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# A STUDY TO COMPARE THE EFFECT OF FENTANYL AND TRAMADOL AS ADJUVANT TO BUPIVACAINE HYDROCHLORIDE IN EPIDURAL ANAESTHESIA.

Anaesthesiology

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| **Dr. Vinita Kaushik*** | Department of Anaesthesia, Sri Aurobindo Medical College & PG Institute-Indore (M.P.). *Corresponding Author |
| **Dr. P. S. Gandhi** | Department of Anaesthesia, Sri Aurobindo Medical College & PG Institute-Indore (M.P.) |
| **Dr. Dipti Saxena** | Department of Anaesthesia, Sri Aurobindo Medical College & PG Institute-Indore (M.P.) |
| **Dr. Aditi Dugaya** | Department of Anaesthesia, Sri Aurobindo Medical College & PG Institute-Indore (M.P.) |
| **Dr. Chetan Bamoriya** | Department of Anaesthesia, Sri Aurobindo Medical College & PG Institute-Indore (M.P.) |

## ABSTRACT

**Background-** Regional anaesthesia techniques are gaining popularity for surgeries on the upper and lower limbs because they provide the best anaesthetic care, including postoperative analgesia and higher patient satisfaction. Epidural analgesia provides better analgesia when compared to other postoperative analgesic techniques, such as general anesthesia. Physiological benefits of perioperative epidural analgesia may also help to lower perioperative risks and improve postoperative outcomes. Aims and Objective: To compare the efficacy of epidural FENTANYL and TRAMADOL for post-operative analgesia in lower limb surgeries in terms of onset of analgesia, duration of analgesia, quality of analgesia and undesirable effect. **Material Method:** This analytical Cross Sectional Study, which included 100 patients of either sex between the ages of 18 and 75, undergoing lower limb surgeries under Combined Spinal Epidural anesthesia (CSE), was done to compare the analgesic efficacy and side effects of epidural fentanyl and that of epidural tramadol. These were divided into two groups, each with 50 patients. Group T stands for tramadol and Group F stands for fentanyl. Patients in Groups T received 50 mg of Tramadol and 5 ml of 0.125% Bupivacaine, respectively, while patients in Group F received 20 mcg of Fentanyl and 5 ml of 0.125% Bupivacaine . When a patient complained of pain following surgery with a Visual Analog Score of 3 or higher, either an epidural fentanyl or an epidural tramadol was given at random to the patient. In the immediate aftermath of surgery, patients were closely watched until they experienced pain relief. Using a visual analogue scale, the effectiveness of pain relief was evaluated, and side effects like nausea, vomiting, pruritis, and respiratory depression were noted. The patients underwent a thorough physical examination and clinical history, and all vital statistics were meticulously recorded. The patient provided written, fully informed consent for the study. **Result:** The difference between the mean times for analgesia to start after epidural injection in Group F and Group T was found to be statistically significant (5.42 1.18 vs. 12.80 1.62 minutes). The mean duration of analgesia, which was also statistically significant, was 240.22 36.53 in the Fentanyl group and 360.52 24.83 in the Tramadol group. In comparison to tramadol, pruritis was significantly more common in the Fentanyl group. Following epidural Fentanyl administration, the analgesic quality improved. **Conclusion:** Both epidural Fentanyl and Tramadol are effective at relieving post-operative pain; however, Fentanyl was more patient-pleasing than Tramadol, but had a shorter duration of action.

## KEYWORDS

Epidural, analgesia, tramadol, fentanyl

## INTRODUCTION

For surgeries on the upper and lower limbs, regional anaesthesia techniques are becoming more popular because they offer the best anaesthetic care, which includes postoperative analgesia and increased patient satisfaction (1). Compared to other postoperative analgesic methods like general anaesthesia, epidural analgesia offers better analgesia. Additionally, perioperative epidural analgesia has physiological advantages that may help to lessen perioperative risks and enhance postoperative results.

Since bupivacaine, an amide local anaesthetic, has fewer hemodynamic changes and speeds up patients' recovery and mobilisation, it is safe for use with regional anaesthetic techniques. Due to its low lipid solubility, it blocks sensory nerve fibres more quickly than motor fibres, resulting in greater sensory- motor differentiation (2–3). The need for a cumulative dose of local anaesthetics is reduced when adjuvants like fentanyl and ketamine are used to extend the time that the sensory-motor block lasts. Adjuvant co-administration has the potential to enhance perineural block efficacy and lessen local anaesthetic toxicity. To achieve a strong anaesthetic effect, various opioids, including fentanyl, have been used as an adjuvant for epidural administration in combination with local anaesthetics (4). Fentanyl is a synthetic opioid agonist derived from phenylpiperidine that shares structural similarities with meperidine. Fentanyl is 75 to 125 times more potent than morphine as an analgesic. Tramadol is a racemic mixture of two enantiomers that is a synthetic opioid analogue of codeine with synergistic anti- nociceptive interaction. With some degree of receptor selectivity, it acts as an agonist at all different types of opioid receptors, mediating its analgesic activity (5). There is very little respiratory depression caused by tramadol.

Epidural local anaesthetic and opioids have synergistic effects that are well known, but there is little evidence in the literature to support the use of local anaesthetic and dexmedetomidine together. Such a study that compared the dose equivalence of these medications does not exist. This randomised study was designed to assess the clinical effects of fentanyl and tramadol when used as an adjuvant to epidural bupivacaine for lower limb orthopaedic surgeries in light of the advantages of bupivacaine and various adjuvants.

## MATERIALS AND METHODS

The present study is analytical Cross Sectional Study after obtaining approval from the Institutional Ethics Committee of SRI AUROBINDO MEDICAL COLLEGE & P.G. INSTITUTE, INDORE and with the informed consent of the patient study was conducted between the period of 1st APRIL 2021- 30th SEPTEMBER 2022. Patients more than 18 years age and less than 75 years age undergoing Total Hip Replacement, Total Knee Replacement, Sub Trochanteric fracture of femur, Acetabular fracture ofhip, Polytrauma. And with ASA status I–II. Were included. Patient with Bleeding disorders,Infection- site of insertion / systemic, Raised intracranial pressure , Spinal deformity , Surgery of head or neck, on Anti-coagulant therapy or having Allergic to proposed drug were excluded from study. A total 100 patient data was taken in account for analysis , patient were divided in two groups

- Group A: 5 ml of 0.125% Bupivacaine hydrochloride and 20 micrograms fentanyl in epidural postoperatively after effect of subarachnoid block terminated.
- Group B: 5 ml of 0.125% Bupivacaine hydrochloride and 50 milligrams tramadol in epidural postoperatively after effect of subarachnoid block terminated.

After informed written consent was taken, patients were kept fasting for six hours and received a tablet of alprazolam 0.5 mg at night before the surgery. Upon arrival in the operation room, ASA standard monitors, including non-invasive blood pressure and pulse oximeter were attached and baseline parameters were recorded. The heart rate

and rhythm were monitored from a continuous visual display of an electrocardiogram. An intravenous line was secured and all the patients were preloaded with lactated ringer solution. Under all aseptic precautions, the L4 L5 interspace was identified in the sitting position and 1.5 ml of 2% lignocaine was injected over the skin to raise a weal. A 18 G needle was inserted and guided slowly until the epidural space was reached, which was confirmed with the loss of resistance technique using 2 ml of normal saline. After confirmation of the epidural space, an epidural catheter was inserted in the cephalad direction and secured at the 9 cm mark. A test dose of 3 ml lignocaine 2% with adrenaline (5 microgram/ml) was administered to rule out the intrathecal and intravenous placement of the catheter. Patients were monitored for any adverse effects. After three minutes, the patients received the study solution of either group according to the randomization schedule by epidural catheter. Patients were monitored throughout the surgery, at the time of application of block, and thereafter up to 24 hours after the surgery. Subarachnoid Block was administered during intra-operative time.

The following parameters, viz heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure along with oxygen saturation were also recorded at the baseline (0 minutes), fifth minute, 15th minute, 30th minute, 60th minute, and 120th minute. In the postoperative period, vitals were recorded at 15 minutes, 30 minutes, the second hour, third hour, sixth hour, 12th hour, and 24th hour. The sensory block was assessed by the pinprick test using a blunt-end 26-gauge needle at each minute. Data regarding time to achieve the sensory block at the T10 level, two-segment regression, total duration of sensory block, time taken to achieve complete motor block, regression to Bromage 3, total duration of motor block, total duration of analgesia, and total consumption of rescueanalgesic were recorded in 24 hours. Patient pain was evaluated by the visual analog scale (VAS), a scale of 0 to 10, where 0 is no pain and 10 is very severe pain. If the patient experienced the intensity of pain as VAS >3, the intramuscular injection diclofenac (1.5 mg/kg) was administered up to a maximum of 150 mg administered in 24 hours.

All data were recorded, summarized, tabulated, and statistically analyzed using online available free statistical calculator. The statistical analysis of quantitative data (Mean ± SD) between the groups was done by the student's t-test. The statistical analysis of qualitative data (N%) between the groups is done by using the one-way analysis of variance (ANOVA) unpaired t-test. A p-value <0.05 was considered statistically significant.

**RESULTS:-**

| | **Group F** | **Group T** | **p value** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | |
| Onset of analgesia min | 5.42 ± 1.18 | 12.80 ± 1.62 | <0.001 |
| Analgesia duration min | 240.22 ± 36.53 | 360.52 ± 24.83 | <0.001 |

It was noted that the mean time for the onset of analgesia in Group T was 12.80 1.62 min, compared to 5.42 1.18 min in Group F. Furthermore, onset of analgesia showed a significant mean difference, with fentanyl showing a faster onset than tramadol with a p value of 0.001.

It was noted that the mean analgesic duration in Group F was 240.22 36.53 min, whereas the mean analgesic duration in Group T was 360.52 24.83 min. Additionally, it was noted that there was a significant difference in the mean analgesic duration between Group F and Group T (p value 0.001).

| | **Group F** | | | **Group T** | | | **p value** |
|---|---|---|---|---|---|---|---|
| | **Mean ± SD** | **Min - Max** | **Median (IQR)** | **Mean ± SD** | **Min - Max** | **Media** | |
| 15 min vas | 1.09 ± 0.32 | 0 - 2 | 1 (0 - 2) | 2.22 ± 0.25 | 1 - 3 | 2 (1 - 3) | <0.001 |
| 30 min vas | 0.00 ± 0.00 | 0 - 0 | 0 (0 - 0) | 1.60 ± 0.12 | 0 - 2 | 1 (0 - 2) | <0.001 |
| 45 min vas | 0.00 ± 0.00 | 0 - 0 | 0 (0 - 0) | 1.30 ± 0.20 | 0 - 2 | 1 (0 - 2) | <0.001 |
| 60 min vas | 0.00 ± 0.00 | 0 - 0 | 0(0 - 0) | 1.00 ± 0.30 | 0 - 2 | 1 (0 - 2) | <0.001 |
| 120 min vas | 0.00 ± 0.00 | 0 - 0 | 0 (0 - 0) | 0.00 ± 0.00 | 0 - 0 | 0 (0 - 0) | >0.005 |
| 240 min vas | 3.00 ± 0.00 | 3 - 3 | 3 (3 - 3) | 1.50 ± 0.30 | 1 - 2 | 1 (1 - 2) | <0.001 |
| 360 min | - | - | - | 3.00 ± 0.00 | 3-3 | 3(3 - 3) | |

The comparison of VAS between the two groups at different time points is shown in the table and graph above. At 15 minutes, 30 minutes, 45 minutes, 60 minutes, and 240 minutes, there was evidently a significant mean VAS difference (p value 0.001), respectively. While there was no discernible mean difference between Group F and Group T at 120 minutes (p value >0.05), there was.15 minutes after the study drug was administered via epidural, the VAS pain score was 1.090.32 in group F and 2.22 0.25 in group T, which was statistically very significant. VAS pain score at 30 min, 45 min, and 60 min was 0.00 in the fentanyl group and 1.60 min, 0.12 min, 1.30 min, and 0.30 min with a p value of 0.001 in the tramadol group. In Group F and Group T, the VAS at 120 minutes was 0.00 0.00 with a p value >0.05. At the 240 minute mark in group F, It was statistically extremely significant that group T was 1.50 0.30 (p 0.001) and 3.00 0.00 (p 0.001) in both cases.

| **Side effects** | **Group F (n=50)** | **Group T (n=50)** | **P value** |
|---|---|---|---|
| Nausea and vomiting | 3 (6.8%) | 16 (33.33%) | <0.001 |
| pruritis | 7 (13.33%) | 0(0%) | <0.001 |
| Respiratory depression | 0 (0%) | 0 (0%) | |

Incidence of nausea and vomiting (33.33%) was significantly higher in tramadol (p value<0.001). Incidence of pruritis (13.33%) was more in fentanyl group (<0.001). none of the patient in both group had episode of respiratory depression.

## DISCUSSION

A complex physiological response to disease, visceral distension, or tissue damage is acute postoperative pain. Postoperative pain management aims to reduce the nociceptive impulse brought on by surgery and to ease autonomic and somatic pain reflexes in addition to providing subjective comfort, and the discovery of opioid receptors has opened up new horizons in postoperative pain management [6].Because the change in physiology and biochemistry, and consequently the morbidity and mortality, it causes are minor in comparison to general anesthesia, the central neuraxial blockade is a useful tool in the anaesthesiologist's toolbox [7].With effective post-operative pain management, the incidence of cardiac and pulmonary morbidity and mortality may be significantly reduced overall [8].

The purpose of the current study was to compare the effectiveness and side effects of 5ml of 0.125% bupivacaine + 20 mcg of Fentanyl and 5ml of 0.125% bupivacaine + 50 mg Tramadol administered via epidural injection for the treatment of postoperative pain following lower limb orthopaedic surgeries.onset of pain reliefthe average time it took for analgesia to start in the current study was shorter with epidural fentanyl (5.42+1.18 min) than epidural tramadol (12.801.62 min) (p value 0.001). In 1981, Rutter DV et al. reported that after giving 100 mcg of fentanyl via an epidural injection, the mean pain score decreased by 50% within 5 minutes, indicating that it had a quick onset of action. In 1985, Naulty JS et al. observed that 100 mcg of fentanyl produced a pain score of 0 in the parturient within 3-6 minutes while administering various doses of epidural fentanyl after caesarean delivery. In 2016, Ujjwala BK et al. found that the mean time for analgesia to start in the fentanyl group was 5.790.65 minutes, while it took 13.082.6 minutes in the tramadol group. According to Naik GL, et al., tramadol group 7.76 0.65 minutes after fentanyl group 3.79 0.36 minutes saw the earliest onset of analgesia.The current study's findings were consistent with those of earlier studies, leading to the conclusion that fentanyl caused analgesia to start more quickly than tramadol. This quick onset is due to the fentanyl group's high affinity for opioid receptors compared to tramadol and its high lipid solubility.length of the analgesicWhen compared to epidural fentanyl, which had a mean duration of analgesia of 240.22 36.53 min in the current study, epidural tramadol had a longer mean duration of analgesia (360.52 24.83 min; p 0.001).

In contrast to the fentanyl group's 3.06 0.38 hours, the mean duration of analgesia in the tramadol group was 4.92 0.74 hours in 2016, according to Jitendra R, et al. In contrast to epidural fentanyl, which had a mean duration of analgesia of 5.50.97 hours, epidural tramadol had a mean duration of 8.06 12.5 hours. In 1991, Fu Y.P. et al. used 75 mg of tramadol for post-operative analgesia and found that the average length of analgesia was 12 5 hours.In comparison to the current study, similar studies using epidural tramadol and fentanyl showed some variation in the length of analgesia. In several studies, the analgesic

effect of epidural fentanyl lasted between two and six hours; in our study, it lasted about four hours. Tramadol's analgesic effects have been shown to last between 5 and 12 hours when administered by epidural route; in our study, they lasted for 6 hours. In every study, tramadol lasted longer in terms of analgesia than fentanyl.Depending on the VAS score, the analgesic qualityIn our study, VAS scores from both study groups were recorded at intervals of 15 minutes, 30 minutes, 45 minutes, 60 minutes, 120 minutes, 240 minutes, and 360 minutes.Both study groups experienced a decrease in vas score, but the fentanyl group's mean vas score at 15, 30, 45, and 60 minutes after the administration of the epidural study drug was significantly lower (p value 0.001) and statistically highly significant. At two hours, the vas scores for both groups were 0.00 (p value >0.05), which is statistically insignificant.This information demonstrates that, for the duration of analgesia, the fentanyl group's analgesia quality was noticeably superior to that of the tramadol group.In 2016, Ujjwala B.K., et al. noticed that the VAS score was significantly lower in the fentanyl group than the tramadol group and came to the conclusion that the fentanyl group's analgesia was of higher quality.When 50 mg of epidural tramadol was compared to 50 mcg of epidural fentanyl in 2018, Sudhir P, et al. found that the vas score was significantly lower for 12 hours with fentanyl.Tejash H.S., et al. found that the tramadol group's pain management was significantly worse than the fentanyl group's in 2021.Comparing group T of our study to group F, group T had 16 patients (33.33%) with nausea and vomiting, while group F had 7 patients (13.33%) with nausea and vomiting,

7 patients (13.7%) with episodes of puritis, and no patients (none) with episodes of respiratory depression.4% of the patients in a study using 50 mcg of fentanyl conducted by Lytle SA et al. in 1991 reported having pruritis.In 2014, Kaur J. et al. found that patients receiving epidural fentanyl had a higher incidence of pruritis, which affected 25% of the study group.According to Raghunath J et al., patients receiving fentanyl experienced 13.33% more pruritus than those receiving tramadol, while the incidence of nausea and vomiting was 43% higher with the latter drug.According to L. Giridhar et al., 4 out of 20 fentanyl patients and 6 out of 20 tramadol patients experienced nausea and vomiting.More P et al2016 .'s study found that 13.3% of patients in the tramadol group experienced nausea and vomiting.Our research yielded similar findings to the earlier studies. While the incidence of pruritus was significantly higher with fentanyl than tramadol, nausea and vomiting were more common with tramadol.

## CONCLUSIONS

According to the results of the current study, epidural fentanyl provides analgesia more quickly and more effectively but for a shorter period of time than epidural tramadol, and epidural fentanyl providesanalgesia that lasts longer than epidural tramadol. Unwanted side effects like nausea and vomiting were observed in both groups, but they occurred more frequently following the administration of epidural tramadol than they did with fentanyl. In neither group were there any significant negative effects. We draw the conclusion from the current study that epidural fentanyl 50mcg offers better analgesia of rapid onset but shorter duration.

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