

Comparative Study of Effectiveness of Single Incision Laparoscopic Cholecystectomy versus Conventional 3-Port Laparoscopic Cholecystectomy: A Prospective Randomized Controlled Trial

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Abstract

Background: The conventional 3-4 port laparoscopic cholecystectomy is the standard surgery. The single incision laparoscopic cholecystectomy had been developed to reduce pain for a better recovery and improve cosmesis of surgical wounds. However, previous study showed mixed results leading to ambiguous conclusion.

Objectives: To study and compare the effectiveness of short-term single incision laparoscopic cholecystectomy versus conventional 3-port laparoscopic cholecystectomy

Materials and Methods: One hundred and ninety eight patients, who had laparoscopic cholecystectomy from January 2012 to December 2014, were randomized to the single incision laparoscopic cholecystectomy (SILC) and the conventional 3-port laparoscopic cholecystectomy (CLC). The operative time, postoperative complication, postoperative pain, length of hospital stay, time to resume to work, and cosmesis outcome were compared between two groups.

Results: One hundred and ninety eight patients were divided into 99 patients each group. After processing, there were 92 patients in the SILC group and 94 patients in the CLC. Patients' characteristics including gender, age, body mass index, and ASA conditions showed no significant difference. Mean operative time for SILC was significantly longer than that of CLC (35 minutes vs. 30 minutes; $p < 0.01$). The length of hospital stay for both groups was similar (3 days; $p > 0.01$). The time back to work for SILC patients was 14 days and 10 days for the CLC which was not significantly different ($p > 0.01$). There was no postoperative complication in both groups. The mean of postoperative pain level after the surgery in the first 24 hours in SILC was significantly higher than CLC (2.53 ± 1.51 , 1.79 ± 0.98 respectively; $p < 0.01$). The cosmesis outcome of SILC was greater than CLC (23.19 ± 1.31 vs. 22.42 ± 1.45 ; $p < 0.01$).

Conclusion: The SILC had the same length of hospital stay and time to resume to work as the CLC, but took more operative time with more postoperative pain within the first 24 hours. However, the cosmesis outcome of the SILC was better than the CLC.

Keywords: Laparoscopic cholecystectomy, single incision laparoscopic cholecystectomy

INTRODUCTION

Cholecystectomy was frequently found and had been developed from open cholecystectomy to laparoscopic cholecystectomy since 1985 and had become the standard of cholecystectomy nowadays¹.

Although the laparoscopic cholecystectomy was standardized for effective and popular cholecystectomy, practically, it required several port replacements of the patient's body which caused many horrid wounds². So, single incision laparoscopic cholecystectomy (SILC)

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had been evolved to improve the cosmesis and fast recuperation which was first reported by Navarra in 1997³. SILC has been reported to have better cosmesis, less postoperative pain, reduced hospital stay and fast recovery⁴⁻⁶. However, some studies showed that SILC took more operation time and the cosmesis was not any better than conventional laparoscopic cholecystectomy (CLC)⁷. Due to conflicting results, the researcher aimed to study these two types of cholecystectomy to compare advantages and disadvantages which would be a benefit data in choosing the suitable incision method for patients.

RESEARCH METHODS

This research was the prospective randomized controlled trial. The operation was conducted by the only one surgeon. The study was proceeded among the patients who had cholecystectomy in the Detudom Royal Crown Prince Hospital during January 2012 and December 2014 analyzing sample by the method of Waraporn Suksuchano⁸. One hundred and ninety-eight participants were separated into 2 groups, 99 participants in each group. All of them had gallstones, aged between 15-85 years old, and were in healthy state for general anesthesia. The patients must not have acute cholecystitis, pregnancy, cirrhosis, right subcostal incision, ASA > 3 and BMI > 45. The participants would be randomly separated into group by casting lots. The patients' data were collected throughout the study period which were gender, age, ASA, operation time, postoperative complications, pain evaluated by VSA score, length of hospital stay, time to resume work, the cosmesis evaluated by cosmesis score which had 3 questions on the questionnaire and the score ranged from 3-24⁹⁻¹⁰. All participants would be given a description, consent form to sign, and ethic certificate in participation of the study from Ubon Ratchathani provincial public health office.

There were two types of incision

1. Single incision laparoscopic cholecystectomy (SILC)

Prepare the patients according to the standard of laparoscopic cholecystectomy operation. The incision would be cut open 2 cm at subumbilicus transversely and longitudinal cut when it reached the abdominal sheath. Put SILS (TM Port) into the wound and process

the pneumoperitoneum at the pressure level 12 cm H₂O. After completing the cholecystectomy, close the wound by subcuticular technique.

2. Conventional 3-port laparoscopic cholecystectomy (CLC)

When the patients were ready, the incision would be cut open at subumbilicus. Put 10 mm blunt trocar and process the open pneumoperitoneum at pressure level 12 cm H₂O. Then, put the laparoscope and put a 10 mm port at subxiphoid and a 5 mm port at right subcostal in midclavicular line. After completing the cholecystectomy, close the wound by subcuticular technique.

Both groups were given Ibuprofen (400) 1 × 3, Paracetamol (500) 2 tab prn for pain q 4 hr, MO 3 mg. iv. prn for pain q 6 hours after the surgery.

Statistical Analysis

The instrument used in this research was SPSS (Statistical Package for the Social Sciences). Descriptive statistic, frequency, percentage, mean, standard deviation, median, and range were used to analyze the data. Analytic statistic by T-test independent, One-way ANOVA, chi square test and Fisher's exact test were used to compare the result of the treatments.

RESULTS

There were 198 patients who underwent laparoscopic cholecystectomy at Detudom Royal Crown Prince Hospital from January 2012 to December 2014. There were 12 patients found disqualified after the random check. In SILC patient group, there were 7 patients culled out, 3 patients who successfully underwent the conventional 3-port laparoscopic cholecystectomy, 2 patient who underwent open cholecystectomy, and 2 patients who lost contact after surgery. In CLC patient group, there were 5 patients culled out; 2 patients who underwent open cholecystectomy and 3 patients lost contact. Finally, there were 186 patients participated. Most of them were female 78.49% and 33.33% aged 41-50. The average Body Mass Index (BMI) was 24.41 (SE = 0.29) (kg / M²) and the most patients' condition according to ASA standard was at level 2, 54.31%. According to the normal distribution data randomized from the populations of both groups, it is found that gender, age group, body mass index, and body fitness (ASA)

Tablet 1 Amount Percentage Mean and Median of personal information of sample groups categorized by the type of incision

Personal Information	Total (186 patients)	SILC group (92 patients)	CLC (94 patients)	p-value
Gender (%)				0.939*
- Male	40 (21.51)	20 (50.00)	20 (50.00)	
- Female	146 (78.49)	72 (49.32)	74 (50.68)	
Age (%)				0.510***
- 21-30 years	6 (3.23)	4 (66.67)	2 (33.33)	
- 31-40 years	25 (13.44)	15 (60.00)	10 (40.00)	
- 41-50 years	62 (33.33)	28 (45.16)	34 (54.84)	
- 51-60 years	53 (28.49)	28 (52.83)	25 (47.17)	
- Over 60 years	40 (21.51)	17 (42.50)	23 (57.50)	
BMI (Kg/M ²)				0.536**
- Mean(SE)	24.41 (0.29)	24.23 (0.40)	24.59 (0.41)	
- Median (range)	24.24 (14.57-36.22)	24.23 (16.98-36.22)	24.59 (14.57-35.16)	
ASA (%)				0.079*
1	85 (45.69)	48 (56.47)	37 (43.53)	
2	101 (54.31)	44 (43.56)	57 (56.44)	

* Chi-Square test, **independent T-test*** Fisher's Exact test

Table 2 Amount Percentage Mean Median Range and Standard Deviation of the operation result categorized by the operation methods

General Information	Total (186 patients)	Group of patient (SILC) (92 patients)	Group of patient (CLC) (94 patients)	p-value
Operation time (minute)				0.000**
Mean(SD)	36.40 (11.47)	40.29 (12.48)	32.59 (8.94)	
Median (rang)	35.00 (15-75)	35.00 (20-75)	30.00 (15-75)	
Postoperative complication (%)	0 (0.00)	0 (0.00)	0 (0.00)	
Length of hospital stay (hour)				0.071**
Mean(SD)	76.84 (14.90)	8.84 (12.73)	74.89 (16.60)	
Median (rang)	75 (1-149)	75 (64-149)	74 (1-145)	
Time to resume to work (day)				0.164**
Mean (SD)	12.79 (5.03)	13.32 (4.78)	12.29 (5.25)	
Median (rang)	14 (1-30)	14 (5-30)	10 (1-30)	

**independent T-test

were not significantly different ($p > 0.01$) (Table1).

There were 186 patients who underwent laparoscopic cholecystectomy; 92 SILC patients and 94 CLC patients. The approximate operation time was 35 minutes (Mean = 36.40, SD = 11.47). The SILC took 35 minutes (Mean = 40.29, SD = 12.48) and the CLC took 30 minutes (Mean = 32.59, SD = 8.94). The result from the comparison of these two groups showed that the SILC took more operation time than the CLC significantly ($p < 0.01$). The average hospitalized period was 3 days (Mean = 76.84, SD = 14.90 hours). The average hospitalized period for SILC patients was 3

days (Mean = 78.84, SD = 12.73 hours) and 3 days for CLC patients (Mean = 74.89, SD = 16.60 patients). The comparative results showed that these 2 methods were not different significantly ($p > 0.01$). Most of the patients could go back to work within 14 days (Mean = 12.79, SD = 5.03, Med = 14 days, Min = 1 day and Max = 30 days). The SILC patients could go back to work within 14 days (Mean = 13.32, SD = 4.78, Med = 14 days, Min = 5 days and Max = 30 days) and CLC patients could go back to work within 10 days (Mean = 12.29, SD = 5.25, Med = 10 days, Min = 1 day and Max = 30 days). They were not significantly different ($p > 0.01$) (Table 2).

Table 3 The intense of pain after the operation at the 12th, the 24th, and the 48th hours on the 14th and the 30th days

The time after the surgery	Total (186 patients)		Group of patient (SILC) (92 patients)		Group of patient (CLC) (94 patients)		p-value
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	
The 12 th hour	3.328 (1.52)	3 (0-8)	3.61 (1.62)	3 (0-8)	2.97 (1.34)	3 (0-8)	0.004*
The 24 th hour	2.16 (1.32)	2 (0-8)	2.53 (1.51)	2 (0-8)	1.79 (0.98)	2 (0-4)	0.000*
The 48 th hour	1.05 (1.25)	1 (0-8)	1.28 (1.46)	1 (0-8)	0.83 (0.97)	1 (0-5)	0.013*
The 14 th day	0.76 (1.20)	0 (0-6)	0.96 (1.44)	0 (0-6)	0.57 (0.89)	0 (0-4)	0.031*
The 30 th day	0.29 (0.65)	0 (0-4)	0.35 (0.76)	0 (0-4)	0.23 (0.52)	0 (0-2)	0.234*

*independent T-test

Table 4 The score of the cosmesis on the 12th hour, on the 14th and 30th days

The time after the surgery	Total (186 patients)		Group of patient (SILC) (92 patients)		Group of patient (CLC) (94 patients)		p-value
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	
The 2 nd day	20.49 (2.24)	20 (14-24)	20.62 (2.34)	20 (14-24)	20.36 (2.14)	20 (14-24)	0.425**
The 14 th day	22.07 (2.15)	23 (14-24)	22.05 (2.14)	23 (14-24)	22.08 (2.18)	22.50 (14-24)	0.923**
The 30 th day	22.80 (1.43)	23 (17-24)	23.19 (1.31)	24 (19-24)	22.42 (1.45)	23 (17-24)	0.000**

**independent T-test

The postoperative pain was observed on the 12th, the 24th, and the 48th hours on the 14th and the 30th days. On the 12th hours after the operation, it was found that the majority of patients in both groups had the level 3 pain. The SILC patients had the average pain level higher than the CLC patients at the 12th and the 24th hours significantly ($p < 0.01$). After the 48th hour, the intense of the pain would be reduced to level 0 in both SILP and CLC groups. The study found that the average level of pain was not different significantly after the 48 hours ($p > 0.01$) as shown in Table 3.

The cosmesis scores on the 2nd, the 14th, and the 30th days were compared. It is found that the score had a positive tendency; from 20 points on the 2nd day to 23 points on the 30th day. The SILC patients had a better score than the CLC patients significantly ($p < 0.01$) on the 30th day, and the difference was approximately 0.77

points which was 3.43% as shown in Table 4.

DISCUSSIONS

Laparoscopic cholecystectomy had been initiated in 1992 and had been standardized for the cholecystectomy. Then, there is the attempt to reduce the surgical wounds and ports for the cosmesis such as transvaginal laparoscopic cholecystectomy¹¹, and single incision umbilical laparoscopic cholecystectomy. Some study showed the possibility of its best suit for abdominal surgery¹².

This study found that the difference on the operation time of the SILC was greater than the CLC significantly. It was corresponding to the study of Jie Hua¹, et al.¹³ which studied on the systematic review and meta-analysis. The postoperative pain after the

SILC was greater than the CLC significantly at the 12th and the 24th hours after the surgery. The pain would be reducing to the 30th day after surgery which was not different significantly. It also conformed to the study of Ostlie DJ, et al.¹⁴ which found that the SILC left more pain than the CLC and was different significantly. The study of Phillips MS, et al.¹⁵ found that the SILC gave more pain than the CLC but did not have significant difference. Nonetheless, the study of Markar SR, et al.¹⁶ found that the pain after surgery of both methods was not significantly different. And the study of Ramon V, et al.¹⁷ found that the ILC left less pain than the CLC and the difference was significant. For the time to resume to work, the CLC patients was found to have less time to resume to work that allowed the patients to go back to work faster than the SILC patients but did not have the significant difference. The study of Bucher P, et al.¹⁸ found that the SILC patients had better recuperate period than the CLC patients significantly.

The study found that the length of hospital stay was not significantly different as the patients would be admitted to the hospital one day prior to surgery and two days after surgery or until the patients felt comfortable to go home. It was corresponding to the study of Yoen TK van der Linden, et al.¹⁹ which found that the hospitalized period of the two groups were not significantly different. The study of Brittney L, et al.²⁰ found that the SILC allowed less length of hospital stay than the CLC but could not find the significant difference. There were many factors which affected the hospitalized period and caused the difference in the result of each study such as the patients' privilege, family status, employment and duty, and life insurance²¹.

This study reported no complications of the surgery in short-term. The study of Markar SR, et al.²² found that the SILC and the CLC shared the same significant result, no complications. The factor which caused this result might be the fact that the surgeon would change the operation if there was adhesion at Calot's triangle of gallbladder or the difficulty during surgery as it might lead to the bile duct injury. The long-term complications; such as Hernia. The long-term follow up with patients was not conducted so it is left unknown.

The study found that the cosmesis of the SILC was greater than the CLC after 30 days which was different

significantly. The results from several researches also showed that the cosmesis in SILC was better than the CLC as the SILC would have a cut near the umbilicus which aided in wound recovery²³⁻²⁴.

CONCLUSION

This study found that the SILC took more operation time than the CLC and the postoperative pain was tenser in the first 24 hours. There was no difference in length of hospital stay, time to resume to work, and short-term complication. It is also found that the cosmesis of the SILC was better than the CLC. The restriction of this study was the study of the long-term complication in the patients such as incisional hernia.

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บทคัดย่อ การศึกษาเปรียบเทียบประสิทธิผลของการผ่าตัดนิ่วในถุงน้ำดีด้วยวิธีการผ่าตัดแบบแผลเดียว (Single incision laparoscopic cholecystectomy) และแบบ 3 แผล (Conventional 3-port laparoscopic cholecystectomy) การทดลองทางคลินิกประเภทติดตามผลไปข้างหน้า

นพ.วิมลพงษ์ พรหมน้อย

โรงพยาบาลสมเด็จพระยุพราชเดชอุดม จังหวัดอุบลราชธานี

จุดประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิผลของการผ่าตัดนิ่วในถุงน้ำดีด้วยการส่องกล้องวิดิทัศน์แบบแผลเดียว กับแบบ 3 แผลในระยะสั้น

ความเป็นมา: การผ่าตัดนิ่วในถุงน้ำดีด้วยการส่องกล้องวิดิทัศน์แบบ 3-4 แผล เป็นมาตรฐานของการผ่าตัด มีการคิดวิธีการผ่าตัดแบบแผลเดียวเพื่อเพิ่มลดความเจ็บปวดของแผลผ่าตัดทำให้กลับไปทำงานได้เร็วขึ้น และเพื่อความสะดวกของแผลผ่าตัด แต่ยังขาดข้อมูลการศึกษาที่ชัดเจน

วิธีการศึกษา: ผู้ป่วยเข้ารับการศึกษาก่อนการผ่าตัดนิ่วในถุงน้ำดีตั้งแต่ มกราคม 2555 - ธันวาคม 2557 มีจำนวนทั้งสิ้น 198 ราย ทำการสุ่มการผ่าตัดแบบแผลเดียวและแบบ 3 แผล และทำการศึกษาเปรียบเทียบระยะเวลาการผ่าตัด ภาวะแทรกซ้อน การปวดแผล ระยะเวลาการนอนโรงพยาบาล การกลับไปทำงานและความงามของแผลผ่าตัด

ผลการศึกษา: ผู้ป่วยเข้ารวมการศึกษาทั้งหมด 198 ราย แบ่งผู้ป่วยเป็นกลุ่มละ 99 ราย หลังจากคัดแยกผู้ป่วยออกเหลือผู้ป่วยกลุ่มผ่าตัดแบบแผลเดียว 92 ราย และแบบ 3 แผล 94 ราย พบว่าผู้ป่วยทั้ง 2 กลุ่ม มีเพศ อายุ ดัชนีมวลกาย และสถานะของผู้ป่วยตาม ASA ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ระยะเวลาของการผ่าตัดแบบแผลเดียวส่วนใหญ่ใช้เวลา 35 นาที แบบ 3 แผล ใช้เวลาผ่าตัด 30 นาที ซึ่งแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p < 0.01$) ระยะเวลาการนอนโรงพยาบาลส่วนใหญ่ทั้ง 2 กลุ่ม นอน 3 วัน ซึ่งไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p > 0.01$) ผู้ป่วยผ่าตัดแบบแผลเดียวกลับไปทำงาน 14 วัน ผู้ป่วยผ่าตัดแบบ 3 แผล กลับไปทำงาน 10 วัน ซึ่งไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($p > 0.01$) ไม่พบภาวะแทรกซ้อนของการผ่าตัดทั้ง 2 กลุ่ม อาการปวดแผลหลังผ่าตัดภายใน 24 ชม. แรก พบว่าการผ่าตัดแบบแผลเดียวมีค่าเฉลี่ยของระดับการปวดแผลผ่าตัดมากกว่าแบบ 3 แผล (2.53 ± 1.51 , 1.79 ± 0.98 ตามลำดับ) อย่างมีนัยสำคัญทางสถิติ ($p < 0.01$) ส่วนความงามของแผลผ่าตัด พบว่าหลังจาก 30 วัน ผู้ป่วยผ่าตัดแบบแผลเดียวมีความงามของแผลผ่าตัดมากกว่าแบบ 3 แผล (23.19 ± 1.31 , 22.42 ± 1.45 ตามลำดับ) อย่างมีนัยสำคัญทางสถิติ ($p < 0.01$)

สรุป: การผ่าตัดนิ่วในถุงน้ำดีแบบแผลเดียวมีระยะเวลาการนอนโรงพยาบาลและการกลับไปทำงานได้ไม่แตกต่างกับการผ่าตัดแบบ 3 แผล แต่ใช้เวลาในการผ่าตัดมากกว่าและปวดแผลมากกว่าใน 24 ชม. แรก อย่างไรก็ตามความงามของแผลผ่าตัดพบว่าการผ่าตัดแบบแผลเดียวมีมากกว่าแบบ 3 แผล