



## COMPARISON OF EFFICACY OF INTRATHECAL FENTANYL AND INTRATHECAL TRAMADOL AS ADJUVANT TO HYPERBARIC BUPIVACAINE 0.5% IN ELECTIVE CAESAREAN SECTION PATIENTS

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### ABSTRACT

**Introduction:** Subarachnoid block is the preferred technique for caesarean section. Hyperbaric bupivacaine is the most common drug used in spinal anaesthesia for caesarean section. Addition of opioids to local anaesthetics is routinely done in central neuraxial blockade as it provides better intraoperative and early postoperative analgesia. Although intrathecal bupivacaine offers good sensory blockade, a substantial number of patients experience haemodynamic instability, pain and discomfort and may require analgesic supplementation in early postoperative period. **Aim:** To study the duration of postoperative analgesia, intraoperative haemodynamic changes, level of sensory and motor blockade, depth of sedation as well as postoperative haemodynamic changes, pain, nausea & vomiting, depth of sedation, pruritis and shivering and total analgesics required over 24 hours of postoperative period. **Materials And Methodology:** This study was conducted at Katuri Medical College & Hospital, Chinakondrupadu on 60 patients undergoing LSCS both emergency and elective surgery. Informed consent was obtained from patients included in the study. Patients were divided into two groups, Group A received 0.5% hyperbaric bupivacaine 9mg(1.8 ml) + 10mg(0.2ml) of tramadol intrathecally. Group B received 0.5% hyperbaric bupivacaine 9mg(1.8ml) + 10mcg(0.2ml) of fentanyl intrathecally. **RESULTS:** When the pulse rates of two groups are compared at set intervals, there is no obvious difference. When comparing the mean arterial pressure between the pre and post anaesthesia procedure there is statistical difference. When compared postoperatively pain score between the two groups revealed a significant difference. **CONCLUSION:** Both the groups were effective in providing adequate surgical anaesthesia and haemodynamic stability, but fentanyl seems to be a better alternative to tramadol as an adjuvant to spinal bupivacaine in elective caesarean surgeries.

**KEYWORDS :** spinal; bupivacaine; tramadol; fentanyl; mean arterial pressure; postoperative pain.

### INTRODUCTION:

Subarachnoid block is the preferred technique for caesarean section. It is

- I. Easy to perform
- II. Rapid onset of action.
- III. Involves lesser drug doses
- IV. Produces minimal neonatal depression
- V. Lesser incidence of chemical pneumonitis.

However, it also has disadvantages which include producing only a fixed duration of anaesthesia, causing intra-operative hypotension and difficulty in controlling the height of block. Hyperbaric bupivacaine is the most common drug used in spinal anaesthesia for caesarean section. Bupivacaine belongs to amide group of local anaesthetics with high potency, slow onset (5-8 minutes) and long duration of action. For caesarean section intrathecal dose of hyperbaric bupivacaine is 12 to 15 mg.

Addition of opioids to local anaesthetics is routinely done in central neuraxial blockade as it provides better intra-operative and early postoperative analgesia. Spinal anaesthesia is often used for both emergency and elective caesarean section. The advantages of spinal anaesthesia are its rapidity in onset, safety and reliability. Caesarean delivery requires traction of peritoneum and handling of intraperitoneal organs, resulting in intra operative visceral pain. With higher doses of hyperbaric bupivacaine, incidence of intra operative visceral pain associated with organ manipulation is reduced.

Although intrathecal bupivacaine alone offers good sensory blockade, a substantial number of patients experience haemodynamic instability, pain and discomfort and may require analgesic supplementation in early postoperative period.

To overcome these drawbacks, opioids are administered intrathecally along with bupivacaine. Numerous benefits like

- Stable hemodynamics
- Denser analgesia
- Lesser pulmonary complications
- Earlier ambulation of patients
- Prompt return of bowel function and reduced stress response.

### AIM AND OBJECTIVES:

#### Primary Objective:

To study the duration of post-operative analgesia

#### Secondary Objective

To study the intra-operative haemodynamic changes, level of sensory and motor blockade, depth of sedation and duration of surgery as well as postoperative haemodynamic changes, pain, nausea and vomiting, depth of sedation, pruritus and shivering and total analgesics required over 24 hours of postoperative period.

### METHODOLOGY:

This study was done among patients undergoing elective LSCS under SAB in Katuri Medical College & Hospital, chinakondrupadu, Guntur, Andhra Pradesh.

#### Study Population:

All Patients undergoing elective LSCS under SAB in Katuri Medical College & Hospital, chinakondrupadu, Guntur District.

#### Study Design:

A randomized, double-blinded trial

#### Study Setting:

Patients undergoing elective LSCS under SAB in Katuri Medical College & Hospital, chinakondrupadu, Guntur District.

#### Statistical Analysis:

Sample size calculation was done based on previous study

with difference of 66 minutes and SD of 61 minutes - 25 patients/each group will be need with 90% of power& 5% significance.15 to 30 patients will be included in each group to avoid possible dropouts . Statistical analysis was done by independent T-test , Mann Whitney U test, chi square test whichever is applicable.

**Inclusion Criteria:**

Patients consenting for elective caesarean section under spinal anaesthesia belonging to

- ASA II
- Age group of 18 to 35 yrs
- Body Mass Index between 18.5 - 24.9 Kg/m2

**Exclusion Criteria:**

- Refusal to spinal anaesthesia.
- ASA III and above physical status
- Allergic to local anaesthetics and adjuvants.
- Infection at needle site

Contraindications to subarachnoid block like bleeding tendencies, gross spinal deformities.

**Sample Size:**

Total size of 60 patients

Group I - 30 patients

Group II – 30 patients

**Study Procedure**

Group I received 0.5% hyperbaric bupivacaine 9 mg (1.8 ml) + 10 mg (0.2 ml)of tramadol intrathecally (2ml).

Group II received 0.5% hyperbaric bupivacaine 9 mg (1.8ml) + 0.2 ml i.e. 10micro grams of fentanyl intrathecally (2ml).

The patients as well as the anaesthetist involved in the assessment of the block were blinded to the drug used for spinal anaesthesia. Separate independent investigator prepared the syringes with drugs and handed over to the performing anaesthetist. A total of 60 patients who were willing for surgery.

**RESULTS:**

**Mean Arterial Pressure (MAP) :**

The mean and standard deviation of the Mean arterial pressure of the fentanyl and tramadol group at various time intervals during the post-operative period is represented in the following table. The post op mean arterial pressures of Fentanyl and Tramadol groups were statistically insignificant

**Table 1 : Mean Arterial Pressure Of The Fentanyl And Tramadol Group At Varioustime Intervals During The Postoperative Period.**

MAP	GROUP	N	MEAN	STD. DEVIATION	p VALUE BY t TEST
4 hours	Fentanyl	30	89.98	4.47	0.891
	Tramadol	30	89.78	6.57	
8 hours	Fentanyl	30	87.62	5.52	0.685
	Tramadol	30	88.20	5.46	
12 hours	Fentanyl	30	88.98	4.11	0.429
	Tramadol	30	88.11	4.32	
16 hours	Fentanyl	30	87.27	5.82	0.760
	Tramadol	30	86.73	7.55	
20 hours	Fentanyl	30	87.69	6.85	0.463
	Tramadol	30	88.93	6.19	
24 hours	Fentanyl	30	87.82	5.40	0.772
	Tramadol	30	88.27	6.37	
	Tramadol	9	1.00	0.00	

**Pain Score:**

The mean and standard deviation of the pain of the fentanyl and tramadol group at various time intervals during the post-operative period is represented in the following table. The post op pain score of Fentanyl group when compared to Tramadol group was statistically significant at interval of 8 hours (p value = 0.001) and 12 hours (p value = 0.015).

**Table 2 : Pain Of The Fentanyl And Tramadol Group At Various Time Intervals During The Postoperative Period.**

PAIN		Group				p value by Chi sq test
		Fentanyl		Tramadol		
		Count	%	Count	%	
4 hours	Yes	15	53.6%	13	46.4%	0.605
	No	15	46.9%	17	53.1%	
8 hours	Yes	5	21.7%	18	78.3%	0.001*
	No	25	67.6%	12	32.4%	
12 hours	Yes	11	78.6%	3	21.4%	0.015*
	No	19	41.3%	27	58.7%	
16 hours	Yes	5	33.3%	10	66.7%	0.136
	No	25	55.6%	20	44.4%	
20 hours	Yes	7	50.0%	7	50.0%	1
	No	23	50.0%	23	50.0%	
24 hours	Yes	9	52.9%	8	47.1%	0.774
	No	21	48.8%	22	51.2%	

**DISCUSSION:**

We have evaluated the Efficacy of Intrathecal Fentanyl and Intrathecal Tramadol as an adjuvants to hyperbaric Bupivacaine 0.5% In Elective Caesarean Section Patients. We studied the onset of sensory and motor blockade and duration of sensory and motor blockade. We studied the quality of analgesia in terms of pain score and total analgesic requirement, sensory characteristics, motor characteristics in patients receiving bupivacaine with tramadol and bupivacaine with fentanyl. We also studied the haemodynamic changes, incidence of nausea, vomiting, pruritus in the two groups.

The study population had a wide range of age distribution from minimum of 21 years to maximum 34 years. The mean age of the study population was 26.38 ±3.54 years with a mode of 24 years. The onset of sensory in Fentanyl group is 1.73 ± 0.49 min compared to 2 ±0.69 min in Tramadol group and the difference is statistically significant (p < 0.001).

The onset of motor in Fentanyl group is 1.73 ±0.45 min compared to 2.3 ±0.65 min in Tramadol group and the difference is statistically significant (p < 0.001). The time for maximum sensory level in Fentanyl group is 3.7 ±0.65 min compared to 4.3 ±0.7 min in Tramadol group and the difference is statistically significant (p = 0.001). The time for bromage in Fentanyl group is 3.13 ±0.51 min compared to 3.33 ±0.61 min in Tramadol group but the difference is not statistically significant (p = 0.171).

**CONCLUSION:**

Both the groups were effective in providing adequate surgical anaesthesia and hemodynamic stability, but fentanyl seems to be a better alternative to tramadol as an adjuvant to spinal bupivacaine in elective caesarean surgeries.

**Ethics Approval And Consent To Participate:**

Approval was taken from Katuri Medical College and Hospital's Ethics Committee and written informed patients consents were also taken.

**List Of Abbreviations:**

Abbreviation	Expansion
LSCS	Lower Segment Caesarean Section
SAB	Subarachnoid Block

ASA	American Society of Anaesthesiologists
MAP	Mean Arterial Pressure
min	Minutes

**Conflict Of Interest**

None

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Self

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