

Outcome of Single Incision Laparoscopic Cholecystectomy (SILC) versus conventional four port Laparoscopic Cholecystectomy for Cholelithiasis - A Randomized control trial

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ABSTRACT

Aim: To compare the outcome of SIL (single incision laparoscopic) cholecystectomy versus conventional four-port laparoscopic cholecystectomy.

Methods: Two hundred patients are included in this study fulfilling the inclusion and exclusion criteria and are randomly divided into two equal groups (100 in each).

Results: Both the Groups were comparable and there is statistically significant difference among them in terms of Age, Gender and Co-morbid. From Group A 85 patients were discharged from hospital on the same day of surgery while only 31 patients from Group B went home on same day of surgery, the difference between two groups is statistically significant (p value 0.001). The mean pain score in patients of Group A was 2.87 ± 1.30 while in patients of Group B was 5.16 ± 2.31 , which is statistically highly significant (p value 0.001).

Conclusion: Single incision laparoscopic (SIL) cholecystectomy has a better cosmetic profile as compared to conventional (four port) cholecystectomy. Patients undergoing SIL cholecystectomy have short hospital stay and less pain at the wound site.

Keywords: Cholecystectomy, Single Incision Laparoscopic cholecystectomy,

INTRODUCTION

Cholecystectomies were generally painful requiring hospital stay of 5-7 days and prolonged period of rest before the patient could return to normal activity. Many clinical series have clearly shown that laparoscopic cholecystectomy results in a dramatic decrease in hospital stay, post-operative pain, and recovery period. Single incision laparoscopic cholecystectomy is a newly developed technique that has revolutionized the trend of cholecystectomies.

Outcome means postoperative pain and length of the stay in hospital in both the procedures. The obvious advantages of SIL cholecystectomy are that it is nearly scar less and associated with better cosmetic results. Single-incision access also reduces the risk of complications such as port injury and infection. The single incision made with the SILS techniques is nearly invisible if placed within patient's umbilicus. A locally conducted study by Zahid Mehmood et al¹ in March 2010 shows significant difference between the outcome of these two techniques in terms of post-operative pain and hospital stay.

In the study, the mean pain score in SILS group was (5.23 ± 1.52) versus that in four port LC group (2.93 ± 0.98) , p value being <0.001 (significant). In another study conducted by A Parasad

et al² in March 2010, the results were debatable such as mean pain score in SILS group was 2.58 versus 2.78 in the four port laparoscopic cholecystectomy group. Moreover in a study by Brittney³ which shows the same day hospital discharge status in patients undergoing these two procedures is different. In SILS group, 85% patients were discharged the same day of surgery while 70% patients having conventional four-port LC did not have the same day hospital discharge with a p value <0.03 .

However in a study conducted by Trastulli et al⁴, no such difference was observed and the patients were not discharged on the same day. As the different studies show controversial result, we have done this study to find out our experiences regarding the outcome of these two procedures.

PATIENTS AND METHODS

All patients with sonographic evidence of cholelithiasis in the age range of 30-60 years of either sex, presenting to surgical outpatient department Mayo Hospital Lahore and Shalamar Hospital Lahore from 1st July 2012 to 31st December 2013, were randomly divided using random number table into two groups. Group A comprises of 100 patients planned to undergo SIL cholecystectomy while Group B includes 100 patients who were scheduled for conventional four port laparoscopic cholecystectomy. An informed consent was taken from the patients about the study and the operative procedure. The

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following data was recorded: age, gender, post-operative pain, length of hospital stay and co-morbid.

The criteria for exclusion from the study was any contraindication to laparoscopic procedure such as pregnancy, bleeding disorders, obesity (BMI>35Kg/m2) and patient's refusal. All diabetic patients with fasting blood sugar of more than 150mg/dl were excluded. Patients who needed CBD exploration were also excluded.

Outcome of the two procedures will be discussed in terms of the following two parameters.

Postoperative pain was assessed by visual scale (VAS) in all patients until the discharge criteria are met such that VAS 0 means no pain and a higher score (up to 10) means severe pain assessed up to 8 hours after surgery. Mean pain scoring of the two groups was calculated and used as an outcome to compare.

Patients were discharged when the following criteria are met irrespective of the procedure they underwent; patient is tolerating oral fluids and is mobile, pain free (VAS score is less than 3) afebrile. All pre-operative patients were given a 1g bolus dose of a third generation Cephalosporin (Ceftriaxone) intravenously before surgery. Confounding variables like age, gender and co-morbid were studied through stratification.

Data was entered and analyzed by using SPSS version 17.0. The quantitative variables like age and pain score on VAS are presented as mean and + standard deviation. The qualitative variables like sex, co-morbid and hospital stay are presented as percentages and frequencies. For comparison of outcome among both groups chi-square test is applied as a test of significance. p value of ≤ 0.05 is considered as statistically significant.

RESULTS

The mean age of the patients in Group A was 40.83±7.87 years while in Group B the mean age of patients was found to be 42.46±8.66 years. There were altogether 89(44.5%) patients in the age range of 30-39, 70(35%) patients in the age range of 40-49 years and 41(20.5%) patients in the age range of 50-59 years (Table 1).

There were 116(58%) females and 84(42%) males. Group A comprises of 41 males and 59 females while Group B contain 43 males and 57 females (Table 2).

Altogether there were 27 Diabetics, 12 in Group A and 15 in Group B. 50 patients out of 200 were known hypertensive, 24 were in Group A and 26 in Group B (Table 3). According to these statistics the

two groups are comparable and there is statistically no significant difference.

Table 1: Comparison of age and groups

Age in years	Group A	Group B
30-39	49	40
40-49	34	36
50-59	17	24
Mean age	40.83(7.87)	42.46(8.66)

P value: 0.339

Table 2: Comparison of gender and groups

Gender	Group A	Group B
Male	41	43
Female	59	57

P value: 0.774

Table 3: Comparison of co-morbid and Groups

	Group A	Group B
Diabetes mellitus	12	15
Hypertension	24	26

P value: 0.735

Out of 200 patients, 116 patients were discharged from the hospital on the day of surgery while 84 patients had a stay of more than one day. Most of the patients (85 patients) who were discharged on the same day belong to Group A while only 15 patients from Group B were discharged on the same day, which is statistically significant (p value 0.001) (Table 4).

Table 4: Comparison of hospital stay in two groups

Hospital stay	Group A	Group B
Same day	85	31
Lengthy stay	15	69

P value: 0.001

The mean pain in patients of Group A was 2.87±1.30 while in patients of Group B was 5.16±2.31. The p value is 0.001 which is highly significant (Table 5).

Table 5: Comparison of pain among patients of two groups

Pain score	Group A (male)	Group A (female)	Group B (male)	Group B (female)
2-3	35	50	12	19
4-5	4	5	14	10
>5	2	4	17	28
Mean pain	2.87 +1.30		5.16+2.31	

P value: 0.001

DISCUSSION

Eighty-five of patients undergoing SILC went home the day of surgery. This is similar to findings in other reports. There was a statistically significant shorter length of stay for the SILC group. Patients in the SILC group stayed in the hospital on average 12 hours less

than those undergoing conventional (four port) Laparoscopic cholecystectomy. These results are similar to those of Joseph et al, who noted that the mean postoperative hospital stay for SILC patients was 12.7 hours shorter than that of 4PLC patients⁵. Although we did not study the time to normal activity, others reported that patients undergoing SILC tend to return to normal activity earlier than those undergoing 4PLC.

Similar to other studies, operative time was significantly longer in the SILC group than in the conventional four port laparoscopic cholecystectomy group. The mean operative time for SILC was 14 minutes longer than that for conventional four port laparoscopic cholecystectomy group. According to Greaves and Nicholson, the average difference in operative times among other studies is 12 minutes. Longer operative times are likely related to technical difficulties and a learning curve inherent in a new technique⁷. In this study, operative times that significantly deviated from the mean were often due to difficulties such as placing the gallbladder in the retrieval bag, performing a cholangiogram, obtaining a liver biopsy, and dealing with severe inflammation of the gallbladder.

SILC is technically difficult due to poor ergonomics, theorized decreased visualization and inadequate retraction due to limitation of movement. However, much of this difficulty is overcome with experience of both the surgeon and the assistant.

The learning curve for SILC has been studied multiple times. According to Hernandez et al⁸, the slow beginning of the learning curve is associated with rates of conversions and increased complications. This is followed by the steep acceleration phase during which rapid procedural learning takes place. This phase ends with proficiency, after which the curve plateaus. Hernandez et al reported that the learning curve for single-incision surgery actually begins near proficiency. After 75 surgeries, the mean operative time for a single surgeon significantly decreased. Qiu et al reported that after 20 procedures, the training phase appeared to be complete and after 40 procedures, operative time seems to stabilize⁹.

With multiple incisions in the fascia in such close proximity and a longer skin incision, there is a theoretical increased risk of incisional hernias. In a series of 125 patients with follow up as long as 22 months, Cui reported that no patient had presented with an incisional hernia¹⁰. Follow up in our study was limited to 6 weeks however, we noted no incidence of incisional hernia or wound complications.

As with many other reported series in single-incision surgery, there was a noted inherent selection

bias. However, an appropriate selection bias would be necessary when introducing a new technique into a surgeon's practice. Clinical judgment should allow the surgeon to minimize operative complications and risks while optimizing patient satisfaction. In previously reported studies, patients were often excluded from SILC due to previous abdominal surgery, acute cholecystitis, pancreatitis, atypical symptoms and malignancy. American society of Anesthesiologists score of III or more and obesity based on body mass index these exclusion criteria should be considered when first adopting SILC into one's practice.

CONCLUSION

It is concluded from this study that there is a difference in the outcome of the two modes of laparoscopic cholecystectomy that single Incision cholecystectomy (SIL) is associated with greater cosmesis, less pain at wound site and is a day case surgery altogether whereas the conventional (four port) Laparoscopic cholecystectomy in patients with chronic cholecystitis due to cholelithiasis, as in our study was found to be associated with longer length of stay in hospital.

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