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Original Research Article

Comparison between single incision laparoscopic cholecystectomy using conventional laparoscopic instruments vs. four port laparoscopic cholecystectomy in patients of symptomatic cholelithiasis: a prospective randomised study

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ABSTRACT

Background: The desire to reduce invasiveness, pain, discomfort and improve cosmesis and early return of patient to normal activities is the basis for single incision laparoscopic surgery. The primary aim was to compare post-operative pain and the secondary aim to compare duration of surgery, intraoperative bile spill or stone spill, duration of hospital stay, any postoperative complications and cosmetic outcome between SILC and the gold standard for symptomatic gall stone disease, FPLC (Four port laparoscopic cholecystectomy).
Methods: A total of 150 patients were randomized into two groups, A (SILC) and B (FPLC). Post-operative pain and other intra-operative and post -operative parameters were compared.
Results: The age ranged between 20 years to 76 years most of them being females with body mass index ranging between 19 and 35 kg/m^2. Comparison of pain score was done using MEWS scale; which was found to be statistically significantly SILC at 6 hours, mean difference (MD)-0.833 while at 24 hours the difference was not significant (MD-0.234). Duration of surgery was significantly more (MD-12.17 minutes) in SILC. No addition of port or conversion to open cholecystectomy was required. There were no significant difference between post-operative complications between the two groups. Cosmesis was significantly better in terms of look of the scar (MD-0.867) and recommending it to their relatives (MD-0.700) in SILC group.
Conclusions: SILC is a safe and easily learnable procedure which can be safely be done using conventional laparoscopic instruments in low risk patients. Duration of surgery even after expertise is gained remains to be more than FPLC.

Keywords: Single incision laparoscopic surgery, Conventional laparoscopic instruments, Four port laparoscopic cholecystectomy

INTRODUCTION

Cholecystectomy is the commonest operation of the biliary tract and the second most common operative procedure performed today.[1] Jurney of management of symptomatic gall stone disease from open cholecystectomy to minimal invasive surgery has taken nearly 115 years. Four port laparoscopic cholecystectomy (FPLC) is safe and well-

established procedure in modern times. With the development of technology and the expertise and confidence developed by surgeons in laparoscopy the desire to reduce invasiveness, leave less foot prints of surgery the number and size of these incisions needs to be reduced. Single-incision laparoscopic surgery (SILS) refers to the operative technique in which a surgical procedure is carried out through one incision. Single incision laparoscopic cholecystectomy (SILC) was first performed by Navarra et al in 1997, so is a recent minimal access surgery innovation.[2] In the last two decades many different techniques of SILC have been reported but there is no standardized technique. The advantage of SILC over conventional laparoscopic cholecystectomy and one technique of SILC over the other is debatable. We performed this randomized control study in a hilly state of a resource poor country to compare various intra-operative and post -operative parameters of SILC with FPLC.

METHODS

Study design and population

The present study was carried out in department of General Surgery in our unit (by the same team of surgeons) at Indira Gandhi Medical college, Shimla , Himachal Pradesh ,India ,after obtaining approval of the ethical committee of the institution. All consecutive cases who consented to be a part of the study, of symptomatic gall stone disease confirmed ultrasonically between 21 to 80 years and with American Society of Anaesthesiologists (ASA) score <3 over a period of one year from 1st July 2017 to 30th June 2018 were included in the study. We had excluded all high risk cases; acute cholecystitis, choledocholithiasis with cholelithiasis, those with bleeding disorders, previous upper abdominal surgery or a body mass index (BMI) >40 kg/m^2. Before the surgery, all patients had basic investigations such as routine haematological and biochemical investigations, electrocardiogram, ultrasonography of the abdomen and radiologic imaging such as chest radiograph done to exclude any other associated disease. A total of 150 patients were enrolled in the study. All eligible patients were randomized into two groups using sealed envelopes. “Group A” included 75 patients in whom Single incision laparoscopic cholecystectomy (SILC) was done and “Group B” included 75 patients who underwent four port laparoscopic cholecystectomy (FPLC).

Surgical procedure

FLPC was carried out without any modification of American four port technique. SILC was done with conventional laparoscopic instruments and using puppeteer technique with few modifications in the standard technique.[3] A pneumoperitoneum of 12mm Hg was created by CO_2. Umbilicus was everted and an infraumbilical curved (smiling) incision 2.0 to 2.5 cm in length was given. This was deepened through fat and flaps were undermined to expose fascia. In contrast to earlier described procedure, we performed tunneling into subcutaneous tissue and two separate incisions were given in rectus sheath to avoid needling effect of instruments. For introduction of instruments one 10mm and one 5 mm trocar (Covedien Versa Port 5 mm bladeless trocar with fixation cannula) were used. At the left we inserted 5mm port for the camera and 10 mm port was the working port through which laparoscopic needle holder, Maryland forceps and extractor were introduced at the various steps of SILC procedure (Figure 1).

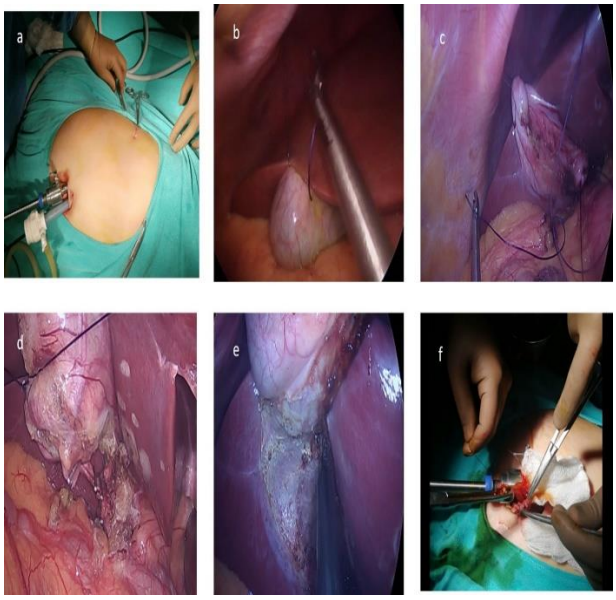

Figure 1: Steps of our technique of single incision cholecystectomy a) Instrument insertion through infraumblical incision b) Suture taken through the fundus of gall bladder c) suture taken through Hartmann pouch d) Clipping and cutting of cystic duct and artery e) Dissection of gall bladder off the bed f) Specimen extraction.

For traction suture of Vicryl no. 1 on a straight 60 mm needle was used. First traction suture for elevation of gall bladder was passed from intercostal space into the fundus of gall bladder and back again (Figure 1). Another traction suture was introduced just below xiphisternum passed through the Hartmann’s pouch, and was brought out at subcostal parietal wall at anterior axillary line (Figure 1). This technique was the crux of puppeteer used for dissection of Calot’s triangle. Dissection was started at posterior peritoneum to free the Hartmann’s pouch and cystic duct.

Cystic artery and duct were identified, skeletonised, doubly clipped and divided (Figure 1). Alternating medial and lateral rotation of the GB using ends of suture placed on Hartmann’s pouch was done to dissect it from liver bed using a diathermy hook (Figure 1). Gall bladder was held by a grasper and extracted through umbilical incision (Figure1 1). To prevent port site infection and hence reduce chances of hernia rectus sheath was closed with vicryl no.1 suture and skin by skin staplers (Figure 2).

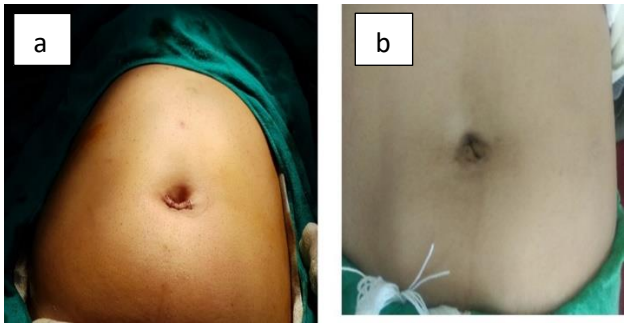

Figure 2: a) Wound after skin closure in SILC b) SILC scar at 1 month follow up.

Observation indices

Data of all patients enrolled in the study was collected and entered in excel spread sheet. The various parameters recorded were: age, sex, BMI, pre-operative ultrasonic finding, surgical approach group (SILC or FPLC), primary outcome (post-operative pain at 6hours and 24 hours) and secondary outcomes (duration of surgery, intraoperative bile spill or stone spill, duration of hospital stay, any postoperative complications and cosmetic outcome). For pain assessment modified early warning score (MEWS) was used. Score 0 when there is no pain either at rest or movement; 1 when no pain at rest but slight pain on movement; 2 Intermittent pain at rest and moderate pain on movement; 3 when there is continuous pain at rest and severe pain on movement is there. Patients in both the groups were given analgesics only if they experienced pain. Injection diclofenac 75 mg was given. Duration of surgery was recorded in minutes from incision to closure of the wound. Any bile spill or stone spill and insertion of drain was observed.

Duration of hospital stay was observed in hours from immediate post-operative period to discharge. For cosmetic outcome after one month post-operatively patients were required to give a score of 1-4 (1- unlikely, 2-less likely, 3 more likely, 4- definitely) to healing, look of scar (Figure 2) and recommendation of this procedure to relatives and friends.

Data analysis

All discrete variables were expressed as percentages or proportions. Continuous variables were presented in Mean±SD. Data was analysed using Epi-info version 7.2.2, p value <0.05 was considered as statistically significant.

RESULTS

The demograpghic profile of the patients was as shown in (Table 1). Pain assessment postoperatively showed that after 6 hours, maximum patients (46.6%) (N=35) in SILC group had a score of 1 while in FPLC maximum patients (53.3%) (N=40) had a score of 2. None of the patient in FPLC group felt no pain while in SILC group 17.3% (N=13) patients had no pain at 6 hours (Figure 3). Comparison of mean pain score (Table 1, Figure 3) showed a significantly less pain in SILC than FPLC.

Table 1: Demographic profile of patients in two groups.

Parameters	SILC	FPLC
Mean age (years)	40.40±13.68	44.300±14.02
Percentage of females	86.7	80
Mean BMI (Kg/m^2)	22.566±2.78	22.550±2.90

After 24 hours of surgery in both the groups' maximum patients felt no pain i.e., 53.3% (N=40) and 48.0% (N=36) in SILC and FPLC group respectively (Figure 3).

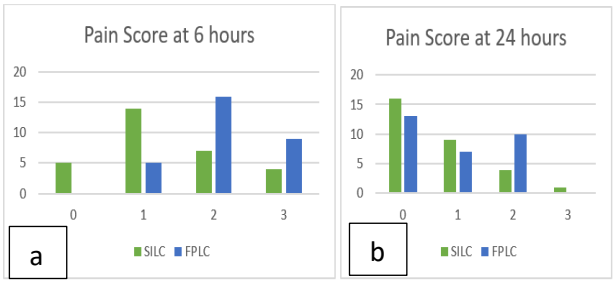

Figure 3: Comparison of pain score at, a) 6 and b) 24 hours post -operatively in the two groups.

There was no significant difference in the mean pain score in the two groups at 24 hours (Table 2). Maximum patients (33.33%) (N=25) in group A required a single analgesic dose.

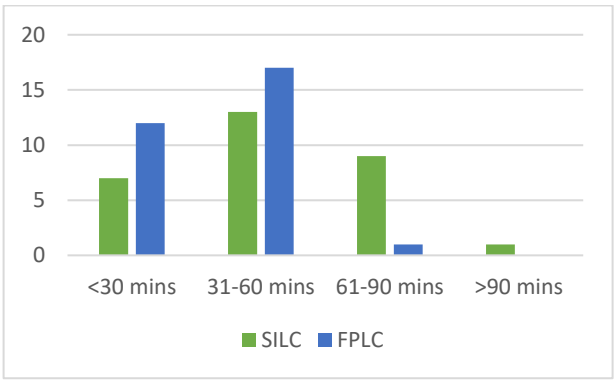

Figure 4: Comparison of duration of surgery in the two groups.

In group B, maximum patients (76.4%) (N=57) required 3 analgesic doses post operatively. No post-operative analgesics were required in 30.6% (N=23) patients in group A while in group B 4% (N=3) were in this category. Mean analgesic requirement post-operatively in SILC was significantly less than in FPLC (Table 2). Though there was significantly more bile spill in SILC group there was no significant difference between the two groups in stone spill.

Table 2: Comparison of SILC and FPLC patients.

Parameters	SILC	FPLC	P value
Pain at 6 hours post-operatively	1.333±0.922	2.166±0.746	0.0003
Pain at 24 hours post-operatively	0.666±0.844	0.900±0.884	0.067
Post-operative analgesic requirement	1.3667±1.217	2.700±0.5621	0.0001
Duration of surgery,	53.00±20.28	40.83±13.77	0.0086.
Conversion to open cholecystectomy/requirement of additional port	nil	nil	-
Post-operative drain requirement	nil	1.33%	-
Intraoperative bile spill	56.7%	23.3 %	0.005
Stone spill	13.3%	6.7%	0.216
duration of hospital stay <24 hours	98.6%	73.3%	0.031
Any postoperative complications	1.33%	1.33%	-
Cosmetic outcome-Heal score	3.733±0.827	3.600±0.813	0.531
Look score	3.900±0.305	3.033±1.188	0.0003
Recommend score	3.766±0.774	3.066±1.112	0.006

There was no other significant intraoperative complication. We did not require addition of a port or conversion to open cholecystectomy in any of our patient. Drain was put in one FPLC patient only. Duration of surgery ranged between 15 mins to 120 mins with a mean of 46.91min ±18.25. Time elapsed during surgery was divided into <30 minutes, 30-60 minutes, 60-90 minutes, >90 minutes. Mean of duration of surgery was observed to be more in SILC group, 30% had an operative time between 61- 90 minutes, while there were only 3.33 % patients of FPLC in this category (Figure 4, Table 2). Comparison of means of various primary and secondary outcomes in the two groups is as shown in tables. Most of our patients in groups A (N=74) were discharged within 24 hours.

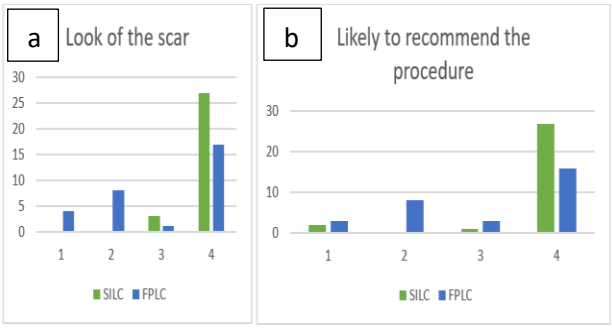

Figure 5: Comparison of a) look score and b) recommend score in both the groups.

In Group A one patient had post operative ileus which was managed conservatively and patient was discharged on day 3. In group B 55 patients (73.3%) were discharged in <24 hours rest except one were discharged after another 24 hours. In Group B one patient had post- operative biliary peritonitis which was managed with percutaneous drainage and ERCP stenting, cause was cystic duct stump leak. No case of port site hernia in any of the groups after 6 month follow up was seen. Cosmesis as observed one month after surgery on the patient's satisfaction of healing and look of the scar, most of the patient felt their scar healed very well (86.7% and 77.3% respectively in the two groups). Look of the scar was given a maximum score in SILC group (90.6% vs. 56%) with a significant difference being there in the two groups (Figure 5). Similarly, there was a significant difference who felt recommending the procedure to their relatives in favour of SILC (90.6% vs. 53.3%) (Figure 5).

DISCUSSION

Surgeons have always tried with their innovative techniques, gain in expertise and developments in technology to decrease invasiveness, hence decreasing patient discomfort, early return to work without compromising safety. This led to development of minimal invasive cholecystectomies like minilaparoscopy, needlescopy, three, two, single incision laparoscopic cholecystectomy (SILC), scarless, NOTES (Natural orifice transluminal endoscopic surgery). The trans umbilical technique for cholecystectomy, without additional incisions, was described first by Navarra et al. in 1997, but failed to gain popularity due to lack of proper instrumentation.[2] They published their report of 30 cases; using two ports at umbilicus and three stay sutures. Curcillo and King in 2007 refined the technique and published subsequently their unique method of entry In their technique, a skin incision at the umbilicus, allowed a flap of the umbilicus to be raised, allowing for three to four separate sheath incisions at distances of 2-3 cms from each other in the 'Mickey Mouse' configuration.[4] The advantage of discrete fascial incisions increased manoeuvrability decreased chances of gas leak during creation of pneumoperitoneum. But multiple fascial defects increased chances of port site hernia due to "swiss cheese defect".[5] A single-access system can be used which is a special purpose made devices, which has multiple ports Surgical glove technique that involved the use of a plastic wound retractor inserted transumbilically with an attached glove to prevent CO_2 leakage, with its fingers functioning as multiple ports.[6] Various singular port assess ports used are R-port, gel port, anchor port, etc.[7] Number of umbilical

ports can be reduced by assistance of either a grasper or anchoring threads for gall bladder retraction.[8] Our puppeteer technique used only two incisions (two ports) into fascia with two tpercutaneous traction sutures which helped in elevating gall bladder and clearing anatomy of Calot's triangle. Puppeteer technique was initially used by Navarra et al and later by Bhandarkar et al and Singh et al have used puppeteer technique in SILC.[3,9]

A variety of modifications to the original method concerning the number, type and size of the trocars, placement of ports along vertical incision or side by side instrumentation, and the preferred method of gallbladder anchorage and exposure of the Calot's triangle have been used.[5] The primary aim of our study was to compare post -operative pain in SILC and FPLC group. We compared pain on basis of MEWS score. We observed that at 6 hours post-operatively there was significantly less pain in SILC group than FPLC however this difference was not significant after 24 hours. Decreased post -operative pain in SILC than FPLC was also observed in various studies.[1014] No significant difference in pain was observed by Guanxiong et al.[15] In a study by Sharma et al post-operative pain in SILC group was more.[16] Mean post-operative analgesic requirement was significantly less in SILC group similar to various studies.[10,15,17]

Secondary aims of our study were to compare various other intra-operative and post-operative parameters In our study, 46.6% patients in SILC group had intraoperative bile spillage. High rate of bile spillage was because of insertion of needle in the gall bladder, needed for retraction. Stone pill was seen in iatrogenic gall bladder perforation. No significant difference in stone spill was seen in two approaches in another study.[18] Post-operative drain was required only in one patient in group B. In a study by Cinar et al drains were used in 7 patients (16.7%) of SILC while in the FPLC group they were used in 62 patients (62%).[19] Additional port was not required in any SILC and no conversion to open cholecystectomy was required in any of the two groups. Like our study, Borle et al did not require any additional port.[20] Sinha et al had a conversion rate of only 0.89%.[21] Park performed 500 SILC and required an additional port in only 1% cases.[22] The conversion rate has been reported to be as high as 16 % where high risk patients were included.[15] The common causes of conversion to FPLC mentioned are inflammation, adhesions, excessive fibrosis and unclear Calot's anatomy. In our study though we had high incidence of pericholecystic adhesions conversion was not required in any case probably we devoted more time for operation in SILC.

Duration of surgery for SILC was significantly longer in our study. Increased operative time has similarly been observed by many studies.[10,18,19,23] Increased duration of surgery is because of lack of triangulation, mindset of surgeon, altered ergonomics, clashing of instruments at very narrow umbilical fulcrum and the required meticulous closure of the umbilical port. Duration of surgery though has been shown to decrease with practice but it is usually more than FPLC. In SILC group patients 74 (98.6%) while in FPLC group 55 (73.3%) patients were discharged within 24 hours. Shorter hospital stay in SILC patients has been reported by Hajong et al.[10] In a meta-analysis and few studies no significant difference in the two groups was observed.[11,20,21] Less area of incision decreases pain and allows early recovery of patient. In our study, one patient in each group had a complication. In group A, one patient had post operative ileus and in group B, one patient had cystic duct stump leak. Similar to our study Sharma et al concluded that SILC is as safe as MPLC if done by experienced hands in selected patients.[16] In a meta-analysis port site hernia was observed in 1.3% of SILC vs. 0.3% for multiport laparoscopic cholecystectomy.[14] Another study reported port site hernia in 8.4 % of SILC in comparison to 1.2 % with FPLC.[24] In SILC technique, the size of the incision is bigger than in multiport approach so one could expect more incisional hernias. This could have a negative impact on the cosmetic outcome after SILC. Also in obese patients, one could expect a higher risk of hernias. We had no report of port site hernia probably because we closed the incision site meticulously, taking more time in operative procedure. Also, we had excluded high risk cases and our follow up period was short thus reducing reports of port site hernia. Post -operative complications as high as 20% were reported during earlier years.[25] In recent studies no significant difference has been reported in post-operative complications in the two groups.[16,21] In our study, the less number of post-operative complications in both the groups could be because we excluded high risk cases and our operation time was longer. We observed that SILC is as safe as FPLC in carefully selected patients.

Comparison of heal score between the two groups showed p value of 0.531; suggesting that patients in both the groups were satisfied with healing of their wound. Look of the scar was felt to be better by SILC than in FPLC (3.900±0.305 vs. 3.033±1.188; p=0.0003). Ninety percent of SILC patients felt that they would definitely recommend the procedure to their relatives vs. 53.3% of FPLC. Sharma et al analysed cosmesis by a questionnaire based cosmetic scale at 1 week and 4 weeks. They suggested that patients in the SILC group not only felt that their scar was cosmetically better but were also more satisfied with the surgery compared to FPLC group.[16] Most of the other studies also by different cosmetic scores reported that cosmesis and patient satisfaction is significantly better with SILC than FPLC.[10,11,15,20-23] SILC with conventional laparoscopic instruments is a safe, easily learnable and feasible procedure without additional cost of SILS port and articulated instruments in low risk patients.

Limitations

Limitations of current study were we had excluded all the high risk cases, so safety of the procedure in difficult cholecystectomies cannot be ascertained. Patient assessed cosmesis and satisfaction scores were recorded. There was no objective parameter. Also, our follow up was relatively

short to determine the post-operative complications like port site hernia. Another limitation is due to the fact that the definition of cosmesis and quality of life is different among the different socioeconomic groups.

CONCLUSION

Recent developments in surgical techniques and technology has paved our way to advanced surgical procedures which reduce patient discomfort. Single incision laparoscopic cholecystectomy (SILC) is a minimal access surgical procedure which is an easily learnable and performable procedure. SILC with conventional laparoscopic instruments is a safe and feasible procedure without additional cost of SILS port and articulated instruments. We conclude that SILC with may become a gold standard for removal of symptomatic gall stone disease in patients with no risk factors.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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