ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 08 | August - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

PROSPECTIVE RANDOMIZED CASE CONTROLLED STUDY TO EVALUATE EFFECTIVENESS OF DRAIN IN LAPAROSCOPIC CHOLECYSTECTOMY

General Surgery

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ABSTRACT

Introduction: Laparoscopic cholecystectomy (LC) is a minimally invasive procedure for gallbladder removal, commonly performed for conditions like gallstones and cholecystitis. While LC offers faster recovery and fewer complications than open surgery, the role of postoperative drains remains debated. Study aims to provide valuable insights into the effectiveness of drain usage in cholecystectomy. **Material And Method:** This prospective randomized case-controlled study was conducted in the General Surgery Department at KD Medical College, Mathura, over two years. A total of 82 patients with ultrasound-confirmed cholelithiasis or cholecystitis were randomized into two groups: with and without drain placement. Statistical analysis included chi-square and t-tests, with $p < 0.05$ considered significant. **Result:** Group A had longer operative times (65.48 ± 6.1 min vs. 48.78 ± 3.99 min, $p < 0.0001$) and higher drain placement (97.56% vs. 0%), leading to a higher risk of drain site infection ($p = 0.01$).. **Conclusion:** This study found no evidence supporting routine drain placement in uncomplicated gallstone disease, as it does not improve outcomes. Instead, ensuring meticulous hemostasis and a dry operative field allows for safe, drain-free surgery, enhancing patient recovery and comfort.

KEYWORDS

Laparoscopic cholecystectomy, drain placement, post-operative outcomes, post-operative pain.

INTRODUCTION

Laparoscopic cholecystectomy (LC) is a minimally invasive procedure used to remove the gallbladder, primarily indicated for conditions such as gallstones and other gallbladder-related disorders. Prior to the advent of laparoscopic techniques, gallbladder removal was performed through open cholecystectomy, which required larger incisions, resulted in longer recovery times, and carried a higher risk of complications and noticeable scarring. Since the early 1990s, LC has become the preferred approach[1]. It is commonly indicated for conditions such as acute and chronic cholecystitis, symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis, and gallbladder masses or polyps [2]. The laparoscopic method offers a less invasive option, ensuring safer procedures, faster recovery, and high success rates.

The primary purpose of a drain is to clear exudates from the surgical site, fostering an environment conducive to optimal healing. Without adequate drainage, postoperative fluid accumulation may form pockets that exert pressure on surrounding tissues, increasing the risk of infection and prolonging recovery [3]. Furthermore, drains provide valuable postoperative monitoring, as the characteristics of the collected fluid—such as its color, volume, and consistency—offer important insights into the patient's recovery and potential complications.

Drains are typically placed for reasons such as bile leakage, risk of fluid accumulation, or concerns about potential infection at the surgical site [4]. Moreover, if the gallbladder is severely inflamed or there are concerns about unintentional injury to surrounding structures, such as the bile duct, a drain may be placed to reduce the risk of fluid buildup and to facilitate postoperative monitoring.

The use of drains following laparoscopic cholecystectomy (LC) has been a topic of considerable debate, with numerous studies examining whether they enhance postoperative outcomes or contribute to avoidable complications. Research comparing outcomes in patients with and without drains has produced mixed findings. Recent studies have determined that routine abdominal drainage after elective, uncomplicated LC is not advisable [5]. This study aims prospective randomized case controlled study to evaluate effectiveness of drain in laparoscopic cholecystectomy.

MATERIALS AND METHODS

A prospective randomized case-controlled study was conducted in the in-patient Department of General Surgery, KD Medical College, Mathura. Duration of study was 2 years. Ethical approval was obtained from the Institutional Ethics Committee, KD Medical College, Mathura. Written informed consent was obtained from all participants before enrollment in the study.

Inclusion Criteria

- Patients aged 18–60 years
- All ultrasound-confirmed cases of cholelithiasis or cholecystitis admitted to KD Medical College, Mathura
- Patients who provided written informed consent

Exclusion Criteria

- Patients who did not provide consent
- Cases with other pathologies such as CBD stones, cholangitis, or pancreatic duct obstruction
- Patients with biliary malignancy.

Methodology

A total of 82 patients were included, with 41 patients in each group.

- **Group 1 (Case Group):** Patients who received a drain
- **Group 2 (Control Group):** Patients who did not receive a drain

Preoperative, Intra operative and post operative assessment was done

Data Analysis

Chi-square test was used to compare categorical variables between the two groups. **T-test** was applied for continuous variables. **Multivariable logistic regression analysis** was performed to adjust for potential confounders. Statistical significance was set at **$p < 0.05$**. **R Programming** was used for statistical analysis.

RESULT AND OBSERVATION

The table compares the operative time between Group A and Group B. The mean operative time in Group A was 65.48±6.1 minutes, while in Group B, the mean operative time was 48.78±3.99 minutes. The p-value of <0.0001 indicates that the difference in operative time between the two groups is highly statistically significant, with Group A requiring significantly longer operative time compared to Group B. (Figure 1)

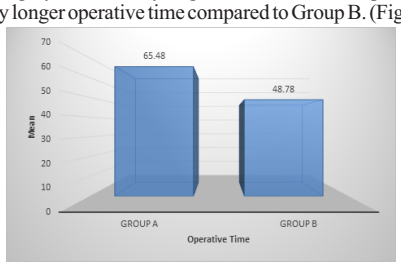

Figure 1- Distribution of patients according to Operative Time

The incidence of **Surgical Site Infection (SSI)** was higher in **Group A** compared to **Group B**, although the difference was **not statistically significant** (**p-value = 0.13**). In **Group A**, **14 patients (34.15%)** developed SSI, whereas **8 patients (19.51%)** in **Group B** experienced the same. The majority of patients in both groups remained free of infection, with **27 patients (65.85%)** in **Group A** and **33 patients (80.49%)** in **Group B** showing no signs of SSI. Although a higher percentage of SSI was observed in Group A, the result did not reach statistical significance. (Figure 2)

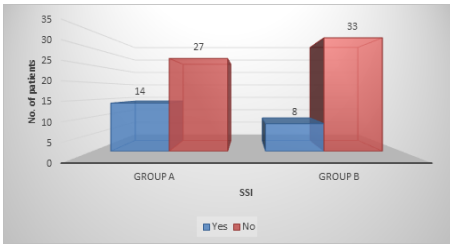

Figure 2- Distribution of patients according to SSI

Drain site infection was observed exclusively in **Group A**, where **8 patients (19.51%)** developed an infection at the drain site. In contrast, **none of the patients in Group B** experienced drain site infection, as no drains were placed in this group. This difference was found to be **statistically significant**, with a **p-value of 0.01**, indicating that **drain placement was associated with a significantly higher risk of infection** at the site in **Group A**. (Figure 3)

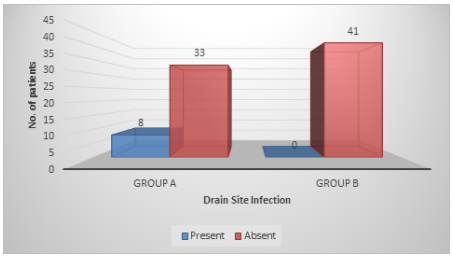

Figure 3- Distribution of patients according to Drain Site Infection

DISCUSSION

In our study, the mean operative time in Group A was 65.48±6.1 minutes, while in Group B, it was 48.78±3.99 minutes. The p-value of <0.0001 indicates a highly statistically significant difference, with Group A requiring significantly longer operative time compared to Group B. **Lucarelli P et al**[6] found that the median operative time was slightly longer in Group A (95 minutes, range: 72–120) compared to Group B (91 minutes, range: 80.4–110). **Abuelzein M L A et al**[7] reported a longer operative time in Group A (57.54 ± 9.56 minutes) compared to Group B (55.96 ± 9.43 minutes), with a statistically significant difference (p = .0186, t-test).

The incidence of Surgical Site Infection (SSI) was higher in Group A compared to Group B, although the difference was not statistically significant (p = 0.13). In Group A, 14 patients (34.15%) developed SSI, whereas in Group B, 8 patients (19.51%) experienced the same. The majority of patients in both groups remained free of infection, with 27 patients (65.85%) in Group A and 33 patients (80.49%) in Group B showing no signs of SSI. Although a higher percentage of SSI was observed in Group A, this difference did not reach statistical significance. **Similarly, Singh M et al.**[8] found that the rate of wound infection was significantly higher in the drain group, where 7 patients (23.33%) developed infections compared to only 1 patient (3.33%) in the no-drain group (p = 0.0226). **In a similar study, Abid Halim (2011)**[9] also reported that due to an increased risk of infection, drain placement in laparoscopic cholecystectomy should be avoided. **Likewise, Gurusamy et al. (2007)**[10] concluded that wound infections were more frequent in patients with drains.

Drain site infection was observed exclusively in Group A, where 8 patients (19.51%) developed an infection at the drain site. In contrast, none of the patients in Group B experienced this complication, as no drains were placed in this group. This difference was statistically significant (p = 0.01), indicating that drain placement was associated with a markedly higher risk of infection at the site in Group A. **Similarly, Singh M et al.**[8] also reported that the insertion of a drain contributed to patient discomfort, with 6 patients (20.00%) in the drain group developing drain site infections. Additionally, the majority of patients (93.33%) in the same group complained of pain upon drain removal, further highlighting the drawbacks of drain placement.

CONCLUSION

Uncomplicated gallstone disease can be effectively managed through laparoscopic cholecystectomy (LC) without the routine use of a drain, provided the procedure is performed by an experienced surgeon. In cases where no drain is placed, there are several notable advantages, including a significant reduction in post-operative nausea and vomiting (PONV), lower levels of post-operative pain, decreased need for analgesics, and a shorter hospital stay. These benefits contribute to improved patient comfort, faster recovery, and overall better post-operative outcomes.

This study did not find any evidence to support the routine use of drains in preventing or reducing complications following LC. On the contrary, the findings suggest that the omission of drains does not compromise patient safety in cases of uncomplicated gallstone disease, provided meticulous hemostasis is ensured and a dry operative field is achieved at the end of surgery. Therefore, it is reasonable and safe to avoid drain placement when there is no intraoperative concern regarding bleeding or bile leakage, reinforcing the shift towards more patient-friendly surgical practices.

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