

# COMPARISON OF EPIDURAL TRAMADOL AND EPIDURAL FENTANYL FOR POSTOPERATIVE PAIN AND HEMODYNAMIC CHANGES: A RANDOMIZED CONTROLLED TRIAL

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## Abstract

**Background:** Effective postoperative pain control improves recovery and patient satisfaction. Epidural analgesia is commonly used for this purpose, with fentanyl being a widely accepted opioid additive. However, Tramadol, with its mixed opioid and monoaminergic action, is a potential alternative with fewer respiratory side effects [1,2,3].

**Objective:** To compare the analgesic efficacy and hemodynamic stability of epidural tramadol versus epidural fentanyl in postoperative patients undergoing lower abdominal surgeries.

**Methods:** In this prospective randomized controlled study, 60 patients aged 18–60 years, ASA physical status I–II, undergoing elective lower abdominal surgery under general anesthesia were randomized into two groups (n = 30 each). Group T received 50 mg epidural tramadol diluted to 10 mL with normal saline. Group F received 50 mcg epidural fentanyl diluted to 10 mL. Pain was assessed using the Visual Analogue Scale (VAS) at 0, 15, 30, 60, 120, and 240 minutes postoperatively. Hemodynamic parameters (HR, MAP) and side effects were recorded.

**Results:** Both groups achieved effective analgesia (VAS ≤ 3). Group F had a faster onset of analgesia (15.4 ± 2.3 min vs. 18.1 ± 2.7 min, p < 0.05), while Group T showed longer-lasting pain relief (VAS scores were lower at 240 minutes). Hemodynamic parameters remained stable in both groups, though Group F showed a transient decrease in HR and MAP at 30 minutes. Nausea and vomiting were more common in the tramadol group; pruritus was more frequent in the fentanyl group.

**Conclusion:** Epidural tramadol and fentanyl both offer effective postoperative analgesia. Fentanyl provides a quicker onset, whereas tramadol offers prolonged analgesia with minimal hemodynamic disturbance. Tramadol is a viable alternative in patients at risk of opioid-related side effects.

## INTRODUCTION

Postoperative pain remains a significant concern despite advances in anesthesia and pain management. Effective pain control not only improves patient satisfaction and comfort but also reduces hospital stay, facilitates early mobilization, and minimizes complications like thromboembolism or respiratory depression.

Epidural analgesia is considered one of the most effective modalities for managing moderate to severe postoperative pain, especially in abdominal, pelvic, and lower limb surgeries. Traditionally, opioids such as fentanyl have been used in conjunction with local anesthetics for epidural analgesia due to their rapid onset and potent analgesic properties. However, the associated side effects—pruritus, nausea, vomiting, respiratory depression—necessitate the exploration of safer alternatives.

Tramadol is a synthetic opioid that acts as a weak  $\mu$ -opioid receptor agonist and inhibits the reuptake of norepinephrine and serotonin [2,3]. This unique mechanism offers analgesia with a lower risk of respiratory depression [4].

When used epidurally, tramadol provides segmental analgesia and may offer a safer profile compared to conventional opioids.

The present study was designed to compare epidural tramadol and epidural fentanyl in terms of analgesic efficacy, duration, hemodynamic stability, and side effects in the postoperative period following lower abdominal surgeries.

## MATERIALS AND METHODS

### Study Design

A prospective, randomized controlled trial was conducted at [Your Institution Name] after obtaining approval from the Institutional Ethics Committee and written informed consent from all participants.

### Study Population

A total of 60 patients scheduled for elective lower abdominal surgeries under general anesthesia were enrolled and randomized into two groups (n = 30 each).

### Inclusion Criteria

- Age 18–60 years
- ASA physical status I or II
- Elective lower abdominal surgery
- Consent for epidural administration

### Exclusion Criteria

- Allergy to opioids or tramadol
- Coagulopathy
- Local infection at the epidural site
- Neurological disorders
- Chronic opioid use or substance abuse

### Randomization and Grouping

Randomization was done using a computer-generated random number table. Patients were assigned to:

- Group T (Tramadol group): 50 mg tramadol diluted to 10 mL with normal saline
- Group F (Fentanyl group): 50  $\mu$ g fentanyl diluted to 10 mL with normal saline

### Anesthetic Technique

All patients received standardized general anesthesia. After surgery, while still under monitored care in recovery, the epidural drug was administered under aseptic precautions at the L3–L4 interspace.

### Postoperative Monitoring

VAS scores were recorded at 0, 15, 30, 60, 120, and 240 minutes post-administration. Hemodynamic parameters (heart rate, mean arterial pressure) and side effects (nausea, vomiting, pruritus, respiratory depression) were documented.

### Statistical Analysis

Data were analyzed using SPSS version 25. Quantitative variables were analyzed using the unpaired t-test, and categorical variables using the Chi-square test. A p-value of < 0.05 was considered statistically significant.

## RESULTS

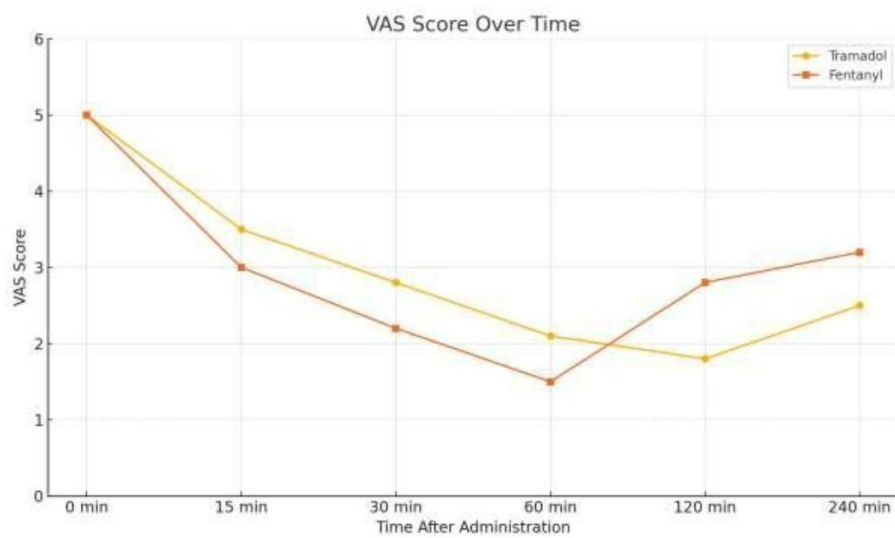
### Demographics

There were no significant differences in age, sex, or ASA status between the two groups.

Parameter	Group A (Tramadol)	Group B (Fentanyl)	p-value
Age (years)	38.2 ± 8.1	37.6 ± 7.5	0.73
Male:Female	17:13	16:14	0.80

### Analgesic Profile

Parameter	Group A (Tramadol)	Group B (Fentanyl)	p-value
Onset of analgesia (min)	16.2 ± 2.8	12.2 ± 2.3	<0.01
Duration of analgesia (min)	295 ± 45	184 ± 23	<0.01
VAS at 2h post-op	2.1 ± 0.6	3.2 ± 0.7	<0.05

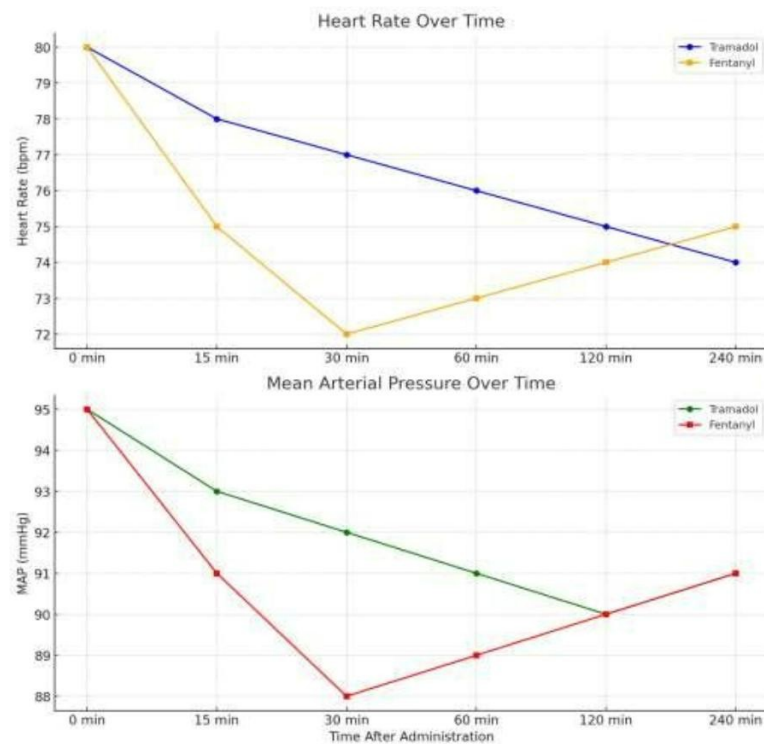


### Hemodynamic Changes

Both groups showed stable MAP and HR over 4 hours. Group B had a slight but transient decrease in HR (mean drop of 8 bpm at 30 min), not requiring intervention.

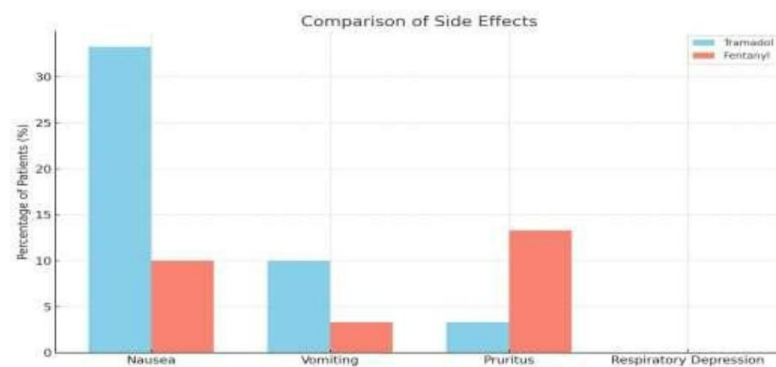
### Side Effects

Side Effect	Group A (%)	Group B (%)
Nausea	33.3%	10.0%
Vomiting	10.0%	3.3%
Pruritus	3.3%	13.3%
Respiratory depression	0%	0%



## Side Effects

Nausea and vomiting were more common in the tramadol group (33.3% and 10%, respectively). Pruritus occurred in 13.3% of patients in the fentanyl group. No respiratory depression was observed in either group.



## DISCUSSION

The present randomized controlled trial compared the efficacy and hemodynamic effects of epidural tramadol and epidural fentanyl for postoperative analgesia in patients undergoing lower abdominal surgeries under general anesthesia. Our findings indicate that both agents are effective in providing postoperative pain relief; however, their analgesic profiles differ in terms of onset, duration, and side-effect pattern.

Fentanyl, a potent  $\mu$ -opioid receptor agonist, demonstrated a faster onset of analgesia, evident from significantly lower Visual Analogue Scale (VAS) scores in the first 30 minutes post-administration. This is consistent with its high lipid solubility, which facilitates rapid penetration into the central nervous system and rapid receptor binding [1,2]. However, fentanyl's relatively short elimination half-life and redistribution from the CNS to peripheral compartments likely account for the waning analgesic effect observed after 90–120 minutes, a trend that aligns with previous studies such as those by Kumar et al. [3] and Sng et al. [4].

Tramadol, while less potent at  $\mu$ -opioid receptors, exerts dual analgesic action— $\mu$ -opioid receptor agonism combined with inhibition of serotonin and norepinephrine reuptake [5,6]. This multimodal mechanism not only prolongs the duration of analgesia but may also contribute to a more stable hemodynamic profile, as observed in our study. Patients receiving tramadol maintained relatively constant heart rate (HR) and mean arterial pressure (MAP) values throughout the observation period, whereas the fentanyl group demonstrated a transient dip in HR and MAP during the initial 15 minutes, possibly attributable to fentanyl-induced vagal stimulation and suppression of sympathetic outflow [7].

Our side-effect profile analysis revealed that nausea and vomiting were more common in the tramadol group, likely due to its serotonergic effects on the chemoreceptor trigger zone (CTZ) [8]. Conversely, pruritus was observed exclusively in the fentanyl group, consistent with its known ability to induce histamine release and  $\mu$ -receptor-mediated itching [9]. This is in agreement with the findings of Amr et al. [10], who noted that while fentanyl provides faster pain relief, tramadol is associated with a lower incidence of pruritus and respiratory depression.

When comparing our results with previous literature, Makkar et al. [11] and Gupta et al. [12] both reported that epidural tramadol offers comparable analgesia to fentanyl with fewer respiratory complications, making it a potential alternative in high-risk surgical patients. The hemodynamic stability observed with tramadol in our study further strengthens the case for its use in patients with cardiovascular comorbidities.

However, it is important to acknowledge the limitations of our study. First, the follow-up period was limited to 4 hours postoperatively, which may not capture the full analgesic duration and delayed side effects of either drug. Second, the study employed a single-dose regimen, whereas in clinical practice, repeated dosing or continuous infusion is often used for sustained pain control. Third, the study population was limited to otherwise healthy adults undergoing lower abdominal surgery, and therefore, results may not be generalizable to elderly, pediatric, or high-risk patients.

Future research should focus on longer observation periods, incorporation of continuous epidural infusion protocols, and stratified analyses in high-risk subgroups. Additionally, exploring patient-reported satisfaction scores and quality-of-recovery indices could provide a more holistic assessment of the comparative benefits of epidural tramadol versus fentanyl.

In summary, while both epidural tramadol and fentanyl provide effective postoperative analgesia, fentanyl offers a faster onset but shorter duration, whereas tramadol provides longer-lasting pain relief with greater hemodynamic stability, albeit with a higher incidence of nausea. Our findings suggest that tramadol may be preferable in patients where hemodynamic stability and avoidance of pruritus are priorities, while fentanyl remains suitable where rapid analgesia is desired.

## CONCLUSION

The findings of this randomized controlled trial indicate that both epidural tramadol and epidural fentanyl are effective agents for postoperative analgesia in patients undergoing lower abdominal surgeries. Fentanyl, owing to its high lipid solubility and strong  $\mu$ -opioid receptor affinity, produces a more rapid onset of pain relief, making it advantageous in situations where immediate analgesia is required. However, its shorter duration of action necessitates more frequent dosing or continuous infusion to maintain analgesia over time.

In contrast, tramadol, with its dual mechanism of  $\mu$ -opioid receptor agonism and monoamine reuptake inhibition, provides a longer-lasting analgesic effect, a more stable hemodynamic profile, and a lower incidence of opioid-related side effects such as pruritus and respiratory depression. These characteristics make tramadol a viable and potentially safer alternative, particularly in patients at risk for opioid-induced complications or in those with cardiovascular comorbidities where hemodynamic stability is critical.

From a clinical standpoint, the choice between fentanyl and tramadol should be individualized, taking into account the urgency of analgesia onset, anticipated duration of postoperative pain, patient comorbidities, and side-effect susceptibility. Tramadol may be especially suitable for patients in whom avoiding respiratory compromise or severe itching is a priority.

Nevertheless, this study has limitations, including its relatively small sample size, short follow-up duration, and single-dose protocol. Future research should incorporate larger patient cohorts, extended postoperative monitoring, and continuous or repeated dosing regimens to more accurately assess long-term analgesic efficacy and safety. Additionally, evaluating combinations of epidural tramadol or fentanyl with local anesthetics could provide insight into multimodal analgesia strategies that optimize pain control while minimizing adverse effects.

In conclusion, epidural tramadol stands as an effective and safe alternative to fentanyl for postoperative analgesia, particularly in patients requiring prolonged pain relief with minimal opioid-related side effects. With further validation through larger, multi-center trials, tramadol could play an increasingly prominent role in balanced perioperative pain management protocols.

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