

COMPARATIVE STUDY OF PORT SITE COMPLICATION IN LAPAROSCOPIC CHOLECYSTECTOMY AFTER GALL BLADDER RETRIEVAL USING INDIGENOUS DRAIN BAG OR DIRECT EXTRACTION

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Abstract

Background: Gallstones are considered the most common biliary pathology. Laparoscopic cholecystectomy is the gold standard for the treatment of symptomatic gallstone disease due to less postoperative pain, early recovery, short hospital stay, and cosmetically small scars compared to open surgery. It is the most common minimally invasive surgical procedure performed worldwide to remove a diseased gallbladder. Although PSI is not very common, it is one of the annoying complications that undermines the benefits of minimally invasive surgery. PSI presents as significant peri-incisional erythema, wound discharge, induration, and fever. An endo bag is usually used to collect and for retrieval of the gallbladder during a laparoscopic approach to reduce complications associated with gallbladder perforation and stone and bile spillage. **Objectives:** To compare port site infection and pain in patient undergoing laparoscopic cholecystectomy with and without use of retrieval bag for specimen extractions and the post-operative length of hospital stay **Materials & Methods:** This prospective observational study was carried out over a period of 18 months (12 months period of data collection and 6 months period of data analysis) from October 2022 to March 2024 in the department of General Surgery at Hind Institute of Medical Sciences, Safedabad, Barabanki, (U.P.) on the 152 patients who underwent laparoscopic cholecystectomy with and without using indigenous retrieval drain bag had been enrolled in the study. Results and outcomes will be depicted in various tables. **Results:** In the present study, port site complications like port site infection, port site pain and late complication like sinus and hernia compared between the group A (gall bladder retrieval with use of endogenous retrieval bag) and group B(direct extraction). PSI occur in 15(9.86%) out of 152 patients in our study. **Conclusion:** The study was conclusive of the fact that gall stone is most commonly occur in the female of middle age group. Endogenous drain bag easy, chief, economical and equivocal to the commercially available endo bag. It also was conclusive that use endo bag is significantly decreased the incidence of port site infection.

INTRODUCTION

Gallstones are the most prevalent biliary pathology.^[1] Incidence of gall stone in Asian

populations from 3.1 to 6.1%, and Iranian populations from 6.3%.^[2]

Because laparoscopic cholecystectomy leaves fewer scars after surgery than open surgery, it is the preferred method for treating symptomatic gallstone

disease.^[3] It also recovers more quickly and causes less discomfort after surgery. To remove a diseased gallbladder, it is the most popular minimally invasive surgical treatment carried out globally. In just twenty years since its debut, laparoscopic cholecystectomy (LC) has transformed minimally invasive surgery.

The first cholecystectomy was carried out in 1882 on a 43-year-old patient who had been afflicted with gallstone disease for the previous 16 years by its pioneer, Carl Johann August Langenbuch.^[4] In 1987, a century later, the first laparoscopic cholecystectomy was carried out. Cholecystectomy has changed significantly since then, including the introduction of the laparoscopic technique, single-port laparoscopic cholecystectomy, and robotic-assisted cholecystectomy.

Stone leakage, bile duct damage, and gallbladder perforation are all possible side effects of laparoscopic cholecystectomy. This generally happens when the hepatic duct is severed, causing leakage into the peritoneal cavity. According to reports, the incidence of perforation varies from 10% to 40% and that of spilling from 6% to 30%.^[5] While it is easier to suction and irrigate during an open cholecystectomy, it is more challenging to remove spilled stones and pieces during a laparoscopic procedure. Complications from spillage can include intra-abdominal abscesses, port site, and abdominal wall; these are most frequently observed in sub-hepatic regions.^[6]

Because of the shorter incision length during a laparoscopic cholecystectomy, the prevalence of port site infection is comparatively low.^[7] PSI is one of the irritating side effects that out-weigh the advantages of minimally invasive surgery, despite the fact that it is not particularly common. It not only raises the morbidity of the patient but damages the surgeon's reputation as well. Significant peri-incisional erythema, wound drainage, induration, and fever are the symptoms of PSI. 8% of individuals who had laparoscopic cholecystectomy without a bag experienced PSI.^[8]

During a laparoscopic procedure, the gallbladder is typically collected and retrieved using an endo-bag to minimise risks related to gallbladder perforation, stone, and bile spilling.

A draining sinus or abscess, induration, and erythema can result from the spilling of infected bile and stones in the peritoneal cavity and port site with an implanted stone in the subcutaneous tissue of the abdominal wall. Gallbladder perforation after laparoscopic cholecystectomy is more likely in some circumstances, such as acutely inflamed gallbladders with friable tissue and inflated gallbladders that have not been decompressed.^[9] Slippage of the cystic clamp or rupture of the gallbladder after its removal from the port site might also result in spilled stones. If pigment stones are not removed after spilling in the peritoneal cavity, they may harbour live bacteria and cause further

infections. Using an endo bag for big and friable gall bladders can help prevent this.

The surgical wound must be microbial contaminated in order to develop a surgical site infection. Microorganisms can originate from external or internal sources. The patient's skin, subcutaneous fat, mucous membranes, or hollow viscera are sources of endogenous flora. Any contaminated object on the sterile surgical field, such as surgical team members, equipment, air, or materials, is the source of exogenous flora.^[10]

A complication from port-site wound manifests as varied degrees of stomach pain, sometimes accompanied by sinus drainage.^[11] or non-healing fistulae, and may or may not show symptoms of peritoneal irritation, nausea, vomiting, or anorexia.^[12]

Postoperative pain during laparoscopic cholecystectomy was discovered to be caused by hemo-peritoneum, abdominal wall trauma during port insertion, the use of carbon dioxide (CO₂) to induce pneumoperitoneum, and gallbladder extraction with big stones.^[13]

It has been observed that between 0.14% to 22% of laparoscopic surgeries result in port-site hernias.^[14] This is brought about by infection, premature breakage of the suture, and neglecting to approach the fascial wound's edges.

A port-site hernia can cause severe side effects such as intestinal blockage, strangulation, and perforation in addition to pain. The course of treatment involves first reducing the imprisoned bowel and then fixing the fascial defect.

Persistent non-healing effusions/fistulas are a major complication in minimally invasive surgery. This type of infection is caused by rapidly growing non-tuberculous mycobacteria (NTB). The incidence of this type of infection varies from 1.39% to 6.7%, they do not respond to conventional antibiotic therapy.^[15]

Aim and Objectives

Aim

- To compare advantage and disadvantage of indigenous retrieval bag used for gall bladder extraction versus direct extraction in laparoscopic cholecystectomy.

Objectives

- Primary
 1. To compare port site infection and pain in patient undergoing laparoscopic cholecystectomy with and without use of retrieval bag for specimen extraction.
- Secondary
 2. To study the post-operative length of hospital stay

MATERIALS AND METHODS

This prospective observational study was conducted in the general surgery department at the Hind Institute of Medical Sciences in Safedabad,

Barabanki, Uttar Pradesh, from October 2022 to March 2024, spanning a period of 18 months (12 months for data collecting and 6 months for data analysis). The study included all patients who had laparoscopic cholecystectomy, both with and without the use of a retrieval drain bag

Alternative selection of patients were done in two groups. (decided prior to surgery)

Group A-Extraction of gall bladder using indigenous retrieval bag.

Group B-Direct extraction of gall bladder and using endo-grasper.

- Gall bladder extraction was done in both groups via epigastric port.

Indigenous drain bag preparation

- Sterile drain bag was used and trimmed about 12 cm in length.
- Sterile plicated drain (retrieval) bag was held with grasper/Maryland and introduced through epigastric port.
- Specimen was placed into the retrieval bag and deliver out through epigastric port.

Study Design

Prospective observational study

Study Period

18 months (12months period of data collection and 6 months period of data analysis)

Sample Size

Sample size is calculated by using formula

$$n = \frac{z_{1-\alpha} + z_{1-\beta}}{p_1 - p_2} \left[\frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2} \right]$$

Where p1 and p2 are the proportions of the two groups

Z α = The critical value of the normal distribution at alpha level of significance

$$\text{at } \alpha = 5\%, z_{\alpha} = 1.96$$

Z $1-\beta$ = Desired power (critical value of normal distribution at beta)

We use p1=0%, p2=10%

$$n = \frac{1.96 - 0.84}{0.1} \left[\frac{0 + 0.1(1-0.1)}{(0.1)^2} \right]$$

n=70.56=71 in each group

Total sample size is 152.

Inclusion Criteria: Patients of any gender in the 18–60 age range., Every individual receiving laparoscopic cholecystectomy who has symptomatic cholelithiasis,

Patients who agreed in writing to take part in the research.

Exclusion Criteria: Cholecystitis gangrene, Gallbladder empyema, Gall bladder rupture, Cancer Gallbladder, converted patient (opening from lap).

Postoperative assessment:

- Severity of port site pain on different post-operative days was noted using VAS (visual analogue score). [16]
 - Analgesic requirement (IV or Oral) was noted.
 - Examine the surgical site for assessment of port site complication on different post-operative days.

Data collection

All data collected on pre-designed Proforma.

Data Compilation and analysis

The data transferred on Excel sheet.

- All statistical analysis done on advanced excel and relevant tools.
- Statistical analysis using SPSS-23 data analysis software & Chi square test.

Ethical Clearance

The ethical clearance was taken from Institutional Ethics Committee, HIMS before the commencement of the study. Written informed consent obtained from each study subject before enrolment.



Figure 1: Preparation of Indigenous Drain Bag

RESULTS

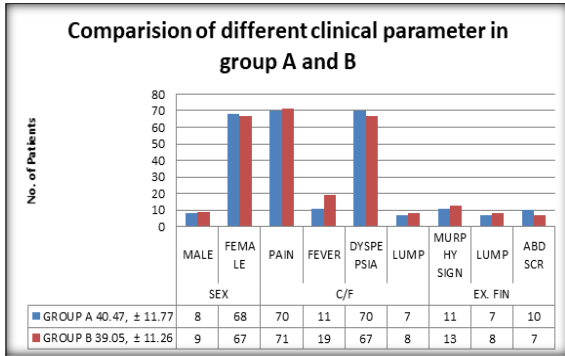


Figure 2: Comparison of different clinical parameter in group A and B

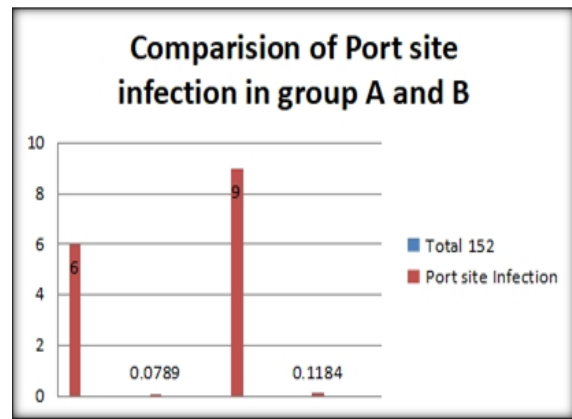


Figure 4: Comparison of Port Site Infection in Group A and B

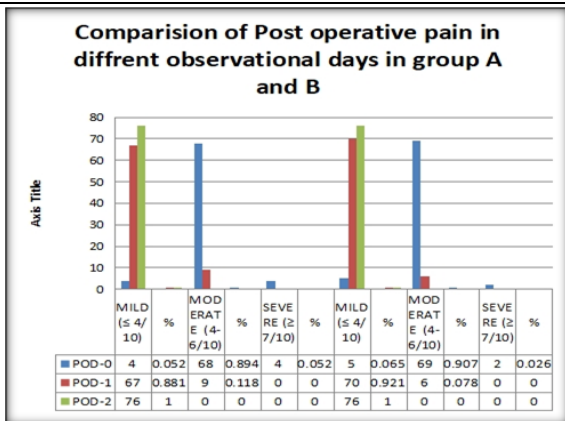


Figure 3: Comparison of Post-Operative Pain in Different Observational Days

Table 1: Clinical parameter in Group A and Group B patients

		GROUP A		GROUP B	
Mean Age with SD		40.47, ± 11.77	%	39.05, ± 11.26	%
Sex	Male	8	10.52%	9	11.84%
	Female	68	89.47%	67	88.15%
C/F	Pain	70	92.11%	71	93.42%
	Fever	11	14.47%	19	25.00%
	Dyspepsia	70	92.11%	67	88.16%
	Lump	7	9.21%	8	10.53%
Exam. Find.	Murphysign	11	14.47%	13	17.11%
	Lump	7	9.21%	8	10.53%
	Abdominal Scar	10	13.16%	7	9.21%

Table 2: Comparison of Different Port Site Complication in Group A and B

Total 152	Group "A" (76)						Group "B" (76)						P Value																																																																			
Port site Infection	6			7.89%			9			11.84%			0.03																																																																			
Port site Pain	MILD (≤ 4/10)	%	MODERATE (4-6/10)	%	SEVERE (≥ 7/10)	%	MILD (≤ 4/10)	%	MODERATE (4-6/10)	%	SEVERE (≥ 7/10)	%	0.00056																																																																			
														POD-0	4	5.26%	68	89.47%	4	5.26%	5	6.57%	69	90.78%	2	2.63%	POD-1	67	88.15%	9	11.84%	0	0	70	92.10%	6	7.89%	0	0	POD-2	76	100%	0	0	0	0	76	100%	0	0	0	0	Late complication														Hernia	NONE						NONE						Sinus
	POD-0	4	5.26%	68	89.47%	4	5.26%	5	6.57%	69	90.78%	2		2.63%																																																																		
	POD-1	67	88.15%	9	11.84%	0	0	70	92.10%	6	7.89%	0		0																																																																		
POD-2	76	100%	0	0	0	0	76	100%	0	0	0	0																																																																				
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DISCUSSION

This study was carried out in the department of general surgery, Hind Institute of Medical Sciences, Barabanki, Uttar Pradesh. It involved 152 patients with symptomatic gallstone disease who were divided into two groups (A and B). In group A, the gallbladder was recovered using a retrieval bag, whereas in group B, the gallbladder was retrieved without a retrieval bag. Out of the total patients, 83 (54.6%) fell within the age range of 20-40 years, while 69 (45.39%) fell within the age range of 40-60 years. The average age of the patients was 39.11 ± 12.36 .

The average age of patients in our study was 40.47 ± 11.77 years in group A and 39.05 ± 11.26 years in group B. The study conducted by Qassem Mohamed et al,^[17] found that the average age of participants in group A was 41.34 ± 11.73 years, whereas in group B it was 42.96 ± 10.53 years.

In our study, the female population consisted of 135 individuals, accounting for 88.81% of the total, while the male population consisted of 17 individuals, accounting for 11.18% of the total. These proportions are consistent with findings from earlier studies. This study has highlighted that cholelithiasis is more prevalent in females. The findings of Dr. Jogendar Pal Singh Shakyet al,^[18] showed that out of 100 patients with symptomatic cholelithiasis, 92% were female and 8% were male. In this study, 141 out of 152 patients (92.76%) reported experiencing abdominal discomfort, followed by 137 patients (90.13%) reporting dyspepsia, 30 patients (19.73%) reporting fever, and 15 patients (9.8%) reporting an abdominal lump. Similar findings were obtained by Renu Pimpale et al,^[19] who reported that pain was present in all patients (92 out of 92, or 100%), dyspepsia in 61 patients (66.30%), and fever in 19 patients (20.65%). Although none of them had an abdominal mass.

Among the 152 patients included in our study, 111 individuals did not have any co-morbidities. Of the remaining patients, 14 (9.21%) had diabetes, 15 (9.86%) had hypertension, 5 (3.28%) had COPD, and 7 (4.60%) had hypothyroidism. While diabetes is recognised as a risk factor for wound infection, our investigation did not discover a significant correlation between diabetes and PSI ($P=0.207$). An explanation for this finding is that all of our patients underwent comprehensive evaluations, and rigorous glycemic control was maintained perioperatively. Port site infection is also linked to co-morbidities such as uncontrolled diabetes, hypertension, COPD, and hypothyroidism. In a study conducted by V. K. Sheeba Mariyam et al,^[20] it was also noted that there was no statistically significant association between diabetes mellitus and other co-morbidities and PSI.

In our study, we found that 15 out of 152 patients (9.86%) experienced port site infection. Among

these, 6 patients (7.89%) were in group A and 9 patients (11.84%) were in group B. The p-value was 0.03, indicating statistical significance. This finding is consistent with a study conducted by Khurshid et al. who observed a port site infection rate of 6.7%. Our results were higher than those reported by Jasim Saud et al,^[21] who found a port site infection rate 2.4%.

CONCLUSION

The current study was carried out at the Department of General Surgery, Hind Institute of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh. The aim was to compare the occurrence of port site infection, level of pain, and duration of hospital stay after laparoscopic cholecystectomy in patients with and without the use of a retrieval bag for specimen extraction. The study comprised a total of 152 patients. These are the findings of the study:

- 1) In our study, out of 152 patients 83(54.6%) the patients were between 20-40 years and 69(45.39%) patients were between 40-60 years with mean age of 39.11 ± 12.36 .
- 2) Majority of patients were females, 135 (88.81%) out of 152 patients.
- 3) More than half of the present with history of or complaints of pain in abdomen and dyspepsia with and without fever and abdominal lump.
- 4) In our study half of the patients (50%, Group-A) gall bladder retrieval done with the use of indigenous retrieval bag and half of the patients(50%, Group-B) gall bladder directly extracted in laparoscopic cholecystectomy
- 5) In this work, we utilised sterile drain bags for the extraction of the gall bladder. These drain bags are manufactured from sterile plastic packings that enclose drain tubes. They are often used in surgical operations to collect bodily fluids.
- 6) Out of the 152 patients, we observed port site infection in 15 patients, which accounts for 9.86% of the total. Among these, 6 patients (7.89%) were from group A, while 9 patients (11.84%) were from group B. The p-value associated with this observation is 0.03, indicating statistical significance.
- 7) Based on the findings, it is evident that using an endogenous drain bag for gallbladder extraction is superior to directly extracting the gallbladder. This is because it effectively prevents port site infection and significantly reduces the risk of spillage of stones and bile. Additionally, using an indigenous drain bag does not require any additional time during surgery or prolong the hospital stay.
- 8) Gall bladder retrieval with endogenous drain bag technique cause of more postoperative pain in comparison to removal of gall bladder without use of endogenous drain bag due to more manipulation and require to increase

length of incision but it is statically significant(pvalue-0.0005)

- 9) None of the patients presented with late port site complications port site hernia and sinus.
- 10) In our study culture and sensitivity finding of patients presenting with port site discharge isolated organism are staphylococcus aureus, enterococcus, E.coli and atypical mycobacteria.

On the basis of above mention findings, it can be concluded that extraction of gall-bladder with the use of endogenous retrieval bag prevent port site infection due to decrease in contamination of bile and stone as compared to direct extraction but use of endogenous retrieval bag leads to more post-operative pain as compare to direct extraction due to more manipulation and require to increase the length of facial incision.

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Conflicts of interest statement: Nil.

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