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Original Research Article

A comparative study of hyperbaric bupivacaine with fentanyl and sequential administration of isobaric and hyperbaric bupivacaine with fentanyl in caesarean delivery

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ABSTRACT

Background: To compare intrathecal sequential plain and hyperbaric Bupivacaine with fentanyl and hyperbaric Bupivacaine with fentanyl for hemodynamic stability, onset of block and duration of block in patients undergoing caesarean delivery under spinal anesthesia.
Methods: This observational, double-blind study, seventy full term parturient, randomly divided to receive either 10 mg 0.5% Hyperbaric Bupivacaine with 25µg Fentanyl or 5 mg each of 0.5% plain and hyperbaric bupivacaine with 25 µg of Fentanyl. Surgery was allowed to proceed when block height reaches T6. Hemodynamic parameters, ephedrine use, time to reach peak dermatomal level and duration of sensory and motor block were compared among two groups.
Results: Demographic data, quality of perioperative anesthesia, Apgar score were identical in both groups. Incidence of Hypotension in HB (77.14%) as compare to 25.71% in PHB. Nausea/Vomiting in both the groups, 68.57% for HB and 25.71% for PHB. For HB, 80% (10.3mg) of patients required Ephedrine while 17 % (4mg) in Group PHB. Peak dermatomal level in minutes was faster in HB (06±1.13) as compare to PHB. (9.06±0.76) Maximum Block level was achieved in HB was T4.94±0.76 and in PHB it was 5.71±0.86. Time to regression of sensory block in minutes for HB was 234.86±10.49 and PHB 258.14±12.37. Recovery from motor block is faster in HB (190.66±10.38) compared to PHB (205.71±11.95).
Conclusions: Sequential administration of low dose of hyperbaric and plain bupivacaine with fentanyl provides better hemodynamic stability, accomplish adequate level of sensory and motor block in obstetric population for caesarean delivery.

Keywords: Hyperbaric bupivacaine, Spinal anesthesia, Caesarean delivery

INTRODUCTION

Spinal anesthesia is widely regarded as a preferred technique for caesarean deliveries due to its simplicity, safety, affordability, low failure rates and minimal risk of systemic toxicity. Fentany, a lipophilic opioid, is commonly used as an adjunct to enhance this technique.[1] Its addition has demonstrated benefits, including reduced intraoperative analgesia requirements, decreased nausea/vomiting incidents and extended time until the need for postoperative pain relief arise.[1] Hypotension is a frequent side effect of spinal anesthesia in caesarean sections and its severity and duration significantly impact both maternal and neonatal outcomes. These all adverse effects depend on severity and duration of Hypotension.[2] To ensure comfort and prevent visceral pain during surgery, achieving a sensory block level of T4 or T5 is essential.[3] Rawal et al, examined the combined spinal-

epidural block for caesarean section, advocating for limiting the dense spinal block to the lower segments and extending analgesia with epidural injections of Local Anesthetics.[4] In pursuit of optimizing spinal anesthesia, this study proposed the sequential administration of low doses of isobaric and hyperbaric bupivacaine. The approach aims to minimize the disadvantages while leveraging the advantages of both solutions.

METHODS

Study type

This was a original article, prospective, randomized, double-blinded, observational study.

Study place

Adarsh Multispecialty Hospital-Kalol. Ananya College of Medicine and Research, Kalol-Gandhinagar

Study period

The study period was from 22/07/2024 to 21/11/2024.

Selection criteria

Patients with full term pregnancy for caesarean delivery under spinal anaesthesia without contraindication to spinal anaesthesia, multiple pregnancies and placenta Previa.

Procedure

After written informed consent, Seventy- full-term parturient of ASA grade I and II, aged 20-33 years, undergoing caesarean delivery under spinal anesthesia, were randomly assign to one of two groups by computer-generated random tables: the hyperbaric bupivacaine group (HB) (n=35) and plain and hyperbaric bupivacaine group (PHB) (n=35).

All patients were fasted for 6 hours, thirty minutes prior to shifting to OT, peripheral line was cannulated with 20 G cannula. Metoclopramide 10 mg, Ranitidine 50 mg and Antibiotic prophylaxis intravenous (iv) were given. Preloading was done with 10 ml/kg of ringer lactate solution within 20 minutes of spinal anesthesia. Group HB (n=35) were given 10 mg (2 ml) 0.5% hyperbaric bupivacaine with 25 µg of fentanyl in single syringe, while Group PHB (n=35) received 5 mg (1 ml) 0.5% isobaric bupivacaine and 5 mg (1 ml) 0.5% heavy bupivacaine with 25 µg of fentanyl in different syringe. All the patients were not informed about the drug they received. An independent anaesthetist, not involved in the study, administered the drug, while the results were noted by another anaesthetist. On arrival in OT, baseline hemodynamic parameters such as non-invasive blood pressure (NIBP), 3 lead electrocardiogram, pulse oximetry (SPO2) and heart rate were recorded and noted in the supine position. Skin infiltration was done with 0.5% Lignocaine with 26 G hypodermic needle, in sitting position. Under aseptic precautions lumbar puncture was performed using midline approach either at L2-3 or L3-4 interspace with 25 G or 27 G Quincke needle, with its bevel facing cephalad. After free flowing about the CSF study drug which was given without barbotage over about 25 seconds. In group PHB 1ml of hyperbaric bupivacaine with 0.5 ml of fentanyl without barbotage followed by 1 ml of isobaric bupivacaine. Each drug was given over 10 seconds, change of syringe takes less than 5 seconds.

After withdrawing needle all women were put in supine position immediately. A wedge was kept under right hip until delivery of baby. Sensory block had been assessed by the use of blunted 24 G hypodermic needle, every 1 min and up to 10 min. It was evaluated for its time to reach highest dermatomal level. Surgery had been allowed to proceed when block level reached T6. Time to the regression up to T12 level and total duration of the sensory block had been recorded. Duration about the sensory block have been defined with time interval from the injection of drug to the regression of sensory block up to level of T12. Modified Bromage Scale had been used to assess motor block. It had been evaluated with regard to its time of onset, degree of motor block and duration of motor block. It was noted immediately after giving supine position, till score reaches 4. Postoperatively it was assessed every 30 minutes up to 4 hours and then hourly till score reaches 0. Onset of motor block was calculated from turning patient supine till it achieves score 4. Duration of motor block was calculated as time interval between attainment of score 4 to 0 in the post-operative period. Arterial Blood pressure in the form of Systolic, Diastolic and Mean was taken every 1 minute for 10 minutes, then every 5 minutes till completion of surgery, thereafter every 30 minutes for 6 hours. Incidence of nausea and vomiting developed till delivery of baby was noted. All neonates were assessed by paediatrician after delivery. Apgar score at 1 minute and 5 minutes after delivery was recorded. Time to give rescue analgesic was noted. Rescue analgesic in the form of injection Diclofenac 75 mg was give

Approval from the Ethics Committee of Ananya College of Medicine and Research, Kalol-Gandhinagar (AIEC/2024/006 dated 22/07/2024).

Statistical analysis

All primary data were collected on excel spread sheet and analyzed using SPSS Demo Version Qualitative data were analyzed by Chi-square test, whereas quantitative data by independent sample t-test and $p<0.05$was considered statistically significant.

RESULTS

All the thirty-five patients in each groups completed the study without any dropouts. Table 1 shows that all patients in both groups were comparable with respect to their age, weight, height, duration of surgery and baseline blood

pressure. There is no statistical difference between them. (p value>0.05). Time to reach motor block modified bromage score 4 (In minutes) in HB group was 5.74±0.74 and n PHB group it was5.97±0.17, there was no statistical difference.

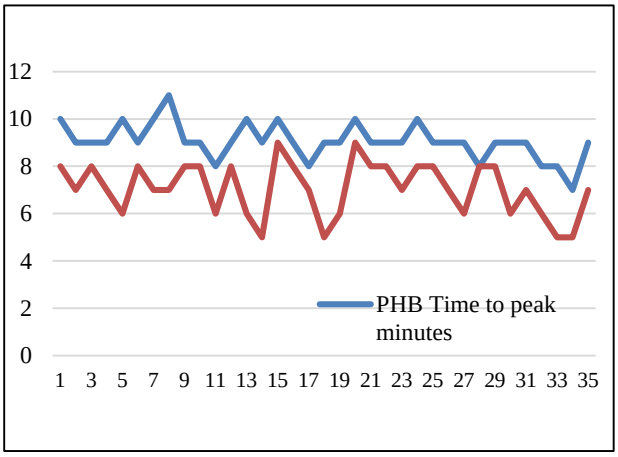

Figure 1: Time to reach Peak Dermatomal Level.

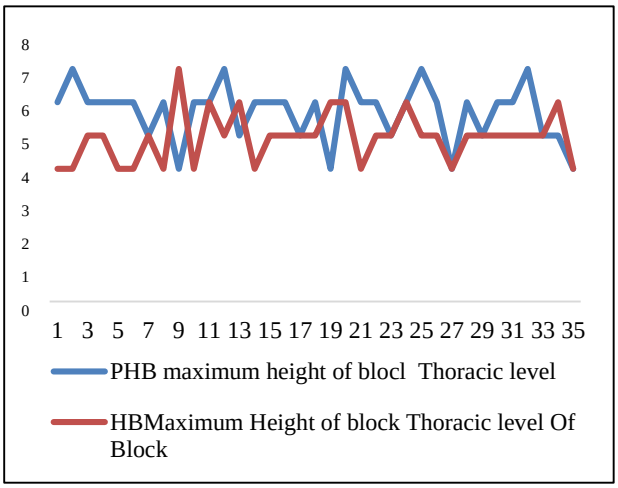

Figure 2: Maximum Height of block (Thoracic level).

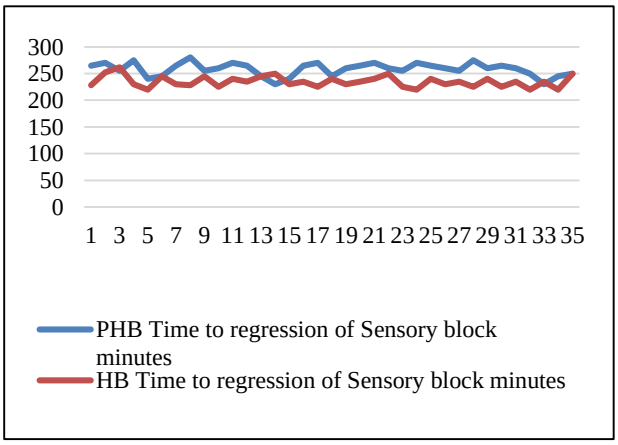

Figure 3: Time to regression of sensory block to the surgical incision.

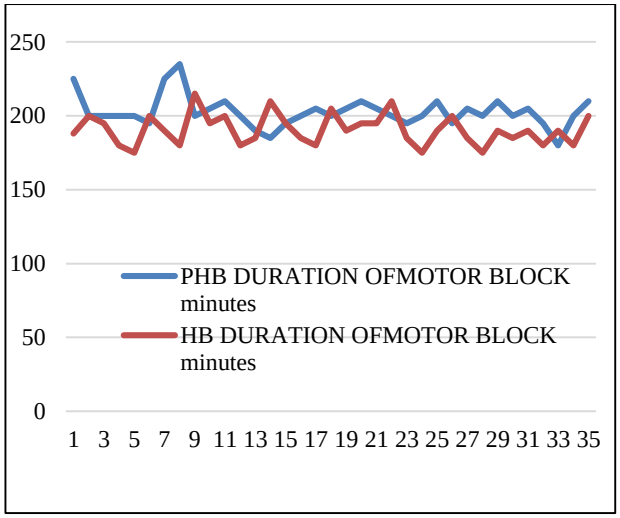

Figure 4: Duration of motor block.

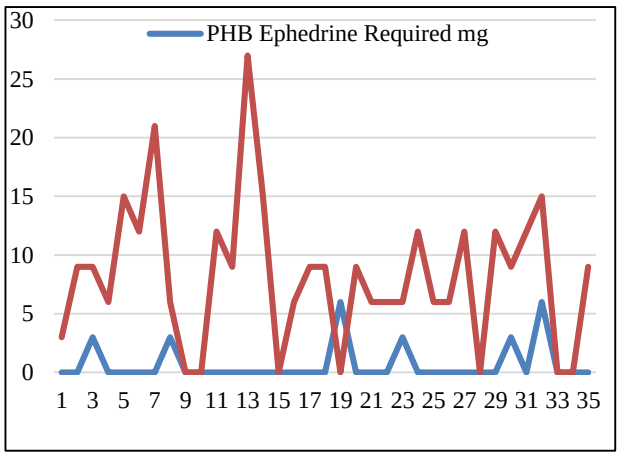

Figure 5: Requirement of ephedrine in milligrams.

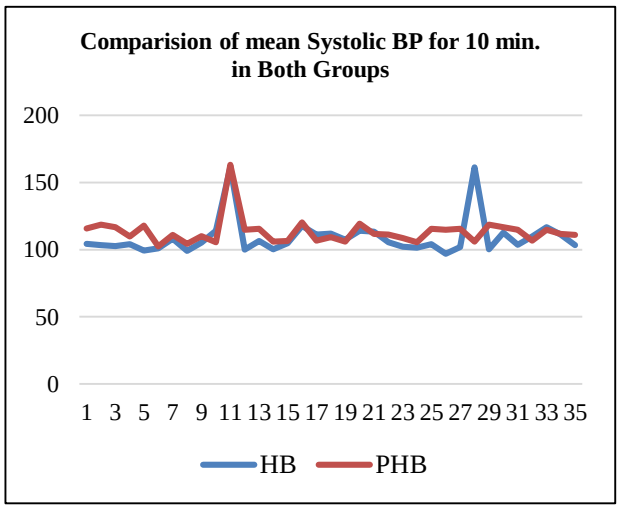

Figure 6: Hemodynamic changes.

Time to regression of sensory block to the surgical incision for group HB was 234.86±10.488 minutes and for group PHB it was 258.14±12.372 minutes. So sensory regression

was longer in group PHB as compare to that of Group HB and the difference was statistically significant (p<0.05) (Figure 3). Duration of motor block was 190.66±10.381 minutes for group HB and it was 205.71±11.952 Minutes for group PHB. So, motor block was seen prolong in group PHB as compare to that of group HB and the difference was statistically significant (p<0.05) (Figure 4). Systolic blood pressure less than 100 mm of Hg was considered as Hypotension, was treated with iv ephedrine either 3 mg or 6 mg. Incidence of hypotension in first 10 minutes or till the delivery of child, was higher in group HB (77.14%) as compare to 25.71% in group PHB (p<0.05). Same difference was observed for Nausea/Vomiting in both the groups (68.57% for group HB and 25.71% for group PHB). One patient from group PHB had stretching pain during delivery of child. For group HB, 80% of patients required ephedrine while 17% required Ephedrine in group PHB. The average required dose of ephedrine for group HB was 10.03 mg as compared to 4 mg for Group PHB.

Table 1: Demographic data.

		Group HB		Group PHB		Test	P value
		No.	%	No.	%		
Age (in years)	18-21	05	14.29	02	5.71	Unpaired T test	0.509
	22-25	13	37.14	18	51.42		
	26-29	11	31.43	09	25.72		
	30-33	06	17.14	06	17.15		
Weight (Kg)	44-49	06	17.14	05	14.29	Unpaired T test	0.755
	50-55	12	34.29	18	51.42		
	56-60	12	34.29	08	22.86		
	61-66	05	14.28	04	11.43		
Height (cm)	145-149	14	40	12	34.29	Unpaired T test	0.490
	150-154	09	25.71	06	17.14		
	155-159	06	17.14	10	28.57		
	160-164	06	17.15	07	20		
Duration of surgery (In Minutes)	50-59	07	20	11	31.42	Unpaired T test	0.587
	60-69	12	34.29	14	40		
	70-79	12	34.29	06	17.14		
	80-89	04	11.42	04	11.42		
Baseline blood pressure							
SBP mm of Hg	100-115	15	42.86	03	8.57	Unpaired T test	0.837
	116-130	13	37.14	29	82.86		
	131-145	03	8.57	02	5.71		
	146-160	04	11.43	01	2.86		
DBP mm of Hg	45-59	07	20	02	5.71	Unpaired T test	0.086
	60-74	10	28.57	12	34.29		
	75-89	16	45.72	14	14		
	90-104	02	5.71	07	20		
MBP mm of Hg	75-84	14	40	08	22.86	Unpaired T test	0.477
	85-94	15	42.86	17	48.57		
	95-104	02	5.71	06	17.14		
	105-114	04	11.43	04	11.43		

Table 2: Characteristics of anaesthesia.

	Group HB (Mean±SD	Group PHB (Mean±SD)	Test	P value
LP interspace L2-L3/L3-L4	7/28	8/27		
Time to reach peak dermatomal level (In minutes)	7.06±1.136	9.06±0.765	Unpaired T test	<0.05*
Maximum height of block (Thoracic level)	4.94±0.76	5.71±0.86	Unpaired T test	<0.05*
Time to reach motor block modified bromage score 4 (in min)	5.74±0.74	5.97±0.17	Unpaired T test	0.08

Continued.

	Group HB (Mean±SD	Group PHB (Mean±SD)	Test	P value
Time to regression of sensory block to the surgical incision (in minutes)	234.86±10.488	258.14±12.372	Unpaired T test	<0.05*
Duration of motor block (In min)	190.66±10.381	205.71±11.952	Unpaired T test	<0.05*
APGAR @ 1 min	9	9		
APGAR @ 5 min	10	10		
Abdominal muscle relaxation				
Excellent N (%)	3 (8.57%)	3 (8.57%)		
Good N (%)	29 (82.85%)	29 (82.85%)		
Fair N (%)	3 (8.57%)	3 (8.57%)		
Poor N (%)	0	0		

*Statistically significant.

Table 3: Surgeon's Satisfaction during surgery.

Excellent N (%)	28 (80%)	28 (80%)	Chi square test	0.481
Good N (%)	6 (17.15%)	7 (20%)	Chi square test	0.481
Fair N (%)	1 (2.85%)	0	Chi square test	0.481
Poor N (%)	0	0		

There was not seen any statistically significant in surgeon's satisfaction.

Table 4: Number of patients with side effects.

Hypotension (<100mmHg) N (%)	27 (77.14%	9 (25.71%)	Chi square test	<0.05
Nausea/vomiting N (%)	24 (68.57%)	9 (25.71)	Chi Square test	<0.05
Pruritus N (%)	0	0		
Pain N (%)	0	1 (2.85%)	Chi Square test	<0.05
Ephedrine required N (%)	28 (80%)	6 (17.15%)	Chi Square test	<0.05

DISCUSSION

Bupivacaine 0.5% available commercially in the market as 4 ml sterile ampoules. Commercially available plain bupivacaine has a baricity of 0.9990, which means it is only just on the edge of being hypobaric and is best referred to as 'plain'.[5]

Russell et al studied equal volumes (2.5 ml, 12.5 mg) of plain 0.5% bupivacaine and hyperbaric 0.5% bupivacaine were compared in 40 patients undergoing Caesarean section under subarachnoid anaesthesia. The median maximum cephalad levels of the analgesia had been (hyperbaric) T1 (range C1-T4), and (plain) T2 (range C1-T4).[6] In our study also the maximum block level was achieved in group HB was T4.94±0.76 and in group PHB it was 5.71±0.86, (p<0.05) Time to reach Peak dermatomal level in group HB was 7.06±1.136 minutes and in Group PHB it was 9.06±0.765 minutes. So Peak dermatomal level was faster in Group HB as compare to Group PHB (p<0.05).

Punshi et al, studied equal volume of plain and hyperbaric bupivacaine 10mg with 25 mcg of fentanyl, plain bupivacaine took more time for two dermatomes sensory level regression below T4 and resulted in the prolonged block duration.[7] We observed, time to regression of sensory block to the surgical incision for group HB was 234.86±10.4 minutes and for group PHB it was 258.14±12.3 minutes. So sensory regression was longer in group PHB as compare to that of group HB (p<0.05).

Sarvela et al, studied Nine milligrams of either plain or hyperbaric bupivacaine with fentanyl intrathecal. In their study motor block developed and diminished faster with the hyperbaric solution.8 In our study we noticed the same, duration of motor block was 190.66±10.381 minutes for group HB and it was 205.71±11.952 minutes for group PHB (p<0.05). Hypotension is common prevalent side effect of spinal anesthesia. The most common definitions of hypotension used in research studies were either'<80%baseline' or< 100 mm of Hg.[2]

Cesur et al, had done double-blind prospective study, in their conclusion, compared to hyperbaric bupivacaine, the combination of plain and hyperbaric bupivacaine provided a marked decrease in the incidence of hypotension (13.9% vs 66.7%, p<0.001) and side effects related hypotension such as nausea and vomiting (13.9% vs. 52.8%, p<0.001).

The amount of the ephedrine administered had been significantly lower in the plain and hyperbaric bupivacaine group (2.2) 1.0 mg vs. (20.5) 8.7 mg (p<0.001).[9] In our present study, the incidence of hypotension in HB group

was 77.14% as compared to 25.71% in PHB group with p value <0.05 and side effects such as nausea and vomiting (HB 68.75% vs PHB 25.71% (p<0.05). Requirement of Ephedrine was lower in PHB (17.5% mean 4 mg) group in comparison to HB (80% mean 10.3 mg) group.

In the obstetric population, however, neither posture during induction of spinal anesthesia nor the density of the intrathecal drugs used has been shown to have any effect on their subsequent spread within the CSF.[10-12] During pregnancy, the fetus compresses the lumbar vertebrae such that they are displaced posteriorly.[13] This causes a general flattening of the spinal column with loss of the thoracic depression, with the result that postural effects seen in the non-obstetric population may not be seen in the pregnant patient.[14] Because the gravid uterus compresses the inferior vena cava with engorgement of the epidural venous plexus, turning a parturient to the supine position causes bulk movement of CSF and enhances rostral spread regardless of baricity.[15-19] After such bulk movement, hyperbaric solutions will redistribute because of gravity and move to the lowest point of the thoracic curve, situated around T6-7 in pregnant, while isobaric solutions mix with CSF with little further spread.[17,20]

Plain bupivacaine is deliberated to be slightly hypobaric, its use in the sitting position during spinal injection may be considered hazardous, although it has been effectively used as if it were clinically isobaric. For this cause and because plain bupivacaine is commercially available, we overlooked this hypothetical risk. The sitting position helps in identification of the spinous process specially in obese parturient when landmarks are not clear. It is used routinely in our institute. This position helps cephalad spread of hypobaric solutions and caudal pooling of hyperbaric solution after injection. Therefore, after injection we did not allow delay of more than 30 s before placing parturient supine and so do not believe that there was significant cephalad spread of plain bupivacaine in the short time.

The small sample size was a limitation of our study, warranted a further large scale study.

CONCLUSION

Our study showed that sequential administration of low dose of Hyperbaric and Plain Bupivacaine with Fentanyl provides better hemodynamic stability, accomplish adequate level of sensory and motor block in obstetric population for cesarean delivery, which can be adopted to other high risk below umbilicus surgery.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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