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Single-Port Laparoscopic Cholecystectomy for Gall Bladder Polyps

Chan Joong Choi, MD, Young Hoon Roh, MD, PhD, Min Chan Kim, MD, PhD, Hong Jo Choi, MD, PhD, Young Hoon Kim, MD, PhD, Ghap Joong Jung, MD, PhD

ABSTRACT

Background and Objectives: Single-port laparoscopic cholecystectomy (SPLC) was introduced to improve patients' postoperative quality of life and cosmesis over the conventional approach (CLC). The purpose of this case–control study was to compare the outcome of SPLC with that of CLC in a specific disease: gall bladder (GB) polyps.

Methods: Eligible for the study were all patients with GB polyps who underwent laparoscopic cholecystectomy between June 1, 2009, and June 30, 2011. The 112 patients studied (56 each for SPLC and CLC) were matched by using a propensity score that included gender, age, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of previous abdominal operation, and pathology outcome. To avoid selection bias caused by the surgeon's choice (often dependent on the degree of inflammation) and to investigate the efficacy of SPLC for a single disease, GB polyps, we excluded patients with acute or chronic cholecystitis.

Results: Characteristics of the patients matched by a propensity score between SPLC and CLC showed no significant difference. Incidentally detected malignancy was in postoperative pathology in cases in both groups. Although operative time was shorter for SPLC, there was no significant difference in time between the 2 groups. There were 3 open conversions in the CLC group, and an additional port was used in the SPLC group. There was no difference between the groups in hospital stay and postoperative complications.

Conclusion: In the management of GB polyps, the operative results of SPLC are comparable to those of CLC. We conclude that SPLC is as safe as CLC and has the potential for greater cosmetic satisfaction for patients than CLC. Further trials for objective appraisal of cosmetic outcomes are needed.

Key Words: Gallbladder polyp, Single-port laparoscopy, Case-control study.

INTRODUCTION

For benign diseases of the gall bladder (GB), laparoscopic cholecystectomy has been established as the gold standard and is preferred over open cholecystectomy.[1] As patient demand has increased for improved postoperative quality of life and cosmesis, surgeons have continued to decrease the number of ports for laparoscopic cholecystectomy. To meet these expectations, single-port laparoscopic cholecystectomy (SPLC) was introduced in 1997, followed by the more recent introduction of natural-orifice transluminal endoscopic surgery (NOTES).[2–5] However, NOTES presents difficulty in obtaining a sterile site of intra-abdominal entry to prevent intra-abdominal spillage and lacks a single effective closure technique, since hollow viscous organs cannot be fully avoided. As such, NOTES has not been accepted as a formal surgical technique in many countries. We have reviewed many early studies for SPLC, but most of these were not randomized, comparative, or disease specific. Recently, randomized controlled trials with meta-analysis have been reported for benign GB disorders.[6,7] However, these studies were not disease specific and excluded GB polyps, which have a risk of malignancy but a lesser inflammatory tendency. In the management of GB polyps, the findings on SPLC studies cannot be generalized, because GB polyps may have a different clinical course from that of acute cholecystitis, with or without GB stones, and most were performed for the study of cholecystitis or symptomatic gallstones.

We reviewed other studies for single-incision laparoscopic cholecystectomy during the design of our study. Most prior studies were focused on the operation itself and neglected the differences between acute cholecystitis

Department of Surgery, Dong-A University College of Medicine, Busan, South Korea (all authors).

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Address correspondence to: Young Hoon Roh, MD, PhD, Department of Surgery, Dong-A University College of Medicine, 1, 3-ga, Dongdaesin-dong, Seo-gu, Busan 602-714, South Korea. Telephone: +8251-240-5147, Fax: +8251-247-9316, E-mail: gsryh@dau.ac.kr

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and noninflammatory GB polyps. The inflammation that was detected in preoperative imaging can cause selection bias by surgeons who may choose an approach according to the degree of inflammation. We focused on a single disease, GB polyps, which is mostly noninflammatory but has the potential for malignancy. We made an effort to avoid selection bias by using a case–control design.

Although we wanted to investigate the efficacy of SPLC for a specific disease, GB polyps, we excluded cases of polyps in the setting of acute or chronic cholecystitis, to avoid the aforementioned selection bias. The purpose of this study was to compare safety and efficacy between SPLC and CLC for GB polyps in a case–control design. We hope that this study will provide guidance in selecting the surgical treatment for this disease. The Institutional Review Board of our center approved this trial.

MATERIALS AND METHODS

Patient Selection Criteria

Between June 1, 2009, and June 30, 2011, 173 patients received a diagnosis of GB polyps, and their records were analyzed retrospectively for this study. Surgical indications were for GB polyps >1 cm or increasing in size (even if <1 cm) on follow-up computed tomography (CT), abdominal ultrasonography (US), or both. Of the 173 patients, 92 underwent conventional laparoscopic cholecystectomy (CLC) with 3 ports; the remaining 81 patients underwent SPLC. Among those, 112 patients (56 patients each for SPLC and CLC) were selected and matched by using a propensity score, which included gender, age, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of previous abdominal operation, and pathologic outcome for case–control design. All of the operations were performed by a single surgeon. The mean postoperative follow-up period was 27 months (range, 15–39).

Surgical Technique

Both types of operations were performed in patients under general anesthesia. Before June 2010, patients were placed in the lithotomy position, with the operator standing at 6 o'clock. The first assistant manipulated the table scope from the left side of patient, and the second assistant was positioned to the right. Since June 2010, we have used the supine position, with the primary operator and first assistant to the patient's left.

The SPLC was performed through a 25-mm transumbilical incision. The instruments were introduced, either through a combination of the Alexis Wound Retractor (Applied Medical, Rancho Santa Margarita, CA) and a surgical glove, or through a commercial multichannel port. CLC was usually performed with 3 trocars, with the camera port at the umbilicus and the remaining 2 ports for trocars used for instrument triangulation. The primary operator had been accustomed to conventional straight laparoscopic instruments, and although flexible instruments for dissection and traction were used early in the SPLC procedure, we generally used hook instruments, rather than flexible ones. Hem-o-Lok clips (Weck Surgical Instruments; Teleflex Medical, Durham, North Carolina) of 10- and 5-mm size were used for ligation of dissected cystic duct and cystic artery, respectively. In both SPLC and CLC, upon dissection from the liver bed, the GB was removed directly through the umbilical port site without the use of a catch bag.

Outcomes of Interest

We analyzed operative time, length of hospital stay, number of complications, bile spillage during operation, intraoperative conversions (SPLC-to-CLC and CLC-to-open cholecystectomy), and verbal pain score (VPS) from 12 h after the operation through day 5. Observed differences were subjected to statistical analysis with Student's t test and the 2-sided Fisher exact test. Null hypotheses of no difference were rejected at $P < 0.05$. Data were analyzed with SPSS 17.0 statistical software (SPSS Inc., Chicago, Illinois).

RESULTS

Comparisons of Patient Characteristics

There was no significant difference in gender, mean age, preoperative BMI, ASA score, operative history, or postoperative pathology between the 2 matched groups (**Table 1**). Eleven obstetrics–gynecology procedures such as Cesarean section and hysterectomy in the SPLC group and 10 in the CLC group were included in the patients' operative histories.

Comparisons of Postoperative Results

There was 1 appendectomy in the SPLC group and 1 colon operation in the CLC group in conjunction with cholecystectomy. The operative time mentioned in **Table 2** was calculated after subtraction of the time consumed by the

Table 1.
Comparison of Patient Characteristics

Characteristics	Total, n (%)	SPLC, n (%)	CLC, n (%)	*P*
All patients	112 (100)	56 (50.0)	56 (50.0)	
Gender				0.85
Male	63 (56.3)	32 (57.1)	31 (55.4)	
Female	49 (43.8)	24 (42.9)	25 (44.6)	
Age, years		50.2 ± 12.0	49.5 ± 9.9	0.16
BMI		23.6 ± 2.5	23.8 ± 2.8	0.39
ASA score				0.52
1	32 (28.6)	14 (25.0)	18 (32.1)	
2	70 (62.5)	37 (66.1)	33 (58.9)	
3	10 (8.9)	5 (8.9)	5 (8.9)	
Operative history				0.83
Yes	29 (25.9)	14 (25.0)	15 (26.8)	
No	83 (74.1)	42 (75.0)	41 (73.2)	
Biopsy				0.34
Benign	110 (98.2)	55 (982)	55 (98.2)	
Malignant	2 (1.8)	1 (1.8)	1 (1.8)	

second surgery. Although there was no significant difference between the 2 groups, the mean operative time in the SPLC group was shorter than that in the CLC group.

Bile spillage occurred in 7 cases in the SPLC group and in 6 in the CLC group. Three open conversions were necessary in the CLC group. One open conversion was prompted by severe GB inflammation caused by gallstones that had not been identified in preoperative imaging. Another conversion was caused by severe adhesion of the GB to the surrounding bowel as a result of a prior abdominal procedure. In the third case, an open conversion with radical cholecystectomy was necessary because an intraoperative frozen section revealed malignancy. In the SPLC group, no open conversions were necessary, but there were 10 cases in which additional ports were used. Among these cases, 7 required 1 additional port, with the remaining 3 cases requiring 2. In one case in the SPLC group, frozen biopsy revealed malignant tissue, but was limited to the mucosa. As such, radical cholecystectomy was not strongly indicated and was not performed.

There were 2 cases of postoperative complications in the SPLC group and 1 in the CLC group ($P > .05$). All 3 of these complications were (superficial) wound infections that were managed with antibiotics and wound dressing without further adverse events. No biliary complications (eg, common bile duct injury, cystic duct leakage, or retained stones) were observed in either group. On final pathologic reports, polyp sizes were not significantly different between the groups (SPLC, 0.98; CLC, 1.06 mm).

Postoperative pain was measured on the VPS for 5 days after surgery. Patients were usually discharged home after 2 days, and the remaining days of VPS were reported in the outpatient clinic during the postoperative follow-up visit. The VPS declined, with similar patterns in the 2 groups and no significant differences (**Figure 1**). Cosmetic outcomes were compared on postoperative day 1 and were considered to be superior in the SPLC group (**Figure 2**).

DISCUSSION

In this study, we selected GB polyps for an evaluation of the outcomes between 2 minimally invasive techniques of cholecystectomy. We needed a disease-specific outcome, because it would have been difficult to assess differences in postoperative pain in cases of acute cholecystitis with severe inflammation. Preventing GB perforation during a procedure is of major importance, to avoid the possibility of cancer cell spreading. No special techniques were used except meticulous control of bleeding and gentle removal of the GB to avoid perforation. Having an experienced laparoscopist was most helpful. We excluded GB polyps that showed a high risk of malignancy in the preoperative evaluation. Therefore, all malignancies were detected by pathology after surgery. We included pseudopolyps in the benign pathology group. Our data may contain many cholesterol polyps (generally, two-thirds of all polyps) that often dissolved before pathologic examination, although they resembled true polyps on preoperative imaging. Therefore, we did not divide the benign pathologies into more detailed categories. Pathologic findings and treatment modalities are subjects for another trial. If a GB polyp was large (>1 cm (without other risk factors, such as infiltration or metastatic lymph nodes), we performed a cholecystectomy (single- or multiple-incision) as usual, with more care taken to avoid perforating the GB. If a malignancy that invaded the submucosal layer or deeper was detected on frozen biopsy, we continued the operation radically. Fortunately, there was no case of perforation with a malignant GB polyp. We demonstrated in our previous study that the GB perforation rates were not different between the single-incision and conventional 3-port laparoscopic cholecystectomy.[3]

Table 2.
Comparison of Postoperative Results

Outcome	Total, n (%)	SPLC, n (%)	CLC, n (%)	*P*
Operation time, minutes		49.1 ± 20.3	52.7 ± 43.1	0.93
Bile spillage during operation				0.76
Yes	13 (11.6)	7 (12.5)	6 (10.7)	
No	99 (88.4)	49 (87.5)	50 (89.3)	
Open conversion				–
Yes	3 (2.7)	0 (0)	3 (5.4)	
No	107 (95.5)	56 (100)	51 (91.1)	
Use of additional port				–
Yes	10 (8.9)	10 (17.9)	0 (0)	
No	102 (91.1)	46 (82.1)	56 (100)	
Hospital stay, days		2.1 ± 1.5	2.2 ± 1.6	0.81
Postoperative complication				0.56
Yes	3 (2.7)	2 (3.6)	1 (1.8)	
No	109 (97.3)	54 (96.4)	55 (98.2)	
Polyp size, mm[a]		0.98 ± 12	1.06 ± 17	0.62

Data are presented as the mean ± SD or number (percentage).
[a]Polyp sizes measured by pathologic findings.

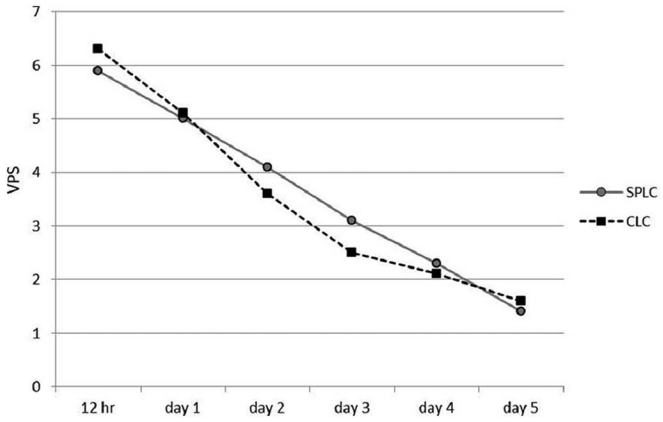

Figure 1. Comparison of postoperative VPS scores.

Among the 112 cases of GB polyps reviewed, 2 proved to involve malignancy. This result is significantly lower than those in previous studies. In a study of 100 patients with GB polyps, Terzi et al[8] reported the prevalence of malignancy to be 26%. Kubota et al[9] reported the rate to be 22% among 72 patients in a similar study. In South Korea, Park et al[10] reported a prevalence of just 3.6% in a study of 689 Korean patients with GB polyp. During the 2-year period under review, the primary surgeon had used SPLC and CLC in 173 cases of gallbladder polyps, of which 7 were found to be GB cancer (4.05%). Only 2 of those cases were included in the review, according to case–control criteria.

Although Shinkai et al[11] suggested aggressive surgical approaches for small gallbladder polyps, current indications for cholecystectomy are made for GB polyps >1 cm in size.[12,13] At our institution, we perform cholecystectomy for GB polyps if a given polyp is >1 cm, or if a polyp <1 cm increases in size during repeated follow-up studies. In this study, GB size from preoperative abdominal CT or US was 1.18 ± 0.37 cm in the SPLC group and 1.24 ± 0.47 cm in the CLC group, with the smallest GB polyp at 0.8 cm.

Although the difference was not significant, the operative time in the SPLC group was shorter than that in the CLC group. Among the causes of the shorter time in the SPLC group could be that the group included 3 cases of open conversion which may have increased the operative time. SPLC cases represented the early experience of the surgeon, but CLC had been performed in 1500 prior cases. We considered bile spillage to be a factor that reflects the quality of the operation. Because GB perforation can release malignant cells and seed the peritoneum, precautions were taken to avoid such an adverse event. There were 7 (12.5%) and 6 (10.7%) cases of intra-abdominal

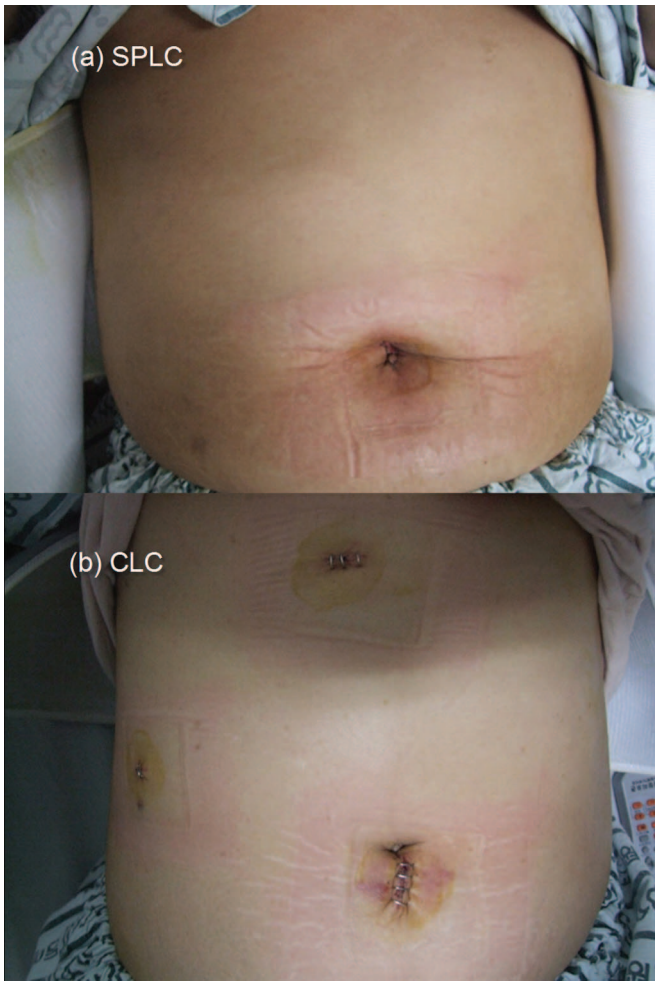

Figure 2. Comparison of postoperative cosmetic outcomes.

bile spillage in the SPLC and CLC groups, respectively. The intergroup difference in spillage occurrence was not significant, and operative quality did not differ significantly between the 2 groups. In the 2 cases of malignancy, bile spillage did not occurr. This outcome is in contrast to a study by Madureira et al,[14] who reported a higher rate of GB perforation during SPLC than during CLC (SPLC, 15.69%; CLC, 5.88%).

In 10 of our SPLC cases, we used additional ports; 7 cases needed 1 additional port. The causes included severe adhesion caused by past abdominal operations, inability to sufficiently and safely dissect Calot's triangle, and bleeding of the cystic artery during dissection. In addition, 3 cases required 2 additional ports because of technical difficulties (instrumental clash), and these represented events in the early experience of the primary operator with SPLC. The intraoperator difference in the single surgeon between the 2 groups may have resulted in variations in operative times, but there were no significant differences. A previous study showed that 30 cases of SPLC represents the learning curve[15]; this finding has been substantiated in another study of similar nature.[16] In addition, there is a report that the learning curve could be as low as 8 cases.[17] Despite these findings on technical requirements, we recommend that an early decision to use additional ports is necessary to avoid serious complications when technical difficulties arise during SPLC.[18]

There were only 3 cases with complications (wound infections) within the 27 months of the median follow-up period. Because there were no significant differences between the groups, these were considered to be general complications, not limited to SPLC or CLC. Alptekin et al[19] and Hall et al[20] have reported that SPLC is associated with more complications, such as incisional hernia, when compared to CLC. Vilallonga et al[7] and Karim et al[21] have demonstrated that complication rates were not different between the 2 techniques. In a meta-analysis, Fransen et al[22] reviewed 38 articles regarding complications of SPLC. They reported that major complications (eg, retained stones requiring endoscopic retrograde cholangiopancreatography, readmission due to pain, and bile duct lesions) and minor complications (eg, seroma and subumbilical hematoma) were relatively more common after SPLC. In our study, no major complications occurred during the study period.

Chang et al[23] and Asakuma et al[24] reported that SPLC is superior to CLC in postoperative pain, whereas Hall et al[20] and Han et al[25] reported contradictory findings. In our study, there was no significant difference in postoperative pain, as measured by VPS. It is plausible that traction by multiple laparoscopic instruments at the single port used in SPLC would cause as much pain as that induced by the multiple incisions in CLC. In laparoscopic operations, traction of the GB is essential. Insufficient traction is associated with many complications and also with GB perforation. In SPLC, sufficient traction for a good view of the operative field is more difficult than in CLC. For good a view of the field, Noguera et al[26] and Joseph et al[27] used a flexible endoscope or special instruments that incorporate magnetic anchoring and guidance systems. These specialized instruments can be useful in operations within limited intra-abdominal space in smaller patients or children.[28] In the first 30 cases of SPLC in our study, articulating laparoscopic instruments were used, but standard laparoscopic instruments were used after the completion of the learning curve, with the exception of the flexible hook instrument.

For patients in need of cholecystectomy, a satisfactory cosmetic outcome is perhaps the most desirable factor.[29,30] Patients wish to have smaller, or invisible, incisional scars, but the severity of scaring is difficult to quantify. In the present study, the incisional scars after SPLC became hollow and atrophied such that most patients were satisfied. We used a skin stapler in the CLC group and subdermal sutures in the SPLC group. Although there were differences in skin closure between the 2 groups, the additional extraumbilical port sites in bare areas of the abdomen (epigastric and right flank) in CLC were not hidden as well as those of SPLC closed by the suture technique. Objectification of patient perceptions and satisfaction with cosmetic outcomes in long-term follow-up will be the subject of another study.

This study was a retrospective nonrandomized controlled trial. To overcome this limitation, we excluded acute or chronic cholecystitis, which can be a burden on the surgeon, depending on the degree of inflammation. In addition, matching subjects of the 2 groups without a significant difference in patient characteristics was necessary for effective comparison of outcomes.

CONCLUSIONS

For management of GB polyps, SPLC can be as safe and efficacious as CLC when it is performed by an experienced surgeon. SPLC has a more satisfactory cosmetic outcome for patients than does CLC. Further objective studies of cosmesis are needed.

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