Abstract

Objective: This study was performed to compare the outcomes of laparoscopic common bile duct exploration (LCBDE) after failed endoscopic retrograde cholangiopancreatography (ERCP) versus primary LCBDE for managing cholecystocholedocholithiasis.

Methods: We retrospectively analyzed data from 59 patients who underwent LCBDE during laparoscopic cholecystectomy (LC) for managing cholecystocholedocholithiasis from January 2013 to August 2019. The patients underwent either primary LCBDE plus LC (Group I) or LCBDE plus LC after failed ERCP (Group II). The demographics, reason for ERCP failure, perioperative details, and postoperative outcomes were evaluated.

Results: CBD stone removal using preoperative ERCP failed in 31 patients (Group II) because of remaining stones after ERCP (n = 9), failed cannulation (n = 6), failed sedation (n = 6), a periampullary diverticulum (n = 5), previous Billroth II gastrectomy (n = 3), a huge stone (n = 1), and an impacted stone (n = 1). The CBD stone clearance rate was >96% in both groups. The mean
operative time, hospital stay, overall complication rate, and open conversion rate were not significantly different between the two groups.

Conclusions: When extraction of CBD stones by ERCP is likely to be difficult or fail, primary LCBDE is an acceptable alternative treatment for managing cholecystocholedocholithiasis.

Keywords
Common bile duct stone, exploration, endoscopic retrograde cholangiopancreatography failure, laparoscopic cholecystectomy, cholecystocholedocholithiasis, stone clearance rate

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Introduction

Common bile duct (CBD) stones are found in approximately 5% to 20% of patients with symptomatic gallstones.1–3 The optimal management of cholecystocholedocholithiasis is still under debate. Therapeutic strategies for CBD stones vary widely and include laparotomy, laparoscopic surgery, percutaneous intervention, and endoscopic retrograde cholangiopancreatography (ERCP). Among these, preoperative ERCP and stone extraction followed by laparoscopic cholecystectomy (LC) are preferred treatments; these are recommended in the European Association for the Study of the Liver clinical practice guidelines on the prevention, diagnosis, and treatment of gallstones.1 However, potential ERCP-related adverse effects include pancreatitis, duodenal perforation, and bleeding.2,4 Moreover, the use of ERCP to extract CBD stones can fail for many reasons, including failed cannulation, previous Billroth II gastrectomy, large CBD stones, and high numbers of CBD stones.5 Single-stage laparoscopic CBD exploration (LCBDE) during LC is now primarily used to treat cholecystocholedocholithiasis, although advanced surgical skills are required to perform the procedure. As the number of surgeons with laparoscopic skill and experience has increased, the number of centers that perform LCBDE has increased as well. A recent meta-analysis showed that LCBDE during LC is superior to preoperative ERCP and stone extraction followed by LC.6 However, few case series have been performed to compare the outcomes of LCBDE after failed preoperative ERCP versus the outcomes of primary LCBDE during LC for managing cholecystocholedocholithiasis. The present study was performed to analyze the reasons for ERCP failure when treating CBD stones and to evaluate our results of primary LCBDE compared with the results of LCBDE after failed ERCP for managing cholecystocholedocholithiasis.

Materials and methods

Data collection

We retrospectively analyzed the medical records of patients with cholecystocholedocholithiasis who underwent LCBDE and LC at the Hallym Sacred Heart Hospital and Chuncheon Sacred Heart Hospital from January 2013 to August 2019. We divided these patients into two groups: those who underwent primary LCBDE and LC (Group I) and those who
underwent LCBDE and LC after failed ERCP (Group II).

At our institution, the general protocol is that the endoscopic approach is initially used to treat CBD stones. The diagnosis of CBD stones was based on the results of radiologic investigations such as ultrasonography and magnetic resonance cholangiopancreatography. The main ERCP procedure involved endoscopic sphincterotomy, endoscopic papillary balloon dilation, and stone removal using a retrieval balloon or basket. We used mechanical lithotripsy for large CBD stones. If this failed, the physician decided whether to repeat the endoscopic procedure or perform a surgical procedure after consulting with the surgeon. Patients whose CBD stones were completely removed after repeating the ERCP procedure were excluded. Primary LCBDE without ERCP was performed if the physician determined that the endoscopic approach would be difficult because of the presence of huge stones, a history of Billroth II surgery, or a huge diverticulum or if the surgeon determined that surgical treatment would be more advantageous. Patients who had a non-dilated CBD with a diameter of <7 mm usually did not undergo LCBDE because of the risk of CBD stricture occurring as a long-term complication.

The following clinical characteristics were analyzed: age, sex, body mass index, American Society of Anesthesiologists physical status, and comorbidities. The following operative data were analyzed: operating time, postoperative complications, open conversion, start of oral intake, and length of hospital stay. The CBD diameter, CBD stone size, CBD stone clearance rate, and CBD stone recurrence rate were also analyzed. We did not perform intraoperative cholangioscopy to confirm CBD clearance. However, duct clearance was confirmed by performing intraoperative cholangiography, postoperative T-tube cholangiography, or magnetic resonance cholangiopancreatography. The data associated with ERCP failure were analyzed. We also analyzed the degree of difficulty in performing ERCP according to the following grading system: grade 1, simple diagnostic ERCP; grade 2, simple therapeutic ERCP; grade 3, complex diagnostic ERCP; grade 4, complex therapeutic ERCP; and grade 5, very advanced ERCP in Group II. Readmission was defined as re-hospitalization within 30 days of discharge. The present study was approved by the Institutional Review Board of the Hallym Hospital. Consent was not required because this was a retrospective study performed using medical records of patients who received standard treatment.

**Surgical procedure**

The type of surgery (transductal or transcystic approach) was determined according to the surgeon’s preference, and the surgical technique was not standardized. We used four trocars (two 12-mm trocars and two 5-mm trocars) for the transductal approach. The transductal approach was performed with various techniques involving primary closure, T-tube insertion, and internal stent insertion. First, choledochotomy was performed 1 to 2 cm vertically at the location of the anterior CBD. Normal saline was injected through a 7-Fr Nelaton catheter or 3-mm pediatric feeding tube to flush obstructive stones through the choledochotomy. Primary closure was performed for patients in whom all CBD stones had been removed, patients in whom the feeding tube passed through the ampulla of Vater (AoV), and patients for whom an intraoperative cholangiogram was available. Internal stent insertion was performed when all CBD stones were removed and the feeding tube passed through the AoV but no intraoperative cholangiogram was obtained. When it was uncertain whether all CBD
stones were removed, or when the feeding tube did not smoothly pass through the AoV, T-tube insertion was performed. During the transcystic approach, we used four trocars (one 12-mm trocar and three 5-mm trocars). The endoscopic basket was passed over a guide wire through the cystic duct to extract stones under fluoroscopic guidance.

**Statistical analysis**

Continuous variables were compared between the two groups using the χ² test and are expressed as median and range or mean ± standard deviation. Categorical variables are reported as number and percentage. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA).

**Results**

**Patient characteristics**

Fifty-nine patients were included in this study (Group I, n = 28; Group II, n = 31). The patients’ clinical characteristics are listed in Table 1. There were no significant differences in the patients’ age, American Society of Anesthesiologists physical status, or history of an abdominal operation between the two groups. Symptoms and comorbidities were also not significantly different between the two groups. The causes of ERCP failure are listed in Table 2. The most common cause of incomplete CBD stone removal was remaining stones after ERCP (n = 9), followed by a huge stone (n = 1) and an impacted stone (n = 1). The reasons for failed cannulation were an abnormal position of the AoV (n = 6), a periampullary diverticulum.

**Table 1.** Patient demographics.

|                         | Group I (n = 28) | Group II (n = 31) | p   |
|-------------------------|-----------------|------------------|-----|
| Age, years              | 70.1 ± 12.3     | 65.0 ± 19.2      | 0.235 |
| Sex, male:female        | 13:15           | 15:16            | 0.880 |
| BMI, kg/m²              | 23.4 ± 3.5      | 24.0 ± 5.1       | 0.586 |
| ASA physical status     |                 |                  | 0.576 |
| 1                       | 1 (3.6)         | 2 (6.5)          |     |
| 2                       | 8 (28.6)        | 10 (32.3)        |     |
| 3                       | 14 (50.0)       | 17 (54.8)        |     |
| 4                       | 5 (17.9)        | 2 (6.5)          |     |
| Operation history       | 8 (28.6)        | 6 (19.4)         | 0.406 |
| Symptoms                |                 |                  |     |
| Fever                   | 9 (32.1)        | 8 (25.8)         | 0.592 |
| Abdominal pain          | 28 (100.0)      | 28 (90.3)        | 0.091 |
| Jaundice                | 15 (53.6)       | 22 (71.0)        | 0.168 |
| Comorbidities           |                 |                  |     |
| Hypertension            | 10 (35.7)       | 12 (38.7)        | 0.812 |
| Diabetes                | 6 (21.4)        | 7 (22.6)         | 0.915 |
| Other cardiovascular disease | 6 (21.4) | 10 (32.2)        | 0.644 |
| Other pulmonary disease | 2 (7.1)         | 1 (3.2)          | 0.513 |
| Other conditions        | 3 (10.7)        | 4 (12.9)         | 0.795 |

Data are presented as mean ± standard deviation, n, or n (%). BMI, body mass index; ASA, American Society of Anesthesiologists.
Incomplete CBD stone removal  
Remaining stones after ERCP  9
Huge stones  1
Impacted stone  1
Failed cannulation  
Abnormal position of ampulla of Vater  6
Periampullary diverticulum  5
Previous Billroth II gastrectomy  3
Failed sedation  6

ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct.

Discussion

The first choice for CBD stone management is endoscopic treatment, which is now performed worldwide. Many reports have indicated high technical success rates with extraction of at least 90% of stones. However, the endoscopic approach occasionally fails when either removing CBD stones or cannulating the CBD. In the present study, the most common reason for incomplete CBD stone removal was the presence of remaining stones (9/31) followed by a huge stone (1/31) and an impacted stone (1/31). Extraction of CBD stones via an endoscopic approach may be difficult for several reasons. In most situations, the size, shape, and number of stones are the key determinants of whether extraction will be easy. A prospective study by Kim et al. showed that large CBD stones (>15 mm), impacted CBD stones, a shorter length of the distal CBD arm (<36 mm), and more acute distal CBD angulation were significant factors affecting the
Failed cannulation is another reason for failed ERCP. The success rate of biliary cannulation is 84% to 94%. However, even the most skilled endoscopist will fail to achieve deep biliary cannulation in a minority of cases. In the present study, the reasons for failed cannulation included an abnormal position of the AoV (6/31), a periampullary diverticulum (5/31), and previous Billroth II gastrectomy (3/31). Hong et al. recently reported that the success rate of cannulation for 107 patients with an ectopic papilla of Vater was 83.2%. They reported that the ectopic opening was so obscure that it may have increased the difficulty of cannulation. Sfarti et al. reported that a periampullary diverticulum can increase the rate of difficult or failed cannulation. Li et al.

| Table 3. Overall comparison of perioperative results. |
|-----------------------------------------------------|
| **Group I** (n=28) | **Group II** (n=31) | **p** |
| Operation time, minutes | 92.0 ± 38.6 | 84.4 ± 30.4 | 0.399 |
| Commencement of water sipping, days | 1.5 ± 6.6 | 1.3 ± 0.7 | 0.113 |
| Commencement of oral diet, days | 2.5 ± 0.8 | 2.2 ± 0.8 | 0.113 |
| Hospital stay, days | 7.4 ± 3.7 | 7.0 ± 2.3 | 0.591 |
| Surgery type | | | 0.140 |
| Transductal approach | 28 (100.0) | 29 (93.5) | |
| T-tube insertion | 7 (25.1) | 14 (45.2) | |
| Primary closure | 17 (60.7) | 11 (35.5) | |
| Internal stent | 4 (14.3) | 4 (12.9) | |
| Transcystic approach | 0 (0.0) | 2 (6.5) | |
| Open conversion | 2 (8.0) | 0 (0.0) | 0.115 |
| All complications | 1 (3.6) | 1 (3.2) | 0.942 |
| Bile leakage | 0 (0.0) | 1 (3.2) | |
| Wound infection | 1 (3.6) | 0 (0.0) | |
| Reoperation | 0 (0.0) | 0 (0.0) | |
| Readmission | 0 (0.0) | 0 (0.0) | |
| Mortality | 0 (0.0) | 0 (0.0) | |

Data are presented as mean ± standard deviation or n (%).

| Table 4. CBD stone clearance and recurrence. |
|------------------------------------------------|
| **Group I** (n=28) | **Group II** (n=31) | **p** |
| CBD stone size, mm | 9.1 ± 6.7 | 9.3 ± 6.7 | 0.932 |
| CBD diameter, mm | 14.8 ± 5.2 | 13.0 ± 5.5 | 0.225 |
| Multiple CBD stones | 13 (46.4) | 16 (51.6) | 0.691 |
| Gallstones | 25 (89.3) | 26 (83.9) | 0.544 |
| CBD stone clearance rate | 27 (96.4) | 34 (100.0) | 0.272 |
| Additional procedures | 1 (3.6) | 0 (0.0) | 0.289 |
| Recurrent stones | 2 (8.0) | 1 (3.2) | 0.513 |

Data are presented as mean ± standard deviation or n (%).

Technical difficulty of CBD stone clearance. Failed cannulation is another reason for failed ERCP. The success rate of biliary cannulation is 84% to 94%. However, even the most skilled endoscopist will fail to achieve deep biliary cannulation in a minority of cases. In the present study, the reasons for failed cannulation included an abnormal position of the AoV (6/31), a periampullary diverticulum (5/31), and previous Billroth II gastrectomy (3/31). Hong et al. recently reported that the success rate of cannulation for 107 patients with an ectopic papilla of Vater was 83.2%. They reported that the ectopic opening was so obscure that it may have increased the difficulty of cannulation. Sfarti et al. reported that a periampullary diverticulum can increase the rate of difficult or failed cannulation. Li et al.
reported that the success rate of duodenal ampullary access and selective biliary cannulation was 84.1% (191/227) and 92.1% (176/191), respectively, in patients with Billroth II anatomy. Patient sedation is also important for ERCP success. Conscious sedation is routinely performed by gastroenterologists for endoscopic procedures; however, ERCP failure is often due to inadequate conscious sedation.\textsuperscript{15} Predicting the possibility of failure in advance is helpful because ERCP fails to remove CBD stones for many of the reasons mentioned above. Many studies have already used a grading system to assess the technical difficulty of ERCP.\textsuperscript{7,10,16,17} We also used a grading scale to analyze the degree of difficulty of ERCP in Group II. Grade 2 was seen in 11 patients, grade 4 in 19, and grade 5 in only 1. The success of ERCP is influenced by the technical difficulty of the procedure. Therefore, a more accurate grading system to predict failure of ERCP is needed.

When ERCP fails, surgery is needed for CBD stone extraction. Recently, LCBDE has been increasingly advocated in the primary management of CBD stones. A prospective study that compared single-stage LCBDE and LC as a two-stage endoscopic stone extraction procedure followed by LC for cholecystocholedocholithiasis illustrated that the former achieved a shorter hospital stay and comparable stone clearance rate compared with the latter.\textsuperscript{18} In addition, a recent meta-analysis showed that LCBDE produced superior results in terms of perioperative safety and short- and long-term postoperative efficacy compared with ERCP.\textsuperscript{6} The meta-analysis concluded that LCBDE should be considered as optimal treatment for cholecystocholedocholithiasis. In the present study, the success rate of laparoscopic management of CBD stones was 98.3%, with an average morbidity rate of 3.4% and mortality rate of 0.0%. We also confirmed that LCBDE is safe and effective for managing cholecystocholedocholithiasis.

In some reports, LCBDE after failed ERCP was described as more technically challenging than primary LCBDE.\textsuperscript{18,19} Di Mauro et al.\textsuperscript{20} reported that the mean operative time was longer in LCBDE after failed ERCP because of local fibrosis around Calot’s triangle. They also reported that patients who underwent LCBDE after failed ERCP had a longer hospital stay because of the longer operative time and the use of a T-tube, which required time to manage.\textsuperscript{20} In our study, however, LCBDE after failed ERCP yielded a similar mean operative time and hospital stay as primary LCBDE. In fact, the 14 patients who underwent failed CBD cannulation and 6 patients who did not remain sedated were the same patients as those who did not undergo ERCP. These may be the reasons why the mean operative time and hospital stay were similar between the two groups in our study. There were also no significant differences in the CBD stone clearance rate and stone recurrence rate between the two groups.

This study has limitations associated with its retrospective nature and small study population. A study with a larger sample size would be needed to reach more definitive conclusions.

In conclusion, our surgical outcomes indicate that LCBDE can be safely and effectively performed for managing cholecystocholedocholithiasis. The outcomes were similar between primary LCBDE and LCBDE after failed ERCP. If endoscopic stone removal is predicted to be difficult or to fail, primary LCBDE is an acceptable alternative treatment for managing cholecystocholedocholithiasis.

**Declaration of conflicting interest**

The authors declare that there is no conflict of interest.
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