# Single Incision Laparoscopic Cholecystectomy versus Four Port Laparoscopic Cholecystectomy

Ankur Kothari<sup>1</sup>, Sanjay Singhal<sup>2</sup> Rajkamal Kanojiya<sup>3</sup>

Author Affiliation: <sup>1</sup>PG Resident <sup>2</sup>Professor <sup>3</sup>Associate Professor Gen. Surgery Mahatma Gandhi Medical College and Hospital, Jaipur Corresponding Author: Ankur Kothari

**Abstract:** The purpose of this study was to evaluate feasibility and safety of Single Incision laparoscopic Cholecystectomy (SILS) in comparison to the conventional Four Port Laparoscopic Cholecystectomy (FPLC). Based on our findings, SILS is a safe and feasible method. It is a promising alternative for gallstone disease as a minimal invasive surgery. The operating time is slightly higher but it is cosmetically better approach with similar intra operative and postoperative complication rate and can be selectively and judiciously performed by surgeons trained in regular laparoscopic surgery.

**Keywords:** SILS, Four port cholecystectomy, Laparoscopic Cholecystectomy

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### I. Introduction:

Gall stones (Cholelithiasis) are a very common entity. Native Americans, Caucasians are at higher risk whereas African Americans are at low risk for developing gall stones. Intermediate risk is seen in Asians. In Indian subcontinent, gallstones are more common in North India. These are mostly seen in overweight and middle aged women. Pregnancy, Oral Contraceptive Pills or hormonal/oestrogen therapy promotes gall stone formation.

Most people have no symptoms (Asymptomatic Cholelithiasis). Symptoms, if present at all are in the form of attacks of pain in the right upper abdomen, typically 30 minutes after a fatty meal. Other associated symptoms can be nausea, vomiting, fever, indigestion and/or bloating.

Surgical removal of gall bladder is called cholecystectomy. The various indications for cholecystectomy include symptomatic gallstone disease, acute or chronic cholecystitis, biliary colic, pancreatitis due to gall stones and risk factors for gall bladder cancer such as porcelain gall bladder and polyps > 1cm. Treatment of gall stones has evolved markedly after first open cholecystectomy was done and described by Langenbach<sup>1,2</sup> in 1881.

Laparoscopic cholecystectomy is conventionally being performed using four ports. Since first laparoscopic cholecystectomy was performed by German surgeon Erich Mühe<sup>3</sup> in 1985, there has been a continuous development of techniques and devices in order to improve cosmesis, reduce invasiveness of procedure and decreased surgical trauma by switching from standard four-port technique to three port and two port and which have been reported as safe and feasible <sup>4-7</sup>.

A new minimal invasive technique has been developed for performing laparoscopic cholecystectomy by using a single umbilical (belly button or navel) incision known as SILS i.e. Single Incision Laparoscopic Surgery<sup>8</sup>. All the instruments i.e. a laparoscope and two working instruments are inserted through this single incision. First documentation of this procedure occurred in late 1990s when Navarra et al<sup>9</sup> in 1997 performed a laparoscopic cholecystectomy using two trans-umbilical trocars and three trans-abdominal stay sutures.

The advantages of SILS include decrease in postoperative pain, faster return to daily activities, better aesthetic results (single small scar) and increased patient satisfaction among others <sup>10-14</sup>. The disadvantages of SILS are restriction of hand movements and clashing of instruments either intra-abdominally or extra-abdominally, thus more difficult to perform than multi port surgery. SILS has a specific learning curve <sup>15</sup>.

Kala et al<sup>16</sup> performed the first case of trans-umbilical single port laparoscopic appendicectomy in 1996. In 1999, Piskun and Rajpal<sup>17,18</sup> performed SILS by the use of two trocars in the umbilical region and by putting additional intra-abdominal sutures for retraction of gall bladder. First reported case of trans-umbilical single port laparoscopic cholecystectomy was performed by Podolsky et al in 2007<sup>19</sup>.

In this study, our aim was to evaluate efficacy and effectiveness of single port laparoscopic cholecystectomy compared to the gold standard multiport laparoscopic cholecystectomy.

### **II. Material And Methods:**

This study is a prospective study, conducted from Nov. 2015 to Nov. 2017 including all the patients presenting with biliary colic with documented gallstones or polyps by imaging operated in Mahatma Gandhi Medical College and Hospital, Jaipur within this period fitting into the study requirements according to inclusion and exclusion criteria.

During this period 25 patients of Four-Port Laparoscopic Cholecystectomy and 25 of Single-Incision Laparoscopic Cholecystectomy were operated. All procedures were performed by a single expert surgeon (>1000 laparoscopic surgeries).

# INCLUSION CRITERIA

- 1. Both males and females, between 18 and 65 years old. The patient has a diagnosis of biliary colic with documented gallstones or polyps by imaging.
- 2. Any patient with calculus or acalculus cholecystitis.
- 3. The patient or patient's legal representative has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent.

#### **EXCLUSION CRITERIA**

- 1. Any female patient who is pregnant, suspected pregnant, or nursing.
- 2. Any patient who has had an upper midline or right sub costal incision.
- 3. Any patient who has an unrepaired umbilical hernia or has had prior umbilical hernia repair.
- 4. Any patient unfit for laparoscopic surgery.

Patients were randomised serial wise first Four-port and second single-incision laparoscopic cholesystectomy and so on.

Oral intake was ceased 8 hours before surgery. A single dose of 3<sup>rd</sup> generation cephalosporin was given for antibiotic prophylaxis. General anaesthesia was used in all patients.

In four port technique, pneumoperitoneum was created by using veress needle through sub umbilical or umbilical incision. Three other standard ports were made in epigastrium, rt. subcostal region mid clavicular line and rt. flank anterior axillary line. Gall bladder grasped at fundus and retracted, infundibulum retracted laterally to expose the triangle of Calot. Dissection is done with dissecting forceps. After the cystic duct was identified and dissected free, dissection and identification of cystic artery was done. A critical view of safety (Strasburg) is achieved before ligation of the cystic duct and artery. When it is not possible to achieve the critical view of safety, the procedure is converted to an open procedure. Three titanium clips were placed on the cystic duct and the duct was divided between the clips. Cystic artery was similarly clipped and divided. Dissection of gallbladder off the liver bed was performed in the retrograde fashion. Any blood or bile accumulated during the procedure was removed with the suction irrigation cannula and if any bile or blood was expected to accumulate, a suction drain (16F) was placed in Morrison's pouch through the flank port. The gall bladder was removed through the epigastric port and ports closed with sutures after removal of all ports under vision.

In SILS a single trans-umbilical 2 cm incision was made by pulling out the umbilicus and deepened in layers. Then a SILS port (Covidien) was introduced (Hasson Technique). Pneumoperitoneum was created with  $CO_2$  at 12-14 mm Hg. Three working channels were placed. Rest of the procedure is similar to four port technique.

The gall bladder was removed through single port device and abdominal wall was closed with Vicryl 2-0 suture and skin sutured with Ethilon 2-0.

Figure 1: SILS Port

**SILS Port** 



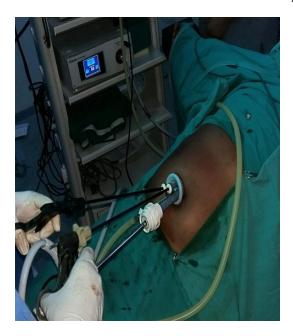
Patients were evaluated in terms of operating time (minutes), conversion to open cholecystectomy, pain assessed by the visual analogue score at 6hr, 24hr and 3 days post surgery, intra-operative (severe bleeding, gall bladder perforation/bile spillage, CBD injury) and postoperative complications (nausea and vomiting, wound

infection, bile Leak [1 and 3 days]) post surgery, length of hospital stay and cosmetic outcome (presence of scar mark, presence of erythema and presence of induration) at 10 days post surgery.

Qualitative and quantitative analysis was done in terms of percentage and proportion (mean + SD). Appropriate test of significance were used as per data yield. p value < 0.05 was considered significant.

Figure 2: Intra operative photos

# **Intra Operative Photos**





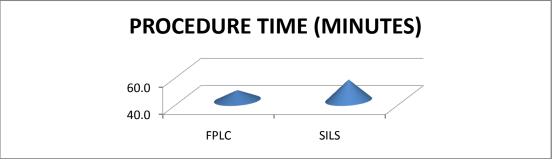
# **OBSERVATION AND RESULTS:**

Majority of presenting patients were in age group 30-49 years. Majority of the patients were females (64%) and 36% were males. Both groups were matched in age and sex.

TABLE 1: Comparison of Procedure Time

Variables	FPLC		SI	P-Value	
	Mean	SD	Mean	SD	1 - value
PROCEDURE TIME (Min)	47.5	5.7	55.2	8.4	0.00

FIGURE 3: Multiple bar diagram showing comparison of procedure time in study groups

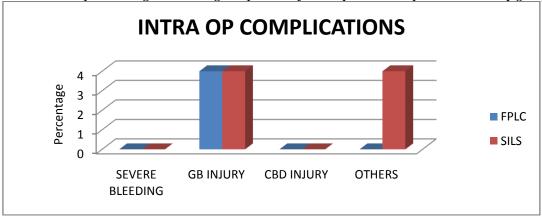


Procedure time was more in SILS group which was statistically significant.

TABLE 2: Intra Operative Complications

INTRA OP COMPLICATIONS	FPLC		-			
	No. of patients	Percentage		No. of patients	Percentage	P-Value
SEVERE BLEEDING	0		0	0	0	0.0000
GB INJURY	1		4	1	4	1.0000
CBD INJURY	0		0	0	0	0.0000
OTHERS	0		0	1	4	0.55152

FIGURE 4: Multiple bar diagram showing comparison of intra operative complications in study groups

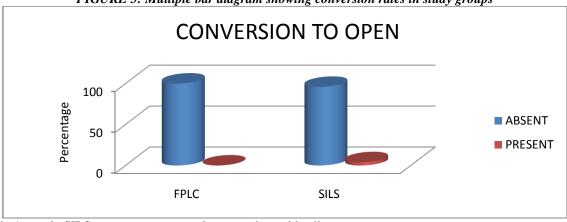


Among the intra operative complications most common was GB injury seen in 4% of cases. No significant difference in complications was observed among the study groups.

TABLE 3: Conversion to Open Cholecystectomy

CONVERSION TO OPEN	FPLC			5 ** 1	
	No. of patients	Percentage	No. of patients	Percentage	P-Value
Absent	25	100	24	96	
Present	0	0	1	4	0.3124
Total	25	100	25	100	

FIGURE 5: Multiple bar diagram showing conversion rates in study groups

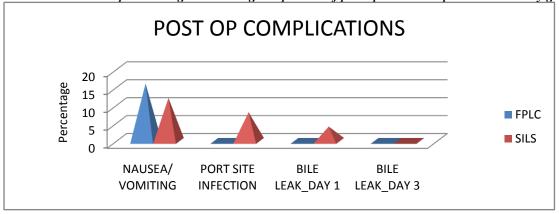


Only 1 case in SILS group was converted to open due to bleeding.

TABLE 4: Post Operative Complications

POST OP COMPLICATIONS		FPLC	S	LS	P-Value
	No. of patients	Percentage	No. of patients	Percentage	
NAUSEA/ VOMITING	4	16	3	12	0.35454
PORT SITE INFECTION	0	0	2	8	0.19340
BILE LEAK DAY 1	0	0	1	4	0.71279
BILE LEAK DAY 3	0	0	0	0	0.00

FIGURE 6: Multiple bar diagram showing comparison of post operative complications in study groups

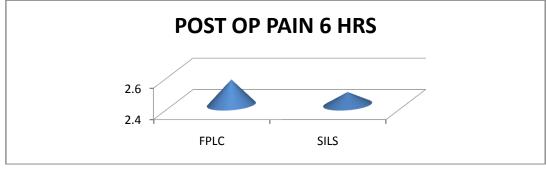


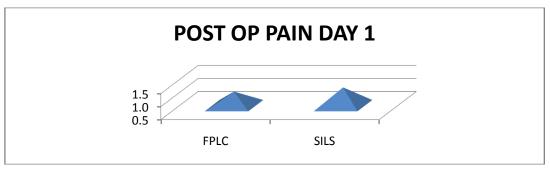
Nausea and Vomiting were the most common post operative complications seen in 14% of cases. Port site infection was seen only in SILS group (4%) but was not significant.

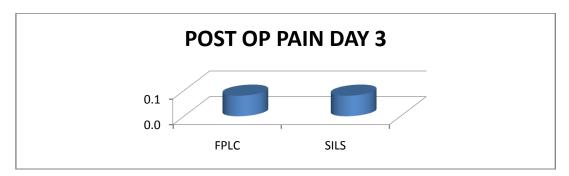
TABLE 5: Comparison of Post Operative Pain

PAIN	FP	LC	SI	LS	P-Value
	Mean	SD	Mean	SD	
PAIN 6 HRS	2.6	0.9	2.5	0.9	0.75
PAIN DAY 1	1.0	1.0	1.2	1.2	0.61
PAIN DAY 3	0.1	0.4	0.1	0.4	1.00

FIGURE 7: Multiple bar diagram showing comparison of pain in post operative period in study groups





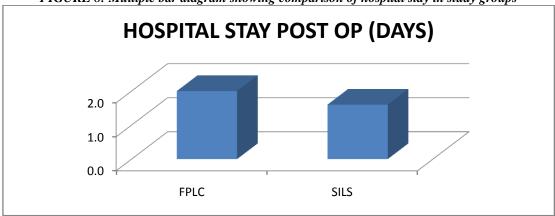


At 6 hrs pain was slightly more in FPLC group (Not Significant) but was comparable at 24 hrs and day 3 with SILS group.

TABLE 6: Comparison of Hospital Stay

Variables	FF	PLC	SI	LS	P-Value
	Mean	SD	Mean	SD	r-value
HOSPITAL STAY POST OP (Days)	2.0	0.8	1.6	0.7	0.07

FIGURE 8: Multiple bar diagram showing comparison of hospital stay in study groups



Hospital stay was less in SILS group with mean of 1.6 + 0.7 days as compared to FPLC group.

TABLE 7: Comparison of Cosmetic outcome

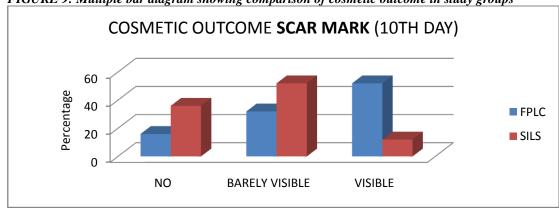
TIBEE 7. Comparison of Cosmence outcome					
Scar mark	FPLC				
	No. of		No. of		P-Value
	patients	Percentage	patients	Percentage	
NO	4	16	9	36	0.01686
BARELY VISIBLE	8	32	13	52	0.01842
VISIBLE	13	52	3	12	0.00243

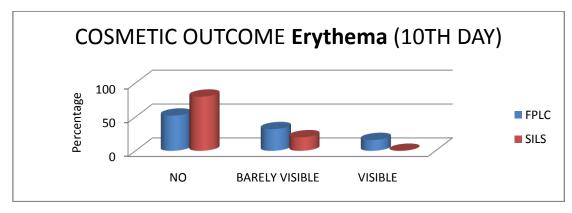
Erythema		FPLC		SILS		
	No. of patients	Percentage	No. of patients	Percentage	P-Value	
NO	13	52	20	80	0.06891	
BARELY VISIBLE	8	32	5	20	0.12282	
VISIBLE	4	16	0	0	0.05070	

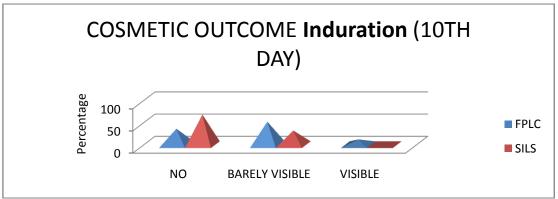
Induration	FPLC		SILS		D.V. I
	No. of patients	Percentage	No. of patients	Percentage	P-Value

NO	9	36	17	68	0.02354
BARELY VISIBLE	13	52	8	32	0.15195
VISIBLE	3	12	0	0	0.19340

FIGURE 9: Multiple bar diagram showing comparison of cosmetic outcome in study groups







After analysis of the above factors in terms of scar mark, erythema and induration cosmetic outcome was superior in SILS which was statistically significant.

# III. Discussion

The mean age of patients in SILS group was 41.6 + 13.5 years (Range 19-61 yrs) and in FPLC group was 44.9 + 10.7 (Range 26-62 yrs) years.

Duration of surgery was higher in SILS group which was statistically significant. In this study the mean time required for single port cholecystectomy was 55 min. and 47.5 min. for four port cholecystectomy. In the case series by Sinan Ersin et al  $(2010)^{20}$ , the duration of surgery for single port cholecystectomy ranges from 105-110 min with a mean of 94 min. Another study done by Rao PP et al $(2008)^{21}$  showed a mean duration of surgery of 40 min. Our results were comparable with other studies.

In this study overall complication rate was 6% out of which 4% had GB injury/perforation. Intra operative complications were similar in both the groups (SILS and FPLC). In the study conducted by Sang Kuon Lee et al (2009)<sup>22</sup> one case of right hepatic duct injury, 11 GB perforations, 2 mesenteric injury was mentioned. A study by Oruc MT et al<sup>23</sup> observed that 16% of patients suffered from GB perforation.

TABLE 8: Comparison of conversion rate with other studies

Study	Conversion to Open(%)
Our Study	4
Hodgeett et al(2009) <sup>24</sup>	6
Sinan Ersin et al(2010) <sup>20</sup>	5
Chow et al(2010) <sup>25</sup>	0
Lee et al(2009) <sup>26</sup>	13
Fransen et al <sup>27</sup>	0.4

Thus this study was comparable with other studies in terms of conversion required to open cholecystectomy. In this study reason for conversion was uncontrolled bleeding in one case. In other studies main reasons for conversion to open surgery were presence of dense adhesions and inflammation.

In this study nausea and vomiting were the most common post operative complications accounting to 14%. Thakur et al<sup>28</sup> had 10 % incidence of nausea and vomiting in their study. Another complication was bile leak which was observed in 4% cases at day 1 and 0% at day 3 in our study. In study conducted by Chow et al (2010)<sup>25</sup> bile leak from accessory duct of Luschka was noted in one case. No difference was seen between SILS and FPLC group in terms of post operative complications.

Port site infection was seen in 2 cases of SILS group and none in FPLC group but was statistically not significant. These were managed with oral antibiotics. Antoniou et al<sup>26</sup> stated that most common post operative complication in SILS group was wound infection and haematoma accounting for 2.1% patients. A study by Yilmaz H et al<sup>5</sup> on 150 cases found 5 cases with port site infection. A study by Mehmood Z et al<sup>27</sup> on 30 cases observed no port site infection.

In this study mean pain score was 2.6 + 0.9 in FPLC group and 2.5 + 0.9 in SILS group at 6 hrs. Mehmood Z et al<sup>27</sup> found mean pain score of 2.93 + 0.98 at 6 hrs in SILS group.

In this study we used VAS scale for pain measurement.

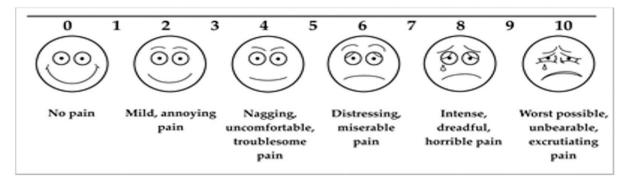


TABLE 9: Comparison of postoperative pain between two groups

Study	Pain Score Compared on VAS at 6 hrs and Day 1 Post Operatively
Our Study	Not Significant
Abd Ellatif ME et al (2013) <sup>28</sup>	Significant
Lai EC et al(2012) <sup>29</sup>	Not significant
Bucher P et al (2011) <sup>30</sup>	Significant
Asakuma M et al (2011) <sup>31</sup>	Significant

In this study pain was compared at 6 hrs, day 1 and day 3 which came out to be not significant i.e. post operative pain was similar in the two groups of FPLC and SILC. Our results were comparable with other studies as described above.

From the results obtained in this study it can be said that cosmetic outcome is superior in SILS demonstrated by the fact that FPLC group were affected by three or more scars with possible sequelae like induration (12% in four port vs 0% in SILS). Scar mark was visible in 52% of patients in four port group as compared to 12% in SILS group. These findings are consistent with prior studies that demonstrated significantly better cosmesis for the SILS group<sup>32-36</sup>.

Length of hospital stay in this study for SILS group was 1.6 + 0.7 days which was shorter than four port surgery patients (2 + 0.8) days but not significant.

TABLE 10: Comparison of post operative hospital stay with other studies

Study	Hospital Stay (Days)
Our Study	1.6 + 0.7 (1-3)
Kravetz et al(2009) <sup>37</sup>	1-4
Hodgett et al(2009) <sup>24</sup>	1±0.61
Lee et al(2009) <sup>26</sup>	2.7±1.5
Chow et al(2010) <sup>25</sup>	1

Postoperative hospital stay in this study ranged from 1-3 days in single port cholecystectomy group which is compared fairly with that in other studies.

#### **IV. Conclusions:**

- 1. Mean operative time was higher in SILS group. The operative time was initially much higher but became reasonable as surgeons became more experienced and familiar with the procedure.
- 2. Conversion to open procedure was done in 1 patient in SILS group.
- 3. No rise in intra and post operative complications occurred in the SILS group even with the technical drawbacks of the procedure i.e. both groups had comparable complication rates.
- 4. Degree of postoperative pain is same in both the groups.
- 5. Post operative hospital stay was slightly less in SILS group but was not significant when compared to FPLC group.
- 6. Post operative port site infection was higher in SILS group as compared to four port cholecystectomy group but was not significant.
- 7. Cosmetic outcome was superior in SILS group due to only single scar.

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