



## การศึกษาเปรียบเทียบการผ่าตัดถุงน้ำดีแบบส่องกล้องระหว่าง การผ่าตัดแบบสองแผลกับแบบแผลเดียวในโรคถุงน้ำดีชนิดไม่ร้ายแรง

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### Comparative Study of Operative Outcomes between Two and Single Incision Laparoscopic Cholecystectomy in Benign Gallbladder Diseases

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#### บทคัดย่อ

**หลักการและวัตถุประสงค์:** จากการศึกษาที่ผ่านมาเรื่องการผ่าตัดถุงน้ำดีแบบส่องกล้องโดยลดจำนวนบาดแผลลง (reduced port laparoscopic cholecystectomy) ได้แก่ การผ่าตัดแบบ 2 แผล (two-incision laparoscopic cholecystectomy: TILC) และแบบแผลเดียว (single-incision laparoscopic cholecystectomy: SILC) พบว่า TILC ใช้ระยะเวลาในการผ่าตัดน้อยกว่า SILC ขณะที่การเสียเลือดจากการผ่าตัด ความเจ็บปวดที่ 24 ชั่วโมงหลังการผ่าตัด ระยะเวลาพักรักษาในโรงพยาบาลและค่าใช้จ่ายในการรักษาใกล้เคียงกัน การวิจัยนี้จึงมีวัตถุประสงค์เพื่อจะศึกษาต่อเนื่องโดยการเปรียบเทียบวิธีการผ่าตัดทั้ง 2 วิธี เพื่อให้สามารถระบุได้อย่างชัดเจนในทางสถิติเกี่ยวกับความแตกต่างของวิธีการผ่าตัด

**วิธีการศึกษา:** เป็นการศึกษาเชิงทดลองทางคลินิกแบบสุ่ม (randomized clinical trial) ในผู้ป่วยโรคถุงน้ำดีชนิดไม่ร้ายแรง (benign gallbladder disease) และเข้ารับการผ่าตัดแบบ reduced port LC โดยใช้ conventional instrument และ handmade glove port ณ โรงพยาบาลมหาสารคาม ตั้งแต่วันที่ 1 มิถุนายน พ.ศ. 2564 ถึงวันที่ 31 พฤษภาคม พ.ศ. 2565 แบ่งผู้ป่วยออกเป็น 2 กลุ่ม ได้แก่ TILC และ SILC

**ผลการศึกษา:** ผู้ป่วยจำนวน 80 ราย แบ่งเป็น 2 กลุ่ม (TILC: SILC) กลุ่มละ 40 ราย ส่วนใหญ่เป็นเพศหญิง (ร้อยละ 57.5 : 75.0) พบว่าอายุเฉลี่ย (53.48 : 57.03 ปี  $p=0.176$ ) ดัชนีมวลกายเฉลี่ย (24.14 : 24.08 กก./ม<sup>2</sup>  $p=0.95$ ) ระยะเวลาอนพักรักษาในโรงพยาบาล (2.05 : 2.13 วัน  $p=0.306$ ) ค่าใช้จ่ายในการรักษา (25,883.81 : 26,196.04 บาท  $p=0.611$ ) ค่าคะแนนความพึงพอใจต่อความสวยงามของบาดแผล (9.2:9.15  $p=0.805$ ) และระยะเวลาที่สามารถกลับไปประกอบกิจวัตรได้ตามปกติ (5.2 : 5.08 วัน  $p=0.73$ ) ไม่แตกต่างกันอย่างมีนัยสำคัญ ในขณะที่ระยะเวลาการผ่าตัด (31.15 : 47.08 นาที  $p=0.000$ ) ปริมาณการเสียเลือดจากการผ่าตัด (6.13 : 8.98 มล.  $p=0.003$ ) และค่าคะแนนความเจ็บปวดที่เวลา 24 ชั่วโมงหลังผ่าตัด (1.53 : 2.15  $p=0.025$ ) มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ

**สรุป:** TILC มีความเหมาะสมและมีประสิทธิภาพมากกว่า SILC เป็นตัวเลือกที่ดีกว่าสำหรับการผ่าตัด reduced port LC โดยใช้ conventional instrument

**คำสำคัญ:** การผ่าตัดถุงน้ำดีแบบส่องกล้องสองบาดแผล, การผ่าตัดถุงน้ำดีแบบส่องกล้องแผลเดียว

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## Abstract

**Background and Objective:** Building on previous studies on reduced port laparoscopic cholecystectomy, single-incision laparoscopic cholecystectomy (SILC) and two-incision laparoscopic cholecystectomy (TILC), it was observed that TILC resulted in a shorter operative time compared to SILC whereas similar levels of operative blood loss, post-operative pain score at 24 hours, length of hospital stay and treatment cost. To further investigate these findings and establish clear statistical differences, This research aimed to continue the study by comparing two types of reduced port LC.

**Method:** A parallel randomized clinical trial was conducted at Mahasarakham hospital between June 1, 2021 and May 31, 2022. Eighty patients with benign gallbladder disease who underwent reduced port LC using conventional instruments and handmade glove port, were divided into TILC and SILC group equally.

**Results:** The majority of patients were female (57.55 : 75.0 %). There were no statistically significant differences of age (53.48 : 57.03 years  $p=0.176$ ), body mass index (24.14 : 24.08  $\text{Kg/m}^2$   $p=0.95$ ), length of hospital stay (2.05 : 2.13 days  $p=0.306$ ), cost (25,883.81 : 26,196.04 Bahts  $p=0.611$ ), cosmetic satisfaction score (9.2 : 9.15  $p=0.805$ ) and time to return to normal activity (5.2 : 5.08 days  $p=0.73$ ), on the other hand operative time (31.15 : 47.08 minutes  $p=0.000$ ), estimated blood loss (6.13 : 8.98 ml  $p=0.003$ ) and post-operative pain score at 24 hours (1.53 : 2.15  $p=0.025$ ) were significantly differences.

**Conclusion:** TILC was more applicability and efficacy than SILC, be a preferred choice for reduced port LC using conventional instruments.

**Keyword:** two-incisions laparoscopic cholecystectomy, single-incision laparoscopic cholecystectomy

## Introduction

Benign gallbladder disease is a commonly found disease in the community. Laparoscopic cholecystectomy (LC) stands as the gold standard treatment<sup>1</sup>. LC has undergone various advancements, evolving from the original standard 4 port LC to micro-LC, reduced port LC, single port LC, robotic cholecystectomy and natural orifice transluminal endoscopic cholecystectomy<sup>2</sup>. Currently, it is accepted that reduced port LC is superior to multiport, offering less operative pain, shorter recovery time and better cosmetic outcomes<sup>3-5</sup>.

From the previous studies on reduced port LC, single incision laparoscopic cholecystectomy (SILC)<sup>6</sup> and two incision laparoscopic cholecystectomy (TILC)<sup>7</sup>, findings revealed shorter operative time in TILC with comparable operative blood loss, post-operative pain score at 24 hours, length of hospital stay and treatment cost. This research aimed to continue the study by comparing two types of reduced port LC, to further investigate these findings and provide clear statistical differences.

## Materials and Methods

A parallel randomized clinical trial was conducted at Mahasarakham hospital between June 1, 2021 and May 31, 2022. The study analyzed data from patients with benign gallbladder disease including gallstone, gallbladder sludge and gallbladder polyp, underwent reduced port LC using conventional instruments and a handmade glove port. Sample size was calculated by G\*power computer program<sup>8</sup>, with a large effect size of 0.80, an alpha value of 0.05 and a power of test (1-beta) set at 0.97, number of groups were two, resulted in a total sample size of 80 patients evenly divided into 2 groups, 40 in Group 1 (TILC) and 40 in group 2 (SILC). Each patient picked up a card by self and was randomly assigned to a group.

The study collected data on various parameters, including sex, age (years old), body weight (Kg), height (cm), body mass index (Kg/m<sup>2</sup>), operative time (minutes), estimated blood loss (ml), length of hospital stay (days), post-operative pain at 24 hours assessed by a visual analogue scale (0 to 10 points, where 0 means no pain and 10 means the most

painful), treatment cost (bahts), complication during peri-operation and 4-week post-operation, cosmetic satisfaction score assessed by the patient at 4-week post-operation (on a scale of 0 to 10, where 0 means the least satisfied and 10 means the most satisfied), and time taken to return to normal activity (days).

The inclusion criteria encompassed patients diagnosed with benign gallbladder disease through ultrasonography, with no contraindications for laparoscopic surgery (including coagulopathy, decompensated liver cirrhosis, severe COPD and congestive heart failure) and an ASA class (American Society of Anesthesiology) rating not exceeding 3. The exclusion criteria comprised patients with acute cholecystitis, acute cholangitis, bile-duct stone, gallbladder tumor, and those who underwent converted open cholecystectomy.

Before surgery, all patients received intravenous antibiotic prophylaxis. During general anesthesia, patients were positioned supine with both upper limbs abducted. The surgeon stood on the left side of patients, while the assistant (camera) stood on the left side of patient and slightly oblique at the left of surgeon. For TILC group, the infraumbilical incision was made, 2 cm in length, for glove port insertion and the epigastrium incision, 1 cm in length, for an additional trocar (figure 1, 2). The incision of SILC group was made only at the infraumbilicus, 2.5 cm in length, for glove port insertion (figure 3, 4). Conventional instruments were used and gallbladder was removed through the infraumbilical wound. All patients were operated by the author.

The data were analyzed by SPSS version 27 software and reported in terms of percentage, range, mean and standard deviation. Nominal variables between two groups were compared using the Chi-square test, while differences in normally distributed continuous variables were compared using the Independent t-test and asymmetrically distributed continuous variables were compared using the Mann-Whitney U test. A p-value less than 0.05 was considered statistically significant difference. The study received approval from the research ethical committee of Mahasarakham hospital, No. MSKH\_REC 64-01-014.

## Results

**Patient characteristics** A total 80 patients were divided into two groups, each consisting of 40 patients. In the TILC group, there were 23 female patients (57.5%) and the male-female ratio was 1:1.35. The age range was from 30 to 73 years old, with a mean of  $53.48 \pm 12.13$  years. Most of patients (32.5%) were between 50-60 years old (13 patients). Of the patients, 32 had symptomatic gallstone, 5 had gallbladder sludge and 3 had gallbladder polyp. Comorbidities in this group included diabetes mellitus (8 patients), hypertension (13 patients) and dyslipidemia (2 patients). The mean body weight was  $60.75 \pm 14.63$  Kg, height was  $158.2 \pm 7.49$  cm and BMI was  $24.14 \pm 4.77$  Kg/m<sup>2</sup>. In the SILC group, there were 30 female (75%) and the male-female ratio was 1:3. The age range was from 22 to 78 years old, with a mean of  $57.03 \pm 11.08$  years. Most patients (45%) were between 50-60 years old (18 patients). Thirty-five patients had symptomatic gallstone, 4 had gallbladder sludge and 1 had gallbladder polyp. Comorbidities included diabetes mellitus (6 patients), hypertension (5 patients) and dyslipidemia (6 patients). The mean body weight was  $61.1 \pm 19.26$  Kg, height was  $156.5 \pm 7.32$  cm and BMI was  $24.08 \pm 3.86$  Kg/m<sup>2</sup>. No statistically significant differences in age, body weight, height and BMI between the two groups (Table 1). Three patients were excluded from the study, one from the TILC group and two from the SILC group. These exclusions were necessary due to the need for converting to open cholecystectomy caused by dense adhesions around Calot's triangle, making laparoscopic dissection challenging.

**Operative results** In the TILC group, the operative time ranged from 15 to 45 minutes, with a mean of  $31.15 \pm 7.48$  minutes. The mean estimated blood loss was  $6.13 \pm 3.2$  ml. The mean length of hospital stay was  $2.05 \pm 0.32$  days. The mean post-operative pain at 24 hours was  $1.53 \pm 1.18$ . The mean treatment cost was  $25,883.81 \pm 3,152.61$  Bahts. The mean cosmetic satisfaction score was  $9.2 \pm 0.76$  and the mean time to return to normal activity was  $5.2 \pm 1.45$  days. There were no complications during peri-operative and post-operative 4-week period. In the SILC group, the operative time ranged from 25 to 70 minutes, with a mean of  $47.08 \pm 9.96$  minutes. The mean estimated blood loss was  $8.98 \pm 4.96$  ml.

The mean length of hospital stay was  $2.13 \pm 0.34$  days. The mean post-operative pain score at 24 hours was  $2.15 \pm 1.27$ . The mean treatment cost was  $26,196.04 \pm 2,247.79$  Bahts. The mean cosmetic satisfaction score was  $9.15 \pm 1.03$  and the mean time to return to normal activity was  $5.08 \pm 1.76$  days. One patient had bile leakage from the gallbladder bed at peri-operative period that treated by placing a drain. The majority of patients were discharged within 24 hours post-operation in both groups. Statistical analysis revealed significant differences in operative time, estimated blood loss and post-operative pain at 24 hours between the two groups (Table 2).



Figure 1 Glove port for TILC group



Figure 2 Glove port and additional trocar installations in TILC group





Figure 3 Glove port for SILC group



Figure 4 Glove port installation in SILC group

Table 1 Patient characteristics

	TILC (n=40) n (%)	SILC (n=40) n (%)	p-value
<b>Sex</b>			
Male	17 (42.5)	10 (25)	
Female	23 (57.5)	30 (75)	
Age (years old)	53.48 ± 12.13	57.03 ± 11.08	0.176
Body weight (kg)	60.75 ± 14.63	61.1 ± 19.26	0.927
Height (cm)	158.2 ± 7.49	156.5 ± 7.32	0.308
Body mass index (kg/m <sup>2</sup> )	24.14 ± 4.77	24.08 ± 3.86	0.950
<b>Disease</b>			
Symptomatic gallstone	32 (80.0)	35 (87.5)	
Gallbladder sludge	5 (12.5.0)	4 (10.0)	
Gallbladder polyp	3 (7.5.0)	1 (2.5)	

Table 2 Operative results

	TILC (n=40)	SILC (n=40)	Mean difference	95% CI	p-value
Operative time (min)	31.15 ± 7.48	47.08 ± 9.96	-15.93±1.97	-19.84- -12.01	0.000 *
Estimated blood loss (ml)	6.13 ± 3.2	8.98 ± 4.96	-2.85±0.93	-4.71- -0.99	0.003 *
Length of hospital stay (days)	2.05 ± 0.32	2.13 ± 0.34	-0.75±0.07	-0.22-0.07	0.306
Post-operative pain at 24 hr	1.53 ± 1.18	2.15 ± 1.27	-0.63±0.27	-1.17- -0.8	0.025 *
Cost (bahts)	25,883.81 ± 3,152.61	26,196.04 ± 2,247.79	-312.23±612.2	-1531.03-906.56	0.611
Cosmetic satisfaction score	9.2 ± 0.76	9.15 ± 1.03	0.05±0.2	-0.35-0.45	0.805
Time return to normal activity (days)	5.2 ± 1.45	5.08 ± 1.76	0.13±0.36	-0.59-0.84	0.73

\* = statistical significant

## Discussion

Reduced port LC is an advanced technique in laparoscopic cholecystectomy, reducing incision numbers from the original 4-port standard to 3-port, 2-port (TILC), and single port (SILC). The objective is to enhance convenience, efficacy, and outcomes. However, SILC presents challenges due to its single incision, causing instruments to align in a narrow angle. This alignment complicates Calot's triangle dissection, making it difficult to achieve a clear critical view of safety. Consequently, SILC demands higher surgical skills compared to other reduced port techniques, particularly with conventional instruments that unable to self-adjusting angulation.<sup>9-11</sup>

In this study, the majority of the population consisted of middle-aged, overweight females, in line with disease epidemiology and previous researches.<sup>5-7, 10-15</sup> The operative time for TILC was significantly shorter than SILC, a finding consistent with studies by Chuang<sup>5</sup>, Justo-Janeiro et al<sup>12</sup> and Khan et al<sup>16</sup>. The additional epigastric port in TILC facilitated proper instrumental angulation and smooth dissection of Calot's triangle led to less operative time, less operative blood loss and less operative pain. Chuang proposed using TILC as an initial step in reduced port LC training before advancing to SILC training.<sup>5</sup>

The difficulty and time-consuming nature of Calot's triangle dissection in SILC resulted in increased operative blood loss and tissue trauma, leading to significant post-operative pain. However, these effects were short-term, as they did not impact the length of hospital stay or the time required to return to normal activity.

The majority of patients in both groups were discharged within 24 hours post-operation, consistent with findings from studies by Abaid et al<sup>9</sup>, Justo-Janeiro et al<sup>12</sup>, Leow et al<sup>13</sup> and Pariwattanasak<sup>15</sup>. These results suggest that reduced port LC could be established as a one-day surgery. In selected patients with good recovery and minimal pain, discharge within 12 hours post-operation could be considered.<sup>12,13</sup>

The cosmetic satisfaction score was a simple self-assessment of wound appearance. The study found no difference between the two groups, contrary to the finding in Xu et al study<sup>11</sup>. This result

could be attributed to the majority of patients being middle-aged and engaged in agricultural work, prioritizing the resolution of their medical condition and a quick return to normal work over cosmetic concerns. Additionally, TILC involved an additional small epigastric wound that did not significantly affect the overall cosmetic outcome.

The limitations of this study include a post-operative follow-up period only 4 weeks, which is insufficient to study long-term complications such as incisional hernia and chronic pain. Additionally, the assessment of post-operative pain lacked certain detailed aspects, including the specific location of pain and details about analgesic drug consumption (type and dose).

## Conclusion

TILC was superior applicability and efficacy over SILC led to reduced operative time, decreased operative blood loss and minimized post-operative pain, be a preferred choice for reduced port LC using conventional instruments.

## Suggestions

Further studies such as a multicenter comparative study for more widely research population between TILC and SILC, conversion rate analysis, a comparative study utilizing articulating or curved instruments, a comparison of three type reduced port LC (3 port vs TILC vs SILC), reduced port LC as a one day surgery etc.

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