

Original Research Paper

Anaesthesiology

EVALUATION OF ADJUNCTIVE ANALGESIA WITH INTRATHECAL FENTANYL ALONG WITH HYPERBARIC BUPIVACAINE IN SPINAL ANESTHESIA FOR ELECTIVE CESAREAN SECTION.

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Abstract Aims & Objective: to compare the effect of intrathecal fentanyl as an adjuvant with hyperbaric Bupivacaine and Bupivacaine alone in spinal anaesthesia for analgesia effect in caesarean section, time for onset of sensory and motor block, Duration of sensory and motor block, Perioperative hemodynamic stability, neonatal outcome and APGAR score, Adverse effects of drugs. Material & Methods: Sixty patients aged between 18 to 40 years with ASA grade 1, 2 and 3 posted for Elective cescarean section. Patients were randomly divided into two groups of 30 patients in each in Group A: 2.0 ml of 0.5% injection Bupivacaine (hyperbaric) with 0.4 ml (20 mcg) of injection Fentanyl citrate. Result: The 2 groups were comparable in demographic data. intrathecal fentanyl in dose of 20 µgm with hyperbaric Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine alone Conclution: we concluded that intrathecal fentanyl in dose of 20 µgm with hyperbaric Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine alone for caesarean section with stable maternal hemodynamics with least maternal side effects and no effect on neonatal APGAR score. Intrathecal fentanyl has better antiemetic action in the caesarean section. However, it is associated with pruritus.

KEYWORDS: Fentanyl, Bupivacaine, Spinal Anesthesia, Cesarean section

INTRODUCTION

Caesarean delivery can be the best way to ensure the safety of the mother and baby especially if the baby is in distress in the later stage of pregnancy. Spinal anaesthesia became a more widely practised anaesthetic technique for cesarean delivery than general anaesthesia because (1) It is simple to perform, Fast in effect, Uniform sensory and motor blocks. Risk of difficult/failed intubation and mask ventilation, aspiration pneumonitis and drug induced foetal depression; such common complications can be avoided. Better suppression of neuroendocrine stress response and maternal mortality, Keeps mothers awake to experience childbirth.

MATERIALS AND METHODS

After approval from the institutional review board, we carried out an observational study of 60 women between 18-40 years of age with ASA grade 1, 2 and 3 presenting for elective caesarean section Patients were randomly divided into two groups of 30 patients in each. Group A: receiving 2.0 ml of 0.5% injection Bupivacaine (hyperbaric) with 0.4ml of normal saline. Group B: receiving 2.0 ml of 0.5% injection Bupivacaine (hyperbaric) with 0.4 ml (20 mcg) of injection Fentanyl citrate.

Exclusion Criteria.

- · Patient refusal
- ASA grade IV OR more
- Patients with foetal abnormality
- Patient with gross spinal deformity or peripheral neuropathy
- · History of previous spinal surgery
- · Patient with coagulation disorder or sepsis
- Hypersensitivity to study drugs
- Hemodynamically unstable patients
- H/o chronic headache / backache
- · Local infection at the sit
- · Inadequate block

History of drug and alcohol abuse

Patient's demographic data like age, sex, height, weight was recorded. Vitals like heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and SpO2 are recorded. Routine investigations like Complete Blood Count, Random

Blood Sugar (RBS), Serum Creatinine, coagulation profile, ECG are done in all patients. Patients are fasted for 6-8 hrs before time of operation.

Before operation patients were explained about the procedure and written informed consent taken. Intravenous line secured, Standard monitors such as electrocardiogram, pulse oximeter, and blood pressure cuff were applied, and patient's baseline parameter such as pulse, blood pressure, respiratory rate, and SpO2 was recorded and preloading was done with Ringer's lactate solution 10 -12 ml/kg in 20-30 min prior to subarachnoid block All patients were premedicated with (on operation table): injection ondansetron 4 mg intravenously.

Patients were placed in left lateral or sitting position, Under all strict aseptic and antiseptic precautions after infiltration of the skin with local anaesthetic solution 2 ml of 1% injection lignocaine, lumbar puncture was performed at L2-L3 space in left lateral or sitting position with 25 G Quincke spinal needle and after confirming free and clear flow of CSF the study drug was injected and time and vitals at that time was noted. Immediately after Spinal anesthesia patients were evaluated for the assessment of onset of sensory and motor blockade

The time noted for sensory block was:

- The onset of sensory block.
- Total duration of sensory block.

Onset of sensory block:

Time interval from intrathecal injection to loss of pin $\;$ prick sensation at $T_{\rm 10}$ dermatome level.

Total duration of sensory block:

Time interval from intrathecal injection to sensory regression at \mathbf{S}_2 dermatome level.

Motor block was assessed with use of modified Bromage scale $_{\scriptscriptstyle (2)}$

Modified Bromage Scale:

Scale	Criteria			
111	Free movement of legs and feet with ability to			
	raise extended legs.			

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1	Inability to raise extended leg and knee flexion decreased, but full flexion of feet and ankle is
2	Inability to raise leg or flex knees, but flexion of ankle and feet present.
3	Inability to raise leg, flex knees or ankle or move toes.

The time noted for motor block was:

- Onset of motor block
- · Duration of motor block

Onset of motor block:

defined as Time to achieve Grade I motor block from intrathecal injection.

Duration of motor block:

Time interval between onset of motor block and time to achieve $\operatorname{grade} 3$ to $\operatorname{grade} 0$ of motor block.

Duration of surgery was noted

After the targeted level of sensory and motor block achieved, Surgery was started and corresponding time and vitals noted. Intraoperatively pulse, blood pressure, SpO2, RR were monitored at 1 minute, 3 minute, 5 minute, 10 minute, 20 minute, 30 minute, 45 minute, 60 minute and 90 minutes and thereafter at 2 hr, 3 hr, 4 hr, 6 hr and 12 hr.

Hypotension:

Fall in SBP by \geq 20% from baseline value or SBP < 90mmHg. Treated with additional boluses of IV fluids and inj. Mephentermine 6mg was given if hypotension persisted.

 ${\bf Bradycardia} \colon {\bf HR} < 60/{\rm min}.$ It was treated with 0.6mg i.v. Atropine.

Respiratory depression: when RR was <10 breaths/min. Treated with 100% O_2 via Bain's circuit followed by O_2 through face mask at the rate of 4 L/min.

APGAR score of baby was noted at $\ 1 \ \text{min}$ and $\ 5 \ \text{min}$ after delivery.

Duration of analgesia:-

- Total duration of analgesia: It was documented from time of sensory onset to time for requirement of first dose of rescue analgesia.
- \clubsuit Rescue analgesia: It was the first additional analgesia given when VAS score ≥ 4 .

Inj. Diclofenac Sodium 75 mg i.v. was given as rescue analgesia.

All the data were filled in proforma and were statistically analyzed by using unpaired student's T test.P value less than 0.05(p<0.05) was considered statistically significant. P<0.001 was considered as highly significant.

RESULTS:

Table 1 shows there was no significant difference between these two groups in their demographic characteristics and duration of surgery. (P>0.05)

Table-1: Demographic Characteristic

CHARACTERISTICS	Group - A		Group- B		P
	MEAN	SD	MEAN	SD	VALUE
Age (Yrs)	27.8	4.49	25.9	4.53	0.12
Height (Cm)	160.13	5.39	159.6	3.93	0.68
Weight (Kg)	68.26	6.78	65.8	5.87	0.14
Duration of surgery (Min)	64.4	5.617	65.53	7.06	0.215

Table -2: Characteristic Of Sensory Block

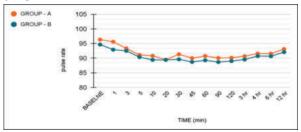
Table 3 shows that there was no significant difference in the time of onset of sensory block between two groups. (P>0.05)

Mean Duration of sensory block (the time for regression of sensory block to S2 dermatome) was highly statistically highly significant among both groups (P<0.001), and the block was longer in Group B than Group A.

Table - 3: Characteristics Of Motor Block

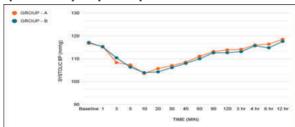
CHARACTERISTIC OF	GROUP - A		GROUP- B		P
SENSORY BLOCK	MEAN	SD	MEAN	SD	VALUE
Time of Onset of sensory block (min)	2.9	0.35	2.73	0.44	0.10
Total duration of sensory block(Time for regression of sensory level to S2 dermatome) (min)	141.5	6.027	181.06	5.67	0.0001

Table 3 shows that there was no significant difference in time of onset and total duration of motor block between the two groups as P>0.05.



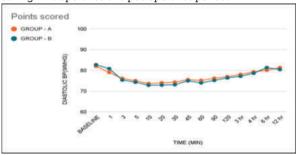
Graph 1 shows mean pulse rate in two groups with respects to time.

Graph1 shows that there was NO significant difference in pulse rate were observed in Group A and Group B during intra operative and postoperative period.



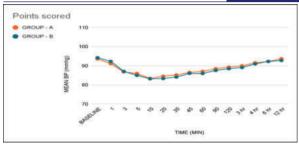
 $\operatorname{Graph} 2$ shows mean systolic blood pressure in two groups with respects to time.

Graph 2 shows that there was NO significant difference in systolic blood pressure was observed in Group A and Group B during intra operative and postoperative period.



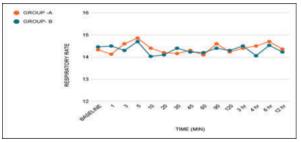
 $\operatorname{Graph} 3$ shows mean diastolic blood pressure in two groups with respects to time.

Graph3 shows that there was NO significant difference in diastolic blood pressure was observed in Group A and Group B during intra operative and postoperative period.



Graph 4 shows mean of Mean blood pressure in two groups with respect to time.

Graph 4 shows that there was NO significant difference in Mean blood pressure was observed in Group A and Group B during intra operative and postoperative period.



Graph 5 shows mean respiratory rate in two groups with respects to time.

Graph 5 shows that there was NO significant difference in respiratory rate was observed in Group A and Group B during intra operative and postoperative period.

Table - 4: Sedation Score

Campbell	GROUP-A		GROUP -	·B
Sedation	No. of	% of	No. of	% of
Score	cases	patients	cases	patients
1	30	100	20	66.66
2	0	0	10	33.33
3	-	-	-	-
4	-	-	-	-

Table 4 shows that all patients were wide awake / awake and comfortable in both groups

Table -5: Apgar Score

	GROUP -A	GROUP - B	P Value
APGAR score at 1 min	9.13±0.68	8.9 ±0.75	0.215
APGAR score at 5 min	9.43 ± 0.50	9.233 ±0.727	0.22

Table 5. Shows that APGAR score at 1 min and 5 min were almost similar in both groups. No adverse effect on neonatal outcome on addition of intrathecal 20 mcg fentanyl for cesarean section. (P>0.05)

Table - 6: Perioperative Complications:

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Complications	NO. OF CA	NO. OF CASES			
	Group A	Group B			
Hypotension	3	2			
Bradycardia	1	1			
Nausea/vomiting	3	1			
Respiratory depression	-	-			
Shivering	2				
Pruritus	-	3			
Uringry retention	-	_			

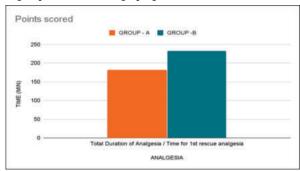
Table 6 compares complications between two groups. Pruritus was seen in only group B. Nausea, vomiting and shivering were more in group A. Bradycardia is equal in both groups and hypotension was lower in group B patients. There

were no respiratory depression and neurological complications in either group.

Table - 7: Duration Of Analgesia (min)

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CHARACTERISTICS	GROUP - A		GROUP -B		P
OF ANALGESIA	MEAN	SD	MEAN	SD	Value
Total duration of analgesia / Time for 1st rescue analgesia (min)	180.4	4.25	232.9	6.05	0.0001

Table 14 shows Total duration of analgesia (time from sensory onset to Time for 1st dose of rescue analgesia) were prolonged in group B. Which was highly significant (P<0.001)



Graph 6 shows total duration of analgesia in both groups.

DISCUSSION

We carried out an observational study of 60 women presenting for elective caesarean section. Patients were randomly divided into two groups of 30 patients each:

Group A: receiving 2.0 ml of 0.5% injection Bupivacaine (hyperbaric) with 0.4ml of normal saline.

Group B: receiving 2.0 ml of 0.5% injection Bupivacaine (hyperbaric) with $0.4 \, \text{ml}$ (20 mcg) of injection Fentanyl citrate.

Demographic data (age, height and weight), ASA grade and duration of surgery in the both groups were compared and there was no significant difference in both groups. (P-value >0.05)

Duration Of Surgery

In this study, Duration of surgery was 64.4 ± 5.617 min in group A and 65.53 ± 7.06 min in group B. There was statistically no significant difference in both groups regarding duration of surgery. (p-value >0.05)

1) Onset of sensory block:

In this study the time for sensory onset were 2.90 ± 0.35 mins in Group A and 2.73 ± 0.55 mins in Group B. There was statistically no significant difference in both groups regarding onset of sensory block. (P-value >0.05) Our findings correlate with below mentioned study.

Ranu Surana et al⁽³⁾

In 2020 studied 60 parturients undergoing caesarean section, divided into two groups of 30 each. Group B received 10 mg Hyperbaric Bupivacaine alone and Group F received 10 mg Hyperbaric Bupivacaine with 20 $\mu \rm g$ Fentanyl citrate intrathecally. They observed time of sensory onset was 5.10±1.18 mins in group B and 6.82±1.53 in group F which shows no statistical significance in time for onset of sensory level between two groups.

2) Duration of sensory block (Time interval from intrathecal injection to sensory regression at S2 dermatome level):

In this study, the duration of the sensory block was 141.5 ± 6.04 mins in Group A and 181.06 ± 5.75 mins in Group B. There was a statistically highly significant difference in duration of

sensory block between two groups. (P-value < 0.001) Our findings correlate with below mentioned study.

Nahakpam S, Dhanachandra L, Joenna Devi N, et al $^{(4)}$

In 2020 Conclude in study of 110 patient in labour with using three doses of fentanyl - 15 mcg, 20 mcg, 25 mcg as an adjuvant to 7.5 mg of 0.5% heavy Bupivacaine for caesarean section deliveries that time for recovery from sensory block in these all groups were 129.71 ± 18.7 min, 193.43 ± 18.46 min and 279.43 ± 31.6 min, which is highly significant

3)Onset of motor block (Time to achieve Grade 1 motor block from time of intrathecal injection):

In this study, the time of motor onset was 3.68 \pm 0.33 mins in Group A and 3.585 \pm 0.33 mins in Group B. There was statistically no significant difference in both groups regarding onset of motor block. (P-value >0.05) Our findings correlate with below mentioned study.

Ali Muhammad Asghar, Samina Ismail et al⁽⁵⁾

Conclude in thier study of 243 parturients undergoing cesarean section that intrathecal fentanyl in a dose of 25 μg compared to lower doses 10 mcg and 15 mcg with 2.0 ml (0.5%) hyperbaric Bupivacaine that there were no statistically significance regarding onset of motor block between all three groups. They observed time of motor onset was 7.2 \pm 2.4 mins in 10mcg fentanyl group, 7.4 \pm 3.3 min in 15 mcg fentanyl group and 7.7 \pm 2.7 mins in 25 mcg fentanyl group.

4)Duration of motor block (time to achieve grade 0 from grade 3 of bromage scale of motor block):

In this study, duration of motor block was 158.93 ± 4.78 mins in Group A and 160.8 ± 4.12 mins in Group B. There was statistically no significant difference in both groups regarding duration of motor block. (P-value > 0.05) Our findings correlate with below mentioned study

Uike S, Chaudhary et al (6)

In 2015 studied 80 patients posted for caesarean section, divided into two groups of 40 each. One group received 10 mg Hyperbaric Bupivacaine alone and another group received 12.5 μ g Fentanyl citrate with 10 mg Hyperbaric Bupivacaine intrathecally. They observed that duration of grade 3 motor block was 109.88 \pm 17.81 mins in Hyperbaric Bupivacaine alone group and 113.38 \pm 37.9 mins in Hyperbaric Bupivacaine + Fentanyl citrate group which was not statistically significant in both the groups

5) Hemodynamic Changes:

In this study, intraoperative and postoperative heart rate, SBP, DBP and MAP were comparable in both groups and statistically insignificant.

In Group A bradycardia was seen in 1 patient (3.33%) and in Group B it was seen in 1 patient (3.33%). It was treated with Inj. Atropine $0.6\,\mathrm{mg}$ iv.

In Group A hypotension was seen in 3 patients (10 %) and in Group B it was seen in 2 patients (6.66%). It was treated with IV fluids and Inj. Mephentermine 6 mg IV accordingly. Our findings correlate with below mentioned study.

Acharya, Shailendra sidgel et al⁽⁷⁾

In 2019 studied 60 patients undergoing caesarean section, divided into two groups of 30 each. One group received 10 mg Hyperbaric Bupivacaine alone and another group received 10 mg Hyperbaric Bupivacaine with $12.5\mu g$ Fentanyl citrate intrathecally. They observed and concluded that hemodynamic parameters are comparable in both groups and statistically insignificant

6) sedation Score:

All the patients of this study were wide awake / awake and comfortable – with Campbell sedation score of 1/2. Our findings correlate with the below mentioned study.

Jayshri Prajapati, Rekha Bayer, Himanshu prajapti at el®

In 2022 studied Campbell sedation score indicates patients' condition (awake or sedated) among 50 patients undergoing caesarean section divided into two groups of 25 each. Group A did not receive Fentanyl citrate, Group B received 12.5 $\mu \rm g$ Fentanyl citrate and with 2.0 ml 0.5 % hyperbaric Bupivacaine intrathecally and found all patients were awake and comfortable with added Fentanyl citrate.

7)Apgar Score:

In this study APGAR scores at 1 min and 5 min were 9.113 \pm 0.68 and 9.43 \pm 0.50 in Group A while 8.9 \pm 0.75 and 9.233 \pm 0.72 in Group B. There was no statistical significance between two groups.(p-value>0.05) Our findings correlate with below mentioned study

Gauchan Thapa et al⁽⁹⁾

In 2014 studied 70 patients undergoing caesarean section, divided into two groups of 35 each. One group received 2.4 ml (12mg) hyperbaric Bupivacaine alone and another group received 10 mg Hyperbaric Bupivacaine with 20 μ g Fentanyl citrate intrathecally They concluded no significant difference regarding neonatal outcome in two groups.

8) Perioperative Complication:

No other complications except nausea-vomiting, shivering and pruritus were found in this study

1) Nausea and Vomiting

Intraoperative nausea and vomiting in most of patients in caesarean section with spinal anaesthesia is mainly related to peritoneal traction, exteriorization of uterus, administration of uterotonic agents like methergine/carboprost and increased vagal activity. (8)

Addition of Fentanyl augments the quality of spinal block, so decreased nociceptive stimulation from peritoneal traction or exteriorization of uterus, hence decreased incidence of nausea or vomiting. (9)

MS Hossain, MS Islam et al $^{\scriptscriptstyle (10)}$

In 2017 studied 80 patients undergoing caesarean section, divided into two groups of 40 each. One group received 12.5 mg Hyperbaric Bupivacaine alone and another group received 10 mg Hyperbaric Bupivacaine with 25 μg Fentanyl citrate intrathecally. They observed that nausea occurred in 4 patients of without fentanyl group and 0 patients with Fentanyl group

2) Shivering:

Shivering is one of the common problems with spinal anaesthesia. Shivering increases O_2 consumption and also makes patients uncomfortable and anxious. Anti-shivering action of Fentanyl is mediated by non- μ opioid receptors. In this study, shivering was seen in 2 patients (6.66%) in Group A and no any patient in Group B. Our findings correlate with below mentioned study.

Jayshri Prajapati, Rekha Bayer, Himanshu prajapti. at el. (11)

In 2022 studied 50 patients undergoing caesarean section divided into two groups of 25 each. Group A not received Fentanyl citrate, Group B received 12.5 μ g Fentanyl citrate and with 2.0 ml 0.5 % hyperbaric Bupivacaine intrathecally and found that 4 patient in control group having shivering compaired to fentanyl group having 2 patients.

3) Pruritus:

Pruritus is thought to be mediated through action of Fentanyl

on μ receptors present in nervous system. (12) In this study, pruritus was found in 3 patients (10%) in Group B and none in Group A. It was treated with Inj. Avil intravenously. Our findings correlate with below mentioned study

Ali Muhammad Asghar, Samina Ismail et al⁽⁵⁾

In 2018 Conclude in their study of 243 parturients undergoing cesarean section and randomly allocated in 3 group receiving 10, 15, 25 mcg intrathecal fentanyl with 10 mg of hyperbaric Bupivacaine and found that pruritus is more common with higher dose of fentanyl group (25 mcg)

4 Respiratory depression and other sequelae:

The lipophilic nature of fentanyl allows its rapid clearance from CSF, so there are least chances of hypoxia or respiratory depression⁽³⁾.

In this study, none of the patients from either group developed hypoxia or respiratory depression or any other complications in intraoperative and post operative period. Our findings correlate with below mentioned study.

Wesla Packer Pfeifer Ferrarezi, Angélica de Fátima de Assunc¸ão Braga et al⁽¹³⁾

In 2021 they studied 124 women and the results demonstrate that fentanyl at a dose of 15 mcg comparing with 7.5 mcg and 10 mcg fentanyl associated with 10 mg of hyperbaric Bupivacaine and 10 mg hyperbaric Bupivacaine alone intrathecally for patients submitted to C-section. They observed that none of patients from all four groups developed hypoxia or respiratory depression.

9)total Duration Of Analgesia:

In this study, total Duration of analgesia was 180.4 ± 4.25 mins in Group A and 232.9 ± 6.05 mins in Group B. There was a statistically highly significant difference between two groups. (P-value < 0.001) Our findings correlate with below mentioned study.

Uike S, Chaudhary et al (6)

In 2015 studied 80 patients posted for caesarean section, divided into two groups of 40 each. One group received 10 mg Hyperbaric Bupivacaine alone and another group received 12.5 μ g Fentanyl citrate with 10 mg Hyperbaric Bupivacaine intrathecally. They observed that duration of analgesia was 176.25 \pm 1.68 min in only bupivacaine group and 269.13 \pm 33.71 min in fentanyl group which was statistically highly significant between the both groups.

CONCLUSION:

In our study of 60 patients we concluded that intrathecal fentanyl in dose of 20 \square gm with hyperbaric Bupivacaine (0.5%) 10 mg produces prolonged sensory block as well as postoperative analgesia compared to Bupivacaine alone for caesarean section with stable maternal hemodynamics with least maternal side effects and no effect on neonatal APGAR score.

Intrathecal fentanyl has better antiemetic action in the caesarean section. However, it is associated with pruritus.

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