

Frequency of port site wound infection after Gall Bladder removal with or without retrieval bag in Laparoscopic Cholecystectomy

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Abstract

Objective: The rationale of the study was to depict the safest method of extracting gallbladder after laparoscopic cholecystectomy to decrease the frequency of wound infection. The objective of the study was to compare the frequency of port site wound infection after gallbladder removal with or without retrieval bag in laparoscopic cholecystectomy.

Methods: The study design was Randomized Parallel group design conducted in the Department of Surgery, Bahawal Victoria Hospital, Bahawalpur. A total of 254 patients of both gender age range 25-60 years, diagnosed as a case of cholelithiasis by ultrasonography were included. Case sheet of patients were prepared for age, gender, duration of cholelithiasis, operating time and presence or absence of wound infection.

Results: Mean age of patients was 40.77 ± 10.95 years. Out of 254 patients, 98 (38.58%) were males and 156 (61.42%) were females with male to female ratio of 1:2.5. Patients were divided in two groups A and B and the frequency of patients having port site wound infection in group A was 1(0.4%) whereas in group B was 14(5.5%).

Conclusion: This study concluded that the use of retrieval bag to remove gallbladder in laparoscopic cholecystectomy resulted in decreased frequency of port site wound infection. The insignificant association of port site wound infection with different age groups, gender categories and with duration of cholelithiasis was revealed. Moreover wound infection proved significantly associated with both categories with operating time.

Keywords: Cholelithiasis, wound infection, laparoscopic cholecystectomy
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Introduction

The gallbladder is a pear-shaped organ lying on the visceral inferior surface of the liver.¹ Gallstones are considered to be the most common biliary pathology. It is estimated that gallstones affect 10-15% of the population in western societies.² In the US, more than 700,000 cholecystectomies are performed each year,³ making cholecystectomy one of the most widespread surgical procedures. Currently the prevalence rate of cholelithiasis varies from 10–15% in western countries and 3–4% in Asian populations.⁴ In Pakistan, gallstones are found in 8% and 20% of patients above 40 and 60 years respectively.⁵ Gallstones are solid pieces of stone like debris formed from bile. More than 80% of gallstone carriers are unaware of their gallbladder disease⁶ being detected incidentally when imaging is performed for other symptoms. Gallstone disease (GSD) has the most prevalent inpatient diagnosis among gastrointestinal and liver diseases in the US.⁷ Prevalence of cholelithiasis has been found to be 3–11% in China,⁸ 7.1% in Northern India⁹ and 5% in Taiwan¹⁰. Data from Pakistan is still insufficient, however, previous study has found the surgical incidence of 9.03% from southern Sindh area of Pakistan.¹¹

The first laparoscopic cholecystectomy was performed in 1986 by Eric Mühe¹² and after a few years it became the “Gold standard” for elective treatment of symptomatic gallstone disease.¹³ A National Institute of Health consensus statement in 1992 reported that laparoscopic cholecystectomy provided a safe and effective modality for most patients with symptomatic gallstones and has become the treatment of choice for many patients.¹⁴ The reasons elicited were decreasing postoperative pain, decreasing the need for postoperative analgesia, shortening the hospital stay from 1 week to less than 24 hours, and returning the patient to full activity within 1 week (compared with 1 month after open cholecystectomy).¹⁵ Laparoscopic cholecystectomy, having definite benefits, was readily accepted and adopted by surgeons worldwide and became the new gold standard for the treatment of cholelithiasis.¹⁶

The incidence of GSD has ranged from 5.2 to 10% in African populations,¹⁷ 3.1 to 6.1% in Asian population¹⁷ and 6.3% in Iranian population.¹⁸ The data from Pakistan was found to be scarce, but a study in southern Sindh area of Pakistan depicted a surgical incidence of 9.03%;¹⁹ particularly a prevalence rate of 4% in males and 14.2% in females of Pakistan.¹⁹

Any surgical procedure conducted has some risks and complications. Large series documented a reduced incidence of port site infection and other wound-related

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complications following laparoscopic surgeries but spillage of bile is more common with laparoscopy as compared to open procedures.²⁰ Certain situations lead to higher risk of gallbladder perforation during laparoscopic cholecystectomy like acutely inflamed gallbladders having friable tissue and distended gallbladder that has not been decompressed.²¹ Spilled stones are also caused by the slipping of the cystic duct clip or the tearing of the gallbladder while it is retrieved from the port site.²²

Surgical-site infection requires microbial contamination of the surgical wound. The microorganisms may originate from either endogenous or exogenous sources. Sources of endogenous flora include the patient's skin, mucous membranes, or hollow viscera. Exogenous flora originate from any contaminated items on the sterile surgical field including surgical team members, instruments, air, or materials.²³ Wound infection manifests with varying degrees of abdominal pain, with or without signs of peritoneal irritation, nausea, vomiting, or anorexia and can present with empyema²⁴ or non-healing fistulae. The conventional method for the removal of the gallbladder is associated with higher incidence of infection.²⁵ The infected gallbladder can be removed in endobag to prevent wound infection and spillage of stones and for the occult malignancy in the gallbladder. Therefore in this study, gall bladders were successfully retrieved from the abdominal cavity using an improvised 'endobag' made from a simple surgical glove in order to recommend more effective method of retrieving gallbladder in laparoscopic cholecystectomy. Conventional endobags are expensive, therefore, in our country improvised endobags are used in some clinical settings to avoid financial burden. However, its use is not a common practice in many setups. Our study emphasizes that its routine use in all clinical settings can decrease the frequency of wound infection remarkably. Primary Outcome Measure of study is comparing frequency of port site wound infection in both groups, with and without endobag. Secondary Outcome Measure is exploration of the two way and post stratified associations of effect modifiers (Age, Gender, Duration of Cholelithiasis and operative time) with response variable, i.e, wound infection.

Methods

This is a Randomized Parallel group design, a comparative study of two groups of patients having undergone two different procedures, conducted at Department of Surgery, Bahawal Victoria Hospital, Bahawalpur during 1st January 2017 to 31st December 2017 with the approval of ethical review committee. Patients were enrolled in the study by consecutive sampling technique with particular inclusion and exclusion criteria, the subjects were selected on the

basis of first come first chosen. All participants who met the eligibility criteria were included as they were found. A sample size for this parallel groups study was estimated using (Open-Epi) version 2.3.1 online software. The estimated sample was 254 assuming ratio 1:1 with a probability of a type 1 error set at 5% and statistical power of 80%. Appropriate sample size of total 254 patients was determined with sample size $n = 127$ in each group fulfilling the inclusion criteria were included in the study after taking informed written consent. In this study participants were randomly allotted to get into group A and group B to study outcome variable. Method of block randomization was planned to randomize participants into two groups of equal sample size. Sample size was balanced in both groups/blocks. Random numbers from random numbers table was used to generate the random allocation sequence. Subsequently groups/blocks were randomly chosen to assign the participants into the groups to study outcome variable. Potential bias can arise due to the prior knowledge of group assignment. But in this study because of proper randomization, participants were not aware about the groups to which a participant will be assigned. Primary investigator of study generated the random allocation sequence, enrolled and assigned participants to both groups. Group A (with a retrieval bag) and the Group B (without a retrieval bag) was the standard practice. In Group A, Laparoscopic cholecystectomy was performed and their gallbladder was removed with the retrieval bag. In Group B, Laparoscopic cholecystectomy was performed and their gallbladder was removed without a retrieval bag.

Case sheet of patients was prepared for age, gender, group allotment, duration of cholelithiasis, operating time & wound infection. Postoperatively the first dressing was changed on the 4th day and Stitches were removed after 8 days of surgery according to local guidelines. Follow up of the patients for wound care was done for 2 weeks and final outcome i.e. wound infection (port site) was noted. All the data were recorded along with a demographic profile of the patients on a pre-designed Performa.

Continuous variables were described using mean and standard deviation, while categorical variables were specified as percentages and frequencies. Initially association of variables with port site wound infection has been verified by chi-square test. The wound infection of the two study groups was compared for the difference. P-value ≤ 0.05 of chi-Square test was considered significant to compare wound infection in both groups. Effect modifiers like age, gender, duration of Cholelithiasis and operating time were stratified and post-stratification chi-square was applied with the same level of significance. All the statistical analysis was performed by using Statistical software SPSS

version 20.

Inclusion Criteria: Patients of both gender between age 25 and 60 diagnosed as a case of cholelithiasis on ultrasonography abdomen describing gallstones as one or more hypodense shadows in the gallbladder, either on the first visit to the surgical outpatient department or subsequently with duration of cholelithiasis from one month to two years. Patients fulfilling inclusion criteria were included in the study to undergo cholecystectomy.

Exclusion Criteria: Patients having one of the following criteria were excluded from the study: Acute cholecystitis confirmed by ultrasonography abdomen; Empyema or mucocele gallbladder; Patients with deranged liver function tests.

Results

Figures I-IV presented percentage of participants according to age, gender, and frequency of port site wound infection, and gender distribution in patients with port site wound infection. The age range in this study was from 25 to 60 years with a mean age of 40.77 ± 10.95 years. Majority of the patients i.e. 107 (42.12%) were between 25 to 35 years of age as shown in Figure I. Out of 254 patients, 156 (61.42%) were females and 98 (38.58%) were males with

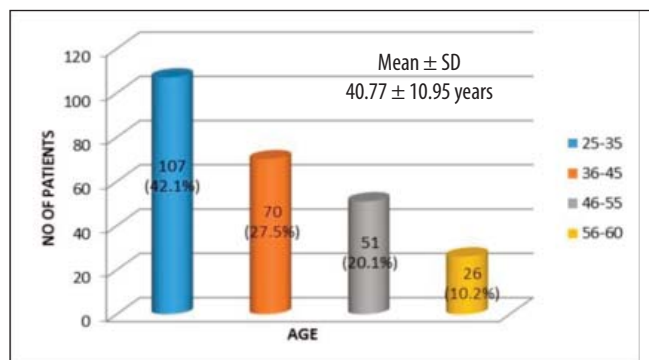


Figure-1: percentage of participants according to Age distribution (n=254).

female to male ratio was 2.5:1 (Figure II). Mean duration of

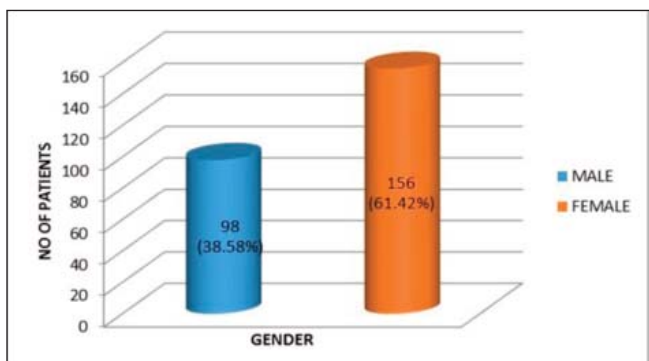


Figure-2: percentage of patients according to Gender (n=254).

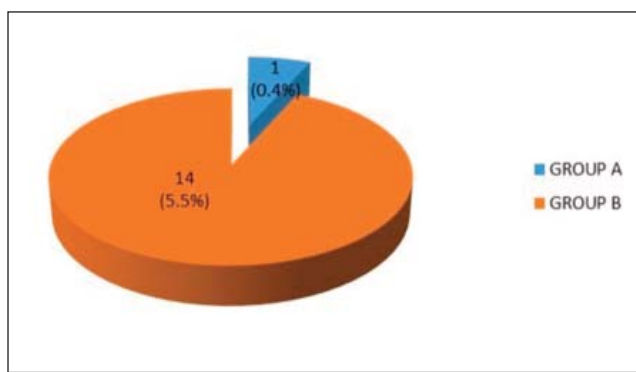


Figure-3: Frequency of port site wound infection (n=254).

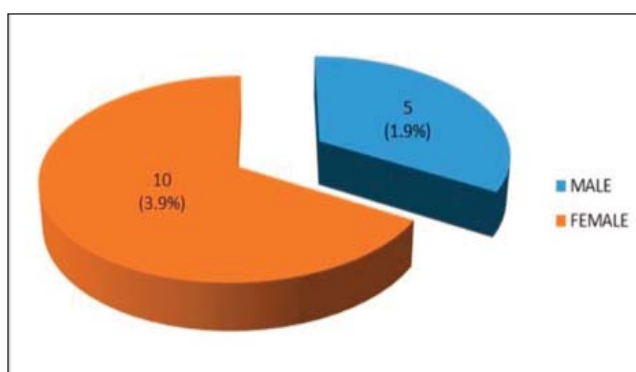


Figure-4: Gender distribution in patients with port site wound infection.

Cholelithiasis was 16.79 ± 6.23 months. Mean operation time was 43.28 ± 9.51 minutes. The number of patients having port site wound infection in group A was 1(0.4%) whereas in group B was 14(5.5%) as shown in Figure 3. Out of 98 male patients, 5(1.9%) patients had port site wound infection while out of 156 female patients, 10 (3.9%) patients had port site wound infection (Figure 4). Stratification of wound infection with respect to age group, gender, duration of cholelithiasis and operative time is shown in Tables 1-4 respectively. In further analysis of categories, Age of patients, age group (25-35) has revealed significance with p-value = 0.04. The female group

Table-1: Stratification of wound infection with respect to age groups.

Age of patients (years)	Group A (n=127)		Group B (n=127)		p-value
	Wound infection		Wound infection		
	Yes	No	Yes	No	
25-35	00	53	04	50	0.043
36-45	01	36	04	29	0.127
46-55	00	25	03	23	0.080
56-60	00	12	03	11	0.088

Table-2: Stratification of wound infection with respect to gender.

Gender	Group A (n=127)		Group B (n=127)		p-value
	Wound infection		Wound infection		
	Yes	No	Yes	No	
Male	01	47	04	46	0.183
Female	00	79	10	67	0.001

Table-3: Stratification of wound infection with respect to the duration of Cholelithiasis.

Duration of Cholelithiasis	Group A (n=127)		Group B (n=127)		p-value
	Wound infection		Wound infection		
	Yes	No	Yes	No	
1-6 months	00	57	04	51	0.038
7-12 months	01	39	05	37	0.102
13-18 months	00	21	02	20	0.157
19-24 months	00	09	03	08	0.089

Table-4: Stratification of wound infection with respect to operative time.

Operative time	Group A (n=127)		Group B (n=127)		p-value
	Wound infection		Wound infection		
	Yes	No	Yes	No	
≤1 hour	01	88	13	73	0.001
>1 hour	00	38	06	35	0.014

appeared significant with p value= 0.001 among A and B group, whereas the male group appeared insignificant with p value= 0.183 among A and B group. That means Male group had no association with wound infection. Among categories of Duration of Cholelithiasis, category of (1-6 months) appeared significant with p value= 0.038. This shows that patients having 1-6 months of duration of cholelithiasis have more chances of infection as compared to greater than 6 months of cholelithiasis duration. Both categories of operating time ≤1 hour and >1 hour resulted as a significant variable with p-value = 0.001 and 0.014 respectively.

Discussion

This study was conducted in the department of surgery, Bahawal Victoria hospital Bahawalpur on 254 patients being entered into two groups A and B in which gallbladder was removed with and without retrieval bag respectively. In our study, mean age was 40.77 ± 10.95 years which is very much comparable to the study of Taj MN et al²⁵ and Mir M et al²⁶ who also observed mean age of 46 and 43 years respectively. Also Raj PK et al²⁷ in their study found comparable mean age i.e. 36 years. In our study, the number of females suffering from cholelithiasis was higher than males with a ratio of 2.5:1 which correlates with many previous studies.²⁵⁻²⁷ . So, this study has accentuated that cholelithiasis was more common in females. We found that majority of patients underwent laparoscopic cholecystectomy were females (61.42%) in comparison with males (38.58%), also most of our patients with port site infection were females (3.9%) in comparison with males (1.9%). These results are consistent with another study done in Al-Basrah hospital on 369 patients, 301 (81.57%) of them were females and 68 (18.43%) were males and port site infection occurred in 11 patients (2.98%), 7(63.63%) females and 4(36.36%) males.²⁸ In another study performed by Al Naser KH²⁹ number of females in the study was higher than males with significant association of port

site wound infection in the male gender (0.03).

In the present study, frequency of port site infection was 5.9% (15 patients from 254) which was lower than 6.7% from study done by Khurshid, et al. in 2012 in an Indian hospital of Kashmir, 26 and higher than 2.4% from the study done by Jasim Saud, et al.²⁸ performed in AL Basrah general hospital 2010. Postoperative wound infection was existent in 14 (5%) patients in which gallbladder was removed without retrieval bag (group A); whereas 1 (0.4%) patient had postoperative wound infection with retrieval bag (group B). This highlighted that gallbladder removed without retrieval bag is associated with higher chances of infection due to spillage of bile and stones. These values are in close comparison with the study performed by Taj MN et al²⁵ with postoperative wound infection present in 26 (5.28%) patients where gallbladder was removed without endogloves; whereas 1 (0.20%) patient had postoperative wound infection with endogloves out of 492 patients.²⁵

In the current study, the relation of wound infection with respect to Age, Gender and duration of cholelithiasis has not been significant with p-value >0.05, which is in concordance with previous studies.^{25,30}

Laparoscopic Cholecystectomy (LC) is preferred over open technique because of less postoperative pain, short hospital stay, early return to work and better cosmetic results. However, gallbladder perforation (10-40%) and stone spillage (6-30%) are the most frequently encountered complications during LC.³¹ Ali SA et al³² have drawn attention that the best way to avoid complication of spilled gallstones and umbilical port site contamination is using retrieval bag. Golash in his series of 772 patients of conventional laparoscopies, retrieved the gallbladder specimen through the umbilical port without using a retrieval bag, hence reported a high incidence of port site contamination and gallstone spillage.³³

Conclusion

This study concluded that the frequency of port site wound infection in group A was 0.4% whereas in group B was 5.5% depicting that the frequency of port site wound infection was less with the use of retrieval bag for removing gallbladder in laparoscopic cholecystectomy. Moreover, port site wound infection the was insignificantly associated with categories of age, gender and duration of cholelithiasis, except category of age group (25-35 years), female gender group and category of the duration of cholelithiasis (1-6 months). Operating time appeared significant for port site wound infection in both categories.

Limitation of Study

Some other confounding variables like diabetes and skin conditions can cause infection in certain cases. Our study has lack of information about these two specific confounders. This point should be considered in further single /multicenter studies of port site wound infection.

Disclaimer: Abstract has not been previously presented or published prior to a conference. This is a part of the research of postgraduate dissertation. The study obtained approval from the Institutional Ethics committee.

Conflict of Interest: None.

Funding disclosure: None.

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