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Title	Correlation between port-to-target distance and procedural difficulty in single-incision laparoscopic cholecystectomy : An observational study
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Citation	Asian journal of endoscopic surgery, 12(3), 255-263 https://doi.org/10.1111/ases.12652
Issue Date	2019-07-04
Doc URL	https://hdl.handle.net/2115/78810
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Type	journal article
File Information	Asian J Endosc Surg 12_255.pdf



Manuscript category: Original article

Title:

Correlation between port-to-target distance and procedural difficulty in single-incision
laparoscopic cholecystectomy: an observational study

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Short running title: Port-to-target distance in SILC

Authorship declaration:

Masafumi Ohira designed the study, analyzed data, and wrote the manuscript. All other authors have contributed to data collection and interpretation, and critically reviewed the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Abstract

Background: Single-incision laparoscopic cholecystectomy (SILC) is more challenging than conventional (multi-port) laparoscopic cholecystectomy (CLC) because of the increased likelihood of instrument collision and the limited surgical workspace. In SILC, procedural difficulties may increase when the port-to-target distance is long. We aimed to assess the correlation between port-to-target distance and procedural difficulty.

Methods: Thirty-six consecutive patients who underwent SILC at our hospital were included in this study. The umbilicus-to-Calot's triangle distance (UCD) was measured intraoperatively. The correlations between the UCD and operative time were analyzed, and for comparison, CLC cases during the same period (n=28) were similarly analyzed. Moreover, UCD was estimated from preoperative computed tomography (UCD-CT), and the usefulness of UCD-CT was assessed during SILC and CLC.

Results: Thirty-four patients successfully underwent SILC. There were positive correlations between the UCD and pneumoperitoneum time. Multivariate linear regression analysis, including body mass index (BMI) and height, which were previously reported to have a correlation with longer operative time in SILC, showed

that UCD is an independent predictive factor for prolonged operative duration.

However, BMI and height were not independent predictive factors. UCD and UCD-CT had a very strong positive correlation; therefore, UCD was estimated from CT. UCD-CT had a strong positive correlation with operative time in SILC, but not in CLC.

Conclusions: A longer UCD is an important predictive factor for difficult cases of SILC, but this finding is not applicable in CLC. The usefulness of UCD is specific to SILC.

Key words:

port-to-target distance, procedural difficulty, single-incision laparoscopic
cholecystectomy

Introduction

Single-incision laparoscopic cholecystectomy (SILC) was first reported by Navarra(1) in 1997. Since then, it has gained popularity because of improvements in laparoscopic instruments and techniques. Previous clinical trials have shown that SILC is comparable to conventional (multi-port) laparoscopic cholecystectomy (CLC) in terms of safety but it is associated with better cosmetic outcomes (2) (3) (4) (5). However, surgeons have reported that the disadvantages of SILC include longer operative times, a higher workload, and excessive stress (2) (3) (5) (6). These disadvantages are due to issues of decreased maneuverability caused by the placement of all instruments through one incision. Problems include the collision of instruments in both the intracorporeal and extracorporeal space, limited instrument triangulation, and limited workspace (7).

Previous papers have reported that body mass index (BMI) and height are predictive factors for prolonged operative duration in SILC patients (8) (9) (10). BMI is also associated with prolonged operative duration in CLC (11) (12). Thus, BMI is a factor that is non-specific to SILC patients. In contrast, height may be associated

specifically with SILC, as it may relate to the longer distance from a port to a target organ. Maneuverability issues occur when the distance from a port to a target organ is long.

The port-to-target distance appears to be correlated with procedural difficulty, and it may be a more important factor for difficult SILC cases than BMI and height. However, this has not been systematically studied. The distance from an umbilical port to Calot's triangle, or the umbilicus-to-Calot's triangle distance (UCD), is representative of the port-to-target distance in SILC. The present study aimed to evaluate the correlation between UCD and SILC in terms of procedural difficulty. Furthermore, we assessed the predictability of UCD based on height, BMI, and preoperative computed tomography (CT); the estimated UCD from preoperative CT was designated as UCD-CT. The CLC cases during the same period were also analyzed in order to confirm the SILC-specificity of UCD (or UCD-CT) for predicting the difficulty of cholecystectomy.

Materials and Methods

Study design

Patients who underwent SILC at our hospital between April 2015 and March 2016 were eligible for this study. They were excluded from analysis if they had had previous upper abdominal surgery, had a suspected malignancy, or were converted to open cholecystectomy or conversion from SILC to CLC.

The decision to perform SILC was based on patients' and surgeons' choice. All patients for whom laparoscopic cholecystectomy was indicated were given the opportunity to undergo SILC. The surgeons decided on the procedure (CLC or SILC) based on the condition of the gallbladder, the available instruments, devices at the time, and patient requests. We measured the UCD intraoperatively for each SILC patient. Data (patient characteristics, intraoperative data, and postoperative course) were obtained prospectively. Also, the data from CLC cases that were successfully completed laparoscopically during the same period were analyzed for comparison. We did not measure the UCD in CLC cases. Accordingly, we assessed the correlation between UCD and UCD-CT, and after confirming an adequate positive correlation between them, we analyzed only UCD-CT instead of actual UCD in CLC.

The study protocol was approved by the Institutional Review Board of the National Hospital Organization Hokkaido Medical Center (No. 27-12-11). All patients provided written informed consent for the use of their clinical data in this study.

Surgical method of SILC

A single surgeon who was considered to have adequate experience with CLC (over 100 cases) and SILC (over 10 cases) performed the SILC procedures. A 2-cm vertical incision was made on the umbilicus. The LAP-PROTECTOR Mini and E·Z ACCESS devices (Hakko Co., Ltd, Tokyo, Japan) were used. We were able to place the necessary number of trocars in a free position using these devices. Three 5-mm trocars were placed, one for an optical instrument and the others for operative instruments. Pneumoperitoneum was maintained at an intra-abdominal pressure of 8-10 mmHg. We used a 30-degree rigid scope. Cephalad gallbladder retraction and exposure of Calot's triangle were achieved with a mini loop retractor II (Covidien Japan, Tokyo, Japan) or a right subcostal transabdominal suture through the mid-body of the gallbladder. The procedure then followed the usual tenets of cholecystectomy. The cystic artery and duct

were clipped or ligated and then divided. A drain tube was not placed in all cases.

Surgical method of CLC

Four surgeons performed the CLC procedure. A 12-mm trocar was placed on the umbilicus for the optical instrument and three other 5-mm trocars were placed along the line of the right subcostal arch. Two trocars were used by an operator to dissect the gallbladder and another trocar was used by an assistant to retract the gallbladder. The procedure then followed the usual tenets of cholecystectomy. The cystic artery and duct were clipped or ligated and then divided. A drain tube was placed if necessary.

Umbilicus-to-Calot's triangle distance

In SILC, after achieving pneumoperitoneum but before dissecting Calot's triangle, we measured the length between Calot's triangle and the end of the trocar using laparoscopic grasping forceps (length X). then, the length between the end and the insertion point of the trocar (length Y) was subtracted from length X. This measurement (length X - length Y) was defined as the UCD (Figure 1). A piece of string was used to

mark the length intraoperatively and the length was verified with a tape measure postoperatively. All UCDs were measured by a single surgeon to eliminate interpersonal variability.

Estimated UCD from preoperative CT

The estimated UCD was calculated from preoperative CT (Figure 1). The calculations took into account the vertical and horizontal distance from the umbilicus to the neck of the gallbladder. The UCD-CT is easy to calculate using an ordinary CT viewer. We used the sum of the adjacent and opposite sides of the right-angled triangle, instead of the hypotenuse, to determine UCD-CT in a simple calculation.

Surgical maneuverability evaluation

We used operative time as a proxy for procedural difficulty. Operative time was defined as the pneumoperitoneum time in order to eliminate the effect of the time needed for trocar placement and wound closure.

Outcomes and statistical analysis

We assessed the correlation between pneumoperitoneum time and clinical data in SILC and CLC. We also examined the relationship between UCD-CT and UCD in order to confirm the possibility of predicting the actual UCD from preoperative CT. Moreover, we analyzed the correlation between UCD-CT and pneumoperitoneum time in both SILC and CLC to evaluate the practicality and specificity of UCD-CT in SILC.

Statistical analyses were performed using Spearman's rank correlation coefficient for correlations, Wilcoxon rank-sum test for examining differences in continuous variable distributions, and Fisher's exact test for categorical variables. Factors with a significant impact on pneumoperitoneum time in univariate analyses were analyzed by multiple linear regression analysis to assess the independence of each factor for pneumoperitoneum time. In addition, multiple linear regression analysis with stepwise model selection using Akaike's information criterion with correction for small sample sizes (AICc) was performed for comparison with variable selection using p-value. The level of significance was set at 0.05. All of the analyses were conducted with JMP software (SAS Institute, Cary, USA).

Results

Thirty-four of 36 patients successfully underwent SILC. Two patients required conversion to open cholecystectomy due to severe inflammation and adhesion. They were excluded from the final analysis. The clinical characteristics and operative findings of the remaining 34 cases are shown in Table 1. To stratify the condition of the gallbladder, including inflammation, the situation of the operation was considered—that is, elective operation cases, emergency operation cases, and cases with preoperative interventions. Preoperative interventions included percutaneous transhepatic gallbladder drainage and stone removal using an endoscope. The emergency operation group and preoperative intervention group were regarded as having comparatively severe acute or chronic inflammation. In contrast, the elective operation group was thought to have no or only mild inflammation.

During the same period, of the 28 CLCs that were performed, 22 cases were completed successfully; six cases required conversion to open cholecystectomy. The data of the 22 successful cases are also shown in Table 1. There were no statistical

differences between the two groups with respect to these data.

Correlations between the clinical factors and pneumoperitoneum time in SILC

The data for the continuous variables (age, height, weight, BMI, and UCD) are shown in Table 1. Simple linear regression models and correlation coefficients for age and pneumoperitoneum time; height and pneumoperitoneum time; weight and pneumoperitoneum time; BMI and pneumoperitoneum time; and UCD and pneumoperitoneum time are shown in Figure 2. There was a strong positive correlation between UCD and pneumoperitoneum time ($r_s=0.68$, $P < 0.0001$), and moderately positive correlations between weight and pneumoperitoneum time ($r_s=0.41$, $P = 0.017$), and between BMI and pneumoperitoneum time ($r_s=0.45$, $P = 0.0077$). Neither age nor height had significant correlation with pneumoperitoneum time ($r_s=0.30$, $P = 0.082$; $r_s=0.027$, $P = 0.88$, respectively).

The pneumoperitoneum times stratified by the categorical variables (sex, ASA, inflammation of the gallbladder, and method of gallbladder retraction) are shown in Table 2. In SILC, there were significant differences with respect to sex, ASA, and

inflammation of the gallbladder ($P = 0.03$, $P = 0.01$, $P = 0.0004$, respectively)

Correlation between the factors related to the somatotype and UCD

A simple linear regression model and the correlation coefficients for the factors related to the somatotype (height, weight, BMI, and UCD-CT) and UCD in SILC are shown in Figure 3. There was a very strong positive correlation between UCD-CT and UCD ($r_s=0.80$, $P < 0.0001$), and a strong positive correlation between weight and UCD ($r_s=0.69$, $P < 0.0001$) and between BMI and UCD ($r_s=0.69$, $P < 0.0001$). There was no correlation between height and UCD ($r_s= 0.26$, $P = 0.14$).

Correlations between clinical factors and pneumoperitoneum time in CLC

Correlations between clinical factors (age, sex, height, weight, BMI, ASA, and inflammation of the gallbladder) and pneumoperitoneum time in CLC are shown in Figure 4 and Table 2. None of the factors had statistically significant correlations with pneumoperitoneum time.

Multiple linear regression analysis

The results of the multiple linear regression analysis of the factors affecting pneumoperitoneum time are shown in Table 3. The UCD and inflammation of the gallbladder were independent prognostic factors for longer operative duration, but sex, BMI, and ASA were not.

With stepwise model selection using AICc, UCD and inflammation of the gallbladder were selected in the optimal model (AICc = 281.455); other factors were excluded from the optimal model (Table 3).

Correlations between UCD-CT and pneumoperitoneum time in SILC and CLC

Correlations between UCD-CT and pneumoperitoneum time in SILC and CLC are shown in Figure 5. UCD-CT showed a strong positive correlation with pneumoperitoneum time in SILC ($r_s=0.73$, $P<0.0001$), but in CLC, no such correlation was observed ($r_s=0.11$, $P=0.63$).

Discussion

This study examined the relationship between the distance from the port to the target organ and surgical maneuverability or procedural difficulty in SILC. We investigated the correlation between the UCD, which may represent the port-to-target distance in SILC, and operative time as a proxy for procedural difficulty. Our findings revealed a strong positive correlation between the UCD and operative time. Therefore, a longer port-to-target distance resulted in increased procedural difficulty in SILC.

Previous studies have shown that SILC has a longer operative time than CLC (5) (13). This is mainly because of the narrow workspace associated with a single incision (7). However, there seems to be varying degrees of difficulty in individual cases. In previous studies, height and BMI were reported as predictive factors for difficult SILC cases (8) (9), with patients with a higher BMI or taller height had longer operative times. These effects are believed to be due to the longer distance to the target organ (14). In single-incision laparoscopic surgery, the operator's hands and the scope get closer to each other in the extracorporeal space, resulting in a narrower workspace and decreased surgical maneuverability when the distance from a port to a target organ is long.

BMI was moderately and positively correlated with operative time, but there was no correlation between height and operative time in this study.

In multivariate analysis, UCD was an independent predictive factor for prolonged operative duration, but BMI and height were not. This shows that UCD is a more important factor for prolonging operative duration than BMI and height.

Because the actual UCD cannot be measured preoperatively, we examined whether we could estimate the actual UCD from preoperative CT. UCD-CT had a very strong positive correlation with the actual UCD. Weight and BMI also had strong positive correlations with UCD. However, height was not correlated with UCD. This means that we can predict the actual UCD from preoperative CT, weight, and BMI. We did not measure UCD in CLC cases, but we used UCD-CT from our results to investigate the usefulness of UCD in CLC cases. There was no correlation between UCD-CT and pneumoperitoneum time in CLC. Ultimately, UCD and UCD-CT were predictors in difficult cases, which were specific to SILC.

The difficulty of laparoscopic cholecystectomy largely depends on the inflammatory condition of the gallbladder. Several reports have referred to the

preoperative evaluating system for the degree of inflammation of gallbladder and the difficulty of laparoscopic cholecystectomy (15) (16) (17) (18) (19). However, most of these evaluation systems consist of multiple factors and are complicated. In order to simply assess the inflammatory condition of the gallbladder, we used an indirect factor: the situation of the cases during the operation (i.e. elective operation cases, emergency operation cases, or cases with preoperative interventions), which was a simple and comprehensible factor. The inflammatory condition of the gallbladder had a significant impact on pneumoperitoneum time. However, UCD remained independent in multivariate analysis in both cases with variable selection using p-value and stepwise model selection using AICc.

There were several limitations to this study. First, all SILCs were performed by a single surgeon. This may have led to information bias as the surgeons may have been aware of the UCD intraoperatively. To minimize this unfavorable effect, the UCD was measured by a single surgeon using a piece of string to mark UCD length intraoperatively, and this string was measured with a tape measure postoperatively. This helped to reduce information bias. However, the limited number of operators in our

study may have eliminated interpersonal variability. In CLC, four surgeons performed the operations and this may have resulted in interpersonal variability. Second, we decided to perform SILC or CLC at the discretion of patients and/or surgeons. We performed a total of 64 laparoscopic cholecystectomies during this study period, including 36 SILCs (56%) and 28 CLCs (44%), which may have led to selection bias. Therefore, we may not be able to generalize the results of this study to all cases requiring laparoscopic cholecystectomy. Finally, another potential limiting factor in the present study was the learning curve for SILC. The surgeon in the present study was considered to have adequate surgical laparoscopic experience with CLC (over 100 cases) and SILC (over 10 cases). A previous study showed that the number of cases needed to overcome the learning curve for SILC was 10 (10). In our study, there were no significant differences in clinical factors, including UCD and pneumoperitoneum times, between the first and last 17 cases (data not shown). Therefore, we concluded that the learning curve was not a major limitation.

Our study showed that the UCD is an important predictive factor for operative difficulty during SILC. We should keep in mind that performing SILC may be difficult

in patients whose UCD seems to be long as determined based on factors such as somatotype and preoperative CT. Moreover, this study suggests that in other types of single-incision laparoscopic surgeries, we need to decide on the site and size of an incision or the use of additional trocars given the distance to the target organ.

Acknowledgement

The authors have no conflicts of interest to declare.

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Figure Legends

Figure 1. (a) Umbilicus-to-Calot's triangle distance (UCD). $UCD = X - Y$. X, the length between Calot's triangle and the end of the trocar; Y, the length between the end and the insertion point of the trocar.

(b) Estimated UCD from preoperative computed tomography (UCD-CT). $UCD-CT = x + y$. x, (number of images between an image that contains the neck of the gallbladder and one that contains the umbilicus) $\times$ (slice thickness); y, the length between the umbilicus and the same coordinate point as the neck of the gallbladder on an image that contains the umbilicus

Figure 2. Scatterplots, linear regression models, and Spearman's rank correlation coefficients between pneumoperitoneum time in single-incision laparoscopic cholecystectomy and each continuous variable: (a) age; (b) height; (c) weight; (d) BMI; and (e) UCD. The gray area of each graph indicates the confidence region for the linear regression. UCD, umbilicus-to-Calot's triangle distance.

Figure 3. Scatterplots, linear regression models, and Spearman's rank correlation coefficients between UCD and factors of somatotype: (a) height; (b) weight; (c) BMI; and (d) UCD-CT. The gray area of each graph indicates the confidence region for the linear regression. UCD, umbilicus-to-Calot's triangle distance; UCD-CT, estimated UCD from preoperative CT.

Figure 4. Scatterplots, linear regression models, and Spearman's rank correlation coefficients between pneumoperitoneum time in conventional laparoscopic cholecystectomy and each continuous variable: (a) age; (b) height; (c) weight; and (d) BMI. The gray area of each graph indicates the confidence region for the linear regression.

Figure 5. Scatterplots, linear regression models, and Spearman's rank correlation coefficients between UCD-CT and pneumoperitoneum time in SILC and CLC. The gray area of each graph indicates the confidence region for the linear regression. CLC, conventional laparoscopic cholecystectomy; SILC, single-incision laparoscopic

cholecystectomy; UCD-CT, estimated umbilicus-to-Calot's triangle distance from preoperative CT.

Fig. 1

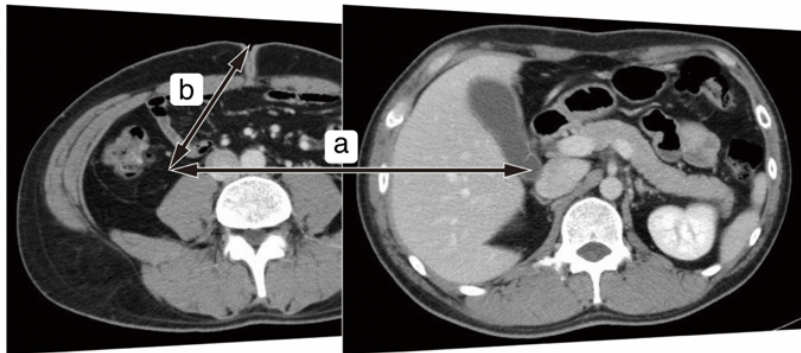
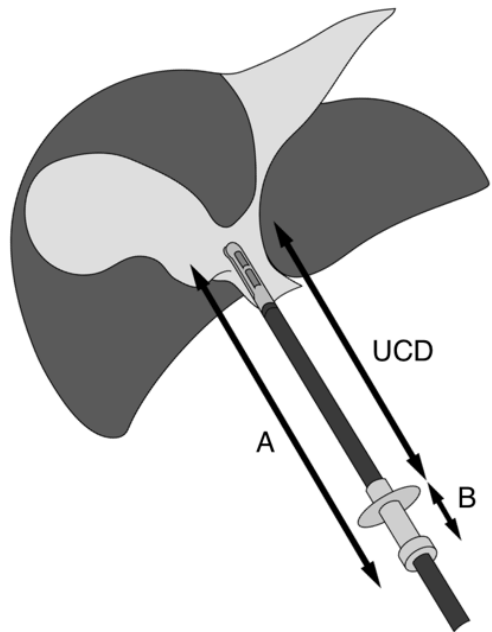


Figure 2

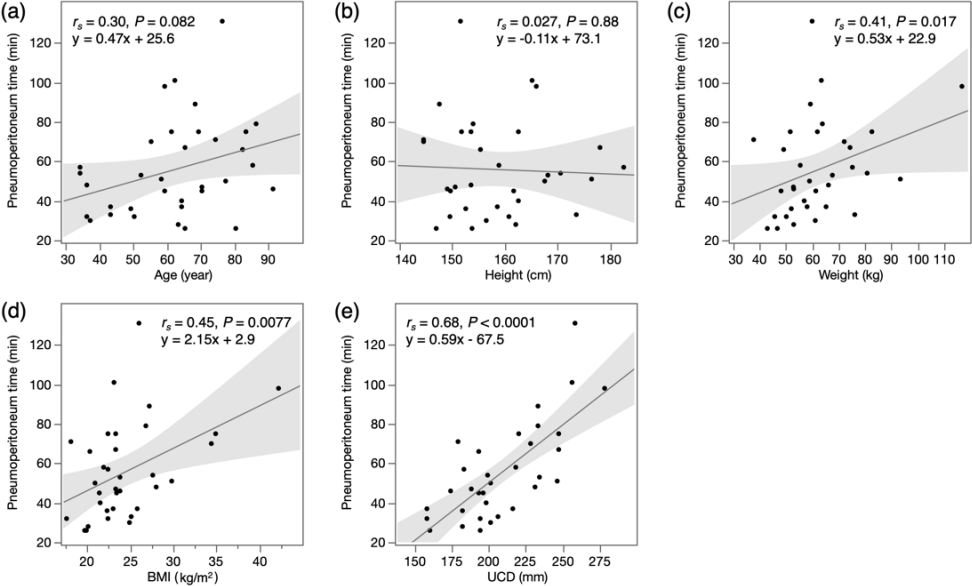


Figure 3

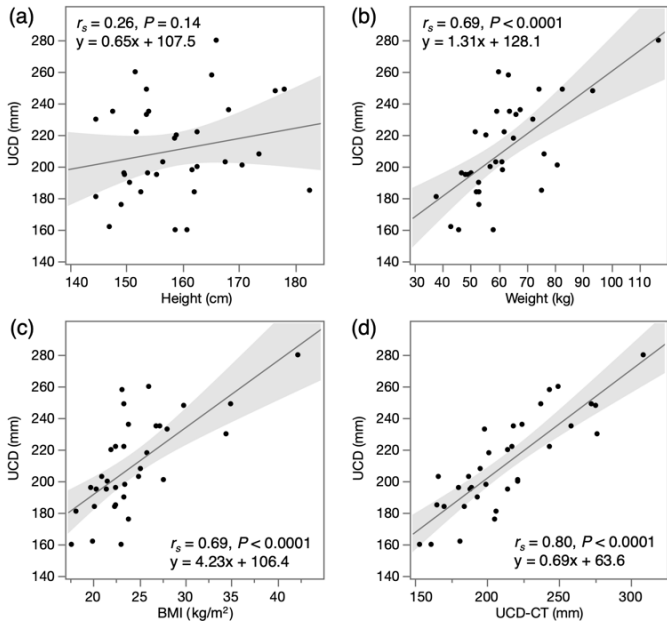


Figure 4

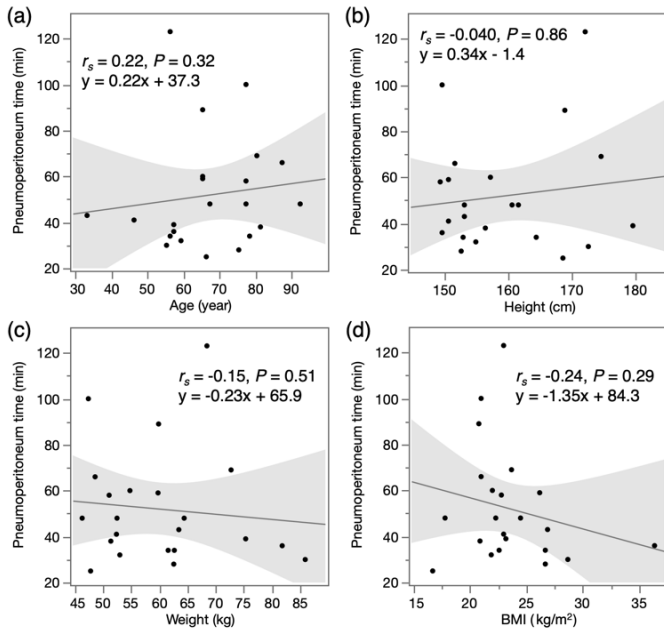


Figure 5

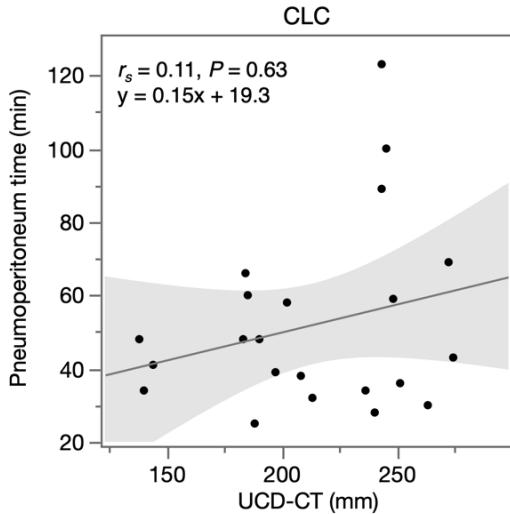
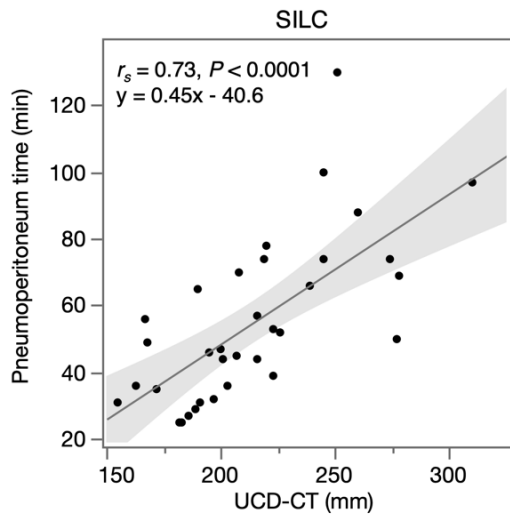


Table 1. Clinical characteristics and operative findings of successful SILC and CLC cases.

		SILC (n = 34)	CLC (n = 22)	P value
Age (years)		65 (52-74)	67 (58-78)	0.29
Sex	Male	17 (50%)	10 (45%)	0.79
	Female	17 (50%)	12 (55%)	
Height (cm)		158.0 (152.1-165.0)	156.1 (151.8-169.1)	0.93
Weight (kg)		60.5 (52.8-69.6)	60.3 (51.7-65.9)	0.68
BMI (kg/m ²)		23.6 (21.9-26.3)	23.1 (21.2-26.5)	0.52
ASA	≤ 2	30 (88%)	20 (91%)	0.37
	≥ 3	4 (12%)	2 (9%)	
Inflammation of the gallbladder	No or mild	19 (56%)	8 (36%)	0.18
	Severe	15 (44%)	14 (64%)	
UCD (mm)		203 (191-235)	NA	NA
UCD-CT (mm)		208 (189-236)	213 (187-248)	0.79
Pneumoperitoneum time (min)		51 (37-71)	46 (34-62)	0.45
Blood loss (ml)		1 (0-5)	0 (0-5)	0.30
LOS (days)		5 (4-6)	5 (4-6)	0.42

Postoperative	Clavien-Dindo $\leq$ II	34 (100%)	22 (100%)	1
complication	Clavien-Dindo $\geq$ III	0 (0%)	0 (0%)	
Gallbladder retraction	Mini-loop retractor	21 (62%)	NA	NA
	Transabdominal suture	13 (38%)	NA	

Data are n (%) or median (interquartile range).

SILC, single-incision laparoscopic cholecystectomy; CLC, conventional laparoscopic cholecystectomy; BMI,

body mass index; ASA, American Society of Anesthesiologists; UCD, Umbilicus-Calot's triangle distance;

UCD-CT, Estimated UCD from preoperative CT; LOS, length of stay; NA, not applicable

Table 2. Correlation between the categorical variables and pneumoperitoneum time in SILC and CLC.

		SILC (n=34)		CLC (n=22)	
		Pneumoperitoneum time	<i>P</i> value	Pneumoperitoneum time	<i>P</i> value
Sex	Male	57 (48-77)	0.03	46 (36-74)	0.55
	Female	45 (31-68)		45 (34-59)	
ASA	≤2	48 (35-66)	0.01	48 (35-65)	0.086
	≥3	77 (75-93)		31 (25-36)	
Inflammation of the gallbladder	No or mild	40 (32-51)	0.0004	38 (33-46)	0.06
	Severe	71 (58-79)		59 (37-74)	
Method of gallbladder retraction	Mini-loop retractor	54 (35-75)	0.57	NA	NA
	Transabdominal suture	50 (37-67)		NA	

Data are median (interquartile range).

SILC, single-incision laparoscopic cholecystectomy; CLC, conventional laparoscopic cholecystectomy;

ASA, American Society of Anesthesiologists; NA, not applicable

Table 3. Multiple linear regression analyses of the factors affecting pneumoperitoneum time in SILC

	Coefficient	Standard error	<i>P</i> value
Sex	3.98	5.82	0.50
BMI	0.23	0.85	0.79
ASA (≥ 3)	1.17	9.66	0.90
Inflammation of the gallbladder	21.01	5.64	0.0009
UCD	0.43	0.14	0.0052
Stepwise model selection using AICc			
	Coefficient	Standard error	<i>P</i> value
Inflammation of the gallbladder	20.43	4.96	0.0003
UCD	0.50	0.082	<0.0001

SILC, single-incision laparoscopic cholecystectomy; BMI, body mass index; ASA, American Society of Anesthesiologists; UCD, Umbilicus-Calot's triangle distance; AICc, Akaike's information criterion with a correction for small sample sizes