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Comparative Study of Single-Port Laparoscopic Cholecystectomy and Four-Port Laparoscopic Cholecystectomy

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ABSTRACT:

Background: The therapy of choice for benign and symptomatic gallbladder disease is laparoscopic cholecystectomy (LC). Standard laparoscopic cholecystectomy has been linked to a conversion rate of 0.2%, biliary complication rates between 0.26 and 0.6%, and intestinal damage rates between 0.14 and 0.3%. Major morbidity is related to pain, wound problems, and cosmetic results and is associated with typical LC access ports. Wound-related complications continue to account for over 2.3% of total mortality.

Aim's & Objectives: To assess the feasibility of Single Incision Laparoscopic Cholecystectomy using conventional laparoscopic instruments and compare it with conventional Four port laparoscopic cholecystectomy .

Methods & Materials: The prospective randomised control Study was conducted in the Department of General Surgery, Santosh Hospital & Medical College, Santosh University, Ghaziabad from March 2014 to September 2015.There were 60 Patients undergoing Cholecystectomy for Choleliathiasis with 30 in each group.

Results: The maximum hospital stay in group I (LC) was 4 days for the patient who developed atelestasis. Whereas in group II (SILC) it was 3 days for patient who developed thrombophebitis. The mean hospital stay in group I (LC) was 1.1 and in group II (SILC) was 1.07. The difference of which was statistically non-significant (p value>0.05).

Conclusion: SILC is a safe and feasible procedure which requires a high degree of technical expertise on the part of surgeon. SILC is a promising alternate method to conventional four port laparoscopic cholecystectomy. Although the idea of SILC seems similar to standard four port laparoscopic cholecystectomy, but practically it has major difference in technique. It involves crowding of all working instrument within one incision and the basic principle of triangulation is lost to one extent.

Keywords: Laparoscopy, minima surgery , cosmesis, lesser operative time, postoperative , Cholecystectomy, Choleliathiasis.

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INTRODUCTION:

Laparoscopic cholecystectomy (LC) is the gold standard treatment for benign and symptomatic gallbladder disease. [1-3] The Standard laparoscopic cholecystectomy has been associated with a conversion rate of 0.2% , biliary complication rate of 0.26 to 0.6 % and bowel injury rate of 0.14 to 0.35 %. Major morbidity is related to pain, wound complications and cosmetic outcomes and is related to the access ports for standard LC. The wound related complications still account for almost 2.3% of the overall morbidity[6]. There has been a continuous endeavour to reduce the invasiveness and thus wound related complications of LC and simultaneously improve the cosmetic outcomes of LC. Various natural orifices including the trans-gastric, trans-rectal, and trans-vaginal route have been used as access, without much success . [6-10]

To reduce the invasiveness of standard four port cholecystectomy, single incision laparoscopic cholecystectomy (SILC) has also become an attractive option for the performance of laparoscopic cholecystectomy [11-14]. There has been tremendous development in this field in the last decade and various access devices and instruments have been developed to carry out SILC. Some case studies and case series have demonstrated the feasibility and efficacy of this single incision technique however risk/benefit ratio of SILC is not well established. There has been concern about the risk of increased complications in this procedure. In a study by Allemann et al [15] the incidence of bile duct injury was 0.4% and in a study by Jørgensen et al[16] the incidence of incisional hernia was 2%. The current published literature is not yet conclusive on efficacy, safety, short and long - term outcome. There are studies concluding lower pain and better cosmetic results in SILC[17,18] and others concluded higher pain and no significant difference in cosmetic results[19,20]. The present prospective randomized controlled study was designed to compare efficacy, safety, success, and cosmesis of SILC related to surgical outcome, acute and chronic pain, cosmetic outcome and quality of life with that from standard four-port LC. The primary objective was to compare the success of the two procedures and secondary objective was to compare pain scores and cosmetic outcome .

Laparoscopy / minimal access surgery provides the advantages of better cosmesis, lesser operative time, decreased postoperative pain and lesser complications [21-25]. Now, having established the safety of LC, interest focused on further reducing the invasiveness and scarring caused by the procedure. Stealth surgery is an emerging surgical paradigm that encompasses a variety of techniques and technologies that allow complex operations to be performed without leaving visible evidence that they occurred. At its most basic level incisions are hidden at inconspicuous locations, but the ultimate goal is to reduce pain, markedly expedite recovery and perhaps avoid incisions altogether. Modifications of the standard four-port laparoscopic cholecystectomy (LC) are common in the literature and have focused primarily on decreasing the number, size and position of access ports. The SILC

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operations are currently the only clinical application of stealth surgery for abdominal conditions.

In three port cholecystectomy three ports are used. Umblical port for camera, subxiphoid port and a single subcostal port are used for gall bladder retraction and dissection. In a study conducted by Leggett PL et al [19] 159 patients who underwent laparoscopic cholecystectomy with three port technique were compared with a group of 100 patients who had undergone conventional four port laparoscopic cholecystectomy and he concluded that patients in the three port group had significantly greater postoperative discomfort but returned to work earlier. There was no significant difference between two groups in terms of operative time, cosmetic outcome, complication rate and hospital stay. In a study by Cerci Cet al [20] one hundred and forty-six consecutive patients who underwent elective laparoscopic cholecystectomy for cholelithiasis were randomized to receive either the three-port or the four-port technique. Operative time (time from the beginning of the insufflation up to the closure of the skin), success rate, visual analogue pain score, analgesia requirements, postoperative hospital stay were compared and no difference was found between these two techniques. In a study by Manoj Kumar et al [21] Seventy-five consecutive patients who underwent elective laparoscopic cholecystectomy were randomized to undergo either the 3-port or the 4-port technique. Patients in the 3-port group had shorter mean operative time and less pain at port sites. Overall pain score, analgesia requirements, hospital stay, and patient satisfaction score on surgery and scars were similar between the 2 groups. From above study it can be concluded that there is no added advantage of three port technique over four port technique.

In two port cholecystectomy umblical port is used for camera and single subcostal port is used for gall bladder dissection. The gall bladder retraction is achieved by two transfacial sutures, one through fundus and one near neck of gall bladder. In study conducted by Poon CM et al[32] one hundred and twenty consecutive patients were randomized to receive either the two-port or the four-port technique. He concluded that patients in the two-port group had shorter mean operative time, less pain at individual subcostal port sites but overall pain score, analgesia requirements, hospital stay, and patient satisfaction score on surgery and scars were similar between the two groups.

Form above studies it is clear that though with modifications in the standard technique of conventional four port cholecystectomy the number of skin incision is decreased but it does not have any significant difference on the cosmetic outcome.

After the development of flexible endoscopy the fields of gastroenterology and surgery have witnessed revolution allowing routine surgical procedures (cholecystectomy, appendectomy, tubal ligation, gastric bypass) to be performed without scars via operating flexible endoscopes passed via natural orifices (mouth, rectum, vagina, and others). The potential advantages of such systems include lack of surgical scars, less anaesthesia, and faster

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recovery. What is not clear are the methods, tools, and training needed to make this development safe and effective.

Of all the routes for NOTES the vagina has gained the most popularity because it not only is readily accessible and easy to decontaminate but it also provides safe entry and simple closure. It is well established that cholecystectomy is the most common procedure that takes place through the vaginal port. There have been number of studies with limited number of patients undergoing NOTES cholecystectomy (Table 1)

Table 1: Cholecystectomy Via Natural Orifice Transluminal Endoscopic surgery

Authors	No. of patients	Operating time	Complications	Hospital stay	Follow up
De Sousa et al33	4	210 mins	0	1 day	30 days
Decarli et al[34]	12	125 mins	1(vulvar laceration)	1.2 day	90 days
Buess et al[35]	6	80 mins	1 (intrabdominal collection)	1 day	180 days
Linke et al[36]	104	-	2 (hernia, stroke)	1 day	-
Cuadrado-Garcia et al[37]	25	120 mins	1(hematuria)	1 day	140 day

In a study by Niu et al 18 a total of 43 transvaginal cholecystectomies were performed successfully without no conversion. There were no intraoperative or postoperative complications. The patients recovered promptly after surgery and all were satisfied with the cosmetic result. He concluded that postoperative pain, hospital stay, and cost of hospitalization with NOTES were much less when compared with conventional four port laparoscopic surgeries. In a study by Solomon DT et al[19] 14 patients who underwent transvaginal cholecystectomy were compared with 22 patients who underwent single incision cholecystectomy and 11 patients who underwent standard four port cholecystectomy. He concluded that transvaginal cholecystectomy is a safe and well tolerated procedure with statistically significant less pain at 1 and 3 days after surgery, with a faster return to work but longer operative times compared with single incision and four-port laparoscopic cholecystectomy. In a study by Santos BF et al[7] seven patients who underwent transvaginal cholecystectomy were compared with seven patients who underwent standard four port cholecystectomy. He concluded that transvaginal hybrid NOTES cholecystectomy using a flexible endoscope for dissection is a technically feasible and safe procedure. Tranvaginal cholecystectomy requires a longer operative time than standard four port cholecystectomy but may result in less pain in the immediate postoperative period with patients subsequently requiring fewer narcotics.

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Surgery via natural orifices is essentially surgery without a visible scar and marks a prominent evolutionary leap in medicine. NOTES seem to offer better cosmesis thanks to the lack of extra incisions and may be associated with reduced postoperative pain when compared with traditional laparoscopic surgeries. Although some of the afore mentioned reports suggested a promising future for these innovative techniques, the promise currently remains unfulfilled because significant ethical, procedural, and technological questions remain unanswered. To date, the expected benefits have not been shown clearly in the literature. All the studies in the literature are done with very small number of patients and none of the study is a randomized prospective study. It was shown that the most feasible and well-established procedure was cholecystectomy, which accounted for 85.3% of all NOTES procedures[9]. In transgastric or transcolonic NOTES, the lack of sterilization and secure closure of the gastric or colonic wall remains the greatest set back because the development of gastrointestinal leaks would represent a catastrophic complication, which rarely follows routine laparoscopic cholecystectomies[7,8,9]. Beyond these differences, there is a necessity to establish the feasibility and safety of other ports because the transvaginal route is available only in women, who comprise only half of the potential candidates for this surgical proposal. In male patients, the transgastric or transcolonic approach should be rigorously explored and evaluated so it can be applied in clinical practice. It seems that until appropriate technology is available and the ethical issues regarding NOTES application are solved, the supposed benefits of better cosmesis can't outweigh the risks of potential immature application.

Single incision laparoscopic surgery was first described as early as 1992 by Pelosi et al who performed a single-puncture laparoscopic appendectomy. The first attempts at single incision laparoscopic cholecystectomy were performed by Navarra et al (1997)[22]. A single incision was made through the umbilicus and two trocars or ports were inserted through the opening with a bridge of fascia (soft connective tissue) between them. Subsequent studies using single umbilical skin incision laparoscopic cholecystectomy have altered the technique, with some using multiple fascial punctures to insert multiple ports in the same incision and others using single-port access systems that allow multiple instruments to be inserted through the same port without clashing.

Single Incision Laparoscopic Cholecystectomy vs Standard Four Port Laparoscopic Cholecystectomy

Laparoscopic cholecystectomy is the gold standard treatment for symptomatic gallbladder disorders all over the world. This operation is conventionally performed by using four ports and has been reported as safe and feasible. In the new era of minimal access surgery, the preferred outcomes under consideration are not only the safety, but also quality, which is often defined by pain and cosmetic results. Keeping this in mind surgeons have started to adopt surgical techniques of scar less surgery like single incision laparoscopic surgery. The two procedures single incision and standard four port laparoscopic cholecystectomy are mainly compared according to following parameters.

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In a meta-analysis by Mate Milas et al[25] operating time (30 trials) was longer with SILC (with mean difference (WMD) =12.4 min, p value <0.001), but difference reduced with experience in 10 large trials (1321 patients) (WMD=5.9, p value=0.105). In a similar meta-analysis by Liangyuan Geng et al[46] LC was superior to SILC in operating time (WMD = 13.6, P<0.001). In a study by Huseyin Sinan et al (2012)[47] the mean operative time was 124.4 ± 29.7 minutes for SILC and 64.1 ± 26.1 minutes for LC; this difference was statistically significant (P < 0.001)

In a study by Alireza Barb et al (2012)[48] the average operative time for patients who underwent SILC was significantly longer in comparison with those who underwent standard laparoscopic cholecystectomy (56.3 vs. 41.7 min). In a study by Jeff Siu-Wang Wong et al (2012)[49] the mean operation time was 78 ± 21.1 and 74 ± 24.3 minutes in the SILC and the LC group, respectively. There was no significant difference in operation time.

From above studies it is clear that operative time in SILC is significantly longer as compared to standard LC but with time and experience the learning curve tends to get smaller with increased precision and lesser operative time.

In a meta-analysis by Mate Milas et al [15] 8 trials with blinded patients when SILC group was compared with LC group in terms of postoperative pain the mean difference was small and insignificant (mean difference (SMD)-0.15, p- value=0.591).

In a study by Alireza Barb et al (2012) [18] the postoperative pain, there was a significant difference at 24 hours after operation (3.3 for SILC group vs. 3.8 for standard technique). At 8 hours after operation the difference was marginally significant (P = 0.058). However, at 2 and 72 hours after operation there was no statistically significant difference between the 2 groups.

In a study by Jeff Siu-Wang Wong et al (2012)[49] the postoperative pain score 1 day after operation was significantly lower in the SILC group (2.9 ± 1.6 in SILC group vs. 4.8 ± 1.5 in LC group, P < 0.01). The median total oral analgesic consumption was 2.5 tabs (0 to 18 tabs) in SILC group versus 3.5 tabs (0 to 23 tabs) in the LC group (P = 0.94).

In a meta-analysis by Pierre Allemann et al[15] the incidence of bile duct injury was 0.4% for SILC compared to 0% for LC but the difference was not statistically different (P-value = 0.36). In a study by Huseyin Sinan et al[47] there was one postoperative complication in the SILC group (incisional hernia at the 4-month follow-up) and 1 post-operative complication in the LC group ileus. In a study by Jeff Siu-Wang Wong et al[49] bile spillage occurred in 3 patients in the SILC group and 4 patients in the LC group and all due to intraoperative gallbladder rupture. One patient from the SILC group also suffered from urinary tract infection requiring antibiotic treatment. The median post-operative hospital stay was one day in both the groups.

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In a study by Elyssa J. Feinberg et al [21] no major complications were seen. One umbilical hernia was seen at the four month post-operative visit. One patient had a retained stone requiring readmission for endoscopic retrograde cholalangiopancreatectomy. No wound infections or cystic duct stump leaks were seen.

From above studies this can be concluded that complications in SILC might be more compared to standard LC but none of the study has shown significant result and with experience the complications are reduced.

In a meta-analysis by Mate Milas et al[45] when LC group and SILC group was compared in terms cosmetic results, 5 trials with non-blinded patients (N=513) goes in favour of SILC (SMD=1.83, p value=0.037), but in 6 trials with blinded patients (N=719) difference was small and insignificant (SMD=0.42, p value=0.548). In a study by Alireza Barb et al (2012)[48] with a follow-up of 90 days the scars receded into the umbilicus and were hardly visible in patients of the SILC group and patients were very satisfied with the cosmetic results.

In a study by Jeff Siu-Wang Wong et al (2012)[29] the mean satisfactory score was 9.2 ± 1.1 in the SILC group versus 8.6 ± 1.4 in the LC group (P = 0.20). In a study by Modesto J. Colon (2012)[31] patient satisfaction score was higher with the final appearance after SILC surgery, as the scar is often completely hidden within the umbilicus. Better cosmetic outcome and more satisfied patient is most important advantage of SILC.

In a meta-analysis by Mate Milas et al[25] overall, procedure failure was reported for 69/1142 SILC-treated patients. The pooled incidence of failure with SILC was 4.39% with high heterogeneity (p value= 0.019) vs. 0.53% with LC (no heterogeneity). However experience with SILC apparently reduced the risk of procedure failure, in 10 trials with >40 SILC it was 3.30% and with lower heterogeneity ($s^2 = 0.89$).

In a study by Jeff Siu-Wang Wong et al (2012)[29] there were no added working ports or conversion to open surgery in both groups. In a study by Elyssa J. Feinberg et al (2012)[50] the conversion rate to conventional laparoscopic cholecystectomy was 10%. Conversion was accomplished through the addition of a 5-mm port elsewhere on the abdominal cavity. After the tenth case, the incidence of conversion went down to zero. When conversions were further stratified, they occurred within each individual surgeon's first ten cases.

So it can concluded taking in account the results of above studies that conversion is a rare scenario in SILC and occasionally occurs only in the cases with poor intraabdominal condition like severe adhesion.

MATERIALS AND METHODS:

The prospective randomised control Study was conducted in the Department of General Surgery, Santosh Hospital & Medical College, Santosh University, Ghaziabad from March 2014 to September 2015.There were 60 Patients undergoing Cholecystectomy for

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Choleliathiasis with 30 in each group. Patients in age group 18-65 years coming to Santosh hospital with USG proven diagnosis of symptomatic gallstones,American Society of Anesthesiologists (ASA) class I & II.

Patients with gallstone disease underwent detailed clinical assesement and laboratory investigations. The demographic profile like age, sex and history of the illness; like duration of symptoms, history of jaundice, history of cholangitis, number of episodes of biliary colic, and any history of acute cholecystitis or pancreatitis were noted in a pre-structured proforma.Baseline blood investigations including liver function test was done. A transabdominal ultrasound was done and findings noted including number of stones, size of stone, gallbladder wall thickness, status of Common Bile Duct (CBD), and other relevant findings.Patients with any coexisting biliary pathology were excluded from the study. A chest x ray and Electrocardiogram (ECG) was done for patients over 30 years of age and other tests were done depending upon the requirements for fitness for surgery like pulmonary function tests, echocardiography etc.

Patients fulfilling the selection criteria were randomized into twogroups of 30 each by picking paper slip from a box .Group I (LC) was offered four port laparoscopic cholecystectomy and in group II (SILC) Single incision laparoscopic cholecystectomy. An informed consent was taken from all the patients. Patient were kept nil per oral after midnight before scheduled surgery. Single dose of injectable 3rd generation cephalosporin was given intravenously as prophylaxis at the time of induction.

All patients were placed in reverse Trendelenburg position with the table tilted downward to the patient's left (15 degree).Pneumoperitoneum was created with Veress needle with closed technique. A 10-mm supraumbilical port was placed for camera and 3 working ports were made 10-mm port in the mid-epigastrium just to the right of the falciform ligament, and two 5-mm ports in the right upper abdomen two finger breadths below the right margin in the mid- clavicular and the mid-axillary line. A 10 mm 30° laparoscope was used. An initial 360° scan of the entire abdomen was made primarily to exclude injury/bleeding during the creation of the pneumoperitoneum, and secondly to identify any gross macroscopic additional disease.

The fundus of the gallbladder was grasped by the assistant and flipped upwards and over the superior edge of the right lobe. A Maryland dissector and a grasper was used to dissect the structures in the Calot's triangle using monopolar electrocautery.The sufficient length of cystic duct and cystic artery on gallbladder side were skeletonised, clipped with 10 mm liga-clips and divided making sure to visualize the gallbladder cystic duct junction and common bile duct cystic duct junction wherever possible. The dissection of the gallbladder from the liver bed was done by laparoscopic hook with monopolar cautery. The gallbladder was then held with toothed grasper and brought out through the epigastric incision. Any bile/blood spillage was irrigated with normal saline and suctioned and any stone spill were retrieved.

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The sufficient length of cystic duct and cystic artery on gallbladder side were skeletonised,clipped with 10 mm liga-clips and divided making sure to visualize the gallbladder cystic duct junction and common bile duct cystic duct junction wherever possible. At the time of clipping laparoscope was changed to 5mm. The dissection of the gallbladder from the liver bed was done by laparoscopic hook with monopolar electrocautery.The gallbladder was then held with toothed grasper and brought out through the umblical incision. Any bile spill was irrigated with normal saline and suctioned and any stone spill were retrieved.Rectus sheath at umbilicus was closed with 1-0 prolene and skin was closed with 3-0 monocryl.

Pain was recorded at 6 hrs,12 hrs 24 hrs and 3rd day after operation on Visual Analogue Scale (VAS). The pain scores were recorded by an independent observer (ward nurse) blinded to technique of surgery.

All information was recorded on the standard proforma attached. Descriptive Statistical analysis was employed to describe data for frequencies, percentages, ratios, range and mean value with one standard deviation. Data were tabulated and entered in Microsoft excel. Analysis was done with the help of IBN SPSS Statistics version 17/GeNIe/Open Bug. Descriptive statistics of the variable from the data collected was carried out. Statistical analysis was performed using the chi-square test or student's t-test as applicable. Statistical significance was defined if the p value was <0.05.

OBSERVATION AND RESULTS:

This study was conducted in the Department of Surgery from March 2014 to September 2015. During this period 60 patients with symptomatic gall stone disease fullfilling the criteria of study were randomised to one of the two groups. Group I included 30 patients who underwent Standard Four Port Laparoscopic Cholecystectomy (LC) and Group II included 30 patients who underwent Single Incision Laparoscopic Cholecystectomy (SILC).

Table 1: Age distribution of subjects

Both groups were comparable in terms of age. The average age of patients in group I (LC) was 38.53 ± 8.46 years. In group II (SILC) the average age of the patient was 38.46 ± 7.15 years. In LC 22 patients & in SILC 21 patients were between 31-50 yrs. The results of which were statistically non-significant (p>0.05).

Age (Yrs)	LC	% age	Mean±SD	SILC	% age	Mean±SD	p value
18-30	6	20%	38.53±8.46	8	26.67%	38.46±7.15	p>0.05 (NS)
31-40	12	40%		15	50%		
41-50	10	33.33%		6	20%		
51-60	2	6.67%		1	3.33%		

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Table 2 : Sex distribution of subjects

In our study 76.67% were female & 23.33% were male under group I (LC), whereas under group II (SILC) 86.67% were female & 13.33% were male. In both the groups female were more in number and the difference between the groups was statistically non- significant.(p value-0.32).

	LC	**%**	**SILC**	**%**
FEMALE	23	76.67	26	86.67
MALE	7	23.33	4	13.33
TOTAL	30		30	

P VALUE = 0.32 (NS)

Table 3: Patients distribution in both the groups according to history of previous abdominal surgery

	LC	**SILC**
Appendectomy	3	1
Tubal ligation	3	2
CS section	4	5
Total	10	8
P- value	p>0.76 (NS)	

Table 4 : Patients distribution in both the groups according to gall bladder wall thickness

GB Wall	**LC**	**SILC**	**P value**
Normal	23	25	P value-0.18 (NS)
Thickened	7	5	

Table 5: Patients distribution in both the groups according to number to stones

Stones	**LC (n= 30)**	**SILC (n= 30)**	**P value**
Number of patients with multiple stones	13	7	p>0.05(NS)
Number of patients with single stone	17	23	p>0.05(NS)

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Table 6: Patients distribution in both the groups according to size of the biggest stone

Size of biggest Stones(mm)	**LC**	**SILC**	**P value**
	7.91±6.0	7.36±5.44	p>0.05(NS)

12 patients had adhesions 7 in group I (LC) and 5 in group II (SILC).The adhesions were mild so were easily removed. Patients with dense adhesions were excluded from the study and another chit was added for same. Edema was seen in 5 patients (3 in group I (LC) and 2 in group II. (SILC). Difficult calot's dissection was done in 8 patients (5 in group I (LC) & 3 in group II (SILC).The results of all these findings were statistically non significant (p-value>0.05).

6 patients had biliary spillage 2 in group I (LC)& 4 in group II (SILC). It was managed by suction. Bleeding was encountered in total 9 patients,2 in group I (LC) & 7 in group II (SILC). Bleeding was taken care by electrocautery in all except one. The difference overall 3 patients in group I& 10 patients in group 11 had intraopratives adverse events. The difference between the two groups were statistically significant. however 1 patient in each group had both biliary spillage & bleeding with a non-significant p-value>0.05

Table 7: Patient distribution in both the groups according to intra-operative adverse events

	LC (n=30)	**SILC**	**p value**
Biliary / stone spillage	2	4	p<0.05(S)
Bleeding	2	7	p<0.05(S)
Both	1	1	p>0.05 (NS)
Total	3	10	p < 0.05 (S)

Both the groups were analysed for difficulty encountered during operation on the basis of instrument crowding, insufficient retraction & compromised vision of which the level of difficulty was comparatively higher in SILC as compared to LC, were instrument crowding was encountered in total,15 patients (O in group I(LC) & 15 in group II (SILC).Insufficient retraction was faced in total 11 patients(2 in group I (LC) & 9 in group II(SILC).Compromised vision in total of 10 patients (1 in group I (LC) & 4 in group II(SILC). So, overall there was much more difficulty encountered SILC as compared to LC. The results of all the finding were however statistically significant(p value <0.05). Gall bladder extraction was difficult in 11 patients with 4 in group I (LC) & 7 in group II (SILC), the results of which were statistically significant (p value-<0.05).

The operating time was recorded from Veress needle insertion to the closure of skin. Maximum operating time was 100 mins in group I (LC).This patient had to be converted to open cholecystectomy because of bleeding from cystic artery. In group II (SILC) maximum

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operating time was130 mins. This patient had to be converted to open cholecystectomy to retrieve multiple spilled stones.[17-19] Operative time ranged in group I (LC) 25-100 mins and in group II (SILC) 50-130 mins. Mean operating time of group I (LC) was 48.36 mins. & group II (SILC) 64.33mins .SILC took more operating time as compared to LC. Difference in mean operating time in between the groups was statistically significant (p value<0.05)

All the patients were given 2 doses of intramuscular diclofenac postoperatively. Extra analgesia was used if demanded or if VAS was >4. If patient needed more analgesia then tramadol 50mg through iv infusion was given. Extra analgesia was required in total 11 patients of which 5 patients (16.67%) were in group I (LC) and 6 patients(20%) in group II (SILC). Difference between the two groups for this variable was statistically non-significant (p-value>0.05)

In this study post-operative complications such as nausea, vomiting, were observed in total 5 patients,2 in group I (LC)& 3 in group II (SILC),which was treated by a course of antiemetics. Urinary retention was seen in total of 7 patients,3 in group I (LC) & 4 in group II (SILC). It was treated by foley's catherisation. Fever was observed in total 3 patients,1 in group I (LC) the reason being atelestasis as the patient was above 60 yrs of age & chronic smoker was treated by a short course of antibiotics, antipyretics & chest physiotherapy and 2 patients in group II (SILC).In one patient the reason was thrombophlebitis while in the other one no specific cause was found and fever subsided in one day with antipyretics only. Difference between two groups for post operative complications was statistically non-significant (p-value>0.05).

The maximum hospital stay in group I (LC) was 4 days for the patient who developed atelestasis. Whereas in group II (SILC) it was 3 days for patient who developed thrombophebitis.[20-22]The mean hospital stay in group I (LC) was 1.1 and in group II (SILC) was

1.07. The difference of which was statistically non-significant (p value>0.05).

At one week follow up seroma was noticed in total 3patients from umbilical port in group II (SILC.) Seroma was taken care by drainage and a course of antibiotics. Wound infection was noticed in total of 3 patients of which 2 were in group I (LC) &1 in group II (SILC). Wounds were drained and daily dressing was done. [23-26] The results were statistically non significant (p value >0.05)

Overall patients in both groups were well satisfied by the cosmetic outcome of the procedure, but patients satisfaction was much higher in SILC as compared to LC. Patients were asked to grade the cosmetic outcome as excellent, fair or poor at 3 months follow up.2 patient in group I (LC) and 16 patients in group II (SILC) stated the cosmetic outcome as excellent, while 20 patients in group I (LC) & 11 patients in group II (SILC) felt the cosmetic outcome as fair. 8 patients in group I (LC) & 3 patients in group II (SILC) felt the cosmetic outcome was poor.

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The difference in the cosmetic outcome between the 2 groups was statistically significant p value <0.05).

DISCUSSION:

Disease affecting gall bladder are of frequent occurrence in our part of country. A significant number of cases of cholecystitis are admitted in our hospital for its treatment. Surgical options include the standard procedure, laparoscopic cholecystectomy and an older more invasive procedure, open cholecystectomy.[27-29] Laparoscopic cholecystectomy has now replaced open cholecystectomy as the first choice of treatment for gall stones and inflammation of gall bladder, unless there is a contraindication to laparoscopic approach.. This is because open surgery is associated with higher postoperative morbidity.[30] To reduce the invasiveness of standard four port laparoscopic cholecystectomy, single incision laparoscopic surgery has also become an attractive option for the performance of laparoscopic cholecystectomy.

In our study patients of age group 18-60 years were included. Ages below 18 & above 60 years were excluded from the study as they represent different subset of population. Analysis of age distributation revealed that maximum number of patients belonged to age group 31-50 yrs. In Group I (LC) 22 patients & in group II (SILC) 21 were between 31-50 yrs.[32-34]This data is supported by Neerja Bharadwaj et al[51] study who found that 70% of patient belonged to age group (31-50yrs).Both our groups were comparable in terms of age. The average age of patients in group I (LC) was 38.53 ± 8.46 years. In group II (SILC) the average age of the patients was 38.56 ±7.15 years. Although the association between gallstone disease and “fat fertile, female and forty” has been observed and taught for a long time it has limited support in formal epidemiological studies.

In our study 76.67% were female & 23.33% were male under group I (LC) whereas under group II (SILC) 86.67% were female & 13.33% were male. In both the groups females were more in number. It is consistent with the available literature suggestive of increased incidence of gall stone in female. Gender (female) is the most common risk factor for formation of gall stones. Male/Female distribution in both the groups was equivalent.

In group I (LC) total of 10 patients had previous abdominal surgeries. Out of which 3 had appendectomy,3 had tubal ligation & 4 had caesarean section. In group II (SILC) total 8 patients had previous abdominal surgeries. 1 had appendectomy, 2 had tubal ligation & 5 had ceasarean section. This factor an indicator of increased risk of intraoperative adverse event and post- operative morbidity was specifically recorded. Difference between the two groups regarding history of previous abdominal surgery (10 vs 8) was statistically non-significant (p-value >0.05).

12 patients had adhesions 7 in group I (LC) and 5 in group II (SILC). The adhesions were mild so were easily removed. Patients with dense adhesions were converted to open

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cholecystectomy and excluded from the study. Edema was seen in 5 patients, 3 in group I (LC) and 2 in group II.

In our study out of 60 patients biliary/stone spillage and bleeding were the only intra-operative complications.6 patients had biliary/stone spillage due to gall bladder rupture in which 4 patients belong to group II (SILC) and 2 patients in group I (LC).[32-34]Bleeding was encountered in 9 patients of which 7 patients belonged to group II (SILC) and 2 patients from group I (LC). Intra- operative adverse events were more in group II (SILC) as compared to group I (LC).[35-36]Complications has been reported by Hernandez JM [41]who has done work on 100 patients of SILC in the form of cystic duct stump leak and cystic artery bleeding. Lee SK[57] reported biliary spillage and also bleeding from cystic artery. Palanivelu C [38-40] reported bleeding from cystic artery in 1 out of 6 patients of SILC. Intra-operative adverse effect indicate the complexity and stress of technically difficult cholecystectomy. This increases operative time, post-operative morbidity and conversion rate.

Instrument crowding hindering free movement of hands, compromised vision due to coaxial placement of scope and instruments and insufficient retaction of gall bladder are major difficulties encountered during SILC. They increase operative time and intraoperative adverse events. In SILC the major difficulty was felt during Calot's triangle dissection and during the application of the liga-clips for ligation of cystic duct and cystic artery. Instrument crowding was seen in 15 patients and all belonged to group II(SILC). Difficult retraction was faced in total 11 patients in our study. 9 belonged to group II(SILC) and 2 to group I(LC). Compromised vision was seen in total 10 patients out of which 9 belonged to group II(SILC). The difference between the groups regarding these difficulties was statistically significant(p value<0.05).

Although some studies have reported decreased pain in SILC as compared to LC. Other studies have found no difference in post operative pain between two techniques. According to meta analysis by Mate Milas e t al[45] post –operative pain difference between SILC & LC was insignificant .Hernandez JM[40] also did not find difference in pain score between two groups. In our study pain score(VAS) at 6,12,24 hours post-operatively was slightly higher in SILC as compared to LC but this difference was insignificant.

There were no major post-operative complications requiring additional intervention were encountered in our study. Only minor complications such as nausea, vomiting, fever & urinary retention occurred.. These were observed in total of 15 patients out of which 9 belonged to group II (SILC). Urinary retention was commonest post-operative complication observed in 10% of patients in group I (LC) and 13% of patients in group II (SILC). Nausea, vomiting seen in 6.66% of group I (LC) and 10% of group II (SILC). Fever was reported in 3.33% patients of group I (LC) and 6.66% of group II (SILC). All the complications were symptomatically managed. The difference between the two groups in term of post-operative

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complication remained statistically non-significant. Studies by Bresadola F[17], Hernandez JM[40] also reported similar complications, although the incidence were different.

During follow - up after 1week no seroma was noted in group I (LC) but was noted in 3 patients of group II (SILC). This may be due to longer periumbilical incision and its contamination during the delivery of the gallbladder, suboptimal hygiene of umbilicus itself despite cleaning because anatomically umbilicus is probably the most difficult location for antiseptic and aseptic precautions and most SILC incision were given through umblicus.

Better cosmesis has been stated as major advantage of SILC. The reason for better cosmesis in SILC is attributed to the fact that the scars recede into the umbilicus and are hardly visible following SILC. Thus patients are very satisfied with the cosmetic results. Patient satisfaction is an indicator of postoperative cosmetic outcomes**.** In a meta-analysis by Mate Milas et al[45,] 5 trials with non-blinded patients (N=513) in favour of SILC (SMD=1.83, p value-0.037), but in 6 trials with blinded patients (N=719) difference was small and insignificant (SMD-0.42, p value- 0.548).

In our study overall patients in both groups were well satisfied by the cosmetic outcome of the procedure, but patients satisfaction was much higher in SILC as compared to LC. Patients were asked to grade the cosmetic outcome as excellent fair or poor at 3 months follow up.2 patient in group I and 16 patients in group II stated the cosmetic outcome as excellent, while 20 in group I & 11 in group II felt the cosmetic outcome as fair. 8 patients in group I & 3 patients in group II felt the cosmetic outcome was poor. The difference in the cosmetic outcome between the 2 groups was statistically significant p value <0.05).Thus SILC offers advantage over standard four port cholecystectomy in terms of cosmesis .

CONCLUSION:

In conclusion, SILC is a safe and feasible procedure which requires a high degree of technical expertise on the part of surgeon. SILC is a promising alternate method to conventional four port laparoscopic cholecystectomy. Although the idea of SILC seems similar to standard four port laparoscopic cholecystectomy, but practically it has major difference in technique. It involves crowding of all working instrument within one incision and the basic principle of triangulation is lost to one extent. Visualisation is obscure because of insufficient retraction & crowding of instrument and longer distance from insertion to operative site presents additional challenges. Operative time was more in group II (SILC) as compared to group I (LC).However postoperative complains such as nausea, vomiting, urinary retention, fever, wound infection and seroma formation& hospital stay were similar in both the groups. Cosmetic outcome and patient satisfaction were much better in group II (SILC). The limitation of our study has been insufficient duration of follow up to determine the development of incisional hernia and its incidence. Thus SILC is feasible but technically difficult procedure. It is similar to LC regarding post-operative morbidity & complications but provides better cosmesis. So at present the standard four port laparoscopic

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cholecystectomy is still the procedure of choice for the majority of patients with symptomatic gallbladder disease.

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