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Comparative analysis of intraperitoneal ropivacaine with and without tramadol for post-operative pain management in laparoscopic cholecystectomy

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Abstract
Aim: This study aimed to compare the postoperative analgesic effect of intraperitoneal instillation of Ropivacaine with and without Tramadol in patients undergoing laparoscopic cholecystectomy.
Material and Methods: Sixty-four patients aged 18-60 years were included and randomly divided into two groups: Group R (Ropivacaine alone) and Group RT (Ropivacaine with Tramadol). Pain intensity was measured using the Visual Analogue Scale (VAS) at various intervals postoperatively.
Results: The mean VAS scores were significantly lower in Group RT compared to Group R at most time points (e.g., 2 hours postoperatively: Group RT: 2.5±1.2 vs. Group R: 4.0±1.5, $p< 0.001$). The time to first rescue analgesic was significantly longer in Group RT (226±21.6 min) compared to Group R (100±29.9 min), with a p-value < 0.001. The total analgesic consumption within 24 hours post-surgery was also significantly lower in Group RT (109±47.44 mg) compared to Group R (179±60.19 mg), with a p-value < 0.0001.
Conclusion: The combination of intraperitoneal Ropivacaine and Tramadol provides superior postoperative analgesia compared to Ropivacaine alone in patients undergoing laparoscopic cholecystectomy.

Keywords: Intraperitoneal, ropivacaine, tramadol, postoperative pain, laparoscopic cholecystectomy

Introduction

Laparoscopic cholecystectomy is a widely performed minimally invasive procedure for the treatment of gallbladder diseases [1]. Despite its minimally invasive nature, patients often experience significant postoperative pain, which can impede recovery and prolong hospital stays. Effective pain management is crucial for enhancing postoperative recovery, improving patient satisfaction, and reducing the risk of chronic pain development.

Postoperative pain following laparoscopic cholecystectomy primarily comprises visceral pain, resulting from peritoneal irritation and the surgical procedure itself [2]. Traditional methods of pain control, such as systemic opioids, are associated with side effects like nausea, vomiting, and respiratory depression. Therefore, there is a growing interest in multimodal analgesia strategies that minimize opioid consumption while effectively managing pain.

Intraperitoneal instillation of local anesthetics (IPLA) has emerged as a promising technique to control postoperative pain by directly targeting the peritoneal surfaces and abdominal wall. Ropivacaine, a long-acting amide local anesthetic, is preferred for its favorable safety profile and reduced cardiotoxicity compared to bupivacaine. Its use in IPLA has shown promising results in various surgical procedures [3, 4].

Tramadol, a centrally acting analgesic with both opioid and non-opioid properties, has been used in combination with local anesthetics to enhance analgesic efficacy. The synergistic effect of Tramadol and Ropivacaine could potentially provide superior pain relief compared to Ropivacaine alone, reducing the need for additional analgesics and their associated side effects.

The objective of this study is to compare the postoperative analgesic efficacy of intraperitoneal instillation of Ropivacaine with and without Tramadol in patients undergoing laparoscopic cholecystectomy. We hypothesize that the combination of Ropivacaine and Tramadol will provide better pain control, prolong the duration of analgesia, and reduce the

overall requirement for rescue analgesics compared to Ropivacaine alone.

Materials and Methods

The study was carried out as a prospective, observational, single-blind study including 64 patients aged 18-60 years undergoing elective laparoscopic cholecystectomy under general anesthesia. After institutional ethical committee approval and written informed consent. Patients of age 16 to 50 years weighing between 50 kg - 80 kg belonging to ASA physical status I&II posted for elective laparoscopic cholecystectomy were included.

Pregnant females, patients with a history of hypersensitivity to ropivacaine/local anaesthetics and or tramadol, malignancy, alcohol or drug abuse were excluded. The preanaesthetic evaluation was done 1 day prior to the surgery. Patients were premedicated with oral diazepam 10 mg.

The patients were divided into two groups: Group R (Ropivacaine) and Group RT (Ropivacaine with Tramadol), each consisting of 32 patients.

All the patients were anesthetized with intravenous (IV) midazolam 0.02 mg/kg; fentanyl 2 µg/kg and propofol 2 mg/kg Intravenously given. Orotracheal intubation was facilitated with vecuronium 0.1 mg/kg IV. General anaesthesia (GA) was maintained with isoflurane and oxygen. Minute ventilation was adjusted to keep EtCO2 at 35-45 mmHg. Neuromuscular blockade was maintained by the top-up doses of vecuronium (0.01 mg/kg) IV when required. Intravenous paracetamol 1 gm was given intraoperatively. At the end of the surgery, before the removal of the trocar the study drug according to the group allocation was instilled over the gall bladder bed, hepato-duodenal ligament and hepatodiaphragmatic space by the operating surgeon who was blinded to the study drug. After instillation, to obtain thorough diffusion of LA, 2 min of trendelenburg position was maintained. The reversal of neuromuscular blockade was done with neostigmine 0.05 mg/kg IV and glycopyrrolate 0.01 mg/kg IV.

Duration of analgesia was defined as the time from which the drug was instilled to the time patient requested for first analgesic medication or NRS 4 and above. Intravenous paracetamol 15 mg/kg Intravenously was given as rescue analgesia when required. Time of the first rescue analgesic requirement was noted. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at various time intervals up to 24 hours post-surgery. Side effects such as nausea, vomiting and shoulder pain were also recorded.

Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2019) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). Quantitative variables were described as means and standard deviations or median and interquartile range based on their distribution. Qualitative variables were presented as count and percentages. For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

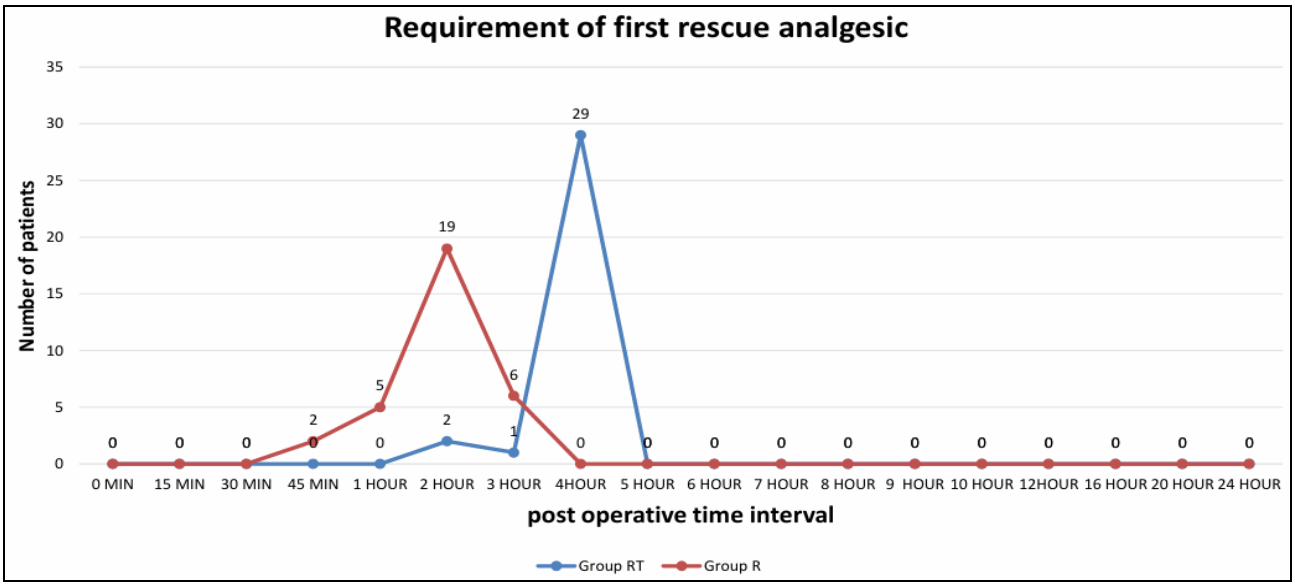
The patient demographic data like age, gender, weight and BMI were comparable between the two groups and the difference was not statically insignificant. There were no statistically significant differences in hemodynamic parameters, such as heart rate (HR) and mean arterial pressure (MAP), between the two groups throughout the postoperative period.

All the laparoscopic cholecystectomy surgery lasted less than 90 min. were included in the study. The mean duration of surgery in min. in both groups is shown in the table.

Table 1: Duration of surgery

Parameters	Group RT Mean (SD)	Group R Mean (SD)	p-value
Duration Of Surgery (in minute)	94.6± 16.25	97.5± 14.91	0.45

The mean time to the first requirement of rescue analgesic in Group RT was significantly longer (226±21.6 min) compared to Group R (100±29.9 min), with a p-value < 0.001. This suggests that the combination of Ropivacaine with Tramadol provides extended postoperative analgesia compared to Ropivacaine alone.



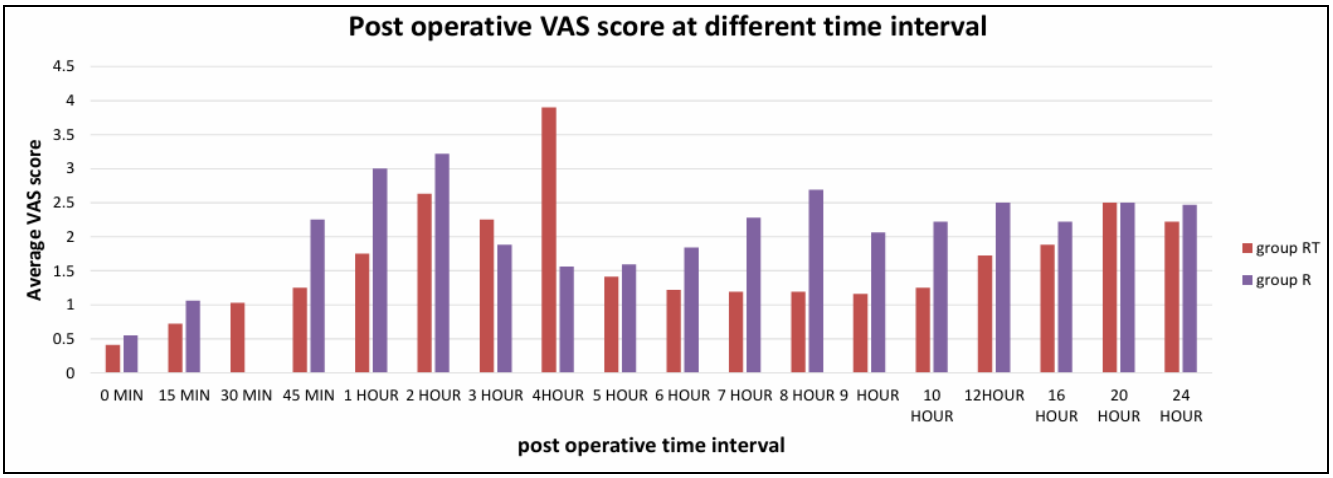
Graph 1: Requirement of first rescue analgesic

The total requirement of rescue analgesic (Inj. Tramadol) within 24 hours post-surgery was significantly lower in Group RT (109±47.44 mg) compared to Group R (179±60.19 mg), with a p-value < 0.0001. This demonstrates the effectiveness of the combined analgesic approach in reducing the need for additional pain medication.

Table 2: Total analgesic consumption in 24 Hours

Variables	Group RT Mean± SD (n-32)	Group R Mean ± SD (n-32)	p-value Overall
Total tramadol (mg) required in 24 hours	109± 47.44	179± 60.19	<0.05

The VAS scores were statistically significant between Group RT and Group R at all time intervals except at 0 min (immediate post-extubation), 15 min, and at 3, 5, 16, 20, and 24 hours postoperatively. Group RT consistently showed lower VAS scores compared to Group R, indicating better pain control when Tramadol was added to Ropivacaine.



Graph 2: Post-operative VAS score at different time interval

Side effects were minimal in both groups. Postoperative nausea was reported in 3.1% of patients in Group RT and 15.6% in Group R. Vomiting was observed in 6.25% of patients in both groups. There were no incidences of significant hemodynamic side effects like hypotension, bradycardia, or respiratory depression in either group.

Discussion

The study aimed to evaluate the efficacy of intraperitoneal instillation of Ropivacaine with and without Tramadol for postoperative pain management in patients undergoing laparoscopic cholecystectomy. The findings demonstrated that the addition of Tramadol to Ropivacaine significantly improved postoperative analgesia.

Laparoscopic surgeries, including cholecystectomy, are associated with less postoperative pain compared to open surgeries. However, effective pain management remains crucial for enhancing patient recovery and reducing hospital stay. The study confirmed that visceral pain is a major component of postoperative discomfort following laparoscopic cholecystectomy, as highlighted by Joris *et al.* (1995) [5]. Intraperitoneal local anesthetics like Ropivacaine have been shown to reduce this visceral pain effectively.

Ropivacaine, a long-acting local anesthetic with a favourable safety profile, was chosen for this study. Previous studies have indicated its efficacy in providing postoperative analgesia with fewer side effects compared to bupivacaine. Tramadol, an opioid analgesic, when used in combination with Ropivacaine, was hypothesized to enhance the analgesic effect without significant adverse reactions.

The results supported this hypothesis, showing that the combination of Ropivacaine and Tramadol (Group RT) provided better pain control, delayed the need for rescue analgesics, and reduced the total analgesic requirement in the first 24 hours post-surgery compared to Ropivacaine alone (Group R). These findings are consistent with studies by Neha T. Das *et al.* (2017) [3], which also reported longer durations of analgesia with Ropivacaine.

In 2009, Tea Han Kim *et al.* [8] conducted a study to investigate the effects of administering ropivacaine directly into the abdominal cavity for alleviating post-operative pain in patients undergoing laparoscopic cholecystectomy. The study involved two groups: Group I, consisting of 20 patients who received ropivacaine at a dose of 2 mg/kg diluted in 100 ml of normal saline at the start of pneumoperitoneum; and Group C, a control group of 20 patients who received 100 ml of normal saline in the same manner.

In a study conducted by Vivek Pratap *et al.* in 2016 [9], the effectiveness of intraperitoneal tramadol for managing postoperative pain following laparoscopic appendicectomy was examined. The study involved 60 patients divided into two groups. Group B, comprising 30 patients, received 40 ml of normal saline intraperitoneally, while group A, also with 30 patients, received 150 mg of tramadol diluted in 40 ml of normal saline at the end of surgery, just before trocar removal. The findings revealed that patients in group A consistently reported significantly lower mean Visual Analog Scale (VAS) pain ratings compared to those in group B (1.53±0.94 vs. 2.93±1.17) immediately post-surgery and throughout the entire postoperative period (<0.001). This trend closely aligns with the results observed in our own investigation.

In 2016, Jairath Ankush *et al.* [10] evaluated the analgesic effect of intraperitoneal tramadol in 100 patients undergoing laparoscopic cholecystectomy. In their study, VAS score was significantly lower in group I than in group II at 0, 15,

30 minutes, 1, and 4 hours postoperatively ($p< 0.05$) and thus this study shows that intraperitoneal tramadol improve early postoperative pain management which is similar to our study.

In 2015 Shukla Usha *et al*. [7] compared antinociceptive effects of the Intraperitoneal bupivacaine alone or with dexmedetomidine or tramadol for postoperative analgesia following laparoscopic cholecystectomy. In their study, mean time to first request of analgesic [inj. diclofenac 75 mg IM] was longest in bupivacaine with dexmedetomidine group (128±20 min) as compared to bupivacaine with tramadol Group (118±22 min) and bupivacaine Group (55±18 min).

In 2018 Radhe Sharan *et al*. [11] observed that mean time of the first rescue analgesic requirement [inj. diclofenac 75 mg IM] was longer in group ropivacaine (162.22±124.16 min) compared to group bupivacaine (150±86.40 min). The difference was found statistically insignificant in the two groups, thus they evaluated that intraperitoneal ropivacaine provide longer duration of analgesia as compared to bupivacaine

In 2013 A Singh *et al*. [6] compared effectiveness of intraperitoneal ropivacaine with or without fentanyl for postoperative analgesia after laparoscopic surgery. A total of 150 patients were divided into 3 groups (n = 50). In their study, the mean time of the first rescue analgesic [inj. diclofenac 75 mg IM] in group 1(normal saline) was 13.00± 7.55 min, group 2 (ropivacaine with normal saline) was 117.55±46.85 min, and group 3 (ropivacaine with Fentanyl) was 138.97±34.10. Therefore, this study demonstrates that intraperitoneal instillation of ropivacaine with opioids improves and prolongs the duration of analgesia compared to ropivacaine alone. Which is similar to our study.

The researchers evaluated the severity of pain using the Visual Analog Scale (VAS) at specific intervals following the surgery: 2, 4, 8, 12, 24, and 48 hours. This method allowed them to compare how effectively ropivacaine mitigated pain compared to the saline control over the post-operative recovery period.

The hemodynamic stability observed in both groups indicates that the addition of Tramadol does not compromise patient safety. The minimal side effects further affirm the safety and efficacy of this analgesic combination for postoperative pain management in laparoscopic cholecystectomy.

Limitations

Postoperative pain is a subjective experience, so postoperatively objective observation of such is difficult to be assessed and compare when comparing various treatment options. Total analgesia consumption could have been ascertained precisely if study were done for large sample size. As there are very few studies done in the past on combination of ropivacaine with tramadol for intraperitoneal instillation; further studies with different doses of tramadol, timing of instillation and various concentrations of ropivacaine to provide maximal post-operative pain relief with minimum adverse effect should be needed after laparoscopic surgery.

Financial support and sponsorship

Nil.

Conflict of Interest

Nil.

Conclusion

Intraperitoneal instillation of 0.5% Ropivacaine with Tramadol provides superior postoperative analgesia compared to 0.5% Ropivacaine alone, without significant side effects. This combination can be considered a better approach for pain management in laparoscopic surgeries, enhancing patient comfort and recovery.

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