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Original Research Paper

General Surgery

A COMPARATIVE STUDY OF POST OPERATIVE OUTCOMES RELATED TO CBD INJURY AND PAIN SCORE BETWEEN SINGLE PORT LAPAROSCOPIC CHOLECYSTECTOMY SURGERY AND STANDARD LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Context And Aims: To do a comparative study of the feasibility, practicality, advantages and shortcomings of Single Incision Laparoscopic Cholecystectomy (SILC), using conventional ports and instruments; with standard laparoscopic cholecystectomy (SLC) with respect to the post operative pain scores and CBD injury.

Study design: This comparative randomised study was conducted in a tertiary care centre teaching hospital, M.L.B. Medical College, Jhansi between October 2017 to March 2019.

Result: Post operative pain on Visual Analogue Score (VAS) scale for first 24hours in SILC group was significantly less than that for SLC. No patient underwent bile leakage or bile duct injury in any of the group. Mean operating time in SILC group is significantly more than SLC group (29.9±10.2 mins v/s 22.5±5.1mins)

Conclusion: Mortality was nil in the present study. The sample size in our study is small to make any definite conclusion. The procedure can be selectively and judiciously performed by surgeons trained in regular laparoscopic surgery specially those doing 3 port laparoscopic cholecystectomy. Widespread application must await results obtained from level 1 evidence from prospective trials.

KEYWORDS : Single Incision Laparoscopic Cholecystectomy, Standard Laparoscopic Cholecystectomy, Pain Score, CBD Injury.

INTRODUCTION

Treatment of gall stones have evolved markedly since open cholecystectomy was first described by Langenbuch in 1881[1-3]. Management has progressed through eras of nonsurgical management, laparotomy, minilaparotomy and now laparoscopic cholecystectomy which is the gold standard for the treatment of gall stone disease today[3].

SILC is a new technique through which laparoscopic surgery takes place through a single umbilical incision without the need for additional laparoscopic ports.

In recent year, SILC has been focused upon as a bridge between NOTES & traditional laparoscopic surgery. The advantages of earlier return of bowel function, less post operative pain, improved cosmesis, shorter length of hospital stay, earlier return to full activity, decreased overall cost were immediately appreciated.

Rather than the traditional four to five small incisions, a single small incision can be used at the entry point. All surgical instruments are placed through this small incision and also the incision site is located in the left abdomen or umbilicus.

In general, SILS techniques take about the same amount of time to do as traditional laparoscopic surgeries. However, SILS is recognized as to be a more complicated procedure because it involves manipulating three articulating instruments through one access port[4].

Single incision laparoscopic surgery (SILS) is an umbrella term used in this article to encompass all such single incision laparoscopic techniques including Single Port Access (SPA) surgery or One Port Umbilical Surgery (OPUS) or Single Port Incision Conventional Equipment utilising Surgery (SPICES) or Natural Orifice Transumbilical Surgery (NOTUS)[3], which allow potentially 'scarless' surgery as the wound is hidden within the umbilicus.

MATERIALS AND METHODS

Study Design:

This comparative randomised study was conducted in a tertiary care centre teaching hospital, M.L.B. Medical College, Jhansi between October 2017 to March 2019.

Methodology:

Age and sex matched patients who fit into the inclusion criteria were included in the study with alternate allocation to standard cholecystectomy arm (SLC) and single port cholecystectomy arm (SILC).

Patient Selection:

The inclusion criteria were:

1.Age of patient between 10 and 85 years 2. Diagnosis of chronic/acute cholecystitis, symptomatic cholelithiasis, recurrent mild biliary pancreatitis, Gall Bladder (GB) polyp, GB sludge, empyema and mucocele.

The exclusion criteria were:

1.Severe co-morbid conditions (uncontrolled diabetes, hypertension, severe direct hyper bilirubinemia)

2.ASA Grade 4 3. GB phlegmon post 1 week

Randomization:

Random allocation of patients presenting with symptoms suggestive of gallbladder disease with confirmatory USG study was done to the two groups after matching for age and sex, using the sealed envelope technique which was opened just before the skin incision. The two groups were as follows-

·**Group1:** Single incision laparoscopic cholecystectomy (SILC)

·**Group2:** Standard laparoscopic cholecystectomy (SLC)

Data Collection:

The details of preoperative assessment, intraoperative observation, postoperative course and postoperative follow up with reference to following points were recorded in a proforma (Annexure) and analyzed by Unpaired t-test.

OperativeTechnique:

The technique of laparoscopic cholecystectomy SLC was performed using a three trocar approach. SILC has been performed using a transumbilical single incision multiport technique as described earlier by Sinha and Yadav et al[5].

RESULT

The study was done on 100 patients. Out of which 50 patients were included in group I (Single Incision Laparoscopic Cholecystectomy /SILC) and 50 patients were

included in Group II Standard Laparoscopic Cholecystectomy/ (SLC).

In case of SILC 46% patients were of 11-30 yrs , 38% patients between 31-50 yrs and 16.00% were more than 50 years of age. In case of SLC 36% patients were of 11- 30 yrs of age ,40% patients between 31- 50 yrs of age and 24% were more than 50 years of age. That is in both the group number of patients were significantly more of middle age group **[Table 1]**.

Table 1: Age Wise Distribution Of Study Population (SILC and SLC)

Age (yrs)	SILC		SLC	
	NoofPatients	Percentage	Noof Patients	Percentage
11-30	23	46.00%	18	36.00%
31-50	19	38.00%	20	40.00%
>51	08	16.00%	12	24.00%
Total	50	100%	50	100%

In case of SILC 78% patients were female and 22% patients were male. In case of SLC 90% patients were female and 10% patients were male. That is in both the groups number of the female patients were significantly more than male patients **[Table 2]**.

Table 2: Sex Wise Distribution Of Study Population (SILC and SLC)

Sex	SILC		SLC	
	No of Patients	Percentage	No of Patients	Percentage
Male	11	22.00%	05	10.00%
Female	39	78.00%	45	90.00%
Total	50	100.00%	50	100%

Mean nutritional status was taken with the help of BMI, hemoglobin and serum albumin.

Mean BMI for SILC group was 23.65±2.42 and for SLC it was 24.24±2.86

Mean hemoglobin for SILC group was 12.82±2.76 and for SLC group was 11.92±1.2.

Mean serum albumin for SILC was 4.95±6.18 and for SLC 4.18±0.35.

The result were not significant **[Table 3]**.

Table 3: Mean Nutritional Status Distribution Of Study Population (SILC and SLC)

Mean Nutritional status	SILC	SLC	pvalue
	Mean± Standard deviation	Mean± Standard deviation	
BMI	23.65±2.419	24.24±2.86	0.2681
Hemoglobin	12.82±2.763	11.92±1.245	0.0387
S.Albumin	4.95±6.182	4.18±0.352	0.3814

Mean serum ALP for SILC group was 117.2±52.7 IU/L and for SLC it was 157.33±96.8 IU/L which was not significant **[Table 4]**.

Table 4: Mean S.alp (IU/L) Distribution Of Study Population (SILC and SLC)

Mean preoperative	SILC	SLC	pvalue
	Mean± Standard deviation	Mean± Standard deviation	
S.ALP(IU/L)	117.2±52.722	157.33±96.844	0.0116

Mean total bilirubin for SILC group was 0.758±0.29 and for SLC group was 0.763±0.43 which was not significant **[Table 5]**.

Mean direct bilitubin for SILC group was 0.469±0.21 and for SLC group was 0.434±0.23 which was not significant **[Table 5]**.

Table 5: Mean S. Bilirubin Preoperative Distribution Of Study Population (SILC and SLC)

S.Bilirubin	SILC	SLC	pvalue
	Mean±Standard deviation	Mean±Standard deviation	
T(mg/dl)	0.758±0.296	0.763±0.433	0.9464
D(mg/dl)	0.469±0.209	0.434±0.234	0.4321

Per operative:

In SILC group 1 (2%) patient out of 50 underwent blood loss of approximately 100ml whereas in rest 49 (98%) out of 50 in SILC group and all 50 (100%) in SLC group underwent <50ml of blood loss.

No patient in either of the groups (SILC and SLC) required conversion to 3 port/4 port/Open in case of SILC and 4 port/Open in case of SLC.

Clipping was done in all the patients (SILC and SLC) for ligating the cystic duct and artery with the help of LT300 and LT400 clips.

No patient underwent bile leakage or bile duct injury in any of the group (SILC and SLC).

1 (2%) patient out of 50 in SILC group required insertion of drain in Morrison pouch.

Mean operating time in SILC group was 29.9±10.2 minutes and 22.5±5.1 minutes in SLC group which is significant (p value-0.0001) **[Table 6]**.

Table 6: Mean Operating Time In Study Population (SILC and SLC)

Mean Operating time (in minutes)	SILC	SLC	pvalue
	Mean± Standard deviation	Mean± Standard deviation	
Mean Operative time	29.92±10.205	22.5±5.119	0.0001

Post Operative:

No patient in either of group (SILC and SLC) developed any wound complication.

No patient in either of the group (SILC and SLC) developed biliary peritonitis.

Post operative pain on visual analogue score (VAS) scale for 0-4 hours in SILC group was 4.14±0.53 and 4.58±0.673 in SLC group; for 4-8 hours in SILC group was 3.3±0.505 and 3.68±0.471 in SLC group; 8-12 hours in SILC group was 2.76±0.431 and 3.14±0.405 in SLC group; 12-24 hours in SILC group was 2.2±0.404 and 2.58±0.498 in SLC group.
The results were significant **[Table 7]**.

Table 7: Mean Visual Analogue Score (vas) In Study Population (SILC and SLC)

visual analogue score (VAS)	SILC	SLC	pvalue
	Mean±Standard deviation	Mean±Standard deviation	
0-4hours	4.14±0.535	4.58±0.673	0.0005

4-8hours	3.30±0.505	3.68±0.471	0.0002
8-12hours	2.76±0.431	3.14±0.405	0.0001
12-24hours	2.20±0.404	2.58±0.498	0.0001

Mean time to initial oral intake was 9.52±2.62 in SILC group and 8.68±1.46 In SLC group which was not significant **[Table 8]**.

Table 8: Mean Time To Initial Oral Intake (in Hrs) In Study Population (SILC and SLC)

Parameters	SILC	SLC	pvalue
	Mean±Standard deviation	Mean±Standard deviation	
Mean time to initial oral intake (in hrs)	9.52±2.620	8.68±1.463	0.0506

Mean hospital stay in SILC group was 2.12±0.48 and 2.16±0.37 in SLC group, which was not significant **[Table 9]**.

Table 9: Mean Hospital Stay (in Days) In Study Population (SILC and SLC)

Parameters	SILC	SLC	pvalue
	Mean±Standard deviation	Mean±Standard deviation	
Mean hospital Stay (in days)	2.12±0.48	2.16±0.370	0.6418

Mean time to resume work was 3.9 days in SILC group and 3.8 days in SLC group which was not significant **[Table 10]**.

Table 10: Mean Time To Resume Work (in Days) In Study Population (SILC and SLC)

Parameters	SILC	SLC	pvalue
	Mean±Standard deviation	Mean±Standard deviation	
Mean time to resume work (indays)	3.9±0.814	3.8±0.699	0.5114

DISCUSSION

Operating Time:

The majority of comparative studies have shown that the time required to complete the SILC procedure is greater as compared to 3 port or 4 port SLC (Marker SR el al[6], Brittney Culp et al[7], L. Geng et al[8], A. Agrusa et al[9], L.N. Jorgensen et al[10], Mathew Zapf et al[11], Sinha et al[5]) but Ugurlu Umit et al[12] from Turkey in 2013 reported that the SILC procedure required less time as compared to SLC procedure.

Our present study (done between 2017-2019) also concurs with the finding of a statistically increased operative time for SILC procedure.

Peroperative Complication:

The majority of comparative studies have shown that the incidence of billiary complication is similar in both the groups (Pierre Allemann et al[13], Sinha et al[5]) but Joseph mark et al in his 2012 study showed increase in the rate of bile duct injury in SILC procedure as compared to SLC procedure.

Our present study (done between 2017-2019) also concurs with the fact that the incidence of bile duct injury is similar in both the groups as in our study, no patient underwent CBD/CHD or any vascular injury in either of the group.

Postoperative Pain Score:

The majority of comparative studies have shown less post operative pain in SILC group as compared to SLC group (Waldemar Kurpiewski et al[14], Zahid Mehmood et al[15], LianhyuanGeng et al[8], A Agrusa et al[9], Partelli et al[16], Sinha Rajeev et al[5]) but Marker SR et al[6], Zehetner et al[17] and Kimbelry M. Brown et al[18] reported no significant difference between both the groups.

Our present study also concurs with the fact that the incidence of post operative pain is less in SILC group as compared to SLC group.

CONCLUSION

In our study the following conclusions were made:

1.Patients presenting to M.L.B Medical College with gall stone diseases were maximally between 31-50 years of age.

2.Time required for single incision laparoscopic cholecystectomy is higher than for standard laparoscopic cholecystectomy, probably because it is technically difficult.

3.No significant rise in intra and post operative complications occurred in the single port surgery as compared to standard laparoscopic cholecystectomy even with the technical difficulties of the procedure.

4.Length of postoperative hospital stay, time to initial oral intake and time to resume work for single port cholecystectomy is almost same as for 3 port cholecystectomy.

5.Significant difference was found in intensity of pain between two procedures. SILC patients had less postoperative pain.

6.Mortality was nil in the present study. The sample size in our study is small to make any definite conclusion. The procedure can be selectively and judiciously performed by surgeons trained in regular laparoscopic surgery specially those doing 3 port laparoscopic cholecystectomy. Widespread application must await results obtained from level 1 evidence from prospective trials.

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