ORIGINAL RESEARCH

"IMPACT OF INTRAPERITONEAL ROPIVACAINE WITH DIFFERENT DOSES OF TRAMADOL AS AN ADJUVANT FOR POST OPERATIVE ANALGESIA IN LAPROSCOPIC CHOLECYSTECTOMY"

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ABSTRACT:
Pain and its management have posed a formidable challenge for humanity throughout history. Few issues in medicine have proven as resistant to a comprehensive solution as the alleviation of pain. It ranks second only to the common cold as a primary reason why patients seek the guidance of a healthcare professional. The conquest of pain stands as one of the most remarkable achievements of science, playing a pivotal role in the evolution and success of surgical interventions.Postoperative pain represents a universal phenomenon, further compounded by associated muscle spasms and visceral distension. While considerable strides have been made in addressing pain during surgical procedures, the challenge persists in managing the subsequent postoperative period.Anaesthesiologists have made significant progress in alleviating pain for patients undergoing surgery, contributing immensely to the success and advancements in surgical procedures. However, once the surgical intervention is completed, patients often find themselves grappling with the distressing reality of postoperative pain. This phase requires a nuanced approach, considering not only the physiological aspects of pain but also the subjective and multifaceted nature of the patient's experience.The understanding of pain has evolved to recognize its intricate dimensions, extending beyond the purely physical to encompass psychological and cultural components. Holistic pain management strategies, involving a combination of pharmacological and non-pharmacological interventions, have become essential in addressing the diverse aspects of postoperative pain. Moreover, advancements in anesthesia techniques and analgesic medications aim to enhance patient comfort and minimize the impact of postoperative pain on recovery.In summary, while considerable progress has been achieved in mitigating pain during surgical procedures, the quest for effective postoperative pain management continues. Acknowledging the multidimensional nature of pain and adopting comprehensive, patient-centric approaches are crucial steps in ensuring that advancements in science and medicine translate into enhanced well-being and comfort for individuals undergoing surgical interventions.

Keywords: Anaesthesia, multidimensional,physiology

INTRODUCTION:

Anesthesia has made significant strides in mitigating patient pain during surgical procedures, marking a crucial advancement in medical care. However, once the surgery is completed, patients often face the challenge of postoperative pain.[1] The advent of laparoscopic procedures has revolutionized modern surgeries, gradually replacing traditional open surgeries. Laparoscopy offers several advantages, including smaller and more cosmetic incisions, reduced blood loss, diminished pain, early mobility, and prompt initiation of enteral feeding. These benefits contribute to a shorter hospital stay, promoting a faster recovery.Postoperative pain following laparoscopic cholecystectomy, a preferred technique for uncomplicated cholecystectomy, is characterized by tissue injury and muscle spasm. Inadequately managed pain not only hampers the recovery process but also places a burden on patients and their families, while simultaneously increasing healthcare costs. The initial 24 hours post-surgery often witness significant pain, peaking within the first 4-6 hours.[2-4] Visceral pain results from the stretching of the intraperitoneal cavity, while parietal pain stems from factors such as port site incision, peritoneal inflammation, and irritation of the phrenic nerve,

often manifesting as shoulder tip pain. Pain, if not managed effectively, can impede proper breathing and lead to pulmonary complications.A variety of modalities are available for postoperative pain relief, ranging from parenteral analgesia (nonsteroidal anti-inflammatory drugs and opioids) to epidural analgesia, peripheral nerve blocks, incisional infiltration, and intraperitoneal instillation using local anesthetics. The use of intraperitoneal local anesthetics has proven effective in providing adequate analgesia without the side effects associated with intravenous opioids. Intraperitoneal instillation of local anesthetic agents alone or in combination with opioids and α-2 agonists has been found to significantly reduce postoperative pain following laparoscopic surgeries.Previous studies suggest that intraperitoneal instillation can theoretically block visceral pain, while parietal pain can be alleviated through port site infiltration of local anesthetics. Various local anesthetics, including Lignocaine, Bupivacaine, and the latest addition, Ropivacaine, have been employed, with Bupivacaine being the routinely used long-acting local anesthetic. However, its cardiotoxic potential has raised concerns. Ropivacaine, on the other hand, has demonstrated lower toxicity to the cardiac and central nervous systems compared to Bupivacaine, presenting a promising alternative for effective and safer pain management in the postoperative period.The study, titled "Impact of Intraperitoneal Ropivacaine with Different Doses of Tramadol as an Adjuvant for Postoperative Analgesia in Laparoscopic Cholecystectomy," is designed to investigate various aspects of pain management in the postoperative period.[5,6] The primary objective is to compare the severity of postoperative pain between patients receiving intraperitoneal Ropivacaine alone and those receiving Ropivacaine combined with different doses of Tramadol, using the Visual Analog Scale (VAS) score as a quantifiable measure. Additionally, the study aims to assess and compare the consumption of rescue analgesia, explore the duration of analgesic effects, investigate potential side effects such as nausea, vomiting, and cardiovascular changes, and finally, evaluate patient satisfaction levels across the different treatment groups. By addressing these objectives, the research endeavors to provide valuable insights into the efficacy, safety, and overall patient experience associated with this particular analgesic regimen in the context of laparoscopic cholecystectomy.

MATERIALSANDMETHODS:

The investigation, titled "Impact of Intraperitoneal Ropivacaine Using Different Doses of Tramadol as an Adjuvant for Postoperative Analgesia in Laparoscopic Cholecystectomy," spanned a duration of one year, emblematic of a comprehensive exploration into optimizing postoperative pain management strategies. Employing a prospective, randomized, and controlled study design, the research sought to rigorously assess the effects of intraperitoneal administration of Ropivacaine with varying doses of Tramadol in the context of laparoscopic cholecystectomy.Ethical considerations were paramount, and the study commenced only after receiving explicit clearance from the Institutional Ethics Committee (IEC). This foundational approval underscored the commitment to ensuring the welfare, rights, and safety of the participants involved in the study. The targeted study population consisted of 90 adult patients falling within the American Society of Anesthesiologists (ASA) grade I and II categories. This cohort was specifically chosen from individuals scheduled to undergo laparoscopic cholecystectomy under the umbrella of general anesthesia.The randomized and controlled nature of the study design was crucial in minimizing biases and confounding factors, thereby enhancing the internal validity of the findings.[7] Patients were allocated to different groups, each receiving intraperitoneal Ropivacaine either alone or in conjunction with varying doses of Tramadol. This deliberate randomization allowed for a systematic evaluation of the impact on postoperative analgesia, leveraging the strengths of a controlled experimental setup.By adopting a prospective approach, the study aimed to capture real-time data, fostering a dynamic understanding of the responses and outcomes associated with the intraperitoneal administration of Ropivacaine and Tramadol. The choice of laparoscopic cholecystectomy as the surgical context was not only clinically relevant but also aligned with the contemporary preference for minimally invasive procedures. This surgical model presented an opportune arena to investigate the nuanced interplay of analgesic agents in a setting characterized by specific physiological and anatomical considerations.In essence, the comprehensive design of the study, encompassing ethical approval, participant selection criteria, randomization, and the choice of surgical context, positions it as a valuable contribution to the field of postoperative pain management.[8] The outcomes of this research endeavor hold the potential to inform clinical practices, enhance patient outcomes, and contribute to the ongoing refinement of analgesic strategies in the domain of laparoscopic cholecystectomy.The study meticulously outlined its criteria for participant inclusion and exclusion to ensure the robustness of its findings. In selecting participants, the inclusion criteria specified the need for adult patients with a body weight surpassing 45 kg, scheduled for laparoscopic cholecystectomy. This criterion aimed to narrow down the study's focus to a specific demographic undergoing a common surgical procedure, enhancing the relevance of the outcomes to this particular patient population.Conversely, the exclusion criteria were thoughtfully designed to mitigate potential confounding factors and safeguard participant well-being. Patient refusal to participate was considered a

valid reason for exclusion, upholding the principle of voluntary participation in clinical research.[9] Excluding individuals with diagnosed psychological disorders or an inability to comprehend the Visual Analog Scale (VAS) aimed to ensure reliable data collection by maintaining participants' cognitive capacity to communicate their pain intensity accurately.The exclusion of pregnant females, individuals allergic to Ropivacaine and Tramadol, and those with a history of malignancy underscored ethical considerations and safety concerns. This approach prevented potential risks associated with the intervention during pregnancy, allergic reactions, and the influence of cancer-related factors on pain perception, respectively.The thorough history-taking process, including medical, surgical, and allergy histories, coupled with a comprehensive pre-anesthetic evaluation, demonstrated the study's commitment to participant safety and the collection of relevant clinical information. The informed consent process, conducted in a language understood by each participant, exemplified transparency and adherence to ethical standards. Educating participants on the VAS score and a patient satisfaction scale empowered them toactivelyengageinthestudy'sassessmentprocedures.Group R0 (n=30) received 18ml of 0.5% Ropivacaine (plain) along with 2ml of normal saline, in addition to the standard postoperative analgesia regimen.Group RT1 (n=30) received 18ml of 0.5% Ropivacaine (plain) and 2ml (50 mg Tramadol) along with the standard postoperative analgesia regimen.Group RT2 (n=30) received 18ml of 0.5% Ropivacaine (plain) and 2ml (100mg) along with the standard postoperative analgesia regimen.The postoperative analgesia regimen included intravenous injection of Paracetamol (1gm, 12-hourly) administered after gall bladder removal, with Pentazocine (0.5mg/kg) available as rescue analgesia. Patients were carefully monitored, and baseline parameters, such as heart rate, blood pressure, SPO2, respiratory rate, and electrocardiographic tracings, were recorded.In the operating room, after routine monitoring and preoxygenation, patients received intravenous fentanyl (2mcg/kg), followed by induction with intravenous propofol (2mg/kg) and succinylcholine (2mg/kg) for endotracheal intubation. Anesthesia was maintained with nitrous oxide (70%), oxygen (30%), and isoflurane (MAC 0.8-1%) in oxygen.[10] Intrabdominal pressure was maintained at around 12 mm of Hg for all patients throughout the procedure. Minute ventilation was adjusted to keep EtCO2 at 35-45mmHg, and neuromuscular blockade was maintained with top-up doses of atracurium.Intraoperatively, intravenous paracetamol (1gm) was given at the removal of the gall bladder. Before trocar removal, a local anesthetic (LA) was instilled through the laparoscopic irrigation system over the gall bladder bed (10ml), hepato-duodenal ligament (5ml), and hepato diaphragmatic space (5ml) by the operating surgeon. Trendelenburg position was maintained for 3 minutes after instillation. The reversal of neuromuscular blockade was achieved with neostigmine (0.05 mg/kg IV) and glycopyrrolate (0.01mg/kg IV). The postoperative analgesic regimen included intravenous injection of paracetamol (1 gram) at 12 and 24 hours.Patients were instructed to score their pain every half hour up to 6 hours, and then at 12 and 24 hours, using a Visual Analogue Scale (VAS) where 0 cm indicated no pain and 10 cm represented the worst pain imaginable.[11,12] If the VAS score was ≥3, intravenous pentazocine (24mg) was administered as rescue analgesia, and the time to the first dose was recorded. The total consumption of pentazocine over 24 hours was also documented.

RESULTS:

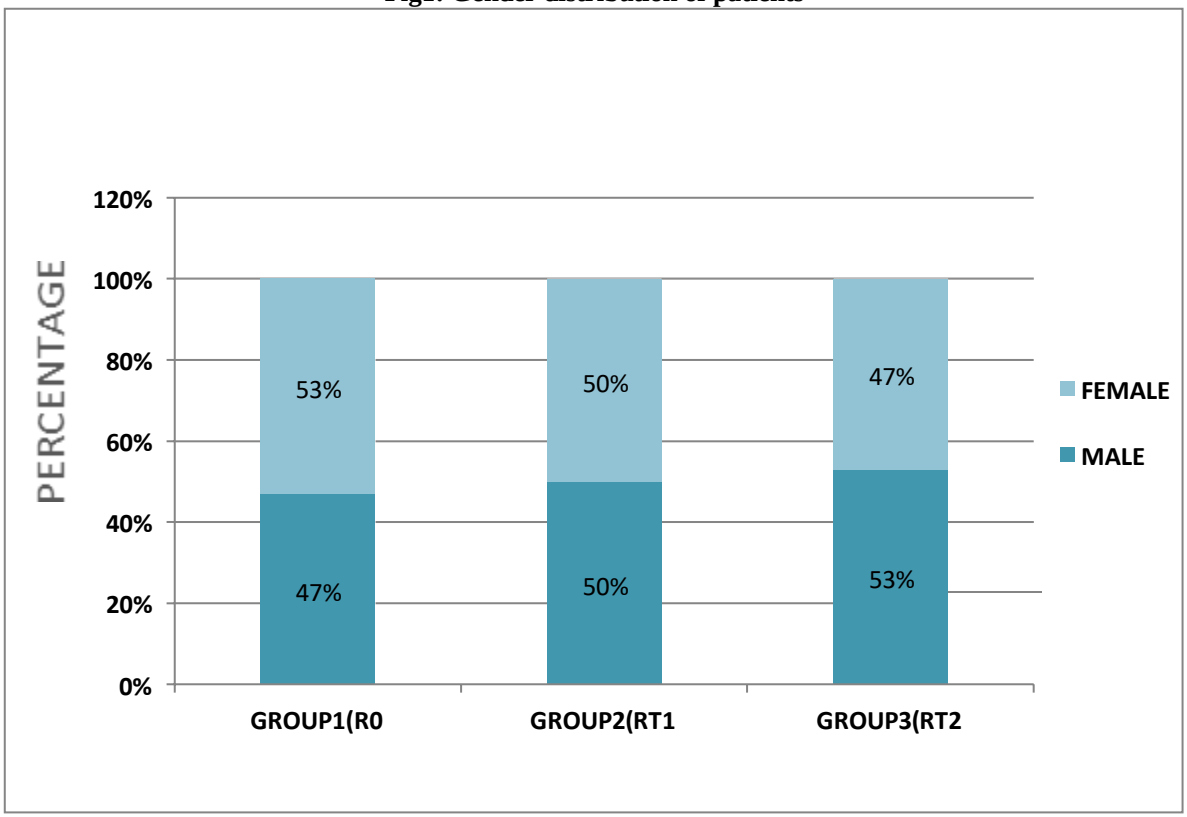
The current investigation, titled "Impact of Intraperitoneal Ropivacaine Using Different Doses of Tramadol as an Adjuvant for Postoperative Analgesia in Laparoscopic Cholecystectomy," was conducted as a prospective, randomized, and controlled study. Following the fulfillment of patient criteria and obtaining approval from the Ethics Committee, a total of ninety adult patients with ASA status I or II undergoing Laparoscopic Cholecystectomy under general anesthesia were systematically divided into three groups.

Table 1: - GROUP DISTRIBUTION

Groups	Drugs use intraperitoneally	N	%
Group1(R0)	Ropivacaine 0.5% 18ml alone	30	33.33
Group2 (RT1)	Ropivacaine 0.5%18ml+tramadol mg50	30	33.33
Group3 (RT2)	Ropivacaine 0.5%18ml+tramadol mg100	30	33.34
Total		90	100

The table above illustrates the distribution of participants across different groups. In Group 1 (R0) (n=30), participants received Intraperitoneal administration of 18ml 0.5% Ropivacaine (plain) along with 2ml of normal saline, in addition to the standard postoperative analgesia regimen. Group 2 (RT1) (n=30) was administered 18ml 0.5% Ropivacaine (plain) + 2ml of 50mg tramadol intraperitoneally, along with the standard postoperative analgesia regimen. Group 3 (RT2) (n=30) received 18ml 0.5% Ropivacaine (plain) + 2ml of 100mg tramadol intraperitoneally, in conjunction with the standard postoperative analgesia regimen, which included intravenous injection of Paracetamol 1gm (12-hourly).

Fig1: Gender distribution of patients

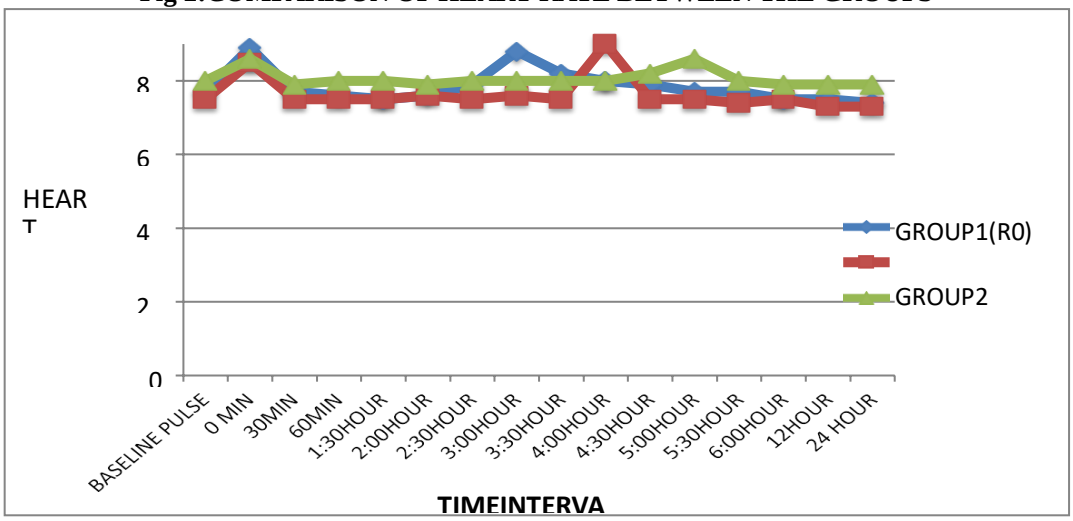


The study population exhibited comparable baseline characteristics across the three groups. The mean body weights were 60.63±10.12 kg for Group 1, 59.33±7.68 kg for Group 2, and 61.47±5.98 kg for Group 3, indicating no significant differences in the average weights of patients among the groups. Similarly, the heights of individuals in the three groups were not statistically distinct. These findings suggest that the distribution of body weight and height was consistent, ensuring a balanced representation of these parameters across the study groups.The homogeneity among the three groups in terms of sex distribution.[13] The graph indicates that there were no significant variations in the proportion of male and female participants among Group 1, Group 2, and Group 3. This uniform distribution of sex within the study groups enhances the comparability of the data and strengthens the validity of the study's findings. Overall, the meticulous attention to matching baseline characteristics contributes to the robustness of the study design and supports the reliability of any observed differences in outcomes, affirming the scientific rigor of the investigation.

TABLE2:DEMOGRAPHICDISTRIBUTIONAMONGTHEGROUPS

PARAMETERS	GROUPS						R0VSRT1	RT1 VSRT2	R0V SRT 2
	GROUP1(R0)		GROUP 2(RT1)		GROUP 3(RT2)		P value	P value	P value
	MEAN	SD	MEAN	SD	MEAN	SD			
AGE	37.1	6.6	36.33	4.5	38.5	4.5	0.6	0.07	0.344
HEIGHT(CM)	139.27	18.01	139.57	5.04	140.23	3.91	0.93	0.06	0.3
WEIGH(KG)	60.63	10.12	59.33	7.68	61.47	5.9	0.5	0.112	0.05
SEXRATIO(F:M)	16:14		15:15		14:16		P Value-0.7301.		

Fig 2:COMPARISON OF HEART RATE BETWEEN THE GROUPS



DISCUSSION:

The study conducted in the Department of Anesthesiology over the course of one year was a prospective, randomized, and controlled investigation titled "Impact of Intraperitoneal Ropivacaine Using Different Doses of Tramadol as an Adjuvant for Postoperative Analgesia in Laparoscopic Cholecystectomy." The primary objective of the study was to assess the postoperative analgesic efficacy among patients who underwent laparoscopic cholecystectomies by employing intraperitoneal Ropivacaine with varying doses of Tramadol.The research methodology included the use of the Visual Analog Scale (VAS) to quantify the postoperative pain experience in different groups, providing a measurable parameter for the assessment of analgesic efficacy. Additionally, the study evaluated patients' satisfaction with postoperative analgesia using a 5-point satisfaction scale, offering a qualitative dimension to the assessment of pain management outcomes.[14,15] The study protocol was executed within a 24-hour timeframe, capturing the immediate postoperative period to gauge the short-term effectiveness of the interventions.Demographic parameters such as age, height, weight, and sex distribution were systematically collected and compared among Group 1, Group 2, and Group 3. The emphasis on ensuring comparability in these baseline characteristics underscored the study's commitment to minimizing confounding variables and enhancing the internal validity of the findings. By addressing the specific context of laparoscopic cholecystectomy, the study aimed to contribute valuable insights to the optimization of postoperative analgesia strategies in this surgical setting.In summary, the study embarked on a comprehensive exploration of the impact of intraperitoneal Ropivacaine and Tramadol on postoperative pain management, employing both quantitative and qualitative measures to assess analgesic efficacy and patient satisfaction. The meticulous consideration of demographic parameters and the controlled study design bolster the credibility of the research outcomes, offering a meaningful contribution to the field of anesthesiology and perioperative care.[16]The duration of analgesia was a key parameter assessed in our study, providing insights into the efficacy of different interventions. In Group 1, the mean duration of analgesia was 3.07±0.45 hours, while in Group 2, it was 3.77±0.43 hours, and in Group 3, it significantly extended to 4.70±0.34 hours. Statistical analysis revealed that the differences between Group 1 and Group 3, Group 2 and Group 3, as well as Group 1 and Group 2, were all statistically significant (p value <0.05). This indicates that the duration of analgesia varied significantly between the groups, with Group 3 exhibiting the longest duration of effective pain relief.These findings suggest that the addition of Tramadol as an adjuvant to intraperitoneal Ropivacaine led to a statistically significant prolongation of the duration of analgesia compared to the groups without Tramadol.[17] The observed differences emphasize the potential impact of the adjuvant Tramadol on the overall postoperative pain management in laparoscopic cholecystectomy cases. The study outcomes contribute valuable information for clinicians aiming to optimize analgesic strategies in this specific surgical context.The total analgesic requirement, as measured by the total pentazocine consumption in the first 24 hours postoperatively, demonstrated notable differences among the study groups. In Group 1, the mean total pentazocine requirement was (72±15.72) mg, while in Group 2, it was (53±9.33) mg, and in Group 3, the requirement was significantly lower at (32±8.86) mg. Statistical analysis revealed that the pentazocine requirement was significantly higher in Group 1 compared to both Group 2 and Group 3, with a p-value < 0.05. However, the difference in pentazocine requirement between Group 1 and Group 2 was not statistically significant.[18]These results suggest that the addition of Tramadol as an adjuvant to intraperitoneal

Ropivacaine (Group 3) led to a significantly reduced total pentazocine requirement in the first 24 hours postoperatively compared to both the plain Ropivacaine group (Group 1) and the Ropivacaine with lower dose Tramadol group (Group 2). This implies that the adjuvant Tramadol played a role in decreasing the overall analgesic consumption, highlighting its potential contribution to enhanced postoperative pain management in laparoscopic cholecystectomy cases. These findings have practical implications for clinicians seeking effective analgesic strategies in similar surgical scenarios.Patient satisfaction is a crucial aspect of postoperative care, and in our study, we observed that patients in Group 3 expressed higher satisfaction compared to Group 1, where dissatisfaction was more prevalent.[19] This trend can be attributed to the administration of Ropivacaine with Tramadol 100mg in Group 3, which provided better and longer-lasting analgesia. The positive correlation between patient satisfaction and the effectiveness of pain management aligns with the idea that prolonged and improved pain relief contributes to a more satisfactory postoperative experience.In terms of adverse effects, the incidence of nausea and vomiting was monitored across the study groups. The results indicated that there were 5 patients with nausea and vomiting in Group 1, 5 patients in Group 2, and 6 patients in Group 3. However, these differences were statistically not significant, suggesting that the addition of Tramadol did not significantly impact the incidence of nausea and vomiting compared to the plain Ropivacaine group. Importantly, no other side effects were noted in any of the study groups.These findings provide valuable insights into the balance between enhanced analgesia, patient satisfaction, and potential side effects associated with the interventions. The statistically insignificant differences in nausea and vomiting suggest that the addition of Tramadol did not exacerbate these common postoperative side effects.[20,21] The study's focus on adverse effects contributes to a comprehensive understanding of the safety profile of the analgesic interventions employed in laparoscopic cholecystectomy cases.

CONCLUSION:

The study's comprehensive findings underscore the efficacy of Ropivacaine combined with tramadol (100mg) as a superior approach to postoperative analgesia in patients undergoing Laparoscopic Cholecystectomy. The results reveal several key advantages of this combination compared to alternative regimens. Firstly, patients receiving Ropivacaine with tramadol (100mg) experienced enhanced pain control, as evidenced by a reduced need for rescue analgesia, indicating the regimen's effectiveness in minimizing postoperative discomfort. Moreover, the lower Visual Analog Scale (VAS) scores observed in this group signify a superior capacity for pain reduction compared to groups receiving lower doses of tramadol or Ropivacaine alone.Patient satisfaction emerged as a notable outcome, with individuals in the Ropivacaine with tramadol (100mg) group expressing higher levels of contentment compared to their counterparts. This positive correlation between increased patient satisfaction and the higher tramadol dose underscores the importance of tailored analgesic strategies for optimizing postoperative experiences. Furthermore, the reduced demand for the first rescue analgesia in the Ropivacaine with tramadol (100mg) group highlights the regimen's ability to prolong pain relief, contributing to a more favorable postoperative course.In summary, the study concludes that Ropivacaine with tramadol (100mg) stands out as a preferable choice for postoperative analgesia in Laparoscopic Cholecystectomy, offering superior pain control, lower VAS scores, increased patient satisfaction, and a delayed need for rescue analgesia. These findings have significant implications for perioperative care, guiding clinicians towards more effective analgesic approaches to enhance patient outcomes in the context of laparoscopic surgical procedures.

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