Original Research Article

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A comparative study of single incision laparoscopic cholecystectomy with conventional laparoscopic instruments versus multiple port laparoscopic cholecystectomy

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ABSTRACT

Background: Treatment of gall stones have evolved markedly since open cholecystectomy was first described by Lange Buch in 1881. 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. Laparoscopic surgery is the procedure of choice for most benign gall bladder diseases unless obvious contraindication exists. There has been a trend toward minimizing the required number and size of ports to reduce postoperative pain with better cosmetic results.

Methods: Comparative randomized study was conducted in Department of Surgery, SDM College of Medical Sciences and Hospital between February 2017 to July 2018. 60 patients who fit into the inclusion criteria were included in the study. 30 patients were included in the multiport cholecystectomy and 30 in the SILC. Random allocation of patients presenting with symptoms suggestive of gall bladder disease with confirmatory USG study. Group1: single incision laparoscopic cholecystectomy, Group2: multiple port laparoscopic cholecystectomy.

Results: Majority of presenting patients were in age group 41-50 years. No significant difference in the mean age of patients, surgical complication, conversion rates and SSI operated by the two techniques. Median time required to complete cholecystectomy by SILC technique was not significantly higher than that required for multiport cholecystectomy. Statistically significant lower postoperative pain score was seen in patients with SILC compared to Multiport laparoscopic cholecystectomy. Patients operated by SILC technique had a postoperative hospital stay of mean 4.04 days, almost same as for patients operated by multiport technique.

Conclusions: Difference of Conversion rates and time required for SILC is not significantly higher than that required for multiport cholecystectomy. No rise in intra and post-operative complications occurred in the single port surgery. Postoperative pain is significantly lower in patients undergoing SILC Length of postoperative hospital stay and incidence of SSI for single port cholecystectomy is almost as same as for multiport cholecystectomy.

Keywords: Multi-port laparoscopic cholecystectomy, Single port laparoscopic cholecystectomy

INTRODUCTION

Gall bladder diseases are one of the major causes of morbidity and mortality around the world. Among gall bladder diseases, benign diseases like gall stones form the majority. Treatment of gall stones have evolved markedly since open cholecystectomy was first described by Langenbuch in 1881.^{1,2} Gall bladder surgeries achieved a major leap in time when Prof Dr Med Erich Mühe of Böblingen of Germany performed the first laparoscopic

cholecystectomy on September 12, 1985.³ In 1992, the statement published by National Institute of Health(NIH) Consensus development conference stated that laparoscopic cholecystectomy provides a safe and effective treatment for most patients with symptomatic gall stones.⁴ In fact laparoscopic surgery is the procedure of choice for most benign gall bladder diseases unless obvious contraindication exists and it is one of the commonest procedures done by the general surgeons all over the world.

Use of laparoscopic surgery has demanded principles of less trauma of access hence less scar and so probably less complications. Today laparoscopic cholecystectomy is the gold standard treatment for the treatment of gallstone diseases.⁵ Since the introduction of laparoscopic cholecystectomy as the gold standard procedure to remove the gallbladder, many surgeons have attempted to reduce the number and size of ports in laparoscopic cholecystectomy to decrease parietal trauma and improve cosmetic results. These efforts are some of the fundamentals of the natural orifice transluminal endoscopic surgery (NOTES) approach, which removes transabdominal incisions completely, but NOTES is technically challenging and current instruments need to be further improved.^{6,7} As a bridge between traditional laparoscopic surgery and NOTES, the recent focus has been on the development of single-incision laparoscopic surgery (SILS) to further minimize the invasiveness of laparoscopic surgery by reducing the number of incisions. In 1996, Kala and his colleagues reported the first case of trans umbilical single port laparoscopic appendectomies.8 The first case of trans umbilical single port laparoscopic cholecystectomy was reported in 2007 by Podolsky et al.9

Traditionally SILS involves the use of special port and special instruments, the cost of which is beyond the reach of common Indian patients. Thus, to inculcate the advantages of SILS as well as to negate the effects of additional cost to the patients, this technique of doing Single Incision Laparoscopic Cholecystectomy with conventional laparoscopic instruments was devised. As it promises all advantages of conventional laparoscopic with additional advantages of reduced postoperative morbidity and improved cosmesis and as both procedures can be done using the same conventional laparoscopic instruments without any additional cost to the patient this study is aimed at assessing the pros and cons of Single Incision Laparoscopic Cholecystectomy using conventional laparoscopic instruments versus Conventional Laparoscopic Cholecystectomy.

Objectives

To study the merits and demerits of single incision laparoscopic cholecystectomy using conventional laparoscopic instruments versus multiple port laparoscopic cholecystectomy with respect to:

Operating time

- Post-operative pain
- Morbidity and complications
- Conversion rates.

METHODS

This comparative randomized study was conducted in Department of Surgery, SDM College of Medical Sciences and Hospital between FEB 2017 to JULY 2018

Study design

60 consecutive patients who fit into the inclusion criteria were included in the study. 30 patients were included in the multiport cholecystectomy arm and 30 in the single port cholecystectomy arm

Inclusion criteria

- Age of patient between 18 and 65 years
- Diagnosis of chronic cholecystitis, symptomatic cholelithiasis, Gall Bladder (GB) polyp

Exclusion criteria

- Patients with complex biliary disease (acute cholecystitis, choledocholithiasis, history of jaundice, pancreatitis, mirza syndrome), prior history of upper surgical procedures and diseased umbilicus (hernia, inflammation, sinus...etc.)
- Suspicion of GB cancer
- Severe co-morbid conditions (Uncontrolled hypertension, Uncontrolled diabetes, or presence of IHD)
- ASA Grade-4 and above

After the admission of a patient in Surgery Dept with Gall Bladder disease, a thorough history and clinical examination of the patient was done.

Relevant investigations like CBC, LFT and USG Abdomen were done following which the patient was taken into the study based on the inclusion and exclusion criteria.

Random allocation of patients presenting with symptoms suggestive of gall bladder disease with confirmatory USG study was done to the two groups using the sealed envelope technique which was opened just before the skin incision.

The two groups were as follows:

Group1: single incision laparoscopic cholecystectomy

Group2: multiple port laparoscopic cholecystectomy arm

The details of preoperative assessment, intraoperative observation, postoperative course and postoperative

follow up with reference to following points were recorded in a proforma (Annexure).

Preoperative observations

- Age
- Sex
- Investigations

Intraoperative observations

- Duration of surgery
- Anatomy of extrahepatic billiary system
- Presence of adhesions
- Complications
 - a) Injury to vessels
 - b) Injury to CBD
 - c) Injury to liver including GB fossa injury
 - d) Injury to GB
 - e) Injury to other organs (bowel etc)
- Conversion of single port surgery to:
 - a) 2 port surgery
 - b) Multi-port surgery
 - c) Open surgery
- Conversion of multiport surgery to open surgery
- Requirement of drain
- Complication due to pneumoperitoneum

Postoperative observations

- Pain on VAS scale at following time points
- 6 hrs after operation
 - a) Morning of postoperative day 1
- Nausea
- Vomiting
- Bleeding
- Bile leak
- Number of days drain kept
- Hospital stays

First follow up

- Port site infection
- Other complaints: pain in epigastric region.

RESULTS

Trial design

60 patients with gall bladder disease meeting the inclusion criteria were randomised to be included in two groups. 30 patients presenting with benign gallbladder disease were operated upon with the general intent of performing single incision laparoscopic cholecystectomy. Outcomes of these patients were recorded along with outcomes of 30 other patients operated by multiport technique for benign gallbladder disease.

3 patients each in the SILC and multiport group were converted to open cholecystectomy due to various reasons. 1 patient in the SILC group was converted to 2 port. They were excluded from the final analysis.

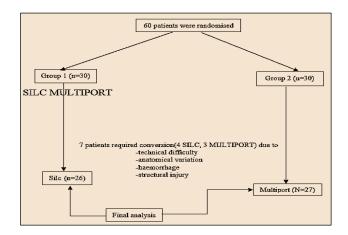


Figure 1: Trial design.

Number of males and females operated in SILC category were 12 and 18 respectively. Number of males and females in multiport category were 14 and 16 respectively. Total of 30 patients in each group.43.33% of the operated patients were males and 56.67% females and there was no significant difference among the two groups (Figure 2).

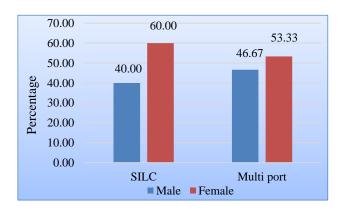


Figure 2: Sex wise distribution of cases in study groups.

Majority of presenting patients were in age group 41-50 years, 7 patients in SILC and 9 patients in multiport, a total of 16 patients, accounting for 23.33% in SILC category and 30% in multiport category. There was no significant difference in the mean age of patients operated by the two techniques (Figure 3).

There was no statistically significant difference in the mean duration required to complete the surgery in both the groups (Figure 4). The mean time required for single port cholecystectomy in present study was 109.23 ± 25.37 min which was not significantly high when compared to mean time of 100.37 ± 28.08 min required for multiport cholecystectomy.

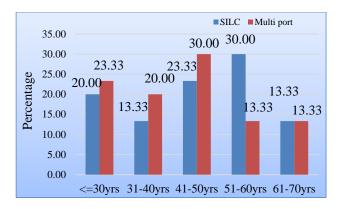


Figure 3: Age wise distribution of cases in study groups.

Out of 27 patients in multiport category, 1 patient had a intrahepatic gallbladder. (Figure 5), accounting for 3.7%. In SILC category out of 26 patients, no patient had intrahepatic gallbladder.

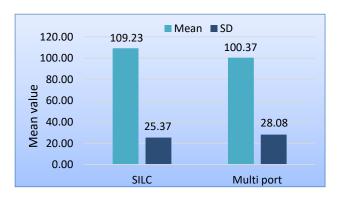


Figure 4: Comparison of mean duration of surgery in study groups.

Out of 26 patients,2 patients in SILC group and out of 27 patients, 1 patient in Multiport group had short dilated cystic duct as anatomical variation (Figure 6), with percentage of 7.69 and 3.70 respectively in SILC category, 6 patients had intraoperative adhesions.

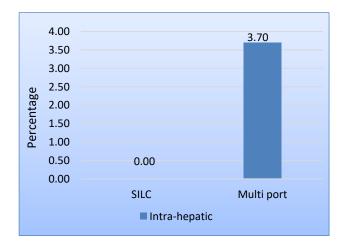


Figure 5: Intra-operative findings of anatomical variations i.e. Gall Bladder.

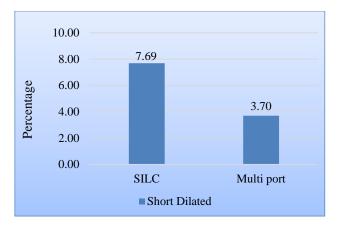


Figure 6: Intra-operative findings of anatomical variations i.e. Cystic Duct in study groups.

In multiport category out of 27 patients, 10 patients had intraoperative adhesions with a average of, 23.08% patients in SILC group and 37.04% of patients in Multiport group had dense adhesions (Figure 7).



Figure 7: Intra-operative findings of anatomical variations i.e. Adhesions in study groups.

Incidence of vessel injury, liver injury and GB injury was 1 each from Multiport group (Figure 8), with average of 3.7%. There was no vessel, cbd, liver or gb injury in the SILC category.

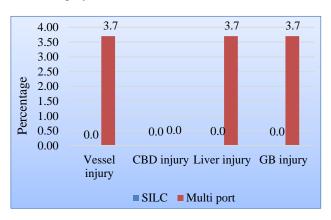


Figure 8: Complications presents in study group.

Out of 30 patients in SILC, 3 patients had to be converted to open and 1 patient was converted to two-port surgery. In multiport category, 3 patients had to be converted to open. Conversion rates to open surgery were 10% each in SILC and Multiport group. On comparing, conversion rates between the two groups were not significant (Figure 9).

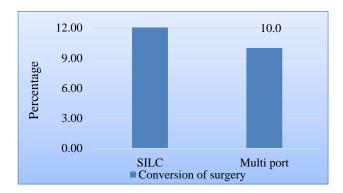


Figure 9: Conversion rates in both groups.

2 patients in SILC category and 3 patients in multiport category required drain to be put accounting for 7.69% of SILC patients and 11.11% of Multiport which was not statistically significant on comparison (Figure 10).



Figure 10: Status of drain in study groups.

In patients who required drain placement, drain was removed in both patients from SILC group by POD 4 while in multiport group, 1 patient had it removed on POD 1 while 2 patients had it removed on POD 3 (Figure 11).

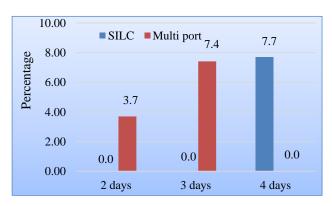


Figure 11: Status of Drain Duration in study groups.

Postoperative pain scores both at 6 hrs and POD 1 were significantly higher in Multiport group compared to SILC group (Figure 12).

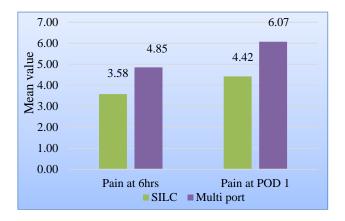


Figure 12: Comparison of postoperative pain score in study groups at 6 hrs after surgery and on postoperative day 1.

Mean Postop stay duration in SILC group was 4.04 days and in Multiport group was 3.93 days which on comparison was not statistically significant (Figure 13).

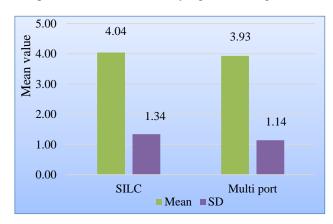


Figure 13: Comparison of mean Post op Stay in study groups.

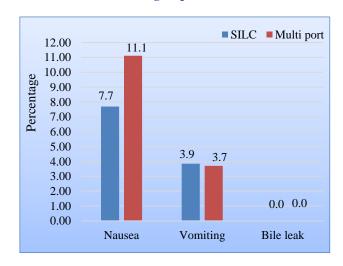


Figure 14: Postoperative complaints in study group.

2 patients I SILC group and 3 patients in Multiport group had complaints of nausea in postoperative period and 1 patient each from both the groups had vomiting in postoperative period (Figure 14). Most common post op complaint was nausea accounting for 7.7% in SILC, and 11.1% in multiport category.

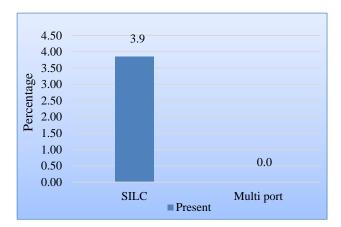


Figure 15: Status of Port site infection in study groups.

1 patient in SILC group had port site infection detected during the first follow-up visit (Figure 15) accounting for 3.9%.

DISCUSSION

Out of 30 patients operated by single incision laparoscopic surgery 12 were males and 18 were females. In the multiport group distribution was 14 males and 16 females. Majority patients were in 41-50 age group. The mean age of patients in SILC group was 45.97±13.16 years and in multi-port group was 42.8±13.98 years.

Table 1: Comparison of age and sex distribution with other studies.

	Age (years)	Sex (%)	
		Male	Female
Present study	45.97 (mean)	40	60
Rao PP,et al ¹⁰	23-67 (range)	20	80
Lee,et al ¹¹	47.5±12.2 (mean)	35.1	64.8
Kravetz,et al ¹²	43.59 (mean)	20	80
Ersin,et al ¹³	44.9 (mean)	10	90
Hodgett,et al ¹⁵	50 (median)	20.6	79.3

Most other studies show female preponderance (Table 1). In present study too, there was a female preponderance. The intra operative observations of anatomy were made. Peri gall bladder adhesions were present in 23.08% patients in SILC and 37.04% patients in multiport group. Two patients from SILC group and one patient from Multiport group had anatomical variation in the form of short dilated cystic duct.

Table 2: Comparison of conversion rate with other studies.

Studies	Rate of conversion (%)
Present study	13.3
Rao PP, et al ¹⁰	15
Lee, et al ¹¹	13
Ersin, et al ¹³	5
Chow, et al ¹⁴	0
Hodgett, et al ¹⁵	6

Majority conversions in SILC group occurred in gall bladders with adhesion suggesting chances of conversion are high if a patient had acute or chronic cholecystitis.

Table 3: Reasons for conversion of single port surgery to two port, multiport or open.

Reasons for conversion	2 port	Multiport	Open	Total
Technical difficulty	1	-	-	1
Anatomical variation	-	-	2	2
Haemorrhage	-	-	-	-
Structure injury	-	-	1	1
Total	1	-	3	4

The conversion rate for Single incision laparoscopic cholecystectomy was 13.33%. In a study conducted by P.P Rao et al¹⁰ single port surgery using Triport a conversion rate of 15% was seen in another study done by Sang Kuon Lee et al¹¹ a conversion rate of 13% was observed. The conversion rate in present study matches fairly with the conversion rates in other studies (Table 2).

Table 4: Comparison of time required for surgery with other studies.

Studies	Time required for surgery (min) Mean/Median
Present study	109.23±25.37
Rao PP, et al ¹⁰	40 (mean)
Lee, et al ¹¹	83.6±40.2 (mean)
Ersin, et al ¹³	94 (mean)
Chow, et al ¹⁴	127(mean)
Hodgett, et al ¹⁵	72±17.3 (median)
Culp BL, Cedillo VE, Arnold DT ¹⁶	65 (mean)
Prasad A, Mukherjee KA, Kaul S ²⁰	67 (mean)

Anatomical variation was the leading causes of conversion in present study (Table 3).

Table 5: Comparison of postoperative pain between the two groups.

Studies	Pain score compared on VAS at 6 hours and on day 1 postoperatively
Present study	Significant
Bucher P et al 17	Significant
Lai EC, et al ¹⁸	Non-significant
Asakuma M,et al ¹⁹	Significant
Prasad A, et al ²⁰	Significant

In present study, no intraoperative complication was seen in SILC group. No rise in intraoperative complication as compared to multiport surgery was observed in present study.

Table 6: Comparison of postoperative complaints with other study.

Studies	Complaints (nausea, vomiting, shoulder pain, others)	
	SILC	Multiport
Present study	11.54%	13.2
Hodgett et al ¹⁵	10%	0%

In the study conducted by Sang Kuon Lee et al one case of right hepatic duct injury, 11 GB perforations, 2 mesenteric injury are mentioned. In most of the other study no intraoperative complications occurred. In the case series by Sinan Ersin et al one case was converted due to failure of Trocar insertion. The results in present study are in agreement with those of other studies. Complication due to pneumoperitoneum did not occur in either group.

Table 7: Comparison of post op hospital stay with other studies.

	Post op hospital stay(days)
Present study	2-4
Lee et al ¹¹	2.7±1.5
Kravetz et al ¹²	1-4
Ersin,et al ¹³	1
Chow,et al ¹⁴	1
Hodgett,et al ¹⁵	1±0.61
Culp BL, Cedillo VE, Arnold DT ¹⁶	2.8

The mean time required for single port cholecystectomy in present study was 109.23±25.37 min which was not significantly high when compared to mean time of 100.37±28.08 min required for multiport cholecystectomy.

In the case series by Sinan Ersin et al 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 showed a mean duration of surgery of 40 min. The duration of surgery for single port cholecystectomy in present study compared satisfactorily with that in other studies.

In a study conducted by Bucher P et al significantly less pain was observed in patient who underwent LESS.In another study done by Prsasad a et al there was significant difference in postoperative pain between the two groups who underwent single port cholecystectomy and multiport cholecystectomy. In present study we had a significantly reduced postoperative pain scores on VAS both at 6 hrs and on POD 1 postoperatively in SILC group compared to Multiport group.^{17,20}

In present study common postoperative complaints were nausea (SILC group 7.69%, multiport group 11.11%), vomiting (SILC group 3.85%, multiport group 3.7%). One Urinary retention in one patient in postoperative period was reported in study conducted by Hodgett et al.¹⁵ No postoperative complication like bleeding or bile leak occurred in either group in present study. In study conducted by Chow et al bile leak from accessory duct of Luschka was noted in one case.¹⁴

Mortality was 0% in both the groups. Length of postoperative stay in present study for SILC group $(4.04\pm1.34 \text{ days})$ was almost same as postoperative stay required by multiport surgery patients $(3.93\pm1.14 \text{ days})$.

In study conducted by Kravetz et al Post-operative stay range was 1-4 days for patients who underwent singleport cholecystectomy.¹² Another study done by Ersin, et al hospital stay for single port group was one day.¹³ Postoperative hospital stays in present study ranged from 2-4 days in patients who underwent Single incision laparoscopic cholecystectomy which is compared fairly with that in other studies.

1 case of port site infection occurred in the SILC group whereas patients who underwent multiport cholecystectomy had no port site infection which is not statistically significant.

CONCLUSION

In present study the following conclusions were made

- Difference of Conversion rates between SILC group and Multiport group is not statistically significant
- No rise in intra and post-operative complications occurred in the single port surgery even with the technical drawbacks of the procedure
- Time required for SILC is not significantly higher than that required for multiport cholecystectomy.
- Degree of postoperative pain is significantly lower in patients undergoing Single incision laparoscopic cholecystectomy compared to patients undergoing Multiport laparoscopic cholecystectomy.

- Length of postoperative hospital stay for single port cholecystectomy is same as for multiport cholecystectomy.
- Incidence of postoperative port site infection was not significantly higher in single port cholecystectomy as compared to multiple port cholecystectomy.

The sample size in present study is small to make solid conclusion. The procedure can be selectively and judiciously performed by surgeons trained in regular laparoscopic surgery. Also, the threshold for conversion should be low in learning phase. Widespread application must await results obtained from level 1 trials.

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Institutional Ethics Committee

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