Original article

Prospective outcomes of single incision laparoscopic cholecystectomy compared to conventional laparoscopic cholecystectomy; an initial experience

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Abstract

Backgroud Single incision laparoscopic cholecystectomy (SILC) has been challenged as an alternative technique to the gold standard conventional (3 or 4 port) laparoscopic cholecystectomy (LC).

Method In a prospective study from March to December 2012, 21 patients with indication of cholecystectomy were randomized into a SILC (n=10) or LC (n=11) group. The primary outcomes were cosmetic result and post operative pain. The secondary outcomes were complications, length of hospital stay (LOS) conversion rate and operative time.

Results Patient characteristics were no different between groups, except for body mass index (BMI), which was lower in the SILC group (mean±SD 20.2±2.5 vs 25.4±3.9 kg/m^2, p <0.01). The SILC group had a higher cosmetic score (mean±SD 9.7±0.5 vs 7.5±1.1, p <0.01) and longer operative time (mean±SD 84±19.9 vs 55±11.2 min, p<0.01), but was equal in visual analog pain score (VAS) (mean ±SD 3.7±1.6 vs 4.1±1.4, p=0.54), opiate used on day 1 (30% vs 45%, p =0.66), LOS (mean±SD 2.1±0.3 vs 2.2±0.6 day, p =0.70), post operative complication rate (10.0% vs 18.2%, p =1.00) and no conversion rate at all.

Conclusion SILC is a safe procedure with better cosmetic results. **Chiang Mai Medical Journal 2014;53(2):81-87.**

Keywords: single incision laparoscopic cholecystectomy (SILC), conventional laparoscopic cholecystectomy (LC), cosmetic score, visual analog score (VAS), post operative complication, operative time

Backgroud

Laparoscopic cholecystectomy (LC) was introduced in order to maximize satisfaction in terms of body image or cosmetic result, and improve clinical outcomes such as reduced post operative pain, shorter length of hospital stay and return to normal activity.

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Since Navarra *et al*[1] reported that laparoscopic cholecystectomy through single umbilical incision may be feasible technically, and could have advantages in certain patients, single incision laparoscopic cholecystectomy (SILC) is one of the most popular techniques performed today.

One abdominal incision instead of the conventional 3 or 4 is expected to improve clinical outcome. However, the major disadvantage of this technique is operational difficulty because it is hard to grasp or dissect the gallbladder from one incision (fighting instrument).

There is very little prospective data on SILC replacing LC as a standard treatment. Although SILC is performed worldwide, it is new to the institute of this study. Therefore, this study aimed to compare the results of this technique to the conventional one in many ways, in order to apply them for use as a standard practice.

Method

This study was a prospective randomized control trial in gallbladder disease patients, who needed an operation by laparoscopic cholecystectomy in Lampang Hospital between March and December 2012.

Primary outcomes of cosmetic results and post operative pain were compared between LC and SILC techniques. Secondary outcomes were safety and applicable in terms of complication, length of hospital stay and operative time.

Patient selection

Patients in Lampang Hospital, with indication of LC, were 20 to 80 years old. Pre operative imaging was carried out by abdominal ultrasound or CT scan. Patients diagnosed clinically or by imaging with acute cholecystitis were excluded from the study. Those needing exploration of the common bile duct and those diagnosed by pre operative imaging as suspected abnormal anatomy of the biliary tract, as well as pregnant women, also were excluded.

Patients were randomized for conventional LC of the 3rd or 4th port arm and single port arm (Figure 1). Prophylactic antibiotics were used in all cases. Nasogastric intubation was performed, with voiding to empty the bladder before operating.

Post operative pain was controlled by paracetamal at 1,000 mg orally, or pethidine intravenously on demand if the pain score was ≥ 4.

Surgical technique and instruments

Trocar in the conventional group was placed using the open technique at the subumbilical and epigastric region, and one or two trocar were placed subsequently at the right subcostal region (in mostly the 3rd port, with the additional 4th port being preserved for more complicated cases).

The same open technique was used in the single port group, placing trocar at the subumbilical region, but using the Single Incision Laparoscopic Surgery Port (SILS port, Covidien® company, Figure 2).

Both groups were given standard operations using usual instruments until the gallbladder was removed from the abdomen. Closed suction drainage was placed in cases when bleeding might not stop completely. The abdominal sheat, subcutaneous tissue and skin were closed by absorbable material.

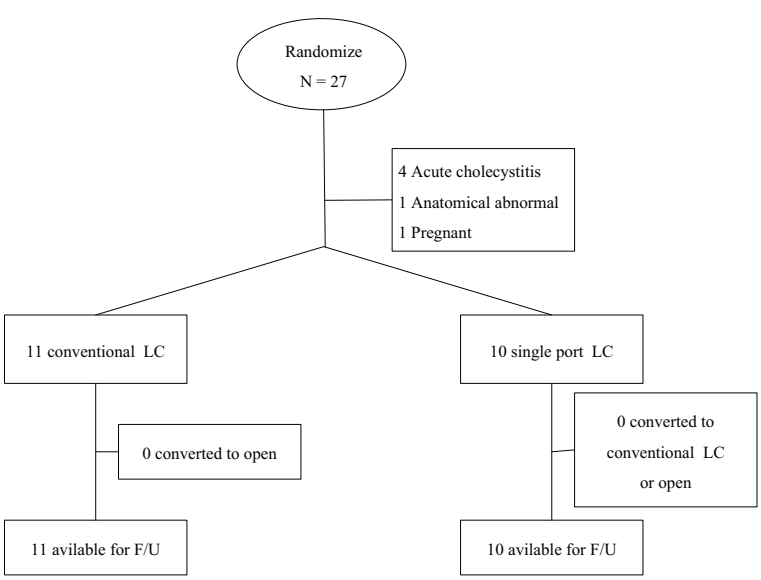

Figure 1. flow of randomized control trial.

Figure 2. Single incision laparoscopic surgery (SILS) port (Covidien® company).

Data collection

General information was collected, including sex, age, body mass index (BMI), indication for surgery, American Society of Anesthesiologist classifications (ASA), and intraoperative findings such as intraabdominal adhesion.

Operative time started from the first skin incision to the last skin closure. Cosmetic score[2-3] was rated at follow up visits about 2 weeks post operation by the patients' own ranking from 1 (worst) to 10 (best).

Pain score, using the visual analog score (VAS) between 0 (no pain) to 10 (maximum pain), was evaluated by the patients at 24 hrs post operation. All complication data were collected from the first day post operation until the last day of follow up (2 weeks later). The first day post operation to discharge from hospital also was counted as post operative length of stay (LOS). Conversion to the open technique in both groups or an additional port in the SILC group was collected and counted as "conversion" cases.

Statistical analysis

Sample size calculation, performed by the difference of cosmetic results, ensured a power of 80% and alpha level of less than 0.05 in one arm of 10 randomized patients. Data were analyzed using the STATA program version 11.0 in terms of mean±SD, range, and percentage calculated by comparing the t-test to Fisher exact probability test, with p <0.05 being significant.

Results

From a total of 27 patients, who had an LC operation, 6 were excluded due to acute cholecystitis (n=4), abnormality in pre operative anatomy (suspected portal varices) (n=1) and pregnancy (Figure 1).

Indications of gallbladder removal are shown in Table 1, including 90% symptomatic gallstones and 10% gallbladder polyp in the conventional group, and 80% symptomatic gallstones and 20% gallbladder polyp in the SILC group (p =0.72).

General characteristics and intraoperative findings were similar in age (mean 48.2 vs 50.5, p =0.70), sex (54.5% M vs 40% M, p =0.6), ASA class (27.3% vs 70% class 1, p=0.08), and intraabdominal adhesion (18.1% vs 40%, p =0.36).

The only significant statistic was body mass index (BMI), which was higher in the conventional group (mean±SD 25.4±3.9 kg/m^2 vs 20.2±2.5 kg/m^2, p <0.01).

A photograph on day 14 post operation is shown in Figure 3. The SILC group had a higher cosmetic score than the conventional one (mean±SD 9.7±0.5 vs 7.5±1.1, p <0.01), but it took a longer operation time (mean±SD 84±19.9 min vs 55±11.2 min, p <0.01). However, there was no difference in post operative pain (opiate use on day 1, 30% vs 45%, p =0.66 and 24 hrs. VAS score 3.7±1.6 vs 4.1±1.4, p =0.54). No conversion rate was found at all. The length of hospital stay (LOS) was similar in both groups (mean±SD 2.1±0.3 day vs 2.2±0.6 day, p =0.70). Post operation complication was not significantly different (p =1.00). Mild post operative complication was found in 2 cases (18.2%) with prolonged ileus and urinary retention in the conventional LC group, while only 1 case (10.0%) in the SILC group had prolonged ileus, but all of

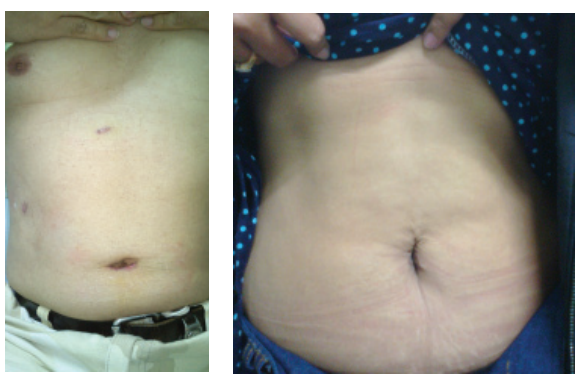

Figure 3. Postoperative image on day 14.

Table 1. Patient characteristics and indications for surgery

	Standard LC (n=11)	Single port LC (n=11)	*p*
Indications for surgery			
Symptomatic gallstone (%)	10 (90.0)	8 (80.0)	0.72
Gallbladder polyp (%)	1 (10.0)	2 (20.0)	
General charactistics			
AGE (year)	48.2±12.7 (24-64)	50.5±13.7 (34-75)	0.70
SEX (M : F) (%)	(6 : 5) (54.5 : 45.5)	(4 : 6) (40 : 60)	
BMI [(BW (kg)/Ht(m^2)]	25.4±3.9 (20.9-34.5)	20.2±2.5 (16.5-24.3)	< 0.01
ASA class (I : other) (%)	3 : 8 (27.3 : 72.7)	(7 : 3) (70 : 30)	0.08
Marked adhesion* (yes : no) (%)	2:9 (18.1 : 81.9)	(4 : 6) (40 : 60)	0.36

Age, BMI: mean ± SD. (range)
*marked adhesion = adhesion at the port site or around the gallbladder needed more time to lysis

Table 2. Clinical results

	Convention LC	Single LC	*p*
Cosmetic score (1 worst, 10 best)	7.5±1.1 (6-9)	9.7±0.5 (9-10)	<0.01
Opiate use on day 1 (%)	5 (45.5)	3 (30.0)	0.66
VAS 24 hr. (0-10)	4.1±1.4 (2-6)	3.7±1.6 (1-7)	0.54
Operative time (min)	55±11.2 (35-80)	84±19.9 (60-110)	<0.01
Conversion n (%)	0(0)	0(0)	N/A*
LOS (day)	2.2+0.6 (2-4)	2.1+0.3 (2-3)	0.70
Postoperative complication (%)	2 (18.2)	1(10.0)	1.00

Cosmetic score, VAS, operative time, LOS: mean ± SD. (range), VAS: pain visual analog score
LOS: length of stay post operation, *not applicable

them improved and could tolerate the condition when discharged from hospital.

Discussion

Published meta analysis data[4-9] of SILC versus conventional LC mostly compared clinical benefit and safety between the two operations. This was a prospective study that confirmed previous ones in many ways.

Patients in this study were no different in each group, except for lower BMI in the SILC group. Reibetana *et al*[10] reviewed 100 SILC patients and compared them between 17% obese patients (median BMI 33.9 kg/m^2) and 83% normal weight patients (median BMI 24.1 kg/m^2), and found no difference in operative time, conversion rate, postoperative complication or length of stay. They concluded that BMI should not be considered a key criterion in the SILC patients selected. In accordance with the Reibetana[10] study, the BMI in both groups of this study were categorized into normal weight patients. Despite using the randomized technique, more cases are required if BMI is used in selecting patients.

This study showed better cosmetic results in the SILC group, which was the same as in most metaanalysis[7-9] and randomized studies[2,11-14]. Studies by Ma *et al*[15] showed no difference in

cosmetic satisfaction between groups (total of 43 patients). In this study, an explanation for its results may be that most of the SILC group had never before had a single incision in any operation, and therefore the cosmetic score may be overestimated.

Early post operative pain was similar in both groups, which resembled results of most other studies[2,6-8,13-17]. However, some randomized studies had different results; for example, Tsimoyiannis *et al*[18] and Wong *et al*[19] found less pain in the SILC group, which was in contrast to Mehmood *et al*[20], who reported more pain in the SILC group. The possible reason for higher postoperative pain in the SILC group might be explained by longer umbilical incision length, longer operation time, more "traction", more tissue trauma and cases of early learning.

Longer operation time in the SILC group was a significant result, as it was the same as most others[6-9,12-16,20]. Some studies[2,11] reported no difference between groups however, and learning curve and skills affected the range. Previous studies reported that operation time improved significantly in approximately 5,[21] 8,[22,23] 10,[24] and 20[25] cases. There are many ways of suggesting how to reduced SILC operation time such as the sutured hanging gallbladder technique or curved instrument, but there is currently no standard technique. More cases to gain experience and newer reported techniques may be adapted in order to improve operative time.

Safety procedure evaluated by complications, LOS and conversion rate was similar in both groups and most previous studies[2,6,8-9,11-13,15-17]. Some studies[7,14,20] reported wound complications or longer LOS in the SILC group. A biliary complication rate of 0.7%[4,26] in the SILC group (0.2-0.5%[27] in conventional LC) is a major concern. Total major complications requiring intervention or readmission occurred in 2.7% of the SILC group[28] Therefore, many opinions suggest that it is too early to conclude SILC as a safe procedure. Large randomized controlled trials are necessary in order to confirm a safe procedure.

In conclusion, SILC in Lampang Hospital was found initially to be a safe procedure, with better cosmetic results, and no inferiority to conventional LC in postoperative pain and LOS. However, the operation time was longer.

Application and further suggestion

From this study, SILC is suitable for patients with cosmetic concerns. However, more cases are required for further study regarding complications.

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ผลของการศึกษาแบบไปข้างหน้าของการผ่าตัดถุงน้ำดีผ่านกล้องและแผลผ่าตัดเดียวเทียบกับการผ่าตัดถุงน้ำดีผ่านกล้องแบบดั้งเดิม; ประสบการณ์เริ่มแรก

สหธรรม สมินทรปัญญา, พ.บ.
กลุ่มงานศัลยกรรม โรงพยาบาลลำปาง จังหวัดลำปาง

ความเป็นมา การผ่าตัดถุงน้ำดีผ่านกล้องแบบแผลผ่าตัดเดียว กำลังท้าทายให้เป็นทางเลือกทดแทนการผ่าตัดถุงน้ำดีผ่านกล้องแบบดั้งเดิม (3–4 แผล)

วิธีการศึกษา เป็นการศึกษาแบบไปข้างหน้าในผู้ป่วยที่มีข้อบ่งชี้การผ่าตัดนิ่วในถุงน้ำดีรวม 21 ราย ระหว่างเดือนมีนาคม 2555 ถึงเดือนธันวาคม 2555 โดยแบ่งเป็น 2 กลุ่มอย่างสุ่มคือ กลุ่มแผลผ่าตัดเดียวจำนวน 10 ราย และกลุ่มผ่าตัดแบบดั้งเดิมจำนวน 11 ราย ประเมินผลการศึกษาหลักคือ ความพึงพอใจในความสวยงามของแผลผ่าตัดและความเจ็บปวดหลังการผ่าตัด ประเมินผลการศึกษารอง คือภาวะแทรกซ้อนหลังผ่าตัด จำนวนวันนอนโรงพยาบาล การเปลี่ยนวิธีการผ่าตัดและระยะเวลาการผ่าตัด

ผลการศึกษา ไม่มีความแตกต่างในลักษณะทั่วไประหว่างกลุ่ม ยกเว้นดัชนีมวลกาย ซึ่งในกลุ่มแผลผ่าตัดเดียวพบว่าน้อยกว่าอย่างมีนัยสำคัญ (เฉลี่ย ± ค่าเบี่ยงเบน 20.2±2.5 เทียบกับ 25.4±3.9 กิโลกรัม/ตารางเมตร, p <0.01) พบว่าในกลุ่มแผลผ่าตัดเดียวมีคะแนนความสวยงามแผลผ่าตัดมากกว่าอย่างมีนัยสำคัญ (เฉลี่ย ± ค่าเบี่ยงเบน 9.7±0.5 เทียบกับ 7.5±1.1, p <0.01) ระยะเวลาการผ่าตัดนานกว่าอย่างมีนัยสำคัญ (เฉลี่ย ± ค่าเบี่ยงเบน 84±19.9 เทียบกับ 55±11.2 นาที, p <0.01) แต่ไม่มีความแตกต่างกันในแง่ของคะแนนความเจ็บปวดหลังผ่าตัด (เฉลี่ย ± ค่าเบี่ยงเบน 3.7±1.6 เทียบกับ 4.1±1.4, p =0.54) การใช้ยาระงับความเจ็บปวดชนิดโอพิเอทในวันแรก (ร้อยละ 30 เทียบกับร้อยละ 45, p =0.66), จำนวนวันนอนโรงพยาบาล (เฉลี่ย ± ค่าเบี่ยงเบน 2.1±0.3 เทียบกับ 2.2±0.6 วัน, p =0.70) ภาวะแทรกซ้อนหลังผ่าตัด (ร้อยละ 10 เทียบกับ ร้อยละ 18.2, p =1.00) โดยไม่พบว่ามีการเปลี่ยนวิธีการผ่าตัดเลยทั้งสองกลุ่ม

สรุปผลการศึกษา การผ่าตัดถุงน้ำดีผ่านกล้องแบบแผลผ่าตัดเดียว เป็นการผ่าตัดที่ปลอดภัยโดยมีผลเด่นในเรื่องความสวยงามของแผลผ่าตัด **เชียงใหม่เวชสาร 2557;53(2):81-87.**

คำสำคัญ: การผ่าตัดถุงน้ำดีผ่านกล้องแบบแผลผ่าตัดเดียว การผ่าตัดถุงน้ำดีผ่านกล้องแบบดั้งเดิม คะแนนความสวยงามแผลผ่าตัด คะแนนความเจ็บปวด ภาวะแทรกซ้อนหลังผ่าตัด ระยะเวลาการผ่าตัด