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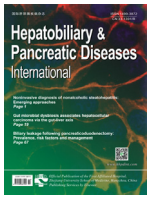

Original Article/Biliary

Feasibility and safety of single-incision laparoscopic cholecystectomy versus conventional laparoscopic cholecystectomy in an ambulatory setting

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ABSTRACT

Background: Single-incision laparoscopic surgery has emerged as an alternative to conventional laparoscopic cholecystectomy (LC) in the clinical setting. Limited information is available on the possibility of performing single-incision laparoscopic surgery as an ambulatory procedure. This study aimed to determine the feasibility and safety of single-incision laparoscopic cholecystectomy (SILC) versus conventional LC in an ambulatory setting.

Methods: Ninety-one patients were randomized to SILC ($n=49$) or LC ($n=42$). The success rate, operative duration, blood loss, hospital stay, gallbladder perforation, drainage, delayed discharge, readmission, total cost, complications, pain score, vomiting, and cosmetic satisfaction of the two groups were then compared.

Results: There were significant differences in the operative time (46.89 ± 10.03 min in SILC vs. 37.24 ± 10.23 min in LC; $P < 0.001$). As compared with LC, SILC was associated with lower total costs (8012.28 ± 752.67 RMB vs. 10258.91 ± 1087.63 RMB; $P < 0.001$) and better cosmetic satisfaction (4.94 ± 0.24 vs. 4.74 ± 0.54; $P=0.031$). There were no significant differences between-group in terms of general data, success rate, blood loss, hospital stay, gallbladder perforation, drainage, delayed discharge, readmission, complications, pain score, and vomiting ($P > 0.05$).

Conclusions: Ambulatory SILC is safe and feasible for selected patients. The advantages of SILC as compared with LC are improved cosmetic satisfaction and lower total costs.

Introduction

Laparoscopic cholecystectomy (LC) was introduced in the 1980s [1]. The advent of LC ushered in an era of minimally invasive surgical treatment for cholelithiasis (gallstones). LC is now considered the gold standard for the treatment of gallstones. In 1997, the drive to achieve less invasiveness and faster recovery precipitated the emergence of single-incision laparoscopic cholecystectomy (SILC) [2]. Previous studies have shown that SILC is a safe and feasible procedure as compared with conventional LC (in short, LC) [3–5]. The suggested benefits of SILC over LC include better cosmetic satisfaction, less postoperative pain, and faster recovery [6]. SILC has aroused great enthusiasm of surgeons worldwide.

Ambulatory LC was initially reported in the 1990s [7]. In recent years, numerous studies have documented the feasibility, safety, and cost-effectiveness of ambulatory LC in selected patients, with a high level of patient satisfaction [7–9]. LC is now routinely performed in an ambulatory setting. Limited information is available on the possibility of performing SILC as an ambulatory procedure. Thus, the aim of this study was to evaluate the feasibility and safety of SILC in comparison with LC in an ambulatory setting.

Methods

Study design

This study protocol was approved by Ethics Committee of Renji Hospital, School of Medicine, Shanghai Jiao Tong University, and conducted between December 2013 and January 2015. The inclusion criteria were as follows: gallbladder polyps $\geq$ 1 cm, symptomatic gallbladder stones without an acute attack in the last month, age older than 18 years and younger than 65 years, American Society of Anesthesiology (ASA) grade I or II, a body mass index (BMI) of $< 30\ kg/m^2$, accompanied by a responsible adult, contactable by telephone/cell phone, and living within an hour's

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drive from the hospital. The exclusion criteria were as follows: atrophic cholecystitis, acute cholecystitis, an intrahepatic gallbladder, previous abdominal surgery, and chronic diseases, including severe diabetes, hypertension, coronary artery disease, and chronic pulmonary disease. The allocation of the patients to the SILC or LC group was done using a computer-generated randomization list, and written informed consent was obtained from all the patients or their relatives.

Study procedure

Preoperative preparation

All the patients underwent the following preoperative investigations in the outpatient department 1 week before surgery: a complete blood count, liver and renal function tests, blood electrolyte tests, fasting blood glucose tests, coagulation profile tests, electrocardiography, and chest X-rays. All the patients were admitted on the day of the surgery after a 12-h fast. An intravenous prophylactic antibiotic (1 g of cefotiam) was given 30 min before making the surgical skin incision.

Surgical procedure

The same surgical team performed all the operations under general anesthesia. In the single-incision approach, a 2-cm, semicircular umbilical incision was made, and a single port trocar with three instrument channels (Kangji Medical Instruments Co., Ltd., Hangzhou, China) was introduced via the umbilical incision. The patient was placed in the reverse Trendelenburg position, with their left side tilted downward. A pneumoperitoneum was created with 12 mmHg of insufflation pressure. An endoscope and two working instruments were inserted through the channels. A harmonic scalpel was first used to dissect the triangle of Calot clearly. After skeletoming of the cystic duct and artery and ligating them with a Hem-o-lok, the gallbladder was removed from the gallbladder fossa using an electronic hook (Kangji Medical Instruments Co., Ltd.) and extracted through the umbilical incision. The umbilical incision was closed with a 1–0 absorbable suture.

The LC was performed using a standardized three- or four-port technique. A 10-mm umbilical trocar (Kangji Medical Instruments Co., Ltd.) was inserted, and a pneumoperitoneum was created. One 5-mm right subcostal at the midclavicular line and one 10-mm subxiphoid trocar (Kangji Medical Instruments Co., Ltd.) were inserted under direct vision. An additional 5-mm trocar (Kangji Medical Instruments Co., Ltd.) was inserted in the anterior axillary line, depending on the intraoperative conditions. The surgical procedure is similar to that of SILC. A subhepatic drain was placed through the lateral port in cases of severe inflammation or exudation, and it was removed on the first postoperative day routinely.

Postoperative treatment

Postoperative care consisted of intravenous antibiotics, antiemetics, and analgesia (1 g of cefotiam plus 5 mg of ondansetron plus 100 mg of tramadol). All the patients were discharged the next morning if they were free from pain, bleeding, nausea or vomiting, and able to consume a semi-liquid diet. Patients who presented with a fever (a temperature of more than 38.5 °C), significant abdominal pain, and jaundice 7 days after discharge met the criteria for readmission.

Endpoints

The primary endpoint was the success rate. The secondary endpoints included the operative time, the amounts of blood loss, duration of hospital stay, gallbladder perforation rate, drainage rate, complications, delayed discharge rate, readmission rate, total cost, pain score, vomiting rate, and cosmetic satisfaction.

Table 1
General data on the patients.

Characteristics	SILC ($n=49$)	LC ($n=42$)	P value
Age (yr)	44.63 ± 10.19	48.62 ± 8.88	0.052
Sex (male/female)	20/29	21/21	0.380
BMI (kg/m^2)	23.02 ± 2.60	23.74 ± 2.66	0.205
Calculi	40 (81.6%)	39 (92.9%)	0.134
Polyp	11 (22.4%)	7 (16.7%)	0.601

SILC: single-incision laparoscopic cholecystectomy; LC: laparoscopic cholecystectomy; BMI: body mass index.

Postoperative pain was evaluated according to a visual analogue scale (VAS) from 0 (no pain) to 10 (maximum pain) 6 h after the operation, combined with a numeric rating scale (NRS) on postoperative days 1, 2, and 3. All the patients took part in a telephone interview, which was administered by a nurse, on days 1, 2, and 3 after discharge until fully recovered. The incidence of incisional hernias and cosmetic satisfaction were evaluated 3 months later in a follow-up visit, with cosmetic satisfaction evaluated on a scale from 1 (worst) to 5 (best).

Statistical analysis

Statistical analysis was conducted using the SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). The Chi-squared test or Student's t-test was used as indicated. Quantitative variables were presented as the mean ± standard deviation (SD). Categorical data were presented by frequencies and percentage. All P values were two-sided. A P value of < 0.05 was considered statistically significant.

Results

From December 2013 to January 2015, 91 patients with gallbladder stones or polyps diagnosed by ultrasonography were enrolled in the study and randomized to the SILC ($n=49$) or LC ($n=42$) groups. General data on the patients and their clinical outcomes are summarized in Tables 1 and 2. There were no significant differences in the age, sex, BMI, calculi ratio, or polyp ratio of the SILC and LC groups.

The success rate was similar in the SILC and LC groups (95.92% vs. 100%, $P=0.497$). There were no conversions to laparotomy. Two SILC procedures converted to conventional LC. In one of these cases, the anatomy of Calot's triangle was difficult due to chronic inflammation. In the other case, the patient had swelling of the gallbladder, which was filled with purulent material. The two conversions were excluded from the data in the following clinical outcomes. The operative time in the SILC group was significantly longer than that in the LC group (46.89 ± 10.03 min vs. 37.24 ± 10.23 min, $P < 0.001$). There were no significant differences between-group in intraoperative blood loss (8.53 ± 8.44 mL vs. 7.69 ± 4.71 mL, $P=0.569$), hospital stays (1.02 ± 0.14 days vs. 1.16 ± 0.92 days, $P=0.290$), intraoperative gallbladder perforation rate (10.64% vs. 2.38%, $P=0.207$), and delayed discharge rate (2.38% vs. 2.38%, $P=1.000$). One patient required placement of a drainage tube due to intraoperative gallbladder perforation and extensive exudation in the LC group. No patients in either group were readmitted after discharge from the hospital. There were no instances of biliary injury, bile leakage, bleeding, incisional hernias, or intra-abdominal infections in either group. Only one patient in the SILC group had an umbilical incision infection. The total cost in the SILC group was significantly lower than that in the LC group (8012.28 ± 752.67 RMB vs. 10258.91 ± 1087.63 RMB, $P <0.001$). The differences in the VAS 6 h after the procedures and the NRS on postoperative days 1, 2, and 3 were not significant (Table 2). None of the patients in either group experienced vomiting in the first 24 h

Table 2
Clinical outcomes of the patients following SILC and LC.

Clinical outcomes	SILC ($n=47$)	LC ($n=42$)	P value
Operative time (min, mean ± SD)	46.89 ± 10.03	37.24 ± 10.23	**<0.001**
Intraoperative blood loss (mL)	8.53 ± 8.44	7.69 ± 4.71	0.569
Hospital stay (d)	1.02 ± 0.14	1.16 ± 0.92	0.290
Intraoperative gallbladder perforation	5 (10.64%)	1 (2.38%)	0.207
Drainage	0	1 (2.38%)	0.472
Delayed discharge	1 (2.38%)	1 (2.38%)	1.000
Readmission	0	0	NA
Total cost (RMB)	8012.28 ± 752.67	10,258.91 ± 1087.63	**<0.001**
Postoperative pain score			
6 h	3.33 ± 1.91	3.80 ± 2.28	0.193
Day 1	2.12 ± 1.58	2.58 ± 1.80	0.301
Day 2	1.48 ± 1.10	1.89 ± 1.43	0.126
Day 3	1.18 ± 0.91	1.57 ± 1.24	0.088
Postoperative vomiting	0	0	NA
Cosmetic satisfaction	4.94 ± 0.24	4.74 ± 0.54	**0.031**

SILC: single-incision laparoscopic cholecystectomy; LC: laparoscopic cholecystectomy; SD: standard deviation; NA: not available.

after surgery. Cosmetic satisfaction was significantly higher in the SILC group as compared with that in the LC group (4.94 ± 0.24 vs. 4.74 ± 0.54, $P=0.031$).

Discussion

With improvements in surgical instruments, evolution of anesthetic techniques, and transformation of nursing concepts, ambulatory surgery tends to be widely carried out by surgeons and accepted by patients. SILC is an emerging technique, which is associated with reduced pain and better cosmetic outcomes, and it has become an alternative to traditional LC. However, the safety and feasibility of SILC in an ambulatory setting remain undetermined due to limited experience and reports. This prospective randomized study was conducted to evaluate the possibility of performing SILC in an ambulatory setting.

The success rate is the most important factor when assessing feasibility. In the present study, the success rate of SILC and LC was 95.92% and 100%, respectively, with no significant difference. In the SILC group, only two patients required conversion to conventional LC. No patient in either group required conversion to laparotomy. In our experience, the high success rate in both groups can be attributed to strict adherence to the selection criteria. Patients with acute cholecystitis were excluded from this study. As reported previously, there is a greater need for additional ports in acute cholecystitis surgery and a higher conversion rate [10,11].

In this study, the operative time of SILC was significantly longer than that of LC, which is in agreement with the findings of most previous studies [4,12]. Lack of triangulation, instrument collisions, and restricted viewing make SILC more challenging than conventional LC [12,13]. Proficiency in this novel technique also involves a learning curve. According to previous data, the SILC learning curve required 10–25 cases [3,14–16]. In a study of 150 SILC procedures undertaken by five surgeons, the average learning curve for each surgeon was 8.5 cases [17]. After 25 cases, the surgeon could consistently complete the SILC procedure successfully [18]. Thus, a reduction in the incidence of conversion to LC could be expected after the first 10 cases of SILC. In our experience, a learning curve of 20 cases was required before the learning plateau was reached. In a previous study, the operative time was significantly reduced after completion of 75 SILC procedures by a single surgeon [16]. Potentially, with the addition of more patients to the study, the operative time of SILC would have been further shortened.

Bile duct injury is a serious complication of a cholecystectomy, and it is associated with significant morbidity and mortality. When LC was first adopted, it was associated with an increased incidence of bile duct injury. The same situation may occur in SILC. A recent review of the literature revealed that the incidence of bile duct injury in SILC was 0.72%, whereas the accepted historic rate of bile duct injury during standard LC was 0.4% to 0.5% [19]. In this study, we did not observe any incidence of bile duct injury. The extensive experience and proficient skill of the surgical team in LC, together with the strict patient selection, likely prevented bile duct injury.

Gallbladder perforation is one of the most common intraoperative complications during a cholecystectomy, with an incidence of 11%–20% [20]. In this study, SILC was associated with a nonsignificant trend toward an increased rate of gallbladder perforation as compared with LC (10.64% vs. 2.38%). We consider that lack of experience resulted in the higher gallbladder perforation rate in SILC because of the technically difficult nature of the procedure and the learning curve. According to a recent meta-analysis of 34 randomized controlled trials, the incidence of gallbladder perforation was 4.0% in an SILC group versus 4.4% in an LC group, with no significant difference [21]. This finding indicates that the frequency of gallbladder perforation may decrease in accordance with an increase in the surgeon's experience. Recent studies demonstrated that gallbladder perforations did not increase the complication risk, reoperations, hospital stays, or postoperative pain, although they increased the operative time [22-25]. The findings of the present study were in accordance with those in the literature. A previous study reported that spillage of bile or gallstones due to gallbladder perforation can lead to postoperative complications [26]. In our opinion, considering the safety of patients, intraoperative gallbladder perforation should be avoided as much as possible. In the case of this event, the spilled stones should be retrieved whenever possible, and the abdominal cavity should be abundantly irrigated to minimize possible adverse outcomes.

An incisional hernia is another postoperative complication of SILC. In a review of the current literature, SILC was associated with a nonstatistically significant trend toward an increase in the rate of incisional hernias as compared with LC (1.43% vs. 0.32%) [27]. The enlarged umbilical incision performed in SILC likely increases the risk of incisional hernias [28]. No incisional hernias occurred in our study during a mean follow-up period of 7 months (range: 1–14 months). However, this follow-up period was short, and the actual incidence may be underestimated. In our experience, an appropriate incisional length, preoperative exclusion of intra-abdominal hypertension, careful closure of the peritoneum and fascia, and prevention of postoperative incision infection can effectively reduce the incidence of incisional hernias.

Postoperative pain is an important factor related to patient satisfaction and may affect the recovery of the patient. Many studies

have investigated postoperative pain following SILC and LC, with contradictory results. Tsimoyiannis et al. [29] reported statistically lower postoperative pain scores and requests less analgesics in an SILC group, especially after the first 12 h postoperatively, whereas Brown et al. [30] found no significant difference in postoperative pain scores or postoperative narcotic use between the SILC and LC groups. Ma et al. [31] reported a relatively higher postoperative pain score in an SILC group as compared with that in an LC group, but there was no significant difference. The present study did not detect a significant difference in the VAS postoperative 6 h or the NRS on postoperative days 1, 2, and 3.

SILC was developed with the aims of obtaining scar-free surgery and improving cosmetic satisfaction. The umbilicus is considered a natural scar and a standard site for access to the abdominal cavity for laparoscopy. As the umbilicus is the only incision in SILC, careful reconstruction can lead to an invisible scar. In many studies, satisfaction with cosmetic outcomes was significantly better in SILC patients than in LC patients [6,32–34], although one study failed to detect any difference in terms of this parameter in SILC- and LC-treated patients [35]. Our results were consistent with the majority of studies in the literature, and showed that SILC was superior to conventional LC in terms of the cosmetic outcome. However, it should be pointed out that cosmetic satisfaction is subjective and thus might be inaccurate. The use of a validated objective scale for the assessment of patient satisfaction with the cosmetic outcome will be explored in future research.

In terms of the total cost, it was significantly lower with SILC than with LC. In this study, disposable trocars were used in the LC group, whereas free charges and reusable single incision three-port trocars were used in the SILC group. With the popularity of single-incision laparoscopic surgery and the advancement of single-incision instruments, increased costs are likely due to the widespread use of disposable trocars. In this respect, Tranchart et al. [36] and Chang et al. [37] found that the costs were slightly higher in an SILC group as compared with those in an LC group. However, for now, ambulatory SILC can play a role in limiting hospital costs, which is in line with healthcare reform.

We found no statistically significant difference in delayed discharge rates, duration of hospital stays, and readmission rates (no patients were readmitted). In our experience, ambulatory surgical procedures require a precise and comprehensive preoperative assessment, in addition to a timely and effective postoperative evaluation. Prompt treatment and evaluation of the need for delayed discharge are necessary in patients with signs or symptoms following surgery. It is inadvisable to pursue “ambulatory surgery” blindly, regardless of the patient’s safety.

The present study has some limitations. First, this was a single-center study, with no blinded arm. Second, the number of patients was relatively small. To better determine the validity of ambulatory SILC, a multicenter, larger scale, prospective randomized clinical trial, with a longer follow-up period should be performed in the future.

In conclusion, the results demonstrated that ambulatory SILC is a feasible and safe procedure. SILC may be superior to conventional LC in terms of the cosmetic satisfaction and total cost but not in terms of operative durations. Strict selection of patients is fundamental to achieve a high success rate.

Contributors

XC and LKW designed the trial. QJW and XC collected and analyzed the data. QJW wrote this manuscript. QJW and YZQ revised the paper. All authors contributed to the surgical procedures of the study. QJW and XC contributed equally to this work. LKW is the guarantor.

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Ethical approval

This study protocol was approved by Ethics Committee of Renji Hospital, School of Medicine, Shanghai Jiao Tong University.

Competing interest

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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