
Original work

A COMPARATIVE STUDY TO EVALUATE TWO DIFFERENT DOSES OF EPIDURAL TRAMADOL FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING UPPER ABDOMINAL SURGERY (EPIDURAL ANALGESIA)

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Introduction: In upper abdominal surgery, postoperative pain relief is the most challenging for anesthesiologist. Among multiple strategies, epidural analgesia using local anesthetics, opioids, or their combination, is popular technique for effective postoperative pain management. The aim of our study was comparison of effects of different doses of epidural tramadol for postoperative analgesia in adult patients scheduled for surgery of upper abdomen.

Methods: This Prospective controlled interventional study included 60 adult patients posted for upper abdominal operations undergoing general anesthesia. The epidural analgesia was provided by administering 10 ml of epidural bupivacaine 0.25% via epidural catheter at the start of surgery and randomized into two different groups: Group A was administered 1 mg/kg tramadol diluted in 8 ml of normal saline and Group B was administered 2 mg/kg tramadol diluted in 8 ml of normal saline before extubation. Duration of analgesia, Pain score (numerical rating score-NRS), hemodynamic parameters and adverse event were monitored and time for need of first of rescue analgesic was recorded in both the groups. The student's t-test was used for analysis of continuous data. P value ≤ 0.05 was considered statistically significant. **Result:** Group B patients had significantly longer duration of postoperative analgesia (12.07 ± 1.48 hours) as compared to Group A (8.13 ± 0.82 hours) with $P < 0.001$. NRS pain score was significantly lower in Group B than in Group A. Hemodynamic parameter were comparable without any side effects in both the groups. **Conclusion:** Epidural tramadol 2 mg/kg resulted in superior and prolonged postoperative pain relief than epidural tramadol 1 mg/kg without compromising patient safety.

Key words: Bupivacaine; epidural analgesia; postoperative pain; tramadol

Introduction:

Pain is considered one of the most challenging symptoms for surgical patients. The management of postoperative analgesia is crucial for better recovery, reducing complications, and improving patient outcomes.^{1,2} In operative procedures on the upper abdomen, postoperative pain is more severe and can restrict diaphragmatic movement, increasing the risk of respiratory complications, prolonged hospital stays, and higher surgical morbidity and mortality.¹ Over time, multiple strategies have been explored to enhance postoperative pain relief.³ Regional analgesia, particularly epidural analgesia using local anesthetics, opioids, or their combination, is one such technique for effective postoperative pain management.^{4,5}

Tramadol, a synthetic opioid with dual mechanisms, a μ -opioid receptor agonist and norepinephrine inhibition and reuptake of serotonin, has been widely investigated for its safety and efficacy in regional techniques⁶.

Epidural tramadol also has the benefit of a lack of respiratory depressant effect along with prolonged postoperative pain relief.¹

Review of previous literature on postoperative pain control and use of epidural tramadol reveals that most studies were done using tramadol as adjuvant to local anesthetics like ropivacaine, bupivacaine etc or at fixed drug dosages and in urological surgeries.⁴ Thus, the aim of our study was to find an optimal dose of tramadol hydrochloride to be used epidurally in upper abdominal surgery

patients, based on body weight and without side effects.

The primary objective was to compare the postoperative analgesia in both groups. The secondary objectives included were postoperative hemodynamic variations and adverse effect of drugs.

Methods:

The written informed consent and local ethical committee approval (Ref No. EC/Approval/129/2024/13/11/2024) were obtained. The prospective CTRI Registration (Ref/2025/01/097392) was done. Sixty patients were included aged between 18 and 60 years, of either sex belonging to American Society of Anesthesiologist (ASA) grades I or II and planned for elective upper abdominal surgery. This prospective, randomized, controlled, study was conducted from October 2024 to March 2025.

Randomization was done by using a computer-generated random number table. Both the observer and the participants were blinded to the intervention.

Inclusion Criteria

ASA grade I and II, Patients aged 18 to 60 years, Patients scheduled for upper abdominal surgeries, Elective surgeries

Exclusion Criteria

ASA grade III, IV and V, Age < 18 and > 60 years, Patients refusing to give consent, Patients who are pregnant or lactating, Patients having any bleeding diathesis or are on anticoagulant therapy.

A day before surgery, preoperative assessment was performed. During the preoperative visit, the epidural analgesia procedure, its benefits, and its side effects were explained to the patients. They were also instructed about the use of 10-point Numerical Rating Scale (NRS) for Pain Intensity for evaluation of post-operative pain (score = 0: No pain; score = 10: Worst possible pain)

Patients were kept nil per orally before surgery. On the day of the surgery, patients were reassessed in the preoperative room. In the operating room, standard monitors including ECG, NIBP, and SpO₂ were attached, and an intravenous line was secured.

The patients were placed in a sitting position for the epidural procedure. Infiltration of the skin

around the epidural injection site was performed with inj. lignocaine hydrochloride 2% (2ml) under full aseptic precautions. Touhy epidural needle (18-gauge) was inserted into the space using a mid-line lumbar approach at L1-L2 interspace. Lumbar epidural insertion at the L1-L2 level for upper abdominal surgery was chosen for safety, as it reduces the risk of spinal cord injury while still providing satisfactory analgesia for upper abdominal pain (which typically ranges from T4 to T10) by allowing the local anesthetic to spread cephalad to the required levels. The lumbar space is easier to identify in many patients compared to the thoracic space.

The loss-of-resistance technique was used to identify the epidural space, and an epidural catheter was inserted and fixed at 4 cm inside the space. Patients turned to the supine position. A test dose of 3 ml of 1.5 % xylocaine with adrenaline (1:2,00,000) was given to rule out intravascular or intrathecal placement of the epidural catheter. Epidural analgesia with inj. Bupivacaine (0.25%) 10 ml was given via epidural route.

General anesthesia was administered. Inj. glycopyrrolate (4 µg/kg), inj. ondansetron (150 µg/kg), inj. fentanyl (1 µg/kg) were used for premedication.

Pre oxygenation was performed for 3 minutes with 100% oxygen. Induction was achieved with inj. propofol (2-3mg/kg) IV and inj. suxamethonium (1-2 mg/kg) IV. Trachea was secured with an appropriately sized endotracheal tube.

Before extubation, as per the randomization, epidural tramadol hydrochloride, either 1 or 2 mg/kg body weight, diluted in NS till 8 ml volume, was administered. Vital signs were recorded at regular intervals for 30 minutes after the injection.

The reversal of neuromuscular block was accomplished with inj. glycopyrrolate 0.008mg/kg and neostigmine 0.05mg/kg IV. Patients were extubated after checking adequacy of muscle tone, power, hemodynamic stability and consciousness. The patients were shifted to the ward and monitored using numerical rating scale for pain intensity. Any side effects like dizziness, sweating, nausea, vomiting and headache were recorded.

Patients were monitored every 15 minutes for the initial 1 hour, every 30 minutes for the next 4 hours, every hour until 12 hours, and then every 3 hours up to 24 hours.

Rescue analgesia, if required, was a repeat dose of tramadol (1 mg/kg diluted in NS to make 8 ml volume) administered via epidural catheter when the NRS score was greater than or equal to 4. The time of first requirement for rescue analgesic was noted.

Sample size was calculated using the online software ClinCalc. The estimation was based on the previous study done by Rasmeet Kour et al⁷ which reported a duration of epidural analgesia of 6 ± 2.3 hours in Group 1 to 14.8 ± 6.7 hours in Group 2. Assuming the clinically significant difference ($\mu_1 - \mu_2$) of 4 hours, and controlling the probability of a Type I error at alpha 0.05 and 80% power, a sample of 25 patients is required in each group. Considering an attrition rate of 10% for drop outs, a total of 30 patients per group is required. A total of 60 patients were included in the study.

Collected data were presented as mean $\pm$ SD, numbers, or percentages, as appropriate. Statistical analysis was carried out using MS Excel 2016 (Microsoft Corporation, USA) and Epi Info 7. Categorical variables were analyzed using the chi-square or Fisher's exact test, while continuous variables were analyzed using the independent t-test

or Mann-Whitney U test. Data were analyzed at a 95% confidence interval, and a value of $p < 0.05$ was considered statistically significant.

Results

Sixty patients were enrolled and randomized into two different groups as mentioned earlier.

Demographic data

Group A patients had mean age 40.67 ± 12.76 years, mean weight 50.33 ± 10.13 kg, and gender: 14 females and 16 males. Group B patients had mean age 43.90 ± 11.97 years, mean weight 50.27 ± 8.70 kg, and gender: 17 females and 13 males.

ASA physical status was similar between the groups: Group A - 11 ASA I and 19 ASA II; Group B - 6 ASA I and 24 ASA II; The duration of operation/anesthesia were comparable in both groups. The demographic data of the two groups were comparable. (Table 1)

Duration of Surgery/Anesthesia

Table 1: Demographic characteristics of patients

Characteristics	Group A	Group B	P value
Age (Years) MD $\pm$ SD	40.67 ± 12.76	43.90 ± 11.97	0.316
Weight(kg) MD $\pm$ SD	50.33 ± 10.13	50.27 ± 8.70	0.978
Gender (Male/Female)	16/14	13/17	0.438
ASA (I/II)	11/19	6/24	0.152
Duration of Surgery/Anesthesia (Minutes)	187.5 ± 29.42	193.9 ± 52.89	0.45

ASA: American society of Anesthesiologists MD $\pm$ SD; Mean and standard deviation

The majority of the patients in both groups underwent Gastrojejunostomy, Hemicolectomy, Incisional hernia repair, Longitudinal Pancreatojejunostomy and Roux-en-Y gastrojejunostomy surgeries. (Table 2)

Duration of analgesia

Group A patients had a significantly shorter duration of analgesia (8.13 ± 0.82 hours) in comparison to Group B patients (12.07 ± 1.48 hours) ($p < 0.001$). This shows that 2 mg/kg epidural tramadol prolongs the postoperative analgesia compared to 1mg/kg epidural tramadol. (Table 3)

Numerical Rating Scale (NRS) Score

The Numeric Rating Scale (NRS) was used to assess the postoperative pain.

At baseline, and during the early postoperative period (up to 4 hours), the NRS scores were not significant between the two groups ($p > 0.05$). However, from the 5th postoperative hour onward, significant differences emerged. Group A demonstrated significantly higher NRS scores compared to Group B at multiple time points—5th, 6th, 7th, 8th, 9th, 15th, 18th, and 24th hours—with p-values < 0.001 , indicating higher pain perception and decreased pain perception after administration of top up doses. Conversely, Group B exhibited significantly higher pain scores at the 10th, 11th, and 12th postoperative hours (also $p < 0.001$), indicating wearing off of analgesic effect at these time points. (Figure 1)

Table 2: Type of Surgery

Surgical Procedures	Group A		Group B		P value
	No.	Percentage	No.	Percentage	
Gastrojejunostomy	5	16.7	4	13.3	1.000
Hemicolectomy	7	23.3	5	16.7	0.738
Incisional hernia repair	8	26.7	10	33.3	0.592
Longitudinal Pancreatojejunostomy	6	20	8	26.7	0.551
Roux-en-Y gastrojejunostomy	4	13.3	3	10	1.000

Table 3: Duration of analgesia

Parameter	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P value
Duration of Analgesia (hrs)	8.13 $\pm$ 0.82	12.07 $\pm$ 1.48	< 0.001

SD; Standard deviation P value < 0.05 is considered significant

Table 4: Requirement of Top Up Doses

Parameter	Group A Mean $\pm$ SD	Group B Mean $\pm$ SD	P value
Number of Top Up Doses Given	2.3 $\pm$ 0.47	1.47 $\pm$ 0.51	< 0.001

SD; Standard deviation P value < 0.05 is considered significant

Requirement of Top Up Doses

Patients in Group A required more top-up doses (mean = 2.30 ± 0.47) than those in Group B (mean = 1.47 ± 0.51) with statistically significant difference ($p < 0.001$). (Table 4) If we calculate 1 mg /kg epidural tramadol, total rescue tramadol does not exceed 120 mg during study period.

Side Effects

Two patients in Group A had nausea and vomiting, while 4 patients in Group B suffered from the same symptoms. The difference was comparable in both group ($p = 0.389$). (Table 5)

Postoperative Heart Rate

In the postoperative period, both groups exhibited stable heart rates without significant fluctuations. The mean heart rate in Group A ranged from 74 to 86 bpm, and in Group B from 72 to 84 bpm. This difference was observed as comparable between the two groups at any time point ($p > 0.05$). (Figure 2)

Postoperative Systolic Blood Pressure

Postoperatively, stable SBP was observed in both groups without significant differences. Mean

values ranged between 112 and 126 mmHg in Group A, and 110 and 124 mmHg in Group B, throughout the 24-hour monitoring period ($p > 0.05$). (Figure 3)

Postoperative Diastolic Blood Pressure

During the postoperative period, DBP continued to be comparable between the groups, with Group A ranging from 70 to 82 mmHg, and Group B from 72 to 84 mmHg. No significant variations were found at any time point ($p > 0.05$). (Figure 4)

Discussion:

Adequate postoperative analgesia is important to enhance patient recovery, reducing hospital stay, and preventing chronic pain syndromes.

Nowadays, epidural and subarachnoid opioids for postoperative pain relief are considered more promising than systemic opioids. Epidural opioids have direct action on specific opioid receptors which are highly distributed in the posterior horn of the spinal cord, and therefore, are safer than systemic opioids. The main advantage of epidural analgesia is better pain relief and minimum

Table 5: Side effects

Side effects	Group A		Group B		P value
	No.	Percentage	No.	Percentage	
Nausea/Vomiting	2	7%	4	13%	0.389
Bradycardia	0	0%	0	0%	
Hypotension	0	0%	0	0%	

P value < 0.05 is considered significant

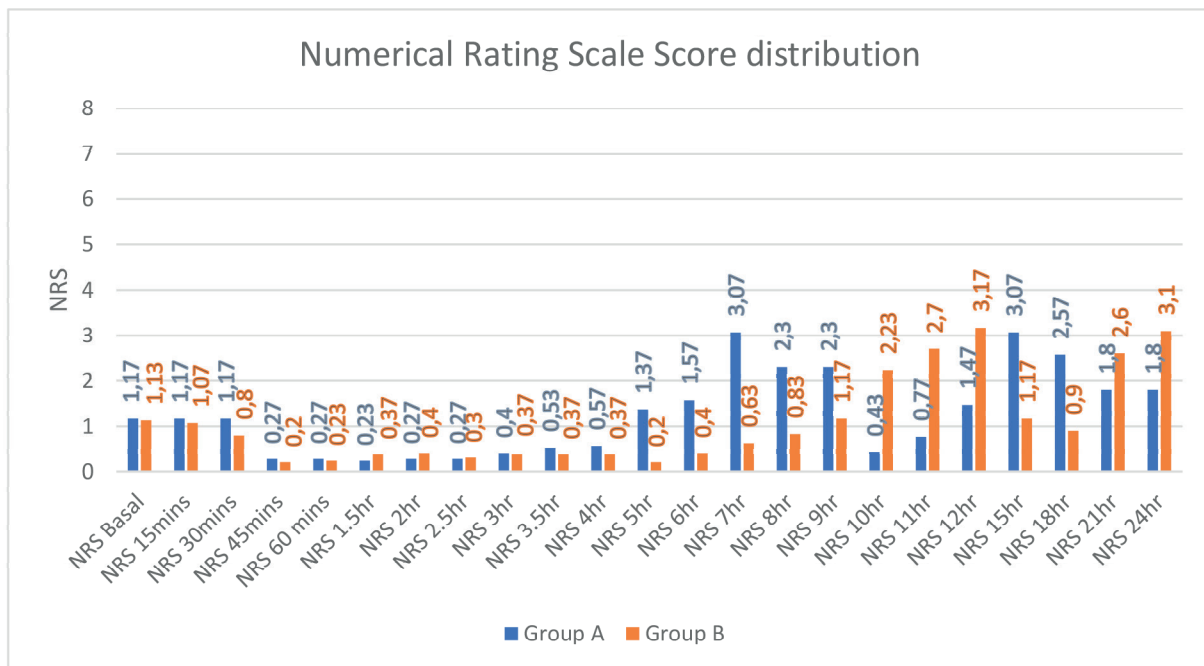
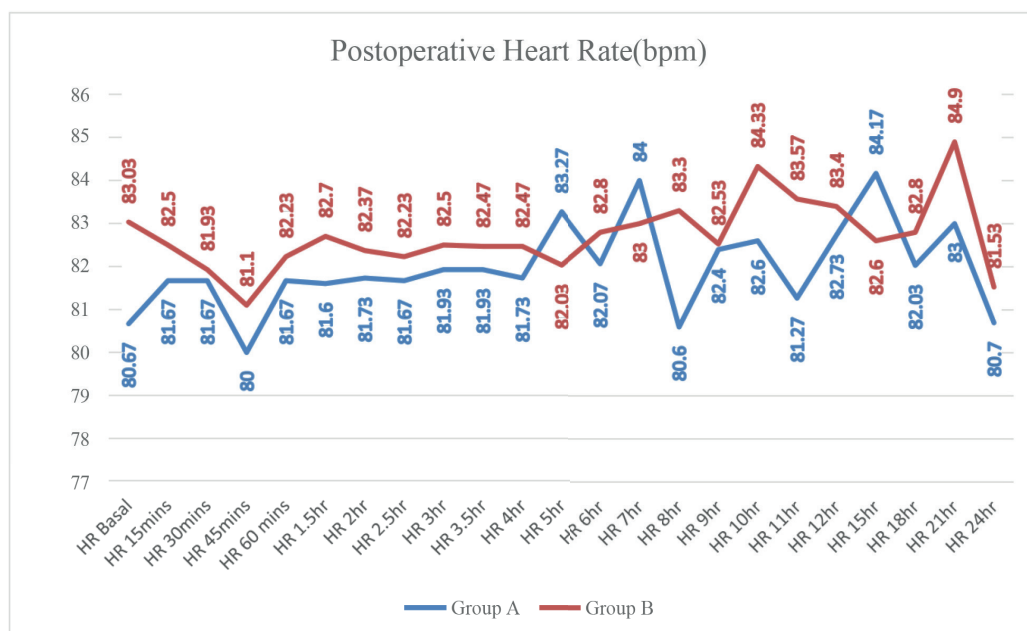
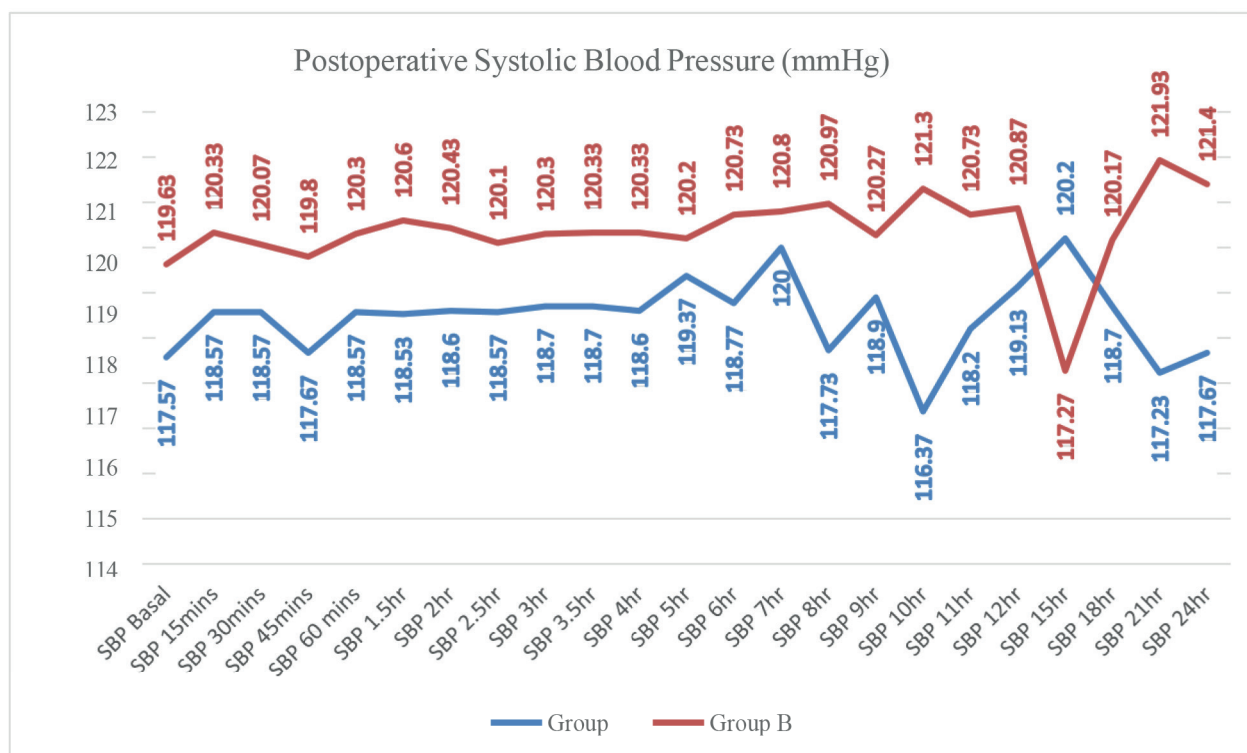
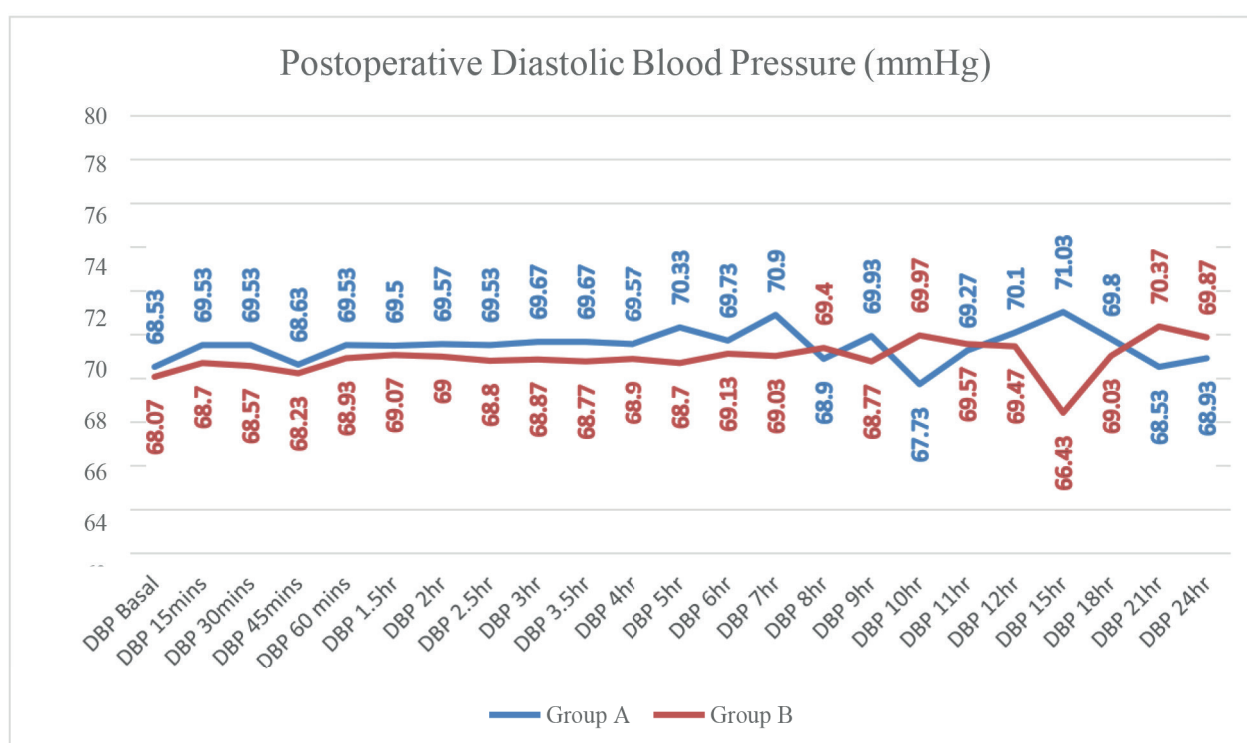
Figure 1: Numerical Rating Scale (NRS) Score**Figure 2:** Comparison of postoperative heart rate in both groups

Figure 3: Comparison of postoperative systolic blood pressure in both groups**Figure 4:** Comparison of postoperative diastolic blood pressure in both groups

side effects in comparison with intermittent parenteral opioid injection.

Other advantages of epidural analgesia include early mobilization of patients and quick resumption of normal activities as compared to parenteral opioids.⁸

Epidural analgesia remains a cornerstone for managing pain in major abdominal surgeries due to its ability to provide segmental analgesia and modulate the stress response to surgery. Tramadol, a synthetic opioid with dual mechanisms— μ -opioid receptor agonist and inhibitory effect on norepinephrine and serotonin reuptake—has been widely investigated for its safety and efficacy in regional techniques⁶.

The dose of tramadol may vary depending on the pain intensity and the sensitivity of individual patient. Tramadol can be administered by various routes and it is available as preservative free for intrathecal or epidural use.

Our aim of this study was to compare the effects and safety of two different doses of epidural tramadol 1 mg/kg and 2 mg/kg for analgesia in postoperative period of patients posted for upper abdominal surgery.

Some authors studied the optimum dose of epidural tramadol (1 mg/kg, 2 mg/kg and 3 mg/kg) for postoperative analgesia in urological surgeries and concluded that 2 mg/kg is the effective dose, balancing prolonged analgesia with minimal adverse effects.^{4,7}

Patil and Kumbhar¹⁰ found that 100 mg tramadol provided a significantly longer analgesia duration (7.58 ± 0.69 hours) than both 50 mg tramadol and bupivacaine.

Singh et al.¹ studied comparison of tramadol 2 mg/kg, tramadol 1 mg/kg and ropivacaine alone and reported a significantly prolongation of analgesia (584 ± 58 min) as compared to (394 ± 46 min) and (283 ± 35 min) respectively.

Gunes and colleagues¹² observed caudal tramadol (2 mg/kg) to be better and prolonged postoperative analgesic (> 24 h) than intra venous tramadol 2 mg/kg (2.20 h).

In our study, we found that postoperative analgesia lasted for 8.13 ± 0.82 hours in Group A, while in Group B it lasted for 12.07 ± 1.48 hours. These findings are in accordance with the study done by Delilkan and Vijayan who used tramadol 100 mg given epidurally (9.4 hr) in adult patients with long duration of effective analgesia in comparison to 0.25% bupivacaine (6 h).

Siddik Sayyid *et al.*⁴ reported the duration of postoperative analgesia to be 10.26 ± 2.73 h in epidural tramadol (100 mg).

In the study by Imam and Hasnat¹¹, epidural tramadol 100 mg provided better pain relief than bupivacaine 0.25%, with lower VAS scores throughout 24 hours. Similarly, Patil and Kumbhar¹⁰ and Delilkan and Vijayan (1993)² demonstrated significantly lower VAS scores in both 50 mg and 100 mg tramadol groups compared to bupivacaine, again highlighting tramadol's effectiveness in controlling postoperative pain.

Swathi N et al.¹³ compared epidural butorphanol versus tramadol as additive to bupivacaine for postoperative analgesia in abdominal surgeries and concluded that onset of action was delayed but postoperative analgesia was prolonged with tramadol. We observed a slightly rapid onset with epidural tramadol 2 mg/kg group. However, Khoirom et al.¹⁴ reported a slightly slower onset of tramadol (10.76 min) compared to fentanyl (7.9 min), indicating that onset may vary depending on the comparator drug.

The NRS scores were consistently lower in Group B (2mg/kg epidural tramadol) at multiple postoperative time points, especially from 1.5 hours to 12 hours, indicating better pain control with the higher dose. This supports the clinical efficacy of 2 mg/kg tramadol in managing moderate to severe postoperative pain. Importantly, while Group B patients required fewer top-up doses of rescue analgesics, the incidence of nausea and vomiting were comparable between groups, suggesting that the higher dose remained within the safety margin.

Hemodynamic parameters including heart rate, systolic and diastolic blood pressures remained stable and comparable between the two groups, suggesting that neither dose caused clinically significant cardiovascular depression. This is consistent with the pharmacologic profile of tramadol, which lacks the severe respiratory depression and hemodynamic instability often associated with other opioids.

This was supported by Singh et al.¹ and Baheti et al.³, who observed stable cardiovascular parameters across all groups receiving tramadol and other adjuvants.

Yadhuraj et al.¹⁵ and Mondal et al.¹⁶ similarly noted that epidural tramadol did not cause significant hemodynamic disturbances, especially when

compared to drugs like pentazocine or buprenorphine, which occasionally induced bradycardia or hypotension.

A major concern with opioid-based analgesia was the risk of side effects, particularly respiratory depression, pruritus, nausea and vomiting. In our study, there was not statistically significant difference between the groups in terms of nausea and vomiting and did not necessitate discontinuation of therapy. This side effect profile was consistent with Kour et al.⁷, who reported dose-related nausea and vomiting, particularly at the 3 mg/kg dose, suggesting a threshold beyond which adverse effects increase significantly.

Similarly, Mondal et al.¹⁶ and Baheti et al.³ noted that while tramadol has a lower incidence of nausea and pruritus than buprenorphine, it may still cause mild gastrointestinal side effects in higher doses. Delilkan and Vijayan² and Patil and Kumbhar¹⁰ also observed dose-related increases in nausea, with a 25% incidence in the 100 mg group versus 10% in the 50 mg group.

Limitation

The sample size was relatively small, with only 30 patients in each group, which may limit the statistical power and generalizability of the results. Being a single-centre study, the findings are not generalizable.

Pain was measured using the Numerical Rating Scale, which, while widely used, is subjective and may be influenced by individual perception.

Lastly, the exclusion of patients with significant comorbidities or opioid tolerance limits the applicability of the findings to broader surgical populations.

Conclusion:

2 mg/kg of epidural tramadol can be considered as a better and safe option for postoperative analgesia in upper abdominal surgical procedures without any side effects.

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Conflict of interest

There is no conflict of interest.