Original Research Paper

Volume : 5 | Issue : 11 | November 2016 • ISSN No 2277 - 8179 | IF : 3.508 | IC Value : 69.48

Comparison Between Epidural Tramadol And Fentanyl For Post Operative Analgesia

Medical Science

KEYWORDS : *epidural, postoperative analgesia,fentanyl,tramadol.*

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ABSTRACT

AIM:*To evaluate the efficacy of epidural tramadol and fentanyl for postoperative analgesia.*

METHODS:*80 patients of ASA grade 1 and 2 aged between 18-55yrs undergoing lower abdominal and lower limb surgeries were randomly allocated into 2 groups. group 1 –received inj.tramadol 50mg, group2 -received inj.fentanyl 50µg.*

RESULTS:*Mean onset of analgesia in group1 was 13.08±2.6min and in group2 was 5.79±1.46min. duration of analgesia in group1 mean±SD of 6.2±0.5hrs while in group 2 ranged between 3-4hrs with a mean of 3.48±0.4hrs.*

Side effects:Group 2 had side effects like nausea (2.5%)and vomiting(2.5%) when compared to Group 1 where 17.5% had nausea and 12.5% vomiting.

CONCLUSION:*Epidural fentanyl provides a rapid ,excellent but shorter duration of analgesia when compared to epidural tramadol. From our study,it appears that both epidural tramadol and epidural fentanyl have equal efficacy except duration of action which is shorter for fentanyl.*

introduction:

Pain is an inevitable component of the postoperative period .Every method of postoperative analgesia must meet three basic criteria.It should be effective, safe and feasible. Existing methods of treating postoperative pain are systemic narcotics, patient controlled analgesia, regional anaesthetic techniques, epidural and intrathecal opioids, epidural local anaesthetic, narcotic mixtures, transcutaneous electrical nerve stimulation, psychological methods etc. Each method has its own merits, demerits and limitations. Epidural administration of opiods for analgesia has recently generated wide spread interest.

AIM:-

To evaluate the efficacy of epidural, tramadol and fentanyl for postoperative analgesia.

MATERIAL AND METHODS

The present study was prospective Randomized controlled single blinded study. After obtaining institutional ethical approval and informed consent a total of 80 patients were studied. The study was conducted from 2013-2015 . The study population (n=80) were randomly divided into two groups with 40 patients in each group(n=40).

Statistical analysis: Using Student "s t test and chi – square test.

Inclusion Criteria:

a) Patients of American Society of anesthesiology Grades I and II.

b) Age group: 18 to 55yrs.

c) Patients undergoing lower abdominal and lower limb surgeries.

Exclusion Criteria:

- Patient's refusal.
- Patient with cardiac disease.
- Hypotension and hypovolemia
- Diabetes Mellitus
- Patient with renal disease
- Neurological disorder
- Patient's with local infection at puncture site.
- Bradycardia
- Bleeding disorders, coagulopathy.
- Hypersensitivity to drugs

METHODS:

80 patients of physical status ASA grade I – II aged between 18 – 55 years under going lower abdominal and lower limb surgeries are randomly allocated into 2 groups.

- Group I – Received Inj. Tramadol 50 mg.
- Group II –Received Inj. Fentanyl 50 mcg.

The patient were explained about the epidural technique with catheter in situ.Its advantage and disadvantage.They were also educated about the usage of Linear visual Analogue scale (VAS)for assessment of the intensity of post operative pain and were instructed to mark on the scale at this point which he/she felt was representative of their level of discomfort.

A written informed consent was taken from each patient.

All patients are kept nil by mouth overnight. In the operation theatre all patients are monitored with electrocardiography, peripheral oxygen saturation (Spo2) and non invasive blood pressure monitor and all basal parameters are recorded. An IV line is obtained with 18 G cannula. All patients are preloaded with Ringer lactate solution 8 ml/kg wt over 15 – 20 minute.

After positioning the patients and taking all aseptic precautions epidural needle introduced at L2–L3 interspace and space identified using loss of resistance to air technique. Epidural catheter is inserted. All patients are given spinal anaesthesia for the surgical procedure one space lower L3–L4interspace than the insertion site of epidural catheter using 25 G spinal needle and 3 ml of heavy bupivacaine 0.5% is given. Sensory and motor effect are checked.

At the end of surgical procedure sensory level and motor effects is determined. When VAS for pain reached 5, then bolus from 10 ml syringe is given to all the patients depending upon groups. Patient in Group I(n=40) received 50 mg of inj. Tramadol dissolved in 9 ml of normal saline (total volume 10 ml) epidurally. For top up 100 mg of inj. Tramadol was dissolved in 18 ml normal saline (total volume 20 ml) and 10 ml of this solution was given as top up-epidurally. Patient in Group II (n=40) received 50 mcg of inj. Fentanyl dissolved 9 ml of normal saline (total volume 10 ml) epidurally. For top up 100 mcg of inj. Fentanyl was

dissolved in 18ml of normal saline (total volume 20ml) and 10 ml of this solution was given as top up epidurally.

For the rest of post operative period, patient will be given top up doses from 20 ml syringe on having pain of VAS >5.

Patient will be assessed at half – hourly intervals for first two hours then at 4,8,12,24, 48 & 72 hour after giving first dose of epidural opioid.

Parameters observed are:

- Visual analogue scale(VAS)
- Sedation score
- Pulse rate
- Respiratory rate
- Blood pressure
- Time of inj.of epidural drugs
- Onset of analgesia
- Duration of analgesia
- Quality of analgesia
- Any other side effects like nausea, vomiting, pruritis, urinary retention.

Onset of analgesia: is the time interval from administration of the study drug (VAS score of >5) till VAS score came down to <5.

Duration of analgesia: Is the time interval between onset of analgesia (VAS score <5) till patient complaints of pain (VAS score>5) when rescue medication was given.

Quality of analgesia: Was assessed during the duration of analgesia using pain score and compared in both the groups.

Sedation score: Quality of sedation after giving the study drug was based on sedation scoring

Grade 0- No sedation , patient wide awake.
Grade 1-Mild sedation, patient awake but drowsy.
Grade 2- Moderate sedation, sleepy but arousable.
Grade 3-severe sedation ,unarousable.

Statistical analysis :
Statistical analysis of data was done using student t test (z test) for parametric data. Non parametric data was analysed by chi – square test.

RESULTS :
The mean age of patients in group I(Tramadol) 40.23+7.9 and in Group II(fentanyl) 42.55 +8.9 Age incidence between groups were comparable.

In group I(Tramadol), 18(45%) were males and 22(55%) were females in group II(Fentanyl) 19 (47.5%) were male and 21 (52.5%) were females.

Out of 80 patients 6 underwent general surgery, 34 underwent gynaecological surgery and 40 patients underwent orthopedics surgery.

Table 1: time of onset of analgesia

Groups	Onset of Analgesia (min)			Significance	
	Range	Mean	SD	t - value	p–value
GroupI(Tramadol)	8 to 18	13.08	2.6	15.103	0.001
GroupII(Fentanyl)	4 to 9	5.79	1.46		

The mean time of onset of analgesia in groupI(Tramadol) was 13.08+2.6(SD)minutes and in group II(Fentanyl) was 5.79+1.46(SD)minutes. The statistical analysis by students unpaired t test showed that the difference between time of onset of analgesia in group I(Tramadol) and group II(Fentanyl) is statistically significant.

(P < 0.001)

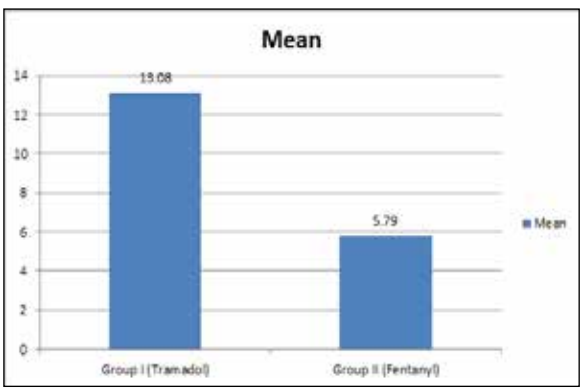
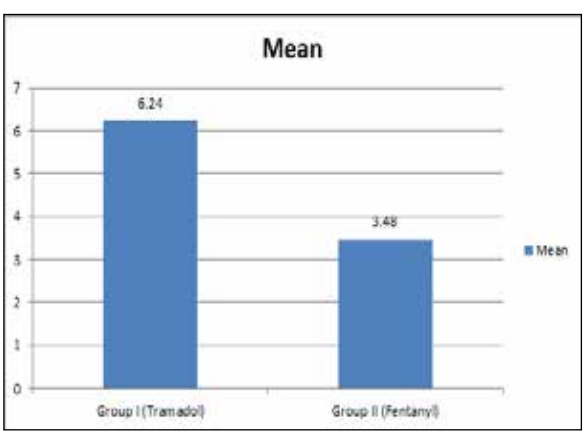


Table 2: Duration of Analgesia

Groups	Duration of Analgesia (hrs)			Significance	
	Range	Mean	SD	t – value	P – value
Group I (Tramadol)	6 to 8	6.24	0.5	27.42	0.001
Group II (Fentanyl)	3 to 4	3.48	0.4		



Duration of analgesia was observed in both groups in post operative period. Time was noted when patient asked for the rescue analgesia. The duration of analgesia in Group I(Tramadol) range from 6-8hrs with mean ± SD of 6.24+0.5hours. Duration of analgesia Group II(Fentanyl) was between 3-4 hrs with mean of 3.48+0.4hours.

Statistically there was no significant difference in the pulse rate between the two groups with P>0.05.

Statistically there was no significant difference in the blood pressure (both systolic and diastolic) between the two groups with P>0.05.

Statistically there was no significant difference in the respiratory rate between the two groups with P>0.05.

Volume : 5 | Issue : 11 | November 2016 • ISSN No 2277 - 8179 | IF : 3.508 | IC Value : 69.48

Table 3: Quality of analgesia (VAS score)

Group	0 hrs	½ hr	1 hr	1.5 hr	2 hrs	4 hrs	8 hrs	12 hrs	24 hrs	48 hrs	72 hrs
Tramadol	6.53± 0.59	3.73±0.452	3.28±0.452	3.05±0.221	3.05±0.221	3.28±0.452	4.08±0.917	4.38±0.740	4.65±0.700	3.43±0.594	3.30±0.73
F entanyl	6.75±0.54	3.25±0.439	3.00±0.00	2.375±0.00	1.65±0.304	4.35±0.770	4.70±0.464	4.78±0.530	3.73±0.751	3.50±0.496	3.43±0.079
P value	0.082	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.0001	0.839	0.250

Results are presented in Mean ±SD

The above table shoes that; quality of analgesia was assessed during the duration of analgesia. Quality of analgesia was assessed based on the following classification.

Quality of analgesia	Pain score	VAS Score
No pain relief	0	10
Poor pain relief	1	8-9
Fair pain relief	2	5-7
Good pain relief	3	3-4
Excellent pain relief	4	0-2

From the above table, it can be noted that VAS score of pain was not statistically different before giving drugs. The mean VAS score between two groups was highly significant (P<0.001), at 1, 1.5, 2, 4, 8, 12, 24hrs and at 48 and 72 hrs it was insignificant statistically (P>0.05).In Group I Tramadol, VAS score increased at 6 hrs whereas in Group II, Fentanyl it increased at 4 hrs.

..VAS score was significantly lower in Fentanyl group than in Tramadol group at many occasions that suggest that pain relief was significantly better in Fentanyl group than Tramadol group.

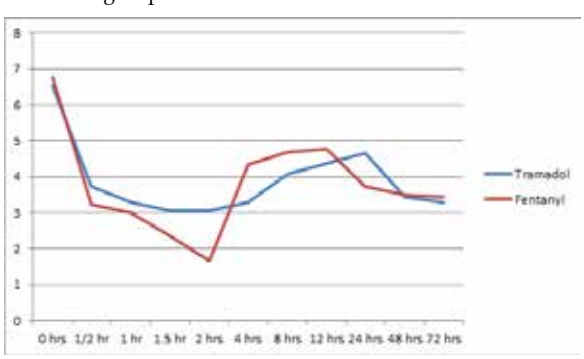
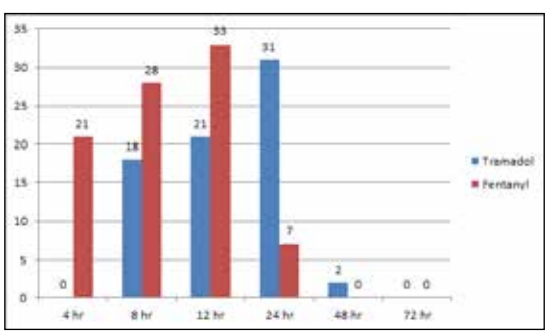
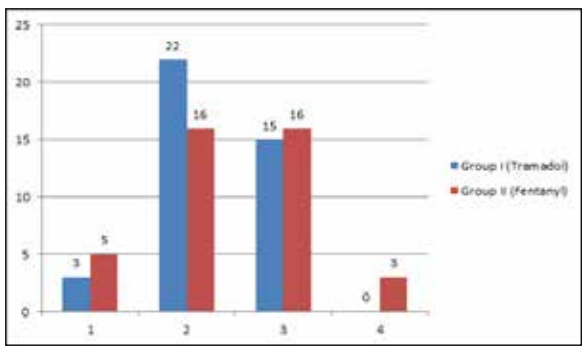


Table 4:Epidural Top up

Top up	4hr	8hr	12hr	24hr	48hr	72hr
Tramadol	0	18	21	31	2	0
Fentanyl	21	28	33	7	0	0
P-value	.001	.001	.001	.001	,247	-



Top up	Group I Tramadol.	GroupII Fentanyl.
1	3	5
2	22	16
3	15	16
4	0	3



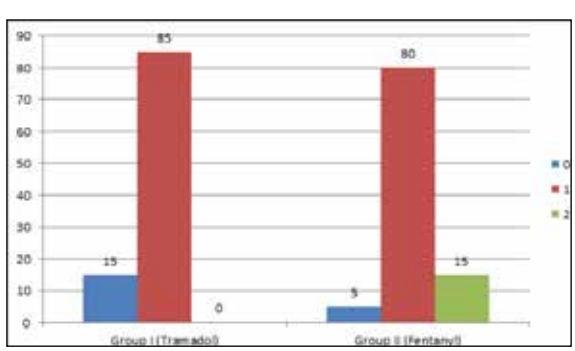
From the above table it has been noted that the number of epidural top up required for Group II Fentanyl was much more than Group I. Tramadol at 4, 8, 12.Hr and at 24 hr tramadol required more than fentanyl which was highly significant (P<0.001).And at 48 and 72hr it was insignificant (P.>0.05).The mean time required for epidural top up of tramadol was much longer compared to fentanyl.

Table 5: Sedation Score (SS)

Sedation Score	Group I (tramadol) (n=40)	Group II (Fentanyl) (n=40)	t test	P value
0	6 (15%)	2 (5%)	8.061	0.01
1	34 (85%)	32 (80%)		
2	0	6 (15%)		

0-Fully awake,1-slightly drowsy, 2- Asleep but easily arousable.

In Group I Tramadol 85% of patient are slightly drowsy,15% are awake and non of the patient had sedation score of 2. In Group II Fentanyl, 80% patient were slightly drowsy, 5% were fully awake and 15% of patient had sedation score 2. Statistical analysis showed that this difference in two group issignificant.(P<0.01)Side effects: In group I Tramadol 17.5% of patient had nausea, 12.5%of patient had vomiting, and none of the patient had sedation. when compared to Group II Fentanyl where 2.5% of patient had nausea and vomiting and 17.5%of patient had sedation score. the difference was statistically significant (P<.001).



DISCUSSION:

Management of post-operative pain poses lot of challenge to anaesthetists paradoxically after all the efforts taken to make the intra-operative period pain free and stress free, the patient is left to fend themselves in the post-operative period.

"Pain free at rest" is a reasonable aim. Pain relief is necessary for both humanitarian and therapeutic reasons. Uncontrolled pain in the postoperative period can have detrimental physiological effects.

Pain can greatly impede the return of normal pulmonary function, inability to cough, bronchospasm - all leads to atelectasis and hypoxemia especially in upper abdominal and thoracic surgeries.

Pain promotes immobility and hence the development of deep vein thrombosis.Alteration in the stress response to surgery, increased catecholamine release, increased oxygen demand and increased cardiac work.

Increased catabolic response to surgical trauma and impaired immune mechanisms and delayed wound healing.

Hence, its relief undoubtedly decreases morbidity and mortality.

In recent times, the role of epidural and subarachnoid opioids for the relief of post-operative pain promotes a new platform in this field. This is because of the direct action of the opioids on specific opioid receptors that are richly distributed in the posterior horn of the spinal cord and epidural opioids have a wider margin of safety as against systemic opioids. Tramadol hydrochloride an opioid agonist and monoamine reuptake blocker has been used extensively in the peri-operative period as an analgesic. It's analgesic potency is 1/5th to 1/10th of morphine and it does not have respiratory depression. But studies have shown that, in higher doses it can have side effects like nausea, vomiting, hypotension.

Fentanyl is a phenylpiperidine - derivative synthetic opioid agonist. It is 75 to 125 times more potent than morphine and has been employed successfully in western countries since its launch in 1970's for the relief of postoperative pain. Fentanyl when administered epidurally, has dose related ceiling effect on respiratory depression, lesser side effects like nausea, vomiting, pruritis. But it produces sedation (which is not seen with tramadol) which is desired in post-operative period.

Here an attempt has been made to assess the efficacy of fentanyl in comparison to drug tramadol through epidural route for the management of post-operative pain.

Onset of Analgesia

In our study, the mean time of onset of analgesia in Group-I (Tramadol) was 13.08 ± 2.6 minutes and in Group-II (Fentanyl) was 5.79 ± 1.46 minutes. The statistical analysis by student's unpaired 't' test showed that, the difference in the time of onset of analgesia in Group-I and Group-II is statistically significant ($p < 0.001$).

A study was conducted by Pinky Rathie, RS Verma, TS Jadav and Ajay Kabra to know the effectiveness and duration of post-operative analgesia with epidural tramadol. The group who received 100 mg of epidural tramadol in 10 ml of normal saline had onset of action 12.08 ± 3.53 minutes.

Onset of analgesia in our study was comparable to above studies.

Welchew E.A.,in 1983 did a randomized, double-blind study, comparing different concentration of fentanyl for postoperative pain relief. 100μg of epidural fentanyl showed a very rapid onset of analgesia of around 5 minutes and concluded that 10μg/ml gives the maximal analgesic effect.

Naulty JS and his colleagues in 1985 also found that epidural fentanyl had the same response as in our study i.e.complete analgesia in approximately 3- minutes with almost 80% pain relief within 3minutes, with duration of around 4 hours with minimal side-effects requiring no treatment.

Duration of Analgesia

The duration of analgesia in Group-I ranged from 6-8hours with a mean±SD of 6.2± 0.5hours, while in Group-II ranged between 3-4hours with a mean of 3.48±0.4hours. Statistical analysis by student's unpaired 't' test showed that time of duration of analgesia in Group-I was significantly more when compared to Group-II ($t = 27.424$, $p < 0.001$).

A study was conducted by PreranaShroff, PreetiAhuja, Shravani Chandra, L. Chaundhari to know the duration of post-operative analgesia with epidural tramadol. The group who received 100mg of epidural tramadol had analgesic effect to last for 5.46±1,25hrs.

Lomessy A. et al, in 1984 found the similar duration of analgesia and concluded that though it is of short duration, i.e.,around for 3hours, when only spontaneous pain was evaluated; still this technique is reliable in regard to the risk of immediate and above all delayed respiratory depression.

Quality of analgesia.

Delilkan AE, Vijayan R in their study noted that, quality of analgesia was significantly better with 100 mg tramadol at 3,12,and 24hrs when compared with bupivacaine 0.25%.Comparison of VAS score at various time interval in both group showed that fentanyl was able to relieve pain in much better way than tramadol. Rawal H et. Al in 1995 there is decrease in VAS score with epidural tramadol with bolus and continuous infusion. Which was comparable with our study.

Rostaing S. and his colleagues in 1991 in their study with epidural fentanyl 100μg recorded duration of action as 250±64minutes, maximum reduction in VAS score ranged from 57 to 100%. All the patients had a slight but significant decrease in BP and respiration rate. This correlating with our study.

Lee MC, Lin YF, Yang YD, Wang KY, Poon KS, Chang WK, Chan KH, Lee TY. In 1989 studied the postoperative pain relief using continuous epidural fentanyl infusion in two different dosages for thoracic and upper abdominal surgeries. Those in group A were given fentanyl 1.5 μg/kg as initial dose and the maintenance dose were respectively 1.0μg/kg and 0.5 μg/kg/hr. Pain was assessed hourly using a visual analogue pain scale with scores from 0 to 10. It was found that analgesic effect apparent to be better in group A, pain relief was satisfactory in both groups.

Sugimoto M et al., in 1997 compared the degree of analgesia using different dose of epidural fentanyl and found that epidural fentanyl 25 μg provides superior analgesia than 12.5μg.

Lytle SA, goldsmith DM, Neuendorf TL, and Lory ME. Studied continuous epidural fentanyl for postoperative an-

Volume : 5 | Issue : 11 | November 2016 • ISSN No 2277 - 8179 | IF : 3.508 | IC Value : 69.48

algesia using a concentration of 50 mcg/ml of fentanyl. The average rate of infusion was 60 µg/hr. The data showed that epidural fentanyl provides good to excellent pain relief with minimal side effects.

Hence our study is comparable to their study.

Sedation Scores (Level of Consciousness)

In our study, 6 (15%) patients of Group-II (fentanyl) had sedation scores of 2 when compared to Group-I (Tramadol) where none had this score.

A study by Vicker MD, et al, noted that, the tramadol patients had less sedation scores compare to pethidine group of patients.

White MJ, Berghausen EJ, Dumount SW, Tsueda K, Schroeder JA, Vogel RL, Heine MF and Hunag KC. Studied somnolence during a 48 hour period of continuous epidural morphine and fentanyl. Somnolance was prominent within several hours in two thirds of patients in both groups. The incidence was higher in the fentanyl group at the48th hour.

A study by Vicker MD et al, noted that, the tramadol patients had less sedation scores compared to pethidine group of patients.

Rutter D.V. and his colleagues in 1981 reported that epidural fentanyl has a rapid onset of action but shorter duration with significant decrease in respiratory rate and increase in sedation but never required any treatment.

Side Effects

In our study, Group-II (Fentanyl) patients had side effects like nausea (2.5%) and vomiting (2.5%). There were less when compared to Group-I (Tramadol) where 17.5% of patients had nausea and 12.5% of patients had vomiting. The difference was statistically significant by Chi-square test ($p<0.001$).

None of the patients in both groups had pruritis, hypotention and respiratory depression.

The study by Delilkan AE, Vijayan MD noted more incidence of nausea and vomiting in group receiving epidural tramadol 100 mg compared to epidural tramadol 50 mg.

Naulty J.S. and his colleagues in 1985 found almost 80% pain relief with dose of 100µg epidural fentanyl, with minimal pruritus and drowsiness requiring no treatment.

Prerana Shroff, Preeti Ahuja, Shravani Chandra noted nausea, vomiting was mucyh more in the tramadol infusion group that subsided with IV ondansetron.

White MJ, Berghausen EJ, Dumont SW, Tsueda K, Schroeder JA, Vogel RLO, Heine MF and Huang KC. Compared respiratory effects, nausea, and pruritus during a 48 hours period of continuous epidural fentanyl and morphine. Side effects were assessed by visual analogue scale and considered to be present when the score was above 30. In fentanyl group, there was no respiratory effects, and nausea was confined to the first few hours.

Overall, frequencies of side effects were less in both groups.

Hence our study results are comparable to above results.

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