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# COMPARATIVE CROSS SECTIONAL STUDY OF EFFECT OF 0.5% HEAVY BUPIVACAINE VERSUS 0.5% HEAVY BUPIVACAINE + FENTANYL 25 MCG ON NEWBORN APGAR SCORE BORN TO TERM GESTATION MOTHER BY LOWER SEGMENT CESAREAN SECTION (LSCS) UNDER SUBARACHNOID BLOCK

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#### ABSTRACT

**Objectives:** The scientific aim of anesthesiology is to temporarily eliminate pain. This goal was first established for surgical pain management, but it has since expanded to include post-operative pain management, chronic pain management, and cancer pain management.

**Methods:** Sixty patients from ASA I and II who were scheduled for elective cesarean sections participated in a comparative cross-sectional study. The patients were divided into two groups at random, Group F and Group B. Fentanyl 25 mcg and 0.5% hyperbaric buprevacaine 12.5 mg were administered intrathecally to parturients in Group F. Group B parturients got 12.5 mg of 0.5% hyperbaric buprevacaine intravenously.

**Results:** The two groups' appearance, pulse, grimace, activity, and respiration (APGAR) scores were compared, and the neonatal APGAR score was unaffected by the intrathecal administration of fentanyl to buprevacaine. In both groups, the durations of sensory blockade onset, motor blockade onset, and resolution to bromage 0 were statistically insignificant. When compared to Group B, group F displayed longer durations for both two-segment regression and total sensory blocking. When compared to Group B, Group F had a lower frequency of side effects such as nausea, vomiting, and shivering.

**Conclusions:** We come to the conclusion that, in elective cesarean sections, 0.5% heavy Bupivacaine combined with 25 mcg of fentanyl is preferable to 0.5% heavy Bupivacaine alone.

Keywords: Bupivacaine, Elective cesarean section, Bromage scale, APGAR score.

#### INTRODUCTION

Spinal anesthesia is helpful for pain relief both during and after surgery. Corning's needle's entrance into the subarachnoid area in 1885 marked the most significant advance in spinal anesthesia. His remarks "Be the density of this observation, what it may have seemed to me on the whole, worth recording" this served as the preface to the term "spinal anesthesia". Cocaine was the first drug tested experimentally in dogs. The first spinal anesthesia in men was performed by "August Bier" using cocaine 3 mL as a 0.5% solution, followed by Matas in America and Tuffier in France [1].

Spinal anesthesia for cesarean delivery has traditionally been popular because it reduces the risk of pulmonary aspiration and avoids the difficulty of tracheal intubation associated with general anesthesia. Other benefits of this technique are its simplicity, rapid onset, and dependability. The discovery of opiate receptors in the substantia gelatinosa of the spinal cord has sparked interest in opiate delivery through intrathecal route [2]. Intrathecal morphine is used to provide postoperative pain treatment in cesarean section. The advantages of neuraxial opioids over neuraxial local anesthetics include extended, powerful, selective, segmental analgesia without motor blockage or sympathetic dysfunction.

#### **METHODS**

After receiving approval from the Institutional Ethical Committee, the study included 60 ASA I and ASA II parturients who underwent elective cesarean delivery. This prospective, randomized, double-blind study was carried out at Niloufer Hospital for Women and Children, Government Maternity Hospital: Sultan Bazar, and Modern Government Maternity Hospital: Petlaburj. All patients were told about the surgery, and their written informed consent was obtained.

Various studies found that 0.5% heavy Bupivacaine with fentanyl given intrathecally in elective cesarean section had no effect on neonatal appearance, pulse, grimace, activity, and respiration (APGAR) score and had more duration of sensory blockade and better hemodynamic stability with less shivering, nausea, and vomiting than 0.5% heavy Bupivacaine alone.

#### Inclusion criteria

ASA-I&II, Parturients above the age of 20, with a height of 160-170 cms, a weight of 50-80 kgs, a gestational age >37 weeks, and term newborns weighing more than 2.5 kgs.

#### **Exclusion criteria**

Pregnancy-related congenital abnormalities include IUGR newborns, LBW babies and neonates, difficult pregnancies such as multiple pregnancies, pregnancy-induced hypertension, placenta previa, prenatal patients with acute fetal distress, and any pregnant women who are contraindicated for spinal anesthetic.

Using the sealed envelope technique, 60 parturients were divided into two groups, Group B and Group F, each consisting of 30 parturients.

Group B patients received 0.5% heavy Bupivacaine of 12.5 mg.

Group F patients received 0.5~% heavy Bupivacaine of 12.5~mg with fentanyl 25~mcg.

All of these patients had pre-operative evaluations that included a thorough case history, a general and systemic examination, an airway assessment, and an appraisal of the investigations. The parturients were instructed to fast for 8 h the day before surgery. An hour before surgery,

all trial participants received injections of metoclopramide (10 mg im) and ranitidine (50 mg im). Ten minutes before to the procedure, a peripheral IV line was set up in the operating room using 18 Gv enflon and pre-loaded with an infusion of 10 mL/kg of Ringer's lactate.

Standard intraoperative monitoring included pulse oximetry (SPO<sub>2</sub>), NIBP, and ECG. Following preloading, patients' skin across their backs was cleaned with an antiseptic solution and covered with sterile towels while their basal parameters were noted. A 25G Quincke's needle was used to perform a subarachnoid block in the L3-L4 interspace. A study medication was injected over a 10-s period, and the free flow of cerebrospinal fluid indicated that the needle was positioned correctly.

The patient was then promptly placed in a supine position. All of the patients received oxygen through a face mask at a rate of 6L/min. Following the baby's birth, 500 mL of normal saline were infused with 10 U of oxytocin.

A bilateral lack of pinprick feeling using a 20-gauge hypodermic needle was used to assess the degree of sensory blockage attained. To reach maximum sensory blocking, the test was run every 2 min for the first 10 min. After that, it was run every 10 min until it regressed to L1.

We used a 2 mm needle protrusion through a guard to examine the bilateral L1, T12, T10, T8, T6, T4, and T2 dermatomes.

### **Motor blockade was evaluated using Bromage score** 0 = no motor blockade

1 = hip blockade (inability to raise extended leg; able to flex knees and feet)

2 = hip and knee blockade (inability to raise extended leg and flex knee; able to move feet)

3 = hip, knee and ankle blockade

The time between the greatest pinprick score and the intrathecal drug delivery was used to determine the beginning of sensory blockage. The time between maximum sensory blockade and two segment regression of sensory blockade was referred to as the two segment regression time (Table 1).

#### Neonatal assessment

The APGAR score was used to assess the newborn. At 1, 5, 10, and 30 min, APGAR scores were computed using the parameters listed below (Table 2). The amount of time between a drug's intrathecal delivery and regression to the L 1 sensory blockade level was known as the duration of sensory block.

#### **APGAR SCORING SYSTEM**

	0 Points	1 Point	2 Points	Points totaled
Activity (muscle tone)	Absent	Arms and legs flexed	Active movement	1
Pulse	Absent	Below 100 bpm	Over 100 bpm	
Grimace (reflex irritability)	Flaccid	Some flexion of Extremities	Active motion (sneeze, cough, pull away)	
Appearance (skin color)	Blue, pale	Body pink, Extremities blue	Completely pink	
Respiration	Absent	Slow, irregular	Vigorous cry	

The amount of time between intrathecal drug delivery and the point at which the Bromage score returned to zero was the definition of

Excellent condition 7-10

the duration of motor block. Time to attain bromage 0, duration of analgesia (request for rescue analgesia) and time to reach the greatest sensory blockage were all noted. For the first 30 min of the procedure, intraoperative hemodynamic parameters were collected every 5 min. After that, they were recorded every 10 min until the end of the procedure, and then again after 30 and 60 min. Hypotension, bradycardia, respiratory depression, nausea, vomiting, and shivering were among the documented intraoperative adverse effects.

#### Rescue measures

When hypotension developed (a reduction in MAP of more than 20% from the baseline value), a 6 mg IV bolus of mephentermine was administered as a rescue dose and repeated as needed. Injection Atropine 0.6 mg iv bolus was used to treat bradycardia (a decrease in heart rate of <50 beats/min). Shivering was treated with tramadol injection at a dose of 0.5 mg/kg. Nausea and vomiting were treated with injections of Ondansetron 0.1 mg/kg. Respiratory depression is described as a respiratory rate of <10/min. To treat respiratory depression, injection naloxone was kept on hand.

#### Statistical analysis

The statistical analysis was carried out using MS Excel. The sociodemographic information, patient profiles, and variables employed in this study were computed using descriptive analysis.

Categorical data from each group were compared using the Chi-square test. Categorical data were compared using contingency tables and the Chi-squared test. The mean value of the two groups was compared using the student t-test.

The data were presented as the mean  $\pm$  standard deviation, median (range), or number of parturients (n). A p<0.05 indicated statistical significance.

#### RESULTS

The age, height, weight, and duration of surgery are all >0.05, indicating that they are not statistically significant. As a result, the difference in these parameters between Groups B and F is statistically insignificant. This implies that patients in two groups come from the same demography.

The p-value for APGAR scores at 1, 5, 10, and 30 min is more than 0.05, indicating non-significance. Thus, there is no difference in the APGAR score between Group B and group F.

The beginning of sensory blockage for Groups B and F is 1.55 (+ 0.18) and 1.58 (+ 0.17) min, respectively. The p-value for the time of beginning of sensory blockage is more than 0.05, indicating that it is not significant.

The p-value for the time of commencement of sensory blockage is <0.05, indicating significance. As a result, the period for two-segment regression differs between Group B and F patients. Group F patients have a longer time for 2 segment regression than Group B. The p value of time for regression to a sensory level <L1 is <0.05, indicating significance. As a result, there is a temporal disparity between the Group B and F patients. The time it takes for patients in Group F to regress to a sensory level below L1 is longer than in Group B (Table 3).

Table 4 shows that the onset of motor blockage for Groups B and F is 2.57 ( $\pm$ 0.35) and 2.68 ( $\pm$ 0.35) min, respectively. The p>0.078 indicates non-significance. As a result, Group B and Group F have the same amount of time

The resolution of BROMAGE 0 for Groups B and F is 164.53 min (+  $3.51\,\mathrm{min}$ ) and 165.43 min (+  $3.28\,\mathrm{min}$ ), respectively. The p-value B is more than 0.05, indicating non-significance. As a result, Group B and Group F have the same amount of time.

The total sensory duration for Groups B and F is 170.73 (+2.9) min and 208.6 (+6.16) min, respectively. The p-value for Group F having less

Table 1: Demographic parameters in present study

Parameter	Group B		Group F	Group F	
	Mean	Standard deviation	Mean	Standard deviation	
Age	26	3	26	3	0.334
Height (cm)	164	3	165	3	0.233
Weight (Kg)	67	6	65	4	0.084
Duration of Surgery (mins)	56	6	55	5	0.29

Table 2: APGAR score in present study

APGAR score at	Group B (n=30)	Group F (n=30)	p-value
1 Min	8-9	8–9	0.64
5 Min	9–0	9–10	0.55
10 Min	9–10	9–10	0.64
30 Min	9–10	9–10	0.64

APGAR: Appearance, pulse, grimace, activity, and respiration

Table 3: Time for onset of sensory blockade in present study

Parameter	Group B		Group F		p-value
	Mean	Standard deviation	Mean	Standard deviation	
Time for onset of sensory blockade	1.55 min	0.18 min	1.58 mins	0.17 min	0.143
Time of 2-segment regression	50.33 min	4.63 mins	84.23 min	3.13 min	< 0.01
Time for regression to sensory level <l1< td=""><td>144.87 min</td><td>3.05 min</td><td>195.6 min</td><td>2.97 min</td><td>&lt; 0.01</td></l1<>	144.87 min	3.05 min	195.6 min	2.97 min	< 0.01

Table 4: Onset and resolution of motor blockade (Bromage 3) in present study

Parameter	Group B		Group F		p-value
	Mean	Standard deviation	Mean	Standard deviation	
Onset of motor blockage (Bromage 3) Resolution to Bromage O (Sec)	2.57 min 164.53 min	0.35 min 3.51 min	2.68 min 165.43 min	0.35 min 3.28 min	0.078 0.155

Table 5: Total sensory duration in groups

Parameter	Group B		Group F		p-value
	Mean	Standard deviation	Mean	Standard deviation	
Total sensory duration	170.73 min	2.9 min	208.6 min	6.16 min	<0.01

time than Group B is zero, indicating that it is significant. As a result, Group F patients had longer overall sensory durations than Group B patients.

The p-value for pulse rate is >0.05 from 0 to 120 min, indicating non-significance. As a result, Group B and Group F have identical pulse rates.

Even though Group F has a slightly higher MAP value than Group B, the difference is significant. Hypotension in Groups B and F is non-significant, at 0.405.

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#### DISCUSSION

Spinal anesthetic is the most used approach in LSCS because it is simple and quick to administer, provides good sensory and motor blockage, and has no substantial effect on the fetus. The addition of opioids prolongs anesthesia without harming the fetus. A plethora of studies have shown that spinal opioids have no influence on APGAR scores in babies born to

term pregnant women by lower segment cesarean surgery and can give substantial analgesia (Table 5).

Adequate sensory and motor blockages, as well as improved hemodynamic stability with minimal side effects, are required for a cesarean section. The most prevalent and unavoidable consequences of subarachnoid block are hypotension and bradycardia, which are exacerbated by aortic compression by the gravid uterus after cesarean section. We conducted a comparative cross-sectional study to assess the APGAR score, efficacy of sensory blockade, efficacy of motor blockade, duration of analgesia, and hemodynamic parameters in both the B and F groups. Weight, age, height, BMI, and physical status (ASA) did not differ significantly between groups (Tables 6 and 7).

A comparative examination of the groups for operation duration and fetus extraction time revealed no significant difference, decreasing the possibility of surgical technique bias. In our study, we looked at the effects of 0.5% heavy Bupivacaine 12.5 mg and 25 mcg of fentanyl given intrathecally in Group F and 0.5% heavy Bupivacaine 12.5 mg in group B. This study determined the prevalence of neonatal respiratory depression using the APGAR score in neonates born to term gestation moms who had intrathecal fentanyl combined with Bupivacaine for lower segment cesarean section.

Table 6: Pulse rate and mean arterial pressure in groups

Pulse rate	pre-op	0 min	5 min	10 min	15 min	20 min	30 min	45 min	60 min	90 min	120 min
group b	85.83 (±5.99)	94.43 (±11.31)	93.83 (±9.11)	93.23 (±8.44)	92.87 (±8.56)	95.33 (±7.84)	93.83 (±7.52)	93.97 (±7.95)	92.67 (±6.74)	91.87 (±6.29)	(6.9±) 6.88
group f	84.1 (±6.67)	94.43 (±7.08)	93.83 (±7.39)	93.23 (±8.66)	92.87 (±7.77)	95.33 (±8.44)	93.83 (±7.32)	93.83 (±7.39) 93.23 (±8.66) 92.87 (±7.77) 95.33 (±8.44) 93.83 (±7.32) 93.97 (±5.65) 92.67 (±4.46) 91.87 (±3.78) 88.9 (±4.7)	92.67 (±4.46)	$91.87 (\pm 3.78)$	88.9 (±4.7)
p value 0.13	0.15	0.44	0.11	90.0	0.07	0.23	90.0	0.12	0.14	0.24	0.19
Mean arterial pr	essure										
Group B	84.4 (±5.5)	80.57 (±4.3)	78.77 (±5.5)	$77.1(\pm 5.6)$	75.57 (±5.7)	76.53 (±2.0)	$76.77(\pm 3.0)$	76.97 (±3.0)	77.2 (±3.5)	77.9 (±3.4)	$80.13(\pm 3.6)$
Group F	83.5 (±4.3)	78.47 (±5.0)	76.8 (±5.7)	75.57 (±6.3)	74.57 (±5.7)	75 (±5.1)	75.77 (±5.2)	75.6 (±4.8)	76 (±5.0)	_	$78.57(\pm 4.2)$
P value	0.24	0.3	0.18	0.1		0.05	0.00	0.15	0.17	0.18	0.19

Table 7: Adverse effects in present study

Adverse effects	Group B (n=30) (%)	Group F (n=30) (%)	p-value
Hypotension Nausea Vomiting	11 (37) 12 (40) 9 (30)	8 (26) 3 (10) 1 (3)	0.405 0.007 0.006
Shivering	9 (30)	2 (10)	0.019

In our study, APGAR scores were comparable between the two groups at 1 min, 5 min, 10 min, and 30 min. Groups F and B had APGAR ratings of 8–9 at 1 min, and 9–10 at 5 min, 10 min, and 30 min. Yesuf *et al.* found no significant change in APGAR scores between the Bupivacaine fentanyl group (BF group) and the Bupivacaine alone group (BS group) [3]. Bogra *et al.* did a study to determine the synergistic effect of intrathecal fentanyl and Bupivacaine in spinal anesthesia during cesarean delivery; they found that infants' APGAR scores were consistent across all groups [4].

Our findings are consistent with the previous two trials, and we may conclude that intrathecal fentanyl administration during lower-segment cesarean surgery is not related with a low APGAR score at birth.

In our investigation, adding 25 mcg fentanyl to 12.5 mg bupivacaine had no significant effect on the onset of maximal sensory analgesia (p>0.05). In addition, there was no difference in the greatest cephalic spread obtained by both groups at T4. Gauchan  $et\ al.$  [5] utilized 3 mL of 0.5% bupivacaine with 25 mcg fentanyl and 3 mL 0.5% bupivacaine, which was a slightly greater dose than our trial, and they found no significant time difference for the maximum sensory analgesia. In our investigation, the start of sensory analgesia in the F and B groups was 1.58 $\pm$ 0.17 and 1.55 $\pm$ 0.18 min, respectively.

The addition of 25 mcg intrathecal fentanyl to 12.5 mg bupivacaine had no effect on the onset of sensory analgesia or the height of the block, as confirmed by Gauchan *et al.* [5] and Yesuf *et al.* [1].

Motor blockade began at  $2.57 \pm 0.35$  min in group B and  $2.68 \pm 0.35$  min in Group F. All of the patients experienced grade 3 motor blockage. From this, we can conclude that fentanyl has no effect on motor blockage. Group B experienced motor obstruction for  $164.53 \pm 3.51$  min, while Group F experienced it for  $165.43 \pm 3.28$ . There was no significant difference in the duration of motor blockage since both groups received the same dose of Bupivacaine. Singh *et al.* [6] and Biswas *et al.* [7] found that adding fentanyl did not change the duration of the motor block, which was consistent with our findings.

The time for 2 segment regression in Group F was  $84.23\pm3.13$  min, compared to  $50.33\pm4.63$  in the B group. Our findings are comparable to those of Attri et~al. [8]. Our study found that adding 25 mcg of fentanyl increased the duration of full analgesia by  $208.6\pm6.16$  min compared to the bupivacaine group, which was  $170.73\pm2.9$  min (p=0.000). In a study conducted by Shashikala and Srinivas [2], 99 parturients were divided into two groups: FB, who were given 2 mL of 0.5% Bupivacaine plus 12.5 mcg fentanyl, and BC, who were given 2 mL of 0.5% Bupivacaine only. The total duration of mean analgesia was longer in the FB group. Our results are consistent with the above study.

More than 66% of cesarean deliveries are accompanied by intraoperative nausea and vomiting. This is primarily connected to peritoneal traction and uterine exteriorization performed under regional anesthesia. In addition, blocking sympathetic cardiac accelerator fibers with high doses of simple bupivacaine might cause hypotension. This is significantly associated with nausea and vomiting. In our study, three patients in the F group and 12 in the B group got nausea, but only one patient in the F group and nine in the B group experienced vomiting, and the p-value is statistically significant. These findings are consistent with the findings of a research conducted by Bogra *et al.* [4].

In our investigation, there was no statistical significance in mean heart rate and mean arterial blood pressure at various time intervals in both groups, which is consistent with the findings of Dhumal *et al.* [9] and Shashikala and Srinivas [2]. In terms of intraoperative hypotension, we found no statistical difference between Groups F and B. Our study found that eight patients in the F group and eleven in the B group suffered hypotension, which was treated with IV fluid and injection of mephentermine 6 mg IV. Our findings were comparable to those of Akanmu *et al.* [10].

In his study, eight patients in his control group, BS (26.67%), compared to six patients (20%) in the FB group, developed hypotension that necessitated a fast crystalloid infusion. Intrathecal fentanyl reduces shivering by acting as a thermo-regulator and affecting spinal afferent heat inputs. It is a highly ionized, lipophilic  $\mu$ -receptor agonist with a unionized component that is quickly transported into the spinal cord. Shivering was reported by two patients in the F group compared to nine in the B group. A study by Sadegh *et al.* [11] found similar results, stating that intrathecal Bupivacaine coupled with fentanyl reduces the occurrence and intensity of shivering.

Intrathecal fentanyl-induced pruritus is most likely caused by the opioid's cephalic migration in CSF and subsequent contact with opioid receptors in the trigeminal nucleus, rather than histamine release. In our investigation, none of the group patients experienced pruritus. This is consistent with the findings of Bogra *et al.* [4]. Similar to the findings of Bogra *et al.* [4], the addition of fentanyl to Bupivacaine reduced the incidence of nausea and vomiting in our trial.

#### CONCLUSION

Our study found that adding 25 mcg of fentanyl to 0.5% strong Bupivacaine for a lower segment cesarean delivery under subarachnoid block had no effect on newborn APGAR scores. It also increased the quality of anesthesia and reduced the number of intraoperative problems. Thus, the combined action of fentanyl and Bupivacaine is superior to Bupivacaine alone. As a result, we conclude that 0.5% heavy Bupivacaine combined with 25 mcg fentanyl is a better option for elective cesarean section than 0.5% heavy Bupivacaine alone.

#### AUTHOR CONTRIBUTION

Nil.

#### **AUTHOR FUNDING**

Nil.

#### CONFLICTS OF INTEREST

Nil.

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