## ORIGINAL ARTICLE

# SINGLE TRANS-UMBILICAL VERSUS MULTI-INCISION LAPAROSCOPIC CHOLECYSTECTOMY USING CONVENTIONAL LAPAROSCOPIC INSTRUMENTS; A RANDOMIZED CONTROLLED CLINICAL TRIAL

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## Abstract

**Summery Background data:** Laparoscopic cholecystectomy has traditionally been performed using multiple incisions. Single-incision laparoscopic surgery has emerged as an alternative technique to improve cosmoses and minimize complications associated with multiple incisions.

**Objective:** To compare the outcomes of single-incision laparoscopic cholecystectomy (SILC) versus multi-incision laparoscopic cholecystectomy (MILC) using conventional laparoscopic instruments.

**Methods:** 64 patients undergoing cholecystectomy for symptomatic gall stones, dyskinesia or polyp who were willing to be part of this comparison were included in the study. Patients were randomized into two groups of 32 per each. Only conventional instruments were used in both groups to keep the cost of surgery the same. No special ports, reticulating instruments or flexible telescopes were used.

**Results:** Of the attempted SILC cases, 26 (81.25%) were successfully completed, with the remainder requiring one to three additional skin incisions. There were no conversions to open in either group. Operative time was significantly longer in SILC cases compared with MILC [65(45-120) Vs 40(25-70) P_ 0 .0001]. There was a tendency toward greater postoperative pain in the MILC group. No intra-operative complications but two cases of port site hernias reported two months post-operative in SILC group. Significant better cosmetic outcome was observed in SILC cases.

**Conclusion:** SILC is feasible and promising. It is possible to do this procedure without using special equipment and could be an effective alternative to standard four-incision laparoscopic cholecystectomy. With the possibility that after the initial learning curve, when the operative time reduces, the postoperative pain may also decrease. More studies are needed to demonstrate safety, selection criteria and benefits over conventional laparoscopic cholecystectomy.

**Keywords:** Single incision Laparoscopic Cholecystectomy, Multi-incision, Conventional Laparoscopic Cholecystectomy, Trans-umbilical incision, SILS.

## INTRODUCTION

Minimal invasive approach is the standard technique for many surgical procedures. The safety and efficacy of a laparoscopic over open surgery has been well established during the past few decades as it is associated with a reduction in postoperative pain, shortened hospital stay, an early return to work and better cosmoses.[1-2]

From the beginning of laparoscopic technique in 1985, this approach has been continuously developing and research has focused on further minimizing the invasiveness of surgical procedures to reduce intra-operative and post-operative morbidity, and improve post-operative cosmoses.[3]

Over the last two decades, laparoscopic cholecystectomy (LC) has replaced open cholecystectomy as the gold standard for the treatment of symptomatic gallbladder stones or other benign gallbladder pathology. Traditionally, LC has been performed with a 4-port approach. In recent years, many investigators have attempted to improve further on the established technique of LC. Generally, the goal has been to minimize the invasiveness of this procedure by reducing the number of ports and, more commonly, the size of the surgical ports and instruments as well as techniques to reduce the trauma of surgical access that led to the development of SILS and natural orifice transluminal endoscopic surgery (NOTES).[4-7]

Initial data has shown that SILC is a feasible and safe approach.[8] It has been suggested that SILC is comparable to conventional multiport laparoscopic cholecystectomy (MPLC) in terms of complications, rate of conversion to open procedure and length of hospital stay.[9-12] However, SILC has shown better cosmetic outcomes and patient satisfaction.[13] Hence its popularity amongst the surgeons and patients is growing; this has raised the possibility of SILC becoming an alternative approach to multiport laparoscopic cholecystectomy. Although at present, all available literature supports the feasibility of SILC.[14-24]

However, there are only a limited number of comparative studies for the validation of these potential outcomes. Therefore, we conducted this prospective randomized study to evaluate the safety and efficacy of SILC versus MILC using the conventional laparoscopic instruments in regard to the perioperative, functional, and cosmetic outcomes.

## PATIENTS AND METHODS

### Study design

A randomized control trial study, where all patients from age 19 to 62 years, with a preoperative diagnosis of symptomatic gallstones, gallbladder dyskinesia or gallbladder polyp scheduled for elective cholecystectomy at the Department of Surgery, Medical Research Institute Hospital and the Main University Hospital, Alexandria University, were offered the opportunity to participate in this trial. Informed consent was obtained from all participants and approval was obtained from the ethics committee of our institutions.

The exclusion criteria included the following: (1) American Society of Anesthesiologists (ASA) class IV and V; (2) patients with contraindication for laparoscopy; (3) patients with Mirizzi syndrome; (4) patients with suspected presence of common bile duct stones; (5) patients with suspected malignancy; (6) patients with previous upper abdominal surgery; (7) patients on long-term anticoagulant treatment; (8) patients with a previous history of cholangitis or acute cholecystitis.

### Randomization method

Eligible patients were randomized into two groups (SILC group and MPLC group (standard technique) using sealed opaque envelopes containing computer-generated random numbers. The randomization was performed 1 week before surgery during the preoperative assessment.

Data were collected about: Patient clinical history, baseline characteristics, indications and results of the procedure, intraoperative findings, as well as hospital course and postoperative follow-up evaluation.

### Preoperative assessments

All patients underwent the following basic preoperative investigations, including the following: (1) blood tests: complete blood count, coagulation profile, and renal and liver function tests; (2) radiologic imaging: chest radiograph and ultrasonography of abdomen; and (3) electrocardiogram.

### Procedures

Surgical techniques were standardized among the participating surgeons before starting the protocol. Single intravenous dose of antibiotics, ceftriaxone 2 g IV, was administered before the skin incision, if patients had no associated allergy history. After the delivery of general endotracheal anesthesia, the abdomen was prepared and draped sterilely with careful attention to the cleaning of the umbilicus. At this time, the study envelope was opened, and the procedure was continued according to the randomization card.

### MILC

All surgeries were performed under general anesthesia in the supine position with the operating surgeon on the patient's left side. The 10-mm supra-umbilical trocar was inserted. The abdominal cavity was insufflated to a pneumoperitoneum of 12-14 mm Hg, and a 30° laparoscope then was inserted. The patients were placed

in a reverse Trendelenburg position, with the right side elevated. Under direct vision, two 5-mm trocars then were placed in the right subcostal region along the anterior axillary, midclavicular lines, and 10-mm trocar in subxihoid region. Two graspers were passed through the 2 lateral ports to retract the fundus and Hartmann pouch of the gall bladder. Instruments of matching caliber were used for the dissection around the Calot's triangle to expose both the cystic duct and cystic artery from the subxiphoid port. The cystic artery and duct were dissected and transected after endoclips control. The gallbladder was dissected from the gallbladder bed. The specimen was placed inside the retrieval gloves and removed. Dressings were placed over the port wounds.

**SILC**

All surgeries were performed under general anesthesia in the supine position with the operating surgeon in between patient's leg and the camera man on the patient's left side. A 2 cm transverse incision was made at the level of umbilicus. Upper skin flap was raised for a distance of 1 cm. After initial insufflation with Veress needle, a 10 mm cannula was inserted at the incision line and the two 5 mm & 10mm cannulas half cm inferiorly and laterally on both sides through the same incision (Fig. 1). A grasper introduced through the right lateral cannula for traction of Hartmann pouch of the gall bladder. The left lateral cannula was used for introduction of the dissector to define Calot's triangle. The instrument cannulas and telescope cannula were crossed by a chop stick method to avoid sword fighting and clashing of instruments in the abdomen. Elevation of gallbladder fundus was done using either veruss needle introduced through subxyphoid 2 mm incision (Fig. 2) or retraction of gall bladder fundus using Prolene™ 2/0 [Polypropylene Suture ;Ethicon, Johnson & Johnson Intl, Sint-Stevens-Woluwe, Belgium] on straight needle introduced from right subcostal region (Fig. 3). Insertion of 10 mm clip applicator from the right lateral cannula for clipping of the cystic duct and artery. After dissection from the liver bed and hemostasis, the gall bladder was delivered from the central port site. Fascial defects were closed meticulously and skin apposed.

**Outcome measurement**

The primary end point was pain score. The patients usually were discharged on the day of surgery if they had no symptoms of dizziness or vomiting, and no complications or in the next day. A standard visual analog scale (range, 0 [no pain] to 10 [maximum pain]) was used for an objective assessment of incisional pain at 6 hours after surgery, and on postoperative day 7 by the non-operating surgeons. During the assessment, the assessors were blinded from the type of procedure. The patient was not blinded during the study.

The secondary end points were any addition of laparoscopic ports other than a SILS port, and conversion to open cholecystectomy, complications from cholecystectomy, hospital mortality from cholecystectomy, hospital stay, interval for resumption of normal physical activities, and cosmetic satisfaction of the surgical scar. The appearance of each incision was rated on a scale of 1 (worst) to 10 (best) at the 3-month follow-up visit by patients. The 4-port wound score in MILC was averaged.

**Statistical analysis**

Statistical analysis was conducted using PC with the software: SPSS (Statistical Package for the social Sciences) version 16. Statistical significance was set at (P- value <0.05) two sided. Chi- square test ($\chi 2$) and Z test of proportion were used to test the difference between proportions in categorical variables. Shape of distribution was tested and accordingly Mann-Whitney U test was used for comparison of quantitative variables between the two groups.

## RESULTS

64 patients undergoing cholecystectomy were included in the study and they were divided into two Groups, 32 patients in each one; SILC Group & MILC Group.

Patients were in between 19 to 62 years old. We had 2 male and 30 female patients in either group. The average BMI was 35 and 36 respectively. The two groups were statistically matched (Table I).

The main indications for cholecystectomy were cholelithiasis [multiple stones in 38(59.4%) patients and a single stone in 19(29.7%) patients], gall bladder dyskinesia in 6(9.4%) patients and single patient with gallbladder polyp (1.6%) with no significant difference between both groups (Table II).

Operative time was significantly longer in SILC cases versus MILC (Table III). No patients in either group were converted to open cholecystectomy. SILC was completed successfully in 26 (81.25%). The other 6 patients required one to three additional skin incisions and ports, generally to improve retraction of the gall bladder.

The groups had similar lengths of hospital stay, with the majority of patients in both groups being discharged on the day following the operation (Table III). The MILC group showed a trend for higher postoperative pain scores. No intra-operative complications were reported in either group. There were two cases of port site hernias reported in SILC about two months postoperative. All patients returned to their preoperative activity level without any significant difference. Wound satisfaction scoring was significantly higher in SILC group with better cosmetic outcome compared to MILC group (Table III) (Fig. 4).

**Table I. Patient's data.**

| Variable | SILC (n =32) | MILC (n =32) | P-value |
|---|---|---|---|
| Age (y), median (range) | 39 (23-67) | 43.5 (19-62) | 0.629 |
| SEX n (%) MALE | 2(6.2%) | 2(6.2%) | 0.1 |
| FEMALE | 30(93.8%) | 30(93.8%) | 0.1 |
| BMI* median (range) | 35(29-40) | 36 (29-46) | 0.24 |

*BMI (body mass index); Calculated as kg / $m^2$.

**Table II. Indications for cholecystectomy.**

| Indication | SILC | MILC | P-value |
|---|---|---|---|
| Symptomatic cholelithiasis | 28(87.5%) | 29(90.6%) | 0.6913 |
| Single stone | 10(34.5%) | 9(31%) | 0.7655 |
| Multiple stones | 18(62.1%) | 20(69%) | 0.5614 |
| Biliary dyskinesia | 3(9.4%) | 3(9.4%) | 1.000 |
| Gallbladder polyp | 1(3.4%) | 0(0%) | 0.2928 |

**Table III. Results after SILC versus MILC.**

| Outcomes | SILC | MILC | P-value |
|---|---|---|---|
| Operative time (min), median (range) | 65(45-120) | 40(25-70) | 0 .0001 |
| Hospital stay (d), median (range) | 1(1-2) | 1(1-2) | 0 .495 |
| Postoperative pain (pain score), median (range) | 2.3(0.8-4.2) | 3.15(1-5.3) | 0.005 |
| Cosmetic outcome (Wound satisfaction scoring), median (range) | 9(5-10) | 8.5(6-9) | 0 .0001 |
| Interval for resumption of normalphysical activities (d), median (range) | 7(5-9) | 7(4-9) | 0 .0441 |
| Complications n (%)Port site hernia | 2(6.25%) | 0 | 0.1508 |

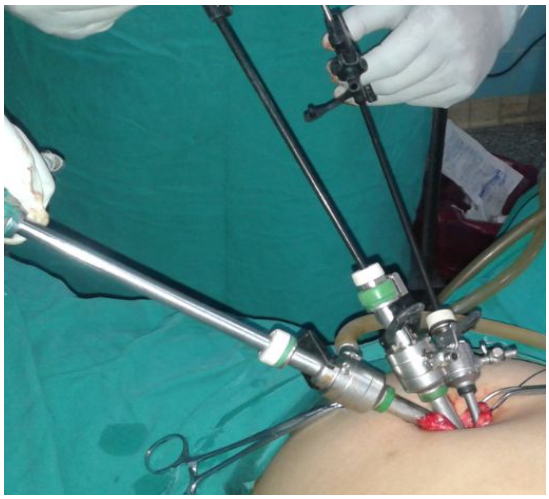

**Fig 1. Three conventional trocars inserted through the umbilical incision.**

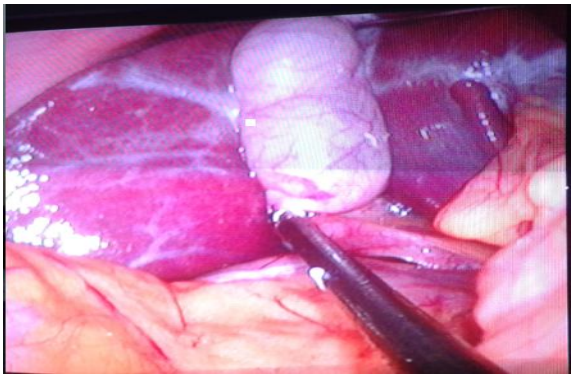

**Fig 2. Gallbladder retraction using Veress needle.**

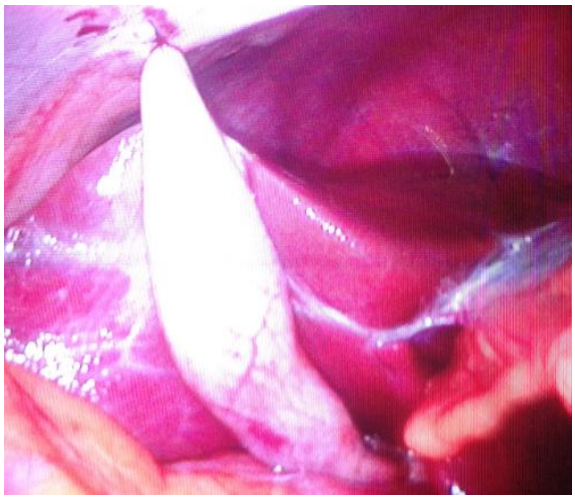

**Fig 3. Gallbladder retraction using Prolene™ 2/0.**

**Fig 4. Umbilical scar after 7 days.**

## DISCUSSION

Since Navara et al[25] reported the feasibility of SILC in 1995 with favorable outcomes; it is a rapidly developing technique which has been demonstrated as a potentially "scarless" procedure.[26] In this technique, multiple laparoscopic instruments are placed either through a single port device with multiple conduit or through multiple closely placed ports.[27] This approach is technically more challenging and the underlying principles are different to that of the conventional laparoscopic approach,[26] that is why this approach has mainly been adopted and promoted by surgeons with advanced conventional laparoscopic skills.

SILC on the other hand, enables the application of a wide range of already existing instruments. The main point for reducing the number of incisions has not only been the cosmetic advantage but also lowered incision risks, morbidity of bleeding, and organ damage. But benefits regarding post-operative pain in SILC have not been confirmed. There were some studies that indicate reduction in post-operative pain [28] but those are small and not sufficient to come to a conclusion. A recent systematic review showed no statistically significant difference in complication rates or postoperative pain scores for those undergoing SILC versus MILC.[29]

However, Phillips et al published a study that showed higher pain scores for those undergoing SILC, but no difference in analgesic use between SILC and MILC patients. They also reported higher rates of superficial wound complications after SILC [13]. From our study we found a significant reduction in post-operative pain in SILC group compared to standard laparoscopy also, a significant higher cosmetic outcome scoring in SILC group.

The real challenge of SILC is to avoid conflict between the operative instruments and the camera, to maintain

the pneumoperitoneum and reduce operative stress. As a result of the limited space with using only a single incision, it is difficult for both the surgeon and the assistant to work in the area[30] that is why operative time is significantly longer in SILC group than in MILC group and with experience and after some time of learning curve operative time is decreasing. We found that a decrease in post-operative pain between early start and later near the end of our SILC series. So, it is evident that post-operative pain may have some relation with operative time. It is likely that with increasing experience operative time as well as post-operative pain may decrease which is similar Prasad et al.[30] With experience the operative time is expected to become comparable with conventional laparoscopic cholecystectomy but we feel that expertise and reduction of operative time may reduce post-operative pain.

Most of the available special ports and flexible instruments are costy and disposable thereby increasing the cost of the procedure significantly. In our series, we used only traditional laparoscopic instrument and traditional ports. We did not use any specialized port, we used different ways to prevent air leak such as applying adhesive dressings, gauze soaked with saline etc around the cannulas. Also, we adopted gallbladder retraction for liver elevation using either a Veruss needle or Prolene™ 2/0 on a straight needle which forms the key step of the procedure.

With multiple incisions in the fascia in such close proximity and a longer skin incision, there is a theoretical increased risk of incisional hernias. In a series of 125 patients with follow up as long as 22 months, Cui reported that no patient had presented with an incisional hernia.[31] Follow up in our study was limited to three months; however, we noted no incidence of wound complications but, two cases of incisional hernia were recorded within 8 weeks post-surgery in SILC group.

There were no significant intra-operative complications in the SILC group, supporting the idea that this is a safe and feasible approach. Evidence of this safety and feasibility has already been shown in a number of other studies.[30,32]

SILC for gall bladder removal is a feasible and promising method for the treatment of symptomatic cholelithiasis.[33] This surgery can be performed with traditional re-usable laparoscopic instruments.[34,35] No special telescopes, ports or hand instruments are needed for this procedure but may have a role in advanced laparoscopic procedures. Although it has not been validated in a multicenter trial, SILC may offer the advantage of reduced postoperative pain, earlier return to activities of daily living, and improved cosmoses.

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