

Original Research Article

Comparison of short-term outcomes between single incision laparoscopic cholecystectomy and conventional 4-port laparoscopic cholecystectomy

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ABSTRACT

Background: Various numbers of case series, studies and randomized control trials conducted for comparison of Single port and Multi port cholecystectomy, however the benefit of Single Port cholecystectomy is still debatable.

Methods: A prospective non-randomized comparative study was done to compare short term outcomes between SILS Cholecystectomy and Conventional 4-port Laparoscopic Cholecystectomy. Total of 85 patients underwent surgery out of which 5 cases were excluded (4 due to loss of follow up and 1 due conversion from SILS to LAP). There were 40 cases in each group, two group named as LAP (conventional 4-port laparoscopic cholecystectomy) group and SILS (single incision laparoscopic cholecystectomy) group.

Results: On comparison of pain scores at 6 hours and 12 hours postoperatively and at the time of discharge between two groups there was significant difference at 12 hours postoperatively and at the time of discharge. The mean operative time in SILS group was similar to that of LAP group. The cosmesis score ranges from 2 to 10(1-5 for each questions) with 2 being best and 10 being worst appearance of scar. In LAP group, the mean cosmesis score was 4.65 ± 0.9 (SD) whereas, in SILS group it was 2.25 ± 0.43 (SD). On comparison between two groups there was significant difference ($p= 0.0001$). The quality of life total score on comparison between two groups there was significant difference in quality of life score ($P=0.0001$).

Conclusions: It is concluded that SILS cholecystectomy is better than LAP and it should be preferred.

Keywords: Cholecystectomy, Comparison, Incision, Outcomes

INTRODUCTION

In the gall bladder, gall stone disease is the most common in the category of benign diseases. This trend is seen not only in India but also all over the world. Among the gastrointestinal illnesses, patients suffering from gall stone diseases require more frequent hospitalization. A lot of advances have taken place in the gall stones treatment. Now days, cholecystectomy is the commonly

performed abdominal procedure. First ever successful cholecystectomy was carried out in 1882.¹⁻³

Cholecystectomy continued to be a surgical treatment of choice after 1882, for about 100 years in the treatment of gall stones which were found to be symptomatic as well as most other gall bladder diseases which were found to be benign in nature. Advances have taken place in the surgical management of gall bladder disease which

started with conservative management then came the laparotomy approach, then came the mini laparotomy approach, and now days the surgical treatment of choice is laparoscopic cholecystectomy.^{4,5}

In 1992, The National Institute of Health (NIH) Consensus development conference stated that” for those patients who are having gall stones and these gall stones are symptomatic in nature, and then laparoscopic cholecystectomy should be preferred by the surgeons for majority of such patients.⁶

If there are no contraindications for the surgery, then the treatment of choice for majority of the patients will be laparoscopic cholecystectomy. It has many advantages like pain after the surgery is less, it also preserves the cosmesis, the patient has to stay for a short period in the hospital, patient can go back to his work early, improved bowel habits return back fast. Laparoscopic cholecystectomy has also undergone revolution from four ports to two ports. New techniques are coming up for the benefit and welfare of the patients. Now days “natural orifice trans-luminal endoscopic surgery (NOTES)” is in practice.⁷ At the same time we have now “single-incision laparoscopic surgery (SILS)”⁸

The ultimate goal is to achieve the patient satisfaction in terms of reduced post-operative morbidities.

Surgeries are being performed through mouth, or even through vagina. Apart from NOTES and SILS as mentioned above, other newer techniques are also coming into play like “Natural Orifice Trans-umbilical Surgery (NOTUS)”, “Single Port Incision Less Conventional Equipment Utilizing Surgery (SPICES)” etc.^{7,9}

Among all these above mentioned techniques, SILS has been found to be more effective. The morbidities after the surgery are less. There is also better cosmesis.⁸

Various numbers of case series, studies and randomized control trials conducted for comparison of Single port and Multi port cholecystectomy, however the benefit of Single Port cholecystectomy is still debatable.

Present study aims at comparing the short term outcomes between laparoscopic cholecystectomy and SILS cholecystectomy.

METHODS

This is a non-randomized prospective comparative study. This study is conducted at the Division of Minimal Access Surgery of General Surgery Department, Apollo Hospitals, Greaves Road, Chennai. 600 bed multispecialty, tertiary care, and urban hospital with 14200 out patients and 1930 admissions annually. The study was carried out from October 2012 to February 2014. 80 patients admitted in Apollo Hospitals for Cholecystectomy satisfying inclusion criteria.

Sample size

Total of 80 patients included in the study analysis after excluding 5 patients out of which 4 patients excluded due loss of follow up (1 in SILS and 3 in LAP group) and one patient excluded due to conversion from one technique to other technique All the study population underwent Laparoscopic / SILS Cholecystectomy by two minimal invasive surgeons. Both surgeons have similar qualifications and experiences

Inclusion criteria

- Age 18 to 70 years
- Undergoing laparoscopic / SILS cholecystectomy.

Exclusion criteria

- Age less than 18 years
- History of previous upper abdominal surgery
- Pregnancy
- Confirmed or Suspected carcinoma of gallbladder
- The patients who lost to follow up or patients whose surgery converted from one technique to other technique.

History and clinical examination were done by consultant surgeon. Each patient asked about history of pain abdomen like site, duration, severity, radiation of pain and associated symptoms like nausea, vomiting, jaundice and fever. History of co-morbidities like diabetes mellitus, hypertension, cardiac and pulmonary diseases asked.

Clinical examination, mainly general physical examination and abdominal examination performed by consultant surgeon, and findings like anemia, jaundice, abdominal tenderness (right upper abdomen) or any mass in the abdomen are noted. Imaging study (minimum of USG whole abdomen) was done by consultant radiologist for all the patients. All the patients after examination sent for investigations.

Once the diagnosis is made and surgery is planned, patient identification number, age and sex noted, and patient sent for pre-anesthetic evaluation to consultant anesthetist.

Consultant anesthetist advised necessary premedication to patient a day before surgery and also gives instructions regarding patient’s regular medications whether to take or to skip the morning doses on the day of surgery.

The type of surgical technique is decided by the consultant surgeon, the patient and an attendant of the patient after explaining the benefits, drawbacks and expenditure of both the techniques (standard laparoscopic / SILS cholecystectomy) in detail.

Duration of surgery in minutes from skin incision to skin closure was noted for each patient in both the groups. Any intraoperative complications if occurred were noted and also how that complication was managed noted for each patient. If there was a conversion from one technique to other technique, also noted and converted cases were excluded from data analysis.

After surgery patient was shifted to recovery room for one hour. After about 4-6 hours of surgery oral clear liquids started and patients were encouraged to ambulate

Postoperative pain score was assessed using VAS (Visual Analogue Scale) at 6th, 12th hour and at the time of discharge. All the patients were reviewed as out-patient on 7th POD to give color coded questionnaires and recollected the answered questionnaires on 30th POD for assessment of cosmesis and quality of life. Patients who fail to follow up were excluded from data analysis.

For each patient data was collected by interviewing them during outpatient visit, on admission, intra-operatively, postoperatively and during follow up at one month.

Statistical analysis

Data collected by a proforma was entered in excel sheet. All the continuous variables were assessed for normality using Shapiro Wilk’s test. If the data follows Gaussian

distribution it was expressed as mean±SD otherwise median (inter-quartile range). All the categorical variables were expressed either as percentage or proportion. Comparison of normally distributed continuous variables was done by either t-test or ANOVA based on the groups. Comparison of non-normally distributed variables was taken care by Mann-Whitney U test or Kruskal-Wallis H test based on the groups. Categorical comparisons were done by Chi-square test or Fisher’s exact test based on the no of observations. All the p values less than 0.05 were considered as statistically significant. Analysis was carried out by a statistical software SPSS version 11.0.

RESULTS

Among the 40 patients in LAP group, the mean age was found to be 49.15±11.37 and the median age was 48.5. The youngest patient was 25 and oldest was 69 years old. Maximum no of patient in LAP group were between age 41 and 50 years (35%). Among 40 patients in SILS group, the mean age was found to be 45.5±10.8 and the median age was 48. The occupation of study participants were classified into Sedentary, Light, Moderate and Vigorous physical activity. There were no patients with vigorous physical activity. Out of 80 patients, 12 belonged to sedentary life style, 46 were light and 22 were moderate physical activity. On comparison between two groups, there was no significant difference (p value >0.05) (Table 1).

Table 1: Comparison of clinical parameters in the two groups.

Parameters	LAP group	SILS group	Total	
Age	<=30	5 (12.5%)	4 (10%)	9 (11.3%)
	31-40	2 (5%)	9 (22.5%)	11 (13.8%)
	41-50	14 (35%)	14 (35%)	28 (35%)
	51-60	11 (27.5%)	10 (25%)	21 (26.3%)
	>60	8 (20%)	3 (7.5%)	11 (13.8%)
Sex	Male	24 (60%)	17 (42.5%)	41 (51.3%)
	Female	16 (40%)	23 (57.5%)	39 (48.7%)
Occupation	Sedentary	5 (12.5%)	7 (17.5%)	12 (15%)
	Light	21 (52.5%)	25 (62.5%)	46 (57.5%)
	Moderate	14 (35%)	8 (20%)	22 (27.5%)

Table 2: Comparison of symptoms and morbidities in the two groups.

Parameters	LAP group	SILS group	Total	
Symptoms	Symptomatic	31 (77.5%)	28 (70%)	59 (73.7%)
	Asymptomatic	9 (22.5%)	12 (30%)	21 (26.3%)
Diabetes	Diabetic	13 (32.5%)	6 (15%)	19 (23.8%)
	Non-diabetic	27 (67.5%)	34 (85%)	61 (76.3%)
Gall bladder disease	acute calculus cholecystitis	12 (30%)	6 (15%)	18 (22%)
	chronic calculus cholecystitis	7 (17.5%)	9 (22.5%)	16 (20%)
	asymptomatic cholelithiasis	21 (52.5%)	21 (52.5%)	42 (52.5%)
	Polyp	0	3 (7.5%)	3 (3.8%)
	Emp-GB	0	1 (2.5%)	1 (1.25%)

Table 3: Comparison of surgical parameters in the two groups.

Surgical parameters		LAP group	SILS group	Total
ASA grade	I	31 (77.5%)	36 (90%)	67 (83.8%)
	II	9 (22.5%)	4 (10%)	13 (16.3%)
Intra-operative finding	Distended GB	16 (40%)	11 (27.5%)	27 (33.8%)
	Presence of Stones	40 (100%)	36 (90%)	76 (95%)
	Presence of inflammation	12 (30%)	6 (15%)	18 (22.5%)
	Presence of sludge	9 (22.5%)	7 (17.5%)	16 (20%)
	Presence of pus	0	2 (5%)	2 (2.5%)
Intra operative complications	Yes	2 (5%)	0	2 (2.5%)
	No	38 (95%)	40 (100%)	78 (97.5%)

Table 4: Comparison of outcome in the two groups.

Outcome		LAP group	SILS group	Total	P value
Required drain	Yes	7 (17.5%)	0	7 (8.8%)	0.012
	No	33 (82.5%)	40 (100%)	73 (91.2%)	
No. of Pt starting post-op orals within 6 hour	Yes	38 (95%)	39 (97.5%)	77 (96.3%)	1
	No	2 (5%)	1 (2.5%)	3 (3.8%)	

Table 5: Comparison of pain score (VAS) between two groups.

VAS	LAP group	SILS group	P value
6 hours	4.95±0.67	4.77±0.65	0.245
12 hours	3.35±0.8	2.65±0.7	0.0001
At discharge	1.7±0.5	1.1±0.4	0.0001

Out of 80 patients, 59 were symptomatic and 21 were asymptomatic. In LAP group 31 (77.5%) were symptomatic and 9 (22.5%) were asymptomatic, whereas in SILS group 28 (70%) were symptomatic and 12 (30%) asymptomatic.

On comparison between two groups there was no significant difference (p value = 0.612). Out of 18 ACC, 12 were in LAP group and 6 in SILS group (among 6 ACC in SILS one was found to have Empyema GB during surgery). Two Emp-GB and 3 gallbladder polyp patients underwent SILS. Out of 16 CCC, 7 were in LAP group and 9 in SILS group (Table 2).

Three patients in SILS group whose diagnosis was gallbladder polyp did not show above intra-operative findings. Out of 40 patients in LAP group who underwent conventional 4-port laparoscopic cholecystectomy, two patients had complications like excessive bleeding due cystic artery injury which were managed safely by using bipolar diathermy device (Table 3).

Authors considered abdominal drain placement in both the techniques only if necessary. In our study, among LAP group 7 patients had abdominal drain whereas none of the patients in SILS group had drain. In our study we encouraged all the patients to start oral liquids within 6 hours of surgery. 38 patients in LAP groups and 39

patients in SILS group started oral liquids within 6 hours of surgery. On comparison there was no significant difference (Table 4).

The pain score by VAS was assessed three times by each patients, first at 6 hours and then at 12 hours postoperatively and finally at the time of discharge. The VAS is an objective pain assessment which range from 0-10. On this scale 0 indicates 'no pain', 1-3 indicates 'mild pain', 4-6 indicates 'moderate pain', and 7-9 indicates 'severe pain' and 10 indicates 'worst possible pain'. On comparison of pain scores at 6 hours and 12 hours postoperatively and at the time of discharge between two groups there was significant difference at 12 hours postoperatively and at the time of discharge (Table 5).

Table 6: Surgical management.

Additional analgesics	LAP	SILS	Total
Yes	7 (17.5%)	1 (2.5%)	8 (10%)
No	33 (82.5%)	39 (97.5%)	72 (90%)
Total	40	40	80

Table 6 shows comparison of number of patients requiring additional analgesia in two groups. The requirement of additional analgesics was noted for all the patients. Total of 8 patients required additional analgesics

for one day, out of which 7 from LAP group and 1 from SILS group.

The mean hospital stay in LAP group was 33.75 ± 10.88 whereas in SILS group was 28.77 ± 9.7 . The mean duration of surgery for SILS group was 49.9 ± 6.19 (SD), ranging from 40 to 66 min. The 95% Confidential Interval for mean was 47.9 to 51.85. The median for both the group was 50. In LAP group, the mean cosmesis score was 4.65 ± 0.9 (SD) whereas, in SILS group it was 2.25 ± 0.43 (SD). On comparison between two groups there was significant difference ($p = 0.0001$). The quality of life total score ranges from 5 to 15, 5 being the best and 15 being worst quality of life. The mean score for LAP group was 6.27 ± 0.6 whereas that for SILS group was 5.17 ± 0.38 . On comparison between two groups there was significant difference in quality of life score ($P = 0.0001$) (Table 7).

Table 7: Comparison of other parameters in the two groups.

Parameters	LAP group	SILS group	P value
Duration of surgery (min)	49 ± 6.84	49.9 ± 6.19	0.55
Length of hospital stay (hours)	33.75 ± 10.85	28.77 ± 9.7	0.01
Cosmesis score	4.65 ± 0.9	2.25 ± 0.43	0.0001
Quality of life score	6.27 ± 0.6	5.17 ± 0.38	0.0001

DISCUSSION

In present study out of 40 patients in SILS group 17 were males and 23 were females whereas in LAP group 24 were males and 16 were females. Most of the patients were in 41-50 age groups. The mean age in SILS group was 45.5 ± 10.8 years and that in LAP group was 49.15 ± 11.37 . Present study with SILS group was compared with other studies; the mean age and female predominance were comparable with other studies. For all the patients' minimum of USG abdomen was done as imaging study to diagnose the gallbladder disease. The p value for all of them was more than 0.05 (no significant difference between two groups). When compared to other studies like Kuon LS et al, Asakuma M et al, Prasad A et al, Tsimoyiannis EC et al, and Bucher P et al, authors found that acute cases were excluded in most of the previous studies.⁹⁻¹³ Intraoperative complications like bile duct injury, bile leak, bleeding from cystic artery blow out, or hepatic artery injury were assessed in both the groups. The duration of surgery was calculated in min from the time of skin incision to the time of skin closure for each patient in both the groups and it was compared. The mean duration of surgery was 49 ± 6.84 in LAP group and it was 49.9 ± 6.19 in SILS group. When compared to other studies, mean duration of surgery in our study was found to be almost equal in both the groups. Some studies

like Hodgett SE et al, and Lai EC et al, showed that mean duration of surgery in SILS is slightly less than CLC indicating that higher experience in SILS can reduce the time of surgery.^{14,15}

The postoperative pain assessed by VAS (visual analogue scale) at 6 hours, 12 hours and at the time of discharge. The median pain score at 6 hours, 12 hours and at discharge was 5, 3 and 2 for LAP group and that for SILS was 5, 3 and 1. The pain score at discharge was significant on comparison. The pain score at discharge of our study was comparable with pain score at 24 hours in other studies like Cao ZG et al, Bucher P et al, Asakuma M et al, Prasad A et al, and Tsimoyiannis EC et al.^{10-13,16} All these studies showed significant difference ($p < 0.05$) in pain scores between SILS cholecystectomy and Conventional laparoscopic cholecystectomy favoring the SILS technique.^{10-13,16}

The mean length of hospital stay in LAP group was 33.75 ± 10.8 hours whereas it was 28.77 ± 9.7 hours in SILS group. Median was 27 (1.125 day) and 24 hours for LAP and SILS group respectively. The median score was 5 and 2 for LAP and SILS group respectively. On comparison SILS group had significantly better cosmesis than LAP group (p value < 0.05), this was because in SILS technique the scar was not visible as it is hidden in the umbilicus. Present study was comparable to other studies like Ostlie DJ et al, concluded that SILS has superior scar benefit at early and long term follow up, Ellatif ME et al, which showed SILS has better cosmesis at 1 and 6 month, Bucher P et al, who used different cosmesis questionnaire but showed SILS was better than Conventional laparoscopic cholecystectomy in relation to cosmesis (p value < 0.05), in a study by Lai EC et al, the median cosmesis score of SILS was higher the LC at 3 months, and Trastulli S et al, also showed significant difference in relation to cosmesis between SILS and CLC (p value < 0.001).^{13,15,17-19}

Quality of life score range from 5 to 15, 5 being best and 15 being worst quality of life. The median score was 6 and 5 for LAP and SILS group respectively. On comparison between two groups in our study, the quality of life was significantly better in SILS group than LAP group (p value < 0.05). Present study was compared with other studies conducted by Abd Ellatif ME et al, in relation to quality of life using EQ-5D which showed significant difference ($p < 0.05$) at 1 week postoperatively and no significant difference at 1 and 6 month between SILC and CLC, in a study conducted by Bucher P et al, quality of life was assessed by using QoL Short form 12 also significant difference between LESS vs. CLC ($P < 0.001$) favoring Single incision technique.^{13,18}

CONCLUSION

The intraoperative complications and duration of surgery were similar to conventional laparoscopic cholecystectomy with additional advantages of reduced

length of hospital stay, good cosmetic and quality of life outcomes. The pain was slightly less in SILS cholecystectomy due to reduced number of incisions. The use of advanced instruments like roticulating forceps reduces the time. The experience of surgeon in SILS is an important tool to reduce the complications. SILS cholecystectomy can be offered to selected acute cases; however, one should not hesitate to use additional ports for better exposure and to avoid complications. Long terms follow up and randomized studies with large number of patients are required for better comparison between two procedures and to study the occurrence of incision site hernias. The traditional laparoscopic cholecystectomy still holds as a “gold standard” procedure.

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