

# A Comparative Study of Intrathecal Tramadol versus Fentanyl as Adjuvant to Bupivacaine in Lower Abdominal and Lower Limb Surgeries

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## Abstract

**Aim:** The study is aimed to compare the effect of intrathecal fentanyl- bupivacaine versus tramadol – bupivacaine on the onset and duration of sensory and motor blockade, as well as postoperative analgesia in lower abdominal surgeries and lower limb surgeries.

**Methods:** After obtaining approval from Institutional Ethical Committee and informed written consent, 60 patients of ASA physical class I and II who were posted for elective lower abdominal and lower limb surgeries were taken for the study. Group BF: Received 12.5 mg (2.5 mL) of 0.5% hyperbaric Bupivacaine with 25 µg of Fentanyl citrate intrathecally. Group BT: Received 12.5 mg (2.5 mL) of 0.5% hyperbaric Bupivacaine with 25 mg of tramadol intrathecally.

**Results:** Motor blockade and sensory blockade onset, maximum level of sensory blockade attained and time taken for the same, and motor blockade maximum level attained were taken.

**Conclusion:** Adding fentanyl or tramadol to bupivacaine induced similar hemodynamic alterations, post-operative analgesia, and sensory blockage without delaying motor recovery. Both the drugs showed equal potency in the study.

**Key words:** Bupivacaine, Fentanyl, Tramadol

## INTRODUCTION

The common regional anesthetic procedures used for lower limb and lower abdominal surgeries are intrathecal and epidural anesthesia.

For lower abdominal procedures, spinal anesthesia is popular and widely utilized around the world. Spinal anesthesia has the advantage of requiring a small amount of anesthetic, being straightforward to administer, and providing a quick onset of effect, dependable operative analgesia, and adequate muscular relaxation. These benefits are sometimes outweighed by the fact that the

action lasts just a short period and causes discomfort when it wears off.

Because spinal anesthesia with only local anesthetics has a shorter duration of action, post-operative pain control is a serious issue. As a result, in the post-operative period, early analgesic management is essential. Nausea, visceral pain, and vomiting are common side effects of lower abdominal procedures performed under spinal anesthesia. A variety of adjuvants, including opioids (morphine, fentanyl, and tramadol) and non-opioids (dexmedetomidine, clonidine), as well as midazolam and steroids, have been explored to extend the effects of spinal anesthesia.

The lipophilic opioid fentanyl has a fast beginning of action. Fentanyl diffuses into the epidural region and then into the bloodstream after intrathecal administration, implying that it operates not just through spinal opioid receptors but also systemically. In comparison to intrathecal Bupivacaine alone, adding Fentanyl to hyperbaric Bupivacaine improves

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the quality of intraoperative and early post-operative subarachnoid block.

This study is designed to quantitatively examine the effects of adding fentanyl and tramadol to hyperbaric bupivacaine hydrochloride spinal anesthesia on duration and recovery of sensory and motor blockade.

### Aim of the Study

The study is aimed to compare the effect of intrathecal fentanyl- bupivacaine versus tramadol – bupivacaine on the onset and duration of sensory and motor blockade, as well as post-operative analgesia in lower abdominal surgeries and lower limb surgeries.

### Objectives of the Study

The objectives of the study are to compare

- Onset of sensory block
- Onset of motor block
- Sensory block duration
- Duration of motor block
- Intraoperative hemodynamic changes.

## METHODS

### Source of Data

After obtaining clinical approval from the Institutional Ethical Committee and informed written consent, 60 patients of ASA physical class I and II who were posted for elective lower abdominal and lower limb surgeries at GGH Vijayawada were selected for the study.

The present, prospective, randomized, double-blinded, and clinical study was conducted from December 2019 to June 2021.

- Group BF: Received 12.5 mg (2.5 mL) of 0.5% hyperbaric Bupivacaine with 25 µg of fentanyl citrate intrathecally
- Group BT: Received 12.5 mg (2.5 mL) of 0.5% hyperbaric Bupivacaine with 25 mg of tramadol intrathecally.

### Inclusion Criteria

The following criteria were included in the study:

- 60 patients of ASA physical grades I and II
- Patients of either sex aged 18–60 years taken for lower abdominal and lower limb surgeries.

### Exclusion Criteria

The following criteria were excluded from the study:

- Patient refusal
- Patient on adrenoreceptor agonists and antagonists
- Patient with cardiovascular comorbidities
- Patient allergic to study drugs

- Patient with ASA grade 3 and 4
- Patients with obesity.

### Methods of Collection of Data

Data were collected from 60 patients in the age group of 18–60 years of ASA class I and II, taken for lower abdominal and lower limb surgeries without any comorbid diseases were grouped randomly. The study drug was prepared by an anesthesiologist, who was not included in the study. All spinal blocks were given by the same anesthesiologist, who was also an observer. Hence, the patient and the observer were blinded for the study drug.

- Pre-operative assessment done for each patient on the night before the surgery
- And written informed consent was taken
- Patients were kept Nil per Oral for solids 6 h and clear fluids 2 h before surgery
- Patients are pre-medicated on the night before surgery with the tablet Alprazolam 0.5 mg
- Patients were not pre-medicated on the day of surgery
- Intravenous line was secured with 18G cannula
- Patients were connected to a multi-channel monitor for continuous monitoring of pulse rate (PR), arterial oxygen saturation (SpO<sub>2</sub>), electrocardiograph (ECG), non-invasive blood pressure, and mean arterial pressure (MAP)
- Patients were positioned in flexed lateral position
- Under aseptic precautions, subarachnoid blocks were performed at L2-L3/L3- L4 inter-space through a midline approach using 25G Quincke's spinal needle after confirming the clear and free flow of CSF and the study drug was injected into the subarachnoid space. Patients are turned to supine posture immediately with the table kept flat and supplemental O<sub>2</sub> was given.

The following parameters were recorded.

- Motor blockade and sensory blockade onset
- Maximum level of sensory blockade attained and time taken for the same
- Time taken for two segments sensory regression
- Motor blockade maximum level attained and time taken for the same
- Total duration of the sensory blockade and motor blockade
- Total duration of analgesia
- Using the pinprick method with a 27G hypodermic needle sensory blockade is tested at every 30 s for the first 2 min, every minute for the next 5 min and every 5 min for the next 15 min, and every 10 min for the next 30 min and every 15 min till the end of surgery and thereafter every 30 min until the sensory block is reduced
- The motor blockade was assessed according to the Modified Bromage scale

- All of the patients monitored during the period of a block and perioperative period employing a multi-channel monitor which displays PR, systolic and diastolic blood pressure (DBP), MAP, ECG, and SpO<sub>2</sub>
- Patients were followed for post-operative discomfort during the recovery period by VAS scale (0–10) initially every hour for 2 h, then every 2 h for the next 8 h, then every 4 h till 24 h, which was explained to the patients preoperatively. When the VAS was, >4 patients were given rescue analgesia with Inj. Diclofenac 75 mg intramuscularly.

## RESULTS

The study population consists of 60 patients (20–50 years) posted for lower abdominal and lower limb surgeries. They were divided into two groups 30 in each group.

- Group-Fentanyl-received 0.5% hyperbaric Bupivacaine 12.5 mg (2.5 mL) + 25 µg Fentanyl
- Group-Tramadol -received 0.5% hyperbaric Bupivacaine 12.5 mg (2.5 mL) + 25 mg Tramadol.

The following observations were made during the study.

### Distribution of Study Population According to Age [Table 1]

Both groups were similar with respect to age distribution and there was no statistically significant difference between 2 groups(P=0.68) [Table 1].

### Distribution of Study Population According to Anthropometric Parameters [Table 2]

There was no significant difference in the weight and height of the study subjects among two groups [Table 2].

### Comparison of Heart Rate among Both the Groups [Table 3]

Significant difference is not present in HR measured at various intervals throughout the surgery among the groups(P>0.05) [Table 3].

### Comparison of Systolic Blood Pressure (SBP) among Both the Groups [Table 4]

No statistically significant difference in SBP(mm of Hg) measured at different intervals throughout the surgery among the groups(P>0.05) [Table 4].

### Comparison of DBP among Both the Groups [Table 5]

Statistically there was no significant difference in DBP measured at different intervals throughout the surgery among the groups(P>0.05) [Table 5].

### Comparison of MAP among Both the Groups [Table 6]

Statistically there was no significant difference among the two groups in MAP (P>0.05) [Table 6].

**Table 1: Age distribution**

Age in mean	Mean±SD	P-value
Fentanyl	40.73±5.41	0.68
Tramadol	40.13±5.81	

Both groups were similar with respect to age distribution and there was no statistically significant difference between 2 groups (P=0.68)

**Table 2: Weight and height distribution in both the groups**

Parameter	Fentanyl Mean±SD	Tramadol Mean±SD	P-value
Weight (kg)	57.17±3.47	55.87±5.2	0.25
Height (cm)	158.27±4.63	160.83±5.42	0.26

There was no significant difference in the weight and height of the study subjects among two groups

**Table 3: Mean HR (Bpm) at various intervals in min**

Heart rate	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	82.23	4.03	81.07	6.02	0.38
0 min	79.20	4.30	78.43	5.31	0.54
5 min	73.90	6.84	76.47	5.92	0.12
10 min	74.10	6.64	74.17	6.79	0.96
15 min	74.43	6.91	72.77	10.49	0.47
30 min	74.80	6.89	73.10	11.42	0.48
45 min	75.13	6.54	71.83	8.15	0.08
60 min	75.47	6.98	72.73	7.83	0.15
75 min	75.37	6.45	72.43	7.91	0.12

Significant difference is not present in HR measured at various intervals throughout the surgery among the groups (P>0.05), HR: Heart rate

**Table 4: Mean SBP at different intervals in minutes**

SBP	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	126.03	5.35	125.33	5.67	0.62
0 min	122.23	4.85	121.67	4.75	0.60
5 min	116.07	4.24	115.27	5.34	0.52
10 min	118.70	6.26	116.00	7.40	0.611
15 min	118.30	4.35	117.0	17.70	0.69
30 min	118.17	4.04	116.47	4.71	0.13
45 min	118.20	3.30	116.87	3.91	0.15
60 min	118.40	4.44	117.73	4.11	0.54
75 min	117.90	4.35	118.93	3.83	0.33

No statistically significant difference in SBP (mm of Hg) measured at different intervals throughout the surgery among the groups (P>0.05), SBP: Systolic blood pressure

### Comparison of SPO<sub>2</sub> among Both the Groups [Table 7]

Statistically significant difference is not seen among the two groups (P>0.05) [Table 7].

### Comparison of Respiratory Rate among Both the Groups [Table 8]

Statistically there is no significant difference in both the groups (P>0.05) [Table 8].

**Table 5: Mean DBP (mm of Hg) at various intervals in minutes**

DBP	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	80.50	3.22	80.63	3.26	0.87
0 Min	78.33	4.05	78.47	4.01	0.89
5 min	73.13	3.14	74.20	4.42	0.28
10 min	72.40	4.08	70.77	5.63	0.29
15 min	72.40	4.59	71.50	5.29	0.48
30 min	73.13	5.00	71.27	3.61	0.10
45 min	72.97	5.01	71.33	4.72	0.19
60 min	74.33	5.55	73.13	4.23	0.35
75 min	75.33	5.55	74.13	4.23	0.35

Statistically there was no significant difference in DBP measured at different intervals throughout the surgery among the groups ( $P>0.05$ ), DBP: Diastolic blood pressure

**Table 6: MAP (mm of Hg) at various intervals in minutes**

MAP at various intervals in minutes	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	95.53	3.17	95.73	3.09	0.80
0 min	92.80	3.34	92.93	3.44	0.80
5 min	87.83	3.62	86.17	2.71	0.04
10 min	85.23	5.75	87.87	4.85	0.07
15 min	85.57	4.54	87.70	4.69	0.07
30 min	85.33	3.28	86.13	3.75	0.38
45 min	88.23	3.93	89.43	3.68	0.22
60 min	88.33	4.56	89.63	4.24	0.25
75 min	89.93	4.59	90.07	4.19	0.90

Statistically there was no significant difference among the two groups in MAP ( $P>0.05$ ), MAP: Mean arterial pressure

**Table 7: Oxygen saturation at various intervals in minutes**

SPO <sub>2</sub>	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	99.27	0.52	99.27	0.45	1.00
0 min	99.17	0.53	99.17	0.46	1.00
5 min	99.07	0.37	99.07	0.37	1.00
10 min	99.07	0.37	99.03	0.32	0.70
15 min	99.17	0.38	99.17	0.38	1.00
30 min	99.07	0.37	99.07	0.37	1.00
45 min	99.07	0.52	99.04	0.33	0.79
60 min	99.03	0.41	99.14	0.45	0.33
75 min	99.03	0.41	99.14	0.45	0.33

Statistically significant difference is not seen among the two groups ( $P>0.05$ )

**Comparison of Sedation Score among Both the Groups [Table 9]**

There is no significant difference statistically ( $P>0.05$ ) [Table 9].

**Comparison of Total Surgery Duration among Both the Groups [Table 10]**

The mean duration of surgery does not show statistically significant difference among the two groups ( $P>0.05$ ) [Table 10].

**Table 8: Comparison of respiratory rate in min**

Respiratory rate	Fentanyl		Tramadol		P-value
	Mean	SD	Mean	SD	
Basal	14.07	0.94	14.21	0.79	0.52
0 min	14.03	0.85	14.07	0.77	0.85
5 min	13.97	0.56	14.07	0.47	0.44
10 min	13.87	0.68	13.96	0.43	0.52
15 min	14.13	0.82	13.93	0.47	0.25
30 min	14.13	0.51	14.00	0.27	0.22
45 min	14.03	0.41	13.89	0.42	0.20
60 min	14.00	0.53	14.04	0.58	0.80
75 min	14.00	0.45	13.86	0.45	0.23

Statistically there is no significant difference in both the groups ( $P>0.05$ )

**Table 9: Mean sedation score**

Parameter	Group	Mean	SD	P-value
Sedation score	Fentanyl	1.97	0.41	0.28
	Tramadol	1.86	0.35	

There is no significant difference statistically ( $P>0.05$ )

**Table 10: Mean duration of surgery in minutes**

Parameter	Group	Mean	SD	P-value
Duration of surgery in min	Fentanyl	74.50	10.21	0.37
	Tramadol	72.14	10.09	

The mean duration of surgery does not show statistically significant difference among the two groups ( $P>0.05$ )

**Table 11: Mean time taken for sensory onset in minutes**

Sensory characteristics	Group	Mean	SD	P-value
sensory block onset time (min)	Fentanyl	1.23	0.39	0.15
	Tramadol	1.37	0.36	

**Table 12: Time taken for maximum sensory blockade in minutes**

Sensory characteristics	Group	Mean	SD	P-value
Max sensory level onset time (min)	Fentanyl	10.64	1.85	0.06
	Tramadol	11.46	1.47	

Statistically significant difference is not seen when both groups are compared ( $P>0.05$ )

**Comparison of Sensory Characteristics among Both the Groups**

The mean time of onset of sensory blockade at T 10 in Group-fentanyl was  $1.23\pm0.39$  mins and Group-tramadol was  $1.37\pm0.36$ mins. Statistically significant difference is not seen among both the groups ( $P > 0.05$ ) [Table 11].

**Comparison of Maximum Sensory Blockade [Table 12]**

Statistically significant difference is not seen when both groups are compared ( $P>0.05$ ) [Table 12].

**Mean Time for Regression of Sensory Block [Table 13]**

Statistically significant difference was not seen among the two groups ( $P>0.05$ ) [Table 13].

**Table 13: Mean time for regression of sensory block by two segments in minutes**

Sensory characteristics	Group	Mean	SD	P-value
2 segment sensory regression (min)	Fentanyl	105.73	8.33	0.16
	Tramadol	102.64	8.32	

Statistically significant difference was not seen among the two groups ( $P>0.05$ )

**Table 14: Mean duration of sensory regression to S1 in minutes**

Sensory characteristics	Group	Mean	SD	P-value
Sensory regression to S1 (min)	Fentanyl	227.80	18.08	0.44
	Tramadol	224.57	13.60	

Statistically significant difference was not seen in both the groups

**Table 15: Mean duration of analgesia at different intervals in minutes**

Sensory characteristics	Group	Mean	SD	P-value
Total duration of analgesia (min)	Fentanyl	193.87	10.19	0.06
	Tramadol	188.61	9.87	

In both groups significant difference is not present statistically

**Table 16: Mean time taken for motor block onset in minutes**

Motor characteristics	Group	Mean	SD	P-value
Motor block onset time (min)	Fentanyl	1.07	0.25	0.59
	Tramadol	1.11	0.31	

Significant difference is not seen statistically in either groups

**Table 17: Mean time taken for maximum motor blockade in minutes**

Motor characteristics	Group	Mean	SD	P-value
Time taken for max motor blockade (min)	Fentanyl	10.33	0.76	0.34
	Tramadol	10.14	0.76	

Significant difference is not seen statistically in either groups

**Table 18: Mean duration of motor blockade in minutes**

Motor characteristics	Group	Mean	SD	P-value
Total duration of motor block (min)	Fentanyl	207.00	11.00	0.77
	Tramadol	206.29	8.39	

Significant difference is not seen statistically in both groups

**Mean Duration of Sensory Regression to S1 in Minutes [Table 14]**

Statistically significant difference was not seen in both the groups [Table 14].

**Mean Duration of Analgesia at Different Intervals in Minutes [Table 15]**

In both groups significant difference is not present statistically [Table 15].

**Table 19: Maximum level of sensory block attained**

Max sensory level attained	Group (No. of patients)		Total	P-value
	Fentanyl	Tramadol		
Level T4	26	25	51	0.317
	86.0%	83.0%		
Level T6	4	5	9	15.0%
	14.0%	17.0%		
Total	30	30	60	100.0%
	100.0%	100.0%		

No significant difference is seen among both groups

**Table 20: Comparison of bradycardia**

Bradycardia	Group		Total	P-value
	Fentanyl	Tramadol		
No	26	27	53	0.565
	89.0%	90.0%		
Yes	4	3	7	14.0%
	11.0%	10.0%		
Total	30	30	60	100.0%
	100.0%	100.0%		

No significant difference in bradycardia is seen among both groups

**Table 21: Comparison of hypotension**

Hypotension	Group		Total	P-value
	Fentanyl	Tramadol		
No	19	23	42	0.22
	63.0%	76.0%		
Yes	11	7	18	30.0%
	37.0%	24.0%		
Total	30	30	60	100.0%
	100.0%	100.0%		

No significant difference in incidence of hypotension is seen among both groups

**Table 22: Comparison of vomiting**

Vomiting	Group		Total	P-value
	Fentanyl	Tramadol		
No	30	28	58	0.117
	100.0%	86.7%		
Yes	0	2	2	3.3%
	0.0%	6.7%		
Total	30	30	60	100.0%
	100.0%	100.0%		

No significant difference in incidence of vomiting is seen among both groups

**Comparison of Motor Characteristics among Both the Groups [Table 16]**

Significant difference is not seen statistically in either groups [Table 16].

**Mean Time Taken for Maximum Motor Blockade in Minutes [Table 17]**

Significant difference is not seen statistically in either groups [Table 17].

**Mean Duration of Motor Blockade in Minutes [Table 18]**

Significant difference is not seen statistically in both groups [Table 18].



### Comparison of Maximum Sensory Level among Both the Groups [Table 19]

No significant difference is seen among both groups [Table 19].

### Comparison of Adverse Effects among Both the Groups [Tables 20-22]

In this study, there was no statistically significant difference in the adverse effects throughout the procedure. Patients who developed hypotension are managed by inj. Mephenteramine 6 mg I.V in incremental doses. In patients who developed bradycardia were managed by inj. Atropine 0.6 mg I.V. Patients who developed vomiting were managed by inj Ondansetron 4 mg I.V.

## DISCUSSION

Effective pain management is critical for providing the best possible care to patients in the post-operative period. Despite breakthroughs in our understanding of pain biology, analgesic pharmacology, and the creation of more efficient treatments, patients continue to feel significant pain following surgery. If a method of analgesia is to be successful and widely available, it must be appropriate for use in a general surgical ward and require just simple routine nurse monitoring.

The medications lidocaine and bupivacaine are routinely used for spinal subarchnoid block. One downside of spinal anaesthesia using local anesthetics is only that analgesia disappears when the block is retracted, meaning a requirement for analgesics soon after surgery. In addition to producing discomfort, post-operative pain has other harmful consequences, particularly on the cardiorespiratory system.

Intrathecal opioids have been increasingly popular in recent years, but at the consequence of an increased risk of respiratory depression. Tramadol, on the other hand, is a centrally acting analgesic with little respiratory depressive effects due to its 6000-fold lower receptor affinity than morphine.

Although epidural tramadol has been found to provide adequate post-operative analgesia in patients undergoing major abdominal surgery or caesarian sections, its efficacy following intrathecal injection has not been adequately explored. As a result, we thought comparing the effects of intrathecally administered tramadol to those of fentanyl, a regularly used intrathecally administered opioid, might be informative.

Following intrathecal injections, fentanyl has a quick start and a short duration of action. It extends the time that bupivacaine causes sensory blockage. As described in an animal study by Wang *et al.*,<sup>[1]</sup> this shows a potential synergism between fentanyl and bupivacaine. Fentanyl is

one among the safest opioids, Because most orthopedic procedures may be performed under spinal anesthetic, orthopedic patients were chosen.

Changes in cardiovascular and respiratory parameters during surgery:

Both groups saw a significant decline in blood pressure during the first 30 min of the experiment, but there was no significant difference in the pattern of decrease in systolic or DBP during this time. According to other studies, neuraxial opioids reduce sympathetic outflow and adding fentanyl to spinal analgesia increases the risk of hypotension after epidural blocking. Wang *et al.*<sup>[2]</sup> discovered that bupivacaine, not the intrathecal opioid employed, is responsible for the decrease in sympathetic efferent activity after spinal anesthesia. The action of 3 mL of bupivacaine, rather than the modest intrathecal opioid dosage, is most likely responsible for the significant reduction in blood pressure reported in this trial.

In 2003, Alhashemi and Kaki<sup>[3]</sup> discovered that intrathecal tramadol had no impact on the intraoperative hemodynamic profile.

In our investigation, no one in the study group had respiratory depression. The mean PaO<sub>2</sub> values in the epidurally injected tramadol group did not alter, according to Baraka *et al.*<sup>[4]</sup> in 1993. Yaddanapudi *et al.*<sup>[5]</sup> observed similar results with epidurally given tramadol in 2000.

The fentanyl group experienced 562.0 min of analgesia, while Group B experienced 551 min. When compared to utilizing a local anesthetic alone, this is a significantly longer period of analgesia. The mean duration of analgesia or the total dose of analgesics required in 24 h did not differ substantially between the two groups. In 2000, Jain and Sarasawat<sup>[6]</sup> discovered that intrathecal tramadol 25 mg combined with bupivacaine offered an average of 8 h of post-operative pain relief, which is similar to our finding. Tramadol given epidurally gave good post-operative pain management, according to Prosser *et al.*<sup>[7]</sup> in 1997, and Delilkan and Vijayan<sup>[8]</sup> in 1993.

The time taken for two-segment regression in sensory level did not show significant difference between two groups, according to our findings. In two groups, the two-segment regression of sensory level took an average time of 90 min. Other investigations found that when a local anesthetic was given alone, it took less time for two segment regression and Singh *et al.*<sup>[9]</sup> in 1995, Goel *et al.*<sup>[10]</sup> reported that intrathecal fentanyl amplifies and prolongs sensory anesthesia in their research.

In terms of intrathecal opioid side effects, patients in both groups experienced minor adverse effects. Only two patients in both groups experienced minor side effects. Pruritis was found in only two patients in both groups. The occurrence of mild pruritis and nausea in our study could be explained by the prophylactic use of ondansetron in both groups.

## CONCLUSION

- Adding both opioids to the mix resulted in little intraoperative and post-operative complications
- Adding fentanyl or tramadol to bupivacaine induced similar hemodynamic alterations, post-operative analgesia, and sensory blockage without delaying motor recovery
- Both the drugs show equal potency in the study.

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