



# Comparison of one-stage laparoscopic common bile duct exploration plus cholecystectomy and two-stage endoscopic sphincterotomy plus laparoscopic cholecystectomy for concomitant gallbladder and common bile duct stones in patients over 80 years old

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**Purpose:** This study was performed to compare the safety and efficacy of one-stage laparoscopic common bile duct exploration (LCBDE) plus laparoscopic cholecystectomy (LC) with those of endoscopic sphincterotomy (EST) plus LC for concomitant gallbladder (GB) and common bile duct (CBD) stones in elderly patients.

**Methods:** This single-center retrospective study reviewed the medical records of patients aged >80 years who were diagnosed with concomitant GB and CBD stones between January 2010 and December 2020.

**Results:** Of the 137 patients included in this study, 46 underwent one-stage LCBDE + LC and 91 underwent two-stage EST + LC. The frequency of previous gastrectomy (23.9% vs. 5.5%,  $p = 0.002$ ) and multiple stones (76.1% vs. 49.5%,  $p = 0.003$ ) was higher in the LCBDE + LC group than in the EST + LC group. Further, patients in LCBDE + LC group had larger CBD stones (11.9 mm vs. 6.0 mm,  $p < 0.001$ ). There were no significant differences in the clearance (91.3% vs. 95.6%,  $p = 0.311$ ) and recurrence (4.3% vs. 8.8%,  $p = 0.345$ ) rates between the groups. The incidence of posttreatment overall complications (17.4% vs. 22.0%,  $p = 0.530$ ) and total hospital stay (12.7 days vs. 11.7 days,  $p = 0.339$ ) were similar in the two groups.

**Conclusion:** One-stage LCBDE + LC is a safe and effective treatment for concomitant GB and CBD stones, even in elderly patients, and may be considered as the first treatment option in elderly patients with previous gastrectomy, multiple large ( $\geq 15$  mm) CBD stones, or inability to cooperate with endoscopic procedures.

**Keywords:** Common bile duct, Gallstones, Laparoscopic cholecystectomy, Endoscopic sphincterotomy

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## INTRODUCTION

Common bile duct (CBD) stones are one of the most common gastrointestinal diseases in clinical practice and are found in approximately 5% to 20% of patients with gallbladder (GB) stones

[1,2]. Both one-stage laparoscopic common bile duct exploration (LCBDE) plus laparoscopic cholecystectomy (LC) and two-stage endoscopic sphincterotomy (EST) plus LC are standard treatment options for patients with GB and CBD stones. However, the optimal treatment for concomitant GB and CBD stones is debated.

The prevalence of GB and CBD stones increases significantly with advancing age [3]. As elderly patients typically have underlying chronic diseases and age-specific deterioration of organ function, they are classified as a high-risk group for surgery under general anesthesia. Although several recent studies [4–7] have reported on the safety and effectiveness of LCBDE in elderly patients, they have not been compared with those of EST plus LC.

Therefore, the aim of this study was to compare the safety and efficacy of one-stage LCBDE + LC with those of two-stage EST + LC for the treatment of concomitant GB and CBD stones in patients over 80 years old.

## MATERIALS AND METHODS

### Patients

Between January 2010 and December 2020, all patients aged >80 years who underwent endoscopic or surgical treatment for concomitant GB and CBD stones were evaluated. Patients who underwent LCBDE + LC following EST failure were excluded. A total of 137 patients were included in this study. Concomitant GB and CBD stones were diagnosed using preoperative imaging studies; ultrasonography, computed tomography, magnetic resonance cholangiopancreatography, and/or endoscopic retrograde cholangiopancreatography (ERCP). The patients were classified into two groups—one-stage LCBDE + LC and two-stage EST + LC groups—according to the treatment method, and we retrospectively reviewed the patients' characteristics.

### Determination of treatment method

In our institution, two-stage EST + LC is considered the first-line treatment for patients with concomitant GB and CBD stones. However, in patients who are unable to undergo EST, a one-stage LCBDE + LC is performed after consultation with a hepatobiliary-pancreatic surgeon. Patients with anatomical alterations due to previous gastrectomy, multiple large ( $\geq 15$  mm) CBD stones, anticoagulants, and inability to cooperate with endoscopic procedures due to mental or physical problems (e.g., dementia, sequelae of cerebrovascular accidents) are classified as having a high risk for EST failure. In other patients, EST is attempted first, followed by LC in successful cases. In patients who underwent gastrectomy, EST was attempted in those who underwent Billroth I anastomosis, and EST was selectively attempted in those who underwent Billroth II anastomosis according to the opinion of the endoscopist.

In our institution, percutaneous transhepatic gallbladder drainage (PTGBD) has been performed in patients with acute cholecystitis (AC) who are not fit for immediate surgery due to the high-risk surgery at the time of presentation. PTGBD was per-

formed in all patients with grade II or III AC if immediate LC was not possible.

### Laparoscopic common bile duct exploration

A standard four-port method and transcholedochal approach were used for LCBDE in our institution. A 5-mm flexible choledochoscope and wire basket (Olympus, Tokyo, Japan) were used to identify and retrieve CBD stones. The choledochotomy site was primarily closed without an internal stent or T-tube. Before primary closure, the proximal and distal bile ducts, including the ampulla, were checked using a choledochoscope to confirm clearance. The detailed surgical technique has been described in a previous report [8].

### Clinical pathway of perioperative management

In the one-stage LCBDE + LC group, all patients started oral intake from the evening of postoperative day 0, and only prophylactic antibiotics were administered if there was no evidence of infection. Abdominal drains were removed on a postoperative day 2 if there was no evidence of bile leakage. After postoperative day 3, discharge was considered based on the patient's condition.

In the two-stage EST + LC group, all patients underwent LC 24 hours after endoscopic clearance. An abdominal drain was not routinely inserted during surgery. After LC, as in the one-stage LCBDE + LC group, oral intake was started on the evening of postoperative day 0 and only prophylactic antibiotics were administered. After postoperative day 2, discharge was considered based on the patient's condition.

Follow-up ultrasonography or computed tomography at postoperative 1 month confirmed CBD stone clearance. CBD stone recurrence was defined as the occurrence of stones 6 months after complete CBD stone removal via index treatment [9].

### Definition of characteristics

Preoperative physical fitness was assessed using the American Society of Anesthesiologists physical status (ASA PS) classification [10]. In the two-stage EST + LC group, the operation time was defined as the time that LC was performed. Posttreatment complications included both postoperative and post-ERCP complications. All complications were graded according to the Clavien-Dindo classification [11]. Serious complications were defined as complications  $\geq$  grade III according to the Clavien-Dindo classification.

### Radiologic imaging and endoscopic findings

We analyzed the radiologic parameters, such as CBD diameter,

CBD stone size, and number of CBD stones on preoperative computed tomography and magnetic resonance cholangiopancreatography. The CBD diameter and CBD stone size were measured at the maximum cross-sectional diameter. They were divided into single or multiple categories according to the number of detected CBD stones.

Endoscopic findings were obtained from formal reports. Bleeding from the EST site was defined as cases requiring blood transfusion, endoscopic or radiologic intervention, or surgery [12]. Post-ERCP pancreatitis was defined using the Cotton criteria [13].

### Statistical analysis

Continuous variables were summarized as mean and standard deviation and were compared using the Student t-test. Categorical variables were presented as counts and percentages and were compared using the chi-square test. All tests were two-sided, and *p* values of <0.05 were considered statistically significant. Analyses were performed using IBM SPSS version 25 (IBM Corp., Armonk, NY, USA).

## RESULTS

### Comparison of patient's characteristics

Patient characteristics of the study population are presented in Table 1. Of the 137 patients included in this study, 46 underwent one-stage LCBDE + LC and 91 underwent two-stage EST + LC. Of the 91 patients, 39 underwent ERCP at least twice. There were no significant differences in age (84.1 years vs. 83.5 years, *p* = 0.353), sex (female, 50.0% vs. 50.4%; *p* = 0.952), ASA PS classification ( $\geq$ III, 60.9% vs. 54.9%; *p* = 0.508), and PTGBD (43.5% vs. 48.9%, *p* = 0.550) between the two groups. Patients in the one-stage group had a lower body mass index (20.9 kg/m<sup>2</sup> vs. 22.8 kg/m<sup>2</sup>, *p* = 0.001) and a higher frequency of previous gastrectomy (23.9% vs. 5.5%, *p* = 0.002) than those in the two-stage group. Patients in one-stage group also had a larger CBD diameter (13.9 mm vs. 10.6 mm, *p* < 0.001) and CBD stone size (11.9 mm vs. 6.0 mm, *p* < 0.001). Multiple CBD stones were more frequent in the one-stage group (76.1% vs. 49.5%, *p* = 0.003). There were no significant differences in laboratory findings, including initial total bilirubin (2.3 mg/dL vs. 2.6 mg/dL, *p* = 0.525), aspartate aminotransferase (142.3 U/L vs. 227.5 U/L, *p* = 0.099), and alanine aminotransferase (93.0 U/L vs. 144.4 U/L, *p* = 0.099) levels.

**Table 1.** Comparison of patient characteristics between one-stage LCBDE + LC and two-stage EST + LC

Characteristic	One-stage LCBDE + LC	Two-stage EST + LC	<i>p</i> value
No. of patients	46	91	
Age (yr)	84.1 ± 3.8	83.5 ± 2.9	0.353
Female sex	23 (50.0)	46 (50.5)	0.952
Body mass index (kg/m <sup>2</sup> )	20.9 ± 3.3	22.8 ± 3.1	0.001
ASA PS classification, $\geq$ III	28 (60.9)	50 (54.9)	0.508
Previous abdominal surgery	15 (32.6)	24 (26.4)	0.445
Previous gastrectomy	11 (23.9)	5 (5.5)	0.002
CBD diameter (mm)	13.9 ± 5.2	10.6 ± 3.5	<0.001
No. of stones			0.003
Single	11 (23.9)	46 (50.5)	
Multiple	35 (76.1)	45 (49.5)	
Maximum stone size (mm)	11.9 ± 7.9	6.0 ± 4.1	<0.001
Initial total bilirubin (mg/dL)	2.3 ± 2.4	2.6 ± 2.1	0.525
Initial AST (U/L)	142.3 ± 187.5	227.5 ± 326.0	0.103
Initial ALT (U/L)	93.0 ± 110.0	144.4 ± 193.9	0.099
PTGBD	20 (43.5)	44 (48.4)	0.550

Values are presented as number only, mean ± standard deviation, or number (%).

LCBDE, laparoscopic CBD exploration; LC, laparoscopic cholecystectomy; EST, endoscopic sphincterotomy; ASA PS, American Society of Anesthesiologists physical status; CBD, common bile duct; AST, aspartate aminotransferase; ALT, alanine aminotransferase; PTGBD, percutaneous transhepatic gallbladder drainage.

**Table 2.** Comparison of treatment outcomes between one-stage LCBDE + LC and two-stage EST + LC

Variable	One-stage LCBDE + LC (n = 46)	Two-stage EST + LC (n = 91)	p value
Clearance of CBD stone	42 (91.3)	87 (95.6)	0.311
Recurrence of CBD stone	2 (4.3)	8 (8.8)	0.345
Operation time (min)	104.5 ± 34.9	57.0 ± 23.2	<0.001
Estimated blood loss (mL)	43.1 ± 92.8	26.4 ± 72.4	0.293
Conversion to open surgery	0 (0)	0 (0)	NA
Adjacent organ injury during operation	0 (0)	4 (4.4)	0.149
Post-ERCP overall complication	NA	11 (12.1)	NA
Post-ERCP pancreatitis	NA	8 (8.8)	NA
Post-ERCP serious complication	NA	3 (3.3)	NA
Postoperative overall complication	8 (17.4)	10 (11.0)	0.295
Postoperative serious complication	4 (8.7)	3 (3.3)	0.175
Postoperative bile leak	3 (6.5)	1 (1.1)	0.075
Posttreatment overall complication	8 (17.4)	20 (22.0)	0.530
Posttreatment serious complication	4 (8.7)	6 (6.6)	0.655
Postoperative hospital stay (day)	6.8 ± 5.8	3.7 ± 2.5	<0.001
Total hospital stay (day)	12.7 ± 6.7	11.7 ± 5.2	0.339
Total number of procedures	1.0 ± 0.0	2.5 ± 0.6	<0.001
In hospital mortality	0 (0)	0 (0)	NA

Values are presented as number (%) or mean ± standard deviation.

LCBDE, laparoscopic CBD exploration; LC, laparoscopic cholecystectomy; EST, endoscopic sphincterotomy; CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography; NA, nonapplicable.

## Comparison of treatment outcomes

The treatment outcomes of the study population are shown in Table 2. There were only two recurrences (4.3%) in one-stage LCBDE + LC group. One in two had a history of gastrectomy. LCBDE was again performed in the two patients who had recurrence. The remaining stones were identified in eight patients. Most patients with residual stones were asymptomatic and were only observed. Only two patients (one in each group) underwent ERCP for stone removal. There were no significant differences in the clearance rate (91.3% vs. 95.6%,  $p = 0.311$ ) and recurrence rate (4.3% vs. 8.8%,  $p = 0.345$ ) between the groups. There was no conversion to open surgery in either group. There was no difference in estimated blood loss (43.1 mL vs. 26.4 mL,  $p = 0.293$ ) between the two groups. The operation time was shorter in the two-stage group (104.5 minutes vs. 57.0 minutes,  $p < 0.001$ ), and adjacent organ injury during surgery only occurred in the two-stage group (0.0% vs. 4.4%,  $p = 0.149$ ). The patients in the one-stage group had a longer postoperative hospital stay than those in the two-stage group (6.8 days vs. 3.7 days,  $p < 0.001$ ); however, the total hospital stay was similar in both groups (12.7 days vs. 11.7 days,  $p = 0.339$ ,

respectively). The incidence of posttreatment overall complications (17.4% vs. 22.0%,  $p = 0.530$ ) and posttreatment serious complications (8.7% vs. 6.6%,  $p = 0.655$ ) was similar in both groups. Hospital mortality did not occur in either group.

The most common postoperative complication in patients who underwent one-stage LCBDE + LC was bile leakage treated with percutaneous drainage, endoscopic nasobiliary drainage, and endoscopic retrograde biliary drainage. There was no statistically significant difference in the rate of postoperative bile leak between the two groups (6.5% vs. 1.1%,  $p = 0.075$ ). Among the serious complications in the two-stage EST + LC group, one had bile leakage, one had pleural effusion requiring percutaneous drainage, and one had pneumonia requiring mechanical ventilation occurred. Details of postoperative complications are shown in Table 3. The most common post-ERCP complication was post-ERCP pancreatitis (8.8%). There were three cases of serious post-ERCP complications: two with EST site bleeding requiring endoscopic hemostasis and one with EST site bleeding requiring embolization. Details of post-ERCP complications are presented in Table 4.

**Table 3.** Comparison of postoperative complications between one-stage LCBDE + LC and two-stage EST + LC

Type of complications	One-stage LCBDE + LC (n = 46)	Two-stage EST + LC (n = 91)
Serious complication (CD grade $\geq$ III)	4 (8.7)	3 (3.3)
Bile leak requiring ENBD, ERBD, or PCD	3	1
Pleural effusion requiring PCD	1	1
Pneumonia requiring mechanical ventilation	0	1
Minor complication (CD grade <III)	4 (8.7)	7 (7.7)
Pneumonia requiring conservative care	2	1
Postoperative ileus requiring conservative care	2	0
Complicated fluid collection requiring antibiotics	0	4
Pleural effusion requiring conservative care	0	1
Acute urinary retention requiring Foley catheter insertion	0	1
Total	8 (17.4)	10 (11.0)

Values are presented as number (%) or number only.

LCBDE, laparoscopic common bile duct exploration; LC, laparoscopic cholecystectomy; EST, endoscopic sphincterotomy; CD, Clavien-Dindo classification; ENBD, endoscopic nasobiliary drainage; ERBD, endoscopic retrograde biliary drainage; PCD, percutaneous drainage.

**Table 4.** Post-ERCP complications in the two-stage EST + LC group (n = 91)

Type of complications	No. (%)
Post-ERCP pancreatitis requiring conservative care	8 (8.8)
EST site bleeding requiring endoscopic hemostasis	2 (2.2)
EST site bleeding requiring embolization	1 (1.1)
Total	11 (12.1)

ERCP, endoscopic retrograde cholangiopancreatography; EST, endoscopic sphincterotomy; LC, laparoscopic cholecystectomy.

### Reasons for performing one-stage LCBDE + LC

The reasons for performing one-stage LCBDE + LC are listed in Table 5. The most common reason was the expectation of poor cooperation for ERCP due to physical or mental problems (45.7%). Altered surgical anatomy (23.9%) and endoscopists' refusal to perform ERCP in patients taking antiplatelet agents (23.9%) were the second most common reasons.

## DISCUSSION

Although recent meta-analyses have compared one-stage LCBDE + LC with two-stage EST + LC [14–16], there is still debate about which treatment is superior. As the elderly population continues to increase worldwide, the proportion of elderly patients with biliary stones is also increasing significantly. Therefore, it is important to confirm the safety and efficacy of one-stage LCBDE + LC and two-stage EST + LC in elderly patients, and to compare the treatment outcomes with the two approaches. The present

**Table 5.** Reasons for performing one-stage LCBDE + LC (n = 46)

Reasons	No. (%)
Expected poor cooperation for ERCP due to physical or mental problem	21 (45.7)
Altered surgical anatomy	11 (23.9)
Endoscopist refused ERCP in patients taking antiplatelet agent	11 (23.9)
Endoscopist refused ERCP due to multiple large stones	3 (6.5)

LCBDE, laparoscopic common bile duct exploration; LC, laparoscopic cholecystectomy; ERCP, endoscopic retrograde cholangiopancreatography.

study is meaningful because very few studies have compared the outcomes of the two treatment options in patients aged >80 years.

Although several randomized controlled trials reported that there were no significant differences in clearance rates between the one-stage LCBDE + LC (91.7%–96.5%) and two-stage EST + LC (88.1%–94.6%), they did not focus on elderly patients [17–19]. In our study, the clearance rates of one-stage LCBDE + LC (91.3%) and two-stage EST + LC (95.6%) were similar to those reported in a previous study. Long-term follow-up studies have reported, that CBD stones recur in approximately 2.1% to 13.5% of cases after LCBDE and 7.5% to 9.5% of cases after EST [19–21]. In the present study, recurrence rates of CBD stones after LCBDE or EST were 4.3% and 8.8%, respectively, which are similar to those of previous studies. It was confirmed that both one-stage LCBDE + LC and two-stage EST + LC were effective treatments in terms of clearance and recurrence rates in patients with concomitant GB

and CBD stones aged >80 years.

Chronic diseases such as heart disease, cerebrovascular disease, pulmonary disease, and diabetes mellitus are common with increasing age. Therefore, elderly patients are traditionally classified as weak or having a high risk of surgery under general anesthesia. However, in the case of LCBDE + LC, according to a recently published meta-analysis [22], there was no statistically significant difference between elderly patients and younger patients regarding the overall complication rate (odds ratio [OR], 1.31; 95% confidence interval [CI], 0.94–1.82;  $p = 0.12$ ) and mortality rate (OR, 2.80; 95% CI, 0.82–9.53;  $p = 0.10$ ). However, pulmonary complications occurred more frequently in elderly patients (OR, 4.41; 95% CI, 1.78–10.93;  $p = 0.001$ ). In the present study, the overall complication rate in the one-stage group was 17.4%, which was slightly higher than the 10.0% of all elderly patients reported in a previous meta-analysis [22]. However, this difference in the complication rates may be attributed to the fact that only studies that set the age limit as 65 or 70 years were included. The complication rate was similar to that reported in a previous study that included patients aged >80 years (14.8%) [23].

In view of the high morbidity associated with surgical procedures in the elderly, endoscopic alternatives may be preferred for the management of CBD stones. However, ERCP is also associated with complications such as pancreatitis, bleeding, and perforation, and advanced age increases these risks. In the present study, the post-ERCP overall complication rate was 12.1%, and the most common post-ERCP complication was post-ERCP pancreatitis (8.8%). The present study showed a relatively similar risk of posttreatment complications between one-stage treatment (surgical) and two-stage treatment (surgical + endoscopic) (17.4% vs. 22.0%,  $p = 0.530$ ). Additionally, the total hospital stay was similar in both groups (12.7 days vs. 11.7 days,  $p = 0.339$ ). Patient cooperation is important for successful ERCP. However, in the case of elderly patients, cooperation is limited due to physical and mental problems such as dementia and sequelae of cerebrovascular accidents. Elderly patients have more frequent periampullary diverticula and large multiple CBD stones, which increase the complexity and risk of endoscopic procedures. Previous studies have reported altered anatomy, periampullary diverticula, and multiple or large impacted stones as the most common causes of failure of CBD stone extraction with EST [24,25].

This study had several limitations. First, we excluded patients who underwent LCBDE + LC following EST failure because of the convenience of analysis and the small number of patients included in this group. However, in clinical practice, many patients undergo LCBDE + LC following EST failure; therefore, additional studies including these patients are needed. Second, since this was a retrospective, single-center study with small sample size, our results may be biased. In addition, our surgical technique of LCBDE is different from that used in other institutions,

and generalizability may be poor. A multicenter, prospective, randomized, controlled trial with long-term follow-up should be conducted to draw a firm conclusion.

In conclusion, one-stage LCBDE + LC and two-stage EST + LC are similar in terms of safety and efficacy of treatment in patients with concomitant GB and CBD stone aged >over 80 years. Therefore, one-stage LCBDE + LC may be considered as the first treatment option in elderly patients with previous gastrectomy, multiple large ( $\geq 15$  mm) CBD stones, or inability to cooperate with endoscopic procedures.

## NOTES

### Ethical statements

This study was approved by the appropriate Institutional Review Board, and the requirement for informed consent was waived due to the retrospective design of the study (No. 2021-03-005).

### Authors' contributions

Conceptualization, Formal analysis, Methodology, Visualization: SJL, ISC, JIM

Data curation, Investigation: All authors

Writing—original draft: SJL

Writing—review & editing: SJL, ISC, JIM

All authors read and approved the final manuscript.

### Conflict of interest

All authors have no conflicts of interest to declare.

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