The Predictive Factors Associated with Longer Operative Time in Single-Incision Laparoscopic Cholecystectomy

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ABSTRACT

Objective: The difficult laparoscopic cholecystectomy (LC) is defined as the presence of one of the following conditions including prolonged operative time, conversion to open cholecystectomy or significant blood loss. At present, there is no evidence of predictive factors related to longer operative time in single-incision laparoscopic cholecystectomy (SILC). The aim of this study is to determine predictive factors associated with longer operative time in SILC procedure.

Materials and Methods: A retrospective study was conducted of patients with benign gallbladder disease who underwent SILC in Thammasat University Hospital between October 2014 and December 2020. Patients' records were reviewed. Primary outcomes were preoperative predictive factors associated with DSLC. Secondary outcomes were perioperative and 3-month postoperative adverse outcomes.

Results: 592 SILC procedures were categorized as 80 DSLC and 512 non-difficult SILC (NDSLC). The median (interquartile range) of operative time in all SILC procedure is 48 (38, 62) minutes. The threshold of operative time of difficult SILC was 72 minutes. The multivariate analysis indicated 5 significant predictive factors. Obesity (body mass index > 25 kg/m^2)) and abdominal pain reflected the difficulty of SILC procedures ($p = 0.041$ and $p = 0.009$). Calcified gallbladder showed the highest RR of 14.08 ($p = 0.011$). Contracted gallbladder and chronic cholecystitis were also predictive factors with RR of 13.79 and 3.64, respectively ($p < 0.001$ and $p = 0.007$).

Conclusion: Obesity, abdominal pain, chronic cholecystitis, contracted gallbladder and calcified gallbladder were preoperative predictive factors. Surgeons should perform the SILC procedure carefully when predictive factors are identified.

Keywords: Laparoscopic cholecystectomy; single-incision laparoscopic cholecystectomy; predictive factors; difficult laparoscopic cholecystectomy (Siriraj Med J 2021; 73: 672-679)

INTRODUCTION

Laparoscopic cholecystectomy (LC) can reduce pain and surgical scar after surgery.[1] Single incision laparoscopic cholecystectomy (SILC) is the LC procedure that has the least number of incisions. It was reported for the first time by Navara et al.[2] without difference in the overall rate of complications, including biliary tract injury, bile leakage and wound infection, when compared with conventional LC. The cosmetic result of SILC was superior to that of conventional LC.[3] However, some reports revealed that SILC had a higher incidence of incisional hernia than conventional LC.[4,5] The SILC

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procedure may not be familiar to the surgeon which may take longer operative time and higher perioperative complication rates than conventional LC.[6]

There were a lot of predictive factors of difficult LC in conventional LC procedure.[6-12] However, there was no report about predictive factors of difficult SILC, which may be different from conventional LC due to a different step of the procedure, surgeon's skill and familiarity. The definition of difficult LC is varied by operative time, bile duct injury, vascular injury, open conversion. The operative time is the important determinant to categorized the difficulty of LC procedure.[6,8,11]

The aim of our study was to investigate predictive factors affecting the difficulty of SILC. The predictive factors included baseline characteristic and demographic data, clinical presentation, and preoperative ultrasound finding.[6-20] The predictive factors are beneficial to caution surgeons, especially those in residency training, and to determine the patient's prognosis before SILC surgery.[21]

MATERIALS AND METHODS

Study design and participants

Retrospective data of patients who underwent SILC in Thammasat University Hospital between October 2014 and December 2020 were reviewed. The inclusion criteria were patients who had indications for cholecystectomy, including: (1) symptomatic gallstone, (2) acute cholecystitis, (3) chronic cholecystitis, (4) gallbladder polyp size more than 1 centimeters or increasing size during imaging surveillance,[22] (5) calcified gallbladder,[23] and (6) biliary dyskinesia.[24] The exclusion criteria included: (1) the patients with malignant gallbladder or suspected gallbladder malignancy by preoperative presentation and imaging, (2) an LC procedure which required additional intraoperative procedures, including choledocholithotomy, choledochoscope or cholangiography and, (3) patients who failed to follow up in the 3 months after the SILC procedure. The patient's characteristics, clinical presentation, pre-operative ultrasound finding, and operative time were collected.

The criteria to categorize as difficult SILC procedure and outcomes

The difficult SILC is defined as the presence of one of the following conditions including prolonged operative duration, conversion from LC to open cholecystectomy or significant blood loss, biliovascular injury. The incidence of significant blood loss and biliovascular injury of our study is very low. So, the operative time which is the important determinant to categorize the difficulty of LC procedure were used in this study. SILC procedure was performed as a standard technique by a single surgeon who was highly experienced in the LC procedure (more than 1,000 cases of LC in 10 years). The operative time is the determinant to categorize the difficulty of LC procedure.[6,8,11,13] Difficult LC was identified for each surgeon when the operative time for a procedure exceeded 1.5 times the surgeon's individual base time. Patients were classified into two groups: non-difficult SILC (NDSLC) (operative time <1.5 times the surgeon's individual operative time) and difficult SILC (DSLC) (operative time ≥1.5 times the surgeon's individual operative time).[6]

The primary outcomes objectives were pre-operative predictive factors which included (1) baseline characteristic and demographic data, including old age, male gender, obesity by body mass index ((BMI (kilograms (kgs) per square meters (m^2) ≥ 25 kg/m^2, diabetes mellitus (DM), dyslipidemia (DLP) (2) the clinical presentation, including symptomatic gallstones, suspected acute cholecystitis (acute cholecystitis by clinical diagnosis at the same admission of SILC operation), history of acute cholecystitis (subside cholecystitis), common bile duct (CBD) stone, history of endoscopic retrograde cholangiopancreatography (ERCP), gallstone (GS) pancreatitis, GS cholangitis, acute cholecystitis and (3) preoperative ultrasound findings including thickening of gallbladder wall, definited acute cholecystitis, chronic cholecystitis, gangrenous cholecystitis, adenomyosis, gallbladder polyps, contracted gallbladder, calcified gallbladder, CBD dilatation. Symptomatic gallstones were included dyspepsia and abdominal pain at any time during follow-up before the SILC operation. The dyspepsia was a non-specific pain in the epigastrium area. The abdominal pain refers to dull aching in the upper part abdomen which specific to biliary colic without evidence of pancreatitis, cholangitis, or cholecystitis. The chronic cholecystitis from the ultrasound imaging was used the clinical correlation to establish the diagnosis of U/S. The SILC was performed via transumbilical incision. The Calot's triangle has been identified for the exposed cystic duct and artery to obtain a critical view of safety. After ligating of cystic duct and cystic artery by clip, the gallbladder was dissected from the liver bed and removed through Alexis® retractor. The pathologic studies were confirmed all of the ultrasonographic results reports. Intra-op complications including bile leakage and cystic artery injury were collected as secondary outcomes objectives

Post-operative care and follow-up

In postoperative care, patients were monitored for

postoperative complications. Most of the patients were discharged within 24 hours after surgery and followed up 2 weeks, 6 weeks, and 3 months postoperatively. The post-operative surgical complications, including infected wound surgical site infection (SSI) and incisional hernia were collected and analyzed to identify adverse outcomes associated with difficult SILC which depend on the operative time.[7]

Sample size calculation

The strong predictive factors for difficult SILC including BMI, history of acute cholecystitis and gallbladder wall thickening were used to calculated sample size. Retrospective data of predictors that affected the difficulty of SILC (measured by operative time) were used to calculate the power of the sample size under 0.05 alpha error and 0.02 beta error.[6,7,11,13,15-20] The power calculations were more than 80% at the total number of 592 procedure.[25]

Statistical analysis

The associations between baseline characteristic and demographic data, clinical presentation, and preoperative predictive factors were assessed and presented in percentage or mean with standard deviation (SD). Student's t-test was used for analysis of independent continuous variables and the χ^2 test for dependent categorized variables. The predictors of difficult SILC were tested using multivariate logistic regression. Relative risk (RR) and 95% confidence interval (CI) were reported. P <0.05 was considered significant. All the statistical analyses were performed with STATA/SE 15.1 for Mac (Stata Corp LP, TX, USA). The study process and report follow the strengthening the reporting of observational studies in epidemiology (STROBE) statement on reports of cohort studies.[26]

RESULTS

A total of 592 SILC procedures were included in this study. The mean operative time with SD was 53.44 ± 22.86 minutes. The distribution of operative time data was an asymmetric pattern. The median (interquartile range) of operative time in all SILC procedure is 48 (38, 62) minutes. So, the threshold of DSLC by operative time was 48 x 1.5 = 72 minutes.[6] 512 (86.5%) patients were classified as NDSLC and 80 (13.5%) patients were classified as DSLC.[6] None of the SILC procedures required conversion to open cholecystectomy.

Baseline characteristic and demographic data between NDSLC and DSLC are shown in Table 1. DSLC was more often associated with male gender. (p = 0.015). The DSLC group had higher BMI than the NDSLC group (27.74 ± 5.70 vs 25.31 ± 4.42, p < 0.001). The weight and height parameters were higher in the DSLC group when compared with the NDSLC group. The distribution of clinical presentation is given in Table 2.

Multivariate logistic regression analysis showed 5 significant predictive factors (Table 3). BMI and clinical presentation of abdominal pain were statistically significant predictive factors that influenced the difficulty of SILC procedures (95%CI 0.002 – 0.084, p = 0.041 and RR 2.35, 95%CI 1.236 – 4.466, p = 0.009, respectively). The preoperative ultrasound findings, which were significant predictive factors are presented in Table 3. Calcified gallbladder showed the highest RR of 14.08 (RR 14.08, 95%CI 1.822 – 108.771, p = 0.011). Contracted gallbladder and chronic cholecystitis were also predictive factors with RR of 13.79 and 3.64, respectively (RR = 13.79, 95%CI 14.512 – 42.193, p < 0.001 and RR = 3.64, 95%CI 1.413 – 9.403, p = 0.007, respectively).

The adverse outcomes of SILC procedures were reported in Table 4. The adverse outcomes which were more frequent in DSLC procedure included bile leakage, cystic artery injury and wound infection. At the end of the three-month follow-up period, the complication was a single case (0.2%) of incisional hernia. The intraoperative bile leakage was not associated with wound infection. In addition, the wound infection was not related to incisional hernia.

DISCUSSION

Our study demonstrated high BMI as the one of predictive factor for difficult SILC procedure. Recent studies have reported that high BMI is associated with difficult LC.[7,11,15,17,18] Obesity increases abdominal wall thickness and mesenteric fat volume.[27] Hassan technique for single-port insertion may be difficult when a thick abdominal wall and pendulous abdomen cause the downward displacement of umbilicus to the level of the pubic symphysis. So, longer operating time is required to encounter the thick abdominal wall and the difficulty of abdominal wall closure when compared with thin abdominal wall. The incidence of incisional hernia in SILC at our study was found to be 1 out of all 592 patients (0.17%). Previous studies report incisional hernia following SILC surgery as well as wound infection related to obesity due to a thick layer of fat on the abdominal wall.[28] However, there are only 8 wound infections and 1 incisional hernia reported in our study. There is no correlation between wound infection, incisional hernia, and BMI in our study.

Abdominal pain was found to be associated with

TABLE 1. Comparison of patients' demographic and clinical data between NDSLC and DSLC groups.

	NDSLC (n1 = 512)	DSLC (n2 = 80)	P-value
Age (years ± SD)	58.68 ± 14.16	61.06 ± 15.31	0.167
Male gender	149 (29.1%)	34 (42.5%)	0.015
Weight (kg ± SD)	64.74 ± 13.50	72.46 ± 13.74	<0.001
Height (cm ± SD)	159.57 ± 8.56	161.95 ± 7.09	0.019
BMI (kg/m^2 ± SD)	25.31 ± 4.42	27.74 ± 5.70	<0.001
Underlying disease			
DM	102 (19.92%)	17 (21.25%)	0.782
HTN	203 (39.65%)	36 (45.00%)	0.364
DLP	212 (41.41%)	32 (40%)	0.812
CAD	14 (2.73%)	3 (3.75%)	0.613
Thalassemia	12 (2.34%)	3 (3.75%)	0.456
CKD	10 (1.95%)	2 (2.50%)	0.746
Asthma	9 (1.76%)	1 (1.25%)	0.743
Other	48 (9.38%)	12 (15.00%)	0.121
Blood thinner used			
Antiplatelet	57 (11.13%)	9 (11.25%)	0.975
Anticoagulant	4 (0.75%)	0 (0%)	0.427
Median operative time (minutes)	46	94.5	<0.001

Abbreviations: kg, kilograms; m, meters; cm, centimeters; NDSLC, non-difficult single-port laparoscopic cholecystectomy; DSLC, difficult single-port laparoscopic cholecystectomy; SD, standard deviation; BMI, body mass index; DM; diabetes mellitus; HTN, hypertension; DLP, dyslipidemia; CAD, coronary artery disease; CKD, chronic kidney disease.

the difficult SILC. Abdominal pain is more present in patients who categorized as DSLC (55%). Abdominal pain is known to be symptomatic of gallstones and multiple episodes of cholecystitis.[6,17,18] Recurrent episodes of inflammation can create adhesion around peritoneal cavity which increase the difficulty of the SILC procedure.[6,9,16]

Chronic cholecystitis, contracted and calcified gallbladder were associated with DSLC procedure due to long operative time. These predictive factors which can be identified preoperatively by ultrasound were caused by chronic, repeated episodes of inflammation.[9] Previous studies have reported association between chronic cholecystitis and the difficulty of LC.[29,30] That contracted gallbladder is related to difficult LC procedure has also been reported in previous studies.[31,32] The calcification of the gallbladder wall is a variant of chronic cholecystitis and inflammatory scarring of the wall. Likewise with abdominal pain symptom, the chronic inflammation parameters lead to surrounding adhesion of Calot's triangle and gallbladder wall.[7,11,13,17,18,20] Thus, chronic cholecystitis, contracted gallbladder and calcified gallbladder on preoperative ultrasound finding can predict the difficulty of SILC procedure.

A lot of previous studies have reported relationships between gallbladder wall thickening ≥ 4 mm and the difficulty of SILC.[7,11,13,17,18,20] In our study, we collected data of gallbladder wall thickening and cholecystitis factors. So, we did not compare DSLC procedure with the factor of isolated gallbladder wall thickening without any evidence of inflammation on clinical and imaging results. Previous studies have revealed that cholecystitis is

TABLE 2. Clinical presentation and preoperative ultrasound finding between NDSLC and DSLC groups.

Variables	NDSLC (n1 = 512)	DSLC (n2 = 80)	P-value
Clinical presentation			
Dyspepsia	495 (96.68%)	79 (98.75%)	0.316
Abdominal pain	199 (38.87%)	44 (55.00%)	0.006
History of acute cholecystitis	25 (4.88%)	13 (16.25%)	<0.001
CBD stone	15 (2.93%)	12 (15.00%)	<0.001
History of ERCP	13 (2.54%)	10 (12.5%)	<0.001
GS pancreatitis	6 (1.17%)	4 (5.00%)	0.013
GS cholangitis*	3 (0.59%)	3 (3.75%)	0.009
Suspected acute cholecystitis**	0 (0%)	3 (3.75%)	<0.001
Pre-operative ultrasound finding			
GS	492 (96.09%)	80 (100%)	0.072
Gallbladder wall thickening ≥ 4 mm	51 (9.96%)	21 (26.25%)	<0.001
Definite acute cholecystitis***	2 (0.39%)	2 (2.50%)	0.032
Gangrenous cholecystitis	0 (0%)	1 (1.25%)	0.011
Chronic cholecystitis****	21 (4.10%)	12 (15.00%)	<0.001
Adenomyosis	30 (5.86%)	6 (7.50%)	0.568
Gallbladder polyp	45 (8.79%)	5 (6.25%)	0.447
Contracted gallbladder	7 (1.37%)	15 (18.75%)	<0.001
Calcified gallbladder	2 (0.39%)	5 (6.25%)	<0.001
CBD dilatation	8 (1.56%)	8 (10.00%)	<0.001

*Systemic inflammation (fever and/or chills or laboratory data) + cholestasis (Jaundice or Laboratory data) + imaging (biliary dilatation or evidence of the etiology on imaging), **Clinical diagnosis (local signs of inflammation (murphy's sign or right upper quadrant mass/pain/tenderness) + systemic signs of inflammation (fever or elevated C-reactive protein or elevated white blood cell count), *** Ultrasound finding characteristic diagnosis, ****Gallbladder wall thickening ≥ 4 mm with non-distended gallbladder with clinical diagnosis.

Abbreviations: NDSLC, non-difficult single-port laparoscopic cholecystectomy; DSLC, difficult single-port laparoscopic cholecystectomy; CBD, common bile duct, ERCP, Endoscopic retrograde cholangiopancreatography; GS, gallstones; mm, millimeters.

related to the difficulty of LC procedure.[6,14,16-19] However, the incidence of acute cholecystitis and gangrenous cholecystitis in this study was very low.

The adverse outcomes of the study, which significantly related to DSLC included intraoperative bile leakage and cystic artery injury. The DSLC from adhesion and inflammation of Calot's triangle had a high risk of major biliovascular injury during SILC.[6,7,17] In addition, biliovascular injury may have increased operative time for controlling bile leakage or stopping bleeding. Wound infections were reported more in DSLC procedure but there was no correlation between wound infection and intraoperative biliary leakage. Cystic artery injury and bile leakage can be managed via laparoscopic technique without open conversion. Three-month follow-up demonstrated one patient with incisional hernia without incarceration. Nevertheless, the DSLC procedure was not associated with incisional hernia. The limitations of the study included the bias inherent in the retrospective nature of the design. In addition, the operative time, intraoperative complication and open conversion surgery was related to the surgeon's

TABLE 3. Multivariate analysis of influencing predictive factors on difficulty of SILC procedures.

Variables	Relative risk (RR)	95% Confidence interval (CI)	P-value
Male gender	0.79	0.419 – 1.502	0.477
Weight (kg)	N/A	0.029 - 0.004	0.136
Height (cm)	N/A	0.003 – 0.023	0.131
Obesity (BMI ≥ 25 kg/m^2)	1.72	1.125 – 2.639	0.041[a]
Clinical presentation			
Abdominal pain	2.35	1.236 – 4.466	0.009[a]
History of acute cholecystitis	1.82	0.616 – 5.406	0.277
CBD stone	2.76	0.431 – 17.660	0.283
History of ERCP	0.62	0.063 – 6.029	0.679
GS pancreatitis	2.59	0.286 – 23.399	0.397
GS cholangitis*	2.35	0.235 – 23.524	0.467
Suspected acute cholecystitis**	N/A	N/A	N/A
Pre-operative ultrasound finding			
Gallbladder wall thickening ≥ 4 mm	1.44	0.657 – 3.154	0.362
Definite acute cholecystitis***	N/A	N/A	N/A
Gangrenous cholecystitis	N/A	N/A	N/A
Chronic cholecystitis****	3.64	1.413 – 9.403	0.007[a]
Contracted gallbladder	13.79	4.512 – 42.193	< 0.001[a]
Calcified gallbladder	14.08	1.822 – 108.771	0.011[a]
CBD dilatation	3.92	0.637 – 24.133	0.140

*Systemic inflammation (fever and/or chills or laboratory data) + cholestasis (Jaundice or Laboratory data) + imaging (biliary dilatation or evidence of the etiology on imaging), **Clinical diagnosis (local signs of inflammation (murphy's sign or right upper quadrant mass/pain/tenderness) + systemic signs of inflammation (fever or elevated C-reactive protein or elevated white blood cell count), *** Ultrasound finding characteristic diagnosis, ****Gallbladder wall thickening ≥ 4mm with non-distended gallbladder.

Abbreviations: N/A, not applicable; kg, kilograms; m, meters; cm, centimeters; BMI, body mass index; a P < 0.05, statistically significant

TABLE 4. Adverse outcomes between NDSLC and DSLC groups.

Variables	NDSLC (n1 = 512)	DSLC (n2 = 80)	SUM (n=592)	P-value
Intraoperative complication				
Intraoperative bile leakage	0 (0%)	1 (1.25%)	1 (0.17%)	0.011
Cystic artery injury	0 (0%)	1 (1.25%)	1 (0.17%)	0.011
Other critical adverse events*	0 (0%)	0 (0%)	0 (0%)	
Post-operative complication				
Wound infection	4 (0.78%)	4 (5.00%)	8 (1.35%)	0.002
Incisional hernia	1 (0.20%)	0 (0%)	1 (0.17%)	0.692

*common hepatic duct, common bile duct, hepatic artery proper injury.

Abbreviations: NDSLC, non-difficult single-port laparoscopic cholecystectomy; DSLC, difficult single-port laparoscopic cholecystectomy.

experience (operator dependent). SILC may not be recommended if performed by a relatively inexperienced laparoscopic surgeon or trainee. Three-month follow-up period cannot represent the long-term complications such as incisional hernia.

The significant preoperative predictive factors for DSLC included BMI (obese), abdominal pain symptom, chronic cholecystitis, contracted gallbladder, and calcified gallbladder.

CONCLUSION

DSLC depends on individual operative time and experience of surgeons. The predictive factors which determine the difficulty of SILC procedure were concordant with conventional LC. Obesity, abdominal pain, chronic cholecystitis, contracted and calcified gallbladder were significant preoperative predictive factors for DSLC. Surgeons should perform the SILC procedure carefully by surgeon who was highly experienced in the LC procedure when predictive factors are identified. Wound infection and biliovascular injury were the major adverse outcomes of the DSLC procedure.

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