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COMPARISON OF OUTCOME OF INTRAPERITONEAL INSTILLATION OF ROPIVACAINE VERSUS NORMAL SALINE FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY IN TERMS OF POSTOPERATIVE PAIN ANALGESIA REQUIREMENT

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Abstract

Gallbladder diseases, managed surgically for over 2000 years, have seen laparoscopic cholecystectomy emerge as the gold standard due to reduced pain and faster recovery. However, effective postoperative pain control remains a challenge, necessitating optimized interventions like intraperitoneal ropivacaine. Given the limited local data, our study aimed to evaluate and establish the efficacy of ropivacaine in reducing postoperative pain and analgesic requirements.

OBJECTIVE: *To compare the outcome of intraperitoneal instillation of ropivacaine versus normal saline for reduction of postoperative pain after laparoscopic cholecystectomy*

SETTING: *North Surgical ward, Mayo hospital Lahore*

DURATION: *Six months after the approval of synopsis from: May 2, 2024 to November 2, 2024*

STUDY DESIGN: *Randomized control trial*

METHODOLOGY: *In this trial we included patients with symptomatic gallstones undergoing laparoscopic cholecystectomy, randomly assigned to receive 30 mL of either 0.5% ropivacaine (Group R) or saline (Group NS) in the gallbladder bed. Pain was assessed at 6 hours using the Visual Analogue Scale (VAS) by independent, blinded assessors. Additional analgesia was administered for VAS scores >6, with data on demographics, pain, and analgesic requirements meticulously recorded for analysis.*

RESULTS: *The ropivacaine group showed significantly lower mean VAS scores (1.98 ± 0.84) compared to the saline group (5.60 ± 1.21; $p < 0.000$). Rescue analgesia was required by 30% in the ropivacaine group versus 60% in the saline*

group (p = 0.003), demonstrating ropivacaine's superior efficacy in reducing postoperative pain and analgesic needs.

CONCLUSION: *Outcome of intraperitoneal instillation of ropivacaine is significantly favorable when compared to those with normal saline for reduction of postoperative pain after laparoscopic cholecystectomy.*

INTRODUCTION

Gall bladder problems have been recognised to the human race for more than two thousand years. The cholecystectomy is the most common type of procedure that is performed on the biliary tract in patients nowadays. [i, ii] For more than a century, Langenbuch's open cholecystectomy has been considered the therapy of choice for patients who are experiencing symptoms of cholelithiasis. At a consensus conference for cholelithiasis that was convened in Bethesda in September 1992, the National Institutes of Health came to the conclusion that laparoscopic cholecystectomy was the therapy of choice for the condition.[iii]

Any cholecystectomy planned to be performed laparoscopically was considered laparoscopic. Laparoscopic cholecystectomy reduces pain, hospital stay, and recovery time, allowing patients to return to normal life and work sooner. [iv] Numerous centres discharge patients on the first postoperative day. Few centres have lately proved that the operation is safe and practical as an outpatient treatment in well selected patients as experience grows. Pain after surgery is unexpected, thus it must be prevented before the patient wakes up. Laparoscopic cholecystectomy causes visceral, abdominal wall, and shoulder pain.[v]

In the first 24 hours, visceral discomfort is worse than abdominal wall pain. Distention-induced neuro-praxia of the phrenic nerves, residual intra-abdominal gas after laparoscopy, insufflated gas humidity, volume, wound size, parietal peritoneum trauma, drains, and anaesthetic drugs and their postoperative effects can cause pain. Carbon dioxide insufflation is the most common pneumo-peritoneum method. Visceral and shoulder tip discomfort has been linked to carbonic acid, which is generated by CO2 and water reaction and leftover pneumo-peritoneum space between liver and diaphragm. [vi] Non-steroidal anti-inflammatory drugs and opioids, intraperitoneal local anaesthetics, port site infiltration of local anaesthetics, intraperitoneal saline, removal of insufflation gas or gas drains, low pressure abdominal insufflations, administration of acetazolamide, and the use of nitrogen dioxide instead of carbon dioxide are some of the different modalities that have been proposed for the purpose of relieving postoperative pain following laparoscopy. [vii]

A large number of people utilise local anaesthetics, they have an excellent safety profile, and they are accessible in preparations that have a long acting time. They offer the advantages of anaesthesia without the systemic negative effects that are associated with it. In a reversible manner, local anaesthetics inhibit the formation and propagation of action potentials in nerve and other excitable tissues. This inhibition occurs most likely at the level of the passive sodium channels. [viii]

The VAS score for abdominal pain in the group that received ropivacaine (group A) was considerably lower than the group that received normal saline (group B) after six hours ($P < 0.040$), twelve hours ($P < 0.002$), and twenty-four hours ($P < 0.001$), according to just one study. When the VAS score was taken at the 48th hour, it was not significant ($P > 0.05$). When comparing group A to group B, the VAS score for shoulder tip pain was found to be significant at the sixth hour ($P < 0.012$). However, at the twelveth hour, the twenty-fourth hour, and the forty-eighth hour, the VAS score was found to be negligible ($P > 0.05$). At the sixth hour, analgesic injections were administered to 66.36 percent of patients in group A and 63.33 percent of patients in group B. It was determined that the estimated P value (<0.0001) was significant between group A and group B. Injections of analgesics were administered to 10% of patients in group A and 33.33 percent of patients in group B after a period of 12 hours. The computed p value of 0.0575 indicated that there was no significant difference between groups A and B. Sixty-six percent of patients in both groups had analgesic injections after twenty-four hours had passed. Analgesic injections were not administered to any of the patients in either of the

groups after a period of forty-eight hours. [ix] In another study, mean pain score at 8 hours was 13.66±3.3 in control vs 8.32±2.4 in ropivacain group. [x]

The study's justification is that there is very little international, and much less local, data on the use of ropivacaine instillation during laparoscopic cholecystectomy to reduce post-operative pain. The purpose of this study was to assess the outcome of intraperitoneal rupivacaine instillation vs normal saline following laparoscopic cholecystectomy in terms of postoperative analgesic demand. With a considerable reduction in post-operative pain, analgesic use, and hospital stay.

METHODOLGY

A randomised controlled experiment was carried out in the North Surgical Ward of Mayo Hospital in Lahore, Pakistan, over the course of a period of six months, beginning on May 2, 2024 and ending on November 2, 2024. The trial was carried out after receiving consent from the institutional ethics council. The non-probability consecutive sampling method was utilised to enrol patients who were diagnosed with symptomatic gallstone disease and were scheduled to have laparoscopic cholecystectomy treatments. The sample size was determined by utilising the World Health Organization's sample size calculator. The calculation was based on the anticipated percentages of patients in both groups who required rescue analgesia. There were a total of 100 patients, with 50 patients in each group. Participants were enrolled in the study if they met the inclusion criteria, which included being between the ages of 20 and 50, being of either gender, having normal liver function tests (LFTs), and having ultrasonographic confirmation of gallstones. Patients were not allowed to participate in the study if they had experienced hypersensitivity to ropivacaine, acute cholecystitis, pregnancy, a history of peritonitis, common bile duct stones, subhepatic drain insertion, or diabetes.

The lottery approach was used to perform the random assignment of patients into two groups after they had provided their informed consent. A 30-milliliter instillation of 0.5% ropivacaine was administered intraperitoneally to Group R, while 30 millilitres of normal saline were administered to Group NS. Laparoscopic cholecystectomy was conducted utilising a four-trocar approach, with the patient in a mild reverse Trendelenburg position. The procedure was performed on the patient. Under the supervision of direct laparoscopic vision, a silicone catheter, also known as an epidural catheter, was inserted through the lateral trocar. The tip of the catheter was then positioned in the gallbladder bed so that the research solution could be administered. There were no drains installed. Antibiotics of the standard preventive regimen, which included three doses of a cephalosporin of the second generation, were provided perioperatively..

An independent nurse who was blinded to the study used the Visual Analogue Scale (VAS) to evaluate the level of pain experienced by the patients six hours after surgery. The VAS is a scale that ranges from 0 to 10, with 0 indicating no pain and 10 indicating the most severe pain possible. In order to guarantee appropriate reporting, patients were given an introduction to the VAS rating method before to the operation. In order to give standard postoperative analgesia, intravenous injections of 30 milligrammes of toradol were administered every eight hours. After a period of six hours, further analgesia in the form of intravenous nalbuphine 4 mg was delivered if the VAS score was reported to be greater than 6. A proforma that had been developed in advance was used to record information about the patient's demographics, the length of the operation, the postoperative pain scores, and any further analgesic needed..

Data was analysed using SPSS 23. Quantitative data like age, BMI, and postoperative pain scores were expressed as means and standard deviations, whereas qualitative factors like gender and additional analgesic requirements were calculated as frequencies and percentages. The independent sample t-test was used to compare mean pain scores between groups, whereas the chi-square test was employed to analyse categorical factors like analgesia required. A p-value < 0.05 indicated statistical significance. Data were stratified by age, gender, and BMI to account for potential confounding factors, and post-stratification statistical tests assessed their effects on study outcomes.

RESULTS

Age distribution was similar across both groups. Group R (Ropivacaine) had 48% aged 20–35 and

52% aged 36–50, while Group NS (Normal Saline) had 42% and 58%, respectively. Mean ages were also comparable (35.66 ± 9.83 vs. 36.50 ± 8.43; p > 0.05). Females predominated in both groups—70% in Group R and 60% in Group NS. Males comprised 30% and 40%, respectively, reflecting common gender patterns in gallbladder surgeries. Group R had more overweight patients (74%) than Group NS (52%). Normal BMI was higher in Group NS (48% vs. 26%). Mean BMI was also slightly higher in Group R (26.20 ± 2.72 vs. 25.34 ± 2.94).

Pain scores were significantly lower in Group R (1.98 ± 0.84) compared to Group NS (5.60 ± 1.21; p < 0.000). Fewer patients in Group R required additional analgesia (30% vs. 60%; p = 0.003), confirming better pain control with Ropivacaine.

In the 20–35 age group, 33.3% in Group R needed extra analgesia compared to 66.7% in Group NS (p = 0.007). In older patients (36–50), the difference was not statistically significant. Among females, 36.7% in Group R required additional analgesia compared to 63.3% in Group NS (p = 0.013). Among males, the difference was not significant. In patients with normal BMI, analgesia need was lower in Group R (7.7%) than Group NS (92.3%; p = 0.013). Among overweight patients, 43.8% in Group R needed analgesia compared to 56.3% in Group NS (p = 0.021). VAS scores remained consistently lower in Group R across subgroups: age 20–35 (2.04 vs. 5.43), age 36–50 (1.92 vs. 5.72), males (2.13 vs. 5.80), females (1.91 vs. 5.47), normal BMI (2.08 vs. 5.75), and overweight BMI (1.95 vs. 5.46), all with p < 0.0001.

Table no. 1: Demographic and Clinical Characteristics of Patients (n = 100)

Variable	Category	Group R n (%)	Group NS n (%)
Age (years)	20–35	24 (48%)	21 (42%)
	36–50	26 (52%)	29 (58%)
	Mean ± SD	35.66 ± 9.83	36.50 ± 8.43
Gender	Male	15 (30%)	20 (40%)
	Female	35 (70%)	30 (60%)
Body Mass Index (BMI)	18–25	13 (26%)	24 (48%)
	>25	37 (74%)	26 (52%)
	Mean ± SD	26.20 ± 2.72	25.34 ± 2.94

Table no. 2 Comparison of Outcomes Between Group R and Group NS (n = 100)

Variable	Group R	Group NS	P value
Visual Analogue Score (VAS)	Mean ± SD: **1.98 ± 0.84**	Mean ± SD: **5.60 ± 1.21**	**0.000**
Additional Analgesia Requirement	Yes: 15 (30%) No: 35 (70%)	Yes: 30 (60%) No: 20 (40%)	**0.003**

DISCUSSION

The hypothesis of this study proposed that intraperitoneal instillation of ropivacaine during laparoscopic cholecystectomy would significantly reduce postoperative pain scores and the requirement for additional analgesics compared to normal saline. The findings of this randomized controlled trial strongly validated the hypothesis. Patients in the ropivacaine group demonstrated substantially lower mean pain scores at the 6th postoperative hour (1.98 ± 0.84) than those in the saline group (5.60 ± 1.21; p < 0.000). Furthermore, the proportion of patients requiring rescue analgesics was significantly lower in the ropivacaine group (30%) compared to the saline group (60%; p = 0.003). These results highlight the effectiveness of ropivacaine in managing postoperative pain, confirming its utility in reducing the reliance on systemic analgesics and improving patient comfort during the early recovery period.

The results of this study align with the findings of multiple previously published studies, emphasizing the effectiveness of ropivacaine for postoperative pain management. A review by Jiang and Ye (2022) discusses the multifactorial nature of postoperative pain in laparoscopic cholecystectomy and highlights the role of pharmacotherapeutic approaches, including local anesthetics like ropivacaine, in mitigating pain. [xi] Their review underscores that intraperitoneal instillation of local anesthetics effectively reduces visceral pain and facilitates earlier recovery, findings that mirror the current study's outcomes.

Additionally, the comparative study from "Anesthesia, Pain & Intensive Care" reported that intraperitoneal instillation of ropivacaine, with or without adjuvants like nalbuphine, significantly reduces postoperative pain scores and analgesic requirements. [xii] These studies collectively validate the analgesic benefits of ropivacaine and its ability to enhance recovery after laparoscopic procedures. Similarly, Shivhare et al. documented lower VAS scores and reduced analgesic use in patients receiving intraperitoneal ropivacaine during laparoscopic cholecystectomy, further corroborating the present study's findings(ropfinal). However, not all studies have yielded uniformly positive results.[xiii],[xiv] A study found that no significant reduction in visceral pain with ropivacaine, suggesting that variability in dosing, timing of administration, and surgical technique may influence outcomes. [xv] This highlights the importance of standardizing ropivacaine administration, as employed in the present study (30 mL of 0.5% solution instilled into the gallbladder bed), to achieve consistent and optimal results. [12]

The stratified analyses in this study revealed interesting nuances regarding the efficacy of ropivacaine across different demographic and physiological subgroups. These findings add depth to the understanding of how specific patient characteristics may influence the analgesic response to intraperitoneal ropivacaine.

Younger patients (20–35 years) appeared to benefit more significantly from ropivacaine, with lower additional analgesic requirements compared to older patients (36–50 years). This trend may be attributed to age-related differences in pain perception and recovery physiology. Younger individuals often demonstrate better physiological reserves and faster healing, which may enhance the analgesic effects of local anesthetics. This observation aligns with existing literature suggesting that younger patients often recover more effectively from surgical interventions (1275)(ropfinal).[11,9]

The study found that female patients in the ropivacaine group required significantly less rescue analgesia compared to females in the saline group ($p = 0.013$). However, among males, the difference was not statistically significant. These findings align with the notion that females generally report higher pain sensitivity but also respond better to targeted analgesic interventions, possibly due to hormonal or psychological factors. Gender-specific responses to pain and analgesics have been previously documented, suggesting a potential area for further exploration.[12]

STRENGTHS OF THIS STUDY

The results of this study strongly support the hypothesis that intraperitoneal instillation of ropivacaine provides superior pain relief and reduces the need for additional analgesics compared to normal saline. The significant differences observed in VAS scores and analgesic requirements validate the proposed benefits of ropivacaine, underscoring its role as a key component of multimodal analgesia strategies in laparoscopic cholecystectomy. Despite its strengths, the study has limitations that should be addressed in future research. One notable limitation is the short follow-up period, with pain assessment limited to the 6th postoperative hour. This restricts the ability to evaluate longer-term outcomes, such as pain relief at 24–48 hours or the incidence of chronic pain. Moreover, the single-center design may limit the generalizability of the findings to other surgical settings or patient populations. Finally, while patients and assessors were blinded, the lack of surgeon blinding introduces the potential for procedural biases. Future studies should aim to extend the follow-up period, include multicenter designs, and evaluate the cost-effectiveness of ropivacaine instillation. Additionally, exploring the combination of ropivacaine with other analgesics or adjuvants, such as NSAIDs or regional nerve blocks, could further optimize pain management protocols.

Our study provides compelling evidence that intraperitoneal instillation of ropivacaine is a safe and effective method for managing postoperative pain in laparoscopic cholecystectomy. By significantly reducing pain scores and analgesic requirements, it validates the hypothesis and aligns with existing literature supporting the use of local anesthetics in minimally invasive surgery. These findings highlight the importance of incorporating ropivacaine into routine surgical care to enhance recovery, improve patient outcomes, and support multimodal analgesia protocols. Future research should build on these results to explore the long-term benefits, economic implications, and potential for further optimizing pain management strategies.

CONCLUSION:

We concluded that the Outcome of intraperitoneal instillation of ropivacaine is significantly favorable when compared to those with normal saline for reduction of postoperative pain after laparoscopic cholecystectomy.

LIMITATION:

This study has various limitations that should be acknowledged. A single-center experiment in a tertiary care hospital limits its applicability to rural or private healthcare settings. After stratification by age, gender, and BMI, the 100-patient sample may be too small to detect modest variations. Pain was assessed at six hours postoperatively, which may not reflect the complete course of postoperative pain or delayed analgesic effects. Pain measurement was blinded, but surgeons performing the intervention were not, adding performance bias. Analgesic effects may vary if ropivacaine volume and concentration are fixed without weight or BMI adjustment.

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