

Clinical Analysis of Single-Port Laparoscopic Cholecystectomies: Early Experience

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Purpose: Single-port laparoscopic cholecystectomy (SPLC) is a technique under development in the field of minimally-invasive surgery. We have considered the feasibility of SPLC based on the advantages or restrictions compared with multi-port procedures.

Methods: Two hundred seventeen patients with benign gallbladder disease who underwent SPLC or multi-port laparoscopic cholecystectomy (MPLC) during the most recent 10 months were retrospectively reviewed.

Results: Patients were divided into two or three groups based on the operative period and disease. The mean age and ASA scale were different between the three groups. The intra-operative bile leakage and post-operative hospital stay were significantly less in the SPLC group; however, the blood loss and operative time was greater in the SPLC group. When patients with empyema of the gallbladder were excluded and all patients were reassigned into two groups based on the operative method, the incidence of bile leakage and post-operative hospital stay were similar between the two groups. The mean blood loss and operative time were higher in the patients who underwent SPLC. The mean numeric rating scale (NRS) and requirement for opioid analgesics were similar in the two groups.

Conclusion: With the exception of increased intra-operative hemorrhage and a longer operative time, the risks associated with SPLC were not greater than MPLC. With adequate analgesics, advances in laparoscopic instruments, and surgical experience, SPLC is expected to gain acceptance amongst physicians. (*J Korean Surg Soc 2011;80:43-50*)

Key Words: Laparoscopic cholecystectomy, Single-incision, One-port surgery, Minimally-invasive surgery

INTRODUCTION

Techniques in laparoscopic surgery have progressed since 1983 when the first laparoscopic appendectomy was performed through the advent of new access devices and efforts to reduce the size and number of incisions vis-a-vis minimally-invasive surgery.⁽¹⁾ Multi-port laparoscopic chole-

cystectomy (MPLC) is recognized as the gold standard for the treatment of benign gallbladder disease. In 1999, a single-incision cholecystectomy was described by Piskun and Rajpal⁽²⁾ with the insertion of two trocars through the umbilical incision. Since 2007, single-port access surgery for laparoscopic cholecystectomy has attracted surgeons.⁽¹⁾ Single-port laparoscopic cholecystectomy (SPLC) has been reported to be safe, effective, cause less pain, improve cosmetic outcomes, and lead to earlier recovery than MPLC.⁽¹⁻⁸⁾ SPLC might be a replacement for traditional MPLC, and an acceptable alternative or bridge to natural orifice transluminal endoscopic surgery (NOTES).^(9,10) SPLC also has

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less bleeding and organ damage, and fewer wound complications, such as incisional hernias and infections.(11-14) SPLC is regarded to be feasible and safe when performed by experienced laparoscopic surgeons.(8)

It has been questioned whether or not SPLC is associated with significant improvement in post-operative pain,(15) and what other benefits can be acquired from SPLC compared to traditional MPLC. Although this procedure has been successfully performed by many surgeons with various adaptations, the technical challenges and learning curve have restricted widespread use. We retrospectively reviewed the effects of SPLC on operative times, post-operative hospital stay, and other surgical complications, including pain. We determined the safety and feasibility of SPLC, especially in patients with benign gallbladder disease through our initial experiences. Lastly, we determined whether potential disadvantages or restrictions of SPLC exist, while taking the indications for surgery into consideration.

METHODS

1) Patients

All of the patients (group 1) who underwent MPLC by one experienced laparoscopic surgeon at one hospital between November 2008 and March 2009, and all patients who underwent MPLC or SPLC between April 2009 and August 2009 by the same surgeon, were reviewed. The patients in the second period underwent either MPLC or SPLC were divided into two separate groups, group 2 and group 3, respectively. There were 6 patients who had combined procedures with MPLC (Table 1), and they were

excluded from our study. One renal transplant patient who had an elevated creatinine after the laparoscopic procedure, and 6 other patients who had delayed hospital discharge because of medical problems, such as underlying multiple myeloma, leukemia, atrial fibrillation, syncope, or skin rash, were also excluded. Therefore, total 13 patients were finally excluded in group 1 and group 2.

All patients were diagnosed pre-operatively by abdominal ultrasonography or abdominal computed tomography (CT) or endoscopic retrograde cholangiopancreatography (ERCP). Patients with choledocholithiasis accompanied by hyperbilirubinemia were treated pre-operatively. In addition to basic patient characteristics, the body mass index (BMI), intra-operative bile leakage, amount of blood loss, peri-operative complications, mean operative time, and post-operative hospital duration were all checked. The post-operative pain sensation as indicated by the numeric rating scale (NRS) and the total amount of intravenous opioid analgesics (pethidine) required until discharge were also analyzed. In all patients of this study, NRS was acquired from the medical records which were filled up by the assigned nurses. They explained about the NRS sheet and acquired the scores during their routine patient rounds between 4 and 6 hours postoperatively. Intravenous opioid analgesics were used if the patients wanted to be injected for control of their pains from any postoperative time until discharge. From the first day of operation, additional peroral opioid was provided three times a day routinely to all the patients.

2) Operative technique

(1) Four-port laparoscopic cholecystectomy: Pre-operative

Table 1. Six patients who underwent other operations combined with MPLC*

Gender/Age	Gallbladder disease	Combined problem	Combined operation
F/52	Stone	Renal cell cancer	Right kidney partial nephrectomy
M/56	Stone	Renal cell cancer	Left radical nephrectomy
F/62	Stone	Renal cell cancer	Left radical nephrectomy
M/51	Stone	Non-function kidney	Left nephrectomy
M/60	Stone	Papillary thyroid cancer	Total thyroidectomy
F/47	Polyp	Adrenal cortical adenoma	Left adrenalectomy

*MPLC = multi-port laparoscopic cholecystectomy.

preparation and anesthesia was performed with standard methods. The patient was positioned in reverse Trendelenburg with the right side slightly tilted up. A 12-mm trocar was introduced through the infra-umbilical incision and a pneumoperitoneum was established with carbon dioxide. The pressure was usually between 12 and 14 mmHg, and the velocity was 20 cc/min. After a 10-mm rigid 30-degree endoscope was introduced, a 5-mm trocar was placed in the subxiphoid space. Two 2-mm trocars were inserted in the right subcostal area crossing the midclavicular and anterior axillary lines. In some cases who were seemed to have difficulties to retract gallbladder safely enough to exposure Calot's triangle, two 5-mm trocars were used instead of 2-mm trocars.

Calot's triangle dissection was performed using a standard approach with a right angle dissector. After proper exposure of the triangle, the cystic duct and artery were doubly ligated using 5-mm laparoscopic clips. The gallbladder bed dissection was performed using a hook cautery. After the gallbladder was completely removed from the bed, it was extracted through the enlarged umbilicus via a specimen bag.

(2) **Single-port laparoscopic cholecystectomy:** SPLC was initiated with the same procedure as MPLC regarding the patient's position and the formation of a pneumoperitoneum. The operator and assistant stood at the patient's left and right sides, respectively. A 2-cm trans-umbilical incision was made and the umbilical stalk was

completely divided. After the fascia was dissected, an Alexis[®] Wound Retractor (Applied Medical, Rancho Santa Margarita, CA, USA) was introduced through the opening to widen the port area, which also gave enough tensile strength and wound protection. A small surgical glove was tightly attached around the outer ring of the retractor to prevent escape of the pneumoperitoneum. After resecting the tips of three digits in the surgical glove, a 10-mm port for a rigid 30-degree endoscope and two 5-mm Separator[®] Access Systems (Applied Medical) were fitted to the glove, thus forming a three-channel, single-port system. We used a combination of articulating and straight instruments in all cases with a grasper and Autonomy Laparo-Angle Maryland Dissector (CambridgeEndo[™], Framingham, MA, USA). At times, additional one 2-mm trocar was used in the right subcostal area for the help of gallbladder retraction in selected cases. Clipping of the cystic artery and duct, and removal of the dissected gallbladder from the abdomen were similar to the MPLC procedures. The incised umbilical fascia was closed with absorbable suture, and before complete skin closure of the umbilical incision, 2 cc of 0.5% bupivacaine mixed with the same volume of normal saline was routinely injected around the umbilical wound at the subcutaneous layer in all patients undergoing SPLC.

3) Statistical analysis

The statistical analysis was performed with SPSS 16.0 statistical software (SPSS, Inc., Chicago, IL, USA). A χ^2 -

Table 2. Pre-operative clinical characteristics of patients

	Group 1 (n=121)	Group 2 (n=41)	Group 3 (n=55)	P-value
Mean age, years (range)	53.7 (14~85)	58.3 (19~86)	43.7 (17~73)	<0.001
Gender, M : F, N (%)	56 (46.3) : 65 (53.7)	24 (58.5) : 17 (41.5)	25 (45.5) : 30 (54.5)	0.354
BMI* (kg/m ²) (mean±SD [†])	24.7±3.3 (15.0~37.5)	24.6±4.8 (16.1~41.3)	24.0±3.9 (17.1~39.8)	0.512
ASA [‡] scale (mean±SD [†])	1.5±0.6	1.9±0.7	1.3±0.5	<0.001
Diagnosis, N (%)				0.017
Gallbladder stone	91 (75.2)	25 (61.0)	39 (70.9)	
Gallbladder polyp	17 (14.0)	2 (4.9)	10 (18.2)	
Glabladder empyema	9 (7.4)	8 (19.5)	1 (1.8)	
Chronic cholecystitis	2 (1.7)	5 (12.2)	4 (7.3)	
Others [§]	2 (1.7)	1 (2.4)	1 (1.8)	

*BMI = body mass index; [†]SD = standard deviation; [‡]ASA = American Society of Anesthesiologists; [§]Others = biliary dyskinesia, acalculus cholecystitis, gallstone pancreatitis.

test and Mann-Whitney test were applied in the case of two discrete variables when necessary to compare differences in proportions. One-way ANOVA was also applied when analysis of three variables' differences were identified. A two-tailed $P < 0.05$ was considered significant.

RESULTS

One hundred twenty-eight patients (group 1) underwent MPLC in the first period. Forty-seven (group 2) and fifty five patients (group 3) underwent MPLC and SPLC in the second period, respectively. Among the patients in group 1 and group 2, one hundred twenty-one and forty one patients were finally reviewed respectively, after 13 patients were excluded in these groups. The patients' pre-operative clinical characteristics are shown in Table 2. There were no significant differences in gender and BMI between the

three groups. The mean patient ages, American Society of Anesthesiologists (ASA) scales, and the pre-operative diagnoses had significant differences. The intra-operative bile leakage and post-operative hospital stay were significantly lower in group 3 (Table 3); however, the mean blood loss and mean operative time were different among the three groups (higher in group 3). There was no open conversion in group 1 or 2, and only one case in group 3. This patient who was diagnosed to cystic duct stone with chronic cholecystitis preoperatively, but finally suspicious of cholecystobiliary fistula (Mirizzi syndrome) in the laparoscopic operational field. This patient underwent the segmental resection of common bile duct and choledochojujunostomy after open conversion.

All patients who underwent laparoscopic cholecystectomy (MPLC [groups 1 and 2]; or SPLC [group 3]) were all reassigned to two new groups according to the operative

Table 3. Post-operative clinical variables

	Group 1 (n=121)	Group 2 (n=41)	Group 3 (n=55)	P-value
Bile leakage, N (%)	9 (7.4)	10 (24.4)	2 (3.6)	0.001
Mean blood loss (cc) (range)	11.0 (0~200)	35.2 (0~500)	32.4 (0~400)	0.034
Mean operative time (min) (range)	52.3 (25~137)	62.2 (29~116)	65.4 (35~113)	<0.001
Mean post-operative hospital stay (day) (range)	1.6 (1~6)	2.1 (1~7)	1.4 (1~3)	0.002
Mean NRS* score (range)	3.2 (0~9)	3.6 (0~8)	4.0 (0~10)	0.096
Mean requirement of pethidine (mg) (range)	30.0 (0~125)	35.0 (0~125)	32.5 (0~100)	0.759
Complications, N (%)	4 [†] (3.3)	0 (0)	0 (0)	0.201
Open conversion, N (%)	0 (0)	0 (0)	1 (1.8)	0.271

*NRS = numeric rating scale; [†]Two voiding difficulty, one biliary stricture, one myocardial ischemia.

Table 4. Peri-operative clinical results between the new two groups

	Group A [†] (n=145)	Group B [‡] (n=54)	P-value
Mean age, years (range)	53.5 (14~85)	43.9 (17~73)	<0.001
Gender, M : F, N (%)	70 (48.3) : 75 (51.7)	25 (46.3) : 29 (53.7)	0.804
BMI* (kg/m ²) (mean±SD [§])	24.7±3.8	24.0±3.9	0.290
ASA scale (mean±SD [§])	1.5±0.6	1.3±0.5	0.050
Bile spillage, N (%)	9 (6.2)	2 (3.7)	0.492
Mean blood loss (cc) (range)	10.5 (0~100)	33.0 (0~400)	0.003
Mean operative time (min) (range)	52.6 (25~111)	65.2 (35~113)	<0.001
Mean post-operative hospital stay (day) (range)	1.6 (1~6)	1.4 (1~3)	0.094
Mean NRS score (range)	3.4 (0~9)	3.9 (0~10)	0.074
Mean requirement of pethidine (mg) (range)	32.5 (0~125)	32.5 (0~100)	0.928
Complications, N (%)	4 (2.8)	0 (0)	0.218

*BMI = body mass index, [†]Group A = patients who underwent MPLC with all diagnosis criteria excluding gallbladder empyema; [‡]Group B = patients who underwent SPLC with all diagnosis criteria excluding gallbladder empyema; [§]SD = standard deviation.

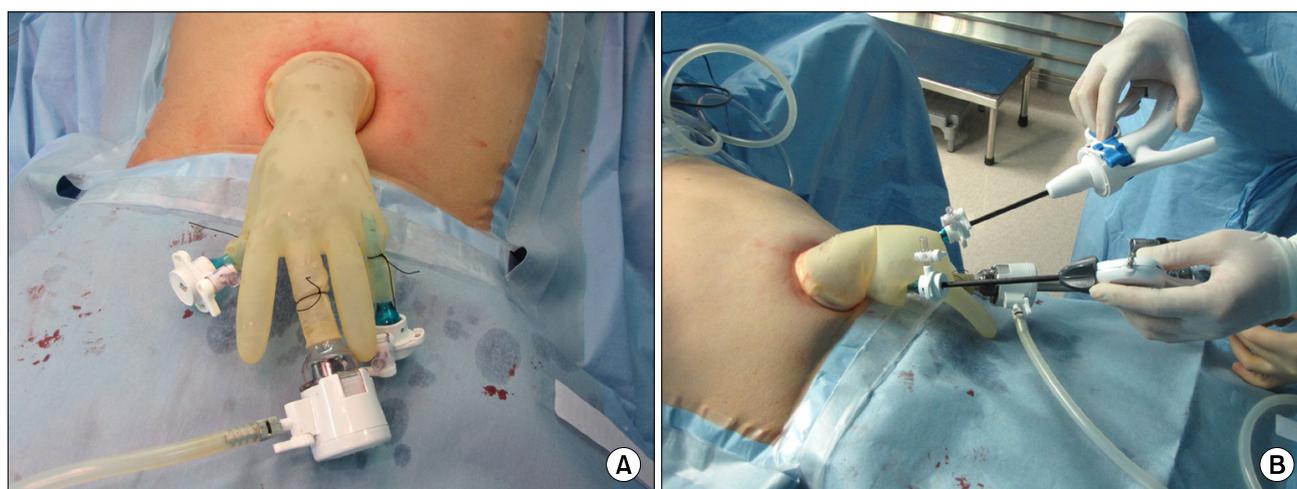


Fig. 1. (A) Hand-made single-port laparoscopic system. (B) Laparoscopic instruments and wound retractor equipped in the umbilical port.

procedure (Table 4). For exclusion of bias according to the diagnosis, the patients with gallbladder empyemas were excluded. In this new analysis of select cases, older patients underwent MPLC more often than SPLC. Bile leakage and the post-operative hospital stay were not significantly different between the two groups. The mean blood loss and mean operative time were higher in the patients who underwent SPLC than MPLC. The mean NRS score and requirement for opioid analgesics were similar in the two groups. Intra-operative cholangiography was not used in any patient during the study period. There were no mortalities or operation-related major complications in any group.

DISCUSSION

Many centers have published reports about their experiences with single incision or SPLC regarding less scarring and pain, safety, efficacy, and lack of major complications. Reducing the port size and number essentially decreases parietal trauma and improves cosmetic results. Several different port systems have been used. A single multiport trocar system, such as the Uni-X Single Port Access Laparoscopic System (Pnavel System, Cleveland, OH, USA; 16), the ASC TriPort (R-port, Advanced Surgical Concepts, Dublin, Ireland; 17,18), the R-Port R (Advanced Surgical Concepts, Wicklow, Ireland; 5), and the Endopath Xcel

Trocar (Ethicon Endo Surgery, Spreitenbach, Switzerland; 8) enable multiple instrument access through a single trocar. The transumbilical Gelpport access technique, including the Alexis[®] Wound Retractor (Applied Medical, Rancho Santa Margarita, CA, USA; 10) or a wound retractor attached to a surgical glove and used as a single port,(11) have similar principles. Single-incision laparoscopic cholecystectomies performed with multiple individual trocars through separate incision within the umbilicus have also been reported.(2,3,12)

Our results of the SPLC procedure, which is a similar method to the procedure described by Hong et al.(4) compared to MPLC, gave some insight about the feasibility of SPLC. First, a learning curve related to a longer operative time and more intra-operative blood loss must be overcome to agree upon a standard operation for benign gallbladder disease. These two drawbacks are closely related to the instruments used and the surgeon's operative skills. In the report by Ponsky et al.,(6) single-incision laparoscopic cholecystectomy has a steep learning curve. Kravetz et al.(13) reported the learning curve in 20 SPLC cases performed on patients with biliary dyskinesia, symptomatic cholelithiasis, and acute cholecystitis to have comparable operative times to traditional three-port laparoscopic cholecystectomy after only 5 cases. Others have reported that using the single-incision technique, operating time was reasonable and can be decreased with experience, so it has

been become the standard method for their elective patients with gallbladder disease.(2) The longer operative time is mainly due to the use of rigid instruments.(16) Curved-designed or articulating instruments and the use of flexible laparoscopes would avoid the interference of rigid instruments or the endoscope, and help to perform more meticulous dissection of Calot's triangle.(2,11,17) Instrumentation and trocars for SPLC are undergoing rapid modification, and will thus be improved. Smaller and more efficient multichannel devices are being evaluated. Spatial restriction caused by closed instruments and cameras also can be important factors in the learning curve(13) because of the limited space for single port and parallel instruments, so instruments with different lengths should be used. SPLC is especially suitable for obese patients because of less incision-related complications.(16) In our study, there was no correlation between the operative time and BMI ($r=0.052$, $P=0.436$). Retraction of the gallbladder for optimal exposure of Calot's triangle is said to be an issue of surgical skill. In some reports involving SPLC, one or two transparietal additional straight needle stitches to retract the fundus or Hartmann's pouch of the gallbladder were needed.(1-3,5,8,13,14,17-19) Other methods for retraction of the gallbladder were introduced by means of magnetic forceps,(20) a 2-mm mini-loop retractor inserted through an extra incision in the right subcostal space,(11) or a 2-mm instrument inserted through the inferior portion of the umbilicus.(17)

Second, a minimum of post-operative pain is a matter to be attended to SPLC. Because the peri-umbilical incision in SPLC is not smaller than traditional MPLC, adequate analgesic treatment has been studied. Spraying bupivacaine over the perihepatic space at any time during surgery in elective traditional MPLC reduces the length of the hospital stay.(21) In this report, there was no medication-related adverse reactions and the earlier discharge rate was dependent on the number of times the patient received bupivacaine. In another report,(22) there was decreased post-operative pain after injection of bupivacaine at the sub-diaphragmatic space and all trocar sites in standard laparoscopic cholecystectomies. Unfortunately, in our study

no statistical significance in post-operative pain or requirement for opioid analgesics was shown, although bupivacaine was routinely injected around the umbilical incision sites in all SPLC cases. Thus, we need further studies about alternative analgesics which have longer analgesic effect than bupivacaine or regarding the effect of time, site, method, or amount of bupivacaine injected.

The third problem involves whether or not SPLC could be the procedure of choice for benign gallbladder disease. Until this time, most reports have only recommended SPLC for symptomatic cholelithiasis cases.(5,9) For example, in the cases of Hong et al.,(4) complicated gallbladder disease, liver cirrhosis, peritonitis, previous upper abdominal surgery, severe obesity, or patients who were high-risk for general anesthesia were excluded. Erbella and Bunch(14) thought that patients with a lower BMI, early disease, or no previous abdominal surgery would be ideal candidates for single- incision laparoscopic cholecystectomy. They reported three acute cholecystitis and one gallstone pancreatitis cases required longer operative time because of greater tissue inflammation and adhesions. Nevertheless, in our experience, which included severe inflammatory cases, such as empyemas, there was a lower incidence in bile leakage and shorter post-operative hospital stay in patients who underwent SPLC even though the operative time was longer. This might be derived from the lower rate of gallbladder empyema in SPLC group than MPLC group. If we exclude the patients with empyemas, which have difficulties in identifying the anatomical structures, the incidence of bile leakage or post-operative hospital stay were statistically similar in the SPLC and MLPC groups. We can hypothesize from this that bile leakage and the post-operative hospital stay are more likely related not to the operative method, but the degree of inflammation of the gallbladder. Thus, severe inflammatory changes, such as empyemas of the gallbladder, may not a contraindication for SPLC, if a longer operative time can be tolerated. However, we need more successful SPLC cases based on the more improved operative experiences for treatment of empyema in order to commonly use of it to the inflammatory gallbladder disease. In addition, elderly

patients who were candidates for SPLC, were not affected by complications, but only longer hospital stays ($P=0.004$). Yet, there are no studies of SPLC for debilitated patients or patients who need combined resection. Roberts et al.(3) excluded ASA classes 3 and 4 in their SPLC study. As in our experience, combined operations, such as nephrectomy and adrenalectomy, were all performed with MPLC. Moreover, incidental findings during SPLC, such as Meckel's diverticulum, usually need conversion to MLPC.(3) Randomized controlled trials and progressive experience might reveal more benefits of SPLC by disclosing detailed indications.

In this study, some restrictions such as small sample size and selection bias are exist. But if allowing this, SPLC was shown to be as feasible and safe as MPLC. Outcomes were comparable with those for conventional endoscopic techniques. Although no patients underwent intra-operative cholangiograms, such a procedure could be performed during SPLC. It is clear that MPLC should be primarily selected if SPLC induces serious complications or patient discomfort, but we did not find any notable disadvantages to SPLC. The potential need for advanced instruments may bring about increased costs as well. With the combined use of commercially available technology and existing instruments, we satisfactorily performed the requisite procedures. Long-term research is essential to determine whether or not long-term complications, such as incisional hernias and biliary strictures, occur.

CONCLUSIONS

We are not able to demonstrate more significant risks with SPLC than MPLC, except intra-operative hemorrhage and a longer operative time in selected patients. SPLC is expected to improve by overcoming the learning curve and advances in laparoscopic instruments. Further serial randomized prospective studies are needed to verify that there are no potential increased risks with SPLC compared to MPLC, so that SPLC can become the gold standard for the treatment of benign gallbladder disease.

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