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Drainage versus no drainage after laparoscopic cholecystectomy: A prospective randomized study

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Abstract
Background: Patients with gallstone disease are often treated with laparoscopic cholecystectomy (LC). In surgical procedures, the decision to drain has always been contentious.
Objectives: Examining the effects of postoperative abdominal drainage vs no drainage after LC on pain, fever, collection and length of stay in the hospital.
Subjects and Methods: This prospective research involved 40 cases aged from 5 to 60 years with symptomatic gall bladder (GB) stones and indicated for elective LC. Individuals were randomly separated into two equal groups by the sealed envelope method. Each group comprised 20 patients: Group A: Abdominal drainage was done routinely and Group B: No abdominal drainage.
Results: In terms of visual analogue score (VAS) pain score, cosmetic outcomes, length of hospital stay and postoperative data, there were significant variations among the groups analysed. There was significant variation among the groups concerning length of hospital stay and postoperative data. There is a significant positive correlation as regard to multi-variant analysis of multiple factors in correlation to each other, pain score, cosmetic results, length of hospital stay and time of drain removal between the groups.
Conclusion: Preventive drainage after non-complicated LC does not significantly improve outcomes and increase the risk of wound infection and the length of time patients spend in the hospital after surgery. Therefore, drain placement after LC should be reserved for very challenging situations.

Keywords: Drainage, laparoscopic, cholecystectomy, pain score

Introduction

Patients with symptomatic cholecystolithiasis are now routinely treated with laparoscopic cholecystectomy (LC) [1]. The benefits of laparoscopic surgery include a shorter recovery period, reduced risk of infection and adhesions, a more aesthetically pleasing result, a quicker return to work, and less time spent in the hospital. In surgical procedures, the decision to drain has always been contentious [2].

Peritoneal cavity draining has been performed routinely after many different surgeries for many years to identify postoperative haemorrhage, anastomotic leakage, biliary leakage, and pancreatic leakage as soon as possible. This method relied more on established norms and habits than on any hard evidence [3].

However, their usefulness following a wide range of intra-abdominal procedures has been called into question considering new evidence that they are associated with a host of negative outcomes, such as intra-abdominal and wound infections, worsened abdominal pain, impaired pulmonary function, and prolonged hospital stays. Similarly, following cholecystectomy, the subhepatic area is often drained, although the procedure's effectiveness is seldom assessed [4].

This prospective study aims at comparing routine abdominal drainage vs no drainage following LC as regard postoperative pain, fever, collection, and duration of hospitalization.

Patients and Methods

This prospective research involved 40 patients, aged from 5 to 60 years with symptomatic gall bladder (GB) stones and indicated for elective LC. Ethical approval was obtained from the ethics committee of Tanta University, Tanta, Egypt. An informed consent was obtained from all participants/parents before participation in the study after explanation of the techniques and method of randomization.

Exclusion criteria
Individuals who refused to be a part of the research, acute or complicated cholecystitis, conversion to open cholecystectomy, cases with previous upper abdominal operations that may interfere with LC and patients with liver cirrhosis, portal hypertension, coagulopathy, major heart, or lung diseases that may affect the prognosis.

Randomization
Individuals were randomly separated into two equal groups by the sealed envelope method. Each group comprised 20 patients: Group A: Abdominal drainage was done routinely and Group B: No abdominal drainage.

Outcomes of the study
This prospective study aims at comparing routine abdominal drainage versus no drainage following LC as regard postoperative pain, fever, collection, and duration of hospitalization.

Preoperative assessment and preparation
Thorough History taking, clinical examination (general and local) and preoperative investigations.

Surgical technique
The patient is placed in supine position. General endotracheal intubation for anaesthesia is used for all patients. A mixture of lignocaine 2% and bupivacaine 0.5% is infiltrated at port sites. Supra-umbilical skin incision is created, and a 10-mm port is inserted using open technique through which a 10-mm, 30-degree telescope is introduced. Pneumoperitoneum is created with CO_2 6 L/minute flow rate and 12-14 mm Hg pressure.
Another 10-mm port is inserted in the midline at sub-xyphoid region (right working port), and a 5-mm right midclavicular (2-fingers below the right costal margin) port is inserted (left working port). Another 5-mm port is inserted in right flank in the anterior axillary line to grasp and provide traction to the gallbladder fundus (assistant port) as shown in (Figure 1).

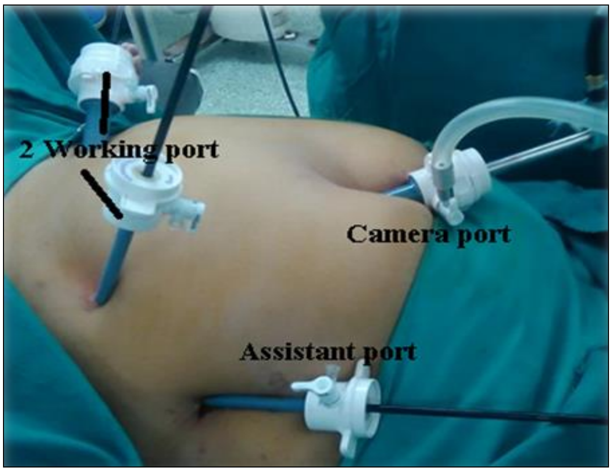


Fig 1: Trocar sites

The fundus is retracted caudolaterally utilizing the medial 5-mm grasper, and the lateral 5-mm grasper is attached to the fundus and utilized to hold it cephalad over the dome of the liver. This action helps to prevent damage to the CBD by straightening the cystic duct (drawing it back at a right angle to the bile duct). In contrast, CBD susceptibility rises when infundibulum cephalad retraction brings the cystic duct into closer proximity to the CBD.
The gallbladder and the omentum or duodenum frequently adhere to one another. A thorough analysis of these is available. Once the gallbladder's hilum region is reached, it is crucial to expose the area and dissect it carefully. To get the crucial perspective of safety, the cystic duct and artery in the triangle of Calot must be dissected and identified. This crucial perspective is attained when the surgeon sees just two structures (the cystic duct and artery) entering the gallbladder, and it is gained prior to any structures being clipped or transected.
After a critical perspective has been attained and the cystic formations have been recognized, they can be trimmed and separated (Figure 2).

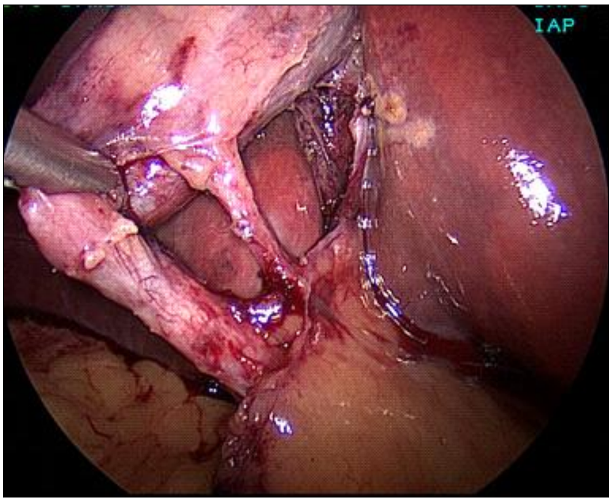


Fig 2: The cystic duct and artery after dissection; the Calot's triangle and critical window of safety are clearly demostrated

Using a 10-mm clip applier inserted into a 10-mm subxyphoid port, the cystic duct and cystic artery are clipped (Figure 3).
(Figure 4) after the GB has been meticulously dissected off the liver bed using hook diathermy, it is subsequently completely separated from the liver. Careful examination of the liver bed to detect and treat any bleeding or small biliary leakage from the Luschka's accessory duct. Both the subxyphoid and the umbilical ports are used during gallbladder removal. When necessary, salt water is used to irrigate the area. Sub-cuticular sutures are used to close any incisions made in the skin. After the procedure was complete, the port sites were taped up using surgical adhesive tapes. The first follow-up appointment was scheduled for one week following the first application of any dressings.

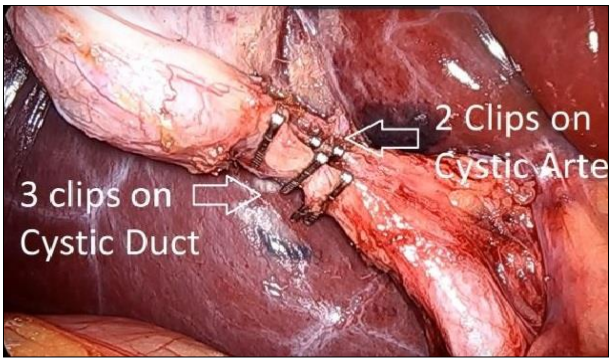


Fig 3: Clipping of the cystic duct and artery

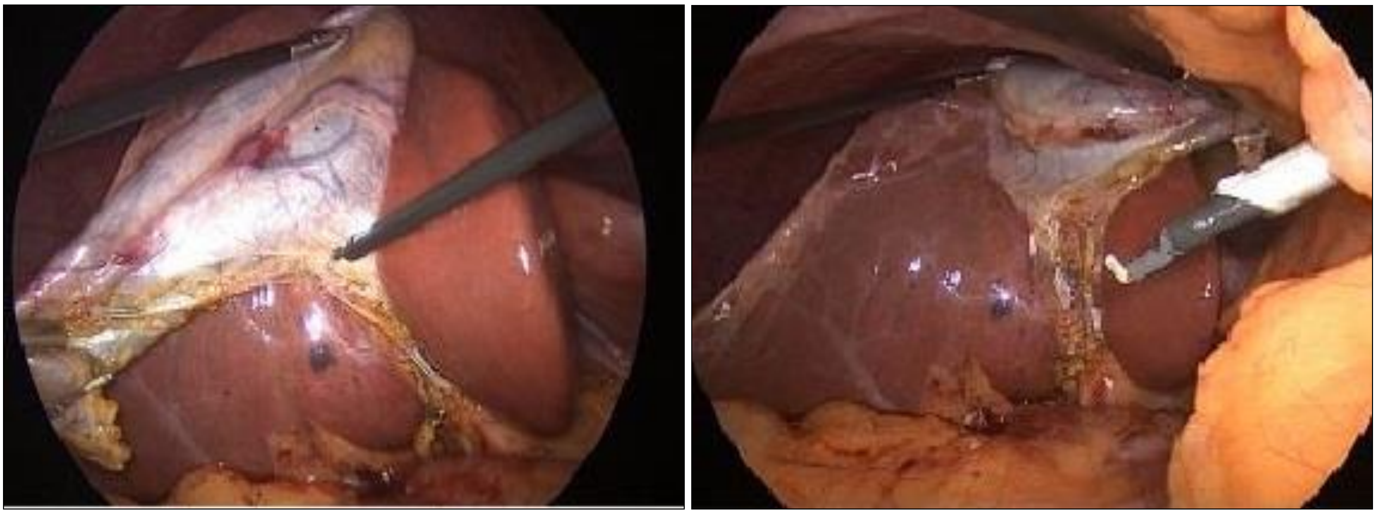


Fig 4: Dissection from the gallbladder bed

In group A

A suction drain size 14 or 16 was placed in the Morrison's pouch through the assistant 5-mm port and removed after 48 hours unless otherwise indicated.

In group B

No drainage is used.

Statistical analysis

The data was analysed utilizing SPSS version 26, the Statistical Package for the Social Sciences. Quantitative characteristics have been summarized by means and standard deviations. Categorical variables were defined by their absolute frequency counts, and comparisons were made using chi-square, Fisher exact, and Monte Carlo tests. Ordinal-binary data was analysed using the chi-square test for linear trend. Kolmogorov-Smirnov (distribution type) and Levene (homogeneity of variances) tests were performed to ensure the assumptions of parametric testing.

Results

There was non-significant variation among the examined groups regarding age or sex, presentation, duration of symptoms, medical or surgical history or findings of abdominal ultrasound Table 1.

Table 1: Comparison of demographic data, history, and examination among groups

		Group A (drain group) (n=20)	Group B (no drain group) (n=20)	p
Age (year)		42.7 ± 10.11	35.65 ± 12.87	0.062
Sex	Female	14 (70%)	18 (90%)	0.235
	Male	6 (30%)	2 (10%)	
Presentation	Abdominal pain	20 (100%)	20 (100%)	0.235
	Nausea	12 (60%)	7 (35%)	0.113
	Vomiting	6 (30%)	3 (15%)	0.451
	Tenderness	6 (30%)	4 (20%)	0.465
Surgical history	Free	9 (45%)	9 (45%)	>0.999
	CS	5 (25%)	7 (35%)	0.49
	Tonsillectomy	0 (0.0%)	3 (15%)	0.072
	Appendicectomy	2 (10%)	2 (10%)	>0.999
	Hernioplasty	1 (5%)	1 (5%)	>0.999
	Thyroidectomy	2 (10%)	0 (0%)	0.147
	Hemorrhoidectomy	1 (5%)	1 (5%)	>0.999
Medical history	Free	12 (60%)	17 (85%)	0.155
	Diabetes	2 (10%)	2 (10%)	>0.999
	Hypertension	2 (10%)	2 (10%)	>0.999
	IHD	1 (5%)	0 (0.0%)	>0.999
	Psoriasis	1 (5%)	0 (0.0%)	>0.999
	Cirrhosis	3 (15%)	0 (0.0%)	0.231
	Bronchial asthma	1 (5%)	0 (0.0%)	>0.999
Liver ultrasound	Normal	7 (35%)	12 (60%)	0.402
	Fatty	7 (35%)	5 (25%)	
	Fibrotic	1 (5%)	1 (5%)	
	Fibro-cirrhotic	5 (25%)	2 (10%)	
GB stone	Multiple	19 (95%)	18 (90%)	>0.999
	Solitary	1 (5%)	2 (10%)	
Duration of symptom		1.25(1 – 2)	1(0.31 – 2)	0.168

Data are presented as mean ±SD or frequency (%) or median (IQR), *significant p value <0.05. CS: Cesarean Section, IHD: ischemic heart disease, GB: gall bladder.

There was non-significant disparity among the groups regarding Hb, PLT count, total leucocytic count, prothrombin time, INR, virology, AST, ALT, total or direct bilirubin Table 2.

Table 2: Comparison among the examined groups as regard laboratory data

	Group A (drain group) (n=20)	Group B (no drain group) (n=20)	p
Hb (g/dl)	12.45 ± 1.49	11.82 ± 1.36	0.17
PLT count ($10^3/mm^3$)	241.55 ± 60.54	278.3 ± 68.01	0.079
TLC ($10^3/mm^3$)	6.26 ± 1.64	7.34 ± 2.31	0.095
PT (Sec)	12.41 ± 0.9	12.09 ± 0.71	0.227
INR	1.04 ± 0.07	1.03 ± 0.04	0.449
HCV positive	2 (10%)	1 (5%)	>0.999
AST (u/l)	16.5(13.4-25.25)	21.5(13.75-34.5)	0.25
ALT (u/l)	17.5(15-29.5)	24 (12-31)	0.828
Total bilirubin (mg/dl)	0.55 (0.43-0.8)	0.6 (0.4-0.8)	0.763
Direct bilirubin (mg/dl)	0.15 (0.1-0.2)	0.2 (0.1-0.2)	0.27

Data are presented as mean ±SD or median (IQR), *significant p value <0.05. Hb: hemoglobin, PLT: Platelet, TLC: Total Leucocyte Count, PT: Prothrombin time, INR: international normalized ratio, HCV: Hepatitis C virus, AST: aspartate aminotransferase, ALT: alanine transaminase.

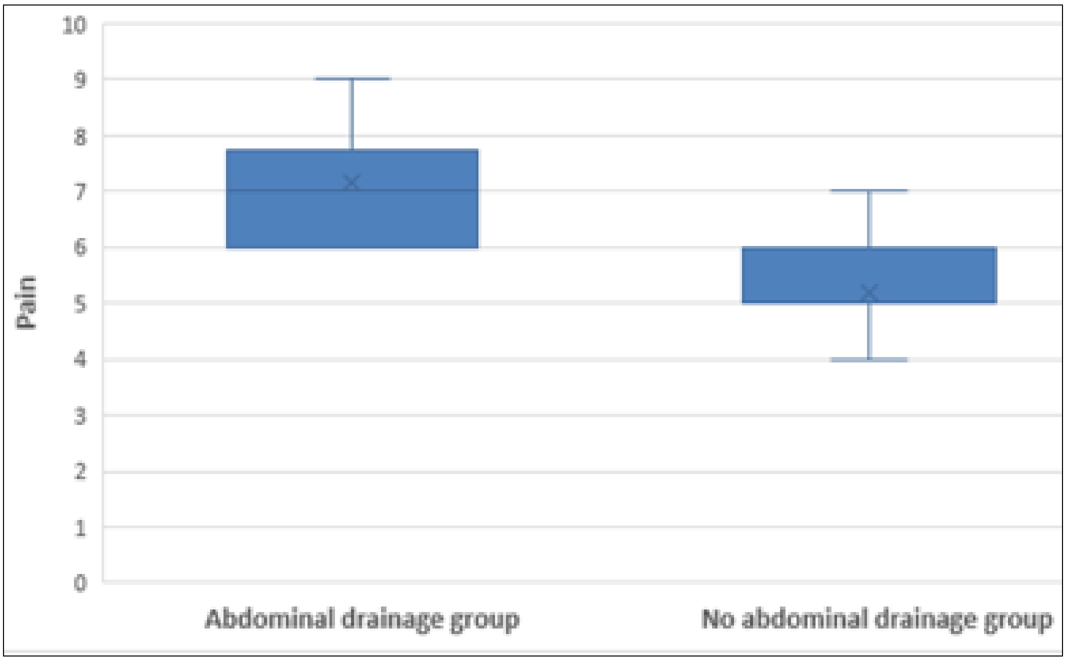
Gallbladder adhesions were found in 21 cases in both groups. Adhesions were found between the gall bladder bed and Calot's triangle and was taken down by meticulous dissection. No major intraoperative hemorrhage, no vascular injuries and no other intraoperative complications were reported in either group Table 3.

Table 3: Comparison between the studied groups regarding operative and postoperative data

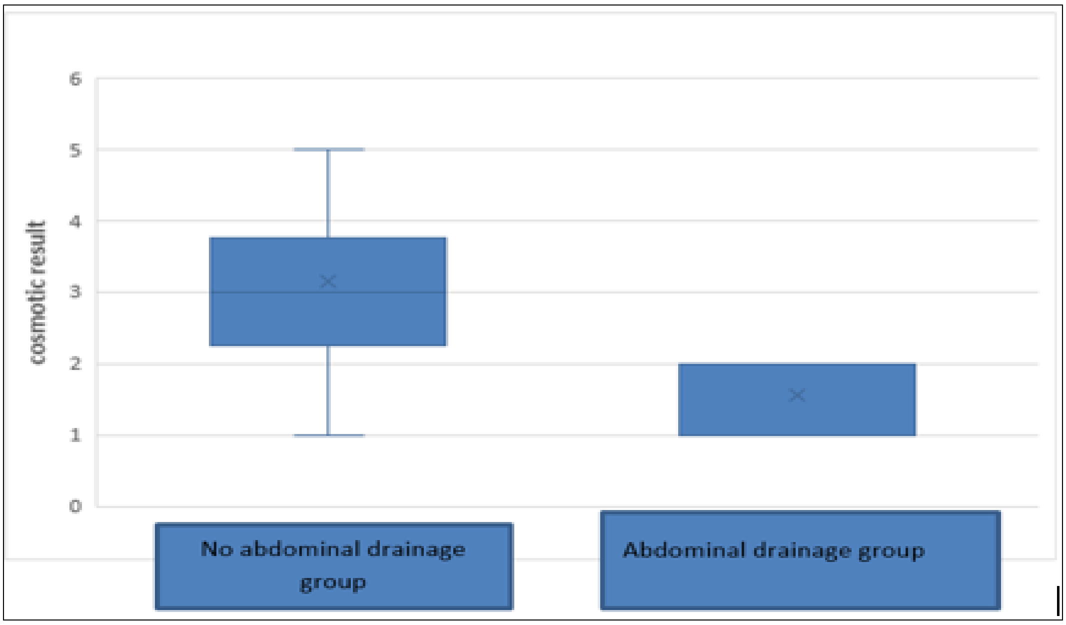
		Group A (drain group) (n=20)	Group B (no drain group) (n=20)	p
Operative time		45.50 ± 6.67	41.09 ± 5.33	>0.999
Intra-operative data	GB adhesions	18 (90%)	3 (15%)	<0.001*
	Acute infection	0 (0.0%)	0 (0.0%)	>0.999
	GB stones spillage	2 (10%)	0 (0.0%)	>0.999
	Bleeding	4 (20%)	0 (0.0%)	0.106
	Visceral injury	0 (0.0%)	0 (0.0%)	>0.999
Postoperative data	Cosmetic result	5 (5 – 6)	7 (6 – 7.75)	<0.001*
	Pain	3.5 (2.25 – 3.75)	2 (1 – 2)	<0.001*

Data are presented as mean ±SD or median (IQR) or frequency (%), *significant p value <0.05, VAS: Visual analogue scale, GB: gall bladder.

Median VAS pain score was 3.5 versus 2 within abdominal drainage and no abdominal drainage groups (p<0.001). There was statistically significant difference between the studied groups regarding postoperative pain. Median cosmetic result score was 5 versus 7 within abdominal drainage and no abdominal drainage groups (p<0.001) Figure 5.



(A)



(B)

Fig 5: Boxplot showing comparison between the studied groups regarding (A)pain and (B)cosmetic result

There was significant variation among the groups concerning length of hospital stay and postoperative data Table 4.

Table 4: Comparison among the groups regarding result and length of hospital stay and postoperative data

		Group A (drain group) (n=20)	Group B (no drain group) (n=20)	p
Length of stay (day)	One day	11 (55%)	19 (95%)	0.005*
	Two days	6 (30%)	1 (5%)	
	Three days	3 (15%)	0 (0%)	
Post-operative complications	Readmission	2 (10%)	0 (0%)	0.047*
	Fever	5 (25%)	0 (0%)	
SSI (epigastric port)		5 (20%)	0 (0%)	0.047*
Oral intake	After one day	20 (100%)	19 (95%)	>0.999
	After two days	0 (0%)	1 (5%)	

Data are presented as frequency (%) or median (IQR), *significant p value <0.05, SSI: surgical site infection.

Time for drain removal in patients with drain group ranged from 1 to 2 days with 25% removed drain in first day. Concerning color of fluid drained, 70% had serous fluid Table 5.

Table 5: Drain characteristics of the studied patients

		N=20
One day		5 (25%)
Two days		15 (75%)
Color	Serous	14 (70%)
	Serosanguinous	6 (30%)

Data are presented as frequency (%).

There is a significant positive correlation as regard to multi-variant analysis of multiple factors in correlation to each other, pain score, cosmetic results, length of hospital stay and time of drain removal between the groups Table 6.

Table 6: Correlation between pain score, cosmetic result and length of hospital stay

	r	P
Pain score	0.511	0.001**
Cosmetic result	0.593	0.009*
Length of hospital stay	0.491	0.028*

r: Spearman rank correlation coefficient.

Discussion

Peritoneal cavity draining has been performed routinely after many different surgeries for many years to identify postoperative haemorrhage, anastomotic leakage, biliary leakage, and pancreatic leakage as soon as possible. This method relied more on established norms and habits than on any hard evidence [5].

There does not seem to be a need for a drain in the absence of a suppurative process or bleeding. The ability to spot problems early is its primary benefit. However, removing the drain might be more painful than any initial discomfort. The patient may be released the next day if the drainage was not significant. If there is an abnormally large amount of blood or bile being expelled, the drain must remain in place [6].

Our analysis of operating time included the whole process, from incision to closure, which included port insertion and removal. LC in group A (drainage group) took an average of 45.50 6.67 minutes (range: 33.58 minutes). LC in group B (non-drain group) took an average of 41.09 5.33 minutes (range: 33-55 minutes).

In terms of operational time, there was no statistically significant difference between the groups**.** Patients requiring drains had a longer mean operating time (93 minutes) than those who did not (86 minutes) in the study by A. Nagbal *et al*. [7] found that the average operating time for patients with drains was 81 minutes, somewhat less than the average operating time for patients without drains (82 minutes).

Two patients in the abdominal drainage group (10%) had gall stone leakage, and four patients in the abdominal drainage group (20%) experienced bleeding, compared to zero patients in the no abdominal drainage group (0.0%).

Three of the four patients had intraoperative bleeding from the GB bed, while the fourth experienced intraoperative bleeding due to the clip slipping over the cystic artery. Laparoscopic surgery was able to successfully stop the little bleeding. Significant bleeding, vascular damage, or other intraoperative problems did not occur in either group during surgery**.** Seven patients (35%) in research by A. Nagbal *et al*. [7] had intraoperative GB perforation; two patients (10%) experienced cystic artery haemorrhage; one case (5%) experienced CBD damage; and one patient (5%) experienced stomach perforation; all these patients required drains [5]. GB perforation was the sole intraoperative event in the same research among individuals who did not have drains (22%)**.** In the study by Rathi *et al*. [8] patients who had drains in place after surgery had no complications, but in patients without drains, peritonitis necessitated the need for re-exploration in one case for duodenal perforation [8].

In our study, five patients in the drainage group experienced fever with surgical site infection, compared to 0% in the no drainage group, and two patients in the drainage group required readmission owing to intra-abdominal collection discovered by ultrasound**.** All the seven patients improved with conservative therapy. Two patients were readmitted for antibiotic treatment after presenting with intra-abdominal collections (detected by abdominal ultrasonography). Following 3 and 5 days, respectively, both cases showed improvement and were released after the resolution of the collection. When drainage does not occur after cholecystectomy, the nature and makeup of the collections in the subhepatic/gallbladder fossa are unknown**.**

Subhepatic GB fossa collections were seen in 12 of 35 (34%) individuals in the Kappor *et al*. [9] study who underwent drainage. A smaller collection was identified in 3 of the 12 patients who received follow-up US, but in 9 of them, the collection completely disappeared. In the non-drainage group, US detected a collection in 24 of 42 patients (57%).

Collections comprised homogenous non-echogenic material more consistent with fluid than organised haematoma or tissue debris, suggesting that poor drainage was to be blamed for their lack of clinical importance. The research conducted by Monson *et al*. [10] found that 11 of 112 people (10%) had sub-hepatic fluid accumulation. From the 54 people who underwent fluid drainage, 10 (18%) were determined to have a collection.

In our investigation, five patients developed an infection at the drain site, although Rathi *et al*. reported no such infections. Infection at the incision site was five times more likely in the drain group, according to Cruse and Food's research [11, 12]. In the postoperative period, nine patients in the drainage group and none in the non-drainage group had a superficial wound infection of the epigastric port [13].

In our research, 11 patients in the abdominal drainage group remained in the hospital for one day, compared to 19(95%) patients in the no abdominal drainage group, and 6(30%) patients in the abdominal drainage group were released after two days. Patients who remained longer than a day reported feeling sick and resumed taking their food by mouth after two days**.**

Hospitalization duration was greater for those who had drainage (1-4 days) compared to those who did not (1-2 days), as reported by Bashar *et al*. [13] Patients were released from the hospital in the study by Rathi *et al*. [8] after it was determined that their overall health was sufficient, and they had commenced oral intake. Patients who did not need drains spent an average of 2.1 days in the hospital, whereas those who did required a longer 3.58 days. As a result, they reasoned, patients may spend less time in the hospital without the drain.

In our research, drain removal took between one and two days, with a quarter of the drains being taken out on the first day**.** Five participants in the drainage group had infection at the surgery site (port site infection), and all seven instances in our research improved with conservative therapy. Myers [14] described drain fever syndrome after cholecystectomy. It was long-lasting fever and ache in the upper right quadrant.

Twenty-three percent of the drain group and four percent of the non-drain group had discomfort and fever that resolved on their own within three to five days [15]. The following might account for this discrepancy: A drain triggers an immune response since it is a foreign object [16].

Patients with drains were more likely to have minor drain site discomfort than those without drains, according to research by Rathi *et al*. [8]. The mean VAS ratings in the drain group were significantly higher at 24 and 48 h compared to the non-drain group. Based on their findings, Bashar *et al*. concluded that patients in the drain group experienced more pain than those in the non-drain group by an average of 2.2 points on the visual analogue scale (VAS).

Ashish *et al*. found no differences in late VAS score or patient satisfaction with cosmetic outcome between the two groups [17].We graded patients based on an objective scale called the aesthetic outcome score. The median aesthetic outcome score for abdominal drainage was 5, whereas the score for no abdominal drainage was 7. When comparing aesthetic outcomes, there was a statistically significant difference between the groups.

Our preliminary data on short-term cosmesis, patient satisfaction, and quality of life after drained and undrained LC suggested that the latter group benefited more.

There is ongoing discussion on whether drains are necessary or not after LC. The purpose of this study was to assess the value of drain placement after LC in patients with non-acute GB. We observed that there is no link between the existence of a drain following LC and the occurrence of postoperative minimum fluid collection. Therefore, in patients without difficulties, placing a drain to avoid minor fluid accumulation is unnecessary since doing so increases hospital stay, postoperative discomfort, and has a worse aesthetic result after uncomplicated LC [17].

Although deflating carbon dioxide is a rationale for drain insertion after LC, our findings show that drain insertion actually increases postoperative discomfort.

Limitations of our study were small sample size, single centre study and prospective study. So, we recommended that further prospective randomised controlled studies are needed. If done by a competent surgeon with the proper training and equipment, LC may be performed without the need for a drain to treat uncomplicated gallstone disease with acceptable safety.

Conclusion

Preventive drainage after non-complicated LC does not significantly improve outcomes. Prophylactic laparoscopic drainage after noncomplicated LC has been shown to increase the risk of wound infection and the length of time patients spend in the hospital after surgery. Therefore, drain placement after LC should be reserved for very challenging situations.

Conflict of Interest
Not available.

Financial Support
Not available.

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