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Comparative Efficacy of Intraperitoneal Bupivacaine-Dexmedetomidine vs. Conventional Intravenous Analgesics Following Elective Laparoscopic Cholecystectomy

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Abstract

Background: Postoperative pain remains a primary clinical hurdle following laparoscopic cholecystectomy (LC), driven by port-site trauma, visceral manipulation, and carbon dioxide (*CO2*) pneumoperitoneum. Systemic regimens using opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are standard but carry dose-dependent adverse effects like respiratory depression, sedation, and gastrointestinal issues. Intraperitoneal (IP) local anesthetic instillation targets visceral nociception directly at its origin, and the addition of *α2*-adrenergic agonists can optimize this localized pathway.

Objectives: To compare the postoperative analgesic efficacy and safety profiles of intraperitoneal administration of bupivacaine combined with dexmedetomidine against conventional systemic intravenous (IV) analgesics in patients undergoing elective laparoscopic cholecystectomy.

Methods: A prospective, comparative, cross-sectional observational study was conducted at the KH Patil Institute of Medical Sciences (KHPIMS), Gadag, over 18 months. Sixty adult patients aged 18–60 years, with American Society of Anesthesiologists (ASA) physical status I or II, undergoing elective LC were randomly allocated to two equal groups (***n = 30*** each). Group BD received an intraperitoneal instillation of 50 mL of 0.25% bupivacaine combined with dexmedetomidine (*1 μg/kg* in 5 mL normal saline) before trocar removal in the Trendelenburg position. Group C received conventional systemic analgesics via IV tramadol (*1 mg/kg* twice daily) or IV paracetamol (*15 mg/kg* twice daily) for cases with tramadol hypersensitivity.

Postoperative pain intensity was monitored using the Visual Analogue Scale (VAS) at 0.5, 1, 2, 4, 6, 12, and 24 hours. The time to first rescue analgesia, cumulative 24-hour rescue analgesic dose, and occurrence of adverse events were evaluated.

Results: Baseline demographics, anthropometric values, and operative durations were highly comparable between the two cohorts ($p > 0.05$). Patients in Group BD demonstrated significantly better pain control, maintaining lower VAS scores across all postoperative intervals up to 24 hours ($p < 0.05$). The mean time to first rescue analgesia request was significantly prolonged in Group BD compared to Group C (*405.3 ± 62.1* minutes vs. *139.3 ± 38.2* minutes; $p < 0.001$). Total rescue analgesic consumption over the initial 24 hours was significantly lower in the intraperitoneal group (*74.3 ± 14.5* mg vs. *211.2 ± 39.8* mg; $p < 0.001$). Adverse events, including hypotension (60.0%), nausea (60.0%), and vomiting (46.7%), were observed exclusively in Group C ($p < 0.001$), while Group BD patients experienced no recorded side effects. No cases of bradycardia occurred in either arm.

Conclusion: Intraperitoneal administration of bupivacaine combined with dexmedetomidine provides superior, long-lasting postoperative pain relief, establishes a pronounced systemic opioid-sparing effect, and features a superior safety profile compared to conventional intravenous analgesia strategies after elective laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy, Intraperitoneal analgesia, Bupivacaine, Dexmedetomidine, Visual Analogue Scale, Opioid-sparing.

Introduction

Laparoscopic cholecystectomy (LC) stands globally as the established gold standard for the treatment of symptomatic gallstone disease. It offers distinct perioperative advantages over open laparotomy, including reduced surgical trauma, shortened hospital admission, accelerated functional recovery, and minimized systemic incisional pain. However, despite its minimally invasive design, the assumption that patients experience minimal postoperative distress has been consistently disproven. A substantial proportion of patients still report moderate to severe acute pain during the initial 24 hours, which delays mobilization, degrades sleep quality, and leads to prolonged recovery times.

The underlying pathophysiology of post-laparoscopic pain is complex and multifactorial. It consists of three distinct components: (1) somatic pain arising from direct fascial and abdominal wall trauma at the trocar insertion sites; (2) visceral pain originating from intra-abdominal organ manipulation, surgical dissection at the liver bed, and stretching of the peritoneum; and (3) referred shoulder pain driven by phrenic nerve stimulation caused by residual carbon dioxide (*CO2*) pneumoperitoneum and secondary diaphragmatic irritation. Visceral pain frequently acts as the dominant and most distressing component within the early postoperative period.

Conventional pain regimens traditionally rely on systemic intravenous interventions, utilizing combinations of opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and paracetamol. While these agents provide baseline systemic pain relief, their efficacy against targeted localized visceral

nociception is often incomplete. Furthermore, systemic administration carries a notable burden of dose-dependent adverse outcomes. Opioids are linked to sedation, respiratory depression, urinary retention, pruritus, and postoperative nausea and vomiting (PONV), which directly conflict with early discharge goals. Similarly, systemic NSAIDs carry risks of gastrointestinal irritation, platelet dysfunction, and renal strain, limiting their utility in high-risk patient groups.

Consequently, modern perioperative medicine emphasizes multimodal, opioid-sparing protocols that act on multiple peripheral and central targets simultaneously. Intraperitoneal (IP) instillation of local anesthetics has emerged as an effective, simple approach to target visceral nociception at its origin. Amide-type local anesthetics, such as bupivacaine, act peripherally by reversibly blocking voltage-gated sodium channels on neuronal membranes, preventing depolarization and nociceptive signal propagation from inflamed peritoneal surfaces. To extend the duration of sensory blockade, modern regimens incorporate adjuvants. Dexmedetomidine, a highly selective $\alpha 2$-adrenergic receptor agonist,

delivers central and peripheral analgesia, sedation, and anxiolysis without causing respiratory depression. When administered into the peritoneal space alongside local anesthetics, it works synergistically to inhibit peripheral nerve conduction, modulate local inflammatory responses, and suppress nociceptive transmission through central $\alpha 2$ pathways following local absorption.

While individual trials support the efficacy of intraperitoneal local anesthetics, additional data comparing these combinations directly against standard systemic regimens in rural tertiary care environments are valuable. This study was undertaken to compare the postoperative analgesic efficacy and safety profiles of an intraperitoneal bupivacaine-dexmedetomidine combination against conventional systemic intravenous regimens following elective laparoscopic cholecystectomy.

Materials and Methods

1. Study Design and Ethical Considerations

This prospective, comparative, cross-sectional observational study was carried out in the Department of General Surgery at the KH Patil Institute of Medical Sciences (KHPIMS), Gadag, Karnataka, India. The study spanned an 18-month institutional framework, with the active intervention phase running from March 2025 to September 2025. Institutional Ethics Committee clearance was formally secured prior to initiation. All eligible patients received comprehensive counseling regarding the protocol in their native language, and written informed consent was acquired preoperatively. The study adhered strictly to the ethical foundations of the Declaration of Helsinki.

2. Participant Selection

The study enrolled a target sample of 60 adult patients undergoing elective laparoscopic cholecystectomy who satisfied the following criteria:

- **Inclusion Criteria:** Age between 18 and 60 years; both genders; classified under ASA physical status I or II; scheduled for elective LC.

- **Exclusion Criteria:** Known hypersensitivity or allergy to amide-type local anesthetics or dexmedetomidine; severe baseline cardiac, pulmonary, hepatic, or renal dysfunction; morbid obesity (*BMI > 35 kg/m2*); history of previous upper abdominal surgeries; intraoperative conversion to open laparotomy; intraoperative findings indicating alternative sources of severe visceral pain; suspected or confirmed gall bladder malignancy.

3. Randomization and Interventions

Simple random sampling was utilized to distribute the 60 participants equally into two study arms ($n = 30$ per group):

Group BD (Intraperitoneal Arm)

A baseline intradermal test dose using 0.1 mL bupivacaine was performed preoperatively to rule out hypersensitivity. At the conclusion of the laparoscopic procedure, prior to final trocar removal, patients were positioned in the Trendelenburg position. The operating team instilled a solution containing 50 mL of 0.25% bupivacaine combined with dexmedetomidine at a dose of *1 µg/kg* (diluted in 5 mL of normal saline) into the hepato-diaphragmatic space, the gall bladder bed, and the vicinity of the hepatoduodenal ligament. If an intra-abdominal drain was placed based on surgical necessity, it was kept clamped for the initial 12–18 hours postoperatively to maximize local retention.

Group C (Conventional Intravenous Arm)

Patients in this cohort received standard systemic intravenous postoperative analgesia consisting of scheduled IV Tramadol (*1 mg/kg* diluted in 100 mL normal saline, administered twice daily). In cases with documented tramadol allergy, scheduled IV Paracetamol (*15 mg/kg* infusion, twice daily) was substituted.

Outcome Assessments

Postoperative pain intensity was assessed at regular intervals (0.5, 1, 2, 4, 6, 12, and 24 hours) using the 10-point Visual Analogue Scale (VAS), where a score of 0 indicated complete absence of pain and 10 represented the worst imaginable pain. Pain levels were classified as Mild (VAS 0–2), Moderate (VAS 3–4), or Severe (VAS ≥ 5).

Breakthrough pain exceeding a VAS score of 3 triggered immediate administration of rescue analgesia according to standardized ward management guidelines. The primary endpoints were the mean time to first request for rescue analgesia (in minutes) and the cumulative total dose of rescue analgesics consumed over the 24-hour postoperative period. Secondary endpoints focused on safety monitoring, documenting the incidence of common adverse events including hypotension, bradycardia, nausea, and vomiting.

5. Statistical Analysis

Raw data were tabulated in Microsoft Excel and processed via the Statistical Package for the Social Sciences (SPSS) version 21.0. Continuous clinical metrics were expressed as mean ± standard deviation (*Mean ± SD*) and evaluated using the independent Student's t-test. Categorical variables and frequency distributions were analyzed using the Chi-square ($\chi 2$) test or Fisher's exact test where appropriate. A *p*-value of less than 0.05 ($p < 0.05$) was established as the threshold for statistical significance.

Results

Baseline Demographics and Operative Variables

Analysis of baseline variables confirmed uniform distribution and statistical equivalence between the two intervention arms, confirming successful randomization ($p > 0.05$), as summarized in Table 1.

Table 1: Demographic and Intraoperative Baseline Characteristics by Group

Parameter	Variable/ Category	Group BD (n=30)	Group C (n=30)	Statistical Metric	p-value
Age (Years)	*Mean ± SD*	41.2 ± 13.5	44.4 ± 12.9	t(58) = -0.97	0.335
Gender, n (%)	Female Male	21 (70.0%) 9 (30.0%)	18 (60.0%) 12 (40.0%)	$\chi2(1) = 0.42$	0.517
ASA Status, n (%)	Grade I Grade II	15 (50.0%) 15 (50.0%)	13 (43.3%) 17 (56.7%)	$\chi2(1) = 0.04$	0.841
Weight (kg)	*Mean ± SD*	66.4 ± 11.3	64.1 ± 9.8	t(58) = 0.82	0.415
Operative Time (min)	*Mean ± SD*	64.7 ± 13.6	68.6 ± 15.1	t(58) = -1.08	0.285

Postoperative Pain Intensity Profiles

Serial pain assessments demonstrated lower postoperative pain scores in Group BD across all recorded intervals up to 24 hours. The distribution of pain severity categories over time is detailed in Table 2.

Table 2: Categorical Distribution of Postoperative VAS Pain Scores by Group

Time Point	Pain Category	Group BD (n=30)	Group C (n=30)	Fisher's Exact p-value
0.5 Hours	Mild (0–2) Moderate (3–4)	30 (100.0%) 0 (0.0%)	11 (36.7%) 19 (63.3%)	1.000
	Mild (1–2)	30 (100.0%)	0 (0.0%)	
1.0 Hour	Moderate (3–4)	0 (0.0%)	13 (43.3%)	1.000
	Severe (5)	0 (0.0%)	17 (56.7%)	
	Mild (1–2)	30 (100.0%)	0 (0.0%)	
2.0 Hours	Moderate (3–4)	0 (0.0%)	9 (30.0%)	1.000
	Severe (5–6)	0 (0.0%)	21 (70.0%)	
	Mild (1–2)	30 (100.0%)	0 (0.0%)	
4.0 Hours	Moderate (3–4)	0 (0.0%)	18 (60.0%)	1.000
	Severe (5–6)	0 (0.0%)	12 (40.0%)	
	Mild (1–2)	29 (96.7%)	1 (3.3%)	
6.0 Hours	Moderate (3–4)	1 (3.3%)	8 (26.7%)	1.000
	Severe (5–7)	0 (0.0%)	21 (70.0%)	
	Mild (2–3)	30 (100.0%)	0 (0.0%)	
12.0 Hours	Moderate (4–5)	0 (0.0%)	11 (36.7%)	1.000
	Severe (6–7)	0 (0.0%)	19 (63.3%)	
	Mild (2–3)	30 (100.0%)	0 (0.0%)	
24.0 Hours	Moderate (4–6)	0 (0.0%)	9 (30.0%)	1.000
	Severe (7–8)	0 (0.0%)	21 (70.0%)	

Rescue Analgesia and Consumption Outcomes

Objective markers of pain relief showed highly significant advantages for the intraperitoneal arm. The mean time to first rescue analgesia request was more than two times longer in Group BD (*405.3 ± 62.1* minutes) than in Group C (*139.3 ± 38.2* minutes), a difference that was highly significant ($t(58) = 20.91, p < 0.001$).

Categorical timing analysis revealed that 100% of Group BD patients required zero rescue interventions before the 300-minute mark. In contrast, 40.0% of Group C patients requested rescue care within 120 minutes, and the remaining 66.7% required intervention between 121 and 300 minutes ($\chi2(2) = 58.00, p < 0.001$).

Furthermore, cumulative 24-hour rescue analgesic requirements demonstrated a significant opioid-sparing effect in Group BD. Group BD required a significantly lower total rescue dose than Group C (*74.3 ± 14.5* mg vs. *211.2 ± 39.8* mg; $t(58) = -17.87, p < 0.001$).

Adverse Effects and Safety Profiles

The localized delivery model in Group BD resulted in a safer clinical profile. Hemodynamic complications and systemic side effects were recorded exclusively within the conventional systemic IV group, as shown in Table 3.

Table 3: Comparative Postoperative Side Effect Profiles by Group

Adverse Event	Category	Group BD (n=30)	Group C (n=30)	Fisher's Exact p-value
Hypotension	Yes No	0 (0.0%) 30 (100.0%)	18 (60.0%) 12 (40.0%)	1.000
Bradycardia	Yes No	0 (0.0%) 30 (100.0%)	0 (0.0%) 30 (100.0%)	1.000
Nausea	Yes No	0 (0.0%) 30 (100.0%)	18 (60.0%) 12 (40.0%)	1.000
Vomiting	Yes No	0 (0.0%) 30 (100.0%)	14 (46.7%) 16 (53.3%)	1.000

Discussion

Effective control of acute postoperative pain following laparoscopic cholecystectomy remains an essential goal of perioperative teams, as it directly impacts early ambulation, functional hospital discharge timelines, and overall patient satisfaction. Visceral nociception, driven by diaphragmatic tissue stretching and direct electrocautery or mechanical tissue trauma at the liver bed, represents a primary source of distress that systemic

IV drug regimens struggle to block cleanly without causing significant side effects. This prospective investigation demonstrates that targeting these visceral pathways locally via intraperitoneal bupivacaine augmented with dexmedetomidine provides a highly effective alternative to standard systemic intravenous drug management.

The demographic data confirmed balanced baselines between the cohorts ($p > 0.05$). This structural balance ensured that subsequent variations in temporal VAS trajectories, emergency rescue triggers, and side effect profiles were directly due to the different pharmacological approaches rather than confounding baseline characteristics.

Throughout the 24-hour monitoring timeline, Group BD maintained lower VAS pain scores, completely avoiding the severe pain categories reported by Group C. This localized clinical efficacy highlights the peripheral action of bupivacaine, which blocks voltage-gated sodium channels along localized peritoneal sensory afferents, paired with the synergistic actions of dexmedetomidine. Dexmedetomidine works via multi-pronged mechanisms: it diminishes localized neurogenic inflammation, stabilizes nerve membranes, and provides central antinociception following absorption across the high surface area of the peritoneal lining.

These findings are consistent with prior literature. Oza *et al*. (2016) [11] demonstrated a significant extension in postoperative analgesia when dexmedetomidine was combined with bupivacaine rather than bupivacaine alone. Similarly, Bhatia *et al*. (2024) [17] reported significantly reduced pain scores from 30 minutes to 10 hours post-instillation when using the same combination. In addition, Shukla *et al*. (2018) [14] reported a highly significant reduction in mean VAS scores at later postoperative intervals (8–20 hours) in patients receiving dexmedetomidine as an intraperitoneal adjuvant, matching the sustained analgesia trends observed in our data up to 24 hours.

Objective measures of analgesia confirmed these findings. The mean time to first rescue analgesia request was more than two times longer in Group BD (*405.3 ± 62.1* minutes) than in Group C (*139.3 ± 38.2* minutes). This prolonged pain-free interval directly corresponds with the work of Punyani *et al*. (2019) [15] and El Baz *et al*. (2018) [13], who noted extended delays in first rescue requests when utilizing dexmedetomidine adjuvants in laparoscopic abdominal procedures.

Furthermore, the cumulative 24-hour rescue analgesic consumption in Group BD was dramatically reduced (*74.3 ± 14.5* mg vs. *211.2 ± 39.8* mg; $p < 0.001$). This strong systemic drug-sparing effect supports the inclusion of intraperitoneal instillation protocols within Enhanced Recovery After Surgery (ERAS) pathways, minimizing dependency on baseline ward opioid infusions.

The safety data highlight a clear advantage for the intraperitoneal approach. Group C experienced high rates of hypotension (60.0%), nausea (60.0%), and vomiting (46.7%), which were completely absent in Group BD (0.0%). This high side-effect burden in Group C is likely due to the adverse effect profiles of systemic tramadol and related systemic drugs. Importantly, despite potential concerns regarding systemic absorption of intraperitoneal dexmedetomidine causing cardiorespiratory depression, no cases of bradycardia or clinically significant hypotension were recorded in Group BD. This demonstrates that the localized drug configuration remains safe when using appropriate weight-based dosing (*1 μg/kg*). These favorable tolerability and safety patterns match the conclusions of Shankar *et al*. (2022) [16] and Sah *et al*. (2025) [18], who reported safe, reliable hemodynamic profiles when combining dexmedetomidine with long-acting local anesthetics.

Study Strengths and Clinical Implications

The strengths of this study include its strict randomized allocation framework, excellent matching of potential baseline confounders (such as operative duration and body weight), a dense serial pain evaluation timeline up to 24 hours, and the use of objective consumption metrics alongside subjective VAS tracking. The clinical implications are clear: integrating bupivacaine-dexmedetomidine instillation into standard laparoscopic cholecystectomy workflows offers a practical, low-cost strategy to optimize postoperative pain management. By providing superior targeted visceral block, this protocol helps minimize breakthrough pain episodes, reduces nursing workloads associated with rescue drug delivery, avoids common opioid-induced side effects, and supports early, comfortable mobilization.

Limitations and Future Directions

This study has certain limitations, including a modest overall sample size ($n = 60$) drawn from a single rural teaching center, a reliance on subjective pain reporting tools, and a follow-up window limited to the initial 24 hours. Additionally, specific details of the systemic arm's antiemetic prophylaxis were not explicitly isolated, and individual components of somatic port-site pain versus deep visceral pain were not separately analyzed.

Future research should focus on large-scale, multicenter double-blind trials to validate these findings across broader patient populations. Evaluating long-term patient outcomes—such as the quality of sleep, time to full mobilization, total length of hospital stay and incidence of chronic post-surgical pain—would provide a more comprehensive understanding of the technique's benefits. Finally, formal cost-benefit analyses could support the systematic adoption of this localized protocol into standard surgical workflows.

Conclusion

This prospective study demonstrates that intraperitoneal administration of 0.25% bupivacaine combined with dexmedetomidine (*1 μg/kg*) provides safe, effective, and long-lasting postoperative pain relief in patients undergoing elective laparoscopic cholecystectomy. This local intervention delivers lower postoperative pain scores across all evaluated time points, significantly delays the need for first rescue analgesia, and reduces overall 24-hour rescue analgesic requirements compared to conventional systemic IV drug regimens. Furthermore, the intraperitoneal combination maintained excellent hemodynamic stability and was associated with zero instances of postoperative nausea, vomiting, or hypotension, which were common in the systemic IV group. These findings support the use of intraperitoneal bupivacaine-dexmedetomidine instillation as a safe, effective component of multimodal, opioid-sparing postoperative pain protocols following laparoscopic cholecystectomy.

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