

## Evaluation of Effective Low Dose Bupivacaine with Fentanyl in Spinal Anaesthesia for Lower Segment Caesarean Section Surgeries

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### Abstract:

**Background:** This randomised study was conducted to compare the synergistic effect of intrathecally administered Fentanyl & hyperbaric Bupivacaine on haemodynamic, sensory & motor block characteristics and side effects, on pregnant women undergoing caesarean section under spinal anaesthesia.

**Methods:** One hundred twenty women were randomized into four groups of thirty each. Group-I (n=30) received 0.5% Bupivacaine 1.8ml (9mg) +25µg Fentanyl, Group-II (n=30) received 0.5% Bupivacaine 1.6ml (8mg) +25µg Fentanyl, Group-III (n=30) received 0.5% Bupivacaine 1.4ml (7mg)+ 25µg Fentanyl and Group-IV (n=30) received 0.5% Bupivacaine 1.2ml (6mg)+25µg Fentanyl.

**Results:** Onset of sensory block to T6 dermatome occurred faster with increasing Bupivacaine doses from 6mg to 9mg. Onset of motor block was also earlier in Group I. Total duration of analgesia and motor block were longer in group I than in other groups. The addition of Fentanyl to Bupivacaine significantly delayed the postoperative pain and sensory recovery.

**Conclusion:** Addition of Fentanyl 25µg to 0.5% hyperbaric Bupivacaine 6mg, & 7mg was effective for spinal anaesthesia in caesarean section surgeries, with minimal side effects. Combinations of 8mg & 9mg of 0.5% bupivacaine with fentanyl 25µg provide more duration of analgesia when compared to 6mg and 7mg, but with increased side effects and prolonged duration of motor block, which interferes with early ambulation.

**Key words:** Bupivacaine, Caesarean section, Fentanyl, Spinal anaesthesia.

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### I. Introduction

The incidence of women undergoing caesarean section has increased dramatically in the last 20 years. Of the 37,00,000 women estimated to give birth each year in the USA, 20-50% receive regional anaesthesia during labour and delivery. The challenges presented by a parturient requiring anaesthesia and analgesia or both, make the role of the obstetric anaesthesiologist challenging and rewarding.

Regional anaesthesia has become more popular in caesarean deliveries because most of the parturients prefer being awake during childbirth. In addition it is safer method than General anaesthesia<sup>1</sup>. Small amounts of local anaesthetics (LA) administered make placental transfer and foetal uptake of drug negligible compared to other regional techniques<sup>2</sup>.

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<sup>3</sup>.

Many mothers require supplemental analgesics to relieve pain associated with exteriorization of the uterus and traction on the abdominal viscera. Larger doses are associated with higher block during spinal anaesthesia<sup>4,5,6</sup>. Hence adjuvants like Opioids<sup>7</sup> (Morphine, Fentanyl, Sufentanyl) and Non opioids such as  $\alpha$ -2 adrenergic agonists (Clonidine<sup>8</sup>, Dexmedetomidine<sup>9</sup>), anticholinesterases (Neostigmine), Midazolam, Steroids and Ketamine can be added<sup>10</sup> to decrease the dose of LA, improve the quality of intra operative anaesthesia and to prolong the duration of postoperative analgesia.

Fentanyl, a lipophilic opioid, has rapid onset of action after intrathecal administration, as it does not tend to migrate to 4th ventricle in sufficient concentrations to cause delayed respiratory depression<sup>11</sup>. After intrathecal (IT) administration, Fentanyl diffuses into epidural space and subsequently into the plasma, suggesting that it acts not only through spinal opioid receptors but also systemically. 25µg of Fentanyl added to

low dose Bupivacaine intrathecally provides better surgical anaesthesia and increased reliability of block than intrathecal Bupivacaine alone or Fentanyl 7.5 or 10 $\mu$ g<sup>12</sup>.

Due to availability of minimal data on comparison of different doses of LA combined with fixed dose of an opioid, the present study was planned to compare the effect of Fentanyl 25 $\mu$ g when mixed with 6mg,7mg,8mg and 9mg of 0.5% hyperbaric Bupivacaine and to evaluate the effective low dose Bupivacaine with Fentanyl in spinal anaesthesia for caesarean section.

## **II. Methodology**

### **Source of data:**

After clinical approval of Institutional Ethical Committee Clearance and Informed written consent, 120 pregnant women posted for caesarean section at Government General Hospital, Vijayawada attached to Siddhartha Medical College, Vijayawada from October 2012 to August 2014, were selected on the basis of simple random sampling method.

### **Inclusion criteria:**

Patients belonging to ASA class I and II with singleton pregnancy with term gestation posted for caesarean section for various indications like cephalo-pelvic disproportion, repeat caesarean section etc, who had no contraindication for spinal anaesthesia.

### **Exclusion criteria:**

1. Patients with co-morbid conditions like anaemia, diabetes mellitus, asthma, hypertension, cardiac diseases and other systemic problems.
2. Patients belonging to ASA class III and above.
3. Patients with PIH, eclampsia, multiple gestation, placenta previa.

Preanaesthetic check-up was done to exclude co-existing medical conditions and complications of pregnancy and to assess the airway and spine. Patients with known allergy to any of the study drugs were excluded from the study. Routine investigations like haemoglobin %, bleeding time, clotting time, blood grouping and typing, urine examination were done. Intravenous (IV) line was obtained with 18 gauge IV cannula and preloading done with Ringer lactate 10ml/kg over 15-20 min.

The parturient was brought into the operation theatre lying in the left lateral position to avoid aortocaval compression and placed on the operating table in supine position with 20 degrees tilt towards left by placing a wedge under the right hip. The sphygmomanometer cuff was tied to the upper arm and baseline line blood pressure was recorded. Pulse oximeter was connected and saturation was noted.

Before the commencement of anaesthesia, patients were instructed on the method of sensory and motor assessments

All safety measures were taken for cardiovascular and pulmonary resuscitation.

### **Technique:**

The parturient is placed in left lateral position. The skin over the back was thoroughly prepared with savlon, spirit and draped with sterile towel. A 25G Quincke needle is introduced into L3-L4 space gently in midline until it reaches subarachnoid space. Position of the needle was confirmed by free flow of CSF. After confirming free and continuous flow of cerebrospinal fluid (CSF), the test drug was injected intrathecally, over 30 seconds with the bevel directed cephalad.

**Group-I:** received 1.8ml(9mg) of 0.5% Bupivacaine heavy & 25 $\mu$ g Fentanyl

**Group-II:** received 1.6ml(8mg) of 0.5% Bupivacaine heavy & 25 $\mu$ g Fentanyl

**Group-III:** received 1.4ml(7mg) of 0.5% Bupivacaine heavy & 25 $\mu$ g Fentanyl

**Group-IV:** received 1.2ml(6mg) of 0.5% Bupivacaine heavy & 25 $\mu$ g Fentanyl

Total volume of agents administered was made equal to 2.5 ml by adding normal saline. The needle is withdrawn after injection of the drug and the patient is placed in supine position with left tilt by placing a wedge under right hip. 100% oxygen via face mask (at a rate of 4 l/min) was administered till delivery of the baby. Cardiac and respiratory parameters were monitored and assessment of the level of sensory and motor blockade was done at regular intervals. The degree of sedation was recorded as per Ramsay sedation scale.

Cardiac parameters like, heart rate and BP were recorded immediately after subarachnoid block, Pulse rate, Oxygen saturation and Respiratory rate were also recorded at specified intervals.

Hypotension, was treated with intravenous boluses of Ringers Lactate, 6mg of Mephentermine and Maternal bradycardia, was treated with 0.6 mg of I V Atropine.

Dermatome sensory block was assessed by pin prick sensation at the mid clavicular line on both sides with a blunt 27G needle every 15 sec, until the block reached T6 dermatome. Thereafter, the level was checked

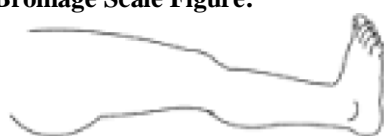
every 2 minutes, until the maximal sensory block was achieved. Surgical incision was allowed when the sensory level is  $\geq$  T6 dermatome and motor blockade is adequate. The height of the block was assessed at regular intervals thereafter until complete recovery of motor function.

Highest level of sensory analgesia is the maximum sensory level attained. Time for two segment sensory regression is the time from maximum attainment of sensory block to regression of blockade by two segments. Total duration of analgesia is the time from drug injection to first request for analgesics. Degree of motor blockade in the lower limbs was assessed subjectively by asking the patient to move the lower limbs, and was noted as follows according to the Bromage scale.

### Bromage Scale

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

### Bromage Scale Figure:



**Bromage 3 (complete)**  
Unable to move feet or knees



**Bromage 2 (almost complete)**  
Able to move feet only



**Bromage 1 (partial)**  
Just able to move knees



**Bromage 0 (none)**  
Full flexion of knees and feet

Assessment of sedation was done using Ramsay sedation score.

### Ramsay sedation score:

- 1- Anxious, agitated
- 2- Cooperative, tranquil, oriented
- 3- Drowsy but responsive to verbal commands
- 4- Asleep, brisk response to stimulus
- 5- Asleep, sluggish response to stimulus
- 6- No response

During surgery, any incidence of visceral pain, drowsiness, shivering were recorded by direct questioning and observation at regular intervals and appropriate treatment was given. Delivery time of the baby was noted and 20 units of synthetic oxytocin was added to i.v drip and oxygen discontinued. Assessment of newborn was done using Apgar score at 1min and 5 mins. The birth weight was noted. Side effects such as

hypotension, bradycardia, nausea, vomiting, shivering and pruritus or itching were recorded during and after surgery.

After surgery, cardiovascular (PR & BP) and respiratory (RR & SpO<sub>2</sub>) parameters and sensory and motor characteristics were noted continuously till complete recovery of sensory and motor function.

Time of first request for analgesics was recorded in postoperative ward. Injection diclofenac sodium 75mg i.m. was given as and when necessary.

### III. Results:

In this study, 120 uncomplicated pregnant women planned to undergo elective caesarean section were chosen. The results encountered in the present study were enumerated in the following tables.

**Table 1: Demographic profile of the participants in study groups**

	Group I	Group II	Group III	Group IV
No. of patients	30	30	30	30
Age in Years	24.5	23.73	23.97	24
Weight in Kg	64.03	61.97	64.0	60.9
Height in Cm	155.67	152.8	151.63	150.73

Most of the pregnant women in our maternity ward, coming for elective caesarean sections are less than 160 cm of height and below 65 kg of weight.

**Table 2: Characteristics of sensory and motor blockade**

	Group I	Group II	Group III	Group IV
Time of onset of sensory analgesia (sec)	137.33	146.27	155.83	162.5
Level of sensory analgesia	T4(56.67%)	T4(53.33%)	T4(46.67%)	T4(40.00%)
Total duration of analgesia(min)	257.03	220.4	179.93	166.67
Time of onset of motor block(sec)	277.67	287.17	355.33	365.67
Total duration of motor block(min)	132.93	128.2	106.9	103.83

**Table 3: Baseline hemodynamic parameters before start of anaesthesia**

	Group I	Group II	Group III	Group IV
SBP	117.23	120.9	121.3	117.6
MAP	87.40	90.33	91.80	90.10
PR	90.33	99.33	97.83	95.97
SPO <sub>2</sub>	98.77	99.23	99.00	99.33

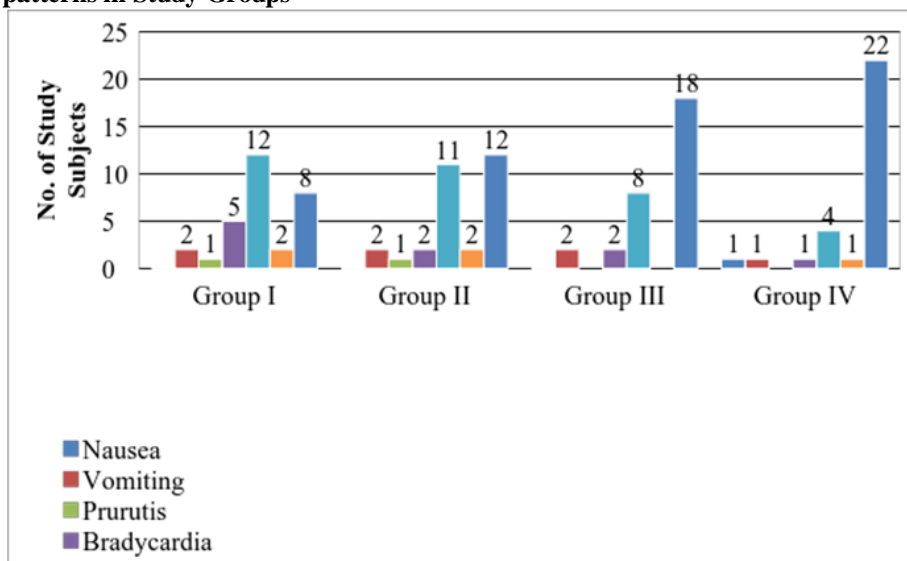
**Table 4: Hemodynamic changes encountered during LSCS**

	Group I	Group II	Group III	Group IV
SBP	108.63	115.4	114.57	115.67
MAP	78.00	79.80	81.30	84.97
PR	90.27	88.90	98.37	98.17
SPO <sub>2</sub>	98.57	98.90	98.70	99.00

**Table 5: Side effects**

Complications	Group I		Group II		Group III		Group IV		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Nausea	0	0.00	0	0.00	0	0.00	1	3.33	1	0.83
Vomiting	2	6.67	2	6.67	2	6.67	1	3.33	7	5.83
Pruritus	1	3.33	1	3.33	0	0.00	0	0.00	2	1.67
Bradycardia	5	16.67	2	6.67	2	6.67	1	3.33	10	8.33
Hypotension	12	40.00	11	36.67	8	26.67	4	13.33	35	29.17
Hypotension, Bradycardia	2	6.67	2	6.67	0	0.00	1	3.33	5	4.17

Side Effects patterns in Study Groups



IV. Discussion:

This randomized study was conducted to show the hemodynamic stability under spinal anaesthesia during caesarean section deliveries, by reducing the dose of bupivacaine from 9mg to 6mg. Most of the pregnant women in our maternity ward, coming for elective caesarean sections are less than 160 cm of height and below 65kgs of weight, so these pregnant women may not require the traditional dose (10 mg of bupivacaine), which has been advocated since long time and is the established practice. So an attempt has been made to study the level of sensory block, effectiveness of motor blockade and recovery by using various doses of bupivacaine (6mg,7mg,8mg and 9mg), each along with fentanyl (25µg).

**P.R.Dhumal et al**<sup>19</sup>, 2013 conducted a study on Synergistic effect of intrathecal Fentanyl and Bupivacaine combination for caesarean section. They concluded that addition of low dose preservative free Fentanyl (25µg) to 0.5% hyperbaric Bupivacaine for spinal anaesthesia causes satisfactory intraoperative sensory and motor blockade, hemodynamic stability, less side effects and effective postoperative analgesia.

Level of sensory blockade and onset of motor blockade were almost similar in all pregnant women in all groups with average T4 [T3– T6] in all groups.

In **Bogra J et al**<sup>12</sup>, 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.

In a study done by **Choi DH et al**<sup>13</sup>, they observed that when doses of Bupivacaine increased, the sensory recovery time was also prolonged and they also noticed that addition of Fentanyl further increased the sensory recovery time.

In **Kiran S et al**<sup>14</sup>. study where they observed that increasing Bupivacaine dose increases the time for two segment sensory regression and also the duration of analgesia The hemodynamic curves depicted clearly shows that there is a maximum fall of SBP and MAP around 6 – 9minutes after induction of spinal anaesthesia in all groups of pregnant women. Group I pregnant women who received high dose Bupivacaine 9 mg with 25µg Fentanyl have resulted in maximum fall of SBP and MAP. It is minimal in group IV (6mg with Fentanyl 25µg). Hypotension and bradycardia were together present in 2(6.67%) of patients, each in group I & II, 1(3.33%) patient in group IV.

The incidence of hypotension was increased with increasing doses of bupivacaine. It indicates low dose bupivacaine group pregnant women can be made ambulatory at the earliest and also had better hemodynamic stability. Lowering the dose of spinal anaesthetic is associated with reduced incidence of maternal hypotension, requirement of vasopressors and episodes of nausea or vomiting.

In the present study, there was no significant change in oxygen saturation and respiratory rate in any patient. Similar results were observed in **Biswas BN et al**<sup>15</sup>, **Singh H et al**<sup>16</sup> and **Hunt CO et al**<sup>17</sup> studies.

There was no significant difference in Apgar scores between the groups ( $P>0.05$ ) and none of them required resuscitation, which is consistent with **Bogra J et al**<sup>18</sup>, **Dahlgren G et al** and **Dhumal et al**<sup>19</sup> studies.

In **Choi DH et al**<sup>13</sup> study, there was no significant difference among different Bupivacaine dosage groups and also Bupivacaine–Fentanyl combination groups, with regard to nausea and vomiting.

### V. Conclusion:

Addition of Fentanyl 25 $\mu$ g to 0.5% hyperbaric Bupivacaine 6mg,&7mg was effective for spinal anaesthesia in caesarean section surgeries, with minimal side effects.

Combinations of 8mg & 9mg of 0.5% Bupivacaine with Fentanyl 25 $\mu$ g were also beneficial in caesarean section surgeries, as they provide prolonged duration of analgesia when compared to 6mg and 7mg. But the same combinations were also associated with more side effects and longer duration of motor block, which may interfere with early ambulation.

Addition of an opioid such as Fentanyl, did not produce any adverse effects in the mother or the neonate.

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