Original Research Article

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Comparative Study of Epidural Ropivacaine HCL-Fentanyl Citrate and Ropivacaine HCL-Tramadol HCL for Postoperative Analgesia in Abdominal Surgeries

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Abstract

Introduction: Central neuraxial adjuvant drugs, alone or in combination, are used intrathecally or epidurally for the treatment of acute and chronic painful conditions. *Aims:* To compare the efficacy and duration of analgesia as well as to compare the hemodynamic parameters and the adverse effects of study drugs. *Method:* 100 adult patients of ASA grade I and II, of either sex, belonging to 18 -65 years of age, posted for elective abdominal surgeries were selected for the study. Patients were randomly divided into two groups of 50 each. Group RT received 13ml of Inj. Ropivacaine hydrochloride (0.2%) + 1ml of Inj. Tramadol hydrochloride (50mg) + 1ml of Normal Saline. Group RF received 13ml of Inj. Ropivacaine hydrochloride (0.2%) + 0.5ml of Inj. Fentanyl citrate (25µg) + 1.5ml of Normal Saline. Total volume = 15 ml, by epidural route at the time of skin closure. Postoperatively, VAS Score at rest and movement, Ramsay sedation score, hemodynamic changes and adverse effects were noted. *Result:* VAS at rest and movement were higher in Group RF at 6 hrs whereas in Group RT at 10 hrs. Ramsay sedation score were also comparable at 6 hrs and 10 hrs. Duration of analgesia was around 8 to 10 hours in Group RT whereas it was around 6 to 8 hours in Group RF. *Conclusion:* Epidural Tramadol hydrochloride along with Ropivacaine hydrochloride provides significant longer duration of analgesia, lower pain scores as compared to Epidural Fentanyl citrate with Ropivacaine hydrochloride.

Keywords: Epidural; Ropivacaine; Fentanyl; Tramadol; Analgesia.

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Introduction

Regional analgesia with the local anaesthetic drug via epidural catheter is established method of satisfactory postoperative pain management. Today, among local anaesthetic drugs, ropivacaine is preferred due to its favourable sensory block profile and lower cardiovascular toxicity compared to others [1]. Since it is less lipophilic than bupivacaine, its penetration is more selective for thin unmyelinated pain-transmitting nerve fibres compared to larger motor nerve fibres [2]. Ropivacaine, the S-enantiomer of the a mide local anesthetic, produces differential neural blockade, less motor blockade, cardiovascular and neurological toxicity [3]. Tramadol not only binds to opioid µ-receptors but also interacts with the central nervous system by inhibiting the withdrawal of noradrenaline and serotonin [4]. Fentanyl is a highly lipid soluble drug, and when placed in the epidural space, peak concentration is reached in about 20 minutes. The low incidence of side effects associated with epidural fentanyl has been explained by the lipid solubility of the agent, which is so great that only low concentration of drug reaches the brain stem [5].

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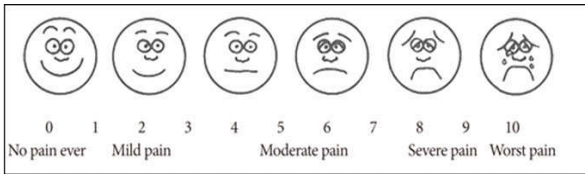
Material and Methodology

Hundred adult patients of ASA grade I and II, of either sex, belonging to 18 -65 years of age, posted for elective abdominal surgeries in general surgery and gynaecology were selected for the study. Patients were randomly divided into two groups (Group RT and Group RF) of 50 each. Group RT received 13ml of Inj. Ropivacaine hydrochloride (0.2%) + 1ml of Inj. Tramadol hydrochloride (50mg) + 1ml of Normal Saline (NS). Total volume = 15 ml and Group RF received 13ml of Inj. Ropivacaine hydrochloride (0.2%) + 0.5ml of Inj. Fentanyl citrate (25µg) + 1.5ml of Normal Saline (NS). Total volume = 15 ml, all received drugs by epidural route. Patients of ventricular dysfunction, coronary disease, valvular heart disease, renal and/or hepatic disorders, bronchial asthma and COPD, bleeding disorders, neurological and spine deficit, local skin infection, physically dependent on opioids, history of drug allergy were excluded from the study. The patients were explained about the epidural technique with catheter in situ, its advantages and disadvantages. They were also educated about the usage of

Visual Analogue Scale (VAS) for assessment of the intensity of postoperative pain and were instructed to mark on the scale at the point which he/she felt was representative of their level of discomfort. A written informed consent was taken from each patient.



To allay the anxiety and apprehension, all patients were given Tablet lorazepam (0.5 mg or 1 mg) at 10 pm in the night before the surgery. Epidural catheter was inserted for postoperative analgesia and all patients were operated under General Anaesthesia. The patient was placed in sitting or lateral position. Under all aseptic and antiseptic precautions, the epidural space was identified using 16G sterile disposable Tuohy needle with hanging drop technique at L1- L2 interspace and about 5 cms of the catheter was in the space. Then patient was induced under general anesthesia. No narcotics were administered during the intraoperative periodexcept Inj. Fentanyl citrate at the time of induction. We gave epidural drug study at the time of skin sutures. After the operation had finished, we reversed and extubated the patients. After completion of the surgery, patient was shifted to postoperative ward and monitoring of HR, Blood pressure, Oxygen saturation and Respiratory Rate, Ramsay Sedation Score and adverse effects was done at 1 hour, 2 hours, 4 hours and every 2 hourly for next 12 hours from the time the study drug was administered. The intensity of pain and pain relief was assessed using VAS at 1 hour, 2 hours, 4 hours and thereafter 2 hourly for 12 hours from the time the study drug was administered postoperatively. As and when the patient complains of further pain during the period of observation, intensity of pain was assessed again using VAS to know the effect of the study drug given earlier. If it was 4 or more, rescue analgesia was given in form of Inj. Paracetamol 15 mg/kg intravenously slowly as per the ward protocol and the time was noted. The Duration of analgesia was noted. The study would end at this stage (provided LFT is normal). The statistical software namely Instat 3 was used for the analysis of the data and to find the significance of each parameter between the two groups.

Result and Observation

Table 1 shows Demographic data is comparable in both the groups and there is no statistical difference between them (p value > 0.05).

Figure 1 shows the changes in heart rate in the postoperative period. Looking from the data in the graph we can see that mean heart rate does not change much in both the groups and is found to be statistically insignificant (p> 0.05).

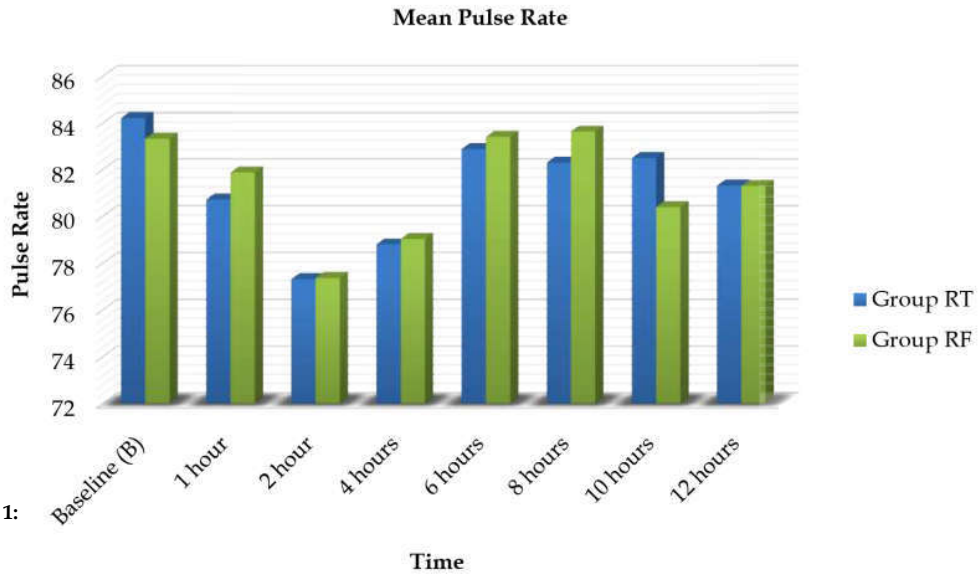
Figure 2 shows the changes in mean blood pressure (MBP) in the postoperative period. Looking from the data in the figure we can see that mean MBP does not change much in both the groups and is found to be statistically insignificant. (p> 0.05).

Looking from the data in the Figure 3 and 4 we can see that VAS scores in the two groups is comparable at Rest and Movement and the statistical difference is not significant (p>0.05) at 1, 2 and 4 hours. It is statistically extremely significant (ES) at 6 hours and 10 hours (p<0.05) as 28 patients of Group RF complain of pain and are having VAS scores ≥ 4 at 6 hours after which they are given rescue analgesia as Inj. Paracetamol 15 mg/kg i.v stat; no patients in Group RT have VAS scores ≥ 4 at 6 hours. Whereas 26 patients of Group RT complain of pain and are having VAS scores ≥ 4 at 10 hours. No patients of Group RF have VAS

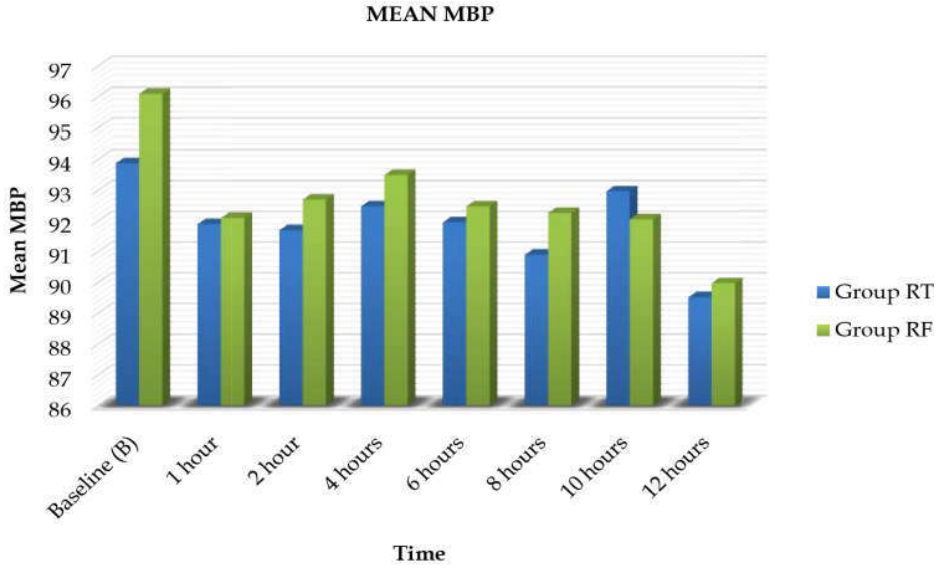
Table 1:

Parameters	Group RT: (n=50)	Group RF: (n=50)	P Value	Result
Age (Yrs)	44.2 ± 10.08	43.76± 10.37	0.8301	NS
Sex Ratio (M :F)	15:35	13:37		
Weight (Kg)	53.04± 7.71	52.02± 5.79	0.4562	NS

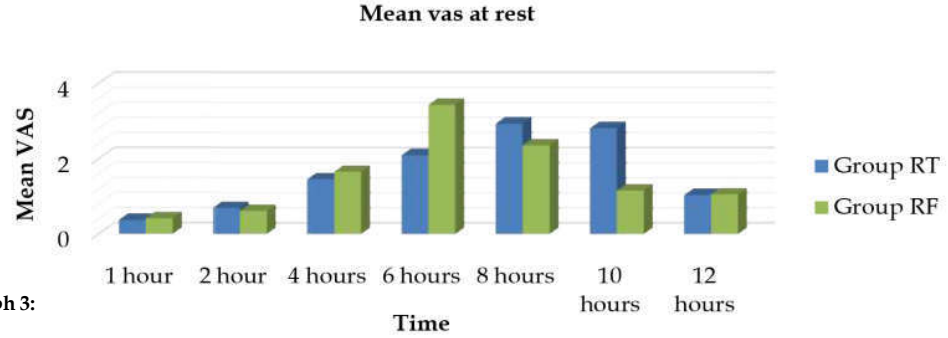
Graph 1:



Graph 2:



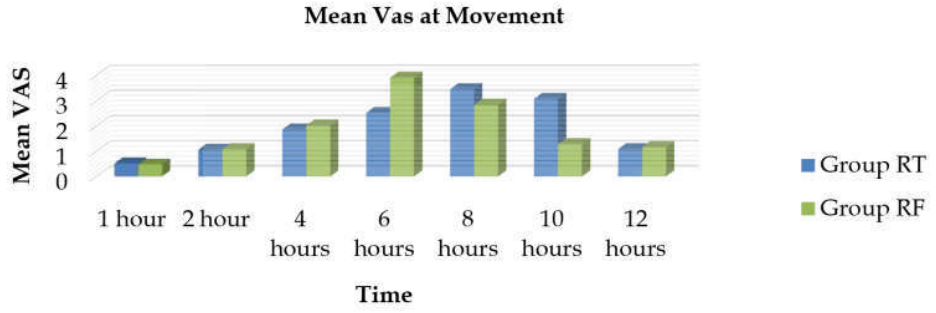
Graph 3:



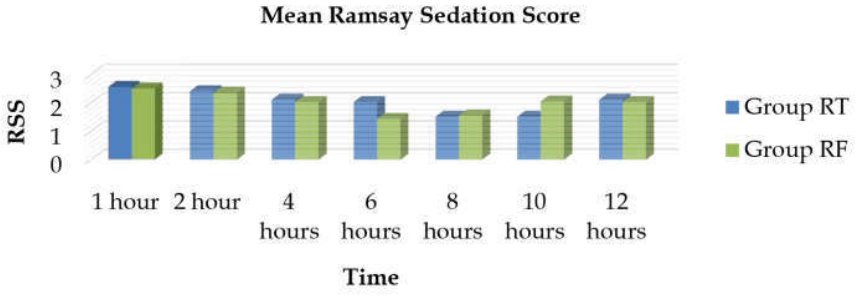
scores ≥ 4 at 10 hours after which they are given rescue analgesia.There is not quite significant (NQS) statistical difference at 8 hours as more patients (24 patients) of Group RT as compared to 22 patients of Group RF complain of pain and are having VAS score ≥ 4 at 8 hours.The statistical difference is again not significant ($p>0.05$) at 12 hours as patients are calmed after giving rescue analgesia.

Looking from the data in the Figure 5 we can see that sedation scores in the two groups is comparable and the statistical difference is not significant ($p>0.05$) at 1, 2 and 4 hours.It is statistically extremely significant at 6 hours and 10 hours ($p<0.05$) as 28 patients of Group RF complain of pain and are agitated with RSS 1 at 6 hours; no patients have RSS 1 in Group RT at 6 hours. Whereas 26 patients of Group RT complain of pain and are agitated with RSS 1 at 10 hours; no patients have RSS 1 in Group RF at 10 hours as their pain was relieved after giving rescue analgesia.There is no statistical difference at 8 hours as rest of the patients in both the groups complain of pain at 8 hours and are agitated with RSS 1 at 8 hours. The statistical difference is again not significant ($p>0.05$) at 12 hours as patients are calmed after giving rescue analgesia.

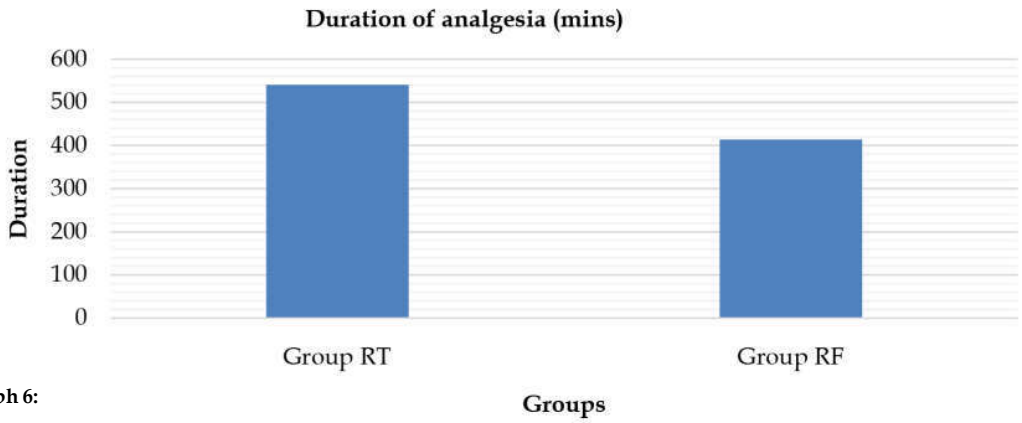
Figure 6 shows the duration of analgesia was around 8 to 10 hours in Group RT whereas it was around 6 to 8 hours in Group RF. The duration of analgesia was longer by around 23% in group RT (mean 540 minutes vs. 414 minutes; $p < 0.001$). Data are shown as the mean ± standard deviation. Rescue analgesia was given to 26 patients of Group RT at 8 hours and to 24 patients at 10 hours whereas it was given to 28 patients of Group RF at 6 hours and to 22 patients at 8 hours.



Graph 4:



Graph 5:



Graph 6:

Pruritis was seen in 7 patients (14%) of group RF and in none of the patients of group RT and was considered statistically significant with p value of 0.0187. Nausea was seen in 4 patients (8%) of group RT and 5 patients (10%) of group RF and Vomiting was seen in 3 patients (6%) of group RT and 4 patients (8%) of group RF which were statistically considered not significant (p >0.05). Hypotension, Bradycardia, Shivering was not seen in any of the patients of group RT and RF.

Discussion

Efficacy of Analgesia

In our study we found out mean hourly VAS scores in patients of GROUP RT was lower till 6 hours after which it started increasing in 26 patients at 8 hours and in 24 patients at 10 hours whereas in patients of GROUP RF, it was lower till 4 hours after which it started increasing in 28 patients at 6 hours and in 22 patients at 8 hours. Thus, the mean hourly pain scores in Group RF was significantly higher than Group RT.

Yunxia Fan et al [2]. observed in their study that the comparative VAS scores obtained in Group tramadol (0.125 % ropivacaine plus tramadol 5mg/ml) and Group fentanyl (0.125% ropivacaine plus fentanyl 3µg/ml) suggested that epidurally tramadol was as effective as fentanyl for labour epidural analgesia but without significant side effects as compared to fentanyl.

In our study, we selected epidural Ropivacaine and concentration was kept 0.2% due to its relative better sensory than motor block profile and lower risk of cardiovascular toxicity.

Scott et al. [6] in a dose finding study with 0.1%, 0.2% and 0.3% Ropivacaine in patients undergoing abdominal surgery demonstrated that 0.2% Ropivacaine 10ml/hr provided the best analgesia and motor block.

Bosenberg A et al. [7] in their study demonstrated that Ropivacaine 0.2% provided satisfactory postoperative pain relief while 0.1% was less effective and 0.3% was associated with higher incidence of motor block with minimal improvement in pain relief.

Duration of Analgesia

In our study, we found out that patients of GROUP RT has longer duration of analgesia than patients of GROUP RF. There is a statistical significance between GROUP RT and GROUP RF where GROUP RT has a duration of analgesia of 540.30±48.53 minutes and GROUP RF has duration of analgesia of 414.00±45.15minutes.

Singh AP, et al. [8] where they found mean duration of analgesia after first epidural bolus of ropivacaine (0.2%) with tramadol (1mg/kg) total volume 10 ml, was 394±46 minutes in patients undergoing adult upper abdominal surgeries.

Doctor TP, et al. [3] in their study found that caudal shot of 0.2% ropivacaine (1mg/kg) with fentanyl (1µg/kg) in children undergoing lower abdominal and urological procedures produced prolonged duration of action of 6.1 hours as compared to 0.25% bupivacaine with fentanyl (1µg/kg) that is 5.6 hours.

Inanoglu, K et al. [9] observed that the duration of analgesia in children undergoing major abdominal surgeries was significantly longer in Group RT receiving epidurally 0.7ml/kg of ropivacaine (0.2%) plus tramadol (2mg/kg) as compared to Group R receiving 0.7ml/kg of ropivacaine alone (0.2%) epidurally (867.9±106.28 minutes and 298.6±28 minutes in Group RT and Group R respectively).

Hemodynamic and Respiratory Changes

In our study, there is no statistical difference between patients receiving epidurally Ropivacaine 0.2% with Tramadol 50 mg (GROUP RT) and patients receiving epidurally Ropivacaine 0.2% with Fentanyl 25 µg (GROUP RF) with respect to Heart Rate, Mean arterial pressure, Respiratory Rate and Oxygen Saturation (p>0.05).

Singh AP et al. [8] where they studied the postoperative analgesic efficacy of epidural tramadol 1mg/kg and 2mg/kg as adjuvant to Ropivacaine (0.2%) in adult upper abdominal surgery would prolong the duration of analgesia without significant changes in HR, RR, MAP and SpO_2 from baseline.

Yunxia Fan et al. [2] in their study found no significant difference in maternal hemodynamic data such as HR, RR, MAP and SpO_2 and neonatal HR between the Group RT receiving epidurally 0.125% ropivacaine plus tramadol (5mg/ml) and Group RF receiving 0.125% ropivacaine plus fentanyl (3µg/ml) at any time points (p>0.005).

Sedation

In our study, there was no statistical difference in sedation scores between two groups at 1, 2, 4, 8

and 12 hours. However, we found extremely significant difference at 6 hours where Ramsay sedation score of patients of GROUP RT was 2.04±0.19 and of patients of GROUP RF was 1.44±0.50; as more patients were agitated in GROUP RF at 6 hours due to complain of pain whereas at 10 hours, Ramsay sedation score of GROUP RT was 1.52±0.61 and of GROUP RF was 2.06±0.23; as more patients were agitated of Group RT at 10 hours due to complain of pain and which was considered statistically extremely significant.

Singh AP et al. [8] observed in their study sedation in 6% patients of Group RT2 receiving epidurally tramadol 2mg/kg with 0.2% ropivacaine and nil in Group RT1 receiving tramadol 1mg/kg with 0.2% ropivacaine in patients undergoing upper abdominal surgeries.

Cohen S et al. [10] in their study observed in patients after caesarean sections that sedation was never described as stronger than mild in all the groups receiving epidurally different concentrations of ropivacaine with fentanyl 3µg/ml and epinephrine 0.5µg/ml.

Adverse Effects

In our study, Pruritis was seen in 7 patients (14%) of patients of GROUP RF and in none of the patients of Group RT.

Yunxia Fan et al. [2] who observed in their study about labour analgesia that pruritis and urinary retention was higher in Group receiving 0.125% ropivacaine plus fentanyl (3µg/ml) and nil in patients receiving epidurally 0.125% ropivacaine plus tramadol (5mg/ml). But in our study, we had catheterised the patients after induction of anaesthesia.

In our study, Nausea were observed in 4 patients (8%) in group RT and in 5 patients (10%) in group RF and Vomiting were observed in 3 patients (6%) in group RT and in 4 patients (8%) of the patients in group RF.

Singh AP et al. [8] observed nausea and vomiting in 10% patients of Group receiving epidurally 10ml of 0.2% ropivacaine with tramadol (1mg/kg) in patients undergoing upper abdominal surgeries.

Korat Reshma et al. [11] observed nausea in 4 patients; vomiting and pruritis in 2 patients receiving 15 ml of 0.75% ropivacaine plus 1µg/kg of fentanyl epidurally in patients undergoing lower limb orthopaedic surgeries.

In our study, no patients were found to have Bradycardia, Hypotension and Respiratory depression.

Conclusion

It can be concluded from the above study that Epidural Tramadol hydrochloride along with Ropivacaine hydrochloride provides significant longer duration of analgesia, lower pain scores and relatively lesser side effects as compared to Epidural Fentanyl citrate with Ropivacaine hydrochloride. Epidurally Tramadol hydrochloride and Fentanyl citrate as an adjuvant to Ropivacaine hydrochloride proved to have stable hemodynamic profile.

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