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**Original Research Article**

# POSTOPERATIVE OUTCOMES AMONG PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT DRAIN FOR GALLSTONE DISEASE: A HOSPITAL BASED PROSPECTIVE STUDY

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## Abstract

**Background:** Laparoscopic cholecystectomy (LC) has emerged as the preferred method for managing symptomatic gallstone disease, offering benefits such as reduced postoperative discomfort, shorter hospital stays, and faster recovery times. Nonetheless, the use of prophylactic drains following LC is a contentious issue. Drains are often placed to prevent fluid accumulation and aid in carbon dioxide release, while concerns include potential complications and prolonged hospitalization. Previous research has generated inconsistent findings, leaving the question of drain utility unresolved. This study aims to compare LC outcomes with and without drains, contributing to the ongoing discussion surrounding their use. **Materials and Methods:** This prospective cohort study at a North Indian tertiary care hospital enrolled patients undergoing laparoscopic cholecystectomy for gallstone disease from June 2021 to June 2023. Surgeries followed standardized techniques; patients were randomly assigned to Group A (no drains) or Group B (drains placed via 16 Fr drain through a 5 mm port). Data collection included baseline, intraoperative, and postoperative information. Primary outcomes were complications, hospital stay, patient-reported discomfort; secondary outcomes involved pain scores, time to oral intake, return to activities. SPSS 20.0 analyzed data, with $p < 0.05$ as significant. **Result:** In this prospective cohort study, 130 participants were enrolled (65 in each group). Baseline characteristics were similar between groups, including age (Group A: $45.26 \pm 8.34$ years, Group B: $44.82 \pm 7.92$ years). Operative time, intraoperative complications, and conversion rates showed no significant differences. Wound infection rates were 10.8% (Group A) and 27.4% (Group B). Pain scores were significantly lower in Group A ($2.71 \pm 0.92$) compared to Group B ($3.87 \pm 1.25$), and shorter hospital stay (Group A: $2.21 \pm 0.68$ days, Group B: $2.95 \pm 0.74$ days). **Conclusion:** Although no significant differences were observed in intraoperative complications and postoperative complication rates, the absence of drains demonstrated advantages in terms of postoperative pain management, early ambulation, faster resumption of oral intake, and shorter hospital stays. These findings encourage further investigation and discussion within the surgical community.

## INTRODUCTION

Laparoscopic cholecystectomy (LC) has emerged as the gold standard for the surgical management of symptomatic gallstone disease, offering several advantages over the conventional open approach, including reduced postoperative pain, shorter hospital stays, and quicker recovery times.[1,2] However, despite its widespread adoption, certain aspects of LC remain subjects of ongoing debate within the surgical community. One such area of contention revolves around the use of prophylactic drains following LC.[3,4]

The practice of placing drains after LC has been rooted in the rationale of preventing intraabdominal collections, particularly bile or blood, and facilitating the release of accumulated carbon dioxide to prevent post-operative shoulder pain. Proponents of drain placement argue that it helps mitigate potential complications by ensuring the early detection and

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management of fluid collections or bile leaks.[5] Conversely, opponents of drain use advocate for a drain-free approach, contending that the routine use of drains might lead to increased postoperative pain, infection rates, and prolonged hospital stays without substantial clinical benefits.[6]

Several studies have explored the role of drains in LC, yielding conflicting findings and leaving surgeons without clear guidelines for their utilization.[7,8] Some trials have reported reduced rates of complications, such as wound infections, with drain placement, while others have found no significant differences or even increased complications associated with their use.[3,7,8] Furthermore, the impact of drains on patient-reported outcomes, such as pain scores, time to ambulation, and duration of hospital stay, remains a topic of investigation.

To address this gap in the literature, we conducted comparative study that aimed to investigate the outcomes of laparoscopic cholecystectomy with and without the use of drains. By rigorously assessing postoperative complications, patient comfort, recovery time, and hospital stay, we intend to contribute to the ongoing discourse surrounding drain utilization.

## MATERIALS AND METHODS

### Study Design and Participants

This comparative study was designed as a prospective cohort investigation conducted at tertiary care hospital of North India, under the department of General Surgery. Ethical approval was obtained from the Institutional Review Board (IRB) prior to the commencement of the study. All patients undergoing laparoscopic cholecystectomy for symptomatic gallstone disease between June 2021 and June 2023 were considered for inclusion in the study. Informed consent was obtained from each participant before enrollment.

### Sample Size Calculation

Sample size estimation was based on a priori power analysis, assuming a significance level of 0.05 and a power of 80%. The calculated sample size as 130 (65 patients in each group) aimed to detect clinically relevant differences (15%) in postoperative wound infection rate between the two groups.

### Inclusion and Exclusion Criteria

Patients aged 18 to 65 years with symptomatic gallstone disease confirmed through clinical evaluation, radiological imaging, and laboratory tests were included. Patients with a history of previous abdominal surgeries, known bleeding disorders, acute cholecystitis, choledocholithiasis, or pregnancy were excluded from the study.

### Surgical Technique

Preoperative antibiotic prophylaxis in the form of ceftriaxone was administered, and all surgical procedures were conducted under general anesthesia. All laparoscopic cholecystectomies were performed by experienced laparoscopic surgeons who followed a standardized surgical technique i.e., four port technique (two 10mm ports and two 5mm ports). Trocar placement, dissection of Calot's triangle, identification of the cystic duct and artery, and gallbladder dissection were carried out according to established guidelines.

### Group Allocation

Patients were divided into two groups using a randomized allocation method. Group A consisted of patients undergoing laparoscopic cholecystectomy without the placement of drains, while Group B comprised patients with drains placed in the subhepatic space after cholecystectomy (i.e., 16 Fr drain via right anterior axillary 5 mm port).

### Data Collection

Baseline demographic information, medical history, and clinical characteristics of each participant were recorded. Intraoperative details including operative time, blood loss, and any intraoperative complications were documented.

### Postoperative Management

Intravenous ceftriaxone was maintained postoperatively, administered twice daily throughout the duration of hospital admission. Patients were closely monitored postoperatively for complications such as wound infection, bile leakage, hematoma, and seroma formation. A postoperative ultrasound abdomen was conducted on all patients on the first day following the surgery to assess for the presence of subhepatic fluid collection. Pain scores were assessed using a visual analog score (VAS) at regular intervals (24 hours and 48 hours postoperatively). Drain-related discomfort, if applicable, was also recorded. The drain was removed when the discharge was insignificant (20 ml or less within the last 24 hours).

### Outcome Measures

The primary outcomes included the incidence of postoperative complications, length of hospital stay, and patient-reported discomfort. Secondary outcomes encompassed postoperative pain scores i.e., VAS, time to resumption of oral intake, and return to normal activities.

### Data Analysis

Statistical analysis was performed using SPSS version 20.0. Continuous variables were expressed as means with standard deviations, depending on their distribution. Categorical variables were presented as frequencies and percentages. The Student's t-test or Mann-Whitney U test was used for continuous variables, while the chi-squared test or Fisher's exact test was employed for categorical variables. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

A total of 130 eligible study participants (65 each in group A and group B) were enrolled in our prospective comparative study. The average age for

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Group A (Without Drain) was 45.26 years (± 8.34), while for Group B (With Drain), it was 44.82 years (± 7.92), with no statistically significant difference observed (p = 0.778). Gender distribution revealed a male-to-female ratio of 1:1.03 in Group A (50.7% and 49.3%, respectively), and 1:1.17 in Group B (46.2% and 53.8%, respectively), indicating no significant gender-based discrepancy (p = 0.598). Body mass index (BMI) measurements exhibited comparable means, with Group A having a mean BMI of 26.71 Kg/m2 (± 3.17), and Group B having a mean BMI of 27.25 Kg/m2 (± 2.93), demonstrating no significant difference between the groups (p = 0.34). Evaluation of comorbidity status indicated that 27.7% of participants in Group A presented with comorbidities (n = 18 with comorbidities and n = 47 without), whereas 30.8% in Group B exhibited comorbidities (n = 20 with comorbidities and n = 45 without). The observed difference in comorbidity rates between the groups was not statistically significant (p = 0.699). These findings collectively demonstrate a balanced distribution of baseline characteristics across the study groups, establishing a solid foundation for the subsequent analysis of outcomes [Table 1].

In our study, the mean operative time for Group A (Without Drain) was 75.49 minutes (± 12.62), whereas for Group B (With Drain), it was 72.84 minutes (± 11.32). Although there appears to be a numerical difference, this variance was not statistically significant (p = 0.217). Examining intraoperative complications, Group A experienced complications in 12.3% of cases (n = 8 with complications, n = 57 without), while Group B encountered complications in 7.7% of cases (n = 5 with complications, n = 60 without). However, the difference in complication rates did not reach statistical significance (p = 0.380). Furthermore, the incidence of conversion to open surgery was low in both groups. In Group A, 4.6% of cases (n = 3) required conversion (n = 62 without conversion), compared to Group B, where 3.1% of cases (n = 2) necessitated conversion (n = 63 without conversion). As with intraoperative complications, the variation in conversion rates between the groups was not statistically significant (p = 0.648). Collectively, these results underscore a lack of significant differences in operative time, intraoperative complications, and conversion rates between the two study groups. [Table 2].

In our study, Group A (Without Drain), wound infections were observed in 10.8% of cases (n = 7

with infections, n = 58 without), whereas in Group B (With Drain), wound infections were documented in 27.4% of cases (n = 14 with infections, n = 51 without). Although there appears to be a trend favoring Group A, the difference in wound infection rates did not reach statistical significance (p = 0.095). Similarly, the occurrence of bile leakage was noted in 3.1% of cases (n = 2 with leakage, n = 63 without) in Group A, and in 6.6% of cases (n = 4 with leakage, n = 61 without) in Group B. This difference in bile leakage rates was not statistically significant (p = 0.403). Likewise, bleeding was recorded in 6.6% of cases (n = 4 with bleeding, n = 61 without) in Group A, and in 10.2% of cases (n = 6 with bleeding, n = 59 without) in Group B, with no significant between-group difference (p = 0.510). Additionally, other surgical complications occurred in 4.6% of cases (n = 3 with complications, n = 62 without) in Group A, and in 3.1% of cases (n = 2 with complications, n = 63 without) in Group B. Once again, the difference in these complications was not statistically significant (p = 0.648). These findings collectively suggest that the presence or absence of drains did not lead to statistically significant differences in the overall incidence of postoperative complications [Table 3].

In our study, participants in Group A (Without Drain) reported significantly lower pain scores, with a mean pain score of 2.71 (± 0.92), compared to Group B (With Drain), where the mean pain score was 3.87 (± 1.25). This difference in pain scores was highly statistically significant (p < 0.0001). The time to ambulation was notably shorter for Group A, with a mean time of 6.95 hours (± 2.13), in contrast to Group B, where the mean time was 8.29 hours (± 2.18). This difference was also statistically significant (p = 0.0006). Similarly, participants in Group A resumed oral intake sooner, with a mean time of 9.86 hours (± 2.53), compared to Group B, where the mean time was 11.54 hours (± 2.81). The difference in time to oral intake between the two groups was statistically significant (p = 0.0004). Furthermore, the duration of hospital stay was significantly shorter for Group A, with a mean stay of 2.21 days (± 0.68), compared to Group B, where the mean stay was 2.95 days (± 0.74). This difference in hospital stay duration was highly statistically significant (p < 0.0001). Collectively, these results highlight the advantages associated with the absence of drains in terms of postoperative pain, early ambulation, quicker resumption of oral intake, and shorter hospital stays [Table 4].

**Table 1: Baseline Characteristics of patients in both groups.**

| Characteristic | Group A (Without Drain) | Group B (With Drain) | p-value |
|---|---|---|---|
| Age (years) | 45.26 ± 8.34 | 44.82 ± 7.92 | 0.778 |
| Gender (Male/Female) | 33/32 (50.7%/49.3%) | 30/35 (46.2%/53.8%) | 0.598 |
| BMI (Kg/m2) | 26.71 ± 3.17 | 27.25 ± 2.93 | 0.34 |
| Comorbidities (Yes/No) | 18/47 (27.7%/72.3%) | 20/45 (30.8%/69.2%) | 0.699 |

**Table 2: Intraoperative and Immediate Postoperative Outcomes of patients in both groups.**

| Parameter | Group A (Without Drain) | Group B (With Drain) | p-value |
|---|---|---|---|
| Operative Time (min) | 75.49 ± 12.62 | 72.84 ± 11.32 | 0.217 |

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|---|---|---|---|
| IO Complications (Yes/No) | 8/57 (12.3%/87.7%) | 5/60 (7.7%/92.3%) | 0.380 |
| Conversion to OS (Yes/No) | 3/62 (4.6%/95.4%) | 2/63 (3.1%/96.9%) | 0.648 |

IO: Intraoperative; OS: Open surgery

**Table 3: Postoperative Complications among patients in both groups.**

| Complication | Group A (Without Drain) | Group B (With Drain) | p-value |
|---|---|---|---|
| Wound Infection (Yes/No) | 7/58 (10.8%/89.2%) | 14/51 (27.4%/72.6%) | 0.095 |
| Bile Leakage (Yes/No) | 2/63 (3.1%/96.9%) | 4/61 (6.6%/93.4%) | 0.403 |
| Bleeding (Yes/No) | 4/61 (6.6%/93.4%) | 6/59 (10.2%/89.8%) | 0.510 |
| Other SC (Yes/No) | 3/62 (4.6%/95.4%) | 2/63 (3.1%/96.9%) | 0.648 |

SC: Surgical complications

**Table 4: Postoperative Pain Scores and Recovery Parameters of patients in both groups.**

| Parameter | Group A (Without Drain) | Group B (With Drain) | p-value |
|---|---|---|---|
| Pain Scores (VAS) | 2.71 ± 0.92 | 3.87 ± 1.25 | <0.0001 |
| Time to Ambulation (hours) | 6.95 ± 2.13 | 8.29 ± 2.18 | 0.0006 |
| Time to Oral Intake (hours) | 9.86 ± 2.53 | 11.54 ± 2.81 | 0.0004 |
| Duration of Hospital Stay (days) | 2.21 ± 0.68 | 2.95 ± 0.74 | <0.0001 |

## DISCUSSION

Laparoscopic cholecystectomy has revolutionized the management of symptomatic gallstone disease, offering numerous advantages over open surgery.[2] Our study, demonstrated a well-balanced distribution of age, gender, BMI, and comorbidities between the two study groups. This ensured that the observed outcomes were less likely to be confounded by significant differences in patient demographics. Notably, the operative time remained comparable between the groups, indicating that the use of drains did not significantly affect the duration of the surgical procedure. This finding aligns with emerging trends suggesting that advances in laparoscopic techniques have mitigated the impact of drain insertion on operative times.[8]

In our study, the gender distribution revealed a male-to-female ratio of 1:1.03 in Group A (50.7% and 49.3%, respectively), and 1:1.17 in Group B (46.2% and 53.8%, respectively), indicating no significant gender-based discrepancy (p = 0.598). However, studies by Berggren et al., and Frazee et al., showed a female preponderance.[9,10] In our study, the average age for Group A (Without Drain) was 45.26 years (± 8.34), while for Group B (With Drain), it was 44.82 years (± 7.92). In the studies by the Schmitz et al., and Hugh et al., the mean age of patients was similar to our study.[11,12]

While the incidence of intraoperative complications and conversion to open surgery was low across both groups, the differences were not statistically significant. This suggests that the presence or absence of drains did not appreciably impact the intraoperative safety profile or the need for conversions to open surgery. This is consistent with the evolving surgical practices that have optimized laparoscopic procedures, thereby reducing the risk of complications and conversions.[9,11]

Our analysis of postoperative complications revealed intriguing trends. Although the rates of wound infections, bile leakage, bleeding, and other surgical complications appeared lower in Group A (with drain) as compared to Group B (without drain), these differences were not statistically significant. The trends observed support the notion that drains could play a role in reducing specific postoperative complications. In our study, Group A (Without Drain), wound infections were observed in 10.8% of cases (n = 7 with infections, n = 58 without), whereas in Group B (With Drain), wound infections were documented in 27.4% of cases (n = 14 with infections, n = 51 without). Hawasli et al., found no statistically significant distinction in terms of wound infection rates within their trials.[13] Rathi et al., found similar rates of wound infections in both groups.[14] Gurusamy et al., noted a decreased incidence of wound infections in the group without drains when contrasted with the group with drains.[15] Halim et al., reported comparable results and recommended against the use of drains following elective LC in their study.[16] Playforth et al., noted that their trials yielded no statistically significant differences in terms of wound infection rates.[17]

Surgical drains have been utilized as a preventive measure to facilitate the drainage of potential bile or blood after laparoscopic cholecystectomy (LC), with the aim of averting the formation of intraabdominal accumulations. Additionally, drains enable the release of any accumulated carbon dioxide, thereby serving as a preventive measure against post-operative shoulder pain.[18] Perhaps the most notable findings emerged in the context of postoperative pain and recovery parameters. In our study, participants in Group A (Without Drain) reported significantly lower pain scores, with a mean pain score of 2.71 (± 0.92), compared to Group B (With Drain), where the mean pain score was 3.87 (± 1.25), demonstrating that the absence of drains may contribute to more effective postoperative pain management. Similar findings were also reported by Tzovaras et al.[19] Uchiyama et al., reporetd that the mean Visual Analog Scale (VAS) scores were notably higher in the drain group compared to the non-drain group, and this difference was statistically significant.[20]

Furthermore, in our study Group A displayed faster ambulation, earlier resumption of oral intake, and shorter hospital stays compared to Group B (With

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Drain). These differences were all statistically significant, indicating that forgoing the use of drains can positively impact the recovery process and facilitate early patient discharge. In our study, the duration of hospital stay was significantly shorter for Group A, with a mean stay of 2.21 days (± 0.68), compared to Group B, where the mean stay was 2.95 days (± 0.74). This difference in hospital stay duration was highly statistically significant (p < 0.0001). Similarly, Rathi et al., demonstrated notably shortened hospital stays among patients who did not have drains.[14] Study by Satinsky et al., indicated an extended mean hospital stay in the drain group.[21] However, the average duration of hospitalization for patients in both groups was comparable in the study conducted by Gurusamy et al.[15]

**Limitations**

While our study offers valuable insights into the use of drains in laparoscopic cholecystectomy, it is essential to acknowledge certain limitations. The sample size, though adequately powered for most outcomes, might have influenced our ability to detect smaller differences in some complications. Additionally, the single-center design and inherent variations in surgical practice could introduce biases. Future multi-center studies with larger sample sizes could further validate our findings.

## CONCLUSION

In conclusion, our study contributes to the ongoing discourse on the use of drains in laparoscopic cholecystectomy procedures. Although no significant differences were observed in intraoperative complications and postoperative complication rates, the absence of drains demonstrated advantages in terms of postoperative pain management, early ambulation, faster resumption of oral intake, and shorter hospital stays. These findings encourage further investigation and discussion within the surgical community. Ultimately, surgeons can consider these findings when tailoring their practices to optimize patient outcomes and experiences.

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