

Comparison of the Morbidity after Laparoscopic Cholecystectomy for Acutely Inflamed Gall Bladder with and without Drain Insertion: A Randomized Controlled Trial

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Abstract

Objective: The study objective is to compare the pain frequency and mean hospital stay in patients with and without drain insertion, following laparoscopic cholecystectomy for acutely inflamed gallbladder.

Materials and Methods: Randomized control trial was carried out in General Surgery Department Shifa International Hospital for a period of 1 year from October 2017 to October 2018. All patients with acutely inflamed gallbladder admitted underwent laparoscopic cholecystectomy using the conventional 4 port method.

Results: Mean age of patients without a drain (group A) was 52.00 ± 14.84 years and in with drain (group B) was 47.50 ± 18.28 years. In without drain (group A), there were 9 (30.0%) males and 21 (70.0%) females, mean VAS was 2.37 ± 1.22 , 16.7% (5 of 60 patients) had pain, and mean hospital stay was 1.93 ± 0.79 days. In with drain (group B), 13 (43.3%) were males and 17 (56.7%) were females, mean VAS was 3.2 ± 1.36 , 36.7% (11 of 60 patients) had pain, and mean hospital stay was 3.17 ± 0.87 days. The difference between the two groups for mean VAS was significant ($P < 0.05$), for the mean hospital stay, was significant ($P < 0.05$) but for pain frequency was insignificant ($P > 0.05$).

Conclusion: It is concluded that laparoscopic cholecystectomy without drain has less morbidity as compared to laparoscopic cholecystectomy with drain.

Keywords: Pain, Hospital Stay, Drain Insertion, Laparoscopic Cholecystectomy, Acutely Inflamed Gall Bladder.

Introduction

The open technique to treat symptomatic cholelithiasis has been replaced by Laparoscopic cholecystectomy for years now and is considered as a gold standard procedure but no standard guidelines have been formulated for drain insertion after laparoscopic cholecystectomy and usually, surgeons decide to place drain according to their beliefs and experiences.¹

Pre-operative diagnosis of acute cholecystitis is usually made in conjunction with clinical symptoms, ultrasound findings, and biochemical laboratory tests.² Clinically patient usually presents with fever and positive Murphy's sign. Lab tests show leukocytosis. Radiologically presence of cholelithiasis, thick-walled gallbladder, and pericholecystic fluid or intraluminal findings of abnormal gas, hemorrhage, or sloughed mucosa is classified as acute cholecystitis. Previous studies have shown that focused ultrasound of the right upper quadrant is ideal for recognizing gall stones and other related biliary diseases having a sensitivity of 90 to 96%.³ Per operatively finding of pus, empyematous, gangrenous, distended, or perforated gallbladder is also additionally categorized as the acutely inflamed gallbladder.¹ Acute cholecystitis may result in severe inflammation, adhesions, and friable inflammatory tissues forming in Calot's triangle which distorts its anatomy making laparoscopic gall bladder dissection difficult. Post laparoscopic cholecystectomy drain placement could be logically justified as the operative site is not directly visualized and there may be an increased incidence of bile injury and leakage, post-operative hemorrhage/collections.⁴ Surgical drains have been widely used prophylactically for timely detection and drainage of post laparoscopic cholecystectomy bleed or biliary leak from gallbladder bed, cystic duct stump, or bile duct iatrogenic injury, or any intra-abdominal particularly sub-hepatic collection.⁵

However recent studies suggest that there is no added benefit of routine placement of drains after laparoscopic removal of gall bladder with acute cholecystitis.^{4,6,7} A review study of combined results of six randomized controlled trials on 1167 patients, by Antonio S et al, showed a comparison of pain scores in patients with and without drains which reported significantly higher pain scores in the drain group, both at 6-12h and at 12-24h after surgery but the insignificant difference was found between the drain and non-drain group for sub-hepatic collection and drainage procedures.⁷

A local study carried out by Rathi PK et al at Liaquat University of Health Sciences, Jamshoro; compared the effects of omitting routine drainage insertion. They found that use of drain was associated with significant drain site pain, and post-op means hospital stay was 2.1 +/-1.28 days in patients without drain and was 3.58 +/-0.93 days in patients with drain. They also reported that frequency of pain with drain was 26% and without drain was 15%.⁵

Previous studies also suggest that patients with post-surgical drain placement present with increased incidences of complications like intra-abdominal infections, surgical wound infection, drain site pain and discomfort, decreased pulmonary function as drain site pain causes difficulty in breathing and prolonged hospital stay thus increasing the economic burden.⁶⁻⁸

Sub-diaphragmatic drain insertion may minimally reduce postoperative pain, nausea, vomiting but this effect is clinically irrelevant.⁸ Furthermore the lumen of the drain can get occluded by the omental tissue giving a false sense of security that post-operatively there is no abdominal collection however it remains unclear if drain insertion prevents or treats post-operative bile collection, bleeding, or bile peritonitis.⁹ On the other hand these complications of cholecystectomy can be detected easily by clinical parameters and by means of radiological modalities commonly available.

Most hospitals in Pakistan still have do not have guidelines for treating acute cholecystitis by early laparoscopic cholecystectomy, primarily because of feared higher conversion rates to open procedure and presumed increased risk of complications.¹⁰ There are fewer local studies to elaborate the role of drain insertion post laparoscopic cholecystectomy in acute cholecystitis. The rationale of this study is to analyze the role of drain placement after laparoscopic cholecystectomy in acute cholecystitis; does it offer any advantage in detecting post-operative bile leak or bleeding. This randomized controlled trial is an effort to compare morbidity after Laparoscopic cholecystectomy for acutely inflamed gall bladder with and without drain insertion.

Materials and Methods

A randomized control trial was conducted in the General Surgery Department, Shifa International Hospital for a period of one year from October 2017 to October 2018. All the patients of either sex with ages between 20-80 years, diagnosed with an acutely

inflamed gallbladder, undergoing laparoscopic cholecystectomy were included in the study. All patients having concurrent operations on other organs, or with a history of previous upper abdominal surgery, or with immunodeficiency states (on immune suppressants due to liver or renal transplant surgery or having acquired immune deficiency syndrome), or surgeries requiring open conversions, or surgeries in which there was hollow visceral organ injury, or patient requiring common bile duct (CBD) exploration or patients having any bleeding disorder, or surgeries where there is doubt of cystic duct stump or CBD injury, were excluded from the study. Patients were selected by non-probability consecutive sampling technique. WHO sample size calculator was used to calculate sample size, by taking significance level as 5%, confidence level as 95%, power of test as 90%, population P1 as 0%, and population P2 as 26%. The sample size was calculated to be 60 in total, 30 in each group.¹¹ The study was conducted after approval of the research and ethical committee of Shifa International Hospital. Patients fulfilling the criteria and willing to be part of research protocol after written and informed consent was included in the study. Initial demographic data including age, sex, and hospital number was recorded on the Performa. All patients with acutely inflamed gallbladder admitted through ER or OPDs underwent laparoscopic cholecystectomy using the conventional 4 port method. Surgery being conducted by the surgical team, comprising of a senior consultant having experience of more than 25 years as a laparoscopic surgeon having performed more than 1000 laparoscopic cholecystectomies, and assisted by general surgery residents. Patients were sorted into two groups by lottery method.

- No drain Group A and
- With drain Group B.

In drain group B, a suction drain was placed in the sub-hepatic region through a 5mm lateral trocar site. Post-operatively parameters of pain severity were determined by visual analog scale (VAS) from 0 (NIL pain) to 10 (most severe pain), assessed after 24 hours of surgery by the duty doctor or the nurse.¹² VAS > 3 was considered as post-surgical pain. Hospital stay was measured to be the total number of days in the hospital from the day of surgery till the discharge day and discharge criteria were taken as a patient having pain as per VAS<3, no fever, and tolerating oral intake.

Data were entered into a standard SPSS sheet version 26. Mean +/- standard deviations were calculated for

quantitative variables like age, pain (VAS), and hospital stay, and frequency and percentages were calculated for qualitative variables like gender and pain. Pain between two groups was compared by the Chi-square test. Mean hospital stay in two groups was analyzed by an Independent sample t-test. Quantitative variables including age and gender were stratified and the post-stratification Chi-square test was applied. P-value< 0.05 was considered significant.

Results

The mean age of patients in without drain (group A) was 52.00 ± 14.84 years and in with drain (group B) was 47.50 ± 18.28 years. In without drain (group A), there were 9 (30.0%) males and 21 (70.0%) females. In with drain (group B), 13 (43.3%) were males and 17 (56.7%) were females. All demographic data of patients are summarized in Table 1.

Table 1: Demographic characteristics of Patients

S. No.	Characteristic		Group	
			With Drain	Without Drain
	Total Number of Patients (60)		30	30
1.	Age (Years)	Mean Age	52.00	47.50 +/-
		with SD	+/-	18.28
			14.84	
		Minimum	25	20
		Maximum	79	72
2.	Sex	Male	22 (36.7%)	9 (30%)
		Female	38 (63.3%)	17 (56.7%)

Mean VAS in without drain (group A) was 2.37 ± 1.22 and in with drain (group B) was 3.27 ± 1.36 and the difference between the two groups for mean VAS was significant (P<0.05). In without drain (group A), 5 (16.7%) patients had pain while in with drain (group B), 11 (36.7%) patients had pain. The difference between the two groups for pain was insignificant (P>0.05). In without drain (group A), mean hospital stay was 1.93 ± 0.79 days and in with drain (group B), mean hospital stay was 3.17 ± 0.87 days and the difference between the two groups for mean hospital stay was significant (P<0.05). The morbidity difference between the two groups A and B as measured by VAS, presence of post-surgical pain, and mean hospital stay is summarized in Table 2.

Table 3: Morbidity difference measured by VAS, post-surgical pain, and mean hospital stay between the two groups the drain and the without drain group

S. No.	Characteristic	Group	
		With Drain	Without Drain
	Total Number of Patients (60)	30	30
1.	VAS (mean with SD)	2.37+/- 1.22	3.27+/- 1.36
Independent samples t-test = 2.698 p-value = 0.009 (Significant)			
2.	Pain	Yes	5 (16.7%)
		No	25 (83.3%)
Chi-square test = 3.068 p-value=0.080 (Significant)			
3.	Hospital Stay in days (mean with SD)	1.93 +/- 0.79	3.17 +/- 0.87

Independent samples t-test = 5.749
p-value = 0.000 (Significant)

Data was stratified for age and gender of all patients comparing the morbidity (i.e. post-surgical pain and mean hospital stay) between the two groups A and B, as detailed in Table 3. It was found that there is an insignificant difference (P>0.05) between the pain in both groups for each age strata and both genders. The mean hospital stay for different age strata showed no difference (P>0.05) between the two groups in the younger age group (20-40years) but in patients older than 40 years significant difference was seen. The difference was significant (P<0.05) in both groups for both genders for the mean hospital stay.

Table 3: Summarized Table Demonstrating Difference of Morbidity between Drain Group and Non-Drain Group According To Stratified Age Groups and Gender

	Characteristics	Group		Total	P-value	
		Pain	Without drain (A)			With drain (B)
Comparison of pain in both groups for age strata	20-40 (years)	Yes	0 (0.0%)	3 (23.1%)	0.168	
		No	7 (100%)	10 (76.9%)		
		Total	7 (100%)	13 (100%)		
	41-60 (years)	Yes	3 (20.0%)	4 (66.7%)	7 (33.3%)	0.064
		No	12 (80.0%)	2 (33.3%)	14 (66.7%)	
		Total	15 (100%)	6 (100%)	21 (100%)	
61-80 (years)	Yes	2 (25.0%)	4 (36.4%)	6 (31.6%)	0.494	
	No	6 (75.0%)	7 (63.6%)	13 (68.4%)		
	Total	8 (100%)	11 (100%)	19 (100%)		
Comparison of pain in both groups for gender strata	Male	Yes	2 (22.2%)	6 (46.2%)	0.38	
		No	7 (77.8%)	7 (53.8%)		
		Total	9 (100%)	13 (100%)		
	Female	Yes	3 (14.3%)	5 (29.4%)	8 (21.1%)	0.426
		No	18 (85.7%)	12 (70.6%)	30 (78.9%)	
		Total	21 (100%)	17 (100%)	38 (100%)	
Comparison of hospital stay in both groups for age strata	20-40 (years)	Hospital stay		Group		0.117
			Without drain (A)	With drain (B)		
		n	7	13		
		Mean	2.29	3		
		SD	0.76	1		
	41-60 (years)	n	15	6	0.001	
		Mean	1.8	3.33		
		SD	0.78	0.82		
	61-80 (years)	n	8	11	0.002	
		Mean	1.8	3.27		
		SD	0.84	0.79		

Comparison of hospital stay in both groups for gender strata	Male	n	9	13	0.021
		Mean	2.11	3.08	
		SD	0.78	0.95	
	Female	n	21	17	0
		Mean	1.86	3.24	
		SD	0.79	0.83	

Discussion

Open cholecystectomy was considered the standard surgical procedure for gall bladder disease for years.¹³ Various prospective randomized controlled trials have evaluated the practice of drain insertions after open cholecystectomy. For cholecystectomy, now laparoscopy has replaced laparotomy as the gold standard but there is inadequate research on the effectiveness of drain placement after laparoscopic cholecystectomy, and the surgeons still practice according to their beliefs and experiences creating a bias on this subject.¹⁴

A review study by Antonio et al. compared pain scores and the development of post-operative collections in patients with and without drains. They reported significantly higher pain scores in the drain group both at 6-12h and at 12-24h after surgery but the incidence of sub-hepatic collections (hematoma, biloma, or seroma) and subsequent drainage and aspirations were almost the same in both the groups.⁷

Nagpal et al. found that the mean pain score was 0.85 ± 0.74 without drain while 1.3 ± 1.17 with drain. The difference was insignificant ($P > 0.05$). But without drain, 70% and with drain 65% patients showed pain after 24 hours of surgery.¹⁵

Tzovaras et al. reported no deaths in either group and also both the groups had similar morbidity with no significant statistical difference considering mean hospital stay but in the drain group patients had significantly increased post-surgical pain and median VAS score was 5 (ranging from 1 to 8) as compared to the non-drain group which has median VAS of 3 (ranging from 1 to 8), ($P < 0.001$). They had placed a drain in 2 to 3 patients against randomization in whom there was suspicion of biliary leakage and interestingly it was beneficial. Thus they concluded that regular placement of drain should be avoided due to its association with increased pain intensity and pain frequency however if there is suspicion of a leak, a drain could be inserted post-surgically keeping in mind that drain insertion would not fully prevent or treat a possible post-op collection.¹⁴

A local study carried out at Liaquat University of Health Sciences, Jamshoro by Rathi et al., compared

the effects of omitting routine drainage insertion. They found that use of drain was associated with significant drain site pain; frequency of pain being 26% with drain and 15% without drain, and prolonged post-op stay at the hospital, 3.58 ± 0.93 days in patients with drain compared to 2.1 days \pm 1.28 days in patients without the drain.⁵

Bawahab et al. reported that patients with drain had a longer post-surgical stay at the hospital, 4.48 ± 2.18 days as compared to 2.50 ± 2.20 days in non-drained group B.¹⁶ Nagpal et al. also found that the mean hospital stay was longer 5.75 days in patients with drain while 3.65 days in patients without drain.¹⁵ So did Kosumi et al. reported that the average stay at the hospital was 4 days in the post-op drained group relative to only 2 days in the post-op non-drained group.¹⁷ Similarly Singh et al. also reported significantly longer mean hospital stay in the drain group, 8.63 ± 4.06 days as compared to 4.63 ± 2.41 days in the non-drain group ($P = 0.00002$).¹⁸ But contradicting, Singh et al. also showed no significant statistical difference for post-operative pain (VAS score) between the patients of the two groups after 0 hours post-surgery ($P = 0.08$), after 24 hours post-surgery ($P = 0.1325$) and after 48 hours post-surgery ($P = 0.7795$).¹⁸

One review by Gurusamy showed that there was no significant difference in the length of hospital stay between the two groups.¹⁹ Recent meta-analysis by Yang et al in 2020 reviewed various RCT studies and concluded that there is no added advantage of drain insertion after non-complicated laparoscopic cholecystectomy however they indicated further evidence is required to establish the need for drain placement after laparoscopic removal of a complicated benign diseased gall bladder.²⁰ Similarly a study by Sharma et al concluded that if the operating site is clear of any visible fluid after the procedure then a drain placement is not beneficial.²¹ Our study revealed similar results to various previous studies, demonstrating increased mean hospital stay of 3.17 ± 0.87 days in the with drain group B as compared to 1.93 ± 0.79 days in the without drain group A (significant P value < 0.05), and increased pain frequency of 36.7 % (11 out of 60) in with drain group

B as compared to 16.7% (5 out of 60) in without drain group A., 11 (36.7%) patients had pain, but this difference was insignificant (P -value > 0.05). Although majority studies show that role of post-operative drain insertion after laparoscopic cholecystectomy is controversial but a recent study by Vafaei et al showed a statistically significant reduction in post-operative shoulder pain after laparoscopic cholecystectomy which is likely due to drainage of insufflated CO₂ during laparoscopy and post-operative sub-hepatic residual gas.²² Meta-analysis by Huang et al also revealed that drain placement is not necessary after laparoscopic removal of acute gall bladder but it may be required and beneficial if there is complicated gall bladder disease.⁴

Few limitations are acknowledged regarding our study. Firstly we did not separately study the complicated gall bladder disease like empyema or gangrenous gall bladder from the non-complicated acute edematous cholecystitis. Secondly, we were not able to perform an analysis of post-surgical abdominal fluid collections, post-surgical shoulder pain, and nausea and vomiting, post-op drain related complications for example drain migration or drain breakage and time consumed for surgery and level of difficulty in dissecting gall bladder during the surgery, as longer procedural time indicates more intensely inflamed gall bladder and the area surrounding it within the Calot's triangle. In our study, we had patients of different body mass indices and it is proposed that there is an increased risk of postoperative complications and postoperative pain in obese patients and comparative study regarding the use of post laparoscopic drains in obese and non-obese persons should be separately studied. Furthermore, the preoperative radiological diagnosis was performed by different sonologists and interpreted by a radiologist, which created a selection bias. For all these limitations and biases, more methodological RCT with homogeneously collected data is required for obtaining accurate results without underestimating or overestimating the use of post-op drains. In our study, we had taken patients of ASA I and ASA II categories of surgical risk after general anesthesia to reduce bias.²³

Conclusion

It is concluded that laparoscopic cholecystectomy without drain has less morbidity as compared to laparoscopic cholecystectomy with drain. Now in the future, we will recommend not putting drain

following laparoscopic cholecystectomy for acute cholecystitis, as this will reduce pain and hospital stay and reduce the burden of surgeons as well as the burden of the hospital.

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