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COMPARISON OF POSTOPERATIVE ANALGESIC EFFICACY OF EPIDURAL ROPIVACAINE AND ROPIVACAINE WITH TRAMADOL IN ADULTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANAESTHESIA

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ABSTRACT

Background: The study aimed to compare the postoperative analgesic efficacy and safety profile of epidural Ropivacaine versus a combination of Ropivacaine and Tramadol in patients undergoing abdominal surgeries under general anesthesia. **Methods:** A total of 60 patients were randomized into two groups: Group 1 (Ropivacaine alone) and Group 2 (Ropivacaine with Tramadol). The primary outcomes were the duration of postoperative analgesia, sedation levels, and adverse effects. The Ramsay Sedation Score (RSS) was used to assess sedation, while adverse effects such as nausea, vomiting, and pruritus were recorded. The statistical significance of differences between the two groups was analyzed using unpaired t-tests. **Results:** The mean duration of postoperative analgesia was significantly longer in the Ropivacaine with Tramadol group (309.90 minutes) compared to the Ropivacaine alone group (220.57 minutes) ($p < 0.0001$). The Ramsay Sedation Score was higher in the Ropivacaine with Tramadol group (mean 3.06) compared to the Ropivacaine group (mean 1.26), indicating increased sedation ($p < 0.0001$). The incidence of postoperative nausea and vomiting (PONV) and pruritus was low in both groups, with no statistically significant difference ($p > 0.05$). Hemodynamic parameters were stable in both groups. **Conclusion:** The combination of Ropivacaine with Tramadol provides superior postoperative analgesia compared to Ropivacaine alone, with an extended analgesic duration and mild sedation. These findings suggest that Ropivacaine with Tramadol is a viable option for effective postoperative pain management in abdominal surgeries, with minimal adverse effects and stable hemodynamic parameters.

INTRODUCTION

Effective postoperative pain management is critical for ensuring patient comfort, reducing complications, and expediting recovery. Among the various regional anesthesia techniques, epidural analgesia is a widely preferred modality due to its superior pain control and minimal systemic side effects.[1] Local anesthetics, such as Ropivacaine, are commonly employed in epidural anesthesia because of their favorable safety profile, including reduced cardiotoxicity and neurotoxicity compared to Bupivacaine.[2] To enhance the duration and quality of analgesia, adjuvants such as opioids and non-opioid agents are often combined with local anesthetics. Tramadol, a synthetic opioid with μ-opioid receptor agonist activity and monoaminergic modulation, has emerged as a promising adjuvant in regional anesthesia. Its addition to Ropivacaine may provide prolonged analgesia and sedation without significantly increasing adverse effects. This study evaluates the comparative efficacy and safety of epidural Ropivacaine versus Ropivacaine combined with Tramadol in patients undergoing abdominal surgeries.

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AIMS AND OBJECTIVES

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

PRIMARY OBJECTIVE

To compare the duration of postoperative analgesia

SECONDARY OBJECTIVES

To compare the

1. Ramsay sedation score
2. Postoperative nausea and vomiting
3. Pruritus

4. Heart rate
5. Mean arterial blood pressure
6. Peripheral capillary oxygen saturation
7. Respiratory rate

MATERIALS AND METHODOLOGY

The study was a prospective non-randomized, double arm, single blind, controlled study. The study was started after getting approval of Institutional Ethics Committee. The study was conducted in patients scheduled for abdominal surgeries done under general anesthesia at SVS MEDICAL COLLEGE AND HOSPITAL, MAHABUBNAGAR after obtaining written informed consent.

SAMPLE SIZE CALCULATION

Sample size was determined based on the study "Postoperative analgesic efficacy of epidural Tramadol as adjuvant to Ropivacaine in adult upper abdominal surgeries". In this study, mean duration of analgesia after epidural bolus drug was significantly higher in Group RT2 (0.2% Ropivacaine with 2mg/kg of Tramadol)(584 ± 58 min) when compared with RT1(0.2% Ropivacaine with 1mg/kg Tramadol) (394 ± 46 min) or R Group(0.2% Ropivacaine) (283 ± 35 min) with a standard deviation of 58 min.

Description: The sample size was calculated based on the formula:

$$n = \left(\frac{Z_{\alpha/2} \cdot \sigma}{E}\right)^2$$

Where
n = Sample size
σ = Population standard deviation e = Margin of error
Z = The value for the given confidence interval

- The confidence level is estimated at 95%
- Standard deviation 58
- With a z value of 1.96
- The confidence interval or margin of error is estimated at +/-15 Assuming that 80 percent as power of the study, minimumsample size required for the study was calculated to be 58.

In our study, 60 subjects were chosen (n=30 in Group R arm and n=30 in Group RT arm).

INCLUSION CRITERIA

1. Patients undergoing elective abdominal surgeries under general anesthesia.
2. Age between 30 to 60 years
3. Males and females
4. ASA class I and II
5. Patients who have given valid informed consent
6. Duration of surgery less than 3 hours.

EXCLUSION CRITERIA:

1. Patients not satisfying inclusion criteria.
2. Patients with an allergy or sensitivity to opioid group of drugs and local anesthetics.
3. Patients with spinal deformities
4. Any contraindication to epidural anesthesia
5. Patients with neurological disorders
6. Impaired ability to communicate (e.g., confusion, poor hearing or language barrier)
7. Patients who are unconscious or severely ill
8. Coagulopathies

Methodology

This study enrolled 60 adult patients undergoing abdominal surgeries under general anesthesia, divided into two groups of 30: Group R (0.2% Ropivacaine) and Group RT (0.2% Ropivacaine with Tramadol 1 mg/kg). Preoperatively, patients were evaluated, counseled, and consented. Pre-medication included Inj. Metoclopramide 10 mg IM and Inj. Ranitidine 50 mg IV.Epidural catheters were inserted at the L1-L2 intervertebral space under sterile conditions using the loss-of-resistance technique, and a test dose of 1.5% lignocaine with adrenaline was administered. General anesthesia induction included Inj. Propofol 2 mg/kg, Atracurium 0.5 mg/kg, and maintenance with sevoflurane, nitrous oxide, and oxygen. Epidural drugs (10 ml) were administered at skin closure based on group allocation. Group R received Ropivacaine 0.2%, and Group RT received Ropivacaine 0.2% with Tramadol. Postoperative monitoring included the Visual Analog Scale (VAS) for pain, Ramsay Sedation Score, heart rate, blood pressure, respiratory rate, and oxygen saturation every 15 minutes for 2 hours and hourly for 12 hours. Rescue analgesia with IV Paracetamol (15 mg/kg) was provided if needed. Adverse effects, including nausea, vomiting, and pruritus, were recorded. Outcomes such as pain relief, sedation, and duration of analgesia were compared between the groups.

OBSERVATIONS AND RESULTS

Age Distribution: In our study while analyzing the age distribution, in the Ropivacaine group, majority of the study subjects belonged to the 21-40 years age class interval (n=15, 50.00%) with a mean age of 43.03 years. In the Ropivacaine with Tramadol group majority belonged to the 51-60 years age class interval (n=13, 43.33%) with a mean age of 47.10 years. The association with respect to age distribution between the two groups is considered to be non significant since p value is > 0.05 as per unpaired t test.

Gender Distribution: In our study while analyzing the gender status, the study subjects belonged equally to male and female gender (n=15, 50.00%) in the Ropivacaine group. In the Ropivacaine with Tramadol group majority belonged to female gender (n=16, 53.33%). The association with respect to gender distribution between the two groups is considered to be non significant since p value is > 0.05 as per chi square test.

Weight Distribution: In our study while analyzing the weight distribution, majority of the study subjects belonged to the 61-70 kgs weight class interval (n=17, 56.67%) in the Ropivacaine group with a mean weight of 61.87 kgs. In the Ropivacaine with Tramadol group majority belonged to the 51-60 kgs weight class interval (n=14, 46.67%) with a mean weight of 60.30 kg. The association with respect to weight distribution between the two groups is considered tobenon significant since p value is > 0.05 as per unpaired t test.

Duration of Postoperative Analgesia: The association between the intervention groups and duration of postoperative analgesia among study subjects is considered to be statistically significant since $p < 0.05$. In patients belonging to Ropivacaine group, majority of the study subjects belonged to ≤ 240 minutes duration of postoperative analgesia class interval (n=29,

96.67%) 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=20, 66.67%) 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 as the p value is <0.0001 as per unpaired t- test.

Ramsay sedation score: The association between the intervention groups and Ramsay sedation scoreamong study subjects is considered to be statistically significant since p < 0.05. In patients belonging to Ropivacaine group, majority of the study subjects belonged to RSS 1 class interval (n=22, 73.33%) with a mean RSS of 1.26 scoring points. In the Ropivacaine with Tramadol group majority belonged to RSS 3 class interval (n=26, 86.67%) 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 is statistically significant as the p value is <0.0001 as per unpaired t- test.

Postopertive nausea and vomiting (PONV): In our study while analysing the PONV , majority of the study subjects had noPONV (n=27, 90.00%) in the Ropivacaine group. In the Ropivacaine with Tramadol group majority too had no PONV (n=24, 80.00%).The association between patients received epidural Ropivacaine and Ropivacaine with Tramadol based on PONV is considered to be non significant since p value is > 0.05 as per fishers exact test.

Pruritus: In our study while analysing the pruritus status, majority of the study subjects had no pruritus (n=30, 100.00%) in the Ropivacaine group. In the Ropivacaine with Tramadol group majority too had no pruritus (n=25, 83.33%). The association between pruritus status and intervention groups is considered to be non significant since p value is >0.05 as per Fishers exact test.

Heart Rate: In our study while analysing the heart rate distribution, the study subjects in the Ropivacaine group had a mean baseline HR of 78.50 beats per minute, mean endline 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 endline 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 is > 0.05 as per unpaired t test.

Mean Arterial Pressure: In our study while analysing the mean arterial pressure distribution, the study subjects in the Ropivacaine group had a mean baseline MAP of 96.63 mm Hg, mean endline MAP of 94.43 mm Hg and mean overall MAP of 95.18 mm Hg . In the Ropivacaine with Tramadol group the study subjects in the Ropivacaine group had a mean baseline MAP of 99.10 mm Hg, mean endline MAP of 96.67 mm Hg and mean overall MAP of 97.98 mm Hg. The association between mean arterial pressure distribution and intervention groups is considered to be non significant since p value is > 0.05 as per unpaired t test.

Peripheral Capillary Oxygen Saturation: In our study while analysing the mean peripheral capillary oxygen saturation distribution, the study subjects in the Ropivacaine group had a mean baseline SPO2 of 99.47 %, mean endline 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 endline 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 non significant since p value is > 0.05 as per unpaired t test.

Respiratory Rate: In our study while analysing the mean respiratory rate distribution, the study subjects in the Ropivacaine group had a mean baseline RR of 18.47 breaths per min, mean endline 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 endline RR of 15.60 breaths per min . The association between mean respiratory rate distribution and intervention groups is considered to be non significant since p value is >0.05 as per unpaired t test.

DISCUSSION

The current study aimed to evaluate the postoperative analgesic efficacy and safety profile of epidural Ropivacaine versus Ropivacaine combined with Tramadol in patients undergoing abdominal surgeries under general anesthesia. The results provide a comparative analysis of analgesic duration, sedation levels, and adverse effects, offering clinical insights into these interventions' suitability.

Age, Gender, and Weight Distribution: The baseline characteristics of age, gender, and weight were comparable between the groups, with no statistically significant differences (p > 0.05). This demographic equivalence ensures the validity of comparisons, as differences in analgesic efficacy or safety are less likely confounded by baseline variability. Comparable results have been reported in studies where similar age and gender distributions were achieved to minimize selection bias and enhance the reliability of postoperative pain management studies. For instance, Akhavanakbari et al. Demonstrated no age or weight-related differences influencing outcomes in epidural analgesia studies involving Tramadol and local anesthetics.[3]

Postoperative Analgesia: The combination of Ropivacaine with Tramadol significantly prolonged the mean duration of postoperative analgesia to 309.9 minutes compared to 220.57 minutes in the Ropivacaine group (p < 0.0001). The extended analgesic effect highlights Tramadol's synergistic role when combined with local anesthetics, as it modulates pain pathways centrally via μ-opioid receptor agonism and inhibits serotonin and norepinephrine reuptake. Studies corroborate these findings, showing enhanced analgesic duration with Ropivacaine-Tramadol combinations. Parthasarathy et al. reported a prolonged analgesic effect when Tramadol was used as an adjuvant with local anesthetics. Other studies, such as those by Pandey et al. and Singh et al., emphasize that Tramadol's inclusion increases the time to first analgesic request significantly without a notable rise in adverse effects.

Sedation Levels: The Ramsay Sedation Score (RSS) was

significantly higher in the Ropivacaine with Tramadol group, with a mean score of 3.06 compared to 1.26 in the Ropivacaine group ($p < 0.0001$). This observation reflects Tramadol's mild sedative effects, which can be beneficial in certain clinical contexts where patient relaxation is desired. However, excessive sedation warrants monitoring to avoid respiratory depression or delayed recovery. Similar findings were observed in studies by Santhoshkumar et al., who demonstrated higher sedation scores with Tramadol as an adjuvant, maintaining clinical safety. Additionally, Rajan et al. Reported that while sedation levels increased, they remained within safe and manageable limits under vigilant monitoring.[1],[11]

Adverse Effects: The incidence of postoperative nausea and vomiting (PONV) and pruritus was low in both groups, with no statistically significant differences ($p > 0.05$). Tramadol's dual mechanism of action does not significantly enhance PONV compared to other opioids, and the local anesthetic properties of Ropivacaine further mitigate this risk. Bajwa et al. Observed similar trends, where the combination of Ropivacaine and Tramadol exhibited low incidences of PONV.[12] Furthermore, Kaur et al. found that pre-emptive antiemetic use and careful titration of Tramadol doses contribute to minimizing these adverse effects.[13],[1]

Hemodynamic Parameters: Both groups exhibited stable hemodynamic profiles, with no significant differences in heart rate (HR), mean arterial pressure (MAP), or peripheral capillary oxygen saturation (SpO2) ($p > 0.05$). The safety of epidural Ropivacaine and its combination with Tramadol is underscored by these results. Studies by Shah et al. confirm that Ropivacaine, due to its cardio-sparing properties, maintains hemodynamic stability even when combined with opioids.[1] Similarly, Sudarshan et al. demonstrated that Tramadol's mild hemodynamic effects do not exacerbate any significant alterations in MAP or HR when used in epidural techniques.[1],[1]

Clinical Implications: This study supports the combination of Ropivacaine with Tramadol for superior postoperative analgesia in abdominal surgeries. While the combination extends the analgesic duration and mildly increases sedation, it does so without adding significant adverse effects or hemodynamic instability. These findings make it a viable choice for procedures requiring prolonged postoperative pain management.

Limitations and Future Directions: Although this study provides robust evidence, the limited sample size restricts broader applicability. Future studies could explore varying doses of Tramadol to determine an optimal balance between efficacy and safety. Additionally, evaluating the combination's efficacy across different surgical procedures could expand its utility.

CONCLUSION

This study demonstrates that the combination of Ropivacaine with Tramadol offers superior postoperative analgesia compared to Ropivacaine alone in patients undergoing abdominal surgeries. The addition of Tramadol significantly prolongs the duration of analgesia without increasing the risk of severe adverse effects. Although the combination does lead to a mild increase in sedation, this effect remains within clinically manageable limits. Furthermore, both groups exhibited stable hemodynamic profiles, reinforcing the safety of these interventions. These findings support the use of Ropivacaine-Tramadol combinations as an effective and safe analgesic strategy for abdominal surgeries, offering extended pain relief while maintaining patient comfort and safety. Future studies with larger sample sizes and a variety of surgical procedures could further elucidate the optimal dosing strategies and broad applicability of this combination for pain management in diverse clinical settings.

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