Original Research Article

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Surveillance of surgical site infections after cholecystectomy

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ABSTRACT

Background: The objective of present study is find out various patient factor including demographic data as well as operative data on occurrence of surgical site infection in patients of cholecyctectomy.

Methods: A Prospective observational study of 273 patients of cholecystitis undergoing cholecystectomies for Surveillance of surgical site infections was conducted in the Department of General Surgery at the SSG hospital and Medical College Baroda during a period from 1st December 2013 to 30th November 2015. All patients operated for cholecystectomy are included irrespective of technique. Data collected from each patient were: Case start date and time, case end date and time, discharge date & time, case length, postoperative length of stay in hospital, patients characteristics (age, sex, ASA score), operative characteristics like, pathological diagnosis report of specimen, microorganism isolated based on culture report and antibiotic resistance pattern from infected wounds, antibiotic prophylaxis given perioperatively and antibiotics administered to treat SSΓs, intra operative spillage and bleeding, date of infection, urgent/elective procedure.

Results: During the period of 24 months total 273 patient were undergone cholecystectomy out of which 12 (4.3%) patients were developed SSI. SSI rate is affected by various factors which are statistically significant are sex of patients, age, type of procedure, ASA score >3.

Conclusions: The overall incidence of SSIs in the present study was 4.3%. The rates of SSI were more in patient with higher age, with male sex, emergency procedure and higher ASA score.

Keywords: Antibiotic prophylaxis, Laparoscopic cholecystectomy, Open cholecystectomy, Surgical site infections

INTRODUCTION

Cholecystectomy is a common surgical procedure. The advent of laparoscopic cholecystectomy in 1989 caused a rapid increase in gallbladder surgeries world over. A real increase in the incidence of cholelithiasis, increased frequency of symptomatic gallstones, very sensitive diagnostic tests and a lowered threshold for surgery are factors that influence the dramatic increase in the number of cholecystectomies world over. Many gallstones are clinically symptomless, an incidental finding often uncovered during abdominal ultrasound performed for

another reason.² The etiology for gallstones is multifactorial. There are genetic factors and environmental reasons for gallstones. Chronic over-nutrition with carbohydrates, depletion of dietary fibers and a 'westernized' high-fat diet seems to increase the risk for developing gallstones.³ The advance of laparoscopy compared to conventional techniques was assumed so obvious that surgeons did not wait for results from randomized studies and laparoscopic cholecystectomy replaced open cholecystectomy as the first-choice of treatment for gallstones and inflammation of the gallbladder.⁴ The laparoscope was introduced in the late 1980s and since then has been a popular surgical

technique. Cholecystectomies are the major operative procedures using a laparoscope. The main advantages of laparoscopy are less postoperative pain, smaller incision and shorter hospitalization.⁵ Although laparoscopic cholecystectomy is less invasive, requires a shorter hospitalization and is associated with faster recovery than open cholecystectomy, little is known about the impact of laparoscopy on the risk of surgical site infections (SSI).6 Equipment used in laparoscopy is very costly and it is used for many years. Rigorous conformation to disinfection and sterilization rudiments is very important. Each disinfection and sterilization procedure have a risk of acquiring micro-damages which may be a source of hepatitis B or C or human immunodeficiency virus as well as infections caused by methicillin resistant staphylococcus aureus. vancomycin-resistant enterococcus or atypical mycobacteria. This problem particularly affects countries with budgets devoted to the health sector lower than in developed ones.⁵ Cholecystectomy is a widely performed surgery worldwide; indications may be acute cholecystitis, acalculous cholecystitis, chronic cholecystitis, cholecystectomy along with common bile duct exploration. The bile which is present in the gall bladder harbors multiple bacteria which may be aerobic and anaerobic.7 Surgical site infection (SSI) comes as third most common healthcare related infection which produces morbidity and deaths at large.⁷ To determine the incidence of surgical site infections and analyse the various factors responsible for SSIs in patients undergoing cholecystectomy, this study was undertaken in our institute.

Present study aim is to determine the incidence of SSIs in patients of both open and laparoscopic cholecystectomy at our institute and also to analyze the impact of patients' demographic factors (like age, sex, ASA physical status classification) in SSI's following cholecystectomies. Present study also aim to stratify and analyze operative data (laparoscopic/open procedure, wound contamination class, intra operative spillage of gall bladder contents, intra operative bleeding, duration of operation, emergency/elective operation, peri-operative prophylactic antibiotic, intra op status of gall bladder (acutely inflamed, emphysematous, mucocele, chronic contracted) and length of hospital stay.

METHODS

A prospective observational study of 273 patients of cholecystitis undergoing cholecystectomies for Surveillance of surgical site infections was conducted in the Department of General Surgery at the Sir Sayajirao General Hospital and Medical College Baroda during a period of 24 months from 1st December 2013 to 30th November 2015. Prior approval for the study was obtained from the Scientific Review Committee and Institutional Ethics Committee for Human research, Medical College and S.S.G. Hospital Baroda. It is prospective and observational type of study.

All patients operated for cholecystectomy that includes Laproscopic cholecystectomy Laproscopic converted to open cholecystectomy and Open cholecystectomy. Patients who had another operative procedure along with a cholecystectomy (e.g. hernioplasty) were excluded. Taking Proportion of calculous cholecystitis as 7%, α error of 5%, desired precision of 5% and confidence interval of 95%, sample size generated was 250. End point for recruitment of study would be either reaching the sample size or completion of period of 24 months

The information obtained for each patient were: CASE start date and time (time of skin incision), case end date and time (time of removal of drapes), discharge date and time, case length(case start time to case end time), Postoperative length of stay (LOS) in hospital, patients characteristics (age, sex, ASA score), operative characteristics like, pathological diagnosis report of specimen sent after cholecystectomy, microorganism isolated based on culture report and antibiotic resistance pattern from infected wounds, antibiotic prophylaxis given perioperatively and antibiotics administered to treat SSI's, intra operative spillage, intra operative bleeding, perioperative prophylactic antibiotics, date of infection, urgent/elective procedure.

RESULTS

A prospective Observational study of 273 patients undergoing cholecystectomy was conducted in the Department of General Surgery at the Sir Sayajirao General Hospital and Medical College Baroda over a period of 24 months starting from the month of 1st December 2013 to 30th November 2015.

Ninety three (279) patients underwent cholecystectomy. Out of 279 patients 273 patients were included in study and six were excluded because they had undergone repair of ventral hernias along with laparoscopic cholecystectomy. Out of 273 patients 228 (84%) patients underwent Laproscopic cholecystectomy and 9 (3.3%) patients underwent open cholecystectomy and remaining 36 (13.19%) patients were underwent laparoscopic chelecystectomy but later converted to open

The total number of male patients were 66 (24%) while the number of female patients were 207 (76%) with female:male ratio 1:3. All the patients who had developed SSIs were males. The difference in the rates of SSI between the 2 groups were statistically significant for P<0.05 (P=0.027). The mean age of the study population was 42years, with the range of 16 to 65years in this study. Analysis of age groups showed a high incidence of calculous cholecystitis among adults between 40-50 years (33%) The highest prevalence of calculous cholecystitis in males was observed in the age group 40 to 50 years (27%) while in females also it was in the same age group i.e. 40 to 50years (35%). The lowest prevalence of calculous cholecystitis in males and female was in less than 20 years and greater than 60 years. The difference of

prevalence of cholecystitis between different age groups of males and females was statistically significant (the Pvalue is 0.036, the result is significant at p < 0.05). The number of elective procedures were 270 whereas only 3 patients was operated in the emergency setting. The rate of SSI when compared in elective and emergency surgery was not clinically significant (p=0.13). The mean duration of surgery in laparoscopic cholecystectomy was 47mins and in open cholecystectomy it was 210 mins and in laparoscopic converted to open cholecystectomy it was 105mins (the difference between the means of duration of surgeries between the three procedures was not statistically significant). The result is not significant at p < 0.05) The increase in rates of SSIs with increased duration of surgery was not statistically significant for P<0.05. Six patients out of 243 (2.47%) with an ASA score less than 3 and 6 patients out of 30 with ASA score more than 3 (20%) had developed wound infections. Although it appeared that an increase in ASA score increased the chance of SSIs but this was statistically insignificant at p <0.05. Out of 228 patients undergoing LC, wound infection was observed in 3 patients (1.3%). Out of 45 patients of converted and open procedures wound infection was observed in 9 (20%). The lower rates of SSI in laparoscopic method was significantly lower than in the open and converted groups. P value 0.001. Intra operative spillage was observed in 153 of the 273 patients. Spillage of bile was observed in 117 patients, pus in one and sludge in 33 patients. Mild spillage was observed in 144 patients (95%), moderate in 3 patients (3%), and severe in patients 6 (2%).

Nine patients out of 135 with intra op spillage had developed wound infections (6.67%) whereas only 3 patient out of 138 without intra op spillage developed infection (2.17%). This was statistically insignificant for P<0.05. Intra operative bleeding was mild in 243 patients (89%), moderate in 18 patients (7%). And severe in 12 patients (4%). Intra operative bleeding was severe in 6 patients of LC, they required blood transfusion, and both were converted to open surgery. Six patients undergoing OC had severe intra operative bleeding and required blood transfusion. No patient having mild bleeding developed SSI whereas 3 out of 18 patients with moderate bleeding and 9 out of 12 patients with severe bleeding had developed SSI. The difference in rates of SSIs with the amount of bleeding was not statistically significant for P <0.05 (P=0.7). Surgical site infection was observed in 12 out of 273 patients (4%). All the 12 patients had superficial incisional type of infection and 9 had class 2 category of wound and 3 had class 3 category wound. Escherichia coli, Enterococcus spp, and Klebsiella spp were isolated from the patients with SSIs and in 3 patient no organism was isolated. All the SSIs were treated by intra venous antibiotics, to which the microorganisms showed the maximum sensitivity. In addition to that local debridement and daily dressings were required. The mean time required for healing of these wounds was 12 days from the detection of SSI. Secondary suturing was done in 3 wound while the rest of the 9 healed by secondary intention. The mean length of stay (LOS) in hospital was 4 days for patients undergoing laparoscopic cholecystectomy with a range of 1 to 7 days. Mean LOS for patients undergoing OC was 13 days with range of 7 to 29 days and mean LOS for patients undergoing laparoscopic converted to cholecystectomy was 9 days with range of 5 to 11 days. Maximum patients were discharged within first five days of surgery (83.52%). The difference in the mean length of stay between the different procedures was not statistically significant for P <0.05 (P=0.3). A pathological diagnosis of chronic calculous cholecystitis was made in 270 patients whereas only 3 patients were diagnosed as having acute cholecystitis. There were no cases of gall bladder polyps, or carcinoma gall bladder. All the patients had received a single dose of injectable third generation cephalosporin (Inj. ceftriaxone 1g IV) before the surgeries. Patient who was operated for acute cholecystitis received Inj. ceftriaxone 1g IV 12hrly therapy for 5 days in addition to Inj metrogyl 500 mg IV 8 hrly.

DISCUSSION

Aim if the study is to assess the impact of LC on SSIs, this study was conducted to describe the characteristics of SSIs for both techniques and assess the SSI risk following LC compared to OC.

Different groups of investigators have reported contradictory results concerning the relationship between increasing age and risk of SSI.^{6,8-10} Several investigators concluded that increasing age was associated with a greater risk of all types of postoperative infections; in some of these studies, increasing age was associated with an increased risk of development of SSI after cholecystectomy. In the present study, out of 273 patients 66 patients were below 30 years of age and had no SSIs. There were 207 patients above the age group 30 years out of which 4 (5.8%) developed SSIs and were in the age group 25-45 years.

Kaye et al, in a cohort study of more than 144000 patients concluded that age independently predicted an increased risk of SSI until age 65 years or more, increasing age independently predicted a decreased risk of SSI. This relationship to increased risk of SSI may be secondary to comorbidities or immunosenescene.¹¹

Richards et al, concluded that age more than 60 years was a significant risk factor for SSI's. Brill et al, in his study found and maximum incidence of SSIs in the age group of 65 to 74 years (3.89%). Saud et al, concluded age greater than 60 years to be an independent risk factor for SSIs. However in the report by den Hoed et al, age was not a significant risk factor for prediction of SSI after cholecystectomy. Although the number of females with cholelithiasis undergoing cholecystectomy were significantly more (75%), the SSI's were observed exclusively in males. Odds ratio (OR) being 27.

Table 1: SSI in patients undergoing cholecystectomies male: female Odds Ratio.

Study	(M:F) Odds Ratio
Present study	27
Saud et al ¹⁰	4.4
Richards et al ⁶	1.47
Bogdanic et al ¹²	5.11

This finding remains unexplained and previous studies have inconsistently reported gender as risk factor. Post-operative SSIs is a major cause of post-operative morbidity with the incidence varying between 4.2 to 21%. Review of published rates after LC shows a variation between 0.3 to 1.8%. The overall SSI in the present study was 4.3% which is similar to the rates of SSI reported by other studies though a bit on the higher side. 5,6,8,9,12-14

Table 2 shows the rates of SSIs in various studies. Different studies reported rates of SSI's after open cholecystectomy to be higher than that after laparoscopic cholecystectomy. 5,6,8,9,12-14

Table 2: SSIs in cholecystectomies.

Author	Overall SSI Rate	Laparoscopic cholecystectomy	Open cholecyst ctomy
Present study	4.3%	1.30%	66.70%
Jawien et al ⁵	2.43%	1.08%	4.41%
Brill et al ⁹	3.57%	2.6%	8.9%
Richards et al ⁶	1%	0.62%	1.82%
Romy et al ¹⁴	2.61%	1.7%	7.9%
Bogdanic et al ¹²	1.44%	0.6%	6.06%
Siddiqui et al ³	4%	2%	6%
den Hoed et al ⁸	14%	5.3%	17.5%

The findings of the present study are consistent with the literature in which open cholecystectomy is associated with an increase in the rate of SSI's.

Certain aspects of laparoscopic surgery that may reduce the occurrence of surgical infections are: a minimal exposure to external environment, carbon dioxide pneumoperitoneum, better visualization of tissues for dissection and hemostasis.¹⁵ Although the rates of SSI in open surgery was higher compared to LC, the percentage of SSI was 10-15 times higher when compared to SSIs in OC in other studies. This may be because of fewer OC (one patient of acute cholecystitis) and longer operative time in 2 patients in whom LC was converted to OC.

Table 3 showing higher rate of surgical site infection in emergency procedures. This higher rate of SSIs in Emergency procedures can be attributed to complicated intra operative findings, higher ASA score in patients.

Increasing duration of surgery has been proposed as a risk factor for an increased risk of SSIs. Two patients with procedures lasting more than 90min upto 3 hours had developed a surgical site infection and two patients with procedure more than 3 hours had developed a surgical site infection. Jan WA et al, in his study found a significant relationship between the duration of surgery and the frequency of port site infection. ¹⁶ of the 17 infected 14 were the one in whom surgery lasted for longer than one hour. Jawien et al, proposed that a duration lasting more than 85 minutes increased the risk of acquiring surgical site infections. ⁵ Richards et al, in his study concluded that a prolonged duration of surgery was a risk factor. ⁶ However Saud et al, did not find a relation between duration of surgery and increased risk of SSI. ¹⁶

Table 3: SSIs Related to emergency and elective cholecystectomy.

Study	Elective operation	Emergency operation
Present study	1.1%	100%
Romy et al ¹⁴	2.4%	3.6

In the present study, all patients with a surgical site infection had a procedure which lasted more than two hours. The reason for an increased risk of SSI with increased duration of surgery could be due to increased duration of exposure to endogenous or exogenous microbiological contaminants from the biliary tract or from the skin surface. The American society Of Anesthesiologists` (ASA) classification of Physical health is a widely used grading system for pre-operative health of the surgical patients. In previous studies, authors have concluded that an ASA score more than 3 would increase the risk of developing a SSI. 10,12 In the present study, 2.47% of patients with ASA score <3 had SSI's while 20% of patients with ASA score >3 had SSI. However, this difference was not statistically significant.

In the present study 6.67% of patients with intra op spillage had developed wound infections whereas only 2.1% of patients without intra operative spillage developed infection. This is in concurrence with other reports that the rate of SSIs is high if there is intra operative contamination.

Jawien et al, reported a high rate of SSIs in both OC and LC after there was intra operative contamination with biliary contents.⁵ Diez et al, in his study on laparoscopic cholecystectomies for acute and chronic cholecystitis observed that rates of SSI were 5% in cases of

contamination whereas it was only 1.3% without contamination.¹⁷ In the setting of appropriate antimicrobial prophylaxis, wound contamination with greater than 105 microorganisms is required to cause SSI.¹⁸ However, the bacterial inoculums required to cause SSI may be much lower when foreign bodies such as sutures or lost stones are present. Presence of sutures in OC in contaminated surgeries could be a cause for increased rates of SSI after open procedures.

Out of patients with single stones, only 3.7% had developed SSI, whereas in patients with multiple stones 3.1% developed SSI. This was found to be statistically insignificant for P<0.05. Bacteria inside gall stones have long been thought to be dead, as is explicit in the wellknown aphorism of Lord Moynihan 'Tomb stone erected to the memory of organism which lie dead within them Hazarah et al, in his study on bacteriologic analysis of Gall stones isolated enteric pathogens in 54% of patients while non enteric pathogens were isolated in 24%.¹⁹ Klebsiella was most common organism isolated (18%) followed by E coli (15%). Enterococcus spp (7.5%) and Enterobacter spp in 7.5%. Salmonella spp was observed in only 1.5% of cases. Pseudomonas spp was the pathogen commonest non-enteric followed Acinetobacter (7.5%) and staphylococcus aureus (3.8%). SSIs were not related to the number of stones in the gall bladder.

Majority of the SSIs reported after LC and OC are gram negative organisms such as Escherichia coli, Klebsiella pneumonia. 10,12 The other organisms responsible are coagulase negative Staphylococci, Enterococcus spp, Streptococcus spp, Staphylococcus epidermidis. Anerobic organisms constitute a very small percentage of the bacteria responsible for SSIs following cholecystectomy. Infections caused by these bacteria occurs within a week of surgery. These bacteria are derived from infection acquired during surgery from the infected gall bladder or the skin or the surgical procedure itself and can be treated by routine antibiotics, debridement and local wound dressing. Faulty sterilisation/disinfection of laparoscopic instruments is usually responsible for such outbreaks, more so in developing countries like India. The use of disposable laparoscopic instruments is the gold standard for prevention of infection. However, in government hospitals like ours most of the time reusable laparoscopic instruments are used for laparoscopic surgery. The instruments should be thoroughly mechanically cleaned after every use with dismantling of parts. This is best achieved using ultrasonic technology. Though not always practical it may be necessary to limit gluteraldehyde disinfectants and replace it with ethylene oxide gas sterilisation or plasma sterilisation. Gluterladehyde must be used in higher concentration (3.4%) and the period of exposure should be increased to 8 to 12 hours. Though most of the studies used antibiotic prophylaxis for both OC and LC, some studies opined that neither form of cholecystectomy should be performed without peri prophylaxis.²⁰⁻²³ operative antimicrobial Others

concluded that routine pre-operative prophylaxis is not necessary in low risk symptomatic gall stone patients undergoing LC.8,24,25 Preoperative singledose cefazolin as an antibiotic prophylaxis has been recommended (by the Centers for Disease Control and Prevention-CDC) and widely used in clean-contaminated surgeries such as cholecystectomy and biliary surgery to reduce surgical site infection (SSI).²⁴ The goal of surgical antimicrobial prophylaxis is to reduce the concentration of potential pathogens at or in close proximity to the surgical incision. Saud et al, concluded that prophylactic antibiotics had no effect on increasing or decreasing rates of SSIs in LC as compared to OC. 10 Harling et al, did not find a significant difference in rate of SSI between prophylactic antibiotic usage and mechanical isolation of the gallbladder with endobag during extraction from the abdomen.25

As shown in the Table 4, a majority of the studies including the present study have reported superficial or deep incisional SSIs. Organ space SSIs were reported by Saud et al, and Richards et al.^{6,16} Richards et al, reported a higher percentage of organ space infections following laparoscopy as compared to the open technique without commenting on the reasons.⁶

Table 4: Comparison of type of SSI.

Study	Superficial incisional	Deep incisional	Organ space
Present study	100%	nil	nil
Saud et al ¹⁰	45.5%	18.8%	36.3%
Mehraj et al ¹⁵	100%	nil	nil
Siddiqui et al ¹³	50%	50%	nil
Hirai et al ²⁶	100%	nil	nil
Memon et al ²⁷	100%	nil	nil
Jan et al ¹⁶	70.5%	29.5%	0
Richards et al ⁶	45.75%	13.6%	40.4%

Table 5: Length of hospital stay in various study is compared in following table.

Studies	L.C	O.C	L.C converted to O.C
Present study	4 days	11 days	9 days
Berggeren et al ²⁸	1.8 days	2.8 days	Not mentioned
Muqim et al ²⁹	2.06 days	3.93 days	Not mentioned
Bogdanic et al ¹²	2.4 days	8.1 days	Not mentioned

CONCLUSION

The overall incidence of SSIs in the present study was 4.3%. The rates of SSI were higher in patients undergoing OC in comparison to LC. Increasing age is a risk factor for SSI. Male sex carried an increased risk of

SSI than females. An ASA >3 was associated with increased risk of SSI. Class 2 (clean-contaminated) is most common type of wound associated with cholecystectomy. Superficial incisional was the most common type of SSI in cholecystectomies. Intra operative spillage of gall bladder contents was associated with increased risk of SSI. Intra op bleeding was not significantly associated with SSIs. Increased duration of operation increased the incidence of SSI in both LC and OC groups. Increased duration of operation was more in OC compared to LC. Patients operated in emergency was associated with increased risk of SSI. Prophylactic antibiotic is a standard of care in our institution and all patients have continued to receive the prophylactic antibiotics. Hence no correlation could be made between the use of antibiotics and SSIs. There was no significant association between risk of SSI and intra operative GB status. Length of hospital stay was increased in patients undergoing OC compared to LC and in patients with SSIs.

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