Section: Anaesthesiology

Original Research Article

COMPARATIVE STUDY OF 8 MG, 9 MG & 10 MG 0.5% HEAVY BUPIVACAINE WITH 15 µG FENTANYL FOR SUBARACHNOID BLOCK IN CAESAREAN SECTION

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ABSTRACT

Background: Though there have been many studies comparing the combination of hyperbaric bupivacaine with fentanyl for spinal anaesthesia for caesarean section, there is still the requirement for further standardization of doses of these drugs, promising single best combination of drugs in providing optimal anaesthesia and minimal to nil adverse effects. Hence, this is the study of comparison of 3 different doses of hyperbaric bupivacaine which is 8mg, 9mg and 10 mg of 0.5% hyperbaric bupivacaine with fentanyl 15 µg with regards to synergistic effect on sensory and motor block, recovery profile, quality of intra-operative and postoperative analgesia, haemodynamic changes, adverse effects.
Materials and Methods: This is a double blinded, prospective comparative study conducted at District Hospital, Bellary, which is a tertiary care hospital. A total of 120 pregnant women of American Society of Anaesthesiologists physical status II posted for caesarean section at DISTRICT HOSPITAL BALLARY were selected on the basis of simple random sampling method.
Results: This study has shown that, the onset of analgesia was longer in lower doses of bupivacaine, the duration of analgesia was longer in higher doses. The hemodynamic parameters were comparable in all the three groups. The incidence of adverse effects was higher with higher doses of hyperbaric bupivacaine. Though the onset of sensory analgesia is faster with higher doses of bupivacaine, the incidence of hemodynamic side effects or complications is more was observed.
Conclusion: We have concluded that 9mg bupivacaine with 15 micrograms of fentanyl would be an ideal choice for subarachnoid block in parturient coming for caesarean section.
Keywords: Caesarean section; Pregnancy; Spinal anaesthesia, hyperbaric bupivacaine.

INTRODUCTION

Spinal anesthesia in obstetrics differs from that of non-pregnant in many ways. Smaller doses of local anesthetics are used for spinal anesthesia during pregnancy since there will be change in CSF volume in spinal subarachnoid space due to compression of inferior venae cava by gravid uterus and increased hormonal influence of the progesterone.[1]
The maternal hypotension during spinal anaesthesia is common, rapid in onset and has adverse effects on both mother and fetus. The principal cause is rapid sympathetic blockade which depends mainly on the dose of hyperbaric bupivacaine and the other cause is aortocaval compression.[2]
Currently there is dearth in the literature related to an ideal dose required for spinal anesthesia in caesarean section and hence this is a study for comparison of 3 different doses of hyperbaric bupivacaine with regards to synergistic effect of intrathecally administered Fentanyl 15 µg with 8mg, 9mg and 10 mg of 0.5% hyperbaric bupivacaine on sensory and

motor block, recovery profile, quality of intra operative and postoperative analgesia, hemodynamic changes, adverse effects.

MATERIAL AND METHODS

After obtaining approval from the Institutional Ethical Committee, this retrospective observational study was carried out with the principles of Helsinki Declaration. A double blinded prospective comparative study was conducted at District Hospital, Bellary which is a tertiary care hospital. A total of 120 pregnant women of ASA physical class II posted for caesarean section at DISTRICT HOSPITAL BALLARY were selected on the basis of simple random sampling method. This study was conducted between 1st January 2021 to 31st December, 2021. An informed and written bilingual consent was obtained from all the subjects included in the study.

The subjects thus selected were divided equally into three equal groups of 40 each. Computer generated random numbers were used to randomize patients into three groups.

The patients selected for the study were subjected for thorough pre-anaesthetic examination and appropriate laboratory investigations were ordered. The patients were kept nil by mouth for six hours before the caesarean section. The peripheral venous access was made using 18G IV Canula before the procedure and the patients were preloaded with ringer lactate solution 10ml/kg body weight half an hour before giving spinal anesthesia. Baseline values of pulse rate, non-invasive blood pressure (NIBP) & oxygen saturation were recorded. Inj. ondansetron 4 mg slow IV and Inj. Pantoprazole 40mg slow IV were given as premedication 30minutes before induction of spinal anesthesia. The position of table was kept horizontal. Under all aseptic precautions lumbar puncture was done using a 25-gauge Quincke's needle. Space used was L3 –L4 in midline in left lateral position and drug was injected and patient was made to lie supine with 15^0 tilt of table to left or a wedge under the right buttock. All the spinal solutions were made to a total volume of 2.3 ml using appropriate volume of NS before injecting intrathecally. The intrathecal preparations were made by a consultant who is not part of the study. Group 8 (G8) received 8 mg of 0.5% hyperbaric bupivacaine hydrochloride, Group 9 (G9) received 9 mg and Group 10 (G10) received 10 mg of hyperbaric bupivacaine along with 15 micrograms of fentanyl hydrochloride in all groups intrathecally aseptically.

The analysis was carried out with the aim to study synergistic effect of intrathecally administered Fentanyl 15 µg with three different doses of hyperbaric bupivacaine which were 8mg, 9mg and 10 mg of 0.5% hyperbaric bupivacaine on sensory and motor block, recovery profile and also quality of intra operative and postoperative analgesia and the hemodynamic changes. The data was collected prospectively using uniform data collection sheet.

Inclusion Criteria

1. Patients belonging to ASA class II with singleton pregnancy with term gestation posted for caesarean section, who had no contraindication for spinal anesthesia
2. Parturients aged 20-30yrs
3. Parturients of height 145-175cm
4. Parturients of weight 45kg-85kg.

Exclusion Criteria

1. Patients with co-morbid conditions like diabetes mellitus, hypertension, asthma, obesity etc.
2. Patients classified to ASA class III and classes above.
3. Patients with PIH, Eclampsia, multiple pregnancy, placenta previa.
4. Short statured parturients according to WHO guidelines.

Anesthesia was administered by two healthcare professionals from the Anesthesia team, including senior Anesthesiologist and an Anesthesia Resident.

Statistical analyses were performed with SPSS 21 Windows (Statistical Package for Social Sciences) package software. Continuous data were expressed in mean, standard deviation, while categorical data were expressed in numbers (percent). Spearman's correlation test and paired t test was used for correlation analysis. The value $p < 0.05$ was taken as statistically significant.

RESULTS

The study population consisted of 120 parturients posted for elective caesarean delivery at Department of Anaesthesiology, District hospital, Ballari

They were randomly divided into three groups of 40 each (n=40).

Group G8: 8mg 0.5% Hyperbaric Bupivacaine+15µg of Fentanyl

Group G9: 9mg 0.5% Hyperbaric Bupivacaine+15µg of Fentanyl

Group G10: 10mg 0.5% Hyperbaric Bupivacaine+15µg of Fentanyl

The following observations were made during the course of the study.

In this study, about 57.5% of the cases in G8 group, 55.0% of the cases in G9 group and 60.0% of the cases in G10 group belonged to 21 – 25 years. The mean height in G8 group was 154.5cm, G9 group was 148.7cm and G10 group was 154.2cm which was not statistically significant. The mean weight in G8 group was 66.7 Kgs, G9 group was 65.2 Kgs and G10 group was 66.1 Kgs which was not statistically significant.

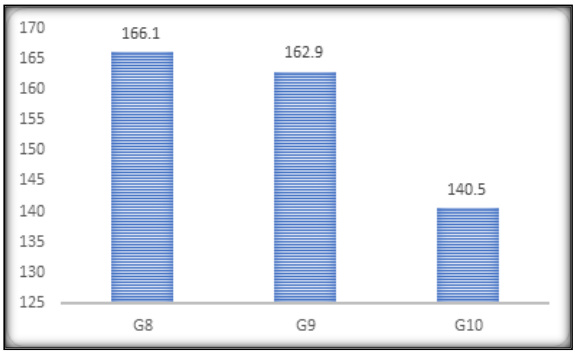

Figure 1: Distribution of the study according to time of onset of sensory analgesia

The mean time of onset of sensory analgesia was 166.1 seconds in G8 group, 162.9 seconds in G9 group and 140.5 seconds in G10 group which was statistically significant between the different doses of drug (see figure 1).

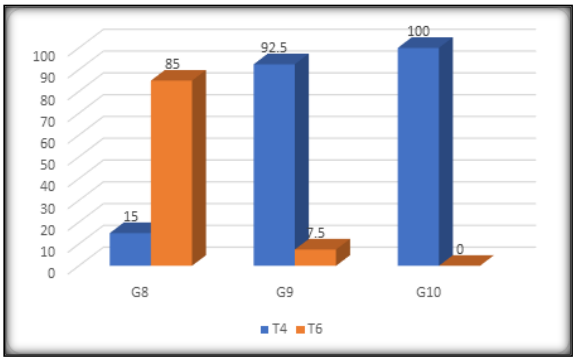

Figure 2: Distribution of the study according to level of sensory analgesia

The level of sensory analgesia was up to T4 in 15.0% of the cases of G8 group, 92.5% of the G9 group and all the cases of G10 group. This difference in level of sensory analgesia was statistically significant (see figure 2).

The total duration of analgesia was 196.9 minutes in G8 group, 239.4 minutes in G9 group and 250.1 minutes in G10 group which was statistically significant. The total duration of onset of motor analgesia was 270.5 seconds in G8 group, 258.1 seconds in G9 group and 254.4 seconds in G10 which was statistically significant. The total duration of motor block in 115.5 minutes in G8 group, 120.1 minutes in G9 group and 137.6 minutes in G10 group which was statistically significant between the different groups with respect to total duration of motor block. [Table 1]

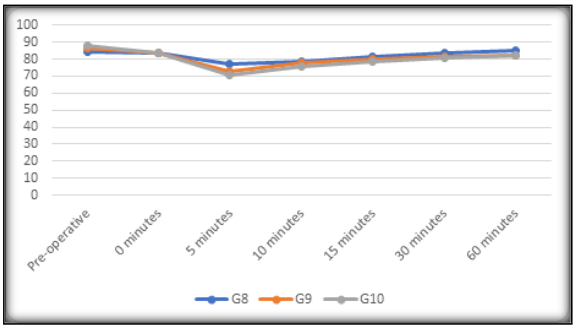

Figure 3: Distribution of the study according to mean arterial pressure

The mean arterial pressure in pre-operative period was 84.6 mm of Hg in G8 group, 86.3 mm of Hg in G9 group and 87.6 mm of Hg G10 group which was not statistically significant. The mean arterial pressure was statistically significant at 5 minutes between the three groups. The mean blood pressure decreased at 5 minutes and reverted back to initial levels at 60 minutes. (see figure 3).

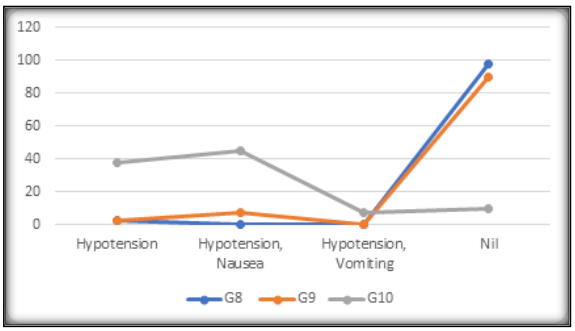

Figure 4: Distribution of the study according to adverse effects

Hypotension was present in 2.5% of the G8 group and G9 group while 37.5% of partutients in G10 group of patients had hypotension. Hypotension and nausea were present in 7.5% of the G9 group of patients and 45.0% of the G10 group of patients. Hypotension and vomiting was present in 7.5% of the cases in G10 group. This difference was statistically significant between the three groups. (see table 2 and figure 4).

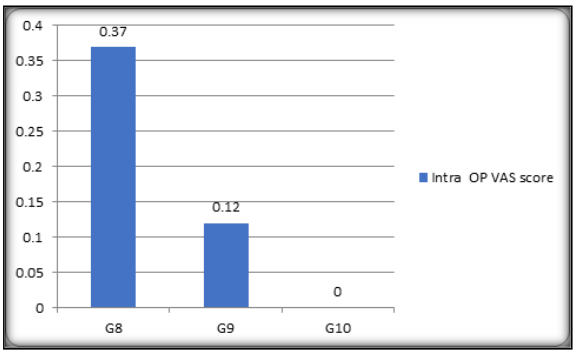

Figure 5: Distribution of the study according to Intra operative VAS score

The intra operative VAS score was 0.37 in G8 group, 0.12 in G9 group and 0 in G10 group which was significantly different. (see figure 5)

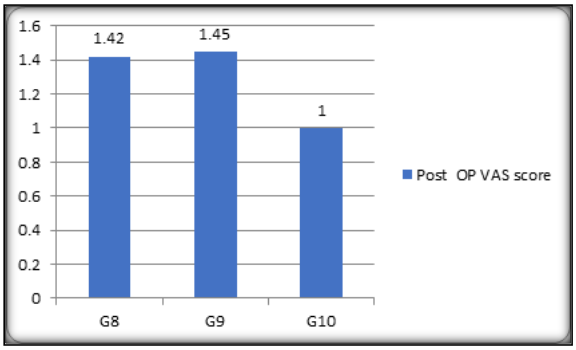

Figure 6: Distribution of the study according to post-operative VAS score

The post-operative VAS score in G8 group was 1.42, 1.45 in G9 group and 1 in G10 group which was statistically significant between the three groups. (see figure 6).

Table 1: Distribution of the study according to total duration of analgesia, onset and duration of motor blockade

	G8 Mean ± SD	G9 Mean ± SD	G10 Mean ± SD	F value	P Value, Sig
Total duration of analgesia (min)	196.9 ± 10.1	239.4 ± 20.5	250.1 ± 5.3	172.998	0.000, Sig
Time of onset of motor analgesia (sec)	270.5 ± 29.6	258.1 ± 22.1	254.4 ± 3.1	6.271	0.003, Sig
Total duration of motor block (min)	115.5 ± 5.34	120.1 ± 3.34	137.6 ± 6.6	194.741	0.000, Sig

Table 2: Distribution of the study according to adverse effects

Adverse effects	G8 n (%)	G9 n (%)	G10 n (%)
Hypotension	1 (2.5)	1 (2.5)	15 (37.5)
Hypotension, Nausea	0	3 (7.5)	18 (45.0)
Hypotension, Vomiting	0	0	3 (7.5)
Nil	39 (97.5)	36 (90.0)	4 (10.0)
Total	40 (100)	40 (100)	40 (100)

DISCUSSION

The incidence of caesarean section is increasing in the last few decades. Spinal anesthesia is the most preferred technique of anesthesia for the caesarean section. Bupivacaine is the local anesthetic used routinely for caesarean section due to its high potency and minimal neurological symptoms. The larger dose of local anesthetic is required to alleviate the visceral pain due to traction of peritoneum and intraperitoneal organs during caesarean section but larger dose is available with high levels of block and undesirable side effects. This study was undertaken to study the efficacy of different doses of bupivacaine in combination with 15 µg of Fentanyl for spinal an esthesia in caesarean section.[3,4,5]

The injection of local anesthetic solutions into subarachnoid space produces important and widespread physiologic responses. The most important physiologic response to spinal anesthesia involves the cardiovascular system. They are mediated by the combined effects of autonomic denervation and, with higher levels of neural blockade, added effects of vagal innervation. The cardiovascular effects of spinal anesthesia are not due to the presence of local anesthetics in ventricular CSF in concentrations sufficient to produce direct depression of medullary vasomotor centers.[6]

Arterial blood pressure is dependent on cardiac output and systemic vascular resistance and is controlled by many factors: Diminished cardiac output as a result of reduction of venous return to heart due to lack of muscular propulsive force in veins. Paralysis of vasoconstrictor nerve fibers leads to dilation of post-arteriolar capillaries and small venules and is seen in all areas including somatic and visceral areas. In non-anesthetized areas, as majority of vasoconstrictor fibers, including those to the arm (T2-T10) are paralyzed.[7]

The maternal hypotension during spinal anesthesia is common, rapid in onset and has adverse effects on both mother and fetus. The principal cause is rapid sympathetic blockade and aortocaval compression. The volume replacement by preloading with 10-15ml/kg body weight of crystalloid is more effective in prevention of hypotension.[8]

The vasopressors like ephedrine, mephentermine and metaraminol have only slight α- adrenergic activity and do not cause vasoconstriction and fetal acidosis.[9]

The fetal condition is not affected if hypotension during spinal block is treated quickly. The infants born by caesarean section under spinal anesthesia are in better condition than those born under general anesthesia.[10]

Post dural puncture headache(PDPH) is another troublesome complication of spinal anesthesia. This can be easily prevented by small needle size. Smaller the needle size, lesser will be the incidence of PDPH.[11]

FENTANYL[12,13,14]

It is one of the most widely used agents in the family of the synthetic opioids. It is available in parenteral, transdermal and trans-buccal preparations. It is the oldest synthetic piperidine opioids agonist, interacting primarily with mu receptors. It is approximately 100 times more potent than morphine and is highly lipophilic and binds to plasma proteins.

Age group

In this study, about 57.5% of the cases in G8 group, 55.0% of the cases in G9 group and 60.0% of the cases in G10 group belonged to 21 – 25 years. A study by Bogra et al also reported similar findings.15 The mean age group was comparable in a study by Rao et al.[16]

Anthropometric measurements

The mean weight in G8 group was 66.7 Kgs, G9 group was 65.2 Kgs and G10 group was 66.1 Kgs which was not statistically significant. A study by Bogra et al. also reported similar findings.15 The results were similar to study by Rao et al.[16]

Time of onset of sensory analgesia

The mean time of onset of sensory analgesia (at T6) was lower in G10 group (140.5 ± 8.4 seconds) and higher in G8 group (166.1 ± 9.1 seconds) and this difference was statistically significant. A study by Bogra et al reported that the onset of sensory block to T6 occurs faster with increasing bupivacaine doses which correlates with our study findings15. In a study by Rao et al, the time of onset of sensory analgesia was higher in lower doses of Bupivacaine similar to results of our study.[16]

Level of sensory analgesia

The level of sensory analgesia was up to T4 in 15.0% of the cases of G8 group, 92.5% of the G9 group and all the cases of G10 group. This difference in level of sensory analgesia was statistically significant. A study by Bogra et al also reported similar findings.15 In a study by Rao et al, the level of sensory analgesia was at T4 in higher doses of Bupivacaine compared to lower doses of Bupivacaine which is similar to the results of our study.[16]

Duration of analgesia

The total duration of analgesia was 196.9 minutes in G8 group, 239.4 minutes in G9 group and 250.1 minutes in G10 group which was statistically significant. In a study by Rao et al, the total duration of analgesia was higher in higher doses of Bupivacaine than the lower doses of Bupivacaine.16 In a study by Kiran et al, the mean time to start regression of sensory block was greater in higher dose of Bupivacaine.[17]

Time of onset of motor block

The onset of motor blockade (Bromage Grade 0) was longer in G8 group (270.5 ± 29.6 seconds) when compared with the G 9(258.1 ± 22.1 seconds) and G10 groups (254.4 ± 3.1 seconds) which was also statistically significant. Similarly, Rao et al, found that the time of onset of motor block was shorter with higher doses of bupivacaine than the lower doses which correlates well with our study findings.[16]

Duration of motor block

The total duration of motor block in 115.5 minutes in G8 group, 120.1 minutes in G9 group and 137.6 minutes in G10 group which was statistically significant between the different groups with respect to total duration of motor block. The total duration motor block was longer in G10 group when compared with the G8 group which was statistically significant. A study by Bogra et al had shown that, the motor recovery had taken longer with increasing doses of bupivacaine.15 Rao et al reported that, the total duration of motor block was higher in higher doses of Bupivacaine.16 In a study by Kiran et al, the duration of motor block was greater in higher dose of Bupivacaine.[17]

Heart rate

The heart rate increased after the intrathecal injection of study drug in all the groups. The heart rate reduced to pre-operative levels at 60 minutes but it was not statistically significant between the three groups. These results were comparable with a similar study by Rao et al.[16]

Complications

Hypotension was present in 2.5% of the G8 group, 2.5% of the G9 group and 37.5% of the G10 group of patients. Hypotension and nausea were present in 7.5% of the G9 group of patients and 45.0% of the G10 group of patients. Hypotension and vomiting were presenting in 7.5% of the cases in G10 group. This difference was statistically significant between the three groups. In a study by Bogra et al, bradycardia was found in 10 – 15% of the cases. The incidence of vomiting was more in bupivacaine alone group.[15] A study by Rao et al also noted similar results.[16] In a study by Kiran et al, the incidence of hypotension was greater with higher doses of bupivacaine. Higher dose of bupivacaine had greater incidence of bradycardia than the lower doses.[17] In a systematic review by

Arzola et al (2011), low dose group exhibited a lower risk of hypotension (RR = 0.78, 95% CI= 0.65 – 0.93) and nausea / vomiting (RR=0.71, 95% CI=0.55 – 0.93). Conversion to general anesthesia occurred only in the low dose group (two events). Neonatal outcomes (Apgar score, acid – base status) and clinical quality variables (patient satisfaction, surgical conditions) showed insignificant differences between low dose and conventional dose. This demonstrated that, low dose Bupivacaine in spinal anesthesia compromises anesthetic efficacy (risk of analgesic supplementation: high grade of evidence), the benefit of lower maternal side effects.[18]

Ahmed et al (2016) included 60 pregnant mothers scheduled for caesarean section who were divided into two groups. Group A received 12mg of 0.5% hyperbaric Bupivacaine with fentanyl and Group B received 8 mg of hyperbaric Bupivacaine with Fentanyl. The mean time required to reach peak sensory level was earlier in group-B than group-A and was statistically significant ($p<0.05$). The decrease in systolic blood pressure in group A was significantly more than group B ($p<0.05$) and

vasopressor requirement was also significantly more in group A compared to group B ($p<0.05$). Mean time of two segment regression of sensory analgesia and complete sensory recovery was significantly early in group B ($p<0.05$). Duration of motor recovery in group B was significantly earlier ($p < 0.05$). The duration of effective analgesia was significantly more in group B ($p<0.05$). They concluded that, Low dose Bupivacaine with fentanyl provided excellent intraoperative sensory and motor blockade, haemodynamic stability, and effective postoperative analgesia for caesarean delivery.[19] This study has almost correlated with our study wherein, 9mg (lower dose) was observed as an ideal anesthetic dosage for pregnant patients

CONCLUSION

This study was undertaken with the aim of comparing three different doses of bupivacaine in caesarean section. This study had shown that, the onset of analgesia was longer in lower doses of bupivacaine, the duration of analgesia was longer in higher dose than the lower doses. The hemodynamic parameters were comparable in all the three groups. The incidence of adverse effects was higher with higher doses of hyperbaric bupivacaine. Though the onset of sensory analgesia is faster with higher doses of bupivacaine, the incidence of hemodynamic side effects or complications secondary to it makes us conclude that 9mg Bupivacaine with 15 micrograms of Fentanyl would be an ideal choice for subarachnoid block in parturients coming for caesarean section.

We recommend further studies on this research topic for finding out the ideal dose combinations of these drugs with nil side effects.

Limitations: More studies have to be focussed and researches should be undertaken to explore ideal dose combinations of hyperbaric bupivacaine and fentanyl for spinal anaesthesia for caesarean section.

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Conflict of interest: None declared

Ethical approval

The study was approved by the Institutional Ethics Committee.

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