e-ISSN: 0976-822X, p-ISSN:2861-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(6); 246-253

Original Research Article

A Randomized Comparative Clinical Assessment of Postoperative Analgesic Efficacy of Epidural Ropivacaine and Ropivacaine with Tramadol in Patients Undergoing Abdominal Surgeries: A Prospective Clinical Study

Bhagwan Das[1], Deepak Kumar[2], Pramod Kumar Sinha[3]

[1]Assistant Professor, Department of Anesthesia, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India

[2]Assistant Professor, Department of Anesthesia, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India

[3]Associate Professor and HOD, Department of Anesthesia, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India

Received: 08-02-2023 / Revised: 15-03-2023 / Accepted: 13-04-2023
Corresponding author: Dr. Deepak Kumar
Conflict of interest: Nil

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 randomized, double arm, single-blind, controlled study. The study was conducted in patients scheduled for abdominal surgeries done under general anesthesia at Anugrah Narayan Magadh Medical College and Hospital, Gaya, India for one year.The sample size was determined based on the study. 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 ≤ 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

Introduction

The aim of postoperative analgesia is to provide subjective comfort with minimum side-effects, with early ambulation and restoration of function. Pain scores of 4–6 on a 10 visual analog scale (VAS) are not unusual after laparotomy and a large number of patients experienced moderate to severe pain. [1] Moreover, in upper abdominal surgery, the severity of postoperative pain is higher, and it restricts the movement of diaphragm. This increases the incidence of respiratory complications (basal atelectasis, pneumonitis), hospital stay, cost, surgical morbidity, and mortality in such surgeries. Regional analgesia with the local anesthetic drug via epidural catheter is established method of satisfactory postoperative pain management. Today, among local anesthetic drugs, ropivacaine is preferred due to its favorable sensory block profile and lower cardiovascular toxicity compared to others. [2] Since it is less lipophilic than bupivacaine, its penetration is more selective for thin unmyelinated pain‐transmitting nerve fibers compared to larger motor nerve fibers. [3,4]

Morphine in 1981, several studies have provided evidence of prolonged analgesia following its use but nausea/ vomiting, pruritus, urinary retention, and respiratory depression are associated side‐effects with epidural opioids. [5,6] Epidural tramadol also provides prolong postoperative pain relief with advantage of lack of respiratory depressant effect. [7,8] Tramadol, a synthetic 4‐phenyl‐piperidine analog of codeine, is a racemic mixture of two enantiomers, with synergistic anti‐nociceptive interaction. [9] The (+) enantiomer has moderate affinity for the opioids μ 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. [7,10,11] Furthermore, animal work has suggested that tramadol may have a selective spinal action. [12,13]

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. [14]

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 randomized, double arm, single-blind, controlled study. The study was conducted in patients scheduled for abdominal surgeries done under general anesthesia at Anugrah Narayan Magadh Medical College and Hospital, Gaya, India for one year. 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	3	3
31-40 years	10	5
41-50 years	6	8
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 42.08 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 SPO2 of 99.47 %, mean ending SPO2 of 100 % and mean overall SPO2 of 99.79 %. In the Ropivacaine with Tramadol group, the study subjects in the Ropivacaine group had a mean baseline SPO2 of 99.33 %, mean ending SPO2 of 99.97 % and mean overall SPO2 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. [15]

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. [16]

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. [17] 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. [18]

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. [19] 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. [20]

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. [21]

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.

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.

References

1. Kuhn S, Cooke K, Collins M, Jones JM, Mucklow JC. Perceptions of pain relief after surgery. British Medical Journal. 1990 Jun 30;300(6741):1687-90.
2. McClellan KJ, Faulds D. Ropivacaine: an update of its use in regional anaesthesia. Drugs. 2000 Nov; 60:1065 -93.
3. Hansen TG. Ropivacaine: a pharmacological review. Expert review of neurotherapeutics. 2004 Sep 1;4(5): 781-91.
4. Rosenberg PH, Heinonen E. Differential sensitivity of A and C nerve fibres to long-acting amide local

anaesthetics. British journal of anaesthesia. 1983 Feb 1;55(2):163-7.
5. Semsroth M, Gabriel A, Sauberer A, Wuppinger G. Regional anaesthetic procedures in paediatric anaesthesia. Der Anaesthesist. 1994 Jan;43:55-72.
6. Krane EJ, Dalens BJ, Murat I, Murrell D. The safety of epidurals placed during general anesthesia. Regional anesthesia and pain medicine. 1998 Sep 1;23(5):433.
7. Vickers MD, O'flaherty D, Szekely SM, Read M, Yoshizumi J. Tramadol: pain relief by an opioid without depression of respiration. Anaesthesia. 1992 Apr;47(4):291-6.
8. Senel AC, Akyol A, Dohman DA, Solak M. Caudal bupivacaine-tramadol combination for postoperative analgesia in pediatric herniorrhaphy. Acta Anaesthesiologica Scandinavica. 2001 Jul;45(6):786-9.
9. Raffa RB, Friderichs EL, Reimann WO, Shank RP, Codd EE, Vaught JL, Jacoby HI, Selve NO. Complementary and synergistic antinociceptive interaction between the enantiomers of tramadol. Journal of Pharmacology and Experimental Therapeutics. 1993 Oct 1;267(1):331-40.
10. O'Flaherty D, Szekely S, Vickers MD. Tramadol versus pethidine analgesia in post-operative pain. Pain. 1990 Jan 1;41:S179.
11. Lehman KA, Jung C, Hoeckle W. Tramadol and pethidine in postoperative pain therapy: a randomized double-blind trial with intravenous on-demand analgesia. Schmerz Pain Douleur. 1985;6:88-100.
12. Mattia A, Vanderah T, Raffa RB, Vaught JL, PORREcA F. Tramadol produces antinociception through spinal sites, with minimal tolerance, in mice. InFASEB JOURNAL 1991 Mar 11 (Vol. 5, No. 4, pp. A473-A473). 9650 ROCKVILLE PIKE, BETHESDA, MD 20814-3998: FEDERATION AMER SOC EXP BIOL.
13. Bernatzky G, Jurna I. Itrathecal injection of codeine, buprenorphine, tildine, tramadol, and nefopam depresses the tail-flick response in rats. European journal of pharmacology. 1986 Jan 14;120(1):75-80.
14. McMahon SB. Mechanisms of sympathetic pain. British medical bulletin. 1991 Jul 1;47(3):584-600.
15. Levine JD, Fields HL, Basbaum AI. Peptides and the primary afferent nociceptor. Journal of Neuroscience. 1993 Jun 1;13(6):2273-86.
16. Manikian B, Cantineau JP, Bertrand M, Kieffer E, Sartene R, Viars P. Improvement of diaphragmatic function by a thoracic extradural block after upper abdominal surgery. Anesthesiology. 1988 Mar 1;68(3):379 -86.
17. Inanoglu K, Ozcengiz D, Gunes Y, Unlugenc H, Isik G. Epidural ropivacaine versus ropivacaine plus tramadol in postoperative analgesia in children undergoing major abdominal surgery: a comparison. Journal of anesthesia. 2010 Oct;24(5):700-4.
18. Güneş Y, Secen M, Özcengiz D, Gündüz M, Balcioğlu O, Işik G. Comparison of caudal ropivacaine, ropivacaine plus ketamine and ropivacaine plus tramadol administration for postoperative analgesia in children. Pediatric Anesthesia. 2004 Jul;14(7):557-63.
19. Ertugrul F, Karakaya H, Pürnek F, Celikbilek G, Akbas M, Titiz TA. Comparison of caudal ropivacaine and ropivacaine plus tramadol administration for postoperative analgesia in children: A-761. European Journal of Anaesthesiology| EJA. 2004 Jun 1;21:187.
20. Baraka A, Jabbour S, Ghabash M, Nader A, Khoury G, Sibai A. A comparison of epidural tramadol and epidural morphine for postoperative analgesia. Canadian Journal of Anaesthesia. 1993 Apr;40(4):308-13.

21. Liu SS, Carpenter RL, Mackey DC, Thirlby RC, Rupp SM, Shine TS, Feinglass NG, Metzger PP, Fulmer JT, Smith SL. Effects of perioperative analgesic technique on rate of recovery after colon surgery. The Journal of the American Society of Anesthesiol ogists. 1995 Oct 1;83(4): 757-65.