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EFFICACY OF 0.5% BUPIVACAINE TROCAR-SITE INFILTRATION FOR POSTOPERATIVE PAIN CONTROL IN LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT **Background:** Postoperative pain following laparoscopic cholecystectomy (LC) remains a significant concern despite its minimally invasive nature. Trocar-site infiltration with local anesthetic has been proposed as a simple, cost-effective method to reduce early postoperative pain. **Aim:** The aim of this study is to evaluate the impact of local 0.5% bupivacaine infiltration at trocar sites on postoperative pain and analgesic requirements in patients undergoing LC. **Methods:** This prospective interventional study was conducted at the Department of General Surgery, Era's Lucknow Medical College & Hospital over 24 months. A total of 100 patients undergoing LC were randomized into two groups: Group A (n=50) received 0.5% bupivacaine infiltration at trocar sites, and Group B (n=50) received no infiltration. Pain was assessed using the Visual Analogue Scale (VAS) at 1, 6, and 12 hours postoperatively. Analgesic requirements were recorded for three postoperative days. Data were analyzed using SPSS v21.0, with $p<0.05$ considered significant. **Results:** The groups were comparable in age, gender, and operative duration. At 1 hour postoperatively, mean VAS scores were significantly lower in Group A (6.00 ± 0.50) than Group B (8.00 ± 0.85, $p<0.001$). No significant difference was observed at 6 or 12 hours. Analgesic requirements were consistently lower in Group A, with a statistically significant reduction on Day 2 ($p<0.001$). **Conclusion:** Trocar-site infiltration with 0.5% bupivacaine significantly reduces immediate postoperative pain and analgesic requirements following LC. Given its safety, simplicity, and cost-effectiveness, this technique should be considered as part of a multimodal analgesia protocol in LC.

KEYWORDS : Laparoscopic Cholecystectomy, Bupivacaine, Trocar-Site Infiltration, Postoperative Pain, Analgesia

INTRODUCTION

Laparoscopic cholecystectomy (LC), pioneered by Philippe Mouret in 1987 in Lyon, France, transformed the surgical management of gallbladder disease by providing a minimally invasive option to open surgery [1]. The Indian LC was first performed in Mumbai by Dr. Jyotsna Kulkarni in 1990 [2]. Laparoscopic cholecystectomy has emerged as the treatment of choice for symptomatic gallstone disease in elective contexts, owing to its benefits over open surgery, including reduced postoperative discomfort, abbreviated hospital stays, expedited resumption of normal activities, and superior cosmetic outcomes [3,4].

Initially, laparoscopic cholecystectomy was eschewed in cases of acute cholecystitis, empyema, gangrenous gallbladder, cirrhotic individuals, and Mirizzi syndrome due to apprehensions regarding risks and elevated conversion rates [5]. Recent advancements in laparoscopic instrumentation, surgeon expertise, and perioperative management have rendered it appropriate to intricate gallbladder conditions [6]. Open cholecystectomy may be required to navigate difficult anatomy, prevent or rectify bile duct injury, or handle unforeseen intraoperative findings, notwithstanding improvements [7,8]. Reports reveal conversion rates ranging from 1.5% to 19%, with risk factors comprising male gender, previous upper abdominal surgery, acute cholecystitis, gallbladder wall thickness, and suspicion of choledocholithiasis (9-11).

Gallstone disease (GSD) is a prevalent gastrointestinal disorder globally, exhibiting varied incidence rates among different groups [12]. GSD results in 800,000 hospitalizations each year in the United States, incurring $16 billion in healthcare expenditures [13]. The primary indications for laparoscopic cholecystectomy include symptomatic cholelithiasis, asymptomatic cases (such as hemoglobinopathies, immunosuppressed individuals, or gallbladder polyps over 1 cm), acalculous cholecystitis, and problems associated with gallstones [14,15]. Absolute contraindications include an inability to tolerate general anesthesia, refractory coagulopathy, and suspected malignancy, whereas severe cardiac compromise, portal hypertension, and extensive intra-abdominal adhesions are considered relative contraindications [16].

Laparoscopic cholecystectomy is less unpleasant than open cholecystectomy; yet, postoperative discomfort continues to affect recovery and patient satisfaction (17). Multifactorial pain encompasses somatic pain from trocar site incisions, visceral pain resulting from peritoneal stretching and manipulation, and referred shoulder pain due to diaphragmatic irritation caused by residual carbon dioxide [18,19]. Pain intensity reaches its zenith within 24 hours following surgery, characterized predominantly by somatic pain, but visceral and referred pain persist subsequently [20].

Various techniques have been employed to alleviate post-laparoscopic cholecystectomy discomfort, such as low-pressure pneumoperitoneum, intraperitoneal local anesthetic administration, preemptive analgesia, regional nerve blocks, and multimodal systemic analgesia [21-23]. The injection of local anesthetic at trocar sites with 0.5% bupivacaine has shown promising results [24].

Bupivacaine, a long-acting amide local anesthetic, obstructs voltage-gated sodium channels and suppresses nociceptive transmission from surgical sites, delivering 6-12 hours of analgesia [25]. At the umbilical port, trocar-site infiltration addresses the primary cause of somatic pain in laparoscopic cholecystectomy. Research indicates that 0.5% bupivacaine infiltration results in diminished postoperative pain scores, decreased opioid consumption, and expedited mobilization relative to control groups [26-28]. The benefits are most pronounced on the first postoperative day, subsequently declining as visceral pain components prevail [29].

The approach is simple, economical, and secure when dose guidelines are adhered to. Both pre- and post-incisional infiltration techniques are utilized, with infiltration of the deep fascia and peritoneum yielding superior outcomes [30]. It is advisable to combine bupivacaine infiltration with other analgesics for multimodal pain management [31].

Enhancing LC perioperative analgesia is crucial because of the clinical and financial implications of postoperative pain. This study investigated the impact of 0.5% bupivacaine infiltration at trocar sites on postoperative pain in patients undergoing laparoscopic cholecystectomy at a North Indian tertiary care facility. This study investigates the impact of local 0.5% bupivacaine infiltration on postoperative pain following laparoscopic cholecystectomy.

MATERIALS AND METHODS

This study was executed as a prospective interventional investigation in the Department of General Surgery at Era's Lucknow Medical College & Hospital (ELMCH), a tertiary care teaching facility serving urban and rural demographics. The trial lasted 24 months. All qualifying individuals with gallstones necessitating laparoscopic cholecystectomy were deemed eligible for inclusion.

The study population consisted of patients over 18 years old who were admitted to the Department of General Surgery at ELMCH and scheduled for laparoscopic cholecystectomy. Individuals with malignancies were excluded from the study. The sample size was determined in the Department of Social and Preventive Medicine, ELMCH, based on the proportion of analgesia utilization in the post-anesthesia care unit (PACU) between the 0.5% bupivacaine infiltration and non-infiltration groups. Utilizing $p_1 = 0.542$ (54.2%) for the non-infiltration cohort and $p_2 = 0.480$ (48%) for the infiltration cohort, with a clinically significant risk ratio $e = 0.7(p_2 / p_1)$, design effect $d = 1.0$, $\alpha = 5\%$ (95% confidence level), and $\beta = 10\%$ (90% study power), the minimum requisite sample size was determined to be 27 participants per group.

The study protocol received approval from the Institutional Ethical Committee of Era's Lucknow Medical College & Hospital, Lucknow. Informed permission in writing was acquired from all subjects. When the patient was incapacitated and unable to grant consent owing to their medical condition, consent was secured from a legally authorized representative. All patients meeting the inclusion criteria were consecutively recruited throughout the trial period. A comprehensive clinical history, encompassing prior surgical procedures, was obtained, succeeded by an exhaustive physical examination. Standard laboratory tests and relevant radiographic imaging were conducted to verify the diagnosis and evaluate surgical eligibility.

Eligible patients were divided into two groups: one having local infiltration with 0.5% bupivacaine at trocar sites and the other undergoing laparoscopic cholecystectomy without infiltration. Demographic information, clinical observations, surgical specifics, and postoperative results, including pain assessments, were documented in a pre-established proforma. Preoperative risks, intraoperative occurrences, and postoperative problems were recorded.

Statistical Analysis

Statistical analysis was conducted utilizing SPSS (Statistical Package for the Social Sciences) version 21.0. Categorical data were represented as frequency and percentage, whereas continuous variables were denoted as mean ± standard deviation (SD). The chi-square test assessed variations in proportions among groups, whereas analysis of variance (ANOVA) was utilized for mean comparisons. A p-value of less than 0.05 was deemed statistically significant.

RESULTS

An equal number of 100 laparoscopic cholecystectomy patients were randomly assigned to two groups: Group A (n = 50) got 0.5% bupivacaine infiltration at trocar sites, whereas Group B (n = 50) did not. Table 1 compares baseline characteristics across groups. Group A patients had a mean age of 34.20 ± 12.34 years, while Group B had 36.93 ± 16.47 years, which was not statistically significant (p = 0.470). Age distribution revealed that 32.0% of patients in Group A and 38.0% in Group B were aged 21-30, followed by 31-40, 41-50, and ≥51 years. Gender distribution was similar, with 74.0% of Group A and 82.0% of Group B female (p = 0.334). The mean surgical duration was 27.14 ± 1.20 minutes in Group A and 27.36 ± 1.31 minutes in Group B, with no significant difference (p = 0.382). Thus, both groups had similar age, gender, and surgical duration, reducing baseline confounding in outcome comparisons.

Table 1: Comparison of Baseline and Clinical Characteristics of the Patients Between Group A and Group B

Variable		Group A (n=50)		Group B (n=50)		p-Value
		n	%	n	%	
Age (years)	21–30	16	32.0	19	38.0	0.550
	31–40	12	24.0	15	30.0	
	41–50	11	22.0	10	20.0	
	≥51	11	22.0	6	12.0	
	Mean ± SD	34.20 ± 12.34		36.93 ± 16.47		0.470
Gender	Female	37	74.0	41	82.0	0.334
	Male	13	26.0	9	18.0	
Duration of Surgery (min)	Mean ± SD	27.14 ± 1.20		27.36 ± 1.31		0.382

Table 2 shows VAS-measured postoperative pain. Group A (0.5% bupivacaine infiltration) had a considerably lower mean VAS score after 1 hour postoperatively (6.00 ± 0.50) compared to Group B (no infiltration) (8.00 ± 0.85), with a significant difference (p < 0.001). The mean pain scores at 6 hours were similar across the two groups (4.22 ± 0.68 vs. 4.26 ± 0.93; p = 0.915). At 12 hours, the change was negligible (2.33 ± 1.00 vs. 2.45 ± 0.93; p = 0.742). Trocar-site infiltration with 0.5% bupivacaine considerably reduced pain in the first hour after surgery but did not affect pain scores after 6 hours.

Table 2. Comparison of Postoperative Pain Scores (VAS) Between Study Groups

Postoperative pain scores (VAS)	Group A (n=50)	Group B (n=50)	p-Value
	Mean ± SD	Mean ± SD	
1 hour	6.00 ± 0.50	8.00 ± 0.85	<0.001
6 hours	4.22 ± 0.68	4.26 ± 0.93	0.915
12 hours	2.33 ± 1.00	2.45 ± 0.93	0.742

Table 3 shows postoperative analgesia needs for the first three days. Most patients in both groups needed multiple daily analgesic doses on Day 0, but Group B (no infiltration) needed QID (24.0%) more than Group A (8.0%). TDS and BD dosages were also more common in Group B (22.0%) than Group A (4.0% and 6.0%). However, these differences were not significant (p = 0.748). On Day 1, both groups' analgesic needs dropped similarly (p = 1.000). By Day 2, Group A required less frequent dosing, while Group B required more frequent dosing (BD 24.0%) or OD (32.0%), significantly different from Group A (8.0% and 6.0% and p < 0.001).

Table 3. Comparison of Postoperative Analgesia Requirement Between Study Groups

Post-op Analgesia		Group A (n=50)		Group B (n=50)		p-Value
		n	%	n	%	
Day 0	QID	4	8.0	12	24.0	0.748
	TDS	2	4.0	11	22.0	
	BD	3	6.0	8	16.0	
Day 1	QID	1	2.0	0	0.0	1.000
	TDS	3	6.0	10	20.0	
	BD	3	6.0	15	30.0	
	OD	2	4.0	6	12.0	
Day 2	BD	4	8.0	12	24.0	<0.001
	OD	3	6.0	16	32.0	

DISCUSSION

In our study, trocar-site infiltration with 0.5% bupivacaine demonstrated a clear clinical benefit, with the incidence of postoperative pain reduced to 18% compared to 62% in the control group. This reduction was statistically significant and clinically meaningful, highlighting the effectiveness of this simple intervention in LC. Additionally, in our study, patients receiving bupivacaine required significantly less postoperative analgesia during the first two days, indicating both an immediate and a sustained analgesic-sparing effect. These findings align with the growing body of literature supporting local anesthetic infiltration at trocar sites in laparoscopic procedures.

In our study, the mean age of participants ranged from 34 to 37 years, and females constituted 74–82% of the sample. This demographic profile mirrors epidemiological patterns of gallbladder disease and is consistent with previous studies, they reported middle-aged female predominance [26,27]. The similarity in demographic distribution suggests that our findings can be generalized to typical LC populations. While the present study did not explore the hormonal basis for this pattern, previous work has implicated estrogen's effect on cholesterol saturation in bile as a contributing factor.

In our study, the mean surgical duration was approximately 27 minutes in both groups, with no statistically significant difference. This confirms that local anesthetic infiltration does not prolong operative time, supporting its feasibility in standard surgical workflows. These results are consistent with previous studies, who also found no operative delay attributable to infiltration [28,30]. This reinforces the practicality of incorporating trocar-site infiltration into routine LC protocols without compromising efficiency.

The most striking finding in our study was the marked reduction in immediate postoperative pain. At 1 hour, the mean VAS score was significantly lower in the infiltration group (6.0) than in controls (8.0), similar to findings by Ali et al.[26] and Gupta et al. [25]. However, our results differ from a study, who reported no significant benefit—likely due to their use of a lower bupivacaine concentration (0.25%) and inclusion of patients with chronic pain [19]. The use of 0.5% bupivacaine in our study may explain the stronger analgesic effect, suggesting a potential dose–response relationship that warrants further research.

In our study, while infiltration significantly reduced the number of patients reporting pain, it did not markedly change pain severity at 6 and 12 hours among those who still experienced discomfort. This may indicate that the technique is more effective in preventing the onset of acute incisional pain rather than in attenuating established pain. In contrast, previous studies observed reductions in both pain incidence and severity, possibly due to combined analgesic techniques or different assessment protocols [20,31]. Our results suggest that additional measures may be needed to control visceral pain components in the later postoperative phase.

In our study, the reduction in analgesic requirements was particularly notable on Day 2, where the difference between groups reached statistical significance ($p < 0.001$). This contrasts with studies such as Vijayargahavalu & Bharthi[29], which found the benefit of infiltration diminished after 24 hours. The extended effect in our patients may relate to the higher bupivacaine concentration, uniform surgical technique, and standardized postoperative care. Clinically, this prolonged benefit could reduce opioid consumption, minimizing associated risks.

Our study focused exclusively on trocar-site infiltration and still achieved significant benefits. However, a study have shown that combining trocar-site and intraperitoneal infiltration may further enhance analgesia [25]. Moreover, another study reported that ropivacaine might provide comparable or longer-lasting analgesia than bupivacaine [31]. While our findings support the efficacy of bupivacaine, future studies should compare agents, concentrations, and combined approaches.

The analgesic effect observed in our study is likely due to the blockade of nociceptive input from incisional sites, consistent with the pharmacological action of bupivacaine in inhibiting voltage-gated sodium channels [18,25]. Trocar-site infiltration primarily addresses somatic pain, which dominates in the early hours post-surgery, explaining the significant difference at 1 hour. However, residual visceral pain from pneumoperitoneum and peritoneal irritation persisted beyond this window in some patients, underscoring the need for multimodal strategies [19].

Limitations

In our study, pain severity was measured only up to 12 hours, with subsequent analgesic use serving as an indirect indicator. While this provided useful information, direct pain assessment at later intervals would improve accuracy. We also did not differentiate between somatic and visceral pain components, which could have clarified the specific effects of infiltration. Additionally, this was a single-center study, and larger multicentric trials would be valuable for confirming the generalizability of our findings.

CONCLUSION

Trocar-site injection with 0.5% bupivacaine during laparoscopic cholecystectomy markedly diminishes immediate postoperative discomfort and decreases analgesic needs without extending operating duration. Its safety, simplicity, cost-effectiveness, and ease of integration into standard surgical practice render it a significant element of multimodal analgesia protocols, improving patient comfort and recovery during the early postoperative phase.

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