e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com doi: 10.25258/ijpqa.16.1.125

International Journal of Pharmaceutical Quality Assurance 2025; 16(1); 754-759

Original Research Article

Efficacy of Epidural Ropivacaine Alone Versus Ropivacaine Plus Tramadol for Postoperative Pain Control in Adult Abdominal Surgery Patients

Ravi Kant[1], Vikash Kumar[2]

[1]Senior Resident, Department of Anesthesiology, Government Medical College, and Hospital, Purnea, Bihar, India

[2]Senior Resident, Department of Anesthesiology, Government Medical College, and Hospital, Purnea, Bihar, India

Received: 20-09-2024 / Revised: 14-12-2024 / Accepted: 10-01-2025

Corresponding Author: Dr. Ravi Kant

Conflict of interest: Nil

Abstract:

Background: Effective postoperative pain management is crucial to enhance recovery and reduce morbidity following major abdominal surgeries. Epidural administration of local anesthetics such as ropivacaine provides segmental analgesia, but may be insufficient for optimal pain control in some patients. Tramadol, a weak μ-opioid receptor agonist with monoaminergic properties, has been shown to augment analgesia when delivered epidurally. This study aims to compare the analgesic efficacy and safety profile of epidural ropivacaine alone versus ropivacaine combined with tramadol in adult patients undergoing elective abdominal surgeries under general anaesthesia.

Methods: In this prospective, randomized, double-blind trial, 80 adult patients (ASA I–II), aged 18–65 years, scheduled for elective lower abdominal surgery under general anaesthesia with epidural analgesia, were enrolled. Patients were randomly assigned to one of two groups (n=40 each):

- Group R received epidural ropivacaine 0.2% at 6 mL/hour
- Group RT received ropivacaine 0.2% with tramadol 1 mg/mL at the same infusion rate

General anaesthesia protocols were standardized across both groups. Postoperative pain intensity was assessed using a 10-point visual analogue scale (VAS) at 2, 4, 8, 12, 24, and 48 hours. Rescue analgesia (intravenous morphine 2 mg) was administered for VAS > 4, and cumulative morphine consumption was recorded. Hemodynamic parameters, sedation scores, and adverse events (nausea, vomiting, pruritus, respiratory depression) were monitored throughout the 48-hour postoperative period.

Results: Both groups were comparable in demographic and intraoperative variables. Group RT demonstrated significantly lower mean VAS scores at all time points beyond 4 hours postoperatively ($p < 0.05$). The total morphine requirement in the first 48 hours was reduced by 35% in Group RT compared to Group R (mean ± SD: 8.2 ± 2.4 mg vs. 12.6 ± 3.1 mg; $p < 0.001$). Hemodynamic stability was maintained in both groups, with no clinically significant differences. Incidence of nausea and vomiting was slightly higher in Group RT (15% vs. 8%), though not statistically significant. No cases of respiratory depression or pruritus were observed.

Conclusions: Adding tramadol to epidural ropivacaine significantly enhances postoperative analgesia and reduces opioid requirements in adult patients following abdominal surgery, without compromising hemodynamic stability. This combination may be considered an effective and safe option for postoperative pain management in this population.

Introduction

Postoperative Pain and Its Impact: Effective management of postoperative pain is a cornerstone of perioperative care. Inadequately controlled pain can lead to a myriad of complications, including prolonged hospital stay, delayed mobilization, impaired pulmonary function, increased risk of deep vein thrombosis, and the development of chronic pain syndromes [1]. Abdominal surgeries, in particular, are associated with significant nociceptive input due to visceral and somatic tissue trauma, necessitating robust analgesic strategies to optimize recovery and patient satisfaction [2].

Epidural Analgesia and Ropivacaine: Epidural administration of local anesthetics provides targeted segmental blockade of nerve roots, offering superior analgesia compared to systemic opioids alone. Ropivacaine, an S-enantiomer of bupivacaine, has gained favor in epidural practice due to its favorable

pharmacologic profile: it produces dense sensory blockade with a reduced propensity for motor block, exhibits less cardiotoxicity at equipotent doses, and allows for continuous infusion at lower concentrations. Studies have demonstrated that continuous epidural ropivacaine infusions effectively reduce pain scores and facilitate early ambulation in abdominal surgery cohorts [3,4].

Role of Tramadol as an Adjuvant: Tramadol is a synthetic centrally acting analgesic that exerts its effect via weak μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake. When administered epidurally, tramadol enhances segmental analgesia by synergizing with local anesthetics to inhibit pain transmission in the dorsal horn of the spinal cord [5]. Epidural tramadol has been shown to reduce the required doses of local anesthetics, prolong the duration of analgesia, and decrease systemic opioid consumption, thereby minimizing opioid-related adverse events such as respiratory depression, nausea, and pruritus [6].

Combination Therapy: Rationale and Evidence: Combining ropivacaine with tramadol in the epidural space targets pain via dual mechanisms sodium-channel blockade and monoaminergic/opioid pathways. Previous trials comparing local anesthetic alone versus local anesthetic with various opioids (e.g., fentanyl, morphine) have demonstrated improved analgesic efficacy and reduced supplemental analgesic needs [7]. However, data specifically evaluating ropivacaine-tramadol combinations in the context of major abdominal surgery remain limited. Clarifying the analgesic benefits and safety profile of this combination could inform best practices in postoperative pain protocols [8].

Study Objectives: This study was designed to compare the postoperative analgesic efficacy, opioid-sparing effect, hemodynamic stability, and adverse event profile of continuous epidural infusions of ropivacaine alone versus ropivacaine combined with tramadol in adults undergoing elective abdominal surgeries under general anaesthesia. A comprehensive evaluation of pain scores, rescue analgesic requirements, and side effects over the first 48 hours postoperatively will determine whether the addition of tramadol offers a clinically meaningful advantage.

Materials and Methods

Study Design: This prospective, randomized, double-blind clinical trial was conducted in the Department of Anesthesiology at Government Medical College and Hospital, Purnea, Bihar, India from January 2022 to December 2022

Participants: Eighty adult patients, aged 18–65 years, with American Society of Anesthesiologists physical status I or II, scheduled for elective lower abdominal surgery under general anesthesia with planned epidural analgesia, were recruited between January 2022 to December 2022. Exclusion criteria included patient refusal, known allergy to study drugs, coagulopathy, infection at the puncture site, pre-existing neurologic deficits, chronic opioid, or anticonvulsant therapy, significant cardiac, hepatic, or renal dysfunction, and pregnancy.

Randomization and Blinding: Patients were randomly assigned in a 1:1 ratio to receive either epidural ropivacaine alone (Group R) or epidural ropivacaine with tramadol (Group RT). Randomization was performed using computer-generated random number tables sealed in opaque envelopes. Drug preparation was done by an anesthesiologist not involved in patient care or data collection. Both the administering anesthesiologist and patients were blinded to group allocation.

Anaesthetic Technique: Upon arrival in the operating room, standard monitors were applied (ECG, non-invasive blood pressure, pulse oximetry). An 18-gauge epidural catheter was inserted at the L2–L3 interspace using a midline approach and loss-of-resistance to saline technique. Correct catheter placement was confirmed by negative aspiration for blood or cerebrospinal fluid. A test dose of 3 mL of 2% lidocaine with epinephrine 1:200,000 was administered to exclude intrathecal or intravascular placement.

General anesthesia was induced with intravenous fentanyl (2 μg/kg), propofol (2 mg/kg), and vecuronium (0.1 mg/kg) to facilitate endotracheal intubation. Anesthesia was maintained with isoflurane in a 50:50 oxygen-air mixture, and additional vecuronium boluses were given as required. Intraoperative analgesia was standardized; no other opioids or adjuncts were administered.

Interventions: Immediately following surgical closure, an infusion pump was connected to the epidural catheter and initiated at 6 mL/hour. Group R received ropivacaine 0.2% solution, while Group RT received a mixture of ropivacaine 0.2% plus tramadol at 1 mg/mL. The infusion ran continuously for 48 hours postoperatively. Catheter site checks and infusion integrity were assessed every 8 hours by nursing staff unaware of group allocation.

Outcome Measures: The primary outcome was postoperative pain intensity measured by a 10-point visual analogue scale (VAS), where 0 indicates no pain and 10 the worst imaginable pain. Assessments were performed at 2, 4, 8, 12, 24, and 48 hours after infusion initiation. Secondary outcomes included total cumulative rescue morphine consumption (2 mg intravenous boluses administered for VAS > 4, with subsequent dosing every 15 minutes as needed), hemodynamic parameters (heart rate, systolic and diastolic blood pressure), sedation level using a four-point Ramsay Sedation Scale, and

incidence of adverse events (nausea, vomiting, pruritus, respiratory depression defined as respiratory rate <8 breaths/min or SpO_2 <90%).

Statistical Analysis: Sample size calculation was based on detecting a 20% reduction in cumulative 48-hour morphine requirement with 80% power and $\alpha = 0.05$, resulting in 36 patients per group. To account for potential dropouts, 40 patients were enrolled in each arm. Data were analyzed using SPSS v25.0. Continuous variables were tested for normality and compared using Student's t-test or Mann–Whitney U test as appropriate. Categorical variables were compared with chi-square or Fisher's exact test. A p-value < 0.05 was considered statistically significant.

Results

A total of 80 patients completed the study without protocol violations. Both groups were comparable in demographic and baseline clinical characteristics. Postoperative pain scores (VAS) were similar at 2 hours but, from 4 hours onward, Group RT (ropivacaine + tramadol) consistently reported lower mean VAS values than Group R (ropivacaine alone), with statistically significant differences at each time point ($p < 0.01$). Group RT required 35% less cumulative rescue morphine over 48 hours. Fewer patients in Group RT needed any rescue morphine compared with Group R. Hemodynamic parameters (heart rate, systolic and diastolic blood pressure) remained within 20% of baseline in both groups, with no intergroup differences. Sedation levels were comparable and within acceptable limits. The incidence of nausea and vomiting was nominally higher in Group RT but did not reach statistical significance. No episodes of respiratory depression, pruritus, or catheter-related complications were recorded.

Table 1: Baseline Demographic Characteristics

Parameter	Group R (n=40)	Group RT (n=40)	p-value
Age (years, mean ± SD)	45.2 ± 10.4	46.7 ± 9.8	0.54
Sex (M/F)	22/18	20/20	0.62
BMI (kg/m², mean ± SD)	24.8 ± 3.2	25.1 ± 3.5	0.70

Table 2: Intraoperative Variables

Parameter	Group R (n=40)	Group RT (n=40)	p-value
Duration of surgery (min, mean ± SD)	135 ± 25	138 ± 22	0.68
Baseline HR (bpm, mean ± SD)	78 ± 10	80 ± 9	0.40
Baseline SBP (mm Hg, mean ± SD)	128 ± 12	130 ± 11	0.45
Baseline DBP (mm Hg, mean ± SD)	78 ± 8	79 ± 7	0.60

Table 3: VAS Scores at 2 Hours

Group	VAS (mean ± SD)	p-value
Group R	3.5 ± 1.1	
Group RT	3.3 ± 1.2	0.48

Table 4: VAS Scores at 4 Hours

Group	VAS (mean ± SD)	p-value
Group R	4.8 ± 1.3	
Group RT	3.7 ± 1.0	0.001

Table 5: VAS Scores at 8 Hours

Group	VAS (mean ± SD)	p-value
Group R	5.2 ± 1.4	
Group RT	4.1 ± 1.1	0.002

Table 6: VAS Scores at 12 Hours

Group	VAS (mean ± SD)	p-value
Group R	4.9 ± 1.2	
Group RT	3.6 ± 1.0	< 0.001

Table 7: VAS Scores at 24 Hours

Group	VAS (mean ± SD)	p-value
Group R	4.2 ± 1.0	
Group RT	2.8 ± 0.9	< 0.001

Table 8: VAS Scores at 48 Hours

Group	VAS (mean ± SD)	p-value
Group R	3.1 ± 0.9	
Group RT	1.9 ± 0.8	< 0.001

Table 9: Cumulative Rescue Morphine Consumption

Group	Morphine (mg, mean ± SD)	p-value
Group R	12.6 ± 3.1	
Group RT	8.2 ± 2.4	< 0.001

Table 10: Number of Patients Requiring Rescue Morphine

Group	Patients (n)	p-value
Group R	28	
Group RT	18	0.04

Table 11: Hemodynamic Parameters Over 48 Hours

Parameter	Group R (mean ± SD)	Group RT (mean ± SD)	p-value
Heart rate (bpm)	78 ± 9	79 ± 8	0.55
Systolic BP (mm Hg)	126 ± 10	127 ± 9	0.60
Diastolic BP (mm Hg)	77 ± 7	78 ± 6	0.65

Table 12: Adverse Events

Adverse Event	Group R (n, %)	Group RT (n, %)	p-value
Nausea and vomiting	3 (8%)	6 (15%)	0.29
Pruritus	0 (0%)	0 (0%)	—
Respiratory depression	0 (0%)	0 (0%)	—

Table 1 shows that both groups were comparable in age, sex distribution, and BMI ($p > 0.05$). Table 2 indicates no significant differences in surgery duration or baseline heart rate and blood pressure ($p > 0.05$). Table 3 demonstrates similar early postoperative pain at 2 hours ($p = 0.48$). Table 4 reveals significantly lower VAS scores in Group RT at 4 hours ($p = 0.001$). Table 5 shows continued pain reduction in Group RT at 8 hours ($p = 0.002$). Table 6 demonstrates a highly significant analgesic benefit for Group RT at 12 hours ($p < 0.001$). Table 7 indicates sustained lower pain scores in Group RT at 24 hours ($p < 0.001$). Table 8 confirms superior analgesia in Group RT at 48 hours ($p < 0.001$). Table 9 reveals a 35% reduction in cumulative morphine consumption with tramadol addition ($p < 0.001$). Table 10 shows fewer patients in Group RT required rescue morphine ($p = 0.04$). Table 11 confirms stable hemodynamic parameters with no intergroup differences ($p > 0.05$). Table 12 indicates no significant increase in adverse events; mild nausea/vomiting was more frequent in Group RT but not statistically significant ($p = 0.29$).

Discussion

The findings of this study demonstrate that adding tramadol to a continuous epidural infusion of ropivacaine provides superior postoperative analgesia compared with ropivacaine alone in adults undergoing elective abdominal surgery [9]. Although initial pain scores at two hours were similar between groups, significant differences emerged from four hours onward, with Group RT consistently reporting lower VAS values at all subsequent time points. This suggests that the combination of local anesthetic and tramadol produces a synergistic effect that becomes most apparent as the pharmacologic action of ropivacaine alone begins to wane [10].

The opioid-sparing effect observed 35 percent reduction in cumulative 48-hour morphine consumption is clinically meaningful. Reduced systemic opioid requirements translate into fewer opioid-related adverse effects, faster mobilization, and potentially shorter hospital stays [11]. In our cohort, although mild nausea and vomiting were somewhat more frequent in the tramadol group, the increase was not statistically significant and did not necessitate discontinuation of the epidural infusion. The lack of pruritus or respiratory depression further underscores the safety of epidural tramadol at the dose studied [12].

Hemodynamic stability was well maintained in both groups. Neither heart rate nor blood pressure differed significantly over 48 hours, indicating that tramadol's sympatholytic and serotonergic effects did not compromise cardiovascular parameters when administered epidurally in conjunction with ropivacaine. Sedation levels remained low and comparable, suggesting that epidural tramadol does not produce excessive central nervous system depression at the infusion rate used [13].

Our results align with previous reports of improved analgesia when opioids are added to local anesthetics in the epidural space, but extend the literature by specifically evaluating tramadol an opioid with monoamine reuptake inhibition properties paired with ropivacaine in major abdominal surgery [14]. The dual mechanism of tramadol may contribute to prolonged segmental analgesia and reduced nociceptive transmission at the spinal level. Given the limited cardiotoxicity and motor-sparing profile of ropivacaine, this combination appears to strike a favorable balance between efficacy and safety [15].

Limitations of this study include its single-center design and exclusion of patients with significant comorbidities (ASA III or higher), which may limit generalizability. Additionally, while tramadol's side effect profile was acceptable, further research could explore optimal dosing to minimize nausea while preserving analgesic benefit. Long-term outcomes, such as the incidence of chronic postoperative pain, were not assessed and warrant investigation in future trials.

Conclusion

Epidural infusion of ropivacaine combined with tramadol provides significantly better postoperative pain control and reduces systemic opioid requirements compared to ropivacaine alone in adult patients undergoing elective abdominal surgery, without compromising hemodynamic stability or causing serious adverse effects. This regimen represents an effective and safe option for multimodal postoperative analgesia in this population.

References

1. Zhang W, Li C. EC50 of Epidural Ropivacaine Combined With Dexmedetomidine for Labor Analgesia. Clin J Pain. 2018 Oct;34(10):950-953. doi: 10.1097/AJP.0000000000000613. PMID: 29595529.
2. Otutaha B, MacFater WS, Xia W, Barazanchi AWH, Autagavaia V, Hill AG. Intraperitoneal Tramadol in Abdominal Surgery: A Systematic Review. J Surg Res. 2020 Mar;247:406-412. doi: 10.1016/j.jss.2019.10.002. Epub 2019 Nov 1. PMID: 31685252.
3. Kulkarni K, Namazi IJ, Deshpande S, Goel R. Cervical epidural anaesthesia with ropivacaine for modified radical mastectomy. Kathmandu Univ Med J (KUMJ). 2013 Apr-Jun;11(42):126-31. doi: 10.3126/kumj.v11i2.12487. PMID: 24096219.
4. Berti M, Casati A, Fanelli G, Albertin A, Palmisano S, Danelli G, Comotti L, Torri G. 0.2% ropivacaine with or without fentanyl for patient-controlled epidural analgesia after major abdominal surgery: a double-blind study. J Clin Anesth. 2000 Jun;12(4):292-7. doi: 10.1016/s0952-8180(00)00154-9. PMID: 10960201.
5. Wang Y, Xu M. Comparison of ropivacaine combined with sufentanil for epidural anesthesia and spinal-epidural anesthesia in labor analgesia. BMC Anesthesiol. 2020 Jan 2;20(1):1. doi: 10.1186/s12871-019-0855-y. PMID: 31898488; PMCID: PMC6939327.
6. Kang HY, Lee CH, Choi SS, Lee MK, Park JS, Oh JS. Comparison of ropivacaine with ropivacaine and fentanyl in continuous epidural analgesia for postherpetic neuralgia: A STROBE-compliant retrospective study. Medicine (Baltimore). 2020 May 29;99(22):e20298. doi: 10.1097/MD.0000000000020298. PMID: 32481399.
7. Dauri M, Costa F, Servetti S, Sidiropoulou T, Fabbi E, Sabato AF. Combined general and epidural anesthesia with ropivacaine for renal transplantation. Minerva Anestesiol. 2003 Dec;69(12):873-84. English, Italian. PMID: 14743119.
8. Berti M, Fanelli G, Casati A, Albertin A, Palmisano S, Deni F, Perotti V, Torri G. Patient supplemented epidural analgesia after major abdominal surgery with bupivacaine/fentanyl or ropivacaine/fentanyl. Can J Anaesth. 2000 Jan;47(1):27-32. doi: 10.1007/BF03020727. PMID: 10626714.
9. Panousis P, Heller AR, Koch T, Litz RJ. Epidural ropivacaine concentrations for intraoperative analgesia during major upper abdominal surgery: a prospective, randomized, double-blinded, placebo-controlled study. Anesth Analg. 2009 Jun;108(6):1971-6. doi: 10.1213/ane.0b013e3181a2a301. PMID: 19448234.
10. Cai S, Zheng J, Meng Q, Chai J, Ma R, Wang Y, Zhang W, Yang Z. Investigation of the Minimum Local Analgesic Concentration of Epidural Sufentanil Combined With Ropivacaine for Labor Analgesia. Clin Ther. 2020 Jan;42(1):210-219. doi: 10.1016/j.clinthera.2019.10.011. Epub 2020 Jan 16. PMID: 31955968.
11. Hong JM, Kim KH, Lee HJ, Kwon JY, Kim HK, Kim HJ, Cho AR, Do WS, Kim HS. Epidural Dexamethasone Influences Postoperative Analgesia after Major Abdominal Surgery. Pain Physician. 2017 May;20(4):261-269. PMID: 28535549.
12. Scott DA, Chamley DM, Mooney PH, Deam RK, Mark AH, Hägglöf B. Epidural ropivacaine infusion for postoperative analgesia after major lower abdominal surgery--a dose finding study. Anesth Analg. 1995 Nov;81(5):982-6. doi: 10.1097/00000539-199511000-00015. PMID: 7486088.
13. Badner NH, Reid D, Sullivan P, Ganapathy S, Crosby ET, McKenna J, Lui A. Continuous epidural infusion of ropivacaine for the prevention of postoperative pain after major orthopaedic surgery: a dose-finding study. Can J Anaesth. 1996 Jan;43(1):17-22. doi: 10.1007/BF03015952. PMID: 8665629.
14. Brodner G, Mertes N, Van Aken H, Pogatzki E, Buerkle H, Marcus MA, Mollhoff T. Epidural analgesia with local anesthetics after abdominal surgery: earlier motor recovery with 0.2% ropivacaine than 0.175% bupivacaine. Anesth Analg. 1999 Jan;88(1):128-33. doi:

10.1097/00000539-199901000-00024. PMID: 9895079.
15. De Cosmo G, Primieri P, Adducci E, Fiorenti M, Beccia G. Epidural analgesia in abdominal surgery: 0.2% ropivacaine with sufentanil. Minerva Anestesiol. 2004 Jun;70(6):503-8. English, Italian. PMID: 15235556.