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Original Research Article

Comparative evaluation of postoperative analgesia using 0.25% ropivacaine for intraperitoneal instillation versus ultrasound-guided rectus sheath block in laparoscopic cholecystectomy: A randomized controlled trial

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Abstract

Background: Effective pain management after surgery is crucial for ensuring optimal recovery and patient contentment, especially in day-care surgery where discomfort can significantly hinder movement and the rehabilitation process**.** This research aimed to compare the effectiveness of intraperitoneal installation and rectus sheath block using 0.25% ropivacaine for managing postoperative pain in laparoscopic cholecystectomy.

Aims and Objectives: The rectus sheath block and intraperitoneal installation of local anaesthetics are two pre-emptive postoperative pain management techniques that may relieve pain. The primary objectives were to compare the Visual Analog Scale (VAS) scores at 30 minutes, 1, 2, 4, 6, 12, 24, and 48 hours. Secondary objectives included determining the time taken for the first rescue analgesic and the consumption of fentanyl in the initial 48 hours.

Material and Methods: The prospective randomised study involved eighty-six adult patients randomly divided into two groups of 40 each. Group I, which underwent intraperitoneal instillation, was administered 30 ml of 0.25% ropivacaine prior to surgery, while Group R received a bilateral rectus sheath block with 30 ml of 0.25% ropivacaine before the procedure.

Results: The VAS in group R was significantly reduced relative to group I at 6 and 12 h (2.72 ±0.87; 95% CI 0.56 to1.37 and 2.53±0.98; 95% CI 0.51 to 1.56) respectively. Additionally, the time to the first rescue analgesic was considerably longer in Group R (16.30±3.05h) than in Group I (7.92±1.47h), with a p-value 0.001. Over 48 hours, total fentanyl consumption was markedly lower in Group R (745±24.21µg) than in Group I (1520±30.63µg) with 95% CI 762.71 to 787.28.

Conclusion: Rectus sheath block with 0.25% ropivacaine provided faster patient recovery and less opioid consumption compared to intraperitoneal instillation following laparoscopic cholecystectomy.

Keywords: Ropivacaine, Rectus sheath, Intraperitoneal, Cholecystectomy.

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1. Introduction

Effective pain management is crucial for patients undergoing day surgery, particularly in laparoscopic cholecystectomy. While this technique has improved surgical outcomes compared to traditional open cholecystectomy, it still causes discomfort, potentially hindering patients' quick return to normal activities and compromising its low morbidity status.[1,2] Following laparoscopic cholecystectomy (LC), patients experience three distinct types of discomfort: somatic pain at the incision site, internal visceral pain, and referred visceral pain in the shoulder region.[3] The severity and duration of post-LC pain vary significantly among individuals and are difficult to predict. Discomfort reaches its peak on the day of the procedure and the subsequent day, then gradually diminishes to minimal levels within 3–4 days.[4]

Compared to bupivacaine, ropivacaine exhibits lower lipophilicity, which reduces its ability to infiltrate large myelinated motor nerve fibres. This characteristic results in a comparatively diminished motor blockade. Consequently, ropivacaine demonstrates enhanced motor-sensory

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differentiation, which can be advantageous when motor blockade is not desired. Additionally, the decreased lipophilicity of ropivacaine is linked to a lower risk of central nervous system and cardiovascular toxicity.[5,6] Various methods exist for managing post-operative pain, including nerve blocks, local anaesthetic infiltration, intraperitoneal instillation, and medication.[7] Intraperitoneal instillation of local anaesthetics has gained attention due to the peritoneum's role in blocking visceral nociceptive transmission. While many studies support the efficacy of intraperitoneal local anaesthetics for pain relief, research on ropivacaine's effectiveness in this context is limited.[8] Additionally, the distribution of regional anaesthetics across peritoneal surfaces may be inconsistent. Alternatively, a rectus sheath block can provide comprehensive anaesthesia to the anterior abdominal wall when intercostal nerves are effectively blocked.[9] Although separate studies have examined intraperitoneal instillation and rectus sheath block,[8,9] there is a lack of comparative research to find out which technique is superior for post-laparoscopic cholecystectomy pain management. This study aimed to objectively evaluate and compare the effectiveness of ropivacaine for postoperative analgesia after laparoscopic cholecystectomy following intraperitoneal instillation and rectus sheath block.

2. Materials and Methods

Following approval from the institutional ethics committee (TMU/IEC/2021-22/36) and obtaining informed consent from participants, the study was registered in the Clinical Trials Registry of India (CTRI) [CTRI/2024/02/062237. The study included 86 patients classified as ASA grade I-II, who were over 18 years of age and planned for laparoscopic cholecystectomy to treat gallstone disease under general anaesthesia. The study participants were divided into two groups of 40 patients each using the opaque sealed envelope method for random assignment (**Figure 1**). The groups differed based on the analgesic technique employed: Group I received an intraperitoneal instillation of 30ml of 0.25% ropivacaine, while Group R underwent bilateral rectus sheath block (RSB) using 30ml of 0.25% ropivacaine, with 15ml administered bilaterally.

The primary goal of the study was to compare the level of pain between group I and group R by visual analogue scale (VAS). The secondary goal was to compare the total dose of rescue analgesic across the groups in 48 hours as well as the time to first rescue analgesia between the groups. Patients were excluded if they had acute cholecystitis, a known allergy to local anaesthetics, were unable to comprehend and utilise the VAS Scale, required conversion to open cholecystectomy for any cause, or had accompanying cardio-respiratory problems.

After placing an 18-gauge cannula in the forearm, 0.9% normal saline infusion was initiated in the operating room. Monitoring was done on the 12-lead Electrocardiogram, arterial oxygen saturation (SpO2), and non-invasive blood pressure (NIBP). Intravenous midazolam 0.03 mg/kg and ondansetron 0.08 mg/kg were used to premedicate the patients. They were then preoxygenated with 100% O2 (6 lit/min) for three minutes and induced with fentanyl (2 μg/kg body weight), followed by a titrated dosage of propofol (2 mg/kg body weight) and atracurium (0.5 mg/kg). A Macintosh laryngoscope with a cuffed endotracheal tube was used for endotracheal intubation. Isoflurane 0.5–1% and a 50–50% oxygen and air combination were used to maintain anaesthesia. When necessary, top-up doses of atracurium 0.1 mg/kg were used to maintain neuromuscular blockade. After surgery, neostigmine 0.04 mg/kg and glycopyrrolate 0.01 mg/kg were used to counteract neuromuscular inhibition.

In group I, all patients underwent peritoneal cavity access through an umbilical incision. A Verres needle was used to create a pneumoperitoneum and insufflate CO2 at a pressure of 12–14 mmHg while the patients were in a 20° Trendelenburg posture. A suction port was inserted via the second trocar, which is located in the epigastrium, under direct laparoscopic supervision following the creation of the pneumoperitoneum and the insertion of the first two trocars. Subsequently, a 30ml solution of 0.25% ropivacaine was applied to the upper surfaces of both liver lobes and the gallbladder bed. Following the solution's application, all patients were kept in a 15° Trendelenburg position for about 5 minutes.

In group R, patients underwent a bilateral rectus sheath block following anaesthesia induction but prior to the start of surgery. The procedure was conducted using ultrasound guidance (Sonosite Edge II, Bothell, USA). A high-frequency (5–10 MHz) ultrasound probe was positioned transversely just lateral to the umbilicus. Using a 24-G, 8-cm stimuplex needle (B Braun Medical International Ltd, USA) aligned with the transducer plane, the layers of the anterior abdominal wall were identified under real-time ultrasonographic visualization, with particular focus on the lateral side of linea semilunaris and rectus abdominis muscle. The target area was the posterior rectus sheath compartment, located between the posterior border of the rectus abdominis muscle and above the posterior rectus sheath. After hydro dissecting the area with 1-3 mL of normal saline and confirming the absence of blood aspiration, 15 ml of 0.25% ropivacaine was administered into the space between the rectus abdominis muscle and the posterior rectus sheath.

Data recorded for patient’s demographics, including age, gender, and weight. Vital signs such as HR, SBP, DBP, MAP, and SpO2 were recorded at baseline and every 15 minutes following extubation. The duration of the operation, from initial incision to final suture, and the length of pneumoperitoneum were noted. Patients were explained during the pre-anaesthetic evaluation to use a VAS for pain assessment and also educated about the availability of rescue analgesia.

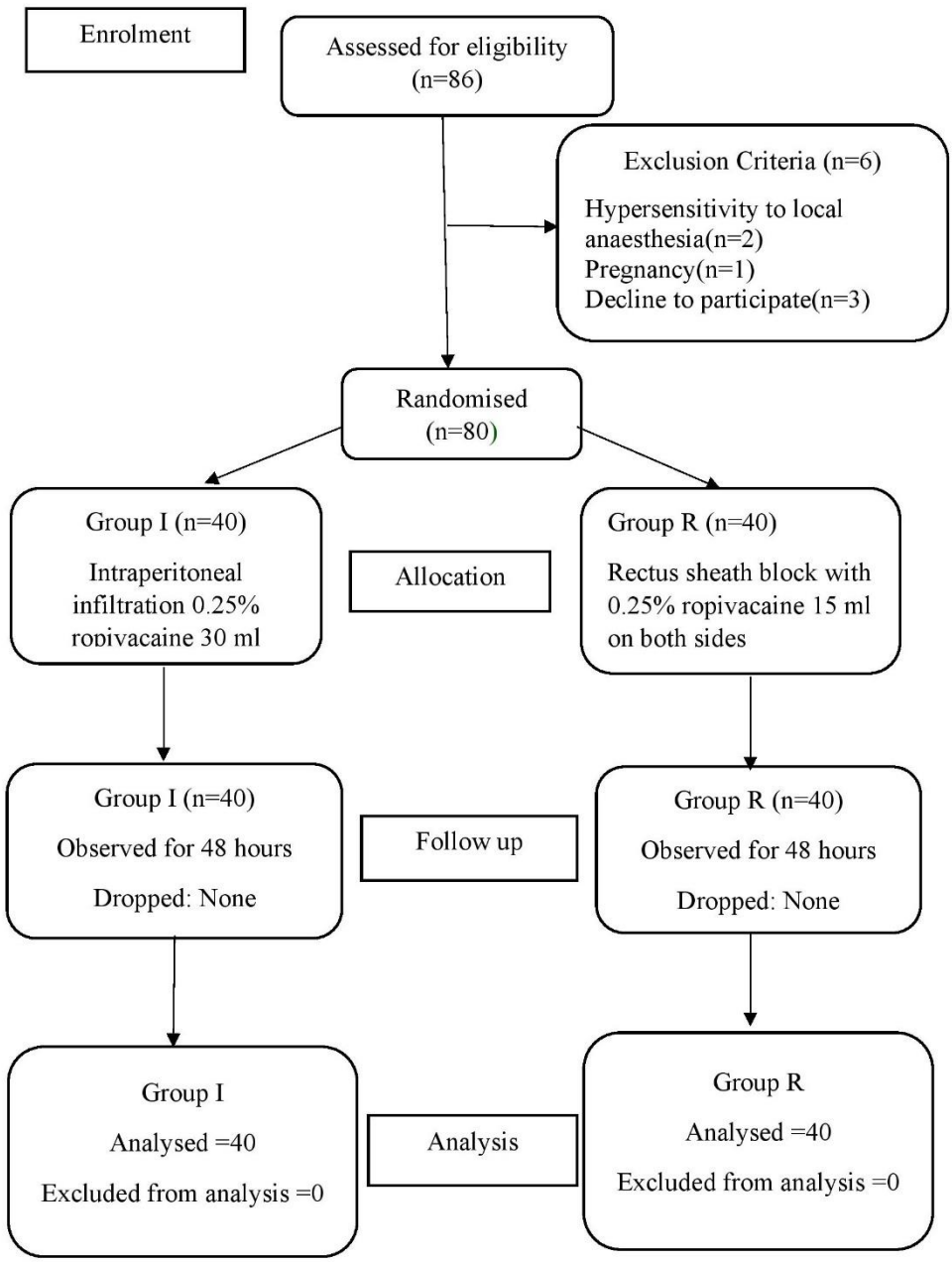

Figure 1: Consort flow chart

Postoperative pain was evaluated using VAS and PHHPS (Prince Henry Hospital Pain Score) at specific intervals: 30 minutes, 1, 2, 4, 6, 12, 24, and 48 hours after surgery.[10] PHHPS score was used to assess the pain associated with strain during cough. The analgesia duration was measured from the end of the operation to post-anaesthesia care. Time to first rescue analgesia was defined as when patients requested their first pain medication or their VAS exceeded 3. Intravenous fentanyl (0.5 µg/kg) served as rescue analgesia. All subjects received 15mg/kg of intravenous paracetamol every 12 hours for the initial 24 hours. The total amount of rescue analgesia administered over 48 hours was documented. Other, detrimental effects such as nausea, vomiting, and shoulder discomfort were documented.

The data was analysed using SPSS version 16.0 (SPSS Ltd, Chicago, IL, USA). Mean values with standard errors or frequencies were used to report continuous variables. For nominal categorical data such as gender and ASA-PS, the Chi-square test was employed, while the student t-test was utilised to compare nominal data like VAS scores and rescue analgesic doses. A P value below 0.05 was considered statistically significant. The study sample size was calculated using the mean standard deviation (±11.215) and effect size from a previous Kim et al study, which measured the difference in visual analogue scale means after 4 hours.[11] The

sample size was determined to get 80% power with an alpha error of 0.05.

3. Results

The study participants in both groups showed similar characteristics regarding age, sex, weight, ASA-PS, and surgery time (**Table 1**). In each group, there were more female subjects (26 and 28) than male subjects (14 and 12), with no statistically significant variation (P > 0.05).

Table 1: Demographic profile

	Group I (n=40)	Group R (n=40)	P value
Age (Years)	58.77±12.87	56.63±13.76	0.47
Sex (M/F)	14/26	12/28	0.73
Weight (Kg)	60.83 ± 11.38	63.98 ± 9.58	0.18
ASA-PS (I/II)	26/14	23/17	0.61
Duration of surgery (minutes)	81.43 ± 10.87	84.52 ± 11.69	0.22

Mean±SD; n=number, *P*<0.05 is significant. ASA-PS – American Society of Anaesthesiolgists physical status

Table 2 illustrates the difference in pain intensity VAS scores (mean and standard deviation) between the two groups. Group I experienced peak VAS scores 6 hours post-surgery, while Group R peaked after 2 hours. However, Group R demonstrated lower maximum pain intensity than Group I. A notable difference in mean VAS scores was observed between the groups at 6 and 12 hours (P= 0.001 and 0.002) respectively. Group I exhibited higher mean PHPSS scores than Group R, with a statistically significant difference (p<0.05) at 30 minutes, 4 and 6 hours, as shown in (**Table 3**).

During the 48-hour postoperative period, all patients in both groups needed rescue analgesics. Group I required the initial dose significantly sooner (7.92 ± 1.47 hours) compared to Group R (16.30 ± 3.05 hours). Within the first 12 postoperative hours, every patient in Group I needed rescue analgesia, while only five in Group R did. The total number of rescue analgesic doses was notably higher in Group I (5.11 ± 0.23) than in Group R (1.89 ± 0.97), P=0.001. From 6-48 hours post-surgery, all patients in both groups needed rescue analgesics. This needs to be continued for all patients in the subsequent 24 hours. The rectus sheath block reduced rescue analgesic use by 50.98% compared to intraperitoneal instillation as illustrated in **Figure 2**.

Fentanyl consumption varied from 25 µg to 115 µg per individual, with a mean Total Analgesic Consumption (TAC) of 38.31 ± 0.45 µg across the entire study population. Group I had a mean TAC of 48 ± 0.25 µg, while Group R's was 24 ± 0.38 µg. The difference in mean TAC between groups was statistically significant (P = 0.001). The total fentanyl used was 1520 µg in Group I and 745 µg in Group R (**Table 4** and **Figure 2**).

Table 2: Comparison of pain score between the two group

VAS	Group I		Group R		p-value	95% confidence interval [CI]
	Mean	SD	Mean	SD		
30 min	2.67	1.34	2.59	1.13	0.77	-0.47 to 0.63
1 hr	2.88	1.07	2.81	1.35	0.79	-0.47 to 0.61
2 hr	2.95	1.01	2.90	1.1	0.75	-0.42 to 0.52
4 hr	2.96	1.01	2.89	1.1	0.76	-0.40 to 0.54
6 hr	3.69	0.96	2.72	0.87	0.0001*	0.56 to 1.37
12 hr	3.57	1.35	2.53	0.98	0.0002*	0.51 to 1.56
24 hr	2.91	1.14	2.45	1.02	0.06	-0.02 to 0.94
48 hr	0.52	1.08	0.26	1.17	0.33	-0.24 to 0.76

VAS: Visual analogue scale, P<0.05 is significant.*, h-Hour, min.-minutes

Table 3: PHPSS score among the study groups

PHPSS	Group I		Group R		p-value	95% confidence interval [CI]
	Mean	SD	Mean	SD		
30 min	1.24	0.37	1.03	0.43	0.02	0.03 to 0.38
1 hr	1.45	0.54	1.29	0.48	0.16	-0.06 to 0.38
2 hr	1.56	0.62	1.41	0.57	0.26	-0.11 to 0.41
4 hr	1.67	0.69	0.84	0.54	0.0001*	0.55 to 1.10
6 hr	3.3	1.2	1.09	0.61	0.0001*	1.78 to 2.63
12 hr	2.92	0.97	2.70	0.90	0.22	-0.19 to 0.63
24 hr	3.65	1.01	3.37	1.08	0.28	-0.18 to 0.74
48 hr	3.16	1.30	3.05	1.05	0.67	-0.41 to 0.63

PHPSS: Prince Henry Hospital Pain Score, P<0.05 is significant*, h-Hour, min.-minutes

Table 4: Rescue analgesia among the study groups

Variables	Group I		Group R		p-value	95% confidence interval [CI]
	Mean	SD	Mean	SD		
Time for 1st dose (h)	7.92	1.47	16.30	3.05	0.001*	-9.44 to -7.31
Total no. of dose required	5.11	0.23	1.89	0.97	0.001*	2.90 to 3.53
Total dose (µg)	1520	30.63	745	24.21	0.001*	762.71 to 787.28

h-Hour, µg-microgram, P<0.05 is significant*

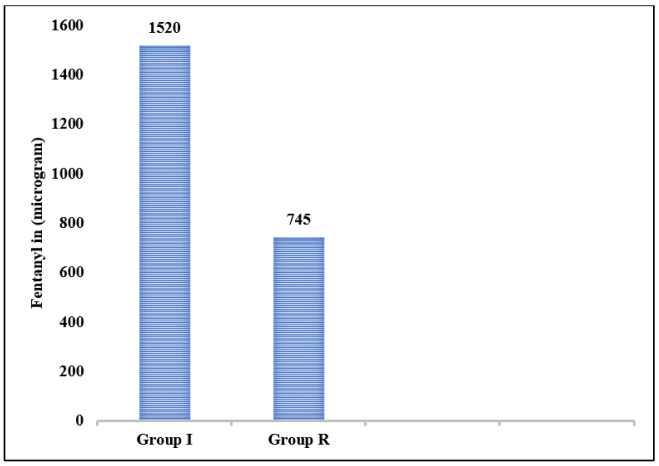

Figure 2: Total Fentanyl (in µg) consumption between the two groups in 48 hour

Adverse events like nausea and vomiting were infrequent in both groups. Two patients in Group I and one in Group R experienced retching, which was treated with 0.1mg/kg of ondansetron. The need for anti-emetics and the occurrence of emetic episodes were similar across the groups.

4. Discussion

Our findings demonstrate that the use of ropivacaine for intraperitoneal instillation and rectus sheath block is highly effective in managing post-operative pain following laparoscopic cholecystectomy. This is evidenced by lower pain scores (VAS and PHHPS), a prolonged time to first rescue analgesic requirement, and a significant reduction in overall rescue analgesic consumption, with the rectus sheath block showing superior efficacy compared to intraperitoneal instillation. Previous studies have similarly explored the benefits of intraperitoneal instillation for post-operative pain relief in laparoscopic cholecystectomy, with local anesthetics such as ropivacaine, bupivacaine, levobupivacaine, and lignocaine yielding favourable outcomes.[12,13] These anaesthetics function by targeting visceral nociceptors in the peritoneum. An additional potential mechanism involves the absorption of the anaesthetic through the extensive peritoneal surface area.[14] However, the limited effectiveness of intraperitoneal instillation in some cases may be attributed to the timing of local anesthetic administration.[15] In this study, the anesthetic was administered intraperitoneally after the surgical procedure rather than pre-emptively. Although a reduction in rescue analgesic requirements was observed, it did not reach statistical significance.

Various factors influencing the efficacy of intraperitoneal anesthesia have been identified. These include the dose and concentration of the local anesthetic, the site of administration (e.g., beneath the diaphragm or liver), and the timing (pre-operative versus post-operative). Additional considerations involve pneumoperitoneum characteristics (volume, pressure, and temperature), residual CO2 levels (which may irritate the diaphragm), potential contamination with bile or blood, the extent of non-visceral pain (e.g., from surgical incisions), and the patient's position during administration (e.g., head-down or supine).

In this study, ropivacaine (0.25%) was administered intraperitoneally before the surgical procedure, with the patient positioned head-down and pneumoperitoneum pressure maintained at 12 mmHg. These combined factors likely contributed to the observed reduction in post-operative pain following intraperitoneal instillation in our research.

Rectus sheath block (RSB) has demonstrated effectiveness in providing postoperative pain relief across various surgical procedures. These include umbilical hernia repair,[16] abdominoplasty,[17] post-laparoscopic procedures,[18] upper abdominal surgeries,[19] and major gynaecological operations.[20] However, the outcomes reported in different studies show significant variations. These disparities can be attributed to several factors, such as the age range of the patients involved, the skill level of the practitioners, the complexity and type of surgical intervention, and the specific RSB technique employed. The rectus sheath block (RSB) delivers local anaesthesia to the nerves as they traverse the rectus abdominis muscle and the posterior sheath layer.[21] When a local anaesthetic is administered within the posterior rectus sheath on both sides, it provides robust pain relief across the central anterior abdominal wall, extending from the T7 dermatome to the L1 dermatome. As a field block, the RSB targets multiple nerve branches (from T9, T10, and T11 intercostal nerves) to achieve near-complete analgesia. However, it's worth noting that only single-site drug infiltration may not effectively anaesthetise all the necessary nerve segments.[22] One notable benefit of the RSB method is the ability for patients to move early. The combination of effective pain relief with minimal limb muscle impairment and no required connection to infusion devices enables patients to become mobile sooner. This early mobilisation offers substantial advantages, including a lower risk of deep vein thrombosis and pulmonary morbidity. In our study, the RSB group demonstrated significantly lower pain scores

(PHHPS) during coughing for up to 24 hours compared to the intraperitoneal groups.

The traditional blind technique for administering the rectus sheath block (RSB), once commonly employed by anesthesiologists, has evolved significantly with the advent of ultrasound-guided nerve blocks. A newer approach involves performing the RSB using ultrasound for direct visualisation during surgery, providing enhanced precision and safety.[23] Although ultrasound-guided blocks are more accurate and reduce the risk of complications, they require advanced technical skills and specialised equipment to ensure effective implementation.

Shoulder tip pain, a frequent complaint following laparoscopic cholecystectomy (LC), is thought to result from trapped carbon dioxide under the right hemidiaphragm after abdominal deflation. Chundrigar et al. demonstrated that positioning the tip of the epigastric cannula above the right liver lobe during abdominal deflation facilitates gas escape from this region, reducing the incidence of shoulder tip pain.[23] In our study, a similar technique was employed, which likely explains the complete absence of shoulder tip pain among participants. This finding highlights the importance of meticulous abdominal deflation techniques in minimizing post-operative discomfort.

Research has shown that patients receiving intraperitoneal bupivacaine experienced a reduction in forced vital capacity and were at risk of hypoxemic events during the initial post-operative hours, likely due to partial paralysis of the phrenic nerve caused by local anesthetic blockade. The traditional rectus sheath block (RSB) technique, which relies on anatomical landmarks and the loss-of-resistance method, carries a minor risk of complications, such as puncturing intraperitoneal organs or epigastric vessels.[24] However, in our study, no complications related to the ultrasound guided RSB technique were observed, highlighting its safety when performed with precision.

Our study did not assess pain scores during rest or movement, which are critical parameters for understanding the impact of movement on visceral pain, due to logistical constraints and the study's specific focus. Additionally, while the rectus sheath block (RSB) requires additional time and specialised skills for administration, intraperitoneal instillation is simpler and can be performed directly by the surgeon. This disparity in procedural complexity should be taken into account when interpreting the results.

5. Conclusion

Ultrasound-guided rectus sheath block (RSB) demonstrated superior outcomes compared to intraperitoneal ropivacaine instillation, including higher patient satisfaction, reduced postoperative pain, and decreased analgesic requirements. Both techniques are safe and associated with minimal adverse reactions, making them viable options for postoperative pain management. However, the choice of technique should consider factors such as procedural complexity and resource availability.

6. Source of Funding

None.

7. Conflict of Interest

All authors have disclosed that they do not have any conflicts of interest.

8. Acknowledgements

None.

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