

## Prospective Non-Randomized Comparative Assessment of the Postoperative Analgesic Efficacy of Epidural Ropivacaine and Ropivacaine with Tramadol in Patients Undergoing Abdominal Surgeries

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### Abstract

**Aim:** The aim of the study was to compare the postoperative analgesic efficacy of epidural Ropivacaine and Ropivacaine with Tramadol in adults undergoing abdominal surgeries under general anesthesia.

**Methods:** The study was a prospective non-randomized, double arm, single-blind, controlled study conducted at Department of Anaesthesiology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar for one year after obtaining written informed consent. The study was started after getting the approval of Institutional Ethics Committee. In our study, 50 subjects were included.

**Results:** In our study while analyzing the age distribution, in the Ropivacaine group, the majority of the study subjects belonged to the 31-40 years age class interval (n=10, 40%) with a mean age of 43.07 years. In patients belonging to Ropivacaine group, the majority of the study subjects belonged to  $\leq 240$  minutes duration of postoperative analgesia class interval (n=24, 96%) with a mean duration of postoperative analgesia of 220.57 minutes. In the Ropivacaine with Tramadol group majority belonged to 300-360 minutes duration of postoperative analgesia class interval (n=15, 60%). The association between heart rate distribution and intervention groups is considered to be non-significant since p-value was  $> 0.05$  as per unpaired t-test. The association between mean peripheral capillary oxygen saturation distribution and intervention groups is considered to be nonsignificant since p-value was  $> 0.05$  as per unpaired t-test. The association between mean respiratory rate distribution and intervention groups is considered to be nonsignificant since p-value was  $> 0.05$  as per unpaired t-test.

**Conclusion:** We concluded that the addition of 1 mg/kg of Tramadol improves the postoperative analgesic efficacy of epidural 0.2% Ropivacaine by prolonging the duration of analgesia and providing good sedation with no significant hemodynamic alterations, nausea, vomiting and pruritus.

**Keywords:** Ropivacaine, Tramadol, Ramsay sedation score, Pruritus, Oxygen saturation

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## Introduction

Postoperative pain is of prime concern following abdominal surgeries. Evidence suggests that surgery causes suppression of the immune system and that this suppression is dependent and proportionate to the invasiveness of the surgery. [1] This deleterious effect can be prevented by good postoperative analgesia and thereby reduce the infection rate and morbidity in the postoperative period. One of the most commonly practiced and efficient methods for providing postoperative analgesia in case of abdominal surgeries is regional analgesia with local anesthetic drugs and other adjuvants via the epidural catheter. By providing epidural analgesia, the patient has adequate pain relief. This helps in abolishing the restriction of movement of the diaphragm. Hence, effective epidural analgesia will enable a patient to take deep breaths, make efficient cough efforts and move with ease. This, in turn, helps in an enhanced early recovery with a reduction in co-morbidities like chest infections and deep vein thrombosis. [2] Local anesthetic Ropivacaine is preferred nowadays for epidural postoperative analgesia as it has favorable sensory block profile. It's less lipophilic nature makes its penetration selective for thin unmyelinated nerve fibers which transmit pain and also causes less incidence of cardiovascular toxicity compared to other local anesthetic drugs. Tramadol, a synthetic analog of codeine, is a centrally acting analgesic. Its affinity for mu receptors is moderate and for kappa and delta receptors is weak. Tramadol, when given via epidural route, causes prolongation of the postoperative analgesia duration, exhibits reduced pain scores and good sedation scores with lack of respiratory depressant effect. It has been used and being studied as an adjuvant to epidural local anesthetic drugs for effective postoperative analgesia. [3] Effective management of postoperative

pain after major surgery is better achieved with epidural administration of local anesthetic drugs and opioids since the 1980s. This would help in providing effective pain relief with minimal side effects and excellent patient satisfaction. It would also reduce the central sensitization and organ dysfunction secondary to pain, resulting in an improved outcome. It helps in producing total dynamic pain relief which means the complete absence of pain on moving and coughing following major upper abdominal surgery. [4]

Local anesthetic Ropivacaine is preferred nowadays for epidural postoperative analgesia as it has favorable sensory block profile. It's less lipophilic nature makes its penetration selective for thin unmyelinated nerve fibers which transmit pain and also causes less incidence of cardiovascular toxicity compared to other local anesthetic drugs. Tramadol, a synthetic analog of codeine, is a centrally acting analgesic. Its affinity for mu receptors is moderate and for kappa and delta receptors is weak. Tramadol, when given via epidural route, causes prolongation of the postoperative analgesia duration, exhibits reduced pain scores and good sedation scores with lack of respiratory depressant effect. It has been used and being studied as an adjuvant to epidural local anesthetic drugs for effective postoperative analgesia. [5]

Tramadol, a synthetic 4-phenyl-piperidine analog of codeine, is a racemic mixture of two enantiomers, with synergistic antinociceptive interaction. [6] The (+) enantiomer has moderate affinity for the opioids  $\mu$  receptor and inhibits serotonin uptake, and the (-) enantiomer is a potent norepinephrine synaptic release inhibitor. The result is an opioid with a lack of respiratory depressant effects despite an analgesic potency that has been shown to be approximately equal to that of pethidine in some studies. [7-9]

Effective management of postoperative pain after major surgery is better achieved with epidural administration of local anesthetic drugs and opioids since the 1980s. This would help in providing effective pain relief with minimal side effects and excellent patient satisfaction. It would also reduce the central sensitization and organ dysfunction secondary to pain, resulting in an improved outcome. It helps in producing total dynamic pain relief which means the complete absence of pain on moving and coughing following major upper abdominal surgery. [10]

The aim of the study was to compare the postoperative analgesic efficacy of epidural Ropivacaine and Ropivacaine with Tramadol in adults undergoing abdominal surgeries under general anesthesia.

### Methods

The study was a prospective non-randomized, double arm, single-blind, controlled study conducted at Department of Anaesthesiology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar India for one year. The study was started after getting the approval of Institutional Ethics Committee. The study was conducted in patients scheduled for abdominal surgeries done under general anesthesia at Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar after obtaining written informed consent. The sample size was determined based on the study Postoperative analgesic efficacy of epidural Tramadol as an adjuvant to Ropivacaine in adult upper abdominal surgeries. In our study, 50 subjects were included (n=25 in Group R arm and n=25 in Group RT arm).

### Inclusion criteria

- Patients undergoing elective abdominal surgeries under general anesthesia.
- Age between 30 to 60 years.
- Males and females.
- ASA class I and II.

- Patients who have given validly informed consent.
- Duration of surgery less than 3 hours.

### Exclusion criteria

- Patients with an allergy or sensitivity to an opioid group of drugs and local anesthetics.
- Patients with spinal deformities.
- Any contraindication to epidural anesthesia.
- Patients with neurological disorders.
- Impaired ability to communicate (e.g., confusion, poor hearing or language barrier).
- Patients who are unconscious or severely ill.
- Coagulopathies.

Patients who satisfied the above-mentioned inclusion criteria selected were counseled about the risks and benefits involved in the study. After getting consent, patients who were willing to be included in the study were enrolled and analyzed. A total of 50 patients were included in the study. Patients were divided into two groups of 25 in each into group R and group RT. Patients were preoperatively evaluated, clinically examined and proper investigations did prior to the assessment. Procedures were explained in detail and written consent was obtained. Inj. Metoclopramide hydrochloride 10 mg IM and Inj. Ranitidine hydrochloride 50 mg IV was given half an hour prior to the surgery.

The statistical analysis was performed with IBM SPSS Statistics for Windows, Version 16.0 (IBM Corp., Armonk, NY, USA). The continuous variables were compared by one-way analysis of variance test. Discrete variables were compared by Fisher's exact test/Chi-square test, whichever appropriate.  $P < 0.05$  was considered significant.

### Results

**Table 1: Age distribution and Duration of postoperative analgesia**

Age in years	Ropivacaine (n)	Ropivacaine + Tamadol (n)
≤30 years	2	2
31-40 years	10	5
41-50 years	5	7
51-60 years	8	11
Duration of postoperative analgesia in minutes		
≤240 minutes	24	0
241-300 minutes	1	10
301-360 minutes	0	15

In our study while analyzing the age distribution, in the Ropivacaine group, the majority of the study subjects belonged to the 31-40 years age class interval (n=10, 40%) with a mean age of 43.07 years. In the Ropivacaine with Tramadol group majority belonged to the 51-60 years age class interval (n=11, 44%) with a mean age of 47.10 years. The association with respect to age distribution between the two groups is considered to be nonsignificant since p-value is > 0.05 as per unpaired t-test.

The association between the intervention groups and duration of postoperative analgesia among study subjects was considered to be statistically significant

since  $p < 0.05$ . In patients belonging to Ropivacaine group, the majority of the study subjects belonged to ≤ 240 minutes duration of postoperative analgesia class interval (n=24, 96%) with a mean duration of postoperative analgesia of 220.57 minutes. In the Ropivacaine with Tramadol group majority belonged to 300-360 minutes duration of postoperative analgesia class interval (n=15, 60%) with a mean duration of postoperative analgesia of 309.90 minutes. The increased mean duration of postoperative analgesia in Ropivacaine with Tramadol group compared to the Ropivacaine group is statistically significant at the p-value is <0.0001 as per unpaired t-test.

**Table 2: The Ramsay sedation score among the patients and Prevalence of pruritus among patients**

Ramsay sedation score	Ropivacaine (n)	Ropivacaine + Tamadol (n)
Score 1	20	0
Score 2	5	1
Score 3	0	22
Score 4	0	2
Prevalence of pruritus among patients		
Absent	25	22
Present	0	3

The association between the intervention groups and Ramsay sedation score among study subjects was considered to be statistically significant since  $p < 0.05$ . In patients belonging to Ropivacaine group, the majority of the study subjects belonged to RSS 1 class interval (n=20, 80%) with a mean RSS of 1.26 scoring points. In the Ropivacaine with Tramadol group

majority belonged to RSS 3 class interval (n=26, 88%) with a mean RSS of 3.06 scoring points. The increased mean Ramsay sedation score in Ropivacaine with Tramadol group compared to the Ropivacaine group was statistically significant at the p-value was <0.0001 as per unpaired t-test.

In our study while analyzing the pruritus status, the majority of the study subjects had no pruritus (n=25, 100.00%) in the Ropivacaine group. In the Ropivacaine with Tramadol group majority too had no

pruritus (n=22, 88%). The association between pruritus status and intervention groups is considered to be nonsignificant since p-value is >0.05 as per Fisher's exact test.

**Table 3: The heart rate variations among two groups**

Ramsay sedation score	Ropivacaine (n)	Ropivacaine + Tamadol (n)
Baseline	78.50	78.67
15 minutes	77.23	77.40
30 minutes	76.83	77.03
45 minutes	76.60	77.37
60 minutes	76.63	77.07
75 minutes	76.13	76.57
90 minutes	76.47	76.77
105 minutes	76.07	76.13
120 minutes	75.87	75.87

In our study while analyzing the heart rate distribution, the study subjects in the Ropivacaine group had a mean baseline HR of 78.50 beats per minute, mean ending HR of 75.87 beats per minute and mean overall HR of 76.71 beats per minute. In the Ropivacaine with Tramadol group the study subjects in the

Ropivacaine group had a mean baseline HR of 78.67 beats per minute, mean ending HR of 75.87 beats per minute and mean overall HR of 76.99 beats per minute. The association between heart rate distribution and intervention groups is considered to be non-significant since p-value was > 0.05 as per unpaired t-test.

**Table 4: Peripheral capillary oxygen saturation among patients**

Peripheral capillary oxygen saturation	Ropivacaine (n)	Ropivacaine + Tamadol (n)
Baseline	99.47	99.33
15 minutes	99.57	99.50
30 minutes	99.80	99.80
45 minutes	99.83	99.80
60 minutes	99.70	99.93
75 minutes	99.80	99.63
90 minutes	99.93	99.90
105 minutes	99.90	99.83
120 minutes	100.00	99.97

In our study while analyzing the mean peripheral capillary oxygen saturation distribution, the study subjects in the Ropivacaine group had a mean baseline SPO<sub>2</sub> of 99.47 %, mean ending SPO<sub>2</sub> of 100 % and mean overall SPO<sub>2</sub> of 99.79 %. In the Ropivacaine with Tramadol group, the study subjects in the Ropivacaine

group had a mean baseline SPO<sub>2</sub> of 99.33 %, mean ending SPO<sub>2</sub> of 99.97 % and mean overall SPO<sub>2</sub> of 99.74 %. The association between mean peripheral capillary oxygen saturation distribution and intervention groups is considered to be nonsignificant since p-value was > 0.05 as per unpaired t-test.

**Table 5: Respiratory rate among patients**

Respiratory rate	Ropivacaine (n)	Ropivacaine + Tamadol (n)
Baseline	18.47	19.00
15 minutes	17.40	17.60
30 minutes	16.80	16.67
45 minutes	16.57	16.93
60 minutes	16.30	16.27
75 minutes	16.20	16.43
90 minutes	16.00	16.50
105 minutes	15.67	15.77
120 minutes	15.27	15.60

In our study while analyzing the mean respiratory rate distribution, the study subjects in the Ropivacaine group had a mean baseline RR of 18.47 breaths per min, mean ending RR of 15.27 breaths per min. In the Ropivacaine with Tramadol group, the study subjects in the Ropivacaine group had a mean baseline RR of 19.00 breaths per min, mean ending RR of 15.60 breaths per min. The association between mean respiratory rate distribution and intervention groups is considered to be nonsignificant since p-value was  $> 0.05$  as per unpaired t-test.

### Discussion

Patients undergoing abdominal surgeries are more prone to adverse effects of acute postoperative pain. Epidural postoperative analgesia with local anesthetics and adjuvants like opioids provides an effective mode of analgesia thereby preventing the occurrence of adverse effects like tachycardia, hypertension, immunosuppression, hyperglycemia, respiratory tract infections, paralytic ileus, delay in ambulation, etc. [11]

Anil P. Singh, et al. have compared the efficacy of postoperative analgesia in upper abdominal surgeries under general anesthesia in adults with two different doses of Tramadol (1 mg/kg and 2 mg/kg) as an adjuvant to 0.2% Ropivacaine via epidural route. The study was conducted in 90 patients divided into 3 equal groups. The results revealed that mean duration of

analgesia was significantly higher in the group that received 2mg/kg Tramadol with Ropivacaine when compared with other two groups. Hemodynamic parameters remained stable in all 3 groups. [12]

Kerem Inanoglu, et al. in a comparative study of postoperative effects of epidural 0.2% Ropivacaine and epidural Tramadol (2 mg/kg) with 0.2% Ropivacaine in a volume of 0.7 ml/kg for major abdominal surgeries in 44 children who belonged to the age group between 2 and 12 years. [13] Güneş MD, et al. studied the effect of caudal 0.2% Ropivacaine (1 mg/kg), Ropivacaine with Ketamine (0.25 mg/kg), Ropivacaine with Tramadol (1 mg/kg) for postoperative analgesia in 99 children of age group 1 and 10 years scheduled for elective inguinal hernia repair under general anesthesia. Both groups were comparable with respect to age, weight, and duration of the operation. [14]

There were no significant changes in HR, RR, and blood pressure from the baseline with the use of epidural tramadol with ropivacaine in this study. Ertugrul et al. findings on hemodynamic changes with epidural ropivacaine and tramadol were similar to our findings. [15] Baraka et al. compared the perioperative hemodynamic status of two groups of patients undergoing major abdominal surgery who received morphine 4 mg and tramadol 100 mg epidurally and found no difference. [16]

Eighty adult patients scheduled for elective lower abdominal surgery were randomly divided to one of four groups to receive analgesics with patient-controlled analgesia pumps. Patients in group I received IV Tramadol, group II patients IV Fentanyl, group III patients epidural Tramadol, and group IV patients an epidural infusion of 0.125% Ropivacaine with 2 micrograms/ml Fentanyl. The patients were observed and followed up hourly up to 6 hours and 4th hourly up to 24 hours after surgery. Results showed that in all group's adequate analgesia was observed. [17]

Our study has two main limitations. First, a different type of upper abdominal surgeries may have different severity of pain due to handling of tissues and diaphragmatic irritation that leads to a difference in dose and frequency of drug requirements. Second, these results may vary from studies performed on other ethnic groups considering the variations in subjective anesthetic sensitivity may contribute to differences in drug requirement. [18]

### Conclusion

We concluded that the addition of 1 mg/kg of Tramadol improves the postoperative analgesic efficacy of epidural 0.2% Ropivacaine by prolonging the duration of analgesia and providing good sedation with no significant hemodynamic alterations, nausea, vomiting and pruritus. However, we suggest that more prospective studies are required to recommend tramadol as a useful adjuvant to ropivacaine for enhancing postoperative analgesia in adult upper abdominal surgeries.

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