Surgery Section

Comparison of Postoperative Outcomes of Laparoscopic Cholecystectomy with or without Abdominal Prophylactic Drainage: A Prospective Interventional Study

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### ABSTRACT

**Introduction:** With increasing surgeon experience and advancements in instrumentation and equipment, Laparoscopic Cholecystectomy (LC) continues to progress as a safer and less invasive procedure. Drainage should not be regarded as obligatory or standard after elective LC, according to the majority.

**Aim:** To evaluate the efficacy of elective LC with and without abdominal drainage and to compare the postoperative outcomes among the groups.

**Materials and Methods:** This prospective interventional study was carried out among all patients admitted for elective LC at the Department of Surgery, Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India from October 2022 to July 2023. A total of 200 patients scheduled for LC were divided into a drain group (n=92) or a no-drain group (n=108). Allocation was non randomised and based on surgeon preference. Along with demographics, surgical details including operation time, estimated blood loss, time to first flatus and tolerance of water and solid nutrition, postoperative hospital stay duration, and postoperative complications were noted and compared. Statistical analysis was performed using Statistical Package for

# INTRODUCTION

Since 1985, LC has been the treatment of choice for benign gallbladder disease. With increasing surgeon experience and advancements in instrumentation and equipment, LC is moving towards a more minimally invasive approach, such as smaller, mini, and reduced ports. It is continuously evolving towards a safer, less invasive technique [1]. With the advent of LC, abdominal drains may be justified due to the increased incidence of biliary injury and resulting bile leakage. The use of prophylactic drainage in LC to prevent the collection of bile and blood necessitating subsequent treatment is mainly unclear [2]. Cholecystectomy without abdominal drainage was first described in 1913; it has been debatable whether it should be used routinely in uncomplicated cases. A group of surgeons continues to use subhepatic drainage despite the possibility of bile leakage and haemorrhage. Regardless of subhepatic drainage, such complications invariably occur [3]. Active or passive drains are frequently used after surgical procedures. Active drains remove accumulated fluid from a laceration by applying negative pressure. To remove fluid from a wound, passive drains rely on the higher pressure within the incision, combined with capillary action and gravity. After surgery or bowel anastomosis, prospective collections are routinely drained using closed suction drains. Passive drains are most commonly used in laparoscopic surgery. The majority of surgeons perform LC in their practice. Several studies have Social Sciences (SPSS) software (SPSS Inc., Chicago, IL, USA) for the Windows program (version 26.0). The continuous and dichotomous variables were evaluated using student's t-test and Chi-square test.

**Results:** The mean age of patients in the drain and no-drain groups was  $57.18\pm14.39$  years and  $55.61\pm14.83$  years, respectively, with a female predominance. The no-drain group had a significantly shorter mean operation time than the drain group ( $93.27\pm30.81$  min vs  $124.86\pm38.64$  min). Hospital stays in the no-drain group were substantially shorter ( $5.47\pm2.61$  days) than those in the drain group ( $7.56\pm3.91$  days). The postoperative morbidity rates were 14 (15.22%) in the drain group and 10 (9.26%) in the no-drain groups in terms of postoperative complications. During the study, no patients in either group required reoperation. The most frequently cited reasons for drain placement were intraoperative haemorrhage (n=11) and difficult operation (n=11).

**Conclusion:** The use of drains after simple, elective, uncomplicated LC could be safely restricted to patients deemed appropriate by the surgeon. Regarding postoperative complications, the no-drain group is superior in its use.

### Keywords: Bile leakage, First flatus, Haemorrhage, Solid nutrition

shown that drains after elective LC for uncomplicated cholecystitis offer no benefit [4,5]. It appears that drainage does not prevent complications after surgery. In contrast, drainage complications, such as fever, wound infection, wound hernia, or haemorrhage, may cause patients unnecessary distress [6]. Many studies, either in favour or against drainage [3,4,7]. Therefore, authors aimed to compare the outcomes of patients undergoing LC who received drainage versus those who did not.

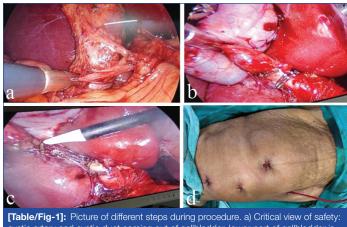
## MATERIALS AND METHODS

This prospective interventional study was carried out among all the patients admitted for elective LC at the Department of Surgery, Era's Lucknow Medical College and Hospital, Lucknow, Uttar Pradesh, India from October 2022 to July 2023. As per international or university standards, the author(s) collected and preserved written ethical permission (R-Cell/EC/2022/167). Informed written consent was taken from the study participants.

**Inclusion and Exclusion criteria:** Patients aged 18-80 years with uncomplicated chronic calculus cholecystitis and patients undergoing elective LC for other aetiologies were included. Participants with obstructive jaundice, conversion to open surgery, the need for an intraoperative cholangiogram, the performance of any additional procedure, and those who did not provide informed consent were excluded from the study.

#### **Study Procedure**

Enrolled patients were divided into the no-drain group (n=108) and drain group (n=92). Allocation was non-randomised and based on surgeon preference according to intraoperative findings. Further, one 1.5-2.0 cm umbilical port, one 1.0 cm port below the xiphoid, and two 0.5 cm ports below the coastal arch were used in conjunction with a pneumoperitoneal pressure of 8-10 mmHg to perform LC [8,9]. At the end of the resection, the surgeon determined whether the case could be closed without drainage prior to peritoneal closure. Indications for drainage included concern for potential haemorrhage or bile leakage, intraoperative gallbladder perforation, or repair following injury to other organs [Table/Fig-1a-d]. For drainage in the drain group, 6-mm open Penrose drainage tubes were inserted below the costal arch and deposited in Morrison's pouch. All procedures involved intermittent pneumatic compression. When drainage was deemed insignificant between the first and second day, the drain was removed.



cystic artery and cystic duct coming out of gallbladder, lower part of gallbladder is free from cystic plate. b) Clip applied separately over cystic duct and cystic artery. c) Cystic duct and cystic artery cut. d) Drain placed and other 3 ports are sutured.

Demographic data such as age, gender, Body Mass Index (BMI), and co-morbidity were evaluated. Surgical details included operation time, estimated blood loss, time to first flatus and tolerance of water and solid nutrition, postoperative hospital stay duration, and postoperative complications. The total blood loss was calculated using the formula: Blood Loss=Total volume suctioned content-total volume of NS wash given. The drain and no-drain categories were compared using this data. The operative report classified the reasons for drain placement as haemorrhage, bile leakage or spillage, organ damage, machine malfunction, and problematic operation.

#### STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, IL, USA) for the Windows program (version 26.0). The continuous variables were evaluated using mean {Standard Deviation (SD)} or range values when required. The dichotomous variables were presented as number/frequency and were analysed using the Chi-square test. For the comparison of means, analysis by Student's t-test with a 95% confidence interval was used. A p-value of <0.05 was considered significant.

### RESULTS

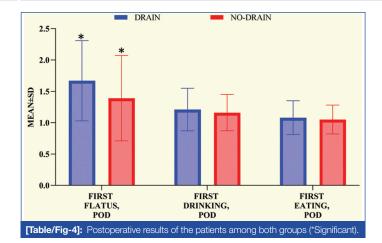
The mean age in the drain and no-drain groups was  $57.18\pm14.39$  and  $55.61\pm14.83$ , respectively. Among the enrolled patients (N=200), the age (p-value=0.6322), gender (p-value=0.2377), BMI (p-value=0.4477), and incidence of co-morbidity (p-value=0.4665) in the two groups were comparable [Table/Fig-2]. The no-drain group had a significantly shorter mean operation time (93.27 $\pm$ 30.81 min) than the drain group (124.86 $\pm$ 38.64 min). There was a significant difference in blood loss between the two groups (p=0.0085\*), with the majority of patients in both groups losing <10 mL of blood. Neither group required blood transfusions [Table/Fig-3].

	Drain (n=92)		No-drain (n=108)		
Variables	n	%	n	%	p-value
Age (in years)					
Mean±SD	57.18±14.39		55.61±14.83		t=0.4805 p=0.6322
Gender					
Male	39	42.39%	37	34.26%	χ²=1.394 p=0.2377
Female	53	57.61%	71	65.74%	
BMI (kg/m²)					
Mean±SD	25.18±3.62		24.58±3.41		t=0.7630 p=0.4477
Co-morbidity					
Absent	40	43.48%	51	47.22%	χ <sup>2</sup> =6.648 p=0.4665
Present	52	56.52%	57	52.78%	
Cerebrovascular disease	6	6.52%	8	7.41%	
Cardiovascular disease	38	41.30%	34	31.48%	
Respiratory disease	2	2.17%	6	5.56%	
Liver disease	7	7.61%	9	8.33%	
Renal disease	1	1.09%	0	0.00%	
Diabetes	9	9.78%	4	3.70%	
[Table/Fig-2]: Demograph	nics of t	he patients a	mong both g	proups.	

	Drain (n=92)		No-drain (n=108)		
Variables	Mean	SD	Mean	SD	p-value
Operation time (min)					
Mean±SD	124.86	38.64	93.27	30.81	t=4.043 p=0.0001
Blood loss					
<10 mL	62	67.39%	90	83.33%	χ²=6.922 p=0.0085*
≥10 mL	30	32.61%	18	16.67%	
Postoperative hospital s	tay (days	5)			
Mean±SD	7.56	3.85	5.47	2.61	t=2.842 p=0.0057*
Morbidity					
Absent	78	84.78%	98	90.74%	χ²=11.66 p=0.1122
Present	14	15.22%	10	9.26%	
Shoulder pain	7	7.61%	5	4.63%	
Transient jaundice	0	0.00%	4	3.70%	
Wound infection	3	3.26%	1	0.93%	
Intra-abdominal abscess	1	1.09%	0	0.00%	
Biliary leakage	0	0.00%	0	0.00%	
Pleural effusion ascites	2	2.17%	0	0.00%	
Atelectasis	0	0.00%	0	0.00%	
Urinary tract infection	0	0.00%	0	0.00%	
Enterocolitis	1	1.09%	0	0.00%	
Mortality	0	0.00%	0	0.00%	

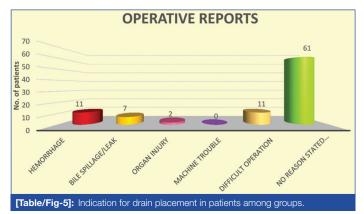
Although the difference was not statistically significant (p=0.5895), the first flatus was detected earlier in the no-drain group (1.39 $\pm$ 0.68) than in the drain group (1.67 $\pm$ 0.64). The mean time for first drinking and eating was also shorter in the no-drain group (1.16 $\pm$ 0.29 and 1.05 $\pm$ 0.23, respectively) than in the drain group (1.21 $\pm$ 0.34 and 1.08 $\pm$ 0.27, respectively). There was no difference between the two groups regarding the time to first drink and eat (p=0.4813 and p=0.5942, respectively) [Table/Fig-4].

Regarding postoperative complications, there was no significant difference between the groups. Shoulder pain was the most prevalent complication in both groups. One patient in the drain group was diagnosed with an intra-abdominal abscess on the postoperative day. Four patients in the no-drain group had transient jaundice. No



complications were noted due to the lack of drain placement in the no-drain group [Table/Fig-3]. No patients required reoperation during the study in either group.

Intraoperative haemorrhage {11 (11.96%)} and difficult operation {11 (11.96%)} were the most frequently mentioned reasons for drain placement [Table/Fig-5].



## DISCUSSION

The current study demonstrated several advantages of LC without drainage compared to LC with drainage. LC without drainage was associated with a shorter time to first flatus, a shorter duration of postoperative hospital stay, and a lower incidence of postoperative complications. No complications were reported as a result of not using a drain. LC without drainage was found to promote faster recovery of Gastrointestinal (GI) function and shorter hospital stays compared to LC with drainage. It may be a more effective treatment option for uncomplicated LC.

Numerous studies have been conducted on prophylactic drainage after open cholecystectomy, which have concluded that GI operations can be safely performed without prophylactic drainage, and it is safe to omit peritoneal drainage. Short-term drains did not increase morbidity, wound infections, respiratory complications, or prolong postoperative hospital stays. However, more randomised controlled trials are needed to establish reliable findings [7,10]. Tzovaras G et al., reported that routine use of a drain in elective LC provided no benefit and was associated with increased discomfort [11].

Despite these findings, many surgeons continue to use abdominal drains following LC. Most studies comparing drainage with nodrainage in LC have been conducted in Western nations [9,11-15]. Some studies have investigated the use of drainage after LC to remove residual gas and reduce postoperative shoulder tip pain [13,14]. However, one trial based on postoperative pain and clinical courses showed a disadvantage of drainage tubes by intensifying postoperative pain [16], but no complications were reported after LC.

Hawasli A and Brown E suggested the routine use of drainage following LC, especially during the initial phases of skill development [13]. However, they noted that routine application of drainage is

unnecessary for uncomplicated elective LC cases once an adequate level of experience has been attained. With increased experience in laparoscopic techniques, LC without prophylactic drainage has become the preferred treatment for managing gallstones. In the present study, none of the patients who did not receive a drain experienced a complication that would have been prevented by a drain. Therefore, the use of a drain after simple, elective, uncomplicated LC could be safely restricted to patients deemed appropriate by the surgeon [17].

Patients must be closely monitored for the first 48 hours if drainage is not performed, as postoperative hypotension, acute blood loss anaemia, and intra-abdominal hypertension can occur, leading to the prompt diagnosis of intra-abdominal haemorrhage. In most cases, symptomatic collections can be successfully treated with interventional therapy [18]. Another study has raised concerns about infectious source control and potential biliary leaks [12]. Zaydfudim V et al., could not justify drain placement in cases of excessive intraoperative blood loss [19]. In the study by Ishikawa K et al., the use of drains after LC was associated with complicated patient presentations, unnecessary intraoperative blood loss, operation difficulty, and intraoperative bile spillage [17]. However, in twothirds of the operative reports, no explanation was provided for the placement of abdominal drains, similar to the findings of the present study. In the future, drains should be used sparingly, and the surgeon should specify the situation and reason for their placement in the operative report.

Although the present study did not find any benefit of drainage, it is possible that the need for re-exploration would be reduced if drainage is used in the event of an unanticipated postoperative blood or bile leak. There were no cases of transient biliary leakage in any of the groups. Occasionally, bile is drained after a seemingly straightforward LC, which eventually stops without re-exploration. This may explain why most surgeons continue to routinely use a drain after LC [20]. After cholecystectomy, some patients may experience minor amounts of bile leakage into the subhepatic space [21,22]. If a bile leak occurs, the patient experiences no adverse effects, indicating that a drain is unnecessary and the peritoneal space can adequately absorb such a volume of bile [22]. There is a possibility that drains may actually contribute to bile leakage [19]. Possible causes include irritation from foreign material in the drain, prevention of tissue tamponade, creation of dead space, and the suction effects of the drain vacuum. However, one patient in the drain group was diagnosed with a postoperative intra-abdominal abscess requiring percutaneous abscess drainage [17]. When a drain is inserted into a peritoneal cavity that contains no fluid, it is rapidly surrounded by omentum and becomes isolated, according to experiments [23]. Additionally, omental growth through the end and side openings completely occludes the tube drain lumen within 48 hours.

Drainage may facilitate the ascent of infection along drains. Therefore, prophylactic drainage may be useful only for early bile leaks but is ineffective for preventing late bile leaks or abscesses. Lewis RT et al., reported that uncomplicated elective cholecystectomy was safe without peritoneal drainage, and short-term drains did not increase the risk of morbidity [10]. Williams CB et al., showed that postoperative morbidity increased when Penrose drains were left in place for more than 48 hours [24]. The absence of wound complications in the present study may be attributed to the brief duration that the drains were left in position.

After laparoscopy, residual carbon dioxide in the abdomen is believed to cause postoperative shoulder tip pain [14,25]. Another study found an advantage of gas drains by demonstrating a decrease in postoperative shoulder pain. In the present study, the no-drain group had a lower incidence of postoperative shoulder pain compared to the drain group [25]. However, in contrast to the present study, Ishikawa K et al., found that shoulder pain was more prevalent in the drain group than in the no-drain group [17].

The extended hospital stays of patients treated with an abdominal drain in the present study suggest that these patients may have been more ill before surgery. Patients treated with an intraoperative drain were more likely to experience excessive intraoperative blood loss and a prolonged duration of surgery [17]. The rates of postoperative infectious or medical complications and the need for postoperative percutaneous interventions did not differ between patients with and without drainage. Additionally, the prolonged time to first flatus in the drain group may delay the return to normal function.

#### Limitation(s)

The present study was limited by being single-centre and having a small sample size. Randomisation was not performed in the present study, but it could be implemented in future trials, following gallbladder dissection, haemostasis, and biliostasis, after surgery, to improve the study design.

## **CONCLUSION(S)**

Routine prophylactic intraperitoneal drainage may not always be required after a straightforward elective uncomplicated LC. The use of a drain after basic, elective, uncomplicated LC could be safely restricted to patients deemed appropriate by the surgeon. The authors recommend further multicentric randomised controlled trials with a large sample size to increase the reliability and generalisability of the present findings.

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