, time to peak sensory block level, time to reach T_4-T_6, time to Modified Bromage Scale of 3, time to two segment regression and time to first rescue analgesic were comparable

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and not significant in all the three groups, however significant prolonged time interval for time to reach T_{10} in seconds was recorded in group B, as shown in table 2.

Table 2. Comparison of block characteristics in the three groups.

Parameter	*Group A N=45 Mean±SD*	*Group B N=45 Mean±SD*	*Group C N=45 Mean±SD*	*Statistical test value (F test value)*	*P value*
Sensory onset time in seconds	11.47±2.40	12.49±4.43	12.18±2.94	1.08	0.34
Time to reach T_{10} in seconds	111.31±39.46	133.51±49.41	110.78±27.36	4.78	0.01*
Time to peak sensory block level in seconds	287.96±129.4	245.73±91.01	263.13±78.26	1.93	0.14
Time to reach T_4-T_6 in seconds	242.58±93.77	231.09±83.68	229.40±63.23	0.35	0.70
Time to Modified Bromage scale of 3 in seconds	165.89±77.48	154.04±57.23	148.49±39.80	0.98	0.37
Time to two segment regression in seconds	3008.7±450.5	2916.0±392.9	2877.2±502.6	1.09	0.33
Time for first rescue analgesic in seconds	6192.6±1053	5800.1±720.4	6070.1±950.8	1.70	0.18

P<0.05 is significant

The incidence of hypotension was significantly reduced in group B (44%) as compared to group A (68%) and group C (66%), with P value of 0.03. The incidence of bradycardia, nausea & vomiting and shivering were recorded in few patients' patients in all the groups and slightly more in group C eventhough it was comparable and statistically insignificant. There was no difference in the APGAR score recorded in all the three groups.

DISCUSSION

Spinal anaesthesia is the technique of choice for patients undergoing elective caesarean section as being simple to perform, economical and producing rapid onset of anaesthesia with complete muscle relaxation. Spinal anaesthesia with bupivacaine is the preferred anaesthetic technique in caesarean section with its various doses tried by different workers in spinal anaesthesia.[1]

Maternal hypotension is the most common complication following Spinal Anaesthesia with 0.5% hyperbaric bupivacaine. Our study recorded block height of more than T_5 in in group A, 31 patients (68%), group B,12 patients (52%) and in group C, 32 patients (71%), which is statistically significant (p<0.05). This may suggest the high incidence of hypotension in Groups A and C compared to Group B. In a study by Harten et al[7], it was also found that there was significant increase in maximum block height in fixed dose group compared to height and weight adjusted dosage group. Siddiqui et al[11] also found no statistically significant difference in the maximum block height between height alone and height and weight calculated dosage group even though more patients in the height alone group had higher block level, which was also in seen in our study.

The conventional dose of bupivacaine in spinal anaesthesia ranged from 5- 20 mg; however, nowadays, the cut off dose is considered as >8mg or ≤ 8mg.[5] Studies by Harten et al[7] and Siddiqui et al[11] had demonstrated a lower incidence of hypotension in height and weight adjusted groups compared to height

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alone adjusted group. In another study by Badheka et al[10] it was found that fractionated dose of bupivacaine provides greater haemodynamic stability compared to bolus dose in patients undergoing elective caesarean section. The main finding of our study was that the dose adjustment of intrathecal hyperbaric bupivacaine on the basis of Harten chart significantly reduced bupivacaine requirement for caesarean section (9.6mg in Group A vs. 9mg in Group B vs. 10mg in Group C) and thus the incidence of hypotension was significantly reduced in the height and weight group (20 patients or 44%) as compared to the height alone group (31 patients or 68%) and the fixed dose group (30 patients or 66%).

Subedi A et al[12] reported a significant number of patients developing bradycardia in fixed dose group compared to height and weight group. In contrast, we have seen that the incidence of bradycardia was negligible and comparable in all the groups which may be due to the dose difference in mephentermine used to treat hypotension in our study, as their study used a higher dose which may theoretically increase the chance of bradycardia and this finding was also supported by Siddiqui KM et al. [11]

The sensory onset time were almost similar in all the groups whereas there was significantly longer time for sensory onset to reach dermatome of T_{10} in Group B (133.51±49.41 secs) compared with Group A (113.31±39.46secs) and Group C (110.78±27.36 secs). Similar result was seen by Siddiqui KM et al.[18]

In our study, the time to reach satisfactory block for surgery was also almost similar in all the three groups (242.58±93.77 vs. 231.09±83.68±229.40±63.23 sec). Similar findings were seen by Nagraj A et al.[8] The time to peak sensory block was comparable between the three groups (Group A 287±129.39 vs. Group B 245.73±91.01 vs. Group C 263.13±78.26 sec). A study by Harten et al[7] and Subedi A et al[12] reported a delayed onset time to target level of T_5 in adjusted dose as compared to fixed dose group, which maybe because of use of higher doses of bupivacaine in their study in the fixed dose group. There was also no significant difference in the time required to get a modified Bromage scale of 3 between the groups (165.89±77.48 vs 154.04±57.23 vs 148.49±39.80 secs). This showed that there was adequate motor blockade in all the three groups.

The time to two segment regression from peak sensory level was almost similar in all the three groups (3008.71±450.52 vs. 2916.02±329.87±2877.18±502.37sec) in our study, which was comparable with the findings of Debbarma B et al.[13] In order to attain satisfying block level, table manipulation (Head tilt) was needed for 3 patients in group A (6%), 5 patients in group B (11%) and 1 patient in group C (2%), which was also in agreement with the study done by Harten et al.[7]

Subedi A et al[12] concluded that adjusting the dose of bupivacaine according to the weight and height of the patient reduces the number of hypotension and thus the side effects associated with it like nausea, vomiting and shivering which are similar with our study. In the study by Harten JM et al. [7] it was observed that the incidence of nausea and vomiting was higher in the patients whose bupivacaine dose was calculated according to the height alone compared to height and weight calculated dose. None of the patients developed allergic reaction or respiratory depression, which were also observed by Subedi A et al. [12]

Belzarena SD [14] in their study demonstrated that the time for first analgesic request was significantly longer in patients where fentanyl was added to bupivacaine. We have found that the time for first analgesic request was not statistically significant in all the three groups and this may be due to the absence of fentanyl or adjuvants in our study.

Limitation and future directions:

- A larger sample size with different and varied ethnicity needs to be studied to come to a definite conclusion with inclusion of other ASA grades
- Does the spinal curvature changes with weight or spinal canal is voluminous in heavy person needs to be pondered?
- Should the volume of local anaesthetic differ with reference to height or weight or both?

CONCLUSION

Patients undergoing elective LSCS under spinal anaesthesia with 0.5% hyperbaric bupivacaine dose adjusted by the height and weight of the patient according to Harten's chart improved the safety of spinal anaesthesia. The amount of local anaesthetic used is significantly reduced thereby reducing the incidence of hypotension, maintain adequate analgesia

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with reduced incidence of nausea and vomiting, which are attributed mainly to lower cephalic spread of local anaesthetic.

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