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ORIGINAL ARTICLE

# Comparison of surgical site infection in patients undergoing laparoscopic cholecystectomy with or without prior ERCP.

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**ABSTRACT… Objective:** To compare the risk of surgical site infections in patients undergoing laparoscopic cholecystectomy with or without prior ERCP. **Study Design:** Prospective Comparative study. **Setting:** Surgical Unit-I of Holy Family Hospital, Rawalpindi. **Period:** December 2021 to May 2022. **Methods:** Total 140 patients were included. Group A had ERCP before their laparoscopic cholecystectomy. Those, who had laparoscopic cholecystectomy without first undergoing ERCP included in Group B. For this study, we used SPSS to analyze the data we gathered (version 23.0). Two groups were compared for surgical site infection using the Chi-square test. The level of significance was set at P 0.05. **Results:** Total 140 patients with biliary tract disease (choledocholithiasis, cholangitis and cholelithiasis) were enrolled in this study. In group-A, there were 16(22.9%) males and 54(77.1%) females, while in Group-B, there were 14(20.0%) males and 56(80.0%) females. In patients with prior ERCP group, 28(40.0%) developed surgical site infections, while in patients without ERCP group, 13(18.6%) developed surgical site infections with a p-value of 0.005, which is statistically significant. **Conclusion:** An increase in the incidence of SSI following laparoscopic cholecystectomy by two- fold is connected with pre-operative (ERCP) so we plan to assess if this technique is linked to a higher risk of wound infection after surgery. we suggest that long term use of antibiotics can reduce the rate of SSI and longer stay of patients in hospital.

**Key words:** ERCP, Laparoscopic Cholecystectomy, CBD Stones.

## INTRODUCTION

Infection at the site of incision after surgery can occur upto 30 days after procedure.[1] it is often seen that patients internal pathogens can be a source of surgical site infection. In a study done by Makadia et al in 2018, it was found that SSI was seen in 4.3 % patients undergoing laparoscopic cholecystectomy.[2]

In patients of cholelithiasis who require ERCP and sphincterotomy for pancreatitis or choledocholithiasis are known to harbour intestinal flora because of ascending infection secondary to biliary reflux.

This theoretically can be a source of endogenous flora leading to infection at port site in post operative period after laparoscopic cholecystectomy. Similar findings were noticed in 2018 by Peponis T. and Panda N, depicting a three fold increase the risk of surgical site infections after laparoscopic cholecystectomy. who had had prior endoscopic retrograde cholangio pancreaticography.[3,4,5]

Based on the research mentioned earlier, any endoscopic procedure conducted before a laparoscopic cholecystectomy substantially elevates the risk of infection at surgical site. The likelihood of adversity escalates if such patients with biliary tract infections, icterus, and pancreatic infections are not promptly treated.[6,7]

ERCP and sphincterotomy are routinely done in patient having choledocholithiasis before laparoscopic cholecystectomy. the known complications of ERCP include injury of

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duodenum, inflammation of pancreas, blood loss after sphincertomy.[8] If cholecystectomy is delayed following ERCP recurrence rate rises from 11 percent to 47 percent for choledocholithiasis.[9]

We routinely perform laparoscopic cholecystectomy in patients who have had ERCP done for choledocholithasis, cholangitis and pancreatitis however in our setup we do not have data regarding post cholecystectomy SSI in such patients. In light of internationally published data it is expected that our patients will also be having high rate of SSI.

We put forth a hypothesis suggesting that ERCP before a laparoscopic cholecystectomy elevate the likelihood of infection at the surgical site. This, in turn, would provide crucial insights that could guide decisions regarding the subsequent course of care for patients which include long term antibiotic course.

## OBJECTIVE

To compare the risk of surgical site infections in patients undergoing laparoscopic cholecystectomy with or without prior ERCP.

## METHODS

The study design was Prospective comparative study and it was conducted at surgical unit 1, Holy Family Hospital, Rawalpindi over 6 months period from December 2021 to May 2022 after approval from ethical review board (07/IREF/RMU/2021), using consecutive sampling technique. The sample size was calculated according to WHO calculation guidelines with level of significance as 5%, power of test as 80% and anticipated percentage of surgical site infection following laparoscopic cholecystectomy without prior endoscopic retrograde cholangiopancreatography (ERCP) - population group 1 = 4%.(2). Assuming 15% difference (increase in surgical site infections following laparoscopic cholecystectomy with prior ERCP) between the two groups, sample size is of 140 patients, with each group of 70 patients. Infection following laparoscopic cholecystectomy without prior endoscopic retrograde cholangiopancreatography (ERCP) - population group 1 = 4%.(2) Assuming 15% difference (increase in surgical site infections following laparoscopic cholecystectomy with prior ERCP) between the two groups, sample size is of 140 patients, with each group of 70 patients. The same team of surgeons from the department performed each and every operation with experience of atleast 15 years. For this study, data was analyzed by using SPSS (version 23.0). Descriptive statistics were obtained. Two groups were compared for surgical site infection using the Chi-square test. The level of significance was set at P 0.05.

All those Patients between 18 to 75 years of age, both male and female gender, who had cholelithiasis, requiring laparoscopic cholecystectomy with prior ERCP or without ERCP were included in the study, (preoperative antibiotics were given to all patients undergoing laparoscopic cholecystectomy and ERCP.) Patients who previous had open cholecystectomy, empyema gall bladder. Gangrenous gall bladder or patients with immunocompromised state like diabetes were excluded from the study.

Study intervention in the study included ERCP prior to laparoscopic cholecystectomy and Laparoscopic cholecystectomy. Infection at the surgical site was the primary outcome variable. The skin and subcutaneous tissue directly under the incision site are affected by surgical site infection. Patients who showed signs of surgical site infection, such as fever, redness at the surgical site, and purulent discharge from the incision, were evaluated further as an outcome.

## RESULTS

Total 140 patients were enrolled in this study, were divided into two groups i.e. Group-A (with prior ERCP) and Group-B (Without ERCP). In group-A, there were 16(22.9%) males and 54(77.1%) females, while in Group-B, there were 14(20.0%) males and 56(80.0%) females (Table-I).

In group-A, 4(5.7%) were in 18-30 years' age group, while 41(58.6%) and 25(35.7%) in 31-50 years and 51-75 years' age groups respectively. In Group-B, 20(28.6%) were in 18-30 years' age group, while 42(60.0%) and 8(11.4%) in 31-50

years and 51-75 years' age groups respectively (Table-II).

In group-A, 1(1.4%) diagnosed with cholelithiasis, 50(71.4%) had cholelithiasis + choledocholithiasis and 19(27.1%) had cholelithiasis + pancreatitis, while in Group-B, 70(100.0%) diagnosed with cholelithiasis (Table-III).

In Group A (with prior ERCP), 28(40.0%) developed SSI while in Group B (without ERCP) 13(18.6%) developed surgical site infections with a p-value of 0.005, which is statistically significant (Table-IV).

In with prior ERCP group, 28(40.0%) developed redness of skin, while in without ERCP group, 13(18.6%) developed redness of skin with a p-value of 0.005, which is statistically significant (Table-V).

In with prior ERCP group, 6(8.6%) developed purulent discharge from incision site, while in without ERCP group, 1(1.4%) developed purulent discharge from incision site with a p-value of 0.043, which is statistically significant (Table-VI).

In with prior ERCP group, 3(4.3%) had fever, while in without ERCP group, 0(0.0%) had fever with a p-value of 0.080, which is statistically insignificant (Table-VII).

Mean age in group-A patients was 48.70±10.91 year and 38.04±12.115 year in Group-B patients. Mean BMI in group-A patients were 24.4±2.34 kg/m$^2$ and 24.7±2.4 kg/m$^2$ in Group-B patients. Mean duration of surgery in group-A patients was 33.77±2.61 minutes and 33.64±3.98 minutes in Group-B patients (p=0.822). Mean duration of hospital stay in group-A patients was 7.17±3.26 days and 4.60±2.01 days in Group-B patients (p=0.001) (Table-VIII).

| Gender | Groups | | Total |
|---|---|---|---|
| | With Prior ERCP | Without ERCP | |
| Male | 16 | 14 | 30 |
| | 22.9% | 20.0% | 21.4% |
| Female | 54 | 56 | 110 |
| | 77.1% | 80.0% | 78.6% |
| Total | 70 | 70 | 140 |
| | 100.0% | 100.0% | 100.0% |

**Table-I. Comparison of gender distribution between groups**

| Age Groups | Groups | | Total |
|---|---|---|---|
| | With Prior ERCP | Without ERCP | |
| 18-30 years | 4 | 20 | 24 |
| | 5.7% | 28.6% | 17.1% |
| 31-50 years | 41 | 42 | 83 |
| | 58.6% | 60.0% | 59.3% |
| 51-75 years | 25 | 8 | 33 |
| | 35.7% | 11.4% | 23.6% |
| Total | 70 | 70 | 140 |
| | 100.0% | 100.0% | 100.0% |

**Table-II. Comparison of age distribution between groups**

| Diagnosis | Groups | | Total |
|---|---|---|---|
| | With Prior ERCP | Without ERCP | |
| Cholelithiasis | 1 | 70 | 71 |
| | 1.4% | 100.0% | 50.7% |
| Cholelithiasis + Choledocholithiasis | 50 | 0 | 50 |
| | 71.4% | 0.0% | 35.7% |
| Cholelithiasis + Pancreatitis | 19 | 0 | 19 |
| | 27.1% | 0.0% | 13.6% |
| Total | 70 | 70 | 140 |
| | 100.0% | 100.0% | 100.0% |

**Table-III. Comparison of diagnosis distribution between groups**

| Surgical Site Infections | Groups | | Total | P-Value |
|---|---|---|---|---|
| | With Prior ERCP | Without ERCP | | |
| Yes | 28 | 13 | 41 | 0.005 |
| | 40.0% | 18.6% | 29.3% | |
| No | 42 | 57 | 99 | |
| | 60.0% | 81.4% | 70.7% | |
| Total | 70 | 70 | 140 | |
| | 100.0% | 100.0% | 100.0% | |

**Table-IV. Comparison of surgical site infections between groups**

| Redness of Skin | Groups | | Total | P-Value |
|---|---|---|---|---|
| | With Prior ERCP | Without ERCP | | |
| Yes | 28 | 13 | 41 | 0.005 |
| | 40.0% | 18.6% | 29.3% | |
| No | 42 | 57 | 99 | |
| | 60.0% | 81.4% | 70.7% | |
| Total | 70 | 70 | 140 | |
| | 100.0% | 100.0% | 100.0% | |

**Table-V. Comparison of redness of skin between groups**

| Purulent Discharge From Incisionsite | Groups | | Total | P-Value |
|---|---|---|---|---|
| | With Prior ERCP | Without ERCP | | |
| Yes | 6 | 1 | 7 | 0.043 |
| | 8.6% | 1.4% | 5.0% | |
| No | 64 | 69 | 133 | |
| | 91.4% | 98.6% | 95.0% | |
| Total | 70 | 70 | 140 | |
| | 100.0% | 100.0% | 100.0% | |

**Table-VI. Comparison of purulent discharge from incision site between groups**

| Fever | Groups | | Total | P-Value |
|---|---|---|---|---|
| | With Prior ERCP | Without ERCP | | |
| Yes | 3 | 0 | 3 | 0.080 |
| | 4.3% | 0.0% | 2.1% | |
| No | 67 | 70 | 137 | |
| | 95.7% | 100.0% | 97.9% | |
| Total | 70 | 70 | 140 | |
| | 100.0% | 100.0% | 100.0% | |

**Table-VII. Comparison of fever between groups**

## DISCUSSION

Currently laparoscopic cholecystectomy is the procedure of choice due to its minimally invasive nature, low postoperative pain, early recovery and lower SSI rate .However in cases where prior ERCP done SSI rate likely to increase.[10] This study was done to see the SSI rate in patients whom prior ERCP done in our setup.

In our study 41 patients out of 140 total patients had SSI which is comparable to international study done by Loor et al in which the rate of SSI was significantly higher Clean contaminated (wound class II) had 1.8% (39/2112) and Clean contaminated or dirty (wound class III or IV) had 89 6.7% (6/89) SSI.[11]

Stones in the CBD can be removed via sphinterotomy, CBD cannulation, balloon sweeps, or Dormia basket extraction, all of which lead to irritation, edema, and adhesion development in the surrounding area. Pancreatitis and peri-portal inflammation are two other conditions they can aggravate.[12] Sphincterotomy likelihood increase rate of ascending cholangitis, this can be source of endogenous infection likely to increase the SSI.[8] About 85% to 90% of bile duct stones can be removed by balloon/basket extraction following BES. In a large, multicenter trial, the overall complication rate of BES was 9.8% in 2347 patients, including pancreatitis in 5.4%, bleeding in 2%, procedure-related cholangitis in 1%, cholecystitis in 0.5%, and perforation in 0.3%.[13] In our study 50 patients out of 140 patients who had choledocholithasis and 19 patients who had biliary pancreatitis underwent prior ERCP developed SSI.

In our study, Group A patients who underwent ERCP before laparoscopic cholecystectomy 28(40.0%) developed SSI while in Group B (without ERCP) 13(18.6%) developed surgical site infections with a p-value of 0.005, which is statistically significant and comparable to study done by peponis et al. Of the 640 patients, 122 (19.1%) received preoperative ERCP with sphincterotomy and 518 (80.9%) did not.

| Variables | Groups | N | Mean | Std. Deviation | P-Value |
|---|---|---|---|---|---|
| Age (years) | With prior ERCP | 70 | 48.70 | 10.90 | 0.001 |
| | Without ERCP | 70 | 38.04 | 12.11 | |
| Body Mass Index | With prior ERCP | 70 | 24.50 | 2.34 | 0.626 |
| | Without ERCP | 70 | 24.69 | 2.40 | |
| Duration of Surgery (minutes) | With prior ERCP | 70 | 33.77 | 2.61 | 0.822 |
| | Without ERCP | 70 | 33.64 | 3.99 | |
| Duration of Hospital Stay (days) | With prior ERCP | 70 | 7.17 | 3.26 | 0.001 |
| | Without ERCP | 70 | 4.60 | 2.02 | |

**Table-VIII. Comparison of mean values of different variables between groups**

However, the rate of surgical site infections was higher in the preoperative ERCP group (11.5% versus 4.0%, p=0.005). There was a statistically significant difference between the two groups in the rates of both intraabdominal abscesses (4.8% versus 0.7%, p=0.008) and superficial/deep incisional surgical site infections (8.7% versus 3.6%, p=0.03).[14]

On multivariate analysis, patients who underwent cholecystectomy after ERCP had a significantly higher SSI rate in comparison to cholecystectomy only even after adjusting for these differences in surgical approach and wound class.[15] 246 4.1% (10/246) 2.16 (1.04–4.49) 0.040 statistically significant.[16]

Supporters of ERCP followed by laparoscopic cholecystectomy see it as safe and successful, while others point to the findings that ERCP increases surgical complexity and operating time. The incidence of surgical site infections was calculated to be 4.3% in a prospective observational research that was carried out by Makadia JM et al. on patients undergoing cholecystectomy either open or laparoscopically.[17]

In our study without prior ERCP SSI is low 13 (18.6%). Peponis T. and Panda N. compared the risk of surgical site infections following laparoscopic cholecystectomy in patients who had previously undergone ERCP with sphincterotomy versus those who had not in a 2018 study. Of the total 640 patients who presented over the course of 6 years, 122 (19.1%) had preoperative ERCP with sphincterotomy before undergoing laparoscopic cholecystectomy. When compared to those without a history of ERCP, those who had the procedure in the past were more likely to develop an infection at incision site. This study indicated that individuals undergoing laparoscopic cholecystectomy who underwent ERCP prior to surgery were three times more likely to develop an infection at the surgical site.[18]

In our study , we have notified that longer stay has been noticed in patients who underwent prior ERCP followed by laparoscopic cholecystectomy, in comparison early discharged was possible in patients who had laparoscopic cholecystectomy without ERCP, similar findings were seen by peponis et al, that longer hospital length of stay (median of 4 versus 3 days, p<0.001). Reason for higher hospital stay in our study is that currently we are keeping patients pre operatively in ward due to logistic reasons but mostly post-operative stay is 24 hours only even in our setup.[19]

A significant finding reported in study done by Loor et al in patients who underwent ERCP and had SSI, resistant organisms in endoscopes could have been the source as per previous epidemiologic and microbiologic studies.[20]

The retrospective design of our study precludes a determination of which was the more likely etiology of SSI, and is a topic which should be explored in future microbiologic studies. Ideally, prospective studies would involve collection of microbiologic specimens at the time of the procedure and follow patients longitudinally for the development of infectious complications. Similarly, the theory that bacteria can spread from the biliary tract to the soft tissue, either hematogenously or via direct contact with colonized biliary fluid at the time of surgery, could be investigated through prospective analysis of cultured isolates. Biliary obstruction and stenting may also predispose to surgical site infection, particularly when the ERCP and cholecystectomy are separated in time over weeks or months. While sphincterotomy or biliary stenting did not occur at significantly higher rates in our study in the group of patients who developed SSI, the role of these factors should be considered further in future.

We suggest that in future studies, we will be further collecting per op cultures from GB and postoperative from patient wounds to compare whether same organism is the source of infection additionally we suggest that long term use of antibiotics can reduce the rate of SSI and longer stay of patients in hospital and in the last but not the least a single-session laparo-endoscopic rendezvous procedure (as compared with ERCP before laparoscopic cholecystectomy) experienced a lower rate of treatment failure, a shorter hospital stay, and reduced total hospital

costs, with no increase in complication rates.

## CONCLUSION

An increase in the incidence of SSI following laparoscopic cholecystectomy by two- fold is connected with pre-operative endoscopic retrograde cholangiopancreatography (ERCP). Hence, ERCP prior to therapeutic surgery may add complications in such complex individuals, since cholecystectomy is the next technical step to achieve at a desired treatment aim. Given the prevalence of ERCP prior to laparoscopic operations, we plan to assess if this technique is linked to a higher risk of wound infection after surgery.[21,22] We suggest that long term use of antibiotics can reduce the rate of SSI and longer stay of patients in hospital.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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