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RESEARCH ARTICLE

RANDOMIZED CONTROL TRIAL OF CONVENTIONAL LAPAROSCOPIC VERSUS SINGLE INCISION LAPAROSCOPIC CHOLECYSTECTOMY

Vaibhav Jaiswal[1], Saumya Singh[2], Surendar Kumar[2] and Devendra Singh[3]

1. Assistant Professor Department of Trauma Surgery,King George`s Medical University, UP, Lucknow, India.
2. Associate Professor Department of General Surgery, King George`s Medical University, UP, Lucknow, India.
3. Professor Department of General Surgery, King George`s Medical University, UP, Lucknow, India.

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Abstract

Background: From big incision to minimally invasive multiport classic laparoscopic cholecystectomy (CLC) and now to single incision laparoscopic cholecystectomy (SILC) surgeryhas travelled a long way. There are proposedadvantages and potential disadvantages of SILC compared to the 'gold standard' CLC. However, debate still exists whether SILC has anything more to offer. We compared various parameters of patient satisfaction, quality of life and short term surgical outcomes between CLC and SILC.

Method: RCT was conducted forduration of one year. Patients were assigned into SILC and CLC groups. Operative time, length of hospital stay, quality of life (SF 36 questionnaire), patients overall and cosmetic satisfaction and postoperative pain using 10-point visual analogue scale (VAS) were assessed.The data analysis was done using software SPSS version20.0.

Results: A total of 36 patients (28 women and 8 men) with mean age 39.88±11.99 yearswere allocated into SILC (n=18) and CLC (n=18) groups.The mean operative time for SILC was significantly longer than CLC (66.33 vs 46.50 minutes, P=0.001). VAS recorded higher pain in first 24 hours postoperatively in SILC than CLC group (4.467 vs 2.667, P=0.06). However, at the time of discharge patients in CLC had greater pain than SILC group (0.22 vs 0.133, P>0.99).No significant variability was seen in length of hospital stay (SILC 3.60 vs CLC 3.38 days, P=0.47). The QOL on first follow up visit showed statistically significant difference in two of the domain of SF 36, namely vitality and bodily pain. Patients overall and cosmetic satisfaction showed no superiority of SILC over CLC.

Conclusions: Although patient prefers SILC in wake of cosmetic reasons, still it is a long way off from replacing CLC. Larger operative time and lack of standardization makes SILC still an evolving procedure and judicious patient selection is must for better outcome.

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Corresponding Author:- Vaibhav Jaiswal
Address:- Assistant Professor Department of Trauma Surgery, King George`s Medical University, UP, Lucknow, India.

Introduction:-

Globally there is an increase in incidence of elective Cholecystectomies. The overwhelming majority of cholecystectomies are now performed laparoscopically, and it has become one of the "safest and most effective operative procedures" of general surgery since its introduction in 1985. Surgical standards of practice continue to evolve toward less invasive surgical approaches with fewer perioperative complications. In journey of surgical access from a big incision to minimally invasive multiple keyhole ports, the road seems to be endless and full of innovative ideas and techniques. Because of the presumed advantages Minimally invasive surgery (MIS) is increasingly being adapted in hepato-pancreato-biliary surgeries throughout the world. Surgery of the biliary tract is by no means the exception. Nowadays, minimally invasive surgeons are solidifying their practice on trans umbilical SILS for what used to be done only through 4 to 5 access Laparoscopic surgery. A concept that encompasses a variety of techniques allowing performance of complex operations without leaving visible evidence that surgery has occurred.

Classic laparoscopic surgery has been associated with wound infection. Furthermore, not only are multiple port sites considering a significant contributor to postoperative pain, there is a reported 0.77% to 3.0 % hernia at these port sites.[1-3] Efforts to improve outcomes of laparoscopic cholecystectomy precipitated the advent of single incision laparoscopic cholecystectomy (SILC) in the 1990. As per Navarra et al. in 1997,single-incision laparoscopic cholecystectomy can be a potential alternative to the four-port laparoscopic cholecystectomy and hence can maximize the benefits of laparoscopic surgery.

The potential advantages of SILC over classic 4 port laparoscopic cholecystectomy (CLC) include few port sites and reduced risk for wound infection, early recovery with less postoperative pain and improved cosmesis. The goals of SILC are decreased pain, decreased length of hospital stay, better aesthetic results, and increased patient satisfaction.

Disadvantages of SILC include learning curve for the performing surgeon, prolonged operative time, and decreased visualization, which raises the safety concern of this operation, e.g. Increased risk of common bile duct injuries. None of these studies addressed the patient's postoperative quality of life (QOL), which is an important component of health outcome. Lack of prospective, randomized controlled trials (RCT) has prevented us from making a true and unbiased comparison of these 2 surgical procedures in term of clinical benefit.

The debate is ongoing whether SILC has anything more to offer to the patients, to the surgeons or to the health care industry compared with CLC. As SILC media coverage rises along with its popularity among surgeons, the importance of this debate gains more significance.

In this work we have compared various parameters of patient satisfaction, and perioperative pros and cons one to one between CLC and SILC.

Our data, together with other RCTs in this regard will provide insight into this procedure, which is currently largely consumer and industry driven.

Methodology:-

From August 2011 to August 2012, cases of laparoscopic cholecystectomy have been attempted at the CSM Medical University. Very few cholecystectomies are now performed at our institution using the traditional "open" method. This reported experience therefore represents the great majority of cholecystectomies performed during this period.

All subjects provided written informed consent to be included in the study.

Patient Selection

Patients were selected for LC based on clinical and radiographic evaluation showing cholelithiasis. All the patients were evaluated with USG whole abdomen. The surgeries were conducted using general anesthesia.

Randomization

Selected patients then randomized using computer generated software named Random Allocation Software. Then they are assigned to a particular category, underwent operative intervention either SILC/ CLC depending upon their group.

Period of Study
One year starting from August 2011 to August 2012.

Study Groups
Group I (n=17): Patients selected for elective cholecystectomy opting for Classic Laparoscopic cholecystectomy (CLC).
Group II (n=15): Patients selected for elective cholecystectomy opting for Single Incision laparoscopic cholecystectomy (SILC).

Operative Technique
Perioperative Protocol:
1. Screened in the pre-anaesthetic clinic.
2. Investigation findings were recorded in pre anaesthetic card.
3. Written and informed consent taken and all procedures explained to the patient.
4. Tablet Alprazolam 0.25 mg orally right before the surgery.

Inclusion Criteria:
1. Indications for laparoscopic cholecystectomy with no evidence of choledocholithiasis.
2. Body mass index (BMI) < 40 kg/m^2.
3. Normal Renal Function Tests
4. Normal Liver Function tests

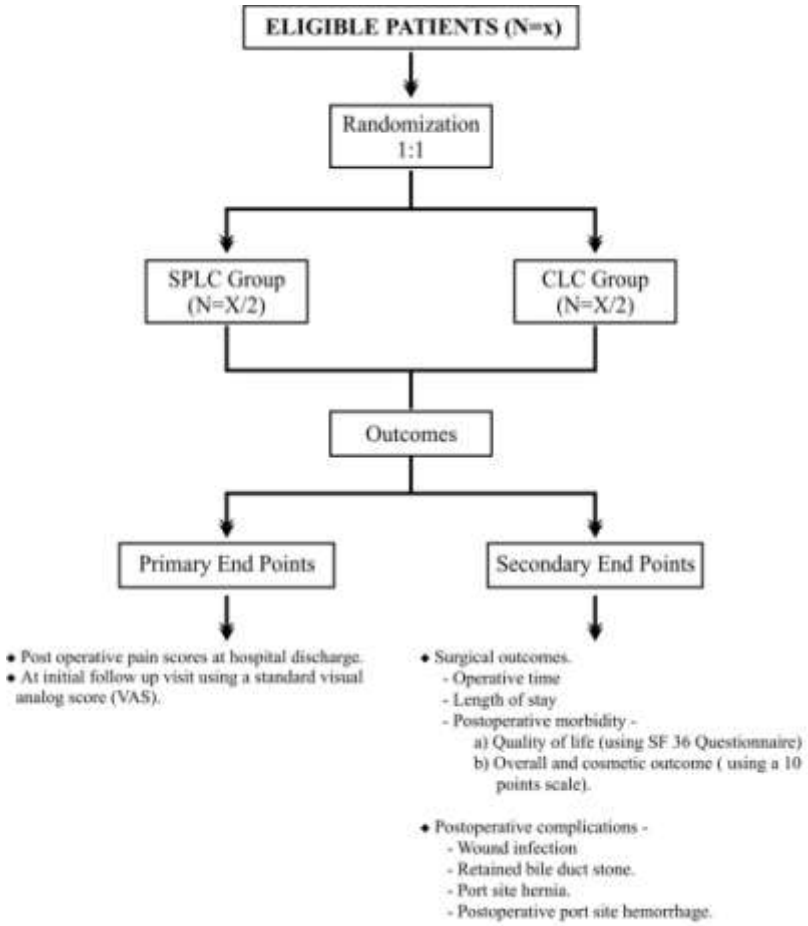
Exclusion criteria:
1. Acute Cholecystitis
2. Choledocholithiasis
3. Jaundice due to other causes
4. Suspected Malignancy

Intraoperative, if the surgeon failed that a save cholecystectomy could not be achieved by SILC then they may convert to either CLC or open cholecystectomy.

Primary end points –
Standard 10-point visual analog scale (VAS) used for assessment of pain, which was recorded in pre-operative period, in immediate post-operative period, on POD1 and at discharge.

Secondary end points –
outcomes –
1. Operative time
2. Length of hospital stay
3. Postoperative morbidity
4. Quality of life

Operative time measured for each patient started at skin incision to skin closure, taken in minutes. Length of hospital stay taken as days patient spent in hospital following operation. Quality of life measured at the admission and at initial postoperative visit by patient reporting SF 36 questionnaire, which was provided to patients in Hindi / English. Patient overall and cosmetic satisfaction rated using a 10 points scale. Patients then assured that scores will not be revealed to the surgeons. The survey process required approximately 15 to 20 min/person.



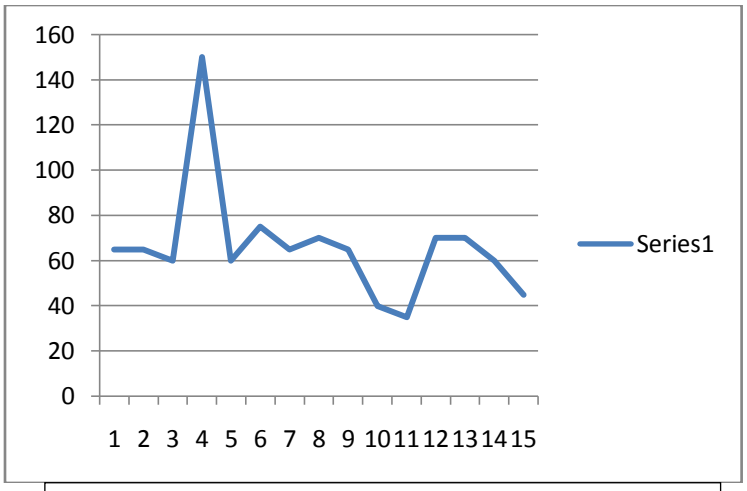
Statistical Analysis and Sample Size:

The number of patients required for study (n=17 each group) is calculated by on the basis of 80% power to detect a significant difference in postoperative pain score at a 5% significant level. SPSS (Statistical Package for Social Sciences) Version 20.0 was used for statistical analysis. The values were represented in Number (%) and Mean ± SD.

1. Two-tailed t-Test was used for statistical analysis of demographic data and perioperative data.
2. Mann- Whitney U Test was used for comparison of pain scores and SF-36 Score.

Results:-

A total of 33 patients (27 women and 6 men) ranging from 22 years to 66 years in age (mean 39.88+- 11.99 years) were randomly assigned to SILC (n=15) or CLC (n=18).There was no statistically significant difference in Age, BMI or gender distribution between the 2 groups. Preoperative characteristics, e.g., existence of comorbid conditions, preoperative diagnosis and history of abdominal surgery were comparable between groups. None of the patients received intraoperative cholangiography or intraoperative ultrasound. The mean operative time for SILC group was significantly longer than CLC group(66.33 minutes vs 46.50 minutes , P =0.001).



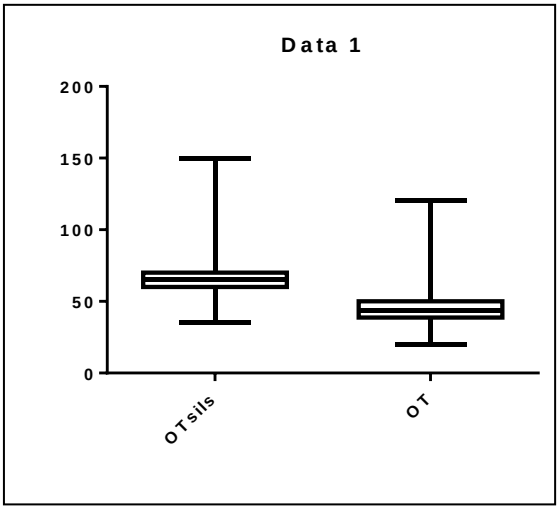
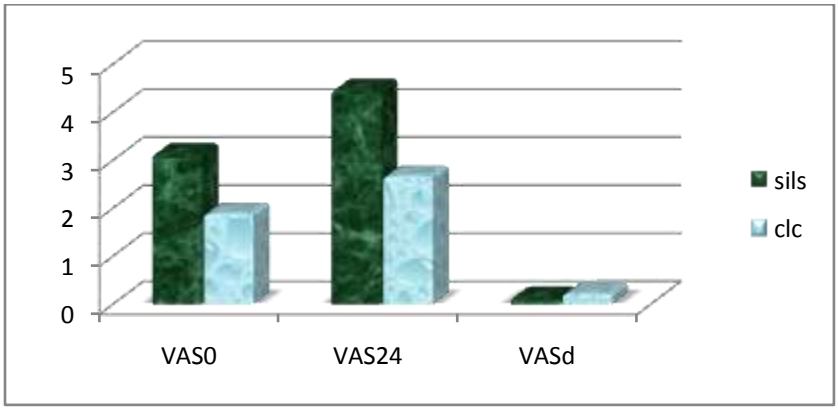
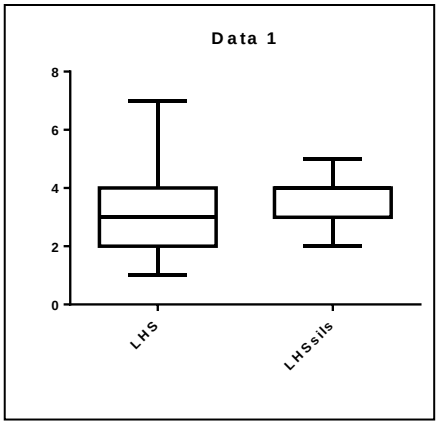


Table: Time trend in Operative time in SILS

Analysis of pain using Visual analogue scale reported higher pain in first 24 hours of post-operative period in SILC group as compared to CLC group (4.467 vs 2.667 , P = 0.06) which was statistically non-significant. But in our study we had seen that at time of discharge patients who underwent CLC experienced greater pain than patients operated with SILC (0.22 vs 0.133, P>0.99) which was also statistically non-significant .Length of hospital stay measured in days shown no significant difference between two groups (SILC 3.60 days vs CLC 3.38 days, P = 0.47). On assessment of quality of life using SF-36 Questioner we did not find any difference in various domains of QOL in preoperative period, between two group.





Quality of life measured at the admission and at initial postoperative visit by patient reporting SF 36 questionnaire, which was provided to patients in Hindi / English. Patient overall and cosmetic satisfaction rated using a 10 points scale. Patients then assured that scores will not be revealed to the surgeons. The survey process required approximately 15 to 20 min/person.

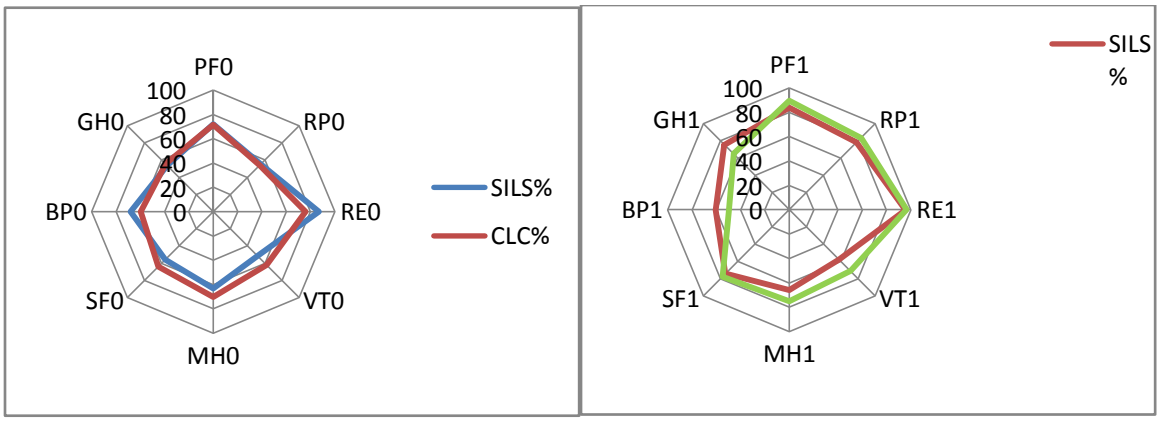


Figure a and b show the mean scores for the 8 health attributes measured by SF-36 questionnaire given to patients during their pre-operative clinical visit and initial post-operative clinical visit. These 8 domains of health status include: physical functioning (PF), role limitations-physical (RP), role limitations-emotional (RE) , bodily pain (BP) , general health (GH), vitality (VT), social functioning (SF) and mental health (MH).

While when we carried same assessment on first follow up visit we had seen statistically significant difference in vitality (SILC 230.7+_ 69.64, CLC 283.3 +- 11.0, P=0.0491) however it was nominal only. One more parameter which had shown statistically significant variation was bodily pain (P = 0.006). Patients overall satisfaction with the procedure was measured using a 10-point scale, and We did not find any statistical significant difference in Overall Satisfaction (SILC 8.733 , CLC 8.611 , P=0.6812) between these two groups, neither we found any superiority of SILC over CLC as far as cosmetic satisfaction is concerned (SILC 8.667, CLC 8.722 ,P=0.810).

Fig. Port positions in SILC

Fig:- Postop scar in SILC on Day7.

Discussion:-

We conducted this Randomized Control Trial over a period of 12 months on patients admitted in Department Of General Surgery, KGMU who were indicated for Cholecystectomy and also fulfil our inclusion criteria as described previously.

It is always difficult for a time bound RCT , to meet with a sophisticated sample size. Our sample size consisted a total of 33 patients and they were allocated to two study groups randomly, using Random Allocation Software. Finally we landed up with 15 patient in SILC group and 18 patients in CLC group.

CLC is a time honoured and gold standard technique for surgical removal of gall bladder while SILC is simply an innovation in stealth surgery. SILC is a step towards even less invasive surgical procedure.

SILC bears the potential disadvantages of posing learning curve for the performing surgeon, as well as limited exposure of surgical field which potentiates increased risk of bile duct injury just like what had been early experience with CLC.

Whether it holds any potential to replace CLC as a procedure of choice or it is simply a health care industry driven gimmick. A lot many studies have been done and many more are under way. In developing nation of India, we wanted this comparison to be made in our own kind of infrastructure. Our study aimed to compare short term surgical outcomes between patients undergoing SILC and CLC, over various parameters as defined previously.

Operative time

In our study overall operative time in CLC group was significantly shorter than that of SILC group (46.50 minutes vs 66.33 minutes, P =0.001). We had also seen role of learning curve in this study, in earlier cases operative time was greater than the cases done latter. It has been acknowledged that once the basics of this advanced surgical skill is grasped along with the attainment of a desired level of learning curve , the novel technique may be feasible for mass adoption, if it is also proven safe and economically advantageous. This fact has also shown harmony with a lot many studies done previously. As shown by Zubaidi et al in 30 patients (22 women 8 men)foundMean operative time was 104.3 ± 44 minutes.[9] The extra time reflected the corelation between the degree of the procedure complexity and the operating surgeon's learning curve, and a declining trend was seen in operative time as no of cases increased.Chang et al, in a case-control study of single-incision versus standard laparoscopic cholecystectomy concluded that there was a significant difference in operative time (SILC was approximately 1.6 times longer).[10]

Post-operative pain

In our study we found that patients of SILC group experienced more pain in first 24hrs of post-operative period than CLC group(4.467 vs 2.667 , P = 0.06) which was statistically non-significant. Hernandez et al also reported increased pain complications in his SILC group compared to CLC group.[11] But in our study we had seen that at time of discharge patients who underwent CLC experienced slightly greater pain than patients operated with SILC (0.22 vs 0.133, P>0.99) which was statistically non-significant. While studies conducted by Tsimoyiannis EC, et al andOsborne D, et al had shown contradictory results that fewer ports results in less pain. [7,15] The reduction in pain perception in SILC was postulated to be less visceral component of surgical pain as a result of reduced trocar number and diaphragmatic irritation from dissolved carbon dioxide in the SILC procedure. In contrast Poon et al, failed to demonstrate any advantage of fewer-port over 4-port laparoscopic cholecystectomy in overall pain score. [12] Chang et al observed no difference in postoperative pain.[10]

Patient satisfaction

We do not found any significant difference in patient overall (SILC 8.733 , CLC 8.611 , P=0.6812) and cosmetic satisfaction between SILC and CLC patients (SILC 8.667, CLC 8.722 ,P=0.810)..Zubaidi, et al concluded that the procedure of single-port cholecystectomy left a barely visible scar in most patients.[9] It provides the same benefit of scarless surgery of NOTE as the incision is well hidden in the umbilical (existing scar) , which in itself is an embryological natural orifice, which is an embryological natural orifice.

Patients are more satisfied with the hidden or infraumbilical single surgical scar than the four scars created by the CLC.[6] Marks, et al. in a RCT of traditional laparoscopic cholecystectomy versus single-incision laparoscopic cholecystectomy.

Adachi, et al Shown thatThe umbilical scar via the SILS Port was larger than that of conventional 4-port LC. [16] Concretely, the umbilical scar length in the case of conventional 4- port LC was about 15mm; however, using the SILS Port it was approximately 25 mm. Time dependent change in satisfaction level is likely due to evolution of tissue healing and scarring. Highly subjective nature of cosmetic satisfaction makes it hard to quantify. Limitation with our study is that the patients do not have the opportunity to make a comparison for cosmetic outcomes. Improved objectivity may be achieved if the comparison between 2 groups repeated along follow up.

Quality of Life

The SF-36 health status questionnaire is a generic health measure that allows comparisons of burden of illness among disease and populations; it is equally applicable to all persons, regardless of condition. We did not find a difference in any of the 8 health status domains, preoperatively between patients allocated to different groups. While when we carried same assessment on first follow up visit we had seen statistically significant difference in vitality (SILC 230.7+_ 69.64, CLC 283.3 +- 11.0, P=0.0491) however it was nominal only. One more parameter which had shown statistically significant variation was bodily pain (P = 0.006).

Intra-op/post op complications

Presence of intraoperative and postoperative complications are key in comparative evaluation of procedures. For a novel procedure to be safe the rate of complications must be similar to current gold standard. Between SILC and LESS cholecystectomy numerous studies have reported no significant difference in complication rate. An increased complication rate when comparing SILC to CLC were found in study of Phillips, et al.[4] Similar results were found by J. Ma, et al.[8] Antoniou et al. analysed the results of 29 different articles reporting the realization of a SILC/LESS cholecystectomy with a total of 1166 patients. [5] Among the reported results there is 9.3% of unsuccessful surgery, generally due to a lack of proper identification of Calot's triangle, along with a cumulative intraoperative complication rate of 2.7% (range 0–20%) with the most common being gallbladder perforation/bile spillage (2.2%) and hemorrhage (0.3%). The most common postoperative complications were wound infection and hematoma in 2.1% of patients.

Curcillo et al. reported in their multi-institutional 297-case series that the use of an additional port outside the umbilicus occurred in only 34 cases, and they concluded that SILC was safe and might serve as an alternative to multiport therapy with fewer scars and better cosmesis.[14]

Roland Raakow studied SILC in 220 patients.[18] Eleven patients (5%) developed complications related to surgery. Seven of these patients (3%) underwent a second operation. Two patients developed a hematoma and two a seroma

at the umbilicus. Because of wound infection, a wound debridement was undertaken in three patients. A severe complication regarding the bile duct was noticed in two patients. One patient developed a 2 cm necrosis of the bile duct after Mirizzi's syndrome, two days after the initial operation. A second patient had a bile duct leakage because of a thermocoagulation injury. A biliodigestive anastomosis was performed in both patients. The following hospital stay was prolonged but without more complications.

Edwards et al**.** described that biliary complications occurred in 3.7% of their SILC patients.[13] Iatrogenic combined bile duct and right hepatic artery injury during SILC has already been reported Chiruvella et al**.**[17]Hernandez et al. reported that biliary complication (cystic duct stump leak) occurred in one of 100 SILC cases. [11]

In the study conducted by Mark Joseph et al ;[19] A total of 76 candidate studies were identified; 45 studies met inclusion criteria for an aggregate total of 2626 patients. Most SILCs were performed in the pateints without acute cholecystitis (90.6%). The aggregate complication rate was 4.2%, and complications were graded according to the Dindo-Clavien Classification System. Nineteen bile duct injuries were identified for a SILC-associated bile duct injury rate of 0.72%,with a conclusion that rate of bile duct injuries during SILC was higher when compared with historic rates during SLC.

In our study we did not faced any injury to CBD. While we reported biliary spillage due to gall bladder rupture in 1 patient in each group. Among post-operative complications we had seen 2 patients in SILC group who developed wound infection and required oral antibiotics. While 1 patient in CLC group reported with Latex allergy due to medicated band-aid application at Epigastric and subcostal port site. No any patient reported with trocar site haemorrhage or any port site hernia either in SILC or CLC group.

Conclusion:-

Current evidence suggests that even though patients prefer for cosmetic reasons SILC over CLC.,SILC is still a long way off from replacing CLC as a gold standard for surgical removal of gall bladder. Larger operative time alongwith lack of standardization and instrumentation makes SILC still an experimental/innovative procedure that requires further development in order to be applicable to general surgeons worldwide. Thus far the only documented benefit of SILC is cosmetic , although it is equivalent to conventional laparoscopic cholecystectomy in all other respect. We concluded that the most important factor for success with SILC is likely in judicious patient selection criteria. With our surgeon's personal experience and literature review, we believe that SILC is a reality that is here to stay especially as experience with SILC grows and learning curve shortens.

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