

# Comparison between epidural tramadol and epidural fentanyl for post operative analgesia

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## Abstract

This study was carried out to compare the analgesic efficacy and side effects of epidural tramadol and that of epidural fentanyl. A total of 60 adult patients of ASA grade I and II undergoing general surgery (lower abdominal), gynecological and orthopedic (lower limb) surgeries were selected for the study. The patients were randomly divided into two groups. Group A Tramadol group, and B Fentanyl group with 30 patients each, using the prospective study method. Group 'A' received 1 mg/kg of Inj. Tramadol as a single bolus dose diluted in 10 ml of normal saline. Group 'B' received 1 mcg/kg of Inj. Fentanyl as a single bolus dose diluted in 10 ml of normal saline. The patients were randomly given epidural tramadol or epidural fentanyl when patient complained of pain post operatively with VAS 2 or 3. Patients were closely monitored in the post-operative period till they had pain relief. Pulse rate, blood pressure, respiratory rate, and oxygen saturation were recorded at 30 min. intervals. Assessment of pain relief was done using visual analogue scale and occurrence of side effects like nausea, vomiting, urinary retention, itching, respiratory depression were noted. The onset, duration and degree of analgesia and the side effects were analyzed using 'Z' test and paired 't' test. These results compared with studies of other workers.

**Keywords:** Epidural, Analgesia, Tramadol, Fentanyl.

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## INTRODUCTION

Pain is a universal experience that can span an enormous spectrum of intensity from mild discomfort to excruciating agony. Many adverse physiological and psychological effects are caused due to postoperative pain. Hence proper control of post operative pain is important to avoid certain post operative complications in addition to provide comfort to the patient. Any method of postoperative analgesia must meet three basic criteria: it must be effective, safe and feasible. Several studies have been conducted to evaluate efficacy and safety of various opioids in providing post-operative analgesia when given epidurally. Various opioid drugs have been tried in search

of a drug that will provide effective post-operative analgesia with minimal side effects. These include morphine, pethidine, pentazocine, methadone, hydromorphone, tramadol, fentanyl etc. All these drugs are associated with side effects such as respiratory depression, pruritus, nausea, vomiting, urinary retention, sedation etc. The incidence and the degree of severity of these side effects vary with each drug. Because of these side effects the search continues for a better drug that will provide effective post-operative analgesia with minimal side effects when given epidurally. This has prompted us to undertake this study of epidural Tramadol and epidural Fentanyl for post-operative analgesia. In this study we have compared efficacy and safety of Tramadol with Fentanyl, both belonging to the opioid group of drugs.

## AIMS AND OBJECTIVES

1. To compare the onset and duration of analgesia with epidural tramadol and fentanyl.
2. To compare the incidence of cardio-respiratory changes in both study groups.
3. To compare the incidence of side effects of the drugs used in both study groups.

## MATERIALS AND METHODS

### Materials

- This study was prospective type of study.
- Approval of ethical committee of our hospital was obtained.
- After assessing the patients for anesthetic fitness during pre-operative visits, 60 patients of either sex between age group of 18-68 years all of ASA grading I or II undergoing general surgery (lower abdominal), gynecological and orthopedic (lower limb) surgeries were selected.
- All patients were investigated routinely and were kept NBM for 6 hours pre-operatively.
- Each patient was explained about the procedure and also about visual analogue scale pain assessment.
- Informed and written consent was taken.
- Preservative free Inj. Tramadol and Inj. Fentanyl used in this study.
- All necessary drugs, monitoring equipments, resuscitation drugs and instruments were kept ready in the wards.

### Following cases were excluded from the study

1. Pregnant and lactating women
2. Pediatric patients (age < 12years)
3. Elderly and debilitated patients
4. Patients with hepatic and renal dysfunction
5. Known intolerance to drugs used in study

The patients were randomly divided into two groups by simple random selection technique. Each group contained 30 patients.

Patient Group	No. of Patients	Epidural Drug	Dose
A	30	Inj. Tramadol hydrochloride	1 mg/kg as a single bolus dose
B	30	Inj. Fentanyl citrate	1 mcg/kg as a single bolus dose

### Method

- After pre-operative clinical evaluation and examination, every patient underwent lignocaine sensitivity test.
- All surgeries were conducted under epidural with general anaesthesia or spinal anaesthesia or only epidural anaesthesia without any sedation.
- Epidural anaesthesia given using epidural needle (Tuohy's) no. 18 G and same size of epidural catheter under all aseptic precautions using 2% Lignocaine for local anaesthesia.
- In post-operative period, when the action of epidural analgesia started wearing off and patients complained of pain with VAS score 2 or 3, they were given epidural opioid according to the group they belonged

to. Inj. Tramadol hydrochloride or inj. Fentanyl citrate was given after diluting with 10 ml of normal saline as a single bolus dose.

Following parameters were closely monitored in all patients at half hourly interval for 6 hours in the recovery room. Patients were shifted to the wards after they were pain free and haemodynamically stable.

1. Pulse rate
2. Respiratory rate
3. Blood pressure (at 5 min. interval by NIBP method)
4. Oxygen saturation by pulse oximetry
5. Onset of pain post-operatively
6. Onset of analgesia after epidural drug
7. Duration of analgesia
8. Degree of analgesia by Visual Analogue Scale
9. Occurrence of side effects like
10. nausea, vomiting, itching, urinary retention etc.

The onset of analgesia was defined as a time interval to achieve VAS pain score 0 after giving epidural drug. The duration of analgesia was measured from onset of analgesia to the VAS pain score of 3. When patient complained of pain of severity equivalent to VAS score of 3, he/ she was given epidural top up with the drug, which he/ she had received and if this was not effective rescue analgesic was given in the form of Inj Pentazocine 0.2-0.6mg/kg intravenously. The observations were tabulated and analyzed by using statistical tests viz. 'Z' test and paired 't' test.

Visual analogue scale: Scale: 0 – 10

0 = No pain

10 = worst pain ever experienced

## OBSERVATIONS AND RESULTS

**Table 1:** Onset of analgesia (Min.) in study groups

Group	Tramadol (A) (n=30)	Fentanyl (B) (n=30)	P-value
Mean ± SD	16.2 ± 2.82	12.2 ± 2.37	<0.001

Onset of analgesia in Tramadol (A) group was 16.2 min, while in Fentanyl (B) group it was 12.2 min. When compared, onset of analgesia with Fentanyl was quicker than with Tramadol and this is statistically significant by 'Z' test.

**Table 2:** Duration of analgesia (Min.) in study groups

Group	Tramadol (A) (n=30)	Fentanyl (B) (n=30)	P-value
Mean ± SD	295 ± 44.6	184 ± 23.3	<0.0001

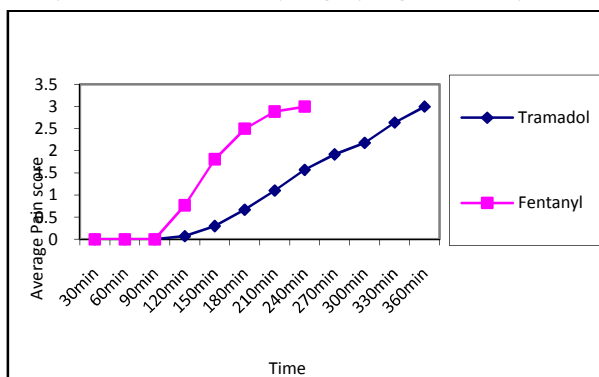
Duration of analgesia in Tramadol (A) group was 295 min, while in Fentanyl (B) group it was 184 min. When compared, duration of analgesia was more with Tramadol than with Fentanyl and this is statistically highly significant by 'Z' test.

1. Change in respiratory rate after giving epidural tramadol in-group A is statistically not significant by paired 't' test.
2. SaO<sub>2</sub> rises after epidural tramadol in-group A, which is statistically significant by paired 't' test.
3. Change in respiratory rate after giving epidural fentanyl in-group B is statistically not significant by paired 't' test.
4. SaO<sub>2</sub> rises after epidural fentanyl in-group B, which is statistically significant by paired 't' test.

**Table 3:** VAS pain score before and after epidural drug in study groups

Time (Min.)	VAS pain score		P-value
	Tramadol (A) n=30 (Mean ± SD)	Fentanyl (B) n=30 (Mean ± SD)	
0	2.73 ± 0.45	2.6 ± 0.5	>0.05
30	0	0	>0.05
60	0	0	>0.05
90	0	0	>0.05
120	0.07 ± 0.25	0.77 ± 0.57	<0.001
150	0.3 ± 0.5	1.81 ± 0.76	<0.001
180	0.67 ± 0.71	2.5 ± 0.7	<0.0001
210	1.1 ± 0.8	2.89 ± 0.33	<0.0001
240	1.57 ± 0.84	3 ± 0	<0.0001
270	1.92 ± 0.83		
300	2.18 ± 0.73		
330	2.64 ± 0.50		
360	3 ± 0		

VAS pain score was 2.73 and 2.6 in group tramadol (A) and fentanyl (B) respectively, before giving epidural drugs. This is statistically not significant by 'Z' test. After giving drugs, VAS pain score in 30 to 90 min was 0 in both groups. These values are statistically not significant by 'Z' test. In 120 to 240 min, VAS pain score was less in tramadol (A) group than fentanyl (B) group. Duration and degree of analgesia was more with Tramadol than with Fentanyl, this is statistically highly significant by 'Z' test.



**Figure 1:** Line chart showing Average Pain score in study groups

In Fentanyl group onset of analgesia was quicker but duration was shorter as compared to Tramadol group.

**Table 4:** Incidence of side effects

Side effects	Tramadol (A) n=30		Fentanyl (B) n=30		P-value
	No.	%	No.	%	
Nausea	10	33.33	3	10	<0.001
Vomiting	3	10	0	0	
Itching	0	0	4	13.33	
Urinary retention	1	3.33	1	3.33	>0.05
Resp. depression	0	0	0	0	

Incidence of nausea (33%) and vomiting (10%) was significantly higher in tramadol (A) group by 'Z' test. Incidence of itching (13.33%) was more in fentanyl (B) group. Incidence of urinary retention was 3.33% in both groups, which is statistically not significant by 'Z' test. There was no respiratory depression found in both the groups.

### DISCUSSION

Despite the universal nature of pain, it is sadly too often true that pain is not treated adequately. Even with recent advances in understanding post-operative pain, pharmacological aspects, routine treatment of post-operative pain remains unsatisfactory. We have used epidural tramadol (1 mg/kg) and epidural fentanyl (1 mcg/kg) and found that degree of analgesia was excellent in both the groups. Duration of pain relief was longer in Tramadol group as compared to Fentanyl group. We have used a method devised to measure the pathological pain, which is known as linear analogue scale or visual analogue scale (VAS). The reliability of linear analogue scale observed by Revill S.I. *et al*<sup>1</sup> in 1976. In our study, the onset of analgesia was quicker with epidural fentanyl (12.2±2.37 min.) than epidural tramadol (16.2±2.82 min.) and this is statistically significant by using 'Z' test. Fu Y. P. *et al*<sup>2</sup> in their study of post-operative analgesia with 75 mg of epidural tramadol noted a mean duration of pain relief for 12 ±5 hours. Torda *et al*<sup>3</sup> used 60 mcg fentanyl epidurally for post-operative analgesia. They found mean duration of analgesia to be 5.7 hours. In our study, we have found the mean duration of pain relief to be longer in epidural tramadol (295±44 min.) when compared to epidural fentanyl (184±23 min) and this is statistically highly significant by 'Z' test. After reviewing the literature there seems to be the variation as far as duration of analgesia is concerned, after receiving epidural fentanyl or tramadol. Analgesic period of epidural fentanyl ranged from 2-6 hrs. in various studies, in our study it was about 3 hrs. When tramadol was given by epidural route, analgesic period was reported from 5-12 hrs, in our study it lasted for 5 hrs. Perhaps the variation could be incriminated to the type of surgery, type of

incision, difference in population, sensitivity to feel pain and different doses of epidural opioids. Before giving epidural tramadol and Fentanyl, pulse rate and blood pressure was above the baseline readings due to pain. After giving epidural tramadol and Fentanyl, these parameters came down to baseline in both the groups, which is statistically significant by paired ‘t’ test. In our study 4 patients (13.33%) in fentanyl group, but no patient in tramadol group complained of itching. Chaney Mark A<sup>(4)</sup> in 1995 observed that nausea and vomiting was approximately 30% with the use of epidural opioids. In our study we have found 10% of patients in fentanyl group and 33% of patients in tramadol group had nausea. While incidence of vomiting was 10% in tramadol group and no such cases found in fentanyl group. In our study 1 patient from the tramadol group and 1 patient from fentanyl group complained of urinary retention and required urinary catheterization, which is statistically nonsignificant by using ‘Z’ test. Respiratory depression is the most feared side effect of intrathecal and epidural opioids. Stoelting R.K.<sup>5</sup> in 1980 observed that Tramadol on the other hand does not produce respiratory depression. In our study we have monitored respiratory rate and oxygen saturation using pulse oximetry. In the tramadol group, the mean respiratory rate was 13.2/min before and it was 13/min after the administration of epidural drug. In fentanyl group, the mean respiratory rate was 12.3/min before and it was 12.2/min after the administration of epidural drug. Thus, in this study we found that the onset of analgesia was faster with epidural fentanyl but with significant occurrences of itching. The duration and degree of analgesia was better with epidural tramadol, however there was significant incidences of nausea and vomiting in this group.

## CONCLUSION

1. Onset of analgesia with epidural fentanyl (12.2 min) was quicker as compared to epidural tramadol (16.2 min), which is statistically significant by ‘Z’ test.
2. The mean duration of analgesia by comparing VAS pain score for epidural tramadol was 295 min. and for epidural fentanyl was 184 min.
3. After giving epidural drugs, VAS pain score in first 30 to 90 min. was 0 in both the groups. In 120 to 240 min. VAS pain score was less in epidural tramadol group as compared to epidural fentanyl group. Duration and degree of analgesia

was more with epidural tramadol than with epidural fentanyl, this is statistically highly significant by ‘Z’ test.

4. Before giving epidural drugs, pulse rate and blood pressure was on higher side as compared to the baseline readings due to pain. After giving epidural tramadol and epidural fentanyl these parameters came down. Thus both drugs are effective in providing analgesia to patients and this is statistically significant by paired ‘t’ test.
5. There was no statistically significant change in respiratory rate after giving epidural tramadol or epidural fentanyl, thus there was no respiratory depression found in both the groups.
6. SaO<sub>2</sub> rises after epidural tramadol as well as epidural fentanyl, which is statistically significant by paired ‘t’ test.
7. Nausea (33%) and vomiting (10%) was more in epidural tramadol group than in the epidural fentanyl group, which is statistically significant by ‘Z’ test and treated immediately by intravenous 4 mg Ondansetron.
8. The incidence of itching (13.33%) was more in epidural fentanyl group, which was for a transient period and no treatment was required.
9. To conclude, in controlling post-operative analgesia we found that the onset of analgesia was faster with epidural fentanyl but with significant occurrences of itching. However, the duration and degree of analgesia was better with epidural tramadol, with significant incidences of nausea and vomiting in this group.

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