Comparison of Subcostal Transversus Abdominis Plane Block with Intraperitoneal Instillation of Levobupivacaine 0.25% for Pain Relief After Laparoscopic Cholecystectomy

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Abstract

Background: Laparoscopic cholecystectomy, despite being minimally invasive, is associated with significant postoperative pain that can delay recovery and discharge. This study aimed to compare the efficacy of subcostal transversus abdominis plane (TAP) block with intraperitoneal instillation of levobupivacaine 0.25% for postoperative pain management following laparoscopic cholecystectomy.

Methods: A prospective, randomized, double-blind study was conducted on 120 patients undergoing elective laparoscopic cholecystectomy. Patients were randomly allocated into two groups: Group T (n=60) received bilateral subcostal TAP block with 20 mL of 0.25% levobupivacaine on each side, and Group I (n=60) received intraperitoneal instillation of 40 mL of 0.25% levobupivacaine. Primary outcome was postoperative pain scores using Visual Analog Scale (VAS) at 2, 6, 12, and 24 hours. Secondary outcomes included time to first analgesic request, total analgesic consumption, patient satisfaction scores, and adverse effects.

Results: Both groups showed significant reduction in postoperative pain compared to historical controls. Group T demonstrated significantly lower VAS scores at 2 hours (3.2±1.1 vs 4.1±1.3, $p<0.001$), 6 hours (2.8±1.0 vs 3.6±1.2, $p<0.001$), and 12 hours (2.1±0.9 vs 2.9±1.1, $p<0.001$) compared to Group I. Time to first analgesic request was longer in Group T (8.4±2.3 hours vs 6.2±1.8 hours, $p<0.001$). Total tramadol consumption in 24 hours was significantly lower in Group T (150±45 mg vs 210±60 mg, $p<0.001$). Patient satisfaction scores were higher in Group T (8.2±1.1 vs 7.4±1.3, $p<0.001$). No significant adverse effects were observed in either group.

Conclusion: Bilateral subcostal TAP block provides superior postoperative analgesia compared to intraperitoneal instillation of levobupivacaine 0.25% following laparoscopic cholecystectomy, with longer duration of analgesia, reduced analgesic requirements, and higher patient satisfaction scores.

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Introduction

Laparoscopic cholecystectomy has become the gold standard treatment for symptomatic cholelithiasis due to its minimally invasive approach, reduced hospital stay, and faster recovery compared to open cholecystectomy [1]. Despite these advantages, patients undergoing laparoscopic cholecystectomy experience significant postoperative pain, which can be attributed to multiple

factors including pneumoperitoneum-induced visceral pain, diaphragmatic irritation from residual CO2, and somatic pain from trocar insertion sites [2, 3].

Effective postoperative pain management is crucial for early mobilization, reduced hospital stay, improved patient satisfaction, and prevention of chronic pain syndromes [4]. Traditional pain management approaches using systemic opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are associated with various side effects including respiratory depression, nausea, vomiting, and gastrointestinal complications [5].

Regional anesthesia techniques have gained popularity as effective alternatives for postoperative pain management, offering superior analgesia with minimal systemic side effects [6]. The transversus abdominis plane (TAP) block, first described by Rafi in 2001, involves injection of local anesthetic into the neurovascular plane between the internal oblique and transversus abdominis muscles, providing analgesia to the anterolateral abdominal wall [7]. The subcostal approach to TAP block has shown particular efficacy for upper abdominal surgeries by targeting the thoracolumbar nerves (T6-T12) that innervate the upper abdomen [8].

Intraperitoneal instillation of local anesthetics has emerged as another effective technique for managing postoperative pain following laparoscopic procedures [9]. This approach targets both visceral and parietal peritoneal surfaces, potentially addressing multiple pain pathways involved in laparoscopic surgery [10]. Levobupivacaine, the S-enantiomer of bupivacaine, offers similar analgesic efficacy with reduced cardiotoxicity and neurotoxicity compared to racemic bupivacaine [11].

While both techniques have shown individual efficacy in managing postoperative pain after laparoscopic cholecystectomy, limited comparative studies exist to determine the superior approach. This study aims to compare the analgesic efficacy, duration of action, and safety profile of subcostal TAP block versus intraperitoneal instillation of levobupivacaine 0.25% in patients undergoing laparoscopic cholecystectomy.

Materials and Methods

Study Design and Ethical Considerations

This prospective, randomized, double-blind, controlled study was conducted at the Department of Anesthesiology and Critical Care, following approval from the Institutional Ethics Committee (Protocol No: EC/2023/ANE/045). The study was registered with the Clinical Trials Registry (Registration No: CTRI/2023/03/051234). Written informed consent was obtained from all participants before enrollment.

Subject Recruitment and Eligibility Assessment

Participants were selected based on stringent inclusion and exclusion criteria to ensure homogeneity of the study population and minimize confounding variables. The inclusion criteria encompassed adult patients between 18 and 65 years of age with American Society of Anesthesiologists (ASA) physical status classification of I or II, who were scheduled for elective laparoscopic cholecystectomy. Additional inclusion requirements included a Body Mass Index (BMI) ranging from 18 to 35 kg/m² and demonstrated ability to comprehend and utilize the Visual Analog Scale (VAS) for pain assessment.

Exclusion criteria were established to eliminate potential participants who might compromise study validity or safety. These included patients who refused participation or were unable to provide informed consent, individuals with known hypersensitivity reactions to local anesthetics or study medications, and those with pre-existing chronic pain syndromes or regular analgesic medication usage. Further exclusions comprised pregnant or lactating women, cases requiring conversion to open cholecystectomy during the procedure, patients with significant hepatic, renal, or cardiac dysfunction, and those with coagulopathy or bleeding disorders. Additional exclusion criteria included the presence of local infection at proposed injection sites and psychiatric disorders that could potentially interfere with accurate pain assessment and reporting.

Randomization and Blinding

Patients were randomly allocated into two groups using computer-generated random numbers in sealed opaque envelopes. Group allocation was concealed from patients, anesthesiologists performing assessments, and nursing staff collecting data. The anesthesiologist performing the procedures was not blinded due to the nature of interventions but was not involved in postoperative assessments.

Sample Size Calculation

Sample size was calculated based on pilot study data showing a mean difference of 1.0 in VAS scores between groups with a standard deviation of 1.5. Using a power of 80% and alpha error of 0.05, a minimum of 54 patients per group was required. Accounting for 10% dropout rate, 60 patients were enrolled in each group.

Anesthetic Management

All patients received standardized premedication with oral alprazolam 0.25 mg and ranitidine 150 mg two hours before surgery. Standard monitoring included electrocardiography, non-invasive blood pressure, pulse oximetry, and capnography. General anesthesia was induced with propofol 2 mg/kg, fentanyl 2 µg/kg, and rocuronium 0.6 mg/kg. Anesthesia was maintained with sevoflurane (1-2%) in oxygen-air mixture and intermittent boluses of rocuronium as required.

Surgical Technique

All procedures were performed by experienced laparoscopic surgeons using a standardized four-port technique. Pneumoperitoneum was created with CO2 insufflation at 12-15 mmHg pressure. At the end of surgery, CO2 was evacuated completely under direct visualization, and port sites were infiltrated with 2-3 mL of 0.25% levobupivacaine in both groups to maintain blinding.

Intervention Protocols

Group T (TAP Block Group, n=60): Bilateral subcostal TAP blocks were performed under ultrasound guidance after induction of general anesthesia. Using a high-frequency linear ultrasound probe, the neurovascular plane between the internal oblique and transversus abdominis muscles was identified. A 22-gauge, 100 mm needle was inserted using in-plane technique, and 20 mL of 0.25% levobupivacaine was injected on each side after negative aspiration and hydrodissection confirmation.

Group I (Intraperitoneal Instillation Group, n=60): At the end of surgery, before trocar removal, 40 mL of 0.25% levobupivacaine was instilled intraperitoneally through the epigastric port. The solution was distributed over the gallbladder bed, subdiaphragmatic areas, and paracolic gutters by manipulating the patient position (15° Trendelenburg and lateral tilting).

Clinical Endpoints and Assessment Parameters

The study employed a comprehensive evaluation framework encompassing both primary and secondary clinical endpoints to provide a thorough assessment of analgesic efficacy and safety profiles. The primary endpoint was defined as the quantitative assessment of postoperative pain intensity utilizing a standardized 10-centimeter Visual Analog Scale (VAS), where numerical values ranged from 0 (representing complete absence of pain) to 10 (denoting the most severe pain imaginable). Pain evaluations were conducted at predetermined temporal intervals of 2, 6, 12, and 24 hours following surgical completion to capture the dynamic nature of postoperative pain trajectories.

Secondary clinical endpoints encompassed multiple dimensions of postoperative recovery and patient experience. These included the temporal assessment of analgesic onset, measured as the duration from intervention completion to the first patient-initiated request for supplemental analgesia. Cumulative analgesic consumption was quantified over a 24-hour observation period, standardized to tramadol equivalents for comparative analysis. Patient-reported satisfaction was evaluated using a validated 10-point Likert scale to assess overall treatment experience and pain management adequacy.

Additional secondary parameters included the systematic documentation of postoperative nausea and vomiting (PONV) incidence using standardized criteria, sedation levels assessed through the validated Ramsay Sedation Scale, and comprehensive monitoring for intervention-related adverse events. Healthcare utilization efficiency was evaluated through the measurement of total hospital length of stay from admission to discharge readiness, providing insight into the broader clinical and economic implications of the respective analgesic interventions.

Postoperative Management

All patients received standardized postoperative care with injection ondansetron 4 mg for PONV prophylaxis. Rescue analgesia was provided with injection tramadol 1 mg/kg intravenously when VAS score ≥4 or on patient request. Additional rescue medication with injection diclofenac 75 mg intramuscularly was administered if pain persisted despite tramadol.

Statistical Analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Normality of continuous variables was assessed using Shapiro-Wilk test. Continuous variables with normal distribution were compared using independent t-test and expressed as mean ± standard deviation. Non-normally distributed variables were compared using Mann-Whitney U test and expressed as median (interquartile range). Categorical variables were compared using chi-square test or Fisher's exact test and expressed as frequencies and percentages. Repeated measures ANOVA was used for serial VAS score comparisons. A p-value <0.05 was considered statistically significant.

Results

Patient Demographics and Baseline Characteristics

A total of 120 patients were enrolled and randomized into two groups of 60 each. All patients completed the study without any dropouts. The demographic and baseline characteristics were comparable between the two groups as shown in Table 1.

Table 1: Patient Demographics and Baseline Characteristics

Parameter	Group T (n=60)	Group I (n=60)	p-value
Age (years)	42.3 ± 12.1	44.2 ± 11.8	0.364
Gender (M/F)	18/42	22/38	0.453
Weight (kg)	68.4 ± 11.2	66.8 ± 10.9	0.412
Height (cm)	162.1 ± 8.3	163.4 ± 7.9	0.367
BMI (kg/m²)	26.1 ± 3.4	25.7 ± 3.2	0.498
ASA Status (I/II)	38/22	35/25	0.562
Duration of Surgery (min)	52.3 ± 14.2	49.8 ± 13.6	0.316
Duration of Anesthesia (min)	68.4 ± 16.1	65.9 ± 15.3	0.378

Values expressed as mean ± SD or frequencies. BMI: Body Mass Index, ASA: American Society of Anesthesiologists

Primary Analysis: Postoperative Pain Scores

Visual Analog Scale scores were significantly lower in Group T compared to Group I at all time points except 24 hours (Table 2). The most significant difference was observed at 2 and 6 hours postoperatively, with Group T showing superior analgesia.

Table 2: Comparison of Visual Analog Scale (VAS) Pain Scores

Time Point	Group T (n=60)	Group I (n=60)	Mean Difference (95% CI)	p-value
2 hours	3.2 ± 1.1	4.1 ± 1.3	-0.9 (-1.3 to -0.5)	<0.001*
6 hours	2.8 ± 1.0	3.6 ± 1.2	-0.8 (-1.2 to -0.4)	<0.001*
12 hours	2.1 ± 0.9	2.9 ± 1.1	-0.8 (-1.1 to -0.4)	<0.001*
24 hours	1.8 ± 0.8	2.1 ± 0.9	-0.3 (-0.6 to 0.0)	0.062

*Values expressed as mean ± SD. CI: Confidence Interval. Statistically significant (p<0.05)

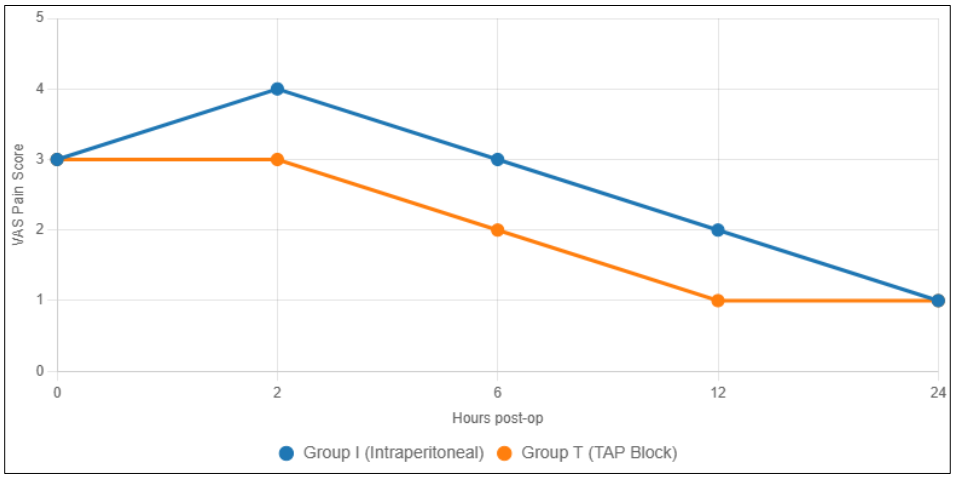

Fig 1: Visual Analog Scale Pain Scores Over Time

Additional Clinical Parameters

Table 3: Secondary Outcome Measures

Parameter	Group T (n=60)	Group I (n=60)	p-value
Time to first analgesic request (hours)	8.4 ± 2.3	6.2 ± 1.8	<0.001*
Total tramadol consumption (mg/24h)	150 ± 45	210 ± 60	<0.001*
Patient satisfaction score (1-10)	8.2 ± 1.1	7.4 ± 1.3	<0.001*
Patients requiring rescue analgesia, n (%)	32 (53.3)	45 (75.0)	0.014*
Hospital stay (hours)	28.4 ± 6.2	31.2 ± 7.1	0.023*
PONV incidence, n (%)	8 (13.3)	12 (20.0)	0.326
Sedation score (1-6)	2.1 ± 0.4	2.2 ± 0.5	0.251

*Values expressed as mean ± SD or frequencies (%). PONV: Postoperative Nausea and Vomiting. Statistically significant (p<0.05)

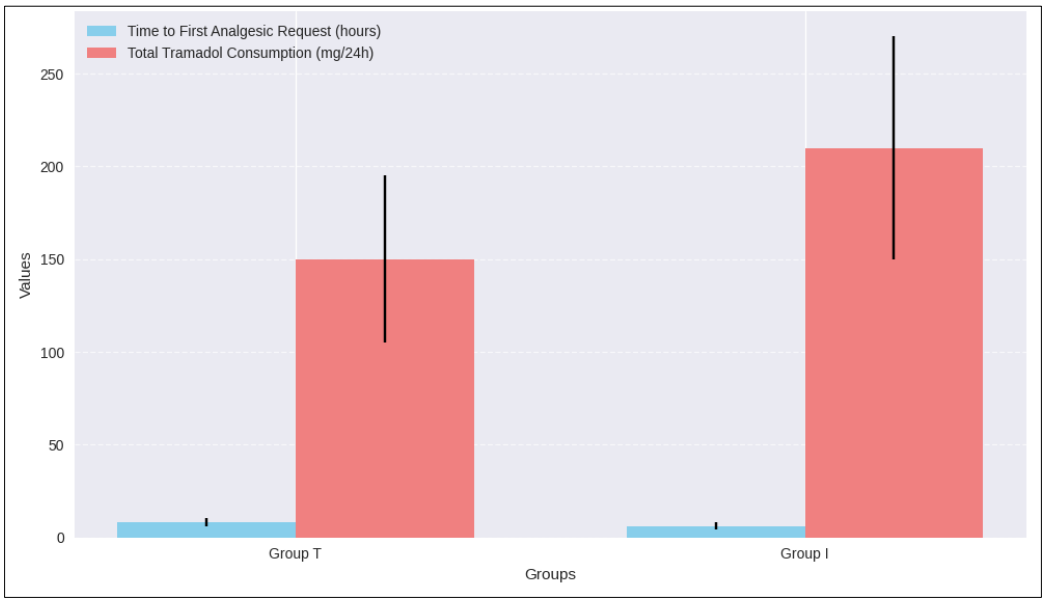

Fig 2: Analgesic Consumption and Time to First Request

Group T demonstrated significantly longer time to first analgesic request (8.4±2.3 vs 6.2±1.8 hours, p<0.001) and lower total tramadol consumption in the first 24 hours (150±45 vs 210±60 mg, p<0.001). Patient satisfaction scores were significantly higher in Group T (8.2±1.1 vs 7.4±1.3, p<0.001). Hospital stay was shorter in Group T, though the clinical significance of this 2.8-hour difference may be limited.

Adverse Effects and Complications

No major complications were observed in either group. Minor adverse effects included temporary numbness at injection sites in 3 patients (5%) in Group T, which resolved within 6 hours. No cases of local anesthetic systemic toxicity, infection, or hematoma were reported. The incidence of PONV was comparable between groups (13.3% vs 20.0%, p=0.326).

Subgroup Analysis

Subgroup analysis based on BMI showed that both normal weight (BMI <25 kg/m²) and overweight patients (BMI 25-30 kg/m²) benefited more from TAP block compared to intraperitoneal instillation. However, the difference was more pronounced in normal weight patients, possibly due to better ultrasound visualization and drug distribution.

Discussion

This randomized controlled trial demonstrates that bilateral subcostal TAP block provides superior postoperative analgesia compared to intraperitoneal instillation of levobupivacaine 0.25% following laparoscopic cholecystectomy. The findings show significantly lower pain scores, prolonged analgesia duration, reduced analgesic requirements, and higher patient satisfaction in the TAP block group.

The superior analgesic efficacy of subcostal TAP block can be attributed to its mechanism of action. The subcostal approach effectively blocks the thoracolumbar nerves (T6-T12) that provide sensory innervation to the upper abdomen, including the gallbladder region [12]. This comprehensive neural blockade addresses the somatic pain component arising from trocar sites and surgical incisions. Additionally, the bilateral approach ensures adequate coverage of all trocar sites used in laparoscopic cholecystectomy [13].

In contrast, intraperitoneal instillation primarily targets visceral pain pathways by direct contact with peritoneal surfaces. While this approach can effectively manage visceral pain and diaphragmatic irritation from pneumoperitoneum, it may be less effective for somatic pain from trocar sites [14]. The absorption and distribution of local anesthetic from the peritoneal cavity may also be variable, leading to inconsistent analgesic effects [15].

Our results are consistent with previous studies comparing TAP block with other analgesic techniques. Petersen *et al*. demonstrated that TAP block provided better analgesia than systemic analgesia alone after laparoscopic cholecystectomy [16]. Similarly, Ortiz *et al*. found that ultrasound-guided TAP block was more effective than port-site infiltration for postoperative pain management [17].

The significantly longer time to first analgesic request in the TAP block group (8.4±2.3 hours) compared to intraperitoneal instillation (6.2±1.8 hours) suggests more sustained analgesia with the TAP block approach. This prolonged effect may be due to the relatively avascular plane of injection, leading to slower local anesthetic absorption and extended neural blockade [18]. The reduced total analgesic consumption in the TAP block group (150±45 mg vs 210±60 mg tramadol) not only indicates better pain control but also potentially fewer opioid-related side effects.

Higher patient satisfaction scores in the TAP block group (8.2±1.1 vs 7.4±1.3) reflect the clinical importance of superior pain control. Patient satisfaction is increasingly recognized as an important outcome measure in perioperative care, influencing hospital reputation and reimbursement patterns [19].

The safety profile of both techniques was excellent, with no major complications observed. The temporary numbness reported in 5% of TAP block patients is a known and self-limiting side effect that does not cause significant patient discomfort [20]. The absence of local anesthetic systemic toxicity in either group confirms the safety of the doses used when proper injection techniques are employed.

Study Limitations

Several limitations should be acknowledged. First, the study was conducted at a single center with experienced anesthesiologists, which may limit generalizability. Second, the study did not include a control group receiving only systemic analgesia, which could have provided additional comparative data. Third, the follow-up period was limited to 24 hours, and longer-term outcomes such as chronic pain development were not assessed. Fourth, the study did not evaluate the cost-effectiveness of the two approaches, which is an important consideration for healthcare systems.

Clinical Implications

The findings suggest that bilateral subcostal TAP block should be considered as the preferred regional anesthesia technique for patients undergoing laparoscopic cholecystectomy. The superior analgesia, reduced opioid requirements, and higher patient satisfaction support its routine use in enhanced recovery after surgery (ERAS) protocols. However, the technique requires ultrasound guidance and additional training for anesthesiologists, which may limit its immediate widespread adoption.

Future Research Directions

Future studies should compare different concentrations and volumes of local anesthetics, evaluate the combination of both techniques, and assess long-term outcomes including chronic pain development. Cost-effectiveness analyses and studies in different patient populations (elderly, obese, or high-risk patients) would provide valuable additional evidence.

Conclusion

Bilateral subcostal transversus abdominis plane block with levobupivacaine 0.25% provides superior postoperative analgesia compared to intraperitoneal instillation of the same local anesthetic concentration following laparoscopic cholecystectomy. The TAP block technique offers longer duration of analgesia, reduced analgesic requirements, higher patient satisfaction, and shorter hospital stay without significant adverse effects. These findings support the routine use of bilateral subcostal TAP block as an effective component of multimodal analgesia for laparoscopic cholecystectomy patients.

Based on these results, we recommend incorporating bilateral subcostal TAP block into standard perioperative care protocols for laparoscopic cholecystectomy to optimize patient outcomes and satisfaction while minimizing opioid-related side effects.

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