

Height Adjusted Doses of Bupivacaine in Caesarean Section and Association with Hypotension, Nausea and Vomiting

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Abstract

Introduction: Spinal anaesthesia is the gold standard for caesarean delivery despite associated side effects of hypotension, bradycardia & post dural puncture headache. Incidence of PDPH has decreased with the advent of newer needles. Variation in doses of spinal anaesthesia have been used for caesarean section. The purpose of our study is to compare the incidence of hypotension, and associated nausea and vomiting in parturients receiving height adjusted dose and fixed dose of 0.5% hyperbaric bupivacaine for caesarean delivery under spinal anaesthesia. **Materials & Methods:** This was a randomized double blind clinical trial. Ethics committee approval was taken. After randomization, 110 patients were assigned into two study groups. **Group H:** Height-adjusted dose of 0.5 percent bupivacaine heavy (0.06 mg/cm) with 10 µg fentanyl was given to patient while in Group F fixed dose 2 ml of 0.5% bupivacaine heavy with 10 µg fentanyl was used. The research was carried in a double-blind manner. The patient and the anaesthesiologist who were involved in patient monitoring and management after administration of the study drug were both blinded to the group assignment. **Results:** 110 full term parturient with singleton uncomplicated pregnancy of ASA physical status grade I or II, aged >18 years were considered. Although many factors affect volume of local anaesthetic like weight, height and dose, only height is taken into account in group H for calculating height adjusted dosages, whereas fixed doses are used in groups F. The mean total volume of drug administered to group H patients was 2.09 ml which is significantly lower than the mean total amount of drug given to group F patients which was 2.2 ml. P value was <0.001 which is significant. There was no statistically significant difference between the mean heart rate, oxygen saturation, mean blood pressure, and diastolic blood pressure measurements. Only in reading of systolic blood pressure statistically significant difference was noted in initial minutes which was managed by small bolus dose of injection mephentermine. **Conclusion:** The height adjusted dose of 0.5 percent hyperbaric bupivacaine when used for caesarean patient provides better haemodynamic stability with a decreased incidence of hypotension, less use of vasopressors although similar incidence of nausea and vomiting in comparison to those receiving a fixed dose of 0.5% hyperbaric bupivacaine in patient of caesarean delivery under spinal anaesthesia.

Keywords: Caesarean section; Body height; Spinal anaesthesia

Introduction

Spinal anaesthesia with bupivacaine is a “Gold standard”, method of anaesthesia for caesarean section although it is associated hypotension due to sympathetic blockade. Maternal hypotension reduces placental perfusion, compromising neonatal outcomes and is also associated with unpleasant symptoms like nausea and vomiting. Amongst the various factor, the key parameter that impacts the optimal level of sensory nerve block for surgical anaesthesia is the dose of local anaesthetic. Because of individual variances among parturients, achieving a sufficient spinal level for caesarean delivery might be difficult for the anaesthesiologist. The parturient characteristics that determine the dose of local anaesthetic for caesarean section include height, weight, body mass index, vertebral column length, abdominal circumference and twin pregnancies. Despite

many studies, no consensus has emerged, and establishing the optimal intrathecal bupivacaine dosage for caesarean section remains a difficult task. As a result, multiple spinal anaesthetic dosage regimens for caesarean section are used. Most common regimen used is fixed dose regime, while others adjust the doses depending upon patient’s characteristics. Evidence suggests that the time it takes to reach an adequate sensory level for surgery is proportional to height and supports adjusted dosing. Previous

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research has shown that patient height and weight can predict the block's level. In few studies doses of spinal drug were adjusted considering the height of patient alone. The optimal dose would allow adequate spinal level spread without fall in blood pressure of a pregnant patient. After comparison in two doses we hypothesized that height adjusted dose of 0.5% hyperbaric bupivacaine will be associated with a decreased incidence of hypotension as compared to fixed doses when used in caesarean patient.

Materials and Methods

After receiving permission from the ethics committee and written informed consent from the patient, this prospective, randomized, comparative, double-blind study was conducted. We selected 110 women of age >18 with singleton pregnancies of gestation >37 weeks, having American Society of Anaesthesiologists physical status, I and II, posted for elective caesarean section. Patients with any other systemic comorbidities, contraindications to neuraxial block, complicated pregnancy, weight <40 kg or >90 kg, height >170 cm or <140 cm, and allergy to local anaesthetics were not included.

After randomization, patients were divided into two study groups

Table 1: Distribution of patients in each group.

Groups	Frequency	Percent
Group H	55	50
Group F	55	50
Total	110	100

Table 2: Distribution of age, height and weight of patients and gestational age.

Parameter	Group H Mean \pm SD	Group F Mean \pm SD	p value
Age (years)	25.53 \pm 4.12	25.18 \pm 3.15	0.622
Height (cm)	154.49 \pm 5.08	154.78 \pm 4.78	0.758
Weight (kg)	61.25 \pm 9.09	62.42 \pm 7.37	0.462
Gestational Age (weeks)	38.00 \pm 0.82	38.24 \pm 0.92	0.158

*The data is expressed in mean \pm SD, P value <0.05 is significant

Table 3: Intergroup comparison of volume of drug bupivacaine (ml) administered.

Study drug	Group H Mean \pm SD	Group F Mean \pm SD	p value
Bupivacaine(ml)	1.89 \pm 0.67	2.00 \pm 0.00	<0.001
Bupivacaine(mg)	9.46 \pm 0.33	10 \pm 0	<0.001
Total drug			
Bupivacaine (ml)	1.89 \pm 0.67	2.00 \pm 0.00	<0.001
Fentanyl (mcg)	0.2(10 μ g)	0.2(10 μ g)	
Total	2.09	2.2	

Table 4: Shows the incidence of hypotensive episode which was significantly higher in group F compared to group H. P value is <0.001 by Chi-square test, the difference was a statistically significant.

Number of hypotensive episodes	Group H		Group F		p value
	Frequency	%	Frequency	%	
0	44	80.00%	17	30.90%	
1	9	16.40%	21	38.20%	
2	2	3.60%	15	27.30%	<0.001
3	0	0.00%	2	3.60%	
Total	55	100%	55	100%	

*Comparison of number and % of hypotensive episodes, P value <0.05 is significant.

1. Group H patients received height adjusted dose (0.06 mg/cm height) of 0.5% bupivacaine heavy with 10 μ g fentanyl [Tables 1-6].

2. Group F patients received fixed dose 2 ml of 0.5% bupivacaine heavy with 10 μ g fentanyl [Table 3].

The research was carried in a double-blind manner. The patient and the anaesthesiologist who were involved in patient monitoring and management after administration of the study drug were both blinded to the group assignment. Patients were advised to keep 8 hours of fast. Tab ranitidine (150 mg) and tab metoclopramide (10 mg) were given to patients two hours preoperatively with sips of water. After shifting patient to operation theatre, supine position was given with 15 degree right to left lateral tilt, on the operating table with table being parallel to the ground. ECG, non-invasive blood pressure, and a pulse oximeter were used for standard monitoring. Baseline readings of heart rate, blood pressure (systolic, diastolic and mean).

18-gauge intravenous cannula was secured. Co-loading was started with rapid intravenous infusion with (10 ml/kg) of Ringer's lactate. The procedure was explained to the patient and given left lateral position for the procedure with head, neck and back flexed. Under all aseptic precautions, skin infiltrated with sterile (1 ml-2 ml) 2% lignocaine. 3 ml syringe was used to prepare drug for each group. Lumbar puncture was obtained with a 25 G Quickie spinal needle at the L2-3 intervertebral space, with midline approach. After confirming free flow of CSF patients in the fixed dose group (Group F) received 2 ml of 0.5%

Table 5: Number of mepentermine bolus doses with percentage.

Number of Mepentermine Bolus Doses	Group H		Group F		p value
	Frequency	%	Frequency	%	
0	44	80.00%	17	30.90%	<0.001
1	9	16.40%	21	38.20%	
2	2	3.60%	15	27.30%	
3	0	0.00%	2	3.60%	
Total	55	100%	55	100%	

*Percentage of patients with number of mepentermine doses. P value <0.05 is significant

Table 6: Percentage of patients requiring atropine bolus doses in both group.

Atropine Bolus Dose Given	Group H		Group F	
	Frequency	%	Frequency	%
No	55	100.00%	53	96.40%
Yes	0	0.00%	2	3.60%

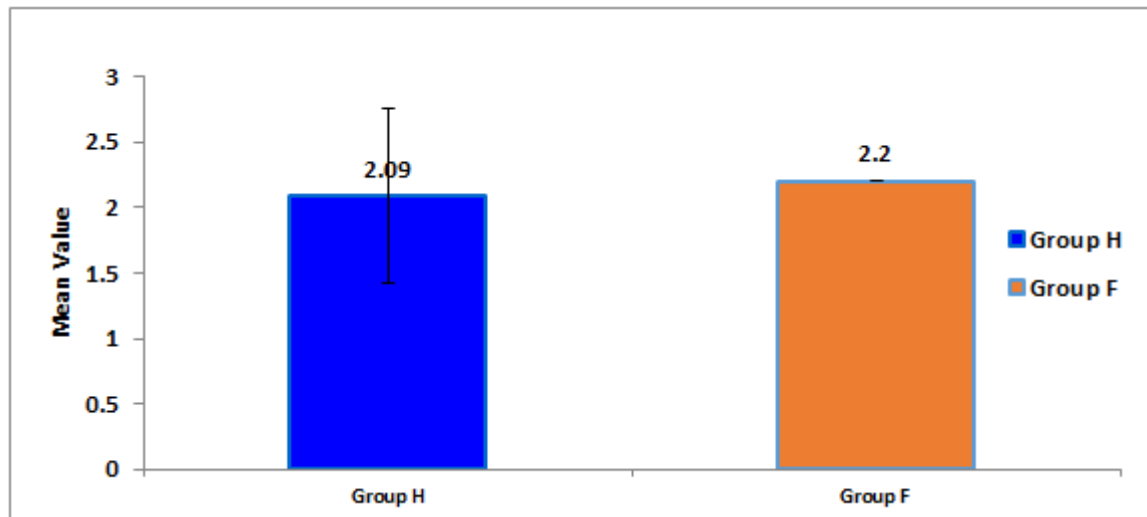


Figure 1: Total study drug volume (ml) administered in the two groups.

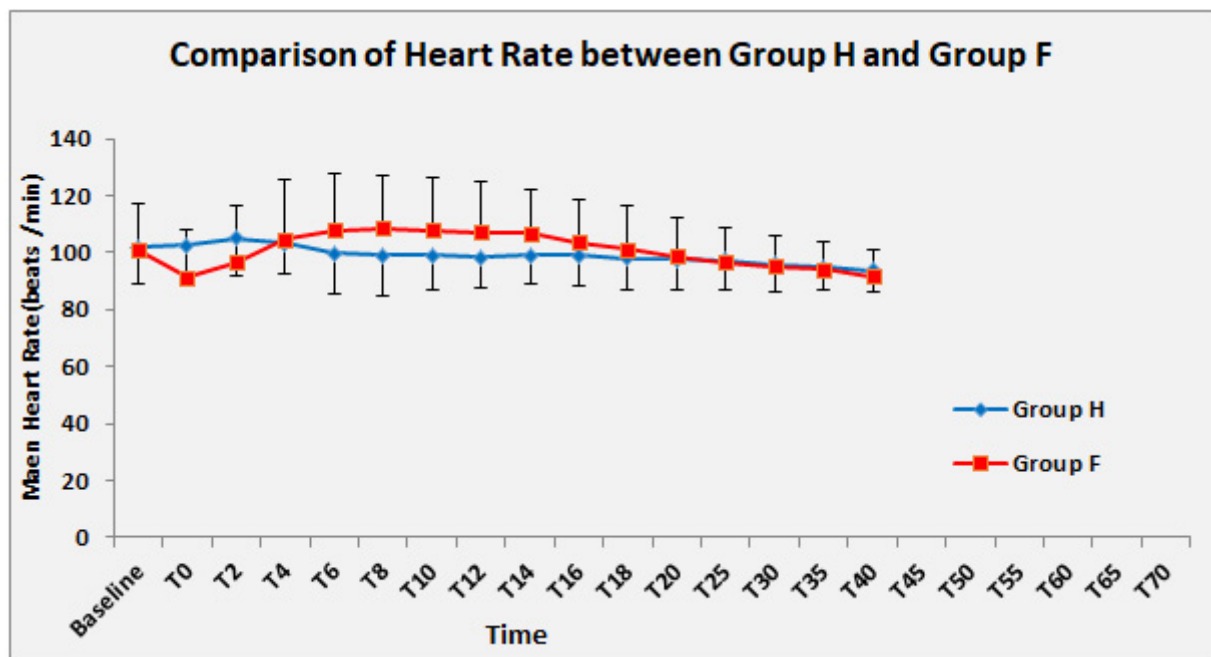


Figure 2: Comparison of mean heart rate in the two-study group at different time points in two groups. TB: Baseline; T0: At spinal block; T2, T4, etc. readings at 2 minutes, 4 minutes etc. from block.

hyperbaric bupivacaine plus 10 µg fentanyl without aspiration [Table 2] while in (Group H) patients received a height adjusted dose calculated as 0.06 mg/cm height of 0.5% hyperbaric bupivacaine plus 10 µg fentanyl without aspiration [Table 2].

Patients were given supine position after spinal block, with a wedge under the right hip for left uterine displacement. All patients were given supplemental oxygen at a rate of 2 l/min through a face mask.

Sensory block to T5 dermatome and motor block of modified Bromage scale 3 was considered adequate. Modified Bromage scale (0=no motor block, 1=inability to raise extended leg, 2=inability to flex the knee and 3=inability to flex the ankle and foot), respectively.

Heart rate, blood pressure (systolic, diastolic and mean) were

noted at time of injection of study drug, every two minutes for the first 20 minutes after study drug injection and every 5 minutes thereafter, till 40 minutes or till the end of surgery whichever is later.

Bradycardia (heart rate <60/min) was treated with intravenous 0.6 mg intravenous atropine. Hypotension (>20% decrease in baseline Mean Arterial Pressure (MAP) and was treated with intravenous 5 mg ephedrine.

Surgery was initiated once adequate the sensory block was achieved. A 10° head-down tilt was given if required to ascend the height of block. In case of patient discomfort, injection 50 µg fentanyl were administered. We converted to general anesthesia if required. The number of hypotensive episodes, total number of mephentermine bolus doses administered and requirement

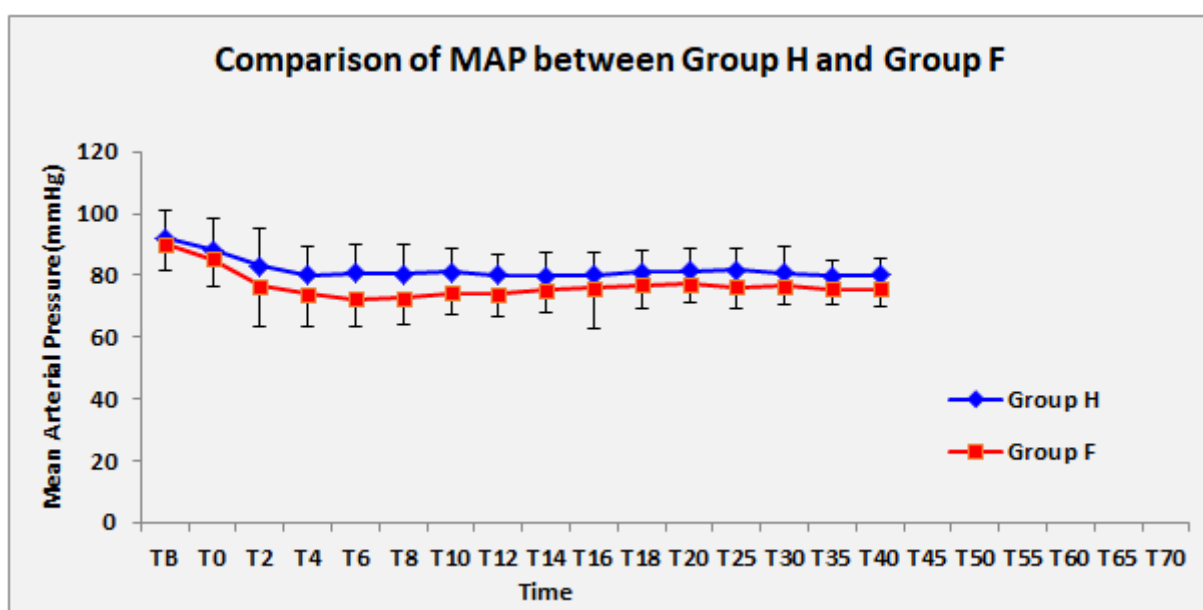


Figure 3: Comparison of mean arterial blood pressure in two groups. TB: Baseline; T0: at spinal block; T2, T4, etc. readings at 2 minutes, 4 minutes etc. from block.

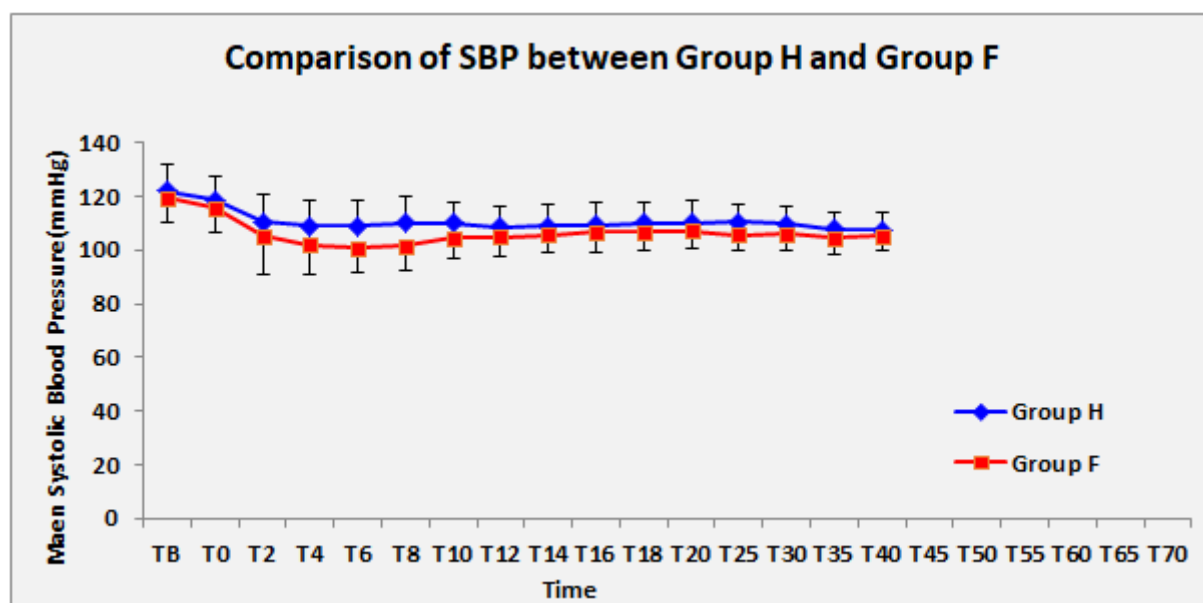


Figure 4: Intergroup comparison of systolic blood pressure in both the study groups at different time points. TB: Baseline; T0: At spinal block; T2, T4 etc. readings at 2 minutes, 4 minutes etc. from block.

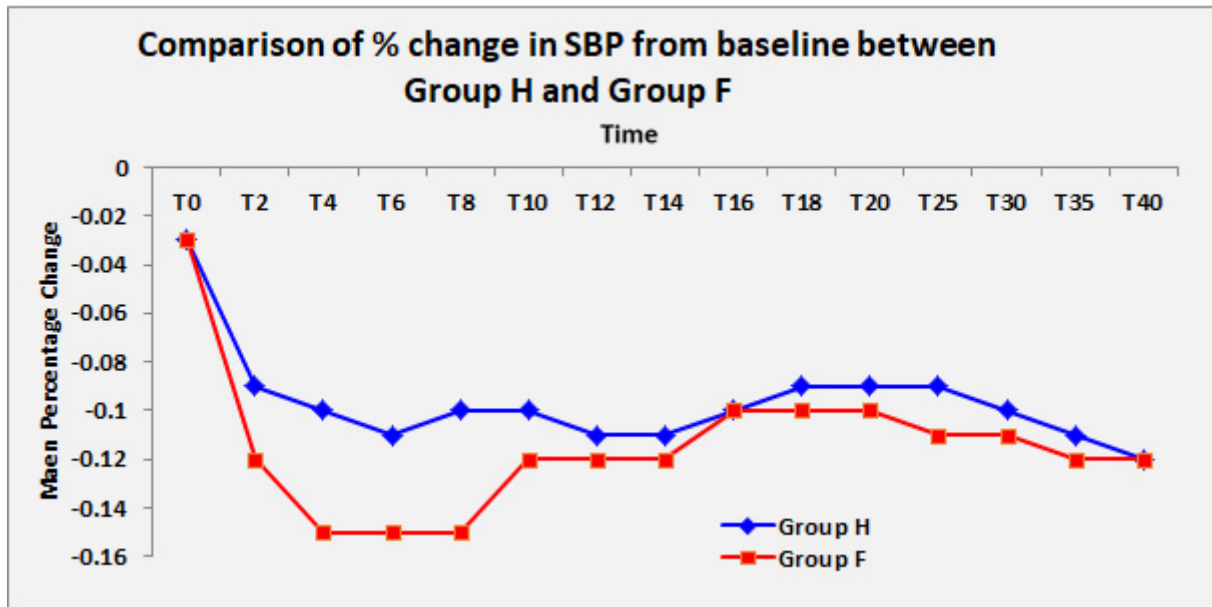


Figure 5: Intergroup comparison of percentage change in systolic blood pressure from baseline in both the study groups at different time points. TB: Baseline; T0 at spinal block; T2, T4, etc. readings at 2 minutes, 4 minutes etc. from block.

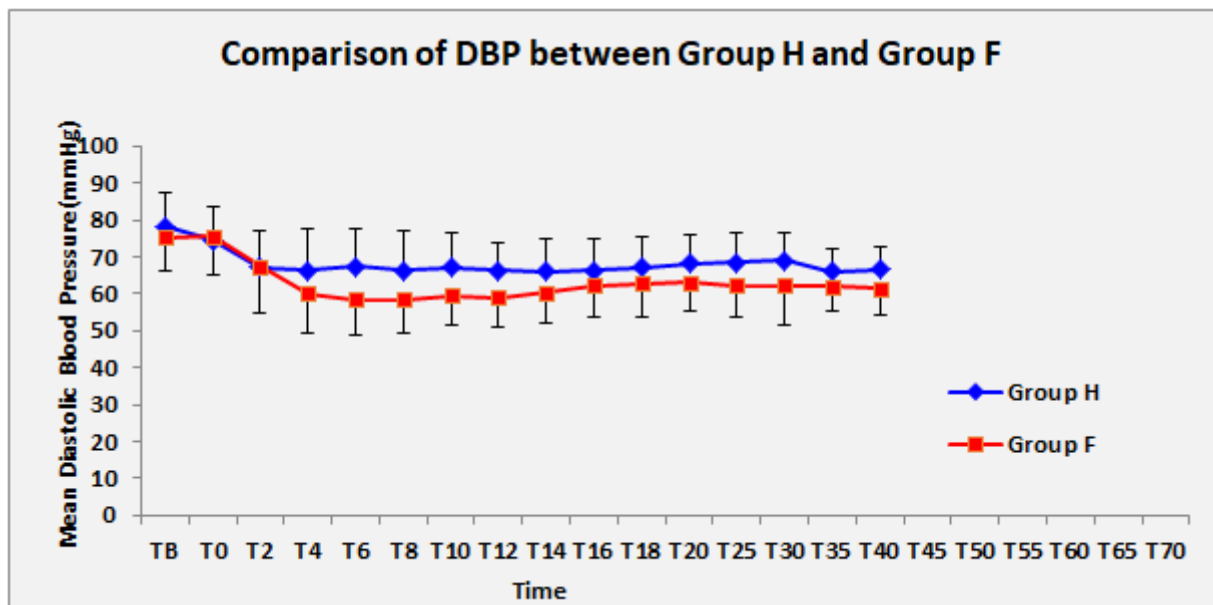


Figure 6: Intergroup comparison of mean diastolic blood pressure in the two study groups at different time points. TB: Baseline; T0 at spinal block; T2, T4, etc. readings at 2 minutes, 4 minutes, etc. from block.

of atropine was noted. The occurrence of nausea (none, mild, moderate, or severe) and vomiting was noted. If nausea or vomiting was not associated with hypotension, it was treated with 4 mg injection ondansetron IV. If there was associated hypotension, then treatment for hypotension was given.

Time (min) to achieve motor block, time (min) to regression of sensory block to S2 (min), time required for complete recovery were also noted.

Results

110 women with singleton pregnancies were analyzed. Patients were randomly divided into two groups with 55 patients in each group.

In group H, the mean volume of bupivacaine administered to

patients was $1.89 \text{ ml} \pm 0.67 \text{ ml}$ which was significantly lower than that in group F which was $2.00 \text{ ml} \pm 0.00 \text{ ml}$, P value was <0.001 by independent samples test to compare means.

In group H the mean total volume of drug (volume including additive drug *i.e.* injection fentanyl) administered to patients was 2.09 ml which was significantly lower in group F where in it was 2.2 ml, P value was <0.001 which is significant.

Mean heart rate in the two study groups was comparable, $P=0.675$ [Figures 1-8]. At time points T6, T8, T10, T12, and T14 statistically significant difference was observed, whereas it was statistically not significant at all other time points.

From time points T2 to T40, there was a statistically significant difference in mean arterial blood pressure whereas it was not significant at baseline and at T0.

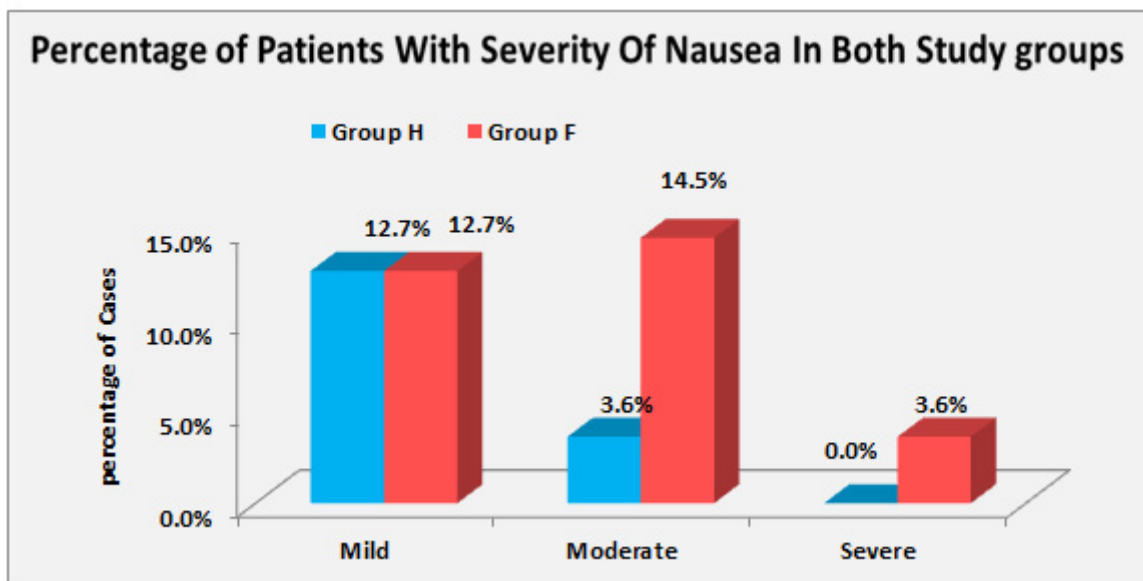


Figure 7: Percentage of patients with nausea in both group.

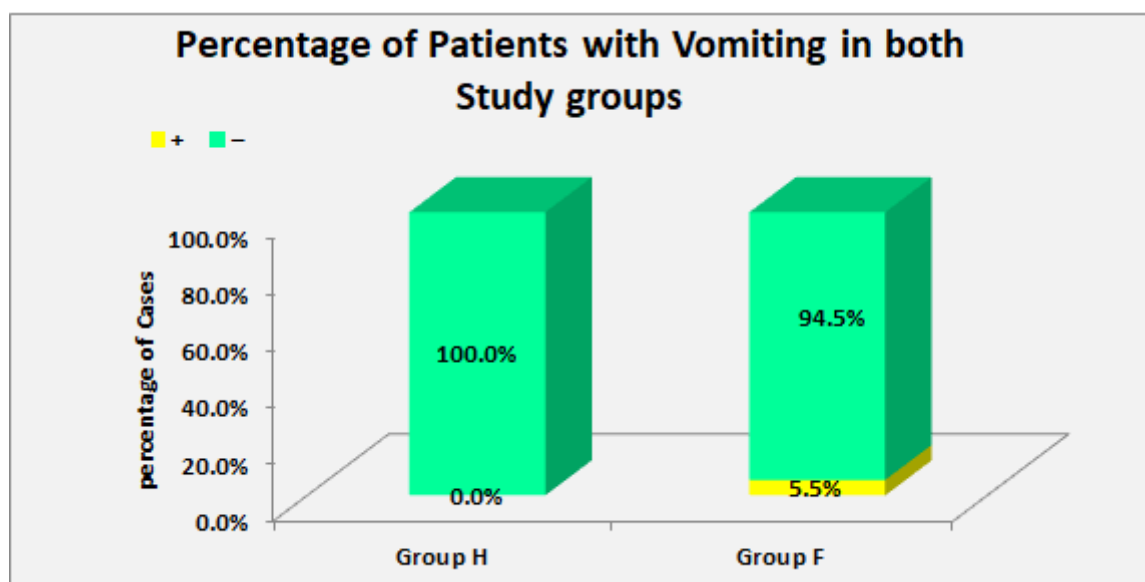


Figure 8: Incidence of vomiting in both study group.

The baseline mean systolic blood pressure in the two groups was comparable, $P=0.169$. However, with the exception of TB, T0, and T16, there was a statistically significant difference in mean systolic blood pressure at all other time points. At most time points, the mean systolic blood pressure in the fixed dosage group (Group F) was considerably lower than that in the height adjusted group (Group H).

At T4, T6, T8, and T10, there was a statistically significant difference in mean percentage change in systolic blood pressure from baseline. The mean percentage change in systolic blood pressure at T0, T2 and T12-T40 in the two groups was comparable.

At time points T4 to T40, a statistically significant difference in mean diastolic blood pressure was observed whereas it was not statistically significant at baseline and time points T0 and T2.

Table 4 shows the incidence of hypotensive episode which was

significantly higher in group F compared to group H. P value is <0.001 by Chi-square test, the difference was a statistically significant.

It was observed that number of mephentermine bolus doses required were statistically significant higher in group F. P value is <0.001 by Chi-square test

In group H none of the patients required atropine bolus doses whereas in group F, 2(3.6%) patients required atropine bolus doses. Between the two study groups, there was no statistically significant difference in the number of atropine bolus doses administered. P value is 0.495 by Chi-square test.

Mean time for effective block was more in group H compared to group F. Patient receiving fixed dosages required more time for regression of both sensory and motor block so the recovery as compared to group H. The 1 and 5 min fetal APGAR score was not affected in our study in both the groups

Head down tilt given during caesarean section

It was observed that very few patients in group H required head down tilt for achieving adequate block level which is not significant.

Supplemental analgesia

In our study while using height adjusted dosage few patients (29.1%) required supplemental analgesia compared to fixed dose group.

Conversion to GA

In our study none of the patient required conversion to general anaesthesia.

Patients with severe nausea

There was no statistically significant difference in mild episodes of nausea (P value is 1.000), between both study groups. Number of patients with moderate nausea were more in group F Compared to group H but statistically was not significant. P value is 0.093 by Chi-square.

Number of patients with severe nausea was 0 and 2(3.6%) in group F, P value is 0.495 by Chi-square test indicates that there was no statistically significant difference in severe episodes of nausea between both study groups.

In group H, there were no episodes of vomiting seen whereas in group F number of episodes of vomiting was 3(5.5%). There was no statistically significant difference in the number of episodes of vomiting between the two research groups. Chi-square calculates a P value of 0.243.

Discussion

Being simple, rapid, and safe technique spinal anaesthesia is the most common anaesthetic technique for performing caesarean section in aparturient. Fall in blood pressure after spinal anaesthesia, on the other hand, is a major concern in caesarean patient which may cause unpleasant symptoms such as nausea, vomiting, and dizziness. Severe hypotension if occurs can cause unconsciousness, apnoea, and cardiac arrest in extreme cases, as well as impede placental perfusion and affect neonatal fate.

For caesarean sections, a variety of spinal anaesthetic dose regimens are available. Previous data suggests a direct correlation between with height and onset of an adequate sensory level.^[1-3]

We compared two spinal anaesthetic dosing regimens for caesarean section depending on height of patient or a fixed dose in this trial and it was postulated that a 0.5% hyperbaric bupivacaine dose adjusted for height would be linked with a decreased incidence of hypotension than a fixed dose. In group F recovery time was longer than in group H, even though difference is not significant. Height has no effect on hyperbaric spinal anaesthesia, according to Norris. The amount and volume of local anaesthetic agent administered, on the other hand, should theoretically alter the severity of hypotension. Herten et al.^[4] stated that severe hypotension can be prevented after using adjusted dose of hyperbaric medication.

Other trials by Nagata et al.^[5] of Japan and Chung et al.^[1] of Korea found that pregnant women require less local anaesthetic than non-pregnant women, and also height-adjusted dose minimizes the danger of maternal hypotension. In these trials, however, these two dose regimes were not compared.

Our results show that spinal anaesthesia can be used safely even with a height-adjusted dosage. Although maternal hypotension found to be decreased in the height-adjusted group, there was no evidence that this was linked to better foetal outcome. Other factors which affect the spinal anaesthesia such as, baricity, position, injection site, type of local anaesthetic solution should also be considered for final outcome.

Under spinal anaesthesia, the incidence of hypotension in women undergoing caesarean section is highest. Female sex, age>50 years, BMI>35 kg/m², and the nature of the procedure are non-modifiable risk factors. A high bupivacaine dose and a sensory block level of T5 are two more controllable risk factors.^[1] In this study, all variables are compared including height.

In our research, only 29.1% of patients in group H required supplemental analgesia, which was statistically significant in comparison to Gupta et al. study (p<0.001). General anaesthesia was not required in either group in the current trial, which is consistent with Harten et al.^[4] findings.

Study reveals that there was no statistically significant difference in nausea and vomiting episodes in the two groups. In group H, 12.7% patients had mild and 3.6% patients had moderate nausea and no patient had severe nausea and vomiting. While in group F, 12.7% patients had mild, 14.5% patients had moderate and 3.6% patients had severe nausea and 5.5% patients experienced vomiting. However, Subedi et al. found nausea and vomiting to be higher amongst patients of fixed dose.

Our findings of significant increase in induction to skin incision time was again similar to the result of Harten et al. and Jain et al.^[5-17] although there was increase in induction to skin incision interval, the baby's APGAR score after 1 minute and 5 minutes had no significant impact.

Hypotension during spinal anaesthesia for caesarean delivery is as high as 80% despite using many methods like preloading of IV fluid, left uterine displacement. A number of studies on use of Bupivacaine were reported.^[18-21] Some of the related studies were reviewed,^[22-24] hypotension, although can be treated with intravenous ephedrine, it is still a difficult challenge, and no single approach is optimal. When the spinal anaesthetic dose is not determined properly, the adverse effects of spinal anaesthesia during caesarean section can be dangerous. In this trial, less ephedrine was needed since the bupivacaine dose was adjusted based on the patient's height, which reduced the incidence of hypotension, nausea, and vomiting in pregnant patients.

Conclusion

The height based dose of 0.5% hyperbaric bupivacaine decreases the chances of hypotension, need of vasopressors with better haemodynamic stability although similar incidence of nausea and vomiting in comparison to those receiving a fixed dose of 0.5% hyperbaric bupivacaine in parturients undergoing caesarean delivery under spinal anaesthesia.

Limitation of our study is that it associated with a lower level of sensory block with greater number of patients requiring a head down tilt. Also the time from study drug injection to skin incision is longer, leading to delay in uterine incision, delivery of baby and its effect on APGAR score of baby. All these parameters need to be studied further by increasing the sample size.

Also present trial was designed for elective cases and emergency cases were excluded. We also need to study whether this research can be applied to emergency cases.

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