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Research Article

A CLINICAL COMPARATIVE STUDY OF 8 mg AND 10 mg OF 0.5% HYPERBARIC BUPIVACAINE AND COMBINATION OF EACH WITH 12.5 μg OF FENTANYL FOR SPINAL ANAESTHESIA IN CAESAREAN SECTION

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ABSTRACT

INTRODUCTION

Spinal anaesthesia is commonly employed for caesarean delivery. Bupivacaine is the commonly used local anaesthetic for caesarean delivery. Intrathecal Bupivacaine alone may be insufficient to provide complete analgesia despite the high sensory block. The use of neuraxial opioids has gained popularity over the last few years; they may augment the analgesia produced by local anaesthetic through direct binding with the specific spinal receptors. Hence the present study was done to compare the synergistic effect of intrathecally administered Fentanyl 12.5 μg with 8 mg and 10 mg of 0.5% hyperbaric Bupivacaine on sensory and motor block characteristics, recovery profile and also quality of intraoperative and postoperative analgesia.

METHODS

One hundred twenty patients belonging to ASA class I and II with singleton pregnancy with term gestation posted for caesarean section, who have no contraindication for spinal anaesthesia were selected. They were randomly divided into four groups of 30 patients each.

Group I–received 8 mg of 0.5% hyperbaric Bupivacaine,

Group II – received 10 mg of 0.5% hyperbaric Bupivacaine

Group III– received 8 mg of 0.5% hyperbaric Bupivacaine plus 12.5 μg of Fentanyl,

Group IV– received 10 mg of 0.5% hyperbaric Bupivacaine plus 12.5 μg of Fentanyl.

The patients were observed intraoperatively for the onset of sensory block, degree of motor block, total duration of analgesia and motor blockade along with maternal and foetal side effects.

RESULTS

Onset of sensory and motor block were similar in low dose of 0.5% hyperbaric Bupivacaine (8 mg) alone and 0.5% hyperbaric Bupivacaine (8 mg) with Fentanyl (12.5μg) combination groups. However it increased with increasing doses of 0.5% hyperbaric Bupivacaine (10 mg) alone and in 0.5% hyperbaric Bupivacaine (10 mg) with Fentanyl(12.5μg) combination groups. Total duration of analgesia (time from injection of drug to first requisite for analgesics) lasted longer in group IV (257.03±8.46) and group III (206.00±11.80) when compared to group II (166.66±7.00)

and group I (143.96±7.25). Quality of anaesthesia was excellent in all the groups. The intraoperative haemodynamic changes were similar in all the groups.

CONCLUSION

Addition of fentanyl to bupivacaine improved the quality of intraoperative anaesthesia and prolonged the postoperative analgesia and also decreased the dose of Bupivacaine. However Bupivacaine 8 mg and 10 mg can also be safely used for spinal anaesthesia in caesarean delivery with lesser duration of post operative analgesia.

KEY WORDS: Bupivacaine; Fentanyl; Spinal anaesthesia; Caesarean section

INTRODUCTION

Regional anaesthesia has become more popular in caesarean deliveries because most of the parturients prefer being awake during child birth. In addition it is a safer method than general anaesthesia.[1] Subarachnoid block (SAB) is the anaesthesia technique of choice and is the gold standard for caesarean section because of the ease, effectiveness as well as the rapidity in establishing adequate levels of analgesia. In addition, the small amounts of local anaesthetics (LA) administered make placental transfer and foetal uptake of drug negligible compared to other regional techniques.[2] Bupivacaine is the most commonly employed LA intrathecally for caesarean section. It is well known that the dose of the drug influences the duration of sensory as well as motor blockade and has a significant effect on the degree of hypotension.[4] However, intrathecal Bupivacaine alone may be insufficient to provide complete analgesia despite high sensory block. 13% of the patients undergoing caesarean delivery had visceral pain even after the intrathecal administration of 15 mg of Bupivacaine. Many mothers require supplemental analgesics to relieve pain associated with exteriorization of the uterus and traction on the abdominal viscera. Large doses are associated with higher block during spinal anaesthesia.[3] Hence adjuvants are added to decrease the dose of LA required.[5] When only LAs were used, high doses of post operative Morphine and other opioids were required to provide adequate post operative analgesia.[6] Adjuvants like opioids (Morphine, Fentanyl, Sufentanyl) and non-opioids like α-2 adrenergic agonists (Clonidine, Dexmedetomidine), anti cholinesterases (Neostigmine), Midazolam, steroids and Ketamine were used.[10] These adjuvants improved the quality of intra operative anaesthesia and prolonged the duration of post-operative analgesia. Therefore smaller doses of Bupivacaine supplemented by intrathecal opioids have been recommended for spinal anaesthesia in parturients undergoing caesarean section.[8,9,10] Neuraxial administration of opioids in conjunction with LAs improves the quality of intraoperative analgesia and also enhances the duration of postoperative analgesia.[11] Animal studies have demonstrated antinociceptive synergism between intrathecal opioids and LAs during visceral and somatic nociception.[12]

Morphine has prolonged duration of action and delayed respiratory depression is not infrequent following spinal administration.

Fentanyl, a lipophilic opioid, has rapid onset of action after intrathecal administration. It does not tend to migrate to 4th ventricle in sufficient concentrations to cause delayed respiratory depression when administered intrathecally.[18] After intrathecal (IT) Fentanyl administration, it diffuses into epidural space and subsequently into the plasma, suggesting that IT Fentanyl not only act through spinal opioid receptors but also act systemically. Therefore Fentanyl provides better intraoperative analgesia.

Dose of 12.5µg of Fentanyl added to low dose Bupivacaine intrathecally provides better surgical anaesthesia and increased reliability of block than intrathecal Fentanyl 7.5 or 10µg.[19]

OBJECTIVES

Primary objective

1. To study and compare the synergistic effect of intrathecally administered Fentanyl 12.5 µg with 8 mg and 10 mg of 0.5% hyperbaric Bupivacaine on sensory and motor block characteristics and postoperative analgesia.

Secondary objectives

1. To study haemodynamic changes in all the groups.
2. To study the side effects if any.

METHODOLOGY

SOURCE OF DATA

After clinical approval of Institutional Ethical Clearance Committee and informed written consent, 120 To pregnant women of ASA physical class I and II posted for caesarean section at tertiary care centre were selected on the basis of simple random sampling method.

INCLUSION CRITERIA

1. Patients belonging to ASA class I and II with singleton pregnancy with term gestation posted for caesarean section, who had no contraindication for spinal anaesthesia.

EXCLUSION CRITERIA

1. Patients with co-morbid conditions like diabetes mellitus, asthma, hypertension, etc.
2. Patients with PIH, eclampsia, multiple pregnancy, placenta previa.
3. Patients with coagulopathy
4. Infection at the site of spinal anesthesia

METHODS OF COLLECTION OF DATA

After obtaining approval from the Institutional Ethical Committee and informed written consent from the patients, 120 ASA class I and II pregnant women were selected. They were randomly divided into four groups of 30 patients each. Preoperative assessment was done for each patient. Baseline readings of pulse rate, blood pressure and arterial oxygen saturation were recorded. Intravenous (IV) line was obtained with 18 guage IV cannula and preloaded with Ringer lactate 10ml/kg over 15 min. Monitoring was done using multi parameter monitor having pulse oximeter, ECG and NIBP. All patients were given IV premedication with Injection (inj.) Ranitidine 50 mg and Inj. Metoclopramide 10mg.Before the commencement of anaesthesia, patients were instructed on the method of sensory and motor assessments.

Sensory level block was measured by pin prick at the mid clavicular line on both sides with a blunt 27G needle every minute, until the block reached T6 dermatome. Thereafter, the level was checked every 2 minutes, until the maximal sensory block achieved.

Motor block in the lower limb was graded according to modified Bromage scale.
0 – No motor blockade, able to lift leg at the hip.
1 – Able to flex the knee but not lift leg extended
2 – Able to move the foot only
3 – Unable to move even the foot (complete blockade)

With patient in right lateral position, midline lumbar puncture was performed at L2-L3 or

L3-L4 interspace with 23G Quincke's spinal needle. After confirming free and continuous flow of Cerebrospinal Fluid (CSF), the test drug was injected intrathecally, over 30 seconds.

Group I – received 8 mg of 0.5% hyperbaric Bupivacaine
Group II – received 10 mg of 0.5% hyperbaric Bupivacaine
Group III– received 8 mg of 0.5% hyperbaric Bupivacaine plus 12.5 µg of Fentanyl
Group IV– received 10 mg of 0.5% hyperbaric Bupivacaine plus 12.5 µg of Fentanyl

Immediately after spinal injection, patients were placed supine with 10 cm wedge placed under the right hip. Sensory and motor assessment was performed immediately. Surgical incision was allowed when sensory level was at or above T6 dermatome, and motor blockade was adequate. Thereafter, the block was assessed until complete recovery of motor function and sensation at the L1 dermatome.

Heart rate and BP were recorded immediately after subarachnoid block, then at 2 min interval for first 10 min, later at 3 min interval till completion of surgery. Maternal bradycardia, is defined as
pulse rate less than 60 beats/min which was treated with 0.6 mg of IV Atropine. Muscle relaxation was assessed by surgeon and rated as poor, good or excellent. Quality of anaesthesia was graded as excellent-no discomfort or pain, good-mild pain, no need for analgesics, fair-pain that required supplemental analgesics and poor severe pain that needed conversion to general anaesthesia. Side effects such as nausea, vomiting, shivering and pruritis or itching were recorded. The time required for sensory recovery to L1, motor recovery to Bromage scale 0 and first requisite for analgesics were recorded in postoperative ward. All these time variables were measured from the beginning of spinal injection. APGAR scores of babies were noted at 1 and 5min. Resuscitation equipments for the baby were kept ready.
The following variables were recorded.
1. Time of onset of sensory analgesia to T10
2. Highest level of sensory analgesia
3. Time taken to achieve highest level of sensory analgesia
4. Time for two segment sensory regression
5. Time for sensory regression to L1
6. Total duration of analgesia
7. Time of onset of grade 3 motor block
8. Total duration of motor block
9. APGAR at 1 and 5 minutes interval
10. Quality of anaesthesia
11. Cardiovascular parameters
12. Respiratory parameters
13. Side effects.

Definitions of various parameters studied
Time of onset of sensory analgesia to T10: It is defined as time taken from th completion of the injection of the study drug till the patient does not feel the pin prick at T10 level.
Highest level of sensory analgesia: It is the maximum sensory level attained
Time taken for highest level of sensory analgesia: It is defined as the time from the completion of the injection of the study drug to the maximum sensory blockade attained.
Time for two segment sensory regression: It is the time from maximum attainment of sensory block to regression of blockade by two segments
Time for sensory regression to L1: It is the time taken for sensory regression to L1 dermatome
Total duration of analgesia: It is the time from drug injection to first request for analgesics.
Time of onset of grade III motor blockade: is defined as the time taken from

the completion of injection of the study drug till patient develops Bromage-scale 3

Total duration of motor blockade: is the time taken from the time of injection till the patient attains complete motor recovery, Bromage- scale 0

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Degree of motor blockade

Grade	Criteria	Degree of block
0	Free movement of legs and feet	Nil (0%)
1	Just able to flex knees with free movement of feet	Partial (33%)
2	Unable to flex knees, but with free movement of feet	Almost complete (66%)
3	Unable to move legs or feet	Complete (100%)

STATISTICAL METHODS APPLIED

Descriptives: The Descriptives procedure displays univariate summary statistics for several variables in a single table and calculates standardized values (z scores). Variables can be ordered by the size of their means (in ascending or descending order), alphabetically, or by the order in which you select the variables (the default).

Crosstabs (Contingency table analysis): The Crosstabs procedure forms two-way and multi-way tables and provides a variety of tests and measures of association for two-way tables. The structure of the table and whether categories are ordered determine what test or measure to use.

Independent samples 't' test: The Independent-Samples T Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be random assigned to two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors.

One way ANOVA and Scheffe's post hoc test: The One-Way ANOVA procedure produces a one-way analysis of variance for a quantitative dependent variable by a single factor (independent) variable. Analysis of variance is used to test the hypothesis that several means are equal. This technique is an extension of the twosample t test.

Repeated Measures ANOVA: GLM Repeated Measures analyzes groups of related dependent variables that represent different measurements of the same attribute. This dialog box lets you define one or more within-subjects factors for use in GLM Repeated Measures. Note that the order in which you specify within-subjects factors is important. Each factor constitutes a level within the previous factor.

All the statistical calculations were done through SPSS for windows (v 16.0)

RESULTS

TIME OF ONSET OF SENSORY ANALGESIA TO T10

Table 1: Time of onset of sensory analgesia to T10

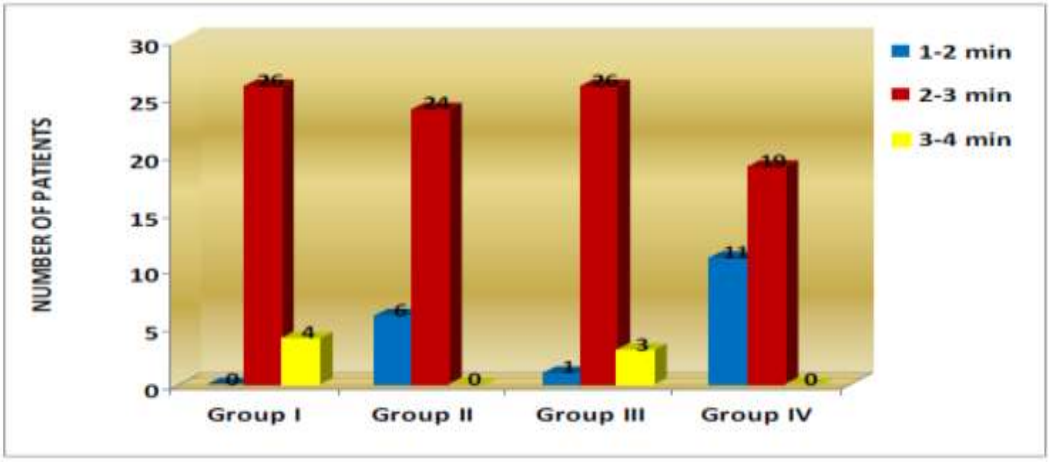
Time of onset of sensory analgesia to T_{10} (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
1-2	00	0%	06	20%	01	3.3%	11	36.7%
2-3	26	86.7%	24	80%	26	86.7%	19	63.3%
3-4	04	13.3%	00	0%	03	10%	00	0%
Total	30	100%	30	100%	30	100%	30	100%

Mean time of onset of sensory analgesia to T10 (minutes)

Group I	2.71±0.33
Group II	2.45±0.29
Group III	2.59±0.43
Group IV	2.23±0.32

The minimum time taken for onset of sensory analgesia to T10 in group I was 2 min 5sec, in group II was 1min 50sec, in group III was 1min 40sec and in group IV was 1min 40sec. The maximum time taken for onset of sensory analgesia to T10 in group I was 3min 40sec, in group II was 3min, in group III was 3min and in group IV was 2min 40sec. 26(86.7%), 24(80%), 26(86.7%) and 19(63.3%) patients in group I, II, III and IV achieved sensory analgesia to T10 level between 2-3min respectively. 6(20%), 1(3.3%), 11(36.7%) patients group II, III and IV achieved sensory analgesia to T10 level between 1-2 min respectively.And also 4(13.3%) and 3(10%) patients in group Iand III achieved T10 level in 3-4min respectively.Where as no patients in group I achieved T10 level in 1-2 min and also no patients in group III and IV achieved T10 level in 3-4min. The mean time of onset of sensory analgesia to T10 in group I was 2.71±0.33 min, in group II was 2.45±0.29min, in group III was 2.59±0.43min and in group IV was 2.23±0.32min which was statistically significant among the groups ($p<0.000$).

Figure 1: Time of onset of sensory analgesia to T10



TOTAL DURATION OF ANALGESIA

Table 2: Total duration of analgesia

Total Duration of Analgesia (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
130-159	29	96.7%	04	13.3%	00	0%	00	0%
160-189	01	3.3%	26	86.7%	03	10%	00	0%
190-219	00	0%	00	0%	24	80%	00	0%
220-249	00	0%	00	0%	03	10%	06	20%
250-279	00	0%	00	0%	00	0%	24	80%
Total	30	100%	30	100%	30	100%	30	100%

Mean time (minutes)

Group I	143.96±7.25
Group II	166.66±7.00
Group III	206.00±11.80
Group IV	257.03±8.46

The minimum total duration of analgesia in group I was 130min, in group II was 150min, in group III was 188min and in group IV was 238min. The maximum total duration of analgesia in group I was 160min, in group II was 180min, in group III was 224min and in group IV was 270min. 29(96.7%) patients in group I, 26(86.7%) patients in group II, 24(80%) patients in group III and 24(80%) patients in group IV had total duration of analgesia between 130-159 mins, 160-189 mins, 190-219 mins and 250-279 mins respectively. The mean time of total duration of analgesia in group I was 143.96±7.25min, in group II was 166.66±7.00min, in group III was 206.00±11.80min and in group IV was 257.03±8.46min which was statistically significant among the groups (p<0.000).

Figure 2: Total duration of analgesia

MOTOR CHARACTERISTICS
TIME OF ONSET OF GRADE III MOTOR BLOCK

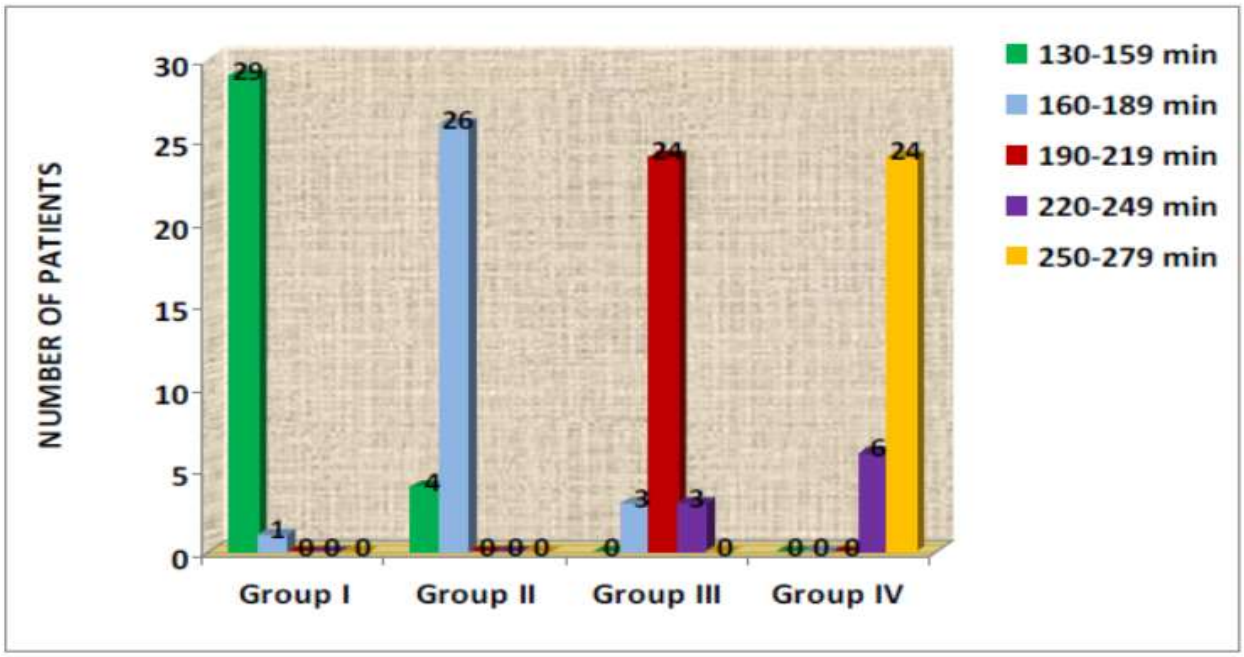


Table 3: Time of onset of Grade III motor block

Time of onset of grade III motor block (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
3-4	00	0%	00	0%	01	3.3%	07	23.3%
4-5	02	6.6%	15	50%	01	3.3%	19	63.4%
5-6	13	43.4%	15	50%	15	50%	04	13.3%
6-7	15	50%	00	0%	13	43.4%	00	0%
Total	30	100%	30	100%	30	100%	30	100%

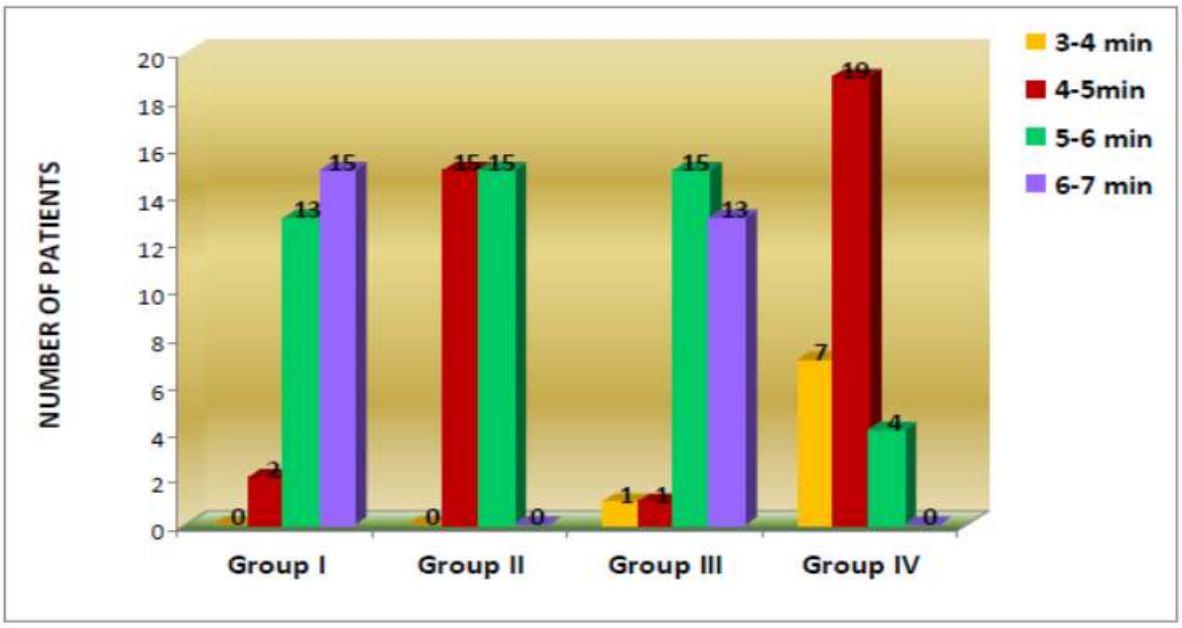
Mean time (minutes)

Group I	6.09±0.54
Group II	4.78±0.57
Group III	5.86±0.63
Group IV	4.62±0.57

The minimum time taken for onset of grade III block in group I was 5min, ingroup II was 4min 30sec in group III was 4min and in group IV was 3min 10sec. The maximum time taken for onset of grade III block in group I was 7min, in group II was 6min, in group III was 6min 30sec and in group IV was 5min 30sec. 15(50%) and 13(43.3%) patients in group I and III had onset of grade III motor blockade between 6-7 min where as no patients in group II and IV had onset ofgrade III motor blockade between 6-7 min. 13(43.3%), 15(50%), 15(50%) and 4(13.3%) patients in group I, II, III and IV had onset of grade III motor blockade between 5-6 min respectively. 15(50%) and 19(63.3%) patients in group II and IV had onset of grade III motor blockade between 4-5min. 1(3.3%) and 7(23.3%) patients in group III and IV had onset of grade III motor blockade between 3-4 min, where as no patient in group I and II had onset of grade III motor blockade in the same time interval.

The mean time of onset of grade III blockade in group I was 6.09±0.54min, in group II was 4.78±0.57min, in group III was 5.86±0.63min and in group IV was 4.62±0.57min which was statistically significant among the groups (p<0.000).

Figure 3: Time of onset of Grade III motor block



TOTAL DURATION OF MOTOR BLOCK

Table 4: Total duration of motor block

Total duration of motor block (minutes)	Group I		Group II		Group III		Group IV	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
80-101	16	53.3%	00	0%	14	46.6%	00	0%
102-123	11	36.7%	11	36.7%	13	43.4%	08	26.7%
124-145	03	10%	16	53.3%	03	10%	17	56.6%
146-167	00	0%	03	10%	00	0%	05	16.7%
Total	30	100%	30	100%	30	100%	30	100%

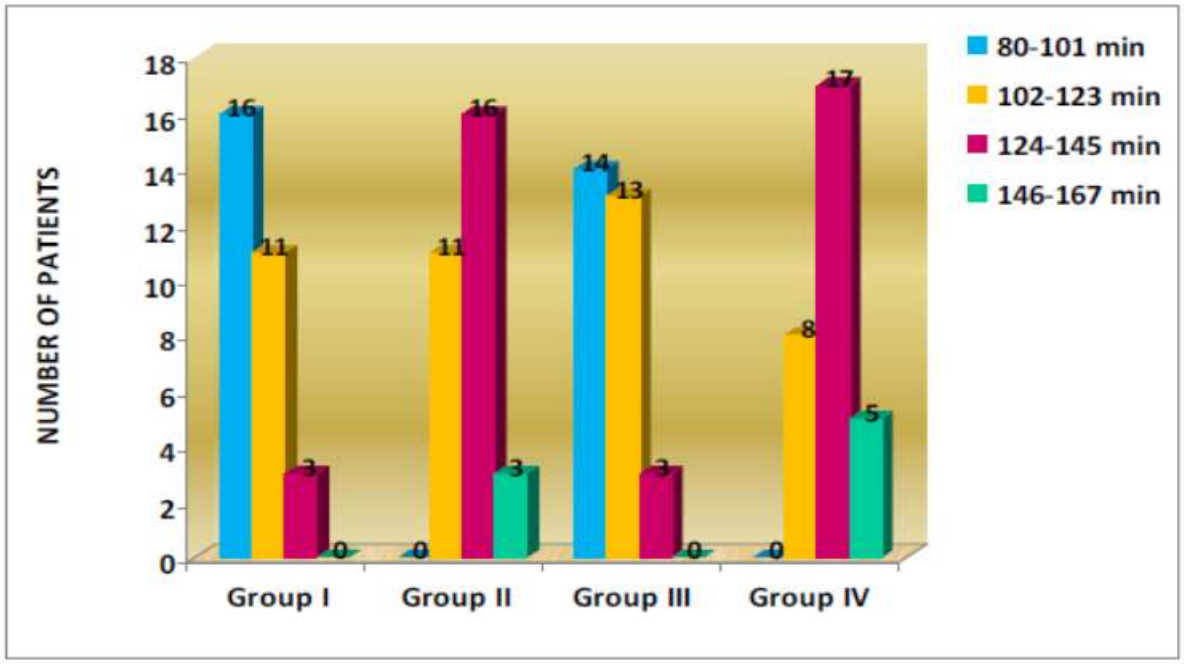
Mean time (minutes)

Group I	103.83±13.24
Group II	128.20±11.57
Group III	106.90±10.92
Group IV	132.93±12.06

The minimum total duration of motor block in group I was 80min, in group II was 105min, in group III was 90min and in group IV was 110min.. The maximum total duration of motor block in group I was 130min, in group II was 150min, in group III was 140min and in group IV was 162min. 16(53.3%) and 14(46.7%) patients in group I and III had total duration of motor block between 80-101min. 16(53.3%) and 17(56.7%) patients in group II and IV had total duration of motor block between 124-145min. No patients in group II and IV had duration of motor block between 80-101min. No patients in group I and III had duration of motor block between 146-167min. The mean time of total duration of motor block in group I was 103.83±13.24min, in group II

was 128.20±11.57min, in group III was 106.90±10.92min and in group IV was 132.93±12.06min which was statistically significant among the groups (p<0.000).

Figure 4: Total duration of motor block



DISCUSSION

The last two decades have seen an increase in the incidence of caesarean section. Spinal anaesthesia is the preferred means for caesarean section. A study conducted by Caplan et al.46 revealed that the cardiac arrest in patients of ASA Grade I and II during spinal anaesthesia was due to sudden decrease in HR and BP. Bupivacaine is the LA used routinely for caesarean section because of its high potency and minimal neurological symptoms. The larger dose of LA is required to obliterate the visceral pain caused due to traction on peritoneum and intraperitoneal
organs during caesarean delivery, but such large doses are associated with high levels of block and undesirable side effects. Opioids are well known to improve the analgesic potency of LA. If

administered intrathecally a short acting lipophilic opioid is known to augment the quality of subarachnoid block Hunt et al.[13] reported that the addition of Fentanyl 6.25 µg to hyperbaric Bupivacaine reduced the intraoperative opioids requirement in patients undergoing caesarean delivery under spinal block. Hence the present study was conducted to compare 8mg and 10mg of 0.5% hyperbaric Bupivacaine and combination of each with 12.5µg of Fentanyl for spinal
anaesthesia in caesarean section.

SENSORY CHARACTERISTICS

Time of onset of sensory block to T10

In the present study the mean time of onset of sensory analgesia to T10 in group I was 2.71±0.33 min, in group II was 2.45±0.29min, in group III was 2.59±0.43min and in group IV was 2.23±0.32min which was statistically significant among the groups ($p<0.000$). Our result concurs with the result observed in Bogra J et al.[20] in their study. they observed that the onset of sensory block to T6 occurred faster with increasing Bupivacaine doses in Bupivacaine only groups and Bupivacaine–Fentanyl combination groups. However they did not measure time of onset analgesia to T10. Choi DH et al.[17] in their study also did not comment on time of onset analgesia to T10.

Highest level of sensory analgesia

Choi DH et al.[17] in their study observed a significant difference in attainment of higher sensory level in Bupivacaine 12mg group but they did not observe any difference between 8mg and 10mg Bupivacaine groups which concurs with the results of our study. Similar results were observed in Biswas BN et al.[18] using 10mg Bupivacaine and Harsoor SS et al.[21] using 8mg of Bupivacaine.

Time taken for highest level of sensory analgesia

Our result concurs with the result observed by Bogra J et al.,[20] in their study they observed that the onset of sensory block to T6 occurred faster with increasing Bupivacaine doses in Bupivacaine only groups and Bupivacaine–Fentanyl combination groups. However they did not measure time taken to achieve highest level of sensory analgesia. The time taken for two segment sensory regression between group I and group II was statistically significant similarly it was significant between group III and group IV. Our study result concurs with the result obtained in Kiran S et al.[19] study where they observed that increasing Bupivacaine doses increases the time for two segment sensory regression. This finding is consistent with Harsoor SS et al.[21] and Biswas BN et al.[18] study in which they have concluded that addition of Fentanyl prolongs time for two segment sensory regression. Similar observations were made by Shende D et al.[8] Singh H et al.[37] and Hunt CO et al.[10]

Time for sensory regression to L1

Biswas BN et al.[18] in their study observed the mean time taken for sensorregression to L1 with 10mg Bupivacaine was 116±14.3min and in Bupivacaine 10mg – Fentanyl 12.5µg combination group was 151±7.33min. This mean duration was slightly less than the mean duration we obtained in our study with group II (Bupivacaine 10mg) and group IV (Bupivacaine 10mg – Fentanyl 12.5µg). Harsoor SS et al.[21] in their study observed the mean time taken for sensory regression to L1 with 8mg Bupivacaine was 100min and in Bupivacaine 8mg – Fentanyl 12.5µg combination group was 167min. This mean duration concurs with the mean duration we obtained in our study with group I (Bupivacaine 8mg) and group III (Bupivacaine 8mg – Fentanyl 12.5µg). Harsoor SS et al.[21] study and Biswas BN et al[18] study where they observed that addition of Fentanyl prolongs time for sensory regression to L1.

Total duration of analgesia

It is the time from drug injection to first request for analgesics. In the present study mean time of total duration of analgesia in group I was 143.96±7.25min, in group II was 166.66±7.00min, in group III was 206.00±11.80min and in group IV was 257.03±8.46min which was statistically significant among the groups (p<0.000). Biswas BN et al.[18] in their study observed the mean total duration of analgesia with 10mg Bupivacaine was 129±9.5 min and in Bupivacaine 10mg – Fentanyl 12.5µg combination group was 183±9 min. Harsoor SS et al. [21] in their study observed the mean total duration of analgesia with 8mg Bupivacaine was 103 min and in Bupivacaine 8mg – Fentanyl 12.5µg combination group was 184 min. According to Hunt CO et al.[10] study, mean total duration of analgesia was 71.8±43.2 min with 7.5mg of Bupivacaine and it increased to 192±74.9min when Fentanyl 6.25µg was added to it. The mean total duration of analgesia between group I and group II was statistically significant similarly it was significant between group III and group IV.

MOTOR CHARACTERISTICS

Time for onset of grade III motor block

In the present study the mean time of onset of grade III blockade in group I was 6.09±0.54min, in group II was 4.78±0.57min, in group III was 5.86±0.63min and in group IV was 4.62±0.57min which was statistically significant among the groups (p<0.000). Harsoor SS et al.[21] in their study observed the mean time of onset of grade III blockade with 8mg Bupivacaine was 4.8 min and in Bupivacaine 8mg – Fentanyl 12.5µg combination group was 4.3 min Biswas BN et al.41 in their study observed the mean time of onset of grade III blockade with 10mg Bupivacaine was 5±1 min and in Bupivacaine 10mg – Fentanyl 12.5µg combination group was 5.4±1.1min. The mean time of onset of grade III blockade between group I and group II was statistically significant similarly it was significant between group III and group IV. This finding is consistent with Choi DH et al.[17] study and Bogra J et al.44 study where they concluded that increase in Bupivacaine dose decreases the time of onset of grade III motor block.

Total duration of motor block

In the present study the mean time of total duration of motor block in group I was 103.83±13.24min, in group II was 128.20±11.57min, in group III was 106.90±10.92min and in group IV was 132.93±12.06min which was statistically significant among the groups (p<0.000). According to Choi DH et al.[17] the mean time of total duration of motor block with 8mg Bupivacaine alone was 119±16min, with 10mg Bupivacaine alone was 131±31min, with Bupivacaine 8mg-Fentanyl10µg was 108±22min and with Bupivacaine 10mg-Fentanyl10µg was 130±31min. This finding is consistent with our present study**.**

Degree of motor blockade

All patients in all the groups had attained grade III motor block. Similar resultswere observed in studies done by Penderson H et al.,[14] Choi DH et al.[39] and Bogra J et al.[20]

CARDIOVASCULAR CHANGES

Our study result concurs with Choi DH et al.[39] study where they noticed no significant difference among different Bupivacaine dose and also noted no significant difference among Bupivacaine–Fentanyl combination groups for hypotension and bradycardia. Similar results were found in studies done by Biswas BN et al.[18] and Hunt CO et al.[10]

RESPIRATORY CHANGES

In the present study we did not notice any incidence of respiratory depression during

study period. This finding is consistent with Biswas BN et al.,[18] Singh H et al.[16] and Hunt CO et al.[10] study.

OTHER SIDE EFFECTS

Nausea was seen in 3.3% of patients in group I, Vomiting was noticed in 3.3% of patients in group I, 6.7% of patients in group II, 6.7% of patients in group III and 6.7% of patients in group IV which was not significant. This result concurs with Choi DH et al.[17] study where they noticed no significant difference among different Bupivacaine dose groups and also noticed no significant difference among Bupivacaine–Fentanyl combination groups. Pruritis was seen in 3.3% of patients in group III and group IV, which was not significant. The higher incidence of pruritis seen in study conducted by Belzerena SD et al.[15] may be due to higher dose of Fentanyl used.

CONCLUSION

Our study concludes that 0.5% hyperbaric Bupivacaine 8 mg with Fentanyl 12.5µg is safe,effective and superior for spinal anaesthesia in caesarean section. 0.5% hyperbaric Bupivacaine 10 mg with Fentanyl 12.5µg combination is also beneficial for spinal anaesthesia which produced longer duration of analgesia when compared to Bupivacaine 8 mg with Fentanyl 12.5µg combination group which is advantageous both intra and postoperatively.

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