Single-incision versus 3-port laparoscopic cholecystectomy in symptomatic gallstones: A prospective randomized study

Mohammed A. Omar, MD,[a] **Alaa A. Redwan, MD, PhD,**[b] *and* **Ahmed G. Mahmoud, MD,**[b] *Qena and Sohag, Egypt*

Background. *Laparoscopic cholecystectomy is the standard treatment for symptomatic gallbladder disease. Single-incision laparoscopic surgery was developed with the aim of decreasing the invasiveness of conventional laparoscopy. The aim of this study was to compare the clinical outcome of single-incision laparoscopic cholecystectomy with 3-port laparoscopic cholecystectomy.*

Methods. *From February 2014 to September 2016, 187 patients with symptomatic cholecystolithiasis were randomized to a single-incision laparoscopic cholecystectomy group (89 patients) or a 3-port laparoscopic cholecystectomy group (98 patients). The primary outcomes were a postoperative pain score (at 6 hours and 1 day) and patients of complications, while the secondary outcomes were operative time, estimated blood loss, opioid requirements, duration of hospital stay, and patient satisfaction with aesthetic effects.*

Results. *When comparing 3-port laparoscopic cholecystectomy and single-incision laparoscopic cholecystectomy, there were differences in the (mean ± standard deviation) operative time (58.9 ± 18.6 minutes vs 45.2 ± 11.8 minutes;* $P < .001$*), success rate (93% vs 99%;* $P < .01$*), conversion rate (7% vs 1%;* $P < .001$*), and aesthetic score (7.9 ± 1.6 vs 6.7 ± 1.4;* $P = .008$*). There were no statistically significant differences in estimated blood loss, postoperative pain, opioid requirement, complications, and hospital stay between both groups.*

Conclusion. *Single-incision laparoscopic cholecystectomy is a safe and feasible procedure in selected patients. The main advantage is the superior aesthetic results, while the main disadvantage is a greater operative time with some technical difficulties. (Surgery 2017;162:96-103.)*

From the General Surgery Department,[a] *South Valley University, Qena, Egypt; and the General Surgery Department,*[b] *Sohag University, Sohag, Egypt*

Laparoscopic cholecystectomy (LC) is the standard treatment for symptomatic gallbladder disease.[1] The technique of LC continues to develop toward less invasiveness by decreasing the number of traditionally used 4 ports resulting in the development of safer and feasible 3-port[2] and 2-port LC.[3] Single-incision laparoscopic cholecystectomy (SILC) appeared as a new method in 1997.[4] With SILC, multiple instruments are used either through a single-port device with multiple channels or through multiple, closely placed ports.[5]

The suggested advantages of SILC include less ports, less postoperative pain and narcotic requirements, a better aesthetic result, and quicker return to normal activity.[6,7] Hence, use of the SILC technique is rapidly growing among surgeons and patients, and in many practices, SILC has become an alternative technique to traditional multiport LC.

In contrast, the disadvantages include a more difficult technique, greater operative time, greater cost, and possibly increased morbidity.[8,9] At the time of this study, there were no available prospective, randomized, controlled trials in the literature sufficient for a fair comparison between SILC and multiport LC. Therefore, we prepared this study to compare SILC and 3-port LC (TPLC) prospectively.

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Reprint requests: Mohammed A. Omar, MD, General Surgery Department, Qena Faculty of Medicine, South Valley University, Qena, Egypt 83511. E-mail: mohamed_ali@med.svu.edu.eg.

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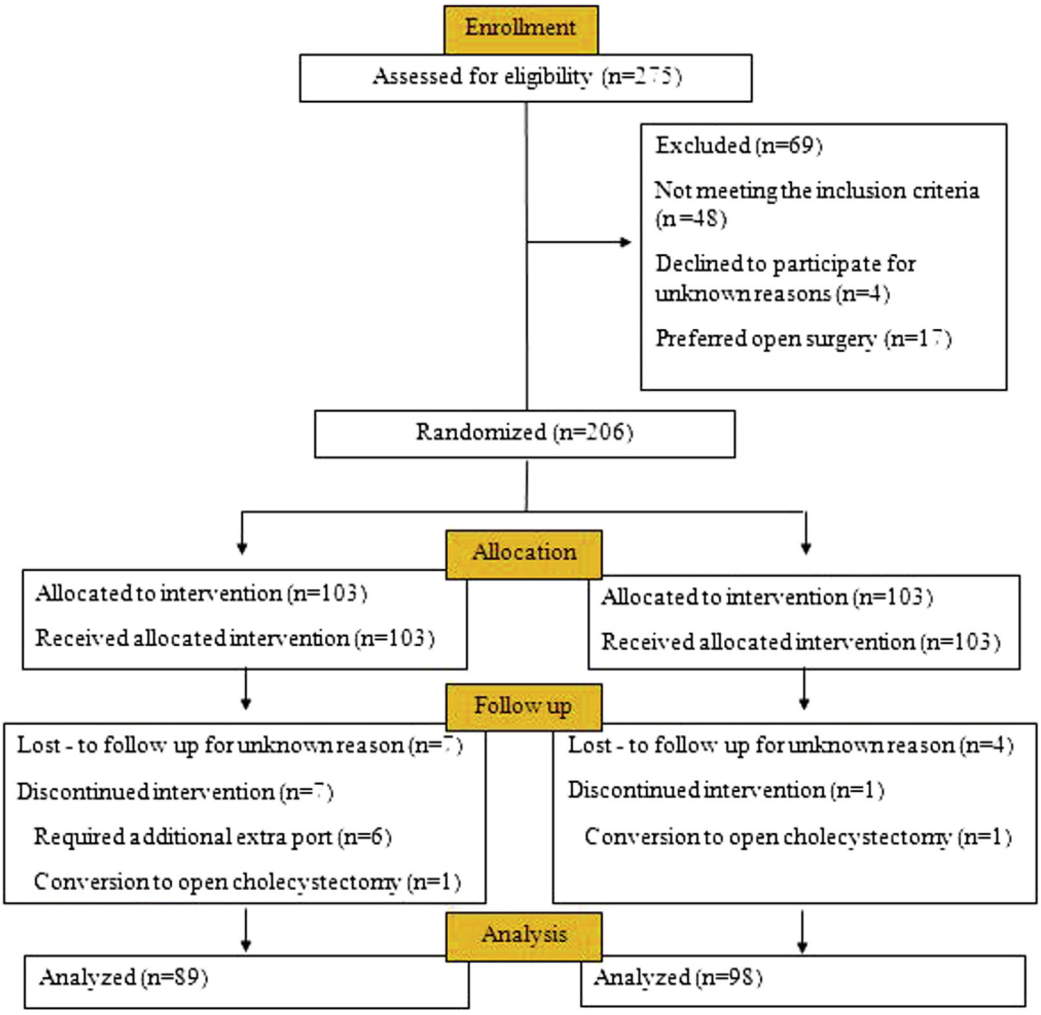

Fig 1. Consort flow diagram of patients.

PATIENTS AND METHODS

From February 2014 to September 2016, patients with symptomatic cholecystolithiasis at 2 university hospitals were enrolled in this study. The inclusion criteria were patients with a preoperative diagnosis of symptomatic gallstones aged from 20 to 60 years, American Society of Anesthesiologists (ASA) grade I, II, or III, and agreement to complete the study requirement. Exclusion criteria were patients with any contraindication to laparoscopy, suspected Mirizzi syndrome, choledocholithiasis, malignancy, previous upper abdominal surgery, previous mesh repair of an umbilical hernia, long-term anticoagulant treatment, pregnancy and a stone(s) >2 cm in preoperative ultrasonography.

The number of patients needed was calculated. Considering a power of 80% and reliability of 0.05, we found that 76 patients should be present in each group. The study was started with a target of 275 patients for the possible loss of patients and data during the study. Eligible patients (206 patients) were randomly divided into 2 equal groups (Group 1: SILC, Group 2: TPLC) according to computer-generated random numbers. Of the 103 patients allocated to intervention in each group, 14 patients were excluded from the SILC group and 5 patients from the TPLC group, and the remaining 89 and 98 patients in the SILC and TPLC groups, respectively, were included in the study (Fig 1).

Routine investigations and the evaluation of operative fitness were done in all cases. Patient demographics, body mass index (BMI), ASA score, indication for cholecystectomy, operative time, estimated blood loss, success and conversion rate,

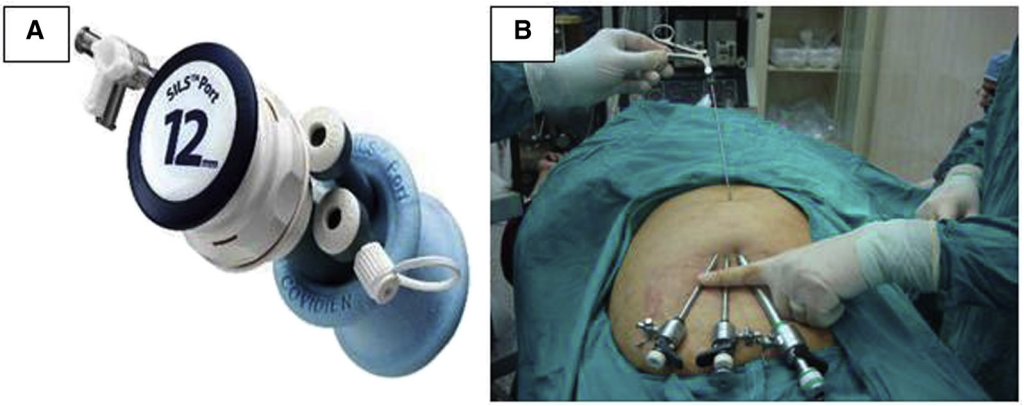

Fig 2. (*A*) SILC port and (*B*) 3 ports and fascial needle closure for SILC. (Color version of this figure is available online.)

postoperative pain score, postoperative analgesia requirements, morbidity and mortality, duration of hospital stay, and patient aesthetic satisfaction were recorded.

A fixed analgesia protocol with an intravenous nonnarcotic (ketorolac tromethamine, 30 mg) was used twice daily. An opioid (pethidine HCl, 50 mg) was added when the pain was not tolerable. Postoperative pain was evaluated according to a visual analogue scale (VAS) from 0 (no pain) to 10 (maximum pain) on the postoperative hour six (VAS-6H) and on postoperative day one (VAS-24H).

Patient aesthetic satisfaction was recorded at the one-month follow-up visit on a scale from 1 (worst) to 10 (best). Patients were shown the same photograph of a right subcostal (Kocher) incision, which was rated 0 on the aesthetic scale, and were asked to rate their satisfaction based on the previous observation. The study protocol was approved by the local ethical committee of our hospitals. Also, a written informed consent was obtained from all patients prior to recruitment to the study.

Operative techniques. All operations were performed by the same experienced surgical team under general anesthesia with standardized techniques.

SILC. SILC was performed through a single, infra-umbilical incision using a single-port device (Fig 2, *A*) or 3 ports closely placed (Fig 2, *B*). Both articulating and straight instruments were used, and they give the same traction and exposure of Calot's triangle.

Single incision 3-port procedure. A 3-cm, infra-umbilical incision was made, and a pneumoperitoneum was created. A 10-mm trocar (Karl Storz, Ltd, Germany) for the laparoscope (Karl Storz, Ltd) was inserted in the left side of the incision and another 2, 5-mm trocars for the working instruments (grasper, Karl Storz, Ltd; harmonic scalpel, Ethicon, US) were inserted into the other side with preservation of interval tissues for prompt trocars fixation and prevention of leakage.

With the help of a facial closure needle forceps (Karl Storz, Ltd), a curved K-wire or suture stitch was inserted precutaneously through the epigastric region, the gallbladder fundus was retracted toward the anterior abdominal wall. A cholecystectomy was performed in the standard fashion.[9] When the gallbladder was free, it was removed via an extraction bag through the 10-mm port after camera exchange.

Single incision single port procedure. A 2-cm, infra-umbilical incision was made, and a pneumoperitoneum was created. A single access port (Covidien Ltd, Ireland) was introduced via the incision. A camera and 2 other trocars were introduced intermittently through the port. A cholecystectomy was then performed in the standard manner.[9] The gallbladder was removed through the incision along with a port device.

In both techniques, the fascia was closed with zero polypropylene sutures, and the skin was closed subcuticularly with 3/0 poliglecaprone. A drain was placed through the umbilical incision when indicated and was withdrawn on the first postoperative day.

TPLC. An infra-umbilical incision, a midepigastric incision and a right midclavicular subcostal incision were made. A 10-mm trocar for laparoscope, a 10-mm trocar for harmonic scalpel, and a 5-mm trocar for the grasper were placed respectively. The cholecystectomy was performed with the standard technique with the specimen removed from the epigastric incision.[9] Only the umbilical fascia was closed with zero polypropylene

Table I. Patient data

Patient data	*SILC*	*TPLC*	P *value*
Age, (mean ± SD)	41 ± 9.6	41 ± 10	.99
Sex (male/female ratio)	34/55	41/58	.88
BMI (kg/m^2)	32 ± 6.6	33 ± 5.7	.24
ASA score	1.8 ± 0.7	1.9 ± 0.7	.57
Indication			
Acute calcular cholecystitis	9	8	
Chronic calcular cholecystitis	80	90	

sutures. Trocar wounds were sutured subcuticularly with 4/0 poliglecaprone. A drain was placed through the right subcostal incision when indicated and was removed on the first postoperative day.

Our primary outcome measures were postoperative pain score (at 6 hours and 1 day) and complication rate, while our secondary outcome measures were operative time, postoperative opioid requirements, duration of hospital stay, and patient aesthetic scores.

Statistical analysis. Statistical analysis was made using the SPSS program for Windows 12.0 (SPSS, Chicago, IL). The χ^2 test or the *t* test was used as indicated. Quantitative variables were presented as mean ± SD.

RESULTS

Patient data. A total of 187 patients were enrolled in the study and stratified randomly to 89 patients for the SILC group and 98 patients for the TPLC group. There were no statistically significant differences between groups in demographic data, clinical presentations, and so on (Table I).

Operative details. In the SILC group, 6 patients (6%) required an additional extra port (due to operative anatomic difficulties, one extra port in 3 cases and 2 extra ports in the other 3 cases) and 1 patient (1%) required conversion to open cholecystectomy due to uncontrolled bleeding from an aberrant artery. In the TPLC group, one patient (1%) with severe adhesions and difficult visualization of Calot's triangle was converted to open cholecystectomy. When comparing the SILC and the TPLC groups, the success rate and need for placement of additional trocars was different between groups (93% vs 99%; $P < .01$ and 6% vs 0%; $P < .001$), respectively, with a similar conversion rate to an open approach (1% vs 1%; $P = 1$) (Table II). Analysis of intraoperative data revealed differences in the operative time (58.9 ± 18.6 minutes vs 45.2 ± 11.8 minutes; $P < .001$). In contrast, there were no statistically significant differences in VAS on 6 and 24 hours, estimated blood loss, opioid requirement, hospital stay, and intraoperative complication rate between groups (Table II).

Postoperative follow-up. There was a significant difference in the aesthetic score between the 2 groups (7.9 ± 1.6 vs 6.7 ± 1.4; $P < .008$), but there were no significant differences in postoperative complications between groups (Table II).

Five patients (4 in the SILC group and 1 in the TPLC group) were readmitted. In the SILC group, 2 patients developed a wound infection and were treated with local wound dressing and antibiotics, 1 patient developed an umbilical hematoma treated conservatively, and 1 patient developed mild bile leakage treated conservatively with ultrasonographic-guided drainage and antibiotics. In the TPLC group, one patient developed a mild bile leakage treated as the previous patient. At the time of submission of this article, no patients had developed a postoperative port site hernia or any biliary stricture. The mean follow-up was 13 ± 9 months (range, 1–35 months).

DISCUSSION

Classical LC with 4 trocars has been the accepted standard technique for symptomatic gallbladder stones.[10] Surgeons have investigated less invasive techniques, so SILC is one of the recent innovations in this field and has been described using a single-incision, single-port technique and single-incision, multiport technique.[11] SILC has gained popularity because of its potential aesthetic results. Over the next few years, SILC may became the gold standard for cholecystectomy,[12] but some advocates have suggested that acceptance, the safety, feasibility, and other potential benefits first need validation.[13]

The success rate and conversion rate (additional trocar and conversion to open approach) are among the major important factors allowing the assessment of value and usefulness of any laparoscopic procedure.[14] The successful rate and rate of need for additional trocar placement

Table II. Patient outcomes

Comparative parameters	*SILC*	*TPLC*	P *value*
Operation time, min (mean)	58.9 ± 18.6	45.2 ± 11.8	.001*
Success rate incidence (%)	96 (93%)	102 (99%)	.01*
Total intraoperative conversion rate	7 (7%)	1 (1%)	.001*
Additional trocars placement	6 (6%)	0 (0%)	.001*
Conversion to open operation	1 (1%)	1 (1%)	1
EBL (mL)	24 ± 6	22 ± 4	.64
VAS (1–10)			
VAS-6H	3 ± 1.5	3 ± 1.6	.82
VAS-24H	2 ± 0.8	2 ± 1	.76
Opioid use (patient)	13 (14.6%)	14 (14.3%)	.67
Intraoperative	7 (7.9%)	4 (4.1%)	.08
Liver injury	1	0	
Blood oozing from gall bladder bed	2	2	
Rupture gall bladder	2	1	
Omental laceration	2	1	
CBD injury	0	0	
Postoperative	9 (10.1%)	4 (4.1%)	.76
Wound infection	2	2	
Bile leakage	1	1	
Umbilical seroma	3	0	
Haematoma	2	1	
Subphrenic abscess	1	0	
Hernia	0	0	
Readmission	4 (4.5%)	1 (1%)	.06
Hospital stay	1.3 ± 1.2	1.2 ± 0.9	.78
Aesthetic score	7.9 ± 1.6	6.7 ± 1.4	.008*

**P* values are statistically significant.
EBL, Estimated blood loss; *CBD*, common bile duct.

was somewhat greater in the SILC group than the TPLC group. For our SILC group, 4 cases need for additional trocar placement were among the first 10 cases early in our low learning curve. When only conversions to open surgery were analyzed, there was no significant difference between the 2 groups. Studies with a similar or greater number of cases than our study revealed similar results.[1,8,15-17] In contrast, many recent studies revealed no significant difference regarding success rate and additional trocar placement.[10,18,19]

Khambaty et al[20] and Han et al[21] suggested that patients with a BMI >35 or with acute cholecystitis were at risk for intraoperative conversion and may not be candidates for SILC, while Deveci et al[10] reported no correlation between BMI and the presence of acute cholecystitis and the conversion rate. We had no substantial additional difficulties in the patients with a BMI >35 or the patients with acute cholecystitis, and we support the observation by Deveci et al[10] regarding no correlation between BMI and acute cholecystitis and the conversion rate.

One of the factors assessed in the previous studies comparing SILC and TPLC was operative time. Our study revealed greater operative time (a mean of 13 minutes) in the SILC group than in the TPLC group, which was similar to many studies,[10,11,16,18,22] while some studies mentioned similar operating times in both groups,[23-25] and another revealed a lesser operating time in the SILC versus standard laparoscopic cholecystectomy.[19]

Certainly, the greater operative time of SILC may impair its popularity and spread, but we should remember that this technique is still novel and immature. Historically, operative durations of the first laparoscopic cholecystectomies were much greater when we compare these results with the initial outcomes of SILC.[14] Indeed our mean operative time in the first 10 cases was 103 minutes, which decreased in the last 10 cases to 47 minutes, probably as a consequence of increasing experience and progressive development of our learning curve. The operative time of the last 10 SILC cases was comparable to our TPLC operative time. Also, there was no significant difference in estimated blood loss between groups and was comparable to many recent reports[10,13,23]

Postoperative pain is an important factor from the point of view of the patient in the success of

any new operative technique, and it is unquestionable that the decrease in postoperative pain is one of the important factors which gives the popularity and superiority of laparoscopic procedures when compared with open technique.[26] The main difference between SILC and TPLC is the number of abdominal wall incisions (1 versus 3). In actuality, a major part of postoperative pain usually results from the trauma of the abdominal incision; therefore, with the decrease in the number of abdominal incisions, one might expect a decrease in postoperative pain which will be reflected in a decreased postoperative analgesic requirement in the SILC technique.

The literature shows conflicting results regarding postoperative pain score and analgesic requirements between SILC and TPLC; some studies report a difference,[23] others do not.[13,22] Our study showed no statistically significant differences regarding postoperative pain and opioid requirements between both groups. Pan et al[23] reported statistically lesser postoperative pain scores and analgesic requirements in an SILC group, which they attributed to the single incision in SILC than those in TPLC, whereas Jung et al[18] found that pain scores and analgesic requirements were significantly greater in the SILC group, which they attributed to more tissue trauma caused by single port and limited mobility of instruments causing more local trauma to the abdominal wall.[27] Deveci et al[10] reported a difference in VAS-24H and lack of difference on VAS-6H and analgesic requirement, while Sharma et al[11] reported more pain in the SILC group in VAS-6H and lack of any difference in VAS-24H.

Operative complications (both intraoperative and postoperative) were similar in both groups regarding frequency and nature. Similarly, most previous studies revealed no significant differences in complication rates between SILC and TPLC.[10,11,13,16,18,19,23] A recent review of the literature revealed that SILC was associated with a nonstatistically significant trend of an increase in the rate of bile duct injuries compared with historically reported rates for standard LC (0.72% vs 0.4%–0.5%)[28] Considering the rarity of bile duct injuries, in order to confirm such a difference, a prospective study would require, on the basis of 80% power at a 5% significance level, approximately 900 patients in both groups.[15] In our study, no bile duct injury was reported. Another postoperative complication of SILC is the incidence of incisional hernias. SILC entails a fascial incision of at least 2.5 cm. Moreover, there is a continuous stretching effect on the access wound due to the nature of the single-port apparatus. Because the periumbilical area is inherently weak anatomically, it would be prone to development of incisional hernia in the postoperative period.[11] In our study, no port site hernia was reported up to the time of collation of the follow-up possibly related to a careful and meticulous closure of the fascial defect. Two controlled trials have reported port site hernias exclusively after SILC,[29,30] but the small number of patients in those studies and the low incidence of this complication does not allow proper conclusion.[15] There was no significant difference regarding the readmission rate in our study which was similar to those of Hawasli et al.[31]

The duration of hospitalization was measured as the time that the patient stayed in hospital after the operation. There was no difference regarding hospital stay between groups. This finding corresponded to some studies,[10,11,18,22,23] but was in contrast with others which reported a significantly shorter stay for the SILC.[16,27,32] Although we did not study the time to normal activity, some studies reported similar results regarding their patients' return to work,[33,34] but some studies still have suggested an earlier return to normal activity in patients who underwent SILC.[35,36]

Evaluation of postoperative aesthetic outcomes is difficult because of the lack of a validated objective scale. Many factors, such as potential observer bias and difference in patient expectations, add confounding factors when evaluating aesthetic outcomes. In our study, patients scored the SILC results as better than after TPLC. Several studies and meta-analysis have also agreed with our study regarding better aesthetic outcomes with improved patient satisfaction after SILC,[10,13,16,22,23] although other studies have found a similar aesthetic outcome.[15,29]

Although cost was not included in our goals, cost considerations must be taken into account when considering any potential advantages of SILC. Many studies reported an equal total cost between SILC and traditional LC when standard materials were used.[23,37] Hwang et al[38] reported the total cost was less for SILC than standard laparoscopic cholecystectomy, which was explained by the decreased number of ports (1 versus 3) and a lesser pain score with less need of pain medications in the SILC group in comparison to TPLC group. In contrast, Tranchart et al[15] reported the total cost was slightly greater in the SILC group.

In conclusion, SILC is a safe and acceptable technique when performed by experienced surgeons. Operative outcomes are acceptable and encouraging, although it is technically difficult and takes longer with better aesthetic results.

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