

## A Comparative Study of Postoperative Outcomes of Laparoscopic Cholecystectomy with or Without Abdominal Prophylactic Drainage: A Prospective Interventional Study

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### Abstract:

**Background:** The present study was conducted for assessing and comparing Postoperative Outcomes of Laparoscopic Cholecystectomy (LC) with or without Abdominal Prophylactic Drainage.

**Materials & Methods:** A total of 200 patients scheduled to undergo LC were enrolled. Distribution of all the patients was done into two study groups as follows: Group 1: Patients with Abdominal prophylactic drainage, and Group 2: Patients without Abdominal prophylactic drainage. Only patients with uncomplicated chronic calculus cholecystitis were enrolled. Data have been collected through interview, clinical examination, and scrutinizing relevant medical records. Incidence of Postoperative nausea and vomiting along with postoperative pain was evaluated. All the results were recorded in Microsoft excel sheet and was subjected to statistical analysis using SPSS software.

**Results:** Mean duration of surgery among group 1 and group 2 subjects was 115.6 minutes and 79.2 minutes respectively (p-value < 0.05). Incidence of postoperative nausea and vomiting was significantly higher among patients of group 1. Like-wise incidence of postoperative pain was significantly higher among subjects of group 1.

**Conclusion:** Patients without abdominal drain were associated with decrease duration of surgery and lower incidence of PONV and postoperative pain.

**Keywords:** Laparoscopic, Cholecystectomy, Abdominal

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### Introduction

Cholecystectomy is a common surgical procedure performed worldwide for acute cholecystitis. Acute cholecystitis occurs when the cystic duct is obstructed by a gallstone, which causes gallbladder distension and subsequent inflammation of the gallbladder [1, 2].

Controversy exists regarding the use and timing of laparoscopic cholecystectomy for both acute and chronic cholecystitis. Technical difficulties can occur in the dissection of the gallbladder in both acute and chronic cases that can lead to poor results. Randomized studies<sup>1</sup> of open cholecystectomy done within 72 hours versus later surgery show no difference in bile duct injury rates [3,4]. Prophylactic drains have been used to prevent intraperitoneal fluid collections and to detect early complications, such as postoperative hemorrhage and leakage of bile. However, in the era of OC, numerous trials failed to demonstrate a reduction of postoperative complications by routine drainage. Several trials examined the use of

drainage after LC with the intent to remove residual gas and decrease postoperative pain [5,6].

**Aims and Objectives:** The present study was conducted for assessing and comparing Postoperative Outcomes of Laparoscopic Cholecystectomy (LC) with or without Abdominal Prophylactic Drainage.

### Materials & Methods

The present prospective, longitudinal Interventional study was carried out in the Department of Surgery, Government Medical College and Hospital, Bettiah, West Champaran, Bihar, India. All patients admitted in General surgical Ward/unit either through OPD or emergency, presenting with perforation peritonitis. The present study was conducted for assessing and comparing Postoperative Outcomes of Laparoscopic Cholecystectomy with or without Abdominal Prophylactic Drainage. A total of 200 patients of either gender scheduled to undergo LC were

enrolled. All were informed regarding the study and their written consent was obtained. The institutional ethical committee granted ethical approval. The duration of study was from January 2021 to December 2023.

**Inclusion Criteria:** Patients with uncomplicated chronic calculus cholecystitis, aged 18 to 60 years, as well as those having elective LC for different aetiologies, and those who did not provide informed consent were included.

**Exclusion Criteria:** The study excluded participants who did not give informed consent, had obstructive jaundice, Intraoperative hemorrhage, Intraoperative biliary tract injury, Choledocholithiasis, needed an intraoperative cholangiogram, converted to open surgery, or performed any additional procedures.

#### Sampling Size Determination and Sampling Technique

The following simple formula would be used for calculating the adequate sample size in prevalence study

$$N = Z^2 P (1-P)/d^2$$

N= sample size, Z= level of confidence, P= prevalence, d= Absolute error or precision

Z = Is standard normal variate (at 5% type 1 error (P< 0.05) it is 1.96 and at 1% type 1 error (P<0.01) it is 2.58). As in majority of studies P values are considered significant below 0.05 hence 1.96 is used in formula. p = Expected proportion in population based on previous studies or pilot studies.

The sample size was calculated using a single population proportion formula, by considering, 95% confidence level, a 5% margin of error, and a 12% estimated proportion of overall prevalence

$$\text{Sample size} = 1.96^2 \times 0.12 (1-0.12)/0.05^2 \\ = 162$$

Considering 10% non-response rate, the total minimum sample size for study was 178 patients.

We included 200 (more than the minimum required number of cases) cases in the present study.

Complete demographic and clinical details of all the patients were recorded. Random distribution of all the patients was done into two study groups as follows: Group 1(Study group): Patients with Abdominal prophylactic drainage, and Group 2(Comparison group): Patients without Abdominal prophylactic drainage. Each group enrolled 100 patients. Only patients with uncomplicated chronic calculus cholecystitis were enrolled. Data have been collected through interview, clinical examination, and scrutinizing relevant medical records. A predesigned and pre-tested questionnaire is used for data collection. Each patient has been followed up after operation. Incidence of Postoperative nausea and vomiting along with postoperative pain was evaluated. VAS scale was used for assessment of pain on a scale of 0 to 10 with 0 indicating no pain and 10 indicating maximum unbearable pain.

#### Statistical Analysis

The data obtain was subjected to statistical analysis using Microsoft Excel spread sheet and analyzed using SPSS version 22.0 software. Categorical data were shown using frequencies and proportions. The data's significance was assessed by the Chi-square test. The continuous data were expressed as the mean and standard deviation. The data's significance was assessed by an independent t-test. A p-value less than 0.005 were deemed significant.

#### Results

Mean age of the patients of group 1 and group 2 was 46.3 years and 48.2 years respectively. There were 58 males and 42 females in group 1 while there were 55 males and 45 females in group 2. Majority subjects were of rural residence. Mean duration of surgery among group 1 and group 2 subjects was 115.6 minutes and 79.2 minutes respectively (p-value < 0.05). Incidence of postoperative nausea and vomiting was significantly higher among patients of group 1. Like-wise incidence of postoperative pain was significantly higher among subjects of group 1.

**Table 1: Comparison of Demographic data among study participants**

Variable	Group I(n=100)	Group II (n=100)	p-value
Mean age (years)	46.3 ± 15.75	48.2 ± 15.91	0.23
Males (%)	58 (58%)	55(55%)	0.77
Females (%)	42 (42%)	45 (45%)	
Rural residence (%)	64 (64%)	52 (58%)	0.93
Urban residence (%)	36 (36%)	48 (48%)	

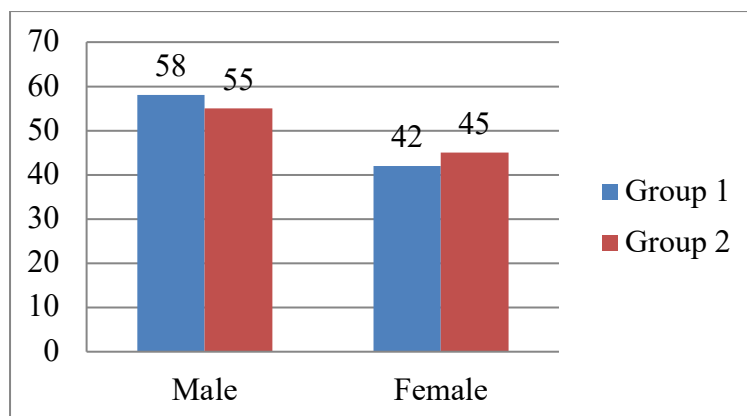


Figure 1: Gender wise distribution of patients in both groups

Table 2: Comparison of duration of surgery (in minutes) among study participants

Duration of surgery (in minutes)	Group I(n=100)	Group II(n=100)	p-value
Mean	115.6	79.2	0.001 (Significant)
SD	23.9	12.5	

Table 3: Comparison of Postoperative nausea and vomiting (PONV) among study participants

PONV	Group I(n=100)	Group II(n=100)	p-value
Number	23	10	0.000 (Significant)
Percentage	23	10	

Table 4: Comparison of Postoperative pain (VAS > 3) among study participants

PONV	Group I(n=100)	Group II(n=100)	p-value
Number	29	8	0.000 (Significant)
Percentage	29	8	

## Discussion

Approximately 10%–15% of American adults have cholelithiasis. Although the majority of these patients remain asymptomatic, roughly 1 in 5 will develop complications from their gallstones. Development of minimally invasive cholecystectomy by French and American surgeons in the late 1980s decreased the potential morbidity associated with cholecystectomy, leading to a broadening of indications for the procedure. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) identifies symptomatic cholelithiasis, biliary dyskinesia, acute cholecystitis, and complications of choledocholithiasis as indications for laparoscopic cholecystectomy in patients healthy enough to undergo the procedure. Laparoscopic cholecystectomy (LC) is one of the most commonly performed surgeries, with 1.3 million of these procedures performed in the United States in 2021 [7-10]. Drains are commonly used after surgical procedures and can be classified as either active or passive. Active drains use negative pressure to remove accumulated fluid from a wound. Passive drains depend on the higher pressure inside the wound added with capillary action and gravity to draw fluid out of a wound.

Closed suction drains are routinely used to drain potential collections after surgery or after bowel anastomosis. In laparoscopic surgery, most commonly used drain is passive drain. Most of the surgeons are performing LC in their practice [11-13]. Hence; the present study was conducted for assessing and comparing Postoperative Outcomes of Laparoscopic Cholecystectomy with or without Abdominal Prophylactic Drainage.

Mean age of the patients of group 1 and group 2 was 46.3 years and 48.2 years respectively. There were 59 males and 42 females in group 1 while there were 55 males and 45 females in group 2. Majority subjects were of rural residence. Mean duration of surgery among group 1 and group 2 subjects was 115.6 minutes and 79.2 minutes respectively (p-value < 0.05). Ishikawa K et al carried a retrospective review of patients undergoing elective LC to evaluate the benefit of routine drainage in simple uncomplicated procedures. Their study of 295 patients with cholelithiasis or gallbladder polyp included 145 patients who underwent LC with drainage and 150 patients who underwent LC without drainage. Allocation to drain or not to drain was non-randomized and based on surgeon preference according to intraoperative findings. Patient

characteristics, operative results, and postoperative outcomes were compared between the two groups with univariate analysis. Time to first flatus and length of postoperative hospital stay in the LC without drainage group were shorter than in the LC with drainage group. There was no significant difference between the two groups with respect to postoperative complication rate. No complications were noted due to the lack of drain placement. The use of drain after simple elective uncomplicated LC could safely be limited to appropriate patients as judged by the operating surgeon [14].

In the present study, incidence of postoperative nausea and vomiting was significantly higher among patients of group 1. Like-wise incidence of postoperative pain was significantly higher among subjects of group 1. Sharma A et al. [15], evaluated the advantages and disadvantages of drainage in patients undergoing Laparoscopic cholecystectomy. Sixty patients underwent laparoscopic cholecystectomy for symptomatic gall stone. Sixty patients were randomized before surgical procedure into two groups. Group A consisted 30 patients in whom a drain was placed in subhepatic space and group B consisted 30 patients without drain. Postoperative pain was assessed using a 10-point visual analog scale. The two groups were evaluated and compared regarding postoperative pain, the time needed for surgery, length of postoperative hospital stay and the incidence of postoperative complications. The mean operative time in group A was 6.16 minutes longer when compared with group B ( $p > 0.05$ ). Although the postoperative mean pain score was same at 6 hours after surgery in both groups (7.53 vs 7.23), the postoperative pain was higher in the group A by more than two points on the average in VAS (visual analogue score) at 24 hours and 48 hours. The proportion of the patients staying in the hospital for more than two days was higher in group A, 14 (46.66%) and 8 (26.66%) in group B ( $p < 0.05$ ). There was no statistical difference in the rate of wound infections, shoulder pain, nausea, vomiting, and respiratory infections between the two groups. The routine drainage of gallbladder bed after elective laparoscopic cholecystectomy may not be justified and appears to cause more postoperative pain and more postoperative complications and prolongs the hospital stay.<sup>15</sup> Bugiantella W et al, in another analysis, carried out a systematic review of the literature in order to perform a meta-analysis about this issue. An unrestricted search in MEDLINE, EMBASE and Cochrane Library up to 31 December 2013 was performed. Overall, seven high-methodological quality randomized controlled trials (RCTs) were included in the meta-analysis, resulting in 1310 patients totally. The incidence of abdominal collections, wound infection and overall mortality according to the presence or absence of the sub-hepatic drainage were meta-analyzed. Sub-

hepatic drainage showed an increase in the abdominal collection rate in patients who underwent elective uncomplicated LC (OR 1.56, 95% CI 1.00-2.43) if compared to patients without drainage. A non-significant correlation was found in overall mortality and infection rates. The meta-analysis showed that the presence of the sub-hepatic drainage does not reduce the incidence of abdominal collection after uncomplicated LC, whereas it does not influence wound infection and mortality rates, postoperative pain and hospital stay [16].

**Limitations of the study:** The study has a small sample size and a short duration, and it has been carried out in a single centre.

### Conclusion

Patients without abdominal drain were associated with lower incidence of postoperative nausea and vomiting (PONV), Postoperative pain, and the duration of hospital stay. The present study was unable to prove that drains were useful in reducing complications in Laparoscopic Cholecystectomy (LC).

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