

A COMPARISON OF POSTOPERATIVE PAIN WITH AND WITHOUT INSTILLATION OF BUPIVACAINE DURING LAPAROSCOPIC CHOLECYSTECTOMY

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DOI: <https://doi.org/10.5281/zenodo.18067762>

Keywords

Laparoscopic Cholecystectomy,
Analgesia, Gallstones, Outcomes,
Postoperative Pain.

Article History

Received on 14 July 2025

Accepted on 20 July 2025

Published on 22 July 2025

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Abstract

Objective: To compare postoperative pain with and without instillation of bupivacaine during laparoscopic cholecystectomy.

Study Design: Randomized Controlled Trial.

Study Setting: Department of General Surgery, Recep Tayyip Erdogan Hospital, Muzaffargarh, Pakistan

Study Duration: Six Months (November-2024 to April-2025).

Methodology: Sixty patients who were planned to undergo laparoscopic cholecystectomy were included in the study. They were divided into Group-A (bupivacaine instillation) and Group-B (normal Saline instillation). Post-operative pain and duration of analgesia was compared between groups.

Results: The study included 60 patients with a mean age of 45.08 ± 8.05 years, of whom 19 (31.67%) were male and 41 (68.33%) were female. At 24 hours postoperatively, the median pain score in Group-A was significantly lower at 1 than Group-B ($p < 0.001$). Additionally, the median duration of analgesia was markedly longer in Group-A at 3.00 hours (IQR: 6.00–2.00) versus 1.00 hour (IQR: 4.00–1.00) in Group-B ($p < 0.001$), indicating superior and more sustained pain control in Group-A.

Conclusion: Bupivacaine instillation into the gallbladder fossa during surgery is a useful practice to reduce post-operative pain and enhance duration of analgesia after operation.

INTRODUCTION

Laparoscopic cholecystectomy (LC) is extensively conducted procedure globally and has supplanted open surgery to remove the gallbladder (GB) as the gold standard for treating patients with cholelithiasis. ^(1, 2) There are several advantages that are offered by LC over the open procedure including reduced postoperative pain and analgesic requirement, improved recovery time, less surgical wound infection and improved cosmetic appearance. ^(3, 4) Compared to this, in the events of

either conversion of procedure to the open approach or performing the procedure through conventional open technique, the chances of cholecystectomy related complications rise significantly with an estimated range of 8-43%. ⁽⁵⁾ When it comes to the pathophysiological process by which post-LC pain originates is a complex one and is affected by multiple factors. This pain can be somatic in nature arising from the incision site or visceral that can arise due to peritoneal distention

and visceral irritation caused by the creation of capnoperitoneum and surgical handling.^(6,7) In fact, if not managed proactively and appropriately it can even lead to development of post-LC pain syndrome which can cause persistent pain after a patient undergoes surgery.⁽⁸⁾ Due to this multifactorial and complex nature, it would be logical to adopt for multi-modal analgesia in this regard for effective pain management.⁽⁹⁾ One such method that has been considered to potentially provide with effective and prolonged analgesia after LC and also increase the duration for which additional doses of analgesic medication are required, is local infiltration of bupivacaine (a local anesthetic) at the operative site.⁽¹⁰⁾ However, it needs further investigation before it can be made standard of care.

Good postoperative control of pain after LC is important to reduce the patient morbidity and early return of patient to normal life activities. So the rationale of this study is to find the ways by minimal and safe intraoperative intervention during LC to reduce the postoperative pain with minimal use of high potency analgesia in less quantity. For this purpose, this study was conducted to compare postoperative pain with and without instillation of bupivacaine during LC.

METHODOLOGY:

The objective of this study was to evaluate postoperative pain and to compare pain outcomes in patients undergoing laparoscopic cholecystectomy with and without intraoperative instillation of bupivacaine in the gallbladder fossa. This randomized controlled trial tested the hypothesis that instillation of bupivacaine after laparoscopic cholecystectomy controlled postoperative pain more effectively than normal saline. The study was conducted at Recep Tayyip Erdogan Hospital, Muzaffargarh, from November 2024 to April 2025. Ethical approval was obtained from the Research and Evaluation Unit of CPSP and the Institutional Review Board (Ref #: CPSP/REU/SGR-2022-293-14375, IHHN_IRB_2024_04_002). The trial was registered at ClinicalTrials.gov (ID: NCT07098429). Sample size calculation was performed using a standard formula with a level of significance of 5% and a study power of 90%. Based on anticipated mean pain scores at 24 hours of 2 ± 1 in the

bupivacaine group and 3 ± 1 in the placebo group, a total sample size of 60 patients was calculated, with 30 patients in each group. Patients were enrolled using a non-probability consecutive sampling technique.

Patients of both genders, aged 14 to 70 years, who were admitted for elective laparoscopic cholecystectomy were included in the study. Patients with hypersensitivity to bupivacaine, acute cholecystitis, empyema of the gallbladder, pregnancy or lactation, and those whose laparoscopic procedure was converted to open cholecystectomy were excluded.

Prior to enrollment, informed written consent was obtained from all participants. Demographic data, including age, gender, and body mass index, were recorded. Patients were randomly allocated into two equal groups using a lottery method. In Group A (n = 30), 20 ml of 0.25% bupivacaine was instilled into the gallbladder fossa after removal of the gallbladder. In Group B (n = 30), 20 ml of 0.9% normal saline was instilled in the gallbladder fossa following gallbladder removal. In both groups, bupivacaine was infiltrated at the port sites as part of standard practice.

All patients underwent routine preoperative evaluation, including complete blood count, renal and liver function tests, electrocardiography, random blood glucose, and chest X-ray. Abdominal ultrasound was performed to confirm the diagnosis of cholelithiasis. Laparoscopic cholecystectomy was performed under general anesthesia administered by a consultant anesthesiologist with at least two years of experience. All surgeries were conducted using a standard four-port technique by a consistent surgical team led by a senior surgeon with more than six years of experience, to minimize procedural variability. The only procedural difference between the groups was the instillation of either bupivacaine or saline into the gallbladder fossa after gallbladder removal.

Postoperative analgesia consisted of a single immediate dose of intravenous diclofenac sodium 75 mg diluted in 100 ml of normal saline. Subsequent doses were administered on patient request. No narcotic analgesics were used postoperatively. Patients were transferred to the post-anesthesia care unit, where postoperative pain was assessed using the

Wong-Baker Faces Pain Rating Scale at 1, 3, 6, 12, and 24 hours after surgery. The duration of analgesia was defined as the time interval between local anesthetic infiltration and the first request for additional analgesia.

Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 22.0. Normality of continuous variables was assessed using the Shapiro-Wilk test. Age and BMI were normally distributed and were expressed as mean $\pm$ standard deviation. Postoperative pain scores and duration of analgesia were not normally distributed and were expressed as median with interquartile range. Categorical variables, including gender, were presented as frequencies and percentages. Comparisons between groups were made using the Mann-Whitney U test, with a p-value of ≤ 0.05 considered statistically significant.

RESULTS:

A total of 60 patients were included in the study, with a mean age of 45.08 ± 8.05 years. There were 19

(31.67%) males and 41 (68.33%) females. The mean body mass index was 31.75 ± 4.71 kg/m². Baseline demographic characteristics, including age, gender, and BMI, were comparable between Group A (bupivacaine) and Group B (normal saline), with no statistically significant differences. Postoperative pain scores assessed using the Wong-Baker Faces Pain Rating Scale were significantly lower in Group A at all postoperative intervals. Median pain scores in Group A at 1, 3, 6, 12, and 24 hours were 7.00, 6.50, 6.00, 5.00, and 1.00, respectively, whereas corresponding scores in Group B were consistently higher at 7.00, 7.00, 6.00, 5.50, and 3.00. The differences between groups were statistically significant at all time points ($p < 0.05$). The median duration of analgesia was significantly longer in Group A at 3.00 hours compared to 1.00 hour in Group B ($p < 0.001$), indicating prolonged pain relief with bupivacaine instillation.

TABLE: COMPARISON OF BASELINE CHARACTERISTICS, POSTOPERATIVE PAIN SCORES, AND DURATION OF ANALGESIA BETWEEN GROUPS (N = 60)

Variable	Group A (Bupivacaine) n = 30	Group B (Normal Saline) n = 30	p-value
Age (years), mean $\pm$ SD	44.73 $\pm$ 8.40	45.43 $\pm$ 7.81	0.740
Gender, n (%)			
Male	9 (30.0%)	10 (33.3%)	0.781
Female	21 (70.0%)	20 (66.7%)	
BMI (kg/m ²), mean $\pm$ SD	31.75 $\pm$ 4.74	31.75 $\pm$ 4.75	1.000
Postoperative Pain Score (Median, IQR)			
Hour 1	7.00 (8.00–5.00)	7.00 (9.00–6.00)	0.002
Hour 3	6.50 (8.00–5.00)	7.00 (9.00–6.00)	<0.001
Hour 6	6.00 (7.00–4.00)	6.00 (8.00–5.00)	0.006
Hour 12	5.00 (6.00–3.00)	5.50 (7.00–4.00)	0.001
Hour 24	1.00 (4.00–0.00)	3.00 (5.00–0.00)	<0.001
Duration of Analgesia (hours), Median (IQR)	3.00 (6.00–2.00)	1.00 (4.00–1.00)	<0.001

DISCUSSION:

Surgical removal of the gallbladder is the gold standard treatment for symptomatic cholelithiasis, which otherwise often remains asymptomatic.^(12, 13) Laparoscopic cholecystectomy is the preferred approach due to its safety and effectiveness; however, as an invasive procedure, it is associated with postoperative complications, among which pain is one of the most common and clinically relevant.⁽¹⁴⁻¹⁶⁾ This study therefore evaluated the role of local bupivacaine instillation as a simple intervention to reduce post-laparoscopic cholecystectomy pain.

In the present study, the mean age of patients undergoing laparoscopic cholecystectomy was above 40 years, consistent with the higher prevalence of gallstone disease in the fourth and fifth decades of life.⁽¹⁷⁾ Female predominance was observed, reflecting the well-documented increased risk of cholelithiasis among women.^(18, 19) The average BMI was in the obese range, supporting obesity as a major risk factor for gallstone formation.⁽²⁰⁾

Postoperative pain assessment using the Wong-Baker Faces Pain Rating Scale demonstrated significantly lower pain scores at all measured intervals in patients who received bupivacaine instillation in the gallbladder fossa compared to those who received normal saline ($p < 0.05$). These findings are consistent with reports by Suma et al. and Tyagi et al., who also observed significantly reduced postoperative pain with local bupivacaine use.^(11, 21) Although Datta et al. did not find a significant difference at 24 hours postoperatively; they reported a clear analgesic benefit during earlier postoperative periods, aligning with the present study's observations.⁽²²⁾

The duration of analgesia was significantly prolonged in the bupivacaine group, with a longer interval before the first request for additional analgesia ($p < 0.001$). Similar findings have been reported by Suma et al. and Jalal et al., who documented prolonged analgesia and reduced analgesic requirements following bupivacaine infiltration.^(11, 23)

Overall, the findings indicate that intraoperative bupivacaine instillation in the gallbladder fossa is an effective and practical method for reducing postoperative pain and prolonging analgesia

following laparoscopic cholecystectomy. Limitations of this study include exclusion of patients with significant comorbidities and the lack of assessment of long-term postoperative outcomes and complications.

CONCLUSION:

In conclusion, local bupivacaine infiltration significantly reduces the severity of pain after LC at different intervals and prolonging the duration of post-operative analgesia.

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