Publisher
MEDRESEARCH
www.medresearch.in

Surgical Review: International Journal of Surgery, Trauma and Orthopedics

2020 Volume 6 Number 3 May-June

E-ISSN:2455-5436
P-ISSN:2456-9518
RNI:MPENG/2017/70870

Research Article
Laparoscopic

Comparative study of Port site infection after gall bladder retrieval using indigenously designed endo-bag and without using endo-bag in Laparoscopic Cholecystectomy.

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DOI: https://doi.org/10.17511/ijoso.2020.i03.04

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Background: Laparoscopic Cholecystectomy is the most common minimally invasive surgical procedure performed worldwide to remove the diseased gallbladder and also the gold standard in the treatment of symptomatic gallstone. The study aims at assessing the comparative utility of indigenously designed endo-bag for gallbladder specimen extraction to prevent infection of the port site in laparoscopic cholecystectomy by using and without using a bag. **Material and Method:** This randomized prospective study was conducted on fifty patients included using random sampling. A predesigned and validated proforma was used to record the clinical data. Indigenously designed endo-bag made of the sterile surgical glove was used for gall bladder specimen retrieval and the epigastric port was used as retrieval port. **Results:** In the present study, 50 patients who underwent surgery only 1 patient was obese with a BMI of 32.38 mg/kg^2. The incidence of PSI in patients who underwent the procedure using a bag was 4% whereas it was 8% in patients without a bag. Distribution of appearance of port site infection in relation to various observational days, it was found that patients, where procedure was performed using bag, at day 3 one patient (4%), had PSI. **Conclusion:** The incidence of infection at the port site was more among the patients where endobag was not used in comparison to those undergoing extraction with endobag.

Keywords: Laparoscopic cholecystectomy, port site infection, endo-bag, gall bladder

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How to Cite this Article

Vergadia A, Diwakar A, Datey A. Comparative study of Port site infection after gall bladder retrieval using indigenously designed endo-bag and without using endo-bag in Laparoscopic Cholecystectomy.. Surgical Review Int J Surg Trauma Orthoped. 2020;6(3):159-165.
Available From https://surgical.medresearch.in/index.php/ijoso/article/view/189

To Browse

Manuscript Received	Review Round 1	Review Round 2	Review Round 3	Accepted
10-06-2020	20-06-2020	25-06-2020		29-06-2020

Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
No	Nil	Yes	16%	

Introduction

The gallbladder is a pear-shaped reservoir underneath the liver that concentrates and stores bile. Its the fluid secreted by the liver and released into the small intestine that helps indigestion.

Alteration in diet, hormones, medications, or rapid weight loss or gain leads to changes in the composition and concentration of bile that results in gallbladder disease like gallstones, cholecystitis, choledocholithiasis, gallbladder cancer, etc. These can cause sharp, constant abdominal pain, fever, nausea, and vomiting, jaundice [1].

Cholecystectomy with lap approach is the most common minimally invasive surgical procedure performed worldwide to remove the diseased gallbladder. It is the gold standard in the treatment of symptomatic gallstone because of less postoperative pain, early recovery, short hospital stay, and cosmetically small scarring comparison with open surgery [2].

Laparoscopic cholecystectomy may be performed by single or up to four-port (5,10 and 11mm size) technique depending on the surgeon. Camera and instruments are introduced into the body through the trocar. Proper positioning of instruments (railroading) and orientation are required for retrieval of gallbladder specimens [3].

Cholecystectomy if done laparoscopically has gall bladder perforation, stone spillage, and biliary injury as common complications that mainly occurs while its dissection from hepatic bed resulting in spillage into the peritoneal cavity. The incidence reported ranges from 10% to 40% for perforation and from 6% to 30%for the spilling of the contents [4].

Irrigation and suctioning in cholecystectomy with an open approach helps remove spilled stones but this method may be difficult to achieve in the laparoscopic scenario. Spillage may cause complications like the abdominal wall, port site, and intra-abdominal abscesses most commonly observed in subhepatic locations [5].

The use of endobag is usually done for the retrieval of the gallbladder during the laparoscopic approach for decreasing the stone spillage complications.

Gallbladder distended with stones always creates problems in retrieval so needle decompression, fragmentation, or increase in the fascial incision to facilitate retrieval, cause postoperative pain at the Port site. An improvised endobag made from the cuff of a surgical glove has been used [5].

The present study is a comparative assessment of the utility of indigenously designed endo-bag for gall bladder specimen extraction in cholecystectomy with a laparoscopic approach with and without the use of endobag.

Material and methods

Study Design/Study Type: a randomized prospective study

Study place and Source of data: IPD patients willing laparoscopic cholecystectomy at surgery department in PCMS and RC.

Duration of the study: 2017-2020

Sample size: 50 patients.

Grouping: 50 patients were randomly divided into two groups; Those using endobag (group A;n=25) and those without using a bag (group B; n=25) for gallbladder extraction.

Inclusion criteria: All patients of symptomatic cholelithiasis willing for cholecystectomy with the laparoscopic approach

Exclusion criteria: Gall bladder gangrene, pyocele perforation, immunocompromised patients like AIDS, Ca GB, steroid, and any comorbid condition like diabetes mellitus and uremia.

Brief description of the technique

01. Indigenous endo-bag was made by tieing the finger end of sterile surgical glove and cutting the distal part so as to create a pouch and then with the help of grasper through 10mm epigastric port bag is introduced in the peritoneal cavity.
02. Gall bladder specimen was collected in the bag and withdrawn using the grasper from the epigastric port.

Apparatus and materials: Endobag is made using the sterile surgical glove for gall bladder specimen retrieval.

Data collection procedure

- This is a randomized trial in which patients are distributed in two groups A and B. In group A patients gall bladder specimens were retrieved with the use of endobag made of sterile surgical gloves.

- In group B patient's gall bladder specimen was removed without using endo-bag. In both, the group gall bladder was retrieved via the epigastric port.
- The port site was examined on a postoperative day three for any sign of wound infection like redness, induration, pain, and swelling, or any discharge.
- Follow up was done for any late infection. Injection cefuroxime 1gm intravenous as prophylaxis and postoperatively twice a day for 3 days was used.
- CTRI approval: The study protocol was submitted and approval was taken from the Clinicals trial research. The Registration number for this trial is CTRI/ 2018/09/015634.

Statistical analysis: All the data analysis was performed using IBM SPSS ver. 20 software. Frequency distribution and cross-tabulation used to prepare the tables. Categorical data were expressed as a percentage.

PRISM and Microsoft office was used to prepare the graphs. A Chi-Square test was used to compare the categorical data. P-value of < 0.05 is considered as significant.

Results

Table 1: Gender distribution in the study cohort.

Gender	No of patients	Percent
Female	31	62.0
Male	19	38.0
Total	50	100.0

In the present study, laparoscopic cholecystectomy was mostly done in females (62%) as compared to males (38%).

Table-2: Distribution of patients according to endobag usage.

Bag status	Frequency	Percent
Without Bag	25	50.0
With Bag	25	50.0
Total	50	100.0

In the present study, patients were divided based on the use of endobag

25 patients underwent cholecystectomy with the laparoscopic approach using Bag and 25patients without the bag

Table-3: Incidence of post site infection in laparoscopic cholecystectomy using endobag.

No of patients (n=25)	Incidence
1	4%

The incidence of infections at the port site (PSI) in patients who underwent lap cholecystectomy using a bag was 4%. This means out of 25 patients who underwent using a bag, one patient had PSI.

Table-4: Incidence of PSI in laparoscopic cholecystectomy without endobag.

No of patients (n=25)	Incidence
2	8%

The incidence of infections at the port site (PSI) in patients who underwent laparoscopic cholecystectomy without a bag was 8%. Means out of 2, two patients had PSI.

Table-5: Incidence of PSI in laparoscopic cholecystectomy with or without endobag.

PSI	Bag status		Total	P-value
	No	Yes		
No	23 (92)	24 (96)	47 (94)	0.002
Yes	2 (8)	1 (4)	3 (6)	

Out of 3 patients who had PSI, 1 (4%) underwent laparoscopic cholecystectomy with a bag whereas 2 (8%) underwent without a bag (p=0.002).

Table 6: Distribution of appearance of infection of pot site in relation to various observational days (group A; with Bag).

Signs	Pre-operative	3rd POD	7th POD	14th POD	28th POD	P-value
Total no of patients	25	25	25	25	25	0.251
Incidence of SSI	0 (0)	1 (4%)	0 (0)	0 (0)	0 (0)	

Distribution of appearance of infection of the port in relation to various observational days, it was found that patients, where lap cholecystectomy was performed using the bag, at day 3 one patient (4%), had PSI (p=0.251).

Table-7: Distribution of appearance of port infection in relation to various observational days (group B; without Bag).

Signs	Pre-operative	3rd POD	7th POD	14th POD	28th POD	P-value
Total no of patients	25	25	25	25	25	0.334
Incidence of SSI	0 (0)	2 (8)	0 (0)	0 (0)	0 (0)	

Distribution of appearance of infection at port site in

Relation to various observational days, it was found that patients where laparoscopic cholecystectomy was performed without the bag, at day 3, two patients (8%) had PSI (p=0.334).

Table-8: Post-operative hospital stay.

Bag status	Hospital stay		P-value
	3 days	5 days	
Without bag	0	2	0.168
With bag	0	1	

In the present study, 2 patients where laparoscopic cholecystectomy was performed without bag had a hospital stay of 5 days were among the patients where the procedure was done with the bag, 1 patient had a hospital stay of 5 days. That means patients who underwent cholecystectomy without endobag had similar hospital stays as compared to those where the bag was used. This is insignificant with a p-value of 0.168.

Table-9: Type of port site infection.

Bag status	Superficial PSI	Deep PSI	P-value
With bag	1 (n=25)	0	0.121
Without bag	2 (n=25)	0	

In the present study, 1 patient with bag had Superficial PSI whereas 2 patients without bag had Superficial PSI. None of the patients in any group had Deep PSI. That means patients who undergo laparoscopic cholecystectomy without endobag had a similar superficial infection in comparison to those where the bag was used. This is not significant with a p-value of 0.121.

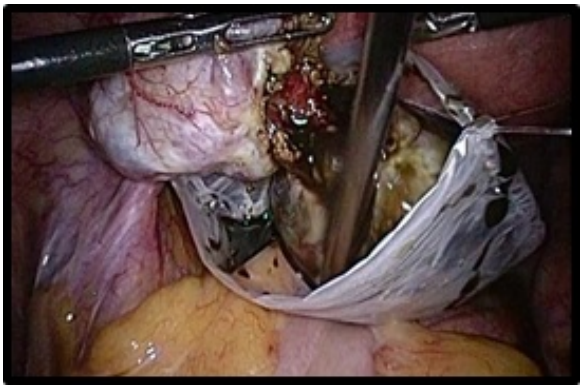

Fig-1: Laparoscopic cholecystectomy in EndoBag "No-Spill Technique".

Discussion

Currently, more than 80% of gallbladder procedures are laparoscopically performed [6]. During the laparoscopic procedure, it's difficult and even time-Consuming to extract gallbladder. Spillage of infected bile and stones in the peritoneal cavity and retrieval port site with implanted stone in the subcutaneous tissues of the abdominal wall cause discharging sinus or abscess as a complication [7]. In order to avoid contamination of the port site from bile and stone spillage, surgeons do not open the gallbladder during dissection from the liver bed and retrieval from the abdominal cavity.

Depending on the choice of surgeon, a retrieval bag is used to extract the gallbladder through a trocar incision [8]. Endobag should be used when gall bladder cancer is suspected, in order to minimize the risk of tumor cell dissemination [9] and in case of acute cholecystitis to avoid spillage of infected bile, stones or pus [10] As a matter of fact, endoscopic bags are commonly used also in elective cholecystectomy despite increased costs and no sound evidence in their favor.

In the present study, laparoscopic cholecystectomy was mostly done in females (62%) with comparison to males (38%). PSIs are responsible for increased length of hospital stay and care costs. Diabetes, mal-nourishment, male gender, anemia, obesity, drug abuse, smoking-related diseases, and previous Staphylococcus aureus infection were reported in several studies as risk factors for SSIs after gall bladder surgery.

The incidence of infection at the port site is quite low in cholecystectomy with lap approach, it may be due to contamination with the contents of the gallbladder or bacteria present on the patient's skin but its unclear. In the present study, the incidence of PSI in patients where laparoscopic cholecystectomy was done without a bag was 8%. In the case of acute gall bladder infection, many authors recommend the extraction of the gallbladder in a bag as spillage of infected bile, stones or pus causes infection of the port site [11,12].

Even if the use of a retrieval bag in the above-mentioned situations seems justified, there is no strong evidence to support its use in elective surgery. A meta-analysis by Regina et al its found that there is no statistically significant reduction in infection rate when the extraction of the gallbladder was done from the abdominal cavity with a retrieval bag [13].

In a similar study by Kuldip Sing et al involving 100 patients after dividing them into 2 groups with 50 patients in each on the basis of a draw after surgical

Assessment and confirming the diagnosis of cholelithiasis reported that in patients using endobag 1 (2%), the patient had an infection of the port site and 4 (8%) patients without endobag [14]. Kadhim et al evaluated the effectiveness and incidence rates of port and intraperitoneal infections when using a sterile male condom as an endobag for extraction of gallbladder specimens and spilled gallstones reported that no intraperitoneal nor port site infections.

A.I. Memon et al [15] reported retrieval port site infection 5 % of their patients despite using endobag. Ali Sa et al [16] and Helme et al [17] showed that the best way to avoid complications of spillage and port site contamination is to use endobag. Turk E et al [18] study had an infection rate of 1.1% despite the use of Cefazolin Prophylaxis. Wound infections can be prevented by administrating antibiotics, aseptic techniques, and the use of endbags for specimen extraction [19]. Endobag facilitates the collection of operative specimens, spilled stones, and decreases the chance of contamination of the abdominal cavity and the retrieval port site.

Golash in his series of 772 patients of Laparoscopic cholecystectomy retrieved the gall-bladder specimen through the umbilical port without using endobag, hence reported a high incidence of infection and gall-stone spillage. According to the "Guidelines for the Laparoscopic Application of Clinical Biliary Tract Surgery? of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the use of an endobag is left at the discretion of the operating surgeon [20].

In the present study out of 3 patients who had PSI, 1 (4%) patients underwent laparoscopic cholecystectomy with a bag whereas 2 (8%) without a bag. The statistical analysis showed a significant difference between the incidence of PSI as reveled by the p-value of 0.002. Majid et al reported that a bag was not used to retrieve the gallbladder in 41% ($n = 152$) patients compared to 69% ($n = 221$) in whom it was used out of 373 total patients undergoing planned elective daycare laparoscopic cholecystectomy.

Distribution of appearance of port site infection in relation to various observational days, it was found that patients where laparoscopic cholecystectomy was performed using a bag, at day 3 one patient (4%). and without bag 2 patients (8%) had PSI. Another previous similar study collected one year

Follow up data for 51.5% ($n = 192$) of patients with the remaining 48.5% ($n = 181$) not returning to their 1year follow up appointment and found that no Post site infection among the patients using bag compared to 2 patients whom the bag was not used.

In the present study, 2 patients where laparoscopic cholecystectomy was performed without bag had a hospital stay of 5 days were among the patients where it was performed with the bag, 1 patient had a hospital stay of 5 days with a mean hospital stay of 3.88 days. In a similar study by Kuldip Singh et al, the minimum hospital stay was one day and max stay was three days in patients using endobag with a mean hospital stay of 2.52 days and the minimum hospital stay in patients without endobag was two days and max stay was four days with a mean hospital stay of 2.94 days [21].

In the present study, 1 patient with bag had Superficial PSI whereas 2 patients without bag had Superficial PSI. None of the patients in any group had Deep PSI. Majid et al 373 patients undergoing planned elective day-case laparoscopic cholecystectomy and found that there were nine (2.4%) recorded wound infections during the study, with the vast majority being superficial wound infections (78%,$n = 7$). Of the patients presenting with superficial infections, 57% ($n = 4$) were in patients in whom retrieval bag was not used and the remaining 43% ($n = 3$) in patients where a bag was used [2]. The present study is not devoid of the limitation, small sample size and cross-sectional nature was the main one. A large randomized clinical trial is needed to provide strength to present study findings.

Limitations

Small sample size. Non-probability criteria for sampling have limitations for the generalizability of the study results and also the small sample size has led to limited results.

Conclusion

Based on present study findings it can be concluded that endobag should be used for the extraction of the gallbladder as it better than the direct extraction of the gallbladder to prevent post site infection however the comparison was significant. Previous authors have also advocated for using endobag as it prevents spillage of stones and bile. It also reduces the incidence of port-site infection, without taking

Any additional time during surgery or prolonging the hospital stay. The previous series have to decrease the cost of endobag used.

In this study, we used a common surgical glove to reduce the cost of it. Hence using endobag is a simple and cost-effective alternative.

What does the study add to the existing knowledge?

The present study makes the conclusion that when laparoscopic cholecystectomy is done the gallbladder retrieval using an endobag has a better advantage over not using the bag as it prevents spillage and also the incidence of PSI is comparative less.

Author's contribution

Dr. Ankita Vergadia, Dr. Arvind Diwakar, Dr. Ashirwad Datey designed the present study. **Dr. Ankita Vergadia** reviewed the literature, collected all data, performed the statistical analysis, and drafted the manuscript. All the authors have reviewed and edited the manuscript.

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