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Postoperative complications following single-incision laparoscopic cholecystectomy: a retrospective analysis in 360 consecutive patients

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Abstract
Background Single-incision laparoscopic cholecystectomy (SILC) is being increasingly performed based on recent evidence showing its cosmetic advantages. However, there is limited information on outcome data for SILC with respect to postoperative complications.
Methods We retrospectively reviewed a consecutive series of 360 patients undergoing SILC to evaluate the rate, features, and risk factors of postoperative complications.
Results During a median follow-up period of 671 days, 17 patients (4.7 %) developed postoperative complications, including bile duct injuries, intraabdominal abscess, wound infection, incisional hernia, paralytic ileus, and pneumonia. Reoperation was required in five patients (1.4 %). Overall inpatient mortality occurred in one patient (0.3 %) who developed aspiration pneumonia. In multivariate stepwise regression analyses, poor physical status (American Society of Anesthesiologists score of ≥3) and preoperative diagnosis of acute cholecystitis were identified as significant risk factors for the development of postoperative complications ($P = 0.0009$ and $P = 0.04$, respectively).
Conclusions These findings suggest that SILC is a relatively safe procedure with an acceptable postoperative complication rate but requires careful attention especially in patients with poor physical status and/or acute cholecystitis.

Keywords Single-incision laparoscopic cholecystectomy · Postoperative complication · Wound complication · Bile duct injury · Acute cholecystitis · Physical status

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Laparoscopic cholecystectomy (LC) has long been recognized as the gold standard procedure for removal of the gallbladder. Recently, single-incision laparoscopic cholecystectomy (SILC), also called as transumbilical LC or laparoendoscopic single site (LESS) cholecystectomy, has been developed to further minimize the invasiveness of LC [1–3]. With improved surgical skills and advanced technologies, SILC has recently been disseminating quite rapidly. A number of randomized controlled trials and meta-analyses have shown that SILC can provide better cosmetic results and, at least in some studies, less postoperative pain as compared to conventional LC [4–12]. On the other hand, SILC is associated with a longer operative time and required additional instruments, resulting in greater hospital charges [12–14].

Some investigators have raised concern about the safety of SILC because of its greater rate of complications, including bile duct injuries, compared with standard LC [15]. In a systemic review of 49 studies (including 2,336 patients), the overall median complication rate of SILC was 7.37 %, and the rate of biliary duct complications was 0.39 % [16]. In another review, the rate of bile duct injuries in SILC was 0.72 %, which is slightly higher compared with that (0.4–0.5 %) reported in standard LC [15]. However, these reports were based on data collected from different studies with heterogenous patient groups. Results from several randomized controlled trials comparing SILC versus conventional LC showed no difference in the rate of postoperative complications [12]. However, the length of follow-up in these randomized trials was generally insufficient to accurately measure the rate of late complications. Currently, literature provides

little information on outcome data for SILC with respect to postoperative complications.

In an attempt to evaluate the rate, features of, and risk factors for postoperative complications in SILC, we retrospectively reviewed a consecutive series of 360 patients undergoing SILC for benign gallbladder diseases including acute cholecystitis. To our knowledge, this is one of the largest series to date of SILC procedures with detailed analysis of postoperative complications.

Patients and methods

Patients

All patients who had attempted SILC from September 2009 to December 2013, at Department of Surgery1, University of Occupational and Environmental Health (Kitakyushu, Japan) were identified through a search of our clinical database and hospital records. This study was approved by the institutional and departmental review board, and a written informed consent was obtained from all patients. Patients were excluded if they had an additional procedure (e.g., common bile duct exploration) at the time of cholecystectomy. In total, 362 patients with gallbladder diseases (including symptomatic cholelithiasis, acute cholecystitis, and gallbladder polyps) were identified as having attempted SILC at our institution. This series is our institution's initial experience with SILC, and there were no exclusion criteria for performing SILC during the study period. The diagnosis of acute cholecystitis was made preoperatively according to the Tokyo guidelines [17]. Briefly, patients exhibiting one of the local signs of inflammation (such as Murphy's sign, or a mass, pain or tenderness in the right upper quadrant), as well as one of the systemic signs of inflammation (such as fever, elevated white blood cell count, and elevated C-reactive protein level) are diagnosed as having acute cholecystitis.

Operative procedure

We used a three-trocar approach through a single umbilical incision and a parallel approach with conventional instruments. Under general anesthesia, patients were placed in the supine position with their legs apart. A 2.5-cm vertical incision was made on the umbilicus. In cases with multiple-trocar approach, a 5-mm trocar (Endopath Xcel, Ethicon Endo-Surgery, Cincinnati, OH, USA) was introduced through the umbilical incision for pneumoperitoneum and a laparoscope (EndoEye camera system, Olympus Medical System, Tokyo, Japan). After exposing the abdominal fascia under the skin flap of the umbilical incision, a grasper for gallbladder retraction was directly inserted without a trocar. Then, two 5-mm trocars (Endopath Xcel, Ethicon Endo-Surgery, or EZ trocar, Hakko Co., Nagano, JAPAN) for operator's manipulation were inserted into the abdominal cavity through the single umbilical incision. In cases with multichannel-port approach, we used a small wound retractor (Alexis wound retractor, Applied Medical, Rancho Santa Margarita, CA, USA) combined with a surgical glove (glove method) or a small wound protector (Lap-Protector, Hakko) combined with a silicon rubber cap (EZ Access or EZ access oval type, Hakko), through which two 5-mm trocars and a grasper were inserted.

Dissection of Calot triangle was performed carefully according to the CVS approach. After confirming that the cystic artery and cystic duct are the only two tubular structures remaining between the gallbladder and the hepatoduodenal ligament, an intraoperative cholangiography (IOC) was routinely attempted. In most cases, IOC was performed using the Kumar cholangiography system (Nashville Surgical Instruments, Nashville, USA) [18, 19]. After completion of IOC, the cystic duct and cystic artery were clipped and divided. The gallbladder was then dissected from the liver bed using a hook electrocautery or Harmonic ACE (Johnson & Johnson, Cincinnati, OH, USA), collected in a bag and removed through the umbilical incision. The fascial defect in the umbilicus was closed using absorbable monofilament suture, and the skin was closed subcuticularly with a 4-0 absorbable monofilament suture.

Postoperative management and complications

Prophylactic antibiotics were administered on the day of surgery (twice a day at the time of skin incision and 3 h later) and postoperative day (POD) 1 (once in the morning). After surgery, the umbilical wound was sealed by an adhesive film providing a moist wound environment for 48 h. Oral diet was started on POD 1 and patients were discharged on or after POD 3, when appropriate. After discharge, patients were scheduled to visit our outpatient clinic at least once (usually at 1 or 2 weeks after discharge) and were instructed to report any symptoms suggestive of postoperative complications of SILC. Data on the diagnosis and treatment of postoperative complications were collected from our in-hospital and outpatient medical records. The types of bile duct injuries were classified according to the Strasberg bile duct injury classification system [20].

Statistical analysis

Categorical variables were analyzed using the Fisher's exact probability test, and continuous variables were analyzed using the Mann–Whitney *U* test. Multivariate analysis was performed for all variables using a stepwise linear regression analysis. A *P* value of less than 0.05 was

Table 1 Patient characteristics and operative variables

Factor	All patients ($n = 360$)
Age (years)	62.5 (7–91)
Gender (M/F)	156/204
BMI (Kg/m^2)	22.7 (13.8–46.6)
ASA score	
1	104
2	231
3	20
Comorbid diseases (yes)	208 (58 %)
Diabetes mellitus (yes)	63 (18 %)
Prior abdominal surgery (yes)	124 (34 %)
Prior upper abdominal surgery (yes)	15 (4 %)
Diseases	
Symptomatic cholelithiasis	280 (78 %)
Acute cholecystitis	52 (14 %)
Gallbladder polyps	14 (4 %)
Adenomyomatosis/wall thickening	14 (4 %)
Operator (residents/senior staff)	140/220
Approach for SILC (MT/MCP)	151/185
Placement of additonal port(s)	67 (19 %)
Operative time (minutes)	143 (55–533)
Intraoperative blood loss (mL)	5 (5–460)

Values shown are median (range)

MT multiple-trocar approach, *MCP* multichannel-port approach

considered statistically significant. All statistical analyses were done using JMP 10 software (SAS Institute Inc., Cary, NC, USA).

Results

Patient characteristics of study population

In total, 362 patients with gallbladder diseases were identified as having attempted SILC during the study period. Of these, two patients who required open conversion were excluded, leaving 360 patients as the study population for analysis of postoperative outcomes (Table 1). They consisted of 156 men and 204 women aged 7–91 years (median age, 62.5 years). The median body mass index (BMI) was 22.7 kg/m^2 (range, 13.8–46.6 kg/m^2). The American Society of Anesthesiologists (ASA) score was 1 in 104 patients, 2 in 231 patients, and 3 in 20 patients. Comorbid diseases (including hypertension, diabetes mellitus, asthma, ischemic heart disease, and others) were present in 208 patients (58 %), of which 63 patients (18 %) had diabetes mellitus. There were 124 patients (34 %) who had undergone previous abdominal surgery. Of these 124 patients, 15 (4 %) had received upper abdominal surgery.

Table 2 Postoperative outcomes

Outcome measure	
Postoperative hospital stay (day)	5 (2–51)
Follow-up period (day)	671 (5–1572)
Postoperative complications (Overall)	17 (4.7 %)
Wound infection	9
Bile duct injuries	2
Incisional hernia	2
pneumonia	2
Intraabdominal abscess	1
paralytic ileus	1
Reoperation	5 (1.4 %)
Inpatient mortality	1 (0.3 %)

Values shown are median (range)

Indications for surgery included symptomatic cholelithiasis in 280 patients (78 %), acute cholecystitis in 52 patients (14 %), gallbladder polyps (over 1 cm in diameter) in 14 patients (4 %), and adenomyomatosis or partial wall thickening of the gallbladder in 14 patients (4 %).

Operative variables

SILC procedures were performed by staff surgeons in 220 patients (61 %) and by surgical residents in 140 patients (39 %). Multiple-trocar approach was used in 151 patients (45 %), while multichannel-port approach was used in 185 patients (55 %). SILC was successfully completed through a single incision in 293 patients (81 %), whereas addition of extra port(s) was required in 67 patients (19 %). Overall, the median operative time was 143 (range, 55–533) min. The median intraoperative blood loss was 5 (range, 5–460) mL. The median length of postoperative hospital stay was 5 (range, 2–51) days and median follow-up period was 671 (range, 5–1572 days) days.

Postoperative complications

Overall, postoperative complications occurred in 17 (4.7 %) patients (Table 2). These included bile duct injuries (two patients, 0.56 % overall), intraabdominal abscess (one patient), wound infection (nine patients), incisional hernia (two patients), paralytic ileus (one patient), and pneumonia (two patients). The types of bile duct injuries in the two patients were categorized as type D (lateral injury to extrahepatic bile ducts) and E (circumferential injury of major bile ducts) according to the Strasberg Bile Duct Injury Classification System [20]. Both patients underwent reoperation (tube drainage of the common bile duct in one patient and hepaticojejunostomy in another). The diagnosis of incisional hernia at the umbilical site was made in two

patients at 12 and 17 months after operation, respectively. Both patients underwent repair surgery for incisional hernia. One patient developed intraabdominal abscess resulting from spilled gallstones (Fig. 1), thereby requiring readmission and drainage operation. In total, reoperation (in the emergency or elective setting) was required in five patients (1.4 %). One patient died of severe aspiration pneumonia on POD 12, resulting in the overall inpatient mortality of 0.3 %.

Identification of factors predicting the postoperative complications in SILC

In an attempt to identify risk factors for postoperative complications in SILC, we first compared clinical variables between 17 patients who developed postoperative complications (complication group) and 343 patients who did not (no-complication group) (Table 3). There were no significant differences in age (≥75 years or <75 years), gender, BMI, comorbid diseases, DM, prior abdominal surgery (all), prior upper abdominal surgery, operator (surgical residents or senior staffs), operation time, and intraoperative blood loss. The proportion of patients with ASA score of ≥3 was significantly higher in the complication group than in the no-complication group ($P = 0.001$). The proportion of patients with preoperative diagnosis of acute cholecystitis was significantly higher in the complication group than in the no-complication group ($P = 0.02$). Specifically, wound infection was significantly more frequent in patients with acute cholecystitis (12 %, 6/52) than in those without acute cholecystitis (1 %, 3/308) ($P = 0.0004$).

We finally used multivariate stepwise regression analyses to identify risk factors for postoperative complications (Table 4). This analysis identified two significant risk factors, ASA score of ≥3 ($P = 0.0009$; adjusted $R^2 = 0.08$) and acute cholecystitis ($P = 0.04$; adjusted $R^2 = 0.11$), for the development of postoperative complications.

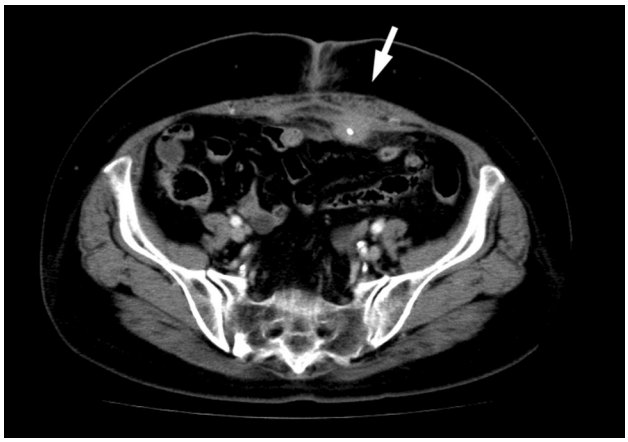

Fig. 1 Abdominal CT in a 69-year-old female patient undergoing SILC shows an intraabdominal abscess with a high-density component, suggestive of a spilled gallstone

Discussion

Since its first description in 1997 by Navarra et al. [1], SILC has emerged as a potentially less invasive alternative to standard LC. With rapid dissemination of this technique, a concern has raised for a propensity for its higher incidence of postoperative complications. Currently, limited information is available on postoperative complications in SILC. The aim of this study was to clarify the rate, features of, and risk factors for postoperative complications in a series of 360 patients undergoing SILC. In total, 17 patients (4.7 %) developed postoperative complications and reoperation was required in 5 patients (1.4 %). Overall inpatient mortality occurred in one patient (0.3 %). Multivariate analyses revealed poor physical status (ASA score of ≥3)

Table 3 Univariate analysis for postoperative complications in SILC between complication group and no-complication group

Factor	Complication group ($n = 17$)	No-complication group ($n = 343$)	P value
Age (≥75 years)	6 (35 %)	68 (20 %)	0.1302
Gender (M/F)	9/8	147/196	0.4584
BMI (Kg/m^2)	22.0 (13.8–38.4)	22.7 (14.8–46.6)	0.6161
ASA score (≥3)	5 (29 %)	14 (4 %)	0.0010*
Comorbid diseases (yes)	10 (59 %)	198 (58 %)	1.0000
Diabetes mellitus (yes)	5 (29 %)	58 (17 %)	0.1928
Prior abdominal surgery (yes)	6 (35 %)	118 (34 %)	1.0000
Prior upper abdominal surgery (yes)	1 (6 %)	14 (4 %)	0.5231
Acute cholecystitis (yes)	6 (35 %)	46 (13 %)	0.0238*
Operator (residents/senior staff)	5/12	135/208	0.4580
Operation time (minutes)	170 (55–324)	143 (55–533)	0.5534
Intraoperative blood loss (mL)	5 (5–350)	5 (5–60)	0.1995

Values shown are median (range)

* Statistically significant

Table 4 Multivariate stepwise regression analysis of risk factors for postoperative complications in SILC

Factor	*P* value	Adjusted R^2
Age (≥75 years)	0.39	0.13
Gender (Male)	0.58	0.15
BMI (Kg/m^2)	0.71	0.15
ASA score (≥3)	0.0009*	0.08
Comorbid diseases (yes)	0.22	0.12
Diabetes mellitus (yes)	0.38	0.13
Prior abdominal surgery (yes)	0.60	0.15
Prior upper abdominal surgery (yes)	0.87	0.15
Acute cholecystitis (yes)	0.04*	0.11
Operation time (minutes)	0.40	0.15
Intraoperative blood loss (mL)	0.49	0.14

Values shown are median (range)

* Statistically significant

and preoperative diagnosis of acute cholecystitis to be significant risk factors for the development of postoperative complications ($P = 0.0009$ and $P = 0.04$, respectively). To our knowledge, this is one of the largest series to date of SILC procedures with detailed analysis of postoperative complications and their risk factors.

The overall complication rate in this series (4.7 %) was comparable to or even lower than that reported in previous studies of SILC. For example, a multi-institutional report of the 297 SILC procedures described postoperative complications (including wound seromas, umbilical abscess, umbilical hematomas, ileus, and others) in 20 patients (6.7 %) [21]. In another study of SILC procedures performed in about 200 patients, 11 patients (5 %) developed surgery-related complications and 9 (4 %) of these required a reoperation [22]. According to a systemic review of 2,336 patients undergoing SILC reported in 49 studies, the overall median complication rate was 7.4 % [16]. However, because follow-up period after SILC was highly variable among reports and was relatively short (<1 year) in most studies, this figure may underestimate true complication rates. On the other hand, the higher complication rates reported in earlier studies may be related to the learning curve. Therefore, further studies of SILC performed by experienced hands with longer follow-up periods are necessary to determine the exact complication rate and profile. Although this series is the first 360 cases of SILC performed in our institution, there may be no effect of learning curve on the rate of postoperative complications because there is no difference in the rate between the early period (4.4 % in the first 180 cases) and late period (5.0 % in the last 180 cases).

Wound complication related to the transumbilical incision has been considered as a common complication specific for single-incision surgeries. In a prospective randomized study comparing SILC with conventional LC, Navarra et al. [23] found a higher incidence of umbilical hernia due to a larger umbilical incision. A large series of 1,145 transumbilical single-incision surgeries (including 388 SILC procedures) described the occurrence of incisional hernia in 16 (1.4 %) patients [24]. In this study, the incidence of umbilical incisional hernia was 0.6 %. Notably, the diagnosis of incisional hernia was made at 12 and 17 months after operation, suggesting a requirement for a longer follow-up period. Importantly, Weiss et al. [24] identified longer skin incisions as one of the risk factors for the development of wound complications after single-incision laparoscopic procedures.

Wound infection may be the most frequent complication of SILC, accounting for 2.5 % in this series. We also demonstrate that SILC for acute cholecystitis was highly associated with the development of wound infection; this complication was found in 6 (12 %) of 52 patients undergoing SILC for acute cholecystitis. This increased incidence of wound infection could be attributed to various factors, including the infective nature of the pathology and prolonged operative time. We performed SILC in recent cases with acute cholecystitis using a new protocol to prevent surgical site infection, including the routine use of wound protector, vinyl bag for gallbladder removal, and antibacterial sutures for fascial closure.

Bile duct injuries during conventional LC remain a major complication with a reported rate of 0.4–0.5 % [25, 26]. In this study, the rate of bile duct injuries was 0.56 %, which is comparable to the rate reported in conventional LC. A previous study reviewing complications in 45 studies of SILC showed a higher rate (0.72 %) of bile duct injuries [15]. In an attempt to prevent bile duct injuries during SILC, we applied two techniques, CVS technique and IOC [19]. Retrospectively, in one of the two patients with bile duct injuries, IOC was not performed because of a suspicion of gallbladder cancer (in which spilled bile from the puncture site may cause cancer dissemination). In another patient, CVS was not obtained due to poor surgical view. Therefore, these cases highlight the importance of both CVS and IOC to minimize the risk of bile duct injuries during SILC. Alternatively, further improvement in the strategies to prevent bile duct injuries (e.g., near-infrared fluorescent cholangiography [27]) during SILC is necessary.

One major concern raised against the present results is a relatively longer stay (a median of 5 days) after SILC, although this is a normal practice in our institution. In general, the length of stay is longer in Japan as compared to other Western countries, primarily due to the differences in the health insurance systems. Efforts are currently being made to shorten the length of stay and reduce the cost of

medical care, for example, by introducing clinical pathways and day surgery for SILC.

In summary, we reviewed our series of 360 SILC procedures to elucidate the rate and risk factors for this procedure. Our results suggest that SILC is a relatively safe procedure with an acceptable postoperative complication rate but requires careful attention especially in patients with poor physical status and/or acute cholecystitis.

Disclosures Norihiro Sato, Kazunori Shibao, Yasuhisa Mori, Aiichiro Higure, and Koji Yamaguchi have no conflicts of interest or financial ties to disclose.

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