



A STUDY ON INCIDENCE AND FACTORS ASSOCIATED WITH PORT SITE INFECTIONS POST LAPAROSCOPIC CHOLECYSTECTOMY

General Surgery

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ABSTRACT

Today, laparoscopic cholecystectomy is the gold standard for symptomatic gall stones. A port site infection (PSI) is defined as an infection of the skin and subcutaneous tissue at the site of ports created during laparoscopic cholecystectomy which discharges purulent material spontaneously or is opened to drain the same by the surgeon. Increased number of performed cholecystectomies, increased number of port site infections, although rare, it has significant influence in overall outcomes of lap cholecystectomy and its final results like delay in return to work, increase in cost and bad cosmetic results.

AIM: To find out the incidence of Port site infections after laparoscopic cholecystectomy by clinical assessment and confirmed by swab test after culture and sensitivity.

MATERIALS AND METHODS: Hospital based prospective observational study was done on patients undergoing laparoscopic surgeries during a period of one year in a tertiary care centre of Eastern India. Patients were examined for infections and if suspected swabs were sent for culture and sensitivity and treated accordingly. For statistical analysis data were analyzed by SPSS software.

RESULTS: In our study, 69 patients were females and 31 were males who underwent Laparoscopic cholecystectomy and the mean age of patients was 40 years. The PSI was seen most commonly at epigastric port i.e. 4 among 6 patients, hence the port used for gall bladder retrieval and PSI was statistically significant. We found that the most common organism was Staphylococcus aureus and all the cases were superficial site infections.

CONCLUSION: We can prevent port site infections by using endo bag for all cases which prevents the spillage of bile during surgery, by reducing the intra-operative time and by preventing iatrogenic perforation of the gall bladder during the surgery.

KEYWORDS

Surgical site infection, Port site infection, laparoscopic cholecystectomy, gall stone disease

INTRODUCTION

Minimally invasive surgical techniques have dramatically affected many surgical sub specialties, driven by advances in port access and video instrumentation and the desire to lessen incision pain and length of hospital stay. The total complication rate was 3.6/1000 procedures, and the rate of major complications was 1.4/1000 procedures.¹ Recent study concluded that the currently prevalent practice of immersing laparoscopic instruments for 20 min in 2% alkaline glutaraldehyde should be re-examined.² They recommend that the disinfectant solution used for sterilization was responsible for port site infection. For prevention of infection, proper sterilization and storage of instruments is recommended.

Skin is a natural barrier against infection³, so any surgical wound can be a potential source of infection since it will cause a break in the continuity of the epithelium and this can lead to a postoperative infection. The advantages offered by laparoscopic surgery are vast, like decreased postoperative pain, quicker return to normal activity, and less post-operative complications.⁴ It is probably because of a smaller incision, faster mobilization, early enteral nutrition, reduction of post-operative hospital stay and better preservation of immune system function with a limited inflammatory response to tissue injury. It has been observed that metabolic complications due to surgical injury are less in laparoscopic surgery as compared to open surgery. However, laparoscopic surgery is associated with unique complications related to gaining access to the peritoneal cavity. Port site infection is an infrequent complication. Sometimes these infections become protracted and recurrent and pose a dilemma for the surgeon and become distressing for the patients. Since port site infections have not been given much attention in the medical literature, the objective of this study is to assess the influence and determine the association of laparoscopic surgery and port site infection.

Surgical site infection is defined as, "infection which occurs within 30 days of the surgical procedure." A port site infection (PSI) is defined as an infection of the skin and subcutaneous tissue at the site of

ports created during laparoscopic cholecystectomy which discharges purulent material spontaneously or is opened to drain the same by the surgeon. Organisms have to be isolated from an area of infection, and the surroundings show typical signs of inflammation like pain, redness, swelling, etc. The wound infection rates fell dramatically after the advent of antibiotics. The fact that laparoscopic surgeries are associated with fewer surgical site infections (SSIs) intuitively makes sense as laparoscopy access ports are short in length and only a fraction of the length of incision used in open laparotomy. The elective laparoscopic approach has a low risk of infection, but many surgeons still use prophylactic antibiotics.⁵ Even when there is port site infection, it is far less in severity and easily controlled by local means in the majority of cases. The causative organisms are generally those which more prevalent in the institute e.g. Staph aureus, E. coli. These types of infections are easily treated with antibiotics which are most commonly prescribed in the Institute. Atypical mycobacteria have been reported at the port site in the literature. They are collectively indicated as M. Fortuitum complex. Primary or secondary anti-tubercular treatment is required in such cases.^{6,7} Few refractory cases required debridement and excision of sinus tract followed by anti-tubercular or antibacterial treatment.⁸

Today, laparoscopic cholecystectomy is the gold standard for symptomatic gall stones.⁹ Port site infections, though rare should be evaluated and studied so as to improve the quality of health care. Increased number of performed cholecystectomies, increased number of port site infections, although rare it has significant influence in overall outcomes of lap cholecystectomy and its final results like delay in return to work, increase in cost and bad cosmetic results.^{10,11,12}

The centre for Disease Control (CDC), USA, classifies surgical site infections into three categories:

- 1) Superficial port site infection within 30 days post-surgery
- 2) Deep site infection after 30 days of surgery with purulent discharge from deep incised dehiscence of deep incision and an abscess
- 3) Organ/space SSI infection which involves any organ or space

other than incision which was opened or manipulated during surgery.¹³

RESEARCH QUESTION

To find out the incidence of Port site infections after laparoscopic cholecystectomy by clinical assessment and confirmed by swab test after culture and sensitivity.

MATERIALS AND METHODS

Patients of all age groups and both sexes undergoing laparoscopic surgeries during a period of one year between June 2018 to June 2019 to be followed up. Patients were meticulously examined for infections and if suspected swabs were sent for culture and sensitivity and treated accordingly.

1. STUDY AREA:

Department of General Surgery, B. R. Singh Hospital, Kolkata

2. STUDY POPULATION:

Patients undergoing laparoscopic cholecystectomy at B. R. Singh hospital

INCLUSION CRITERIA:

Patients of all age groups and both sexes were included.

EXCLUSION CRITERIA:

All laparoscopic cholecystectomies getting converted to open procedure.

3. SAMPLE SIZE: The number of subjects for this study was 100 with power 84%(from the different studies done, expected proportion of the patients amongst the cases had been assumed to be 7%). The formula used for sample size collection is as follows

$n = z^2pq/d^2$, n =required sample size, $p=7\%$, $q=100-p$, $q=93\%$, $z=1.96$, d =allowable error here 5% absolute precision (assumption), so, $n=99.9$, $n=100$

4. STUDY DESIGN: Hospital based prospective observational study

5. STUDY INTERVENTION: None

6. STUDY DURATION: One year

7. PROCEDURE INFLUENCING OUTCOME OF INTEREST

Preoperative preparation was done by proper bath prior to surgery using antiseptic soaps and the ports were prepared by clipping method. All patients received prophylactic antibiotics one hour before surgery. Pneumoperitoneum was created using veress needle in infraumbilical or supra umbilical incision. All the other steps were done through conventional method.

All specimens of gall bladder were extracted through epigastric port without endobag. All ports were irrigated with povidone iodine and normal saline and all 10 mm ports were closed with absorbable sutures. All laparoscopic instruments were sterilized by 2% glutaraldehyde solution with contact time of 20 minutes. Before surgery all instruments were washed with warm saline.

8. DATA COLLECTION METHODS

All patients to be followed up for port site infections after surgery and swab Culture and sensitivity in all clinically positive patients are sent to microbiological laboratory of B R SINGH hospital.

9. STATISTICAL ANALYSIS:

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test (χ^2 test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. In each case, the formula for a test statistic that either exactly follows or closely approximates a t -distribution under the null hypothesis is given. Also, the appropriate degrees of

freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a t value is determined, a p -value can be found using a table of values from Student's t -distribution. If the calculated p -value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis. p -value ≤ 0.05 was considered for statistically significant.

RESULTS AND ANALYSIS

Observation 1: Distribution of Sex

69(69.0%) patients had female and 31(31.0%) patients had male.

Observation 2: Distribution of Patients according to BMI

55(55.0%) patients are Non Obese and 45(45.0%) patients are obese.

Observation 3: Distribution of Diabetes Mellitus

88(88.0%) patients were Non Diabetic and 12(12.0%) patients were diabetic.

Observation 4: Distribution of Clinical Diagnosis

15(15.0%) patients had acute clinical diagnosis and 85(85.0%) patients had chronic clinical diagnosis.

Observation 5: Distribution of Bile spillage

13(13.0%) patients had bile spillage.

Observation 6: Distribution of Pus during Surgery

3(3.0%) patients had pus during surgery.

Observation 7: Distribution of Port Site Infection

6(6.0%) patients had port site infection.

Observation 8: Distribution of Organism

2(33.3%) patients had escherichia coli and 4(66.7%) patients had staphylococcus aureus.

Observation 9: Distribution of Port Site Infection Site

4(66.7%) patients had epigastric and 2(33.3%) patients had umbilical.

Observation 10: Distribution of SSI

6(100.0%) patients had superficial SSI.

Observation 11: Distribution of Specimen Retrieval

80(79.2%) patients had with bag and 21(20.8%) patients had without bag.

Observation 12: Distribution of Time interval between Surgery and PSI in Weeks

3(50.0%) patients had 1 week interval between surgery and PSI and 3(50.0%) patients had 2 weeks interval between surgery and PSI.

Observation 13: Association of Sex: Port Site Infection

In no port site infection, 66(70.2%) patients had female and 28(29.8%) patients had male. In port site infection, 3(50.0%) patients had female and 3(50.0%) patients had male. Association of sex vs. port site infection was not statistically significant ($p=0.2993$).

Observation 14: Association of Obesity: Port Site Infection

In port site infection, 2(33.3%) patients are Non Obese and 4(66.7%) patients are Obese. The association between port site infection vs BMI Group was not statistically significant ($p=0.2711$).

Observation 15: Association of Diabetes Mellitus: Port Site Infection

In no port site infection, 10(10.6%) patients had Diabetes Mellitus. In port site infection, 2(33.3%) patients had Diabetes Mellitus. Association of Diabetes Mellitus vs. port site infection was not statistically significant ($p=0.0971$).

Observation 16: Association of Clinical Diagnosis: Port Site Infection

In no port site infection, 13(13.8%) patients had acute clinical diagnosis and 81(86.2%) patients had chronic clinical diagnosis. In port site infection, 2(33.3%) patients had acute clinical diagnosis and 4(66.7%) patients had chronic clinical diagnosis. Association of clinical diagnosis vs. port site infection was not statistically significant ($p=0.1945$).

Observation 17: Association of Gall Stones: Port Site Infection

In no port site infection, 85(90.4%) patients had gall stones. In port site infection, 6(100.0%) patients had gall stones. Association of gall stones vs. port site infection was not statistically significant ($p=0.4268$).

Observation 18: Distribution of mean Age: Port Site Infection

In no port site infection, the mean age (mean $\pm$ s.d.) of the patients was 40.7128 ± 9.5677 years. In port site infection, the mean age (mean $\pm$ s.d.) of the patients was 42.3333 ± 10.0731 years. Distribution of mean age vs. port site infection was not statistically significant ($p=0.6892$).

Observation 19: Association of Specimen Retrieval vs. Port Site Infection

In no port site infection, 77(81.9%) patients had with bag and 17(18.1%) patients had without bag. In port site infection, 3(50.0%) patients had with bag and 3(50.0%) patients had without bag. Association of specimen retrieval vs. port site infection was statistically significant ($p=0.0581$).

Table 1: Distribution of Operative time

Operative time	Frequency	Percent
30	77	77.0%
45	13	13.0%
60	7	7.0%
90	3	3.0%
Total	100	100.0%

77(77.0%) patients had 30 min of operative time, 13(13.0%) patients had 45 min of operative time, 7(7.0%) patients had 60 min of operative time and 3(3.0%) patients had 90 min of operative time.

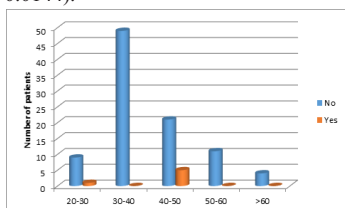
Table 2: Distribution of Age in Years

Age in Years	Frequency	Percent
20-30	10	10.0%
30-40	49	49.0%
40-50	26	26.0%
50-60	11	11.0%
>60	4	4.0%
Total	100	100.0%

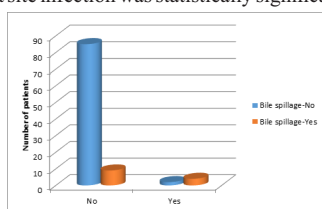
10(10.0%) patients had 20-30 years of age, 49(49.0%) patients had 30-40 years of age, 26(26.0%) patients had 40-50 years of age, 11(11.0%) patients had 50-60 years of age and 4(4.0%) patients had >60 years of age

Diagram 1: Association of Age in Years: Port Site Infection

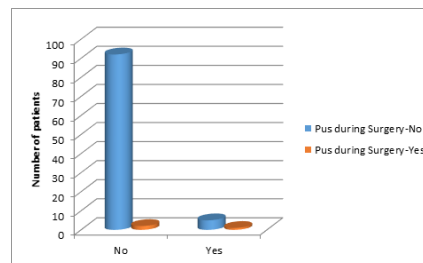
In no port site infection, 9(9.6%) patients had 20-30 years of age, 49(52.1%) patients had 30-40 years of age, 21(22.3%) patients had 40-50 years of age, 11(11.7%) patients had 50-60 years of age and 4(4.3%) patients had >60 years of age. In port site infection, 1(16.7%) patient had 20-30 years of age and 5(83.3%) patients had 40-50 years of age. Association of age in years vs. port site infection was statistically significant ($p=0.0144$).

**Diagram 2: Association of Bile spillage: Port Site Infection**

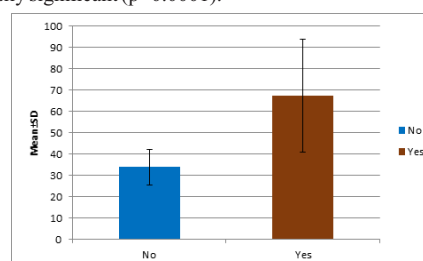
In no port site infection, 9(9.6%) patients had bile spillage. In port site infection, 4(66.7%) patients had bile spillage. Association of bile spillage vs. port site infection was statistically significant ($p<0.0001$).

**Diagram 3: Association of Pus during Surgery: Port Site Infection**

In no port site infection, 2(2.1%) patients had pus during surgery. In port site infection, 1(16.7%) patient had pus during surgery. Association of pus during surgery vs. port site infection was statistically significant ($p=0.0429$).

**Diagram 4: Distribution of mean Operative time: Port Site Infection**

In no port site infection, the mean operative time (mean $\pm$ s.d.) of the patients was 33.8298 ± 8.5013 min. In port site infection, the mean operative time (mean $\pm$ s.d.) of the patients was 67.5000 ± 26.4102 min. Distribution of mean operative time vs. port site infection was statistically significant ($p<0.0001$).

**DISCUSSION**

Laparoscopic cholecystectomy is considered to be the gold standard for symptomatic cholelithiasis and chronic cholecystitis. Port site infections due to Laparoscopic Surgery erodes the advantages of Laparoscopic Surgery and leads the patient to become worried with indolent nagging infection, thereby losing confidence on the operating surgeon.

In our sample, 69 patients were females and 31 patients were males who underwent Laparoscopic cholecystectomy and the mean age of patients was 40yrs (31 – 49 years). The increasing rates of biliary disease in females may be attributed to pregnancy and child birth which has an influence on biliary tract disease, also, female hormones act on gall bladder and reduces motility, which in turn causes stasis, thereby promoting gall stone formation. Among 69 females there were 3 out of 6 Port Site Infection patients, in our study. Other studies showed that incidence is high among males but in our study, no such relation was found.

The incidence of chronic cholecystitis was higher in our study, and there is no association of PSI in acute settings. This might be because of coexistence of confounding factors like no bile spillage and the use of endobag in removal of gall bladder, the incidence of port site infections among clinical diagnosis is not statistically significant. But the study which was done by the Al Nasser et al¹⁴ (2017) found that patients with acute cholecystitis had high incidence of Port Site Infections.

Bile spillage due to iatrogenic gall bladder perforation was seen more in two port method and the incidence of PSI in these cases was found to be statistically significant. The study conducted by Al Nasser et al¹⁴ (2017) showed that bile spillage, stones or pus during surgery leading to 24/80 cases with port site infections (30%). In our study, four patients out of 6 among 100 samples had bile spillage at the time of surgery. In cases of bile spillage during surgery, normal saline wash was given in the operative area and povidone iodine wash was given at the port site after retrieval of the gall bladder.

All the patients with PSI in our study had a gall stone but it is found that there is no association of gall stone and PSI statistically. Similar to bile spillage, gall bladder with pus seen at the time of surgery is seen to be associated with PSI ($P=0.0429$) which is significant. Spillage of pus was managed similarly as bile spillage with normal saline wash at

operative site and povidone iodine wash at port site. In our study, we used epigastric port for removal of the gall bladder in all patients. The PSI was seen most commonly at epigastric port i.e. 4 among 6 patients, hence the port used for gall bladder retrieval and PSI was statistically significant. Mandal P et al¹⁵ (2017) had also found that infection is most commonly seen at the site where gall bladder is extracted. Taj MN et al¹⁶ also established the same finding that they used the umbilical port as the port to extract the specimen and PSI was more common in the umbilical port. The other two cases had PSI at umbilical port which was used as the camera port only. The reason for PSI at this site might be due to exogenous causes for eg. improper sterilization of laparoscopic instruments or improper skin preparation before surgery. In 80 patients, we retrieved the specimen by using endobag and among them 3 patients developed PSI. Endobags were not used in 20 patients and 3 out of them in whom we did not use the endobag had PSI which shows that association between not using endobag and incidence of PSI is statistically significant ($P=0.0581$). So we conclude that the incidence of PSIs after Laparoscopic surgery due to endogenous cause may be decreased by using endobag for specimen retrieval. Taj MN et al in their study recommended that the infected specimen should be removed in an endobag in order to prevent wound infection and accidental spillage of contents.¹⁶ An improvised endobag can be prepared from a simple surgical glove which is easy to make, cheap, readily available and disposable. It was observed that incidence of PSI are more in surgeries with increased duration. Lilan SP et al reported a nil infection rate in surgeries of less than 30 minutes duration.¹⁷ So, the Laparoscopic surgeries done by an expert has less occurrence of PSI than the one which is done by residents. All the 6 cases had superficial site infections and the common organism is *Staphylococcus aureus* followed by *Escherichia coli*. They were treated according to the culture and sensitivity report with Amoxycillin and Clavulanic acid and Cefixime respectively. All patients responded well with the antibiotics and got cured. And the further follow up of the patients for next 4-6 weeks for the occurrence of Atypical Mycobacteria is done and we did not get any case of Deep site infection with Atypical Mycobacteria. In our study association with diabetes was not found. According to WHO classification of BMI, we divided underweight, normal and overweight patients in one group as non-obese and class 1,2,3 obesity patients as obese group and it is found that obesity is associated with PSIs. In a study by Warren DK et al (2017) also showed the same findings, like independent risk factors like Obesity, smoking related issues, male gender, chronic anemia, diabetes, malnutrition were associated with PSIs.¹⁸

CONCLUSION

Acute cholecystitis is not associated with increased incidence when compared to chronic cholecystitis. There is a significant association of PSI with spillage of bile and pus with the port of gall bladder extraction.

4(66.6%) patients had epigastric and 2(33.3%) patients had umbilical infection which is the port site where the gall bladder was extracted. The infected specimen should be removed in an endobag in order to prevent port site infection and accidental spillage of contents or occult malignant cells. Increased operative time leads to increasing risk of PSIs. We found that most common organism was *Staphylococcus aureus* followed by *Escherichia coli* and all the cases were superficial site infections. We can conclude that port site infections can be prevented by using endo bag for all cases which prevents the spillage of bile during surgery, by reducing the intra-operative time and by preventing iatrogenic perforation of the gall bladder during the surgery.

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