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ORIGINAL ARTICLE

Evaluation of pain scores after single-incision and conventional laparoscopic cholecystectomy: A randomized control trial in a rural Indian population

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Abstract

Introduction: Single-incision laparoscopic cholecystectomy (SILC) is considered to be less invasive and have less morbidity than conventional laparoscopic cholecystectomy (CLC). However, there is a relative paucity of data regarding postoperative pain scores in rural Indian populations following SILC. Also, data pertaining to the applicability of SILC in rural Indian population are scant.
Methods: In the present randomized control trial, pain scores after SILC and CLC were evaluated. Sixty patients with gallstone disease were randomly assigned to one of two groups with 30 patients each: the CLC group and the SILC group. Postoperative pain scores were recorded on the visual analog scale at 8 hours, 24 hours and 7 days after surgery.
Results: The patients were comparable with respect to age, sex and BMI. Operative time was longer for the SILC group (47.73 ± 5.57 min vs 69.53 ± 8.96 min; $P < 0.0001$).The pain scores were similar in both groups at 8 hours (3.61 ± 0.41 vs 3.50 ± 0.51; $P = 0.36$) and 24 hours (3.30 ± 0.59 vs 3.20 ± 0.40; $P = 0.44$) postoperatively. On day 7, the SILC group had lower pain scores than the CLC group (2.56 ± 0.56 vs 1.16 ± 0.37; $P < 0.01$).
Conclusion: There was no distinct advantage to SILC with regard to immediate postoperative pain. Pain was significantly less ($P < 0.01$) in the SILC group on postoperative day 7.

Introduction

In 1882, Langenbuch performed the first cholecystectomy through a subcostal incision (1). This technique remained the gold standard for over 100 years. Then, in 1985, Muhe performed the first laparoscopic cholecystectomy (2). The advantages of SILC over an open approach are better cosmetic outcome, less postoperative pain and faster recovery. These benefits have made laparoscopic surgery a gold standard procedure for gallbladder removal (3).

Each incision inflicts surgical trauma and increases the likelihood of pain in postoperative period. Thus, with the arrival of laparoscopic cholecystectomy, surgeons have strived hard to further reduce the invasiveness of the surgery and the number of ports in laparoscopic surgery. Mini-laparoscopic surgical techniques employ smaller instruments to reduce invasiveness. Single-incision laparoscopic cholecystectomy (SILC) was developed with the aim of reducing the invasiveness of traditional laparoscopy. Additionally, NOTES has enabled the treatment of cholecystectomy via the trangastric and transvaginal routes without the need for incisions. However, NOTES is technically more demanding and requires greater expertise than SILC. SILC is considered a bridge between conventional laparoscopic cholecystectomy (CLC) and NOTES (4). SILC was first described in 1997 (5), but until recently, it remained reserved for select patients because of its technical difficulties (6,7). With advancements in the development of instruments, many reports of SILC have demonstrated its feasibility (8–11).

SILC uses three ports through a single skin incision at the umbilicus, and it has shown to reduce postoperative

Asian J Endosc Surg **7** (2014) 38–42

pain in some studies (4,12,13). However, the majority of SILC studies have been conducted in an urban population. There have been fewer studies conducted in a rural population in India, where the practice of laparoscopic cholecystectomy has yet to be firmly established. Hence, the present study was conducted in such a population to determine whether SILC is equally effective in reducing pain as in urban populations. The aim of the study was to ascertain postoperative pain scores, determine whether SILC offers less postoperative pain than conventional laparoscopic surgery, and evaluate other parameters such as cost-effectiveness.

Materials and Methods

The present prospective randomized clinical trial was carried out at the Mahatma Gandhi Institute of Medical Sciences (Sevagram, India), a rural medical school in central India. The 2-year study was conducted from October 2010 to November 2012, and included 60 consecutive patients with symptomatic gallstones were included.

Patients over 18 years of age with documented gallstones on ultrasonography were included, irrespective of the sex. Patients with pregnancy, acute cholecystitis, presence of previous scars in upper midline or right subcostal region, suspicion of gallbladder malignancy, or who were unfit for general anesthesia were excluded.

Written informed consent was obtained from each patient. The study protocol was approved by the institutional ethics committee. Sixty patients (17 men; 43 women) with a mean age of 41.2 ± 13.1 years (range, 18–70 years) were randomly assigned to one of two groups with 30 patients each: the CLC group and the SILC group. All procedures were performed by a single senior surgeon who has performed about 25 SILC and over 100 CLC. Conventional instruments were used in both groups to maintain cost-effectiveness, given the lower economic status of the patients. The investigator was blinded to each patient's group and independently recorded the pain scores.

Operative technique

In both groups, the intra-abdominal pressure during laparoscopy was kept at 12–14 mmHg by CO_2 insufflation. All patients received ranitidine, ondansetron, glycopyrrolate (5–10 μg/kg), midazolam (0.3 mg/kg) and fentanyl (1.5 μg/kg) as premedication. Anesthesia was induced using propofol (2–2.5 mg/kg) and succinylcholine (1.5–2.5 mg/kg). All patients received general anesthesia with isoflurane and N_2O, with oxygen in a ratio of 50:50. A long-acting muscle relaxant, atracurium, was administered in a dose of 0.5 mg/kg, and 0.1-mg/kg top-ups were administered every 20 min to ensure adequate muscle relaxation to facilitate the surgical procedure. Postoperatively, all patients were kept nil by mouth for 24 hours and received diclofenac sodium 75 mg intramuscular injection every 8 hours on the day of surgery. Subsequently, diclofenac sodium 50 mg was administered orally to all patients every 8 hours.

CLC

Each patient was placed in the supine position with the table tilted toward the patient's left. Pneumoperitoneum was created using the closed Veress needle method. CLC was done using two 10-mm trocars inserted in the umbilical region and epigastrium, and two 5-mm trocars inserted in right upper quadrant and right lumbar region. The cystic artery and duct were clipped. The gallbladder was dissected from the bed with coagulation shears. The fascial wounds were closed with absorbable sutures, and the skin was closed with non-absorbable sutures.

SILC

Each patient was placed in the supine position with the surgeon and first assistant on the patient's left side and the second assistant on the right. The umbilicus was grasped at its base and then everted. An approximately 2-cm skin incision was placed within the umbilical fold. The SILS Port (Coviden™, Mansfield, USA) was inserted, and pneumoperitoneum was created using CO_2. The intra-abdominal pressure was kept at 12–14 mmHg. One 10-mm and two 5-mm trocars were placed through the single port.

The patient was tilted to the left. The gallbladder was sutured to the anterior abdominal wall by passing the suture through its fundus (puppeteering). The dissection was performed using conventional laparoscopic instruments. The cystic duct and artery were clipped. The gallbladder was dissected from the bed with coagulation shears. After the dissection, the 10-mm laparoscope was replaced by a 5-mm laparoscope, and the gallbladder was grasped. Hemostasis was achieved and the gallbladder delivered from central port site. Fascial defects were closed with absorbable sutures and the skin incision was closed with non-absorbable sutures.

The postoperative care and medications for the SILC group were the same as for the CLC group. The postoperative abdominal pain scores were registered at 8 hours, 24 hours, and 7 days after surgery. The visual analog scale (VAS), a 10-point scale with scores ranging from 0 (no pain) to 10 (severe pain), was used. Student's *t*-test was used for assessing statistical significance.

Table 1 Demographic data and operative variables†

	CLC (n = 30)	SILC (n = 30)	P-value
Age(years)‡	40.2 ± 14.4	42.3 ± 11.81	0.58
Gender (M/F)§	7/23	10/20	0.39
BMI‡	23.43 ± 1.79	23.04 ± 1.81	0.40
Mean operative time(min)‡	47.73 ± 5.57	69.53 ± 8.96	<0.0001
Mean blood loss (mL)‡	16 ± 5.62	14.06 ± 3.58	0.11

†Data expressed as mean ± SD.
‡Student's *t*-test.
§χ^2 test.
CLC, conventional laparoscopic cholecystectomy; F, female; M, male; SLC, single-incision laparoscopic cholecystectomy.

Table 2 Postoperative outcomes

	CLC (n = 30)	SILC (n = 30)	P-value§
Score on body image scale†			
1 week	8.26 ± 1.08	6.23 ± 0.89	<0.0001
1 month	8.00 ± 1.31	5.50 ± 0.68	<0.0001
Score on cosmetic scale‡			
1 week	15.00 ± 1.20	19.56 ± 1.07	<0.0001
1 month	15.63 ± 1.06	21.13 ± 0.57	<0.0001

†On a scale from 5 (best result) to 20.
‡On a scale from 3 to 24 (best result).
§Student's *t*-test.
CLC, conventional laparoscopic cholecystectomy; SLC, single-incision laparoscopic cholecystectomy.

Results

Demographic characteristics of both groups are given in Table 1. Both groups were comparable with respect to age, sex, BMI and preoperative diagnosis. The minimum age of patients in the study was 18 years, and the oldest patient was 70 years old.

Operative data

No extra skin incisions or additional ports were required in the either group. No conversions to open surgery were required. The mean operating time for SILC was 69.53 ± 8.96 min (range, 57–88 min), and for CLC, it was 47.73 ± 5.57 min (range, 39–59 min). Thus, the operating time was significantly higher in the SILC group. The operative blood loss in both groups was statistically comparable.

Postoperative outcome

There was no statistically significant difference in the VAS scores between the SILC group and CLC group at 8 hours after surgery (Table 2). The minimum VAS at 24 hours was 3 points in both the CLC and SILC groups; the maximum score was 4 points in the CLC group and 5 in the SILC group. This difference in VAS scores at 24 hours after the surgery in both groups was not statistically significant. At 7 days after surgery, the minimum VAS score was 1 point; the maximum score was 3 points in the CLC group and 2 in the SILC group. This difference was found to be statistically significant ($P < 0.01$).

Discussion

CLC offers patients the advantages of preserving the integrity of the abdominal wall, less operative trauma, early recovery and improved cosmesis (14–16). Over the years, the goal has been to minimize the invasiveness of the procedure by reducing the number and size of operating ports and instruments. This has resulted in the emergence of mini-laparoscopic techniques such as SILC and NOTES. Mini-laparoscopic techniques are based on instruments that reduce the total length of trocar incisions to less than 2.5 cm. These are considered useful and reproducible alternatives to scarless surgery that offer easy adaptability (17,18). The recent progress in SILC is driven mainly by the cosmetic advantages if offers, without the risks and technical limitations of NOTES (7).

As reflected in the statistically significant operative time difference ($P < 0.0001$), SILC is difficult to perform with conventional instruments. There was difficulty in achieving the critical view of safety due to inflexible CLC instruments. Specialized SILC instruments are costlier than conventional instruments. As such, given that these surgeries were performed in a rural setting on patients with severe financial constraints, a conscious effort was made to keep the cost of surgery low to make it affordable. There were no adverse events during surgery or the short-term follow-up. We think that SILC is feasible and cost-effective when performed with conventional instruments.

In the present prospective trial, SILC patients had less pain on postoperative day 7 than CLC patients. However, at 8 and 24 hours postoperatively, the pain scores did not statistically differ between the groups ($P = 0.36$ and $P = 0.44$, respectively). The pain was evaluated only on the basis of the VAS. A standard regimen of analgesics was followed in both groups postoperatively.

Pain evaluation may be done using various pain scales or based one the number of analgesics required and length of hospital stay. In the present study, both groups had similar analgesic requirements, and no supplemental analgesics were required. Also, patients in both groups were discharged on the day after surgery. Considering the non-conclusive nature of these two variables, emphasis was placed exclusively on the VAS. Two recent

Asian J Endosc Surg **7** (2014) 38–42

meta-analyses by Garg *et al*. and Markar *et al*. used VAS to analyze postoperative pain at 24 hours. As in the present study, they concluded that there was no statistically significant difference between postoperative CLC and SILC pain scores (19,20).

Postoperative pain is dependent on multiple factors such as inflammation due to tissue handling, infection at the incision site, bile leakage, intraperitoneal pressure and the pain threshold of the patient (21–23). In the present study, only scar site and size varied, so it is likely that these incision-specific variables had the greatest bearing on pain scores. In SILC patients, a single transumbilical incision was to easily introduce the SILC port without causing much the trauma to adjacent soft tissue and thus reducing the inflammatory reaction and pain. In CLC patients, four different ports were introduced (two 11-mm ports and two 5-mm ports), and the length of the incisions were 1.5 cm and 1 cm, respectively. The liberal incisions in CLC facilitate easy passage of the ports.

Another contributing factor to pain could be postoperative infection, which was largely absent in both groups. However, two SILC patients had minor infections at the incision site. None of the patients in either group had hematoma at the incision site.

Some studies have shown that pain scores in SILC are higher than or comparable to that in CLC (24,25). This could be because SILC requires greater stretching and handling of the adjacent tissue to accommodate the insertion of the larger port and instruments through the single umbilical wound. In our study, we used a slightly longer incision to avoid stretching of the tissues and found the pain scores after SILC to be less than after CLC, but this difference was not statistically significant.

On the postoperative day 7, although the SILC patients had statistically significant less pain ($P < 0.01$) than the CLC patients, no contributory clinical factors for this difference were ascertained. The most probable cause for that SILC involved less surgical trauma and less inflammation. SILC patients had a mean VAS of 1.16 (range, 1–2), whereas CLC patients had a mean VAS of 2.56 (range, 1–3). This pain was mild, and none of the patients required additional analgesics to control the pain. Although there was a statistically significant difference in the pain scores between the two groups ($P < 0.01$), it was found to be clinically insignificant. In a randomized control trail, Lai *et al*. observed that the SILC group had a significantly higher pain score on day 7 (1 vs 0) than the CLC group (26). This finding contradicts the findings of the current study, but a VAS score of 1 signifies very mild pain, which could be considered clinically insignificant. Hence, the findings studies could be considered practically similar.

In conclusion, SILC offered no distinct advantage with regard to postoperative pain in the immediate postoperative time.

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