

## Long-term results of laparoscopic common bile duct exploration by choledochotomy for choledocholithiasis: 15-year experience from a single center

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**Purpose:** The aim of this study is to assess the long-term results of laparoscopic common bile duct exploration (LCBDE) and validate its effectiveness as a primary treatment modality for CBD stone.

**Methods:** A retrospective review of the medical records of 157 patients who underwent LCBDE from 1997 to 2011 was conducted. All LCBDE were performed by choledochotomy. Clinical demographics, operative outcome, recurrence rate of CBD stones, and long-term bile duct complications were analyzed. The mean follow-up period was 51.9 months.

**Results:** LCBDE was completed in 152 patients (96.8%) and 5 patients (3.2%) had open conversion. The male/female ratio was 78/79 and mean age was 67.3 years. Stone clearance was successful in 149 of 152 patients (98.0%). Nonlethal complications were noted in 11 patients (7.2%), including bile leakage in 6 patients (3.9%). Recurrent CBD stones developed in 9 of 152 patients (5.9%). Preoperative endoscopic sphincterotomy ( $P = 0.492$ ) and choledochotomy repair type (T-tube drainage vs. primary closure,  $P = 0.740$ ) were not significantly related to stone recurrence. There were no signs of any type of biliary injury or stricture observed in any of the patients during the follow-up period.

**Conclusion:** LCBDE can be performed without increased risk of long-term complications such as bile duct stricture and recurrent CBD stones. LCBDE is a safe and effective treatment option for choledocholithiasis in terms of long-term outcome as well as short-term outcome.

[Ann Surg Treat Res 2014;86(1):1-6]

**Key Words:** Choledocholithiasis, Laparoscopic surgery, Common bile duct

## INTRODUCTION

Choledocholithiasis is encountered in approximately 10%–15% of patients with cholelithiasis. The incidence of choledocholithiasis increases in elderly patients. It can result in biliary colic, obstructive jaundice, cholangitis, or pancreatitis.

The traditional approaches of open common bile duct (CBD) exploration have been replaced by newer, less-invasive procedures. The principal minimally invasive options in the treatment of CBD stones include endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic stone

extraction and laparoscopic CBD exploration [1].

ERCP has been the treatment of choice for symptomatic CBD stones for decades. However, the major drawbacks of ERCP are that it requires two stage approach (laparoscopic cholecystectomy and preoperative/postoperative ERCP) and can cause the life-threatening complications such as bleeding, perforation, and pancreatitis [2]. It has been reported that sphincterotomy may cause recurrent ductal stones, stenosis of the papilla with cholangitis, and late development of bile duct cancer, which is a cause of concern particularly in younger patients [3].

Received August 16, 2013, Revised October 11, 2013, Accepted October 24, 2013

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Laparoscopic common bile duct exploration (LCBDE) has been proven to be a safe, reliable, and effective treatment for CBD stones and has gained wider acceptance with its added advantage of being a single-stage procedure. LCBDE has become the main treatment for CBD stones associated with cholelithiasis [4]. The UK guidelines recommended LCBDE as the treatment of choice for patients with CBD stones undergoing laparoscopic cholecystectomy [5]. Moreover, results from prospective randomized trials have shown that LCBDE has the advantage of shorter hospital stay and lower medical cost than ERCP [6].

LCBDE can be approached either through the cystic duct or directly through a choledochotomy incision. The main advantage of choledochotomy is that it provides unrestricted access to both the CBD and the common hepatic duct, enabling access to more difficult stones [7]. Thus, we chose choledochotomy as the main method for approaching CBD stones. However, long-term complications such as bile duct strictures can develop after the surgery. As of yet published data regarding the long-term results of LCBDE remains undocumented in Korea. Thus, the aim of this study is to assess the long-term results of LCBDE and validate its effectiveness.

## METHODS

From January 1997 to November 2011, authors collected, retrospectively, the data on 157 unselected patients who underwent LCBDE for choledocholithiasis. Diagnosis of CBD stones was based on image studies such as ultrasonography, computed tomography and magnetic resonance cholangio pancreatography with supporting laboratory test results. Laparoscopic choledochotomy was indicated only when the CBD diameter based on image studies exceeded 10 mm. Currently, magnetic resonance cholangio pancreatography is routinely used to document the presence of CBD stones and identify biliary anatomy before surgery. Data based on a chart review for each of the 157 identified patients was generated. The demographic data, operative outcome, postoperative complication, recurrence rate of CBD stones and long-term biliary complications were collected and analyzed. Mean follow-up period was 51.9 months (range, 6 to 162 months).

A patient was placed supine and a 10-mm trocar was used in the subumbilical area for camera port, a 10-mm trocar in the epigastric area, 5-mm trocar in the right upper abdomen area, and a 10-mm trocar in the right subcostal area. Exposure of the CBD was facilitated by upward retraction of the liver with anterior and cephalad retraction of the gallbladder. Careful dissection was used to identify the anterior surface of the CBD, where a longitudinal choledochotomy was performed. After that, a choledochoscope was routinely used to find and to extract stones. A combination of saline irrigation, basket, or

balloon extraction techniques and electro-hydraulic lithotripsy under a choledochoscope was used to remove CBD stones. After the removal of stones, a choledochoscope was used to find residual stone in intrahepatic duct and CBD. If no residual stone was confirmed, the choledochotomy incision was primarily closed using 3–0 absorbable suture. A silicone T-tube of 16 Fr was inserted at the surgeon's discretion in the setting of residual stones, or when numerous stones were extracted from the biliary tree. Laparoscopic cholecystectomy was done after finishing suture of the CBD incision site. A closed suction drain was inserted routinely on Morison's pouch. T-tube cholangiogram was done 2–4 weeks after the procedure in the case of T-tube insertion group and T-tube was removed if no residual stone was observed.

In respect to follow-up of patients, we gave them physical examinations and performed laboratory tests with the interval of 3 or 6 months. If there were unusual findings, image studies like ultrasonography and computed tomography were performed.

IBM SPSS ver. 20.0 (IBM Co., Armonk, NY, USA) was used for statistical analysis. Chi-square test and Student t-test were used for comparing categorical variables. Significance was assigned at  $P < 0.05$ .

## RESULTS

### Short-term results

LCBDE was attempted in 157 patients and completed in 152 patients. The five patients had open conversion (3.2%) due to severe adhesion, iatrogenic CBD transaction, and CBD

**Table 1.** Characteristics of patients

Characteristic	Value
Patients	157
Male	78 (49.7)
Female	79 (50.3)
Age (yr), mean $\pm$ SD	67.3 $\pm$ 28.1
Comorbidity	74 (47.1)
Cardiovascular disease	56
Diabetes mellitus	23
Liver disease	6
Pulmonary disease	12
Others	6
ASA score	
1	12 (7.6)
2	129 (82.2)
3	16 (10.2)
Preoperation EST	56 (35.7)

Values are presented as number (%) unless otherwise indicated. SD, standard deviation; ASA, American Society of Anesthesiologists; EST, endoscopic sphincterotomy.

narrowing. There were 116 patients (76.3%) over 60 years of age and 74 patients (47.1%) who had comorbidities. Mean age was 67.3 years. Abdominal operation history was present in 25 patients (15.9%). As for American Society of Anesthesiologists (ASA) scoring, 12 patients were classified as ASA 1 (7.6%), 129 were ASA 2 (82.2%), and 16 were ASA 3 (10.2%). Preoperative ERCP failed to remove CBD stones in 56 patients (35.7%) (Table 1).

Stone clearance was successful in 149 of 152 patients (98.0%). Retained bile duct stones were found in 3 patients (2%); two patients had retained stones removed through T-tube and one patient through postoperative ERCP.

After the CBD exploration was performed, T-tube drain was used in 60 patients (39.5%) and primary closure was done in 92 patients (60.5%). The mean operative time was  $187 \pm 67.0$  minutes. The mean hospital stay was  $11.0 \pm 6.1$  days (Table 2).

Postoperative complications occurred in 11 of 152 patients (7.2%). Bile leakage developed in 6 patients (3.9%). The patients

with bile leakage recovered through conservative management with drainage (Table 2).

### Long-term results

CBD stones recurred in 9 of 152 patients (5.9%). Mean time of recurrence was  $30.0 \pm 26.0$  months after the operation. ERCP was used to remove recurrent CBD stones in 5 patients, hepatico-jejunostomy was performed in 2 patients, and only observation was done in 2 patients (Table 3). There were no signs of any type of biliary injury or stricture observed in any of the patients during the follow-up period.

The univariate analysis showed that factors such as age, sex, comorbidity, the use of preoperative endoscopic sphincterotomy, the method of choledochotomy repair, preoperative level of total bilirubin, and the number of CBD stones were not significantly related to the CBD stones recurrence (Table 4).

We divided the patients with LCBDE into two groups according to time period. Group A ( $n = 73$ ) is from 1997 to 2004 and group B ( $n = 79$ ) is from 2005 to 2011. The mean operation time was longer in group A than in group B (209.3 minutes vs. 166.7 minutes,  $P < 0.001$ ). It is possible that an accumulation of experience and choledochotomy repair by primary closure have shortened operation time. The postoperative hospital stay was shorter in group B than in group A (13.6 days vs. 8.6 day,  $P < 0.001$ ). T-tube insertion was a frequently used method before 2004 ( $n = 55$ , 75.3%) and it may have caused longer postoperative hospital stay. No significant difference was observed in the

**Table 2.** Operative outcome of LCBDE

Variable	Value
LCBDE attempted	157
Open conversion	5 (3.2)
Stone clearance	149 (98.0)
Complications	11 (7.2)
Bile leakage	6 (3.9)
Bleeding	2 (1.3)
Pneumonia	2 (1.3)
Abscess	1 (0.7)
Choledochotomy repair	
T-tube placement	60 (39.5)
Primary closure	92 (60.5)
Mean operation time (min)	$187.0 \pm 67.0$
Postoperation hospital stay (day)	$11.0 \pm 6.1$

Values are presented as number (%) or mean  $\pm$  standard deviation.

LCBDE, laparoscopic common bile duct exploration.

**Table 3.** Long term results after LCBDE for CBD stones

Variable	Value
Recurrent CBD stone, n (%)	9 (5.9)
Time to recurrence, n (%)	
Within 2 yr	5 (55.6)
After 2 yr	4 (44.4)
Treatment of recurrence	
ERCP	5
Hepaticojejunostomy	3
Observation	1
Biliary injury or stricture	0

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

**Table 4.** Univariate analysis of factors associated with CBD stone recurrence

Variable	Recurrence (n = 9)	No recurrence (n = 143)	P-value
Age (yr)	$70.4 \pm 10.1$	$67.0 \pm 14.3$	0.402
Sex			0.496
Male	6 (66.7)	72 (50.3)	
Female	3 (33.3)	71 (49.7)	
Preoperation EST			0.492
Yes	2 (28.6)	52 (36.4)	
No	7 (71.4)	91 (63.6)	
Comorbidity			0.307
Yes	6 (66.7)	65 (45.5)	
No	3 (33.3)	77 (54.5)	
Closure method			0.740
T-tube insertion	4 (44.4)	56 (39.2)	
Primary closure	5 (55.6)	87 (60.8)	
Preoperation TB (mg/dL)	$3.4 \pm 2.8$	$3.6 \pm 3.6$	0.871
CBD stones	$3.9 \pm 3.8$	$3.9 \pm 4.5$	0.973

Values are presented as mean  $\pm$  standard deviation or number (%).

CBD, common bile duct; EST, endoscopic sphincterotomy; TB, total bilirubin.

**Table 5.** Chronological comparison

Variable	'97-'04 (n = 73)	'05-'11 (n = 79)	P-value
Operation time (min)	209.3 ± 74.6	166.7 ± 51.8	<0.001
Hospital stay (day)	13.6 ± 6.4	8.6 ± 4.8	<0.001
Choledochotomy repair			<0.001
T-tube placement	55 (75.3)	5 (6.3)	
Primary closure	18 (24.7)	74 (93.7)	
Complication	4 (5.5)	7 (8.9)	0.498
Recurrence	3 (4.1)	6 (7.6)	0.498

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

operative complication and recurrence rate (Table 5).

## DISCUSSION

The purpose of this study was to evaluate the long-term efficacy of LCBDE for CBD stones. There has been no documentation about the long-term follow-up results after LCBDE via choledochotomy in Korea. This study showed that LCBDE could be performed without increased risk of long-term complications such as bile duct stricture and recurrent CBD stones.

In a study of open CBDE with 5,530 patients, bile stricture was noted in 1.1% of the patients by 60 months after the operation and recurrent CBD stones were noted 7.9% of the patients by 40 months [8]. In another study of open CBDE with 257 patients, recurrent CBD stones were noted at 14% by 60 months [9]. Long-term complications of endoscopic sphincterotomy (EST) were reported in a study of 310 patients with a median follow-up period of 74 months; 7.4% had recurrent ductal stones, 1.6% had cholangitis, 0.6% had stenosis of the papilla, and 0.3% had biliary pancreatitis [3]. As for LCBDE via choledochotomy, the rate of recurrent ductal stones was reported to be 3.6% and no biliary stricture was observed in the study of 138 patients over a mean follow-up period of 72.3 months [10]. This study showed that the rate of recurrent CBD stones in LCBDE via choledochotomy was 5.9%, which is similar to previous data. Biliary complications such as bile leakage and biliary stricture can become a major problem for patients who undergo LCBDE by choledochotomy. In this study, bile leakage occurred in only 6% of patients and they were treated with conservative management with drainage. In the mean long-term follow-up of 51.9 months, no sign of biliary injury or stricture was found. These outcomes demonstrate that LCBDE is a safe and effective option even in the long-term results.

It has been reported that CBD stone clearance rate of open CBDE is 85.3% to 88.8% [11,12]. Mortality rate of open CBDE is

from 0.3% in younger patients to 9.5% in patients older than 80 years. Morbidity rate is reported to be 7.3% to 20.1% [13,14]. The overall success rate of ERCP is reported to be between 85% and 98% [3,11]. In a study by Schreurs et al. [3] with 552 patients, complication of ERCP occurred in 8.3% and mortality rate was 0.4%. Although ERCP is a less invasive procedure than open CBDE, a Cochrane database review published in 2006 has suggested that ERCP was less successful than open surgery in CBD stone clearance and there was no significant difference in morbidity rates between them. Mortality rates were even higher in ERCP than in open CBDE [15]. According to two studies conducted on a large group of patients who underwent LCBDE, overall success rate was 94.6% to 97.3%, and complication rate was 9.5% to 10.2% [10,16]. In this study, stone clearance was successful in 98.0% of cases and complications were noted in 7.2% of cases, which compares favorably with other published studies of LCBDE.

Currently, the optimal treatment for concomitant gallstones and CBD stone is still in dispute. Several studies have reported on the efficacy, safety, and efficiency of CBD stones removal whether by ERCP or LCBDE. A prospective randomized trial that included 122 patients by Rogers et al. [17] compared LCBDE and ERCP, and concluded that both procedures have equal efficacy in terms of ductal stone clearance as well as similar rates of morbidity. Both groups had similar patient acceptance rates and quality of life scores. The meta-analysis, which included 7 RCTs composed of 787 patients, detected no statistically significant difference between the two groups in stone clearance from the CBD, postoperative morbidity, and mortality [18]. As many studies have shown, LCBDE is comparable to ERCP in not only long-term outcomes but also in the short-term outcomes.

A randomized prospective study by Rhodes et al. [19] demonstrated that the median hospital stay was significantly lower in one-stage LCBDE group than two-stage ERCP group (preoperative/postoperative ERCP and laparoscopic cholecystectomy). Some studies showed that LCBDE was more cost effective [20]. ERCP can not only induce several postoperative complications such as bleeding, perforation and pancreatitis [2], but also can lead to disruption of sphincter of Oddi, thereby causing injury to the barrier function of the sphincter which prevents duodenobiliary reflux [21]. Duodenobiliary reflux is responsible for increased incidence of bacterobilia that occur after EST [22]. Neoplastic changes in the biliary epithelium may also occur due to chronic bacterobilia [1]. Preoperative EST seems not to be preventive of the recurrence of CBD stone. This study showed that preoperative EST was not significantly related to the recurrence of CBD stones. Furthermore, there are many cases of choledocholithiasis that cannot be feasibly managed with ERCP. In patients with impacted stone [19], previous history of gastrectomy [23], and periampullary diverticulum [24], the possibility of failure of



ERCP increases.

The LCBDE procedure requires advanced laparoscopic skills, sophisticated equipment. Thus, because of the high start-up costs and surgical expertise involved with LCBDE, the widespread application of LCBDE has been somewhat limited. But, considering the above mentioned drawbacks of ERCP, the excellent treatment outcomes of LCBDE, and equivalent success rates and complication rates between ERCP and LCBDE as previously published trials suggested, it is possible to consider LCBDE as a gold standard for treatment of CBD stone.

The method by which we approached CBD stone in this study was a choledochotomy. Although the choledochotomy approach is a more invasive procedure than the transcystic approach and has higher morbidity rates, the success rate of bile duct clearance of choledochotomy is higher than the transcystic approach (93.3%–97.1% vs. 63%–84%). Also, choledochotomy does not have limitations related to the anatomy of the cystic duct and ductal stone [25,26].

We applied T-tube drainage in 75% of patients who had LCBDE from 1997 to 2004. However, T-tube was used only in 6.3% of patients from 2005 to 2011. Many studies have reported that 10.5%–20% complications related to T-tube, such as bile

leakage, local pain, and inconveniences to the patients could occur [27,28]. It has been reported that T-tube drainage does not prevent the recurrence of ductal stones [29], and this study also found that T-tube drainage was not related to stone recurrence. In this study, biliary stricture did not occur in both T-tube group and primary closure group during follow-up period. Another study of 48 patients with T-tube after LCBDE showed that no long-term strictures or biliary complications were noted over a mean follow-up period of 43 months [16]. Therefore, it is possible to speculate that there is no correlation between T-tube insertion and biliary stricture.

In conclusion, LCBDE can be performed without increased risk of long-term complications such as bile duct stricture and recurrent CBD stones. Therefore, LCBDE is a safe and effective treatment option for choledocholithiasis in terms of long-term outcome as well as short-term outcome.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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