

Research Article

The Safety and Efficacy of Primary Duct Closure without Endoscopic Nasobiliary Drainage after Laparoscopic Common Bile Duct Exploration

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Keywords

Choledocholithiasis · Choledochoscopy · Endoscopic retrograde cholangiopancreatography · Suture · Complications

Abstract

Background: Primary duct closure (PDC) after laparoscopic common bile duct exploration (LCBDE) has been widely applied for choledocholithiasis. However, there has been controversy over the placement of endoscopic nasobiliary drainage (ENBD) during operation. To date, few studies compare the clinical effect of PDC without and with ENBD. The aim of this study was to assess the safety and efficacy of PDC without ENBD for choledocholithiasis.

Methods: From January 2016 to December 2018, a total of 164 patients meeting the inclusion criteria were enrolled and divided into group A (undergone LCBDE + PDC without ENBD, 81 cases) and group B (undergone LCBDE + PDC with ENBD, 83 cases) in this study. The intraoperative conditions and postoperative complications were compared between the 2 groups.

Results: In group A, the time of operation, postoperative first flatus, extubation, antibiotics, and discharge were shorter than in group B ($t = -17.775, p = 0.000$; $t = -7.649, p = 0.000$; $t = -5.807, p = 0.000$; $t = -9.247, p = 0.000$; $t = -9.322, p = 0.000$, respectively). Furthermore, intraoperative blood loss was less ($t = -2.199, p = 0.029$) and hospital costs were lower ($t = -6.685, p = 0.000$). However, there was no significant difference in postoperative complications between the 2 groups ($p > 0.05$). **Conclusions:** In patients who meet the screening criteria, PDC without ENBD after LCBDE is safe and effective and worthy of clinical application.

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Introduction

Choledocholithiasis is a common disease in biliary surgery and relates to severe complications such as cholangitis or pancreatitis [1]. In recent years, with innovation and development in minimally invasive surgical techniques, laparoscopic common bile duct exploration (LCBDE) plus primary duct closure (PDC) have been widely adopted because of the efficacy and safety [2, 3]. Estellés Vidagany et al. [4] reported that the success rate for stone clearance was 96.2%, in addition to the mortality rate and CBD stenosis rate being 0%. However, the overall complication rate was 15% and the biliary complication rate was 7.5%; for example, bile leakage was 6.8%. So, intraoperative endoscopic nasobiliary drainage (ENBD) through endoscopic retrograde cholangiopancreatography (ERCP) has been proposed. But, it is well known that serious complications of this operation include acute pancreatitis, sepsis, bleeding, cholangitis, duodenal perforation, and so on [5, 6]. To date, whether ENBD following LCBDE is necessary for every patient remains a controversial issue [7]. Hence, the aim of this study was to assess the clinical efficacy of PDC with and without ENBD.

Materials and Methods

Patients

The patients with choledocholithiasis were undergone LCBDE at the Department of Hepatobiliary Pancreatic Surgery, the First Affiliated Hospital of Hainan Medical University, Haikou, Hainan, China. The inclusion criteria were based on the following [8, 9]: (1) stones can be cleared within one procedure, (2) <5 stones in CBD, (3) stone size ≤ 1.5 cm, (4) CBD diameter ≥ 0.8 cm, and (5) good functional sphincter of Oddi. The exclusion criteria included the following [10, 11]: (1) intrahepatic bile duct stones, (2) bile duct stricture, (3) acute obstructive suppurative cholangitis, (4) duodenal papilla stenosis or occlusion, (5) accompanying with malignant tumor, (6) biliary pancreatitis, and (7) severe systemic disease leading to inability to tolerate surgery. All patients were identified and assigned to 2 groups: LCBDE plus PDC without ENBD (group A, $n = 81$) and with ENBD (group B, $n = 83$). The ethical approval was obtained from the First Affiliated Hospital of Hainan Medical University Ethics Committee (Grant No. 2016 [scientific research] No [3]), and written informed consents were obtained from all patients.

Surgery

All surgical approaches were performed by the same surgical team with 4-port [12]. In both groups, after removing the gallbladder, a longitudinal incision of 10~15 mm was made in the anterior aspect of the CBD, and a flexible choledochoscope (Olympus-P60; Olympus, Tokyo, Japan) was used to detect the stones. A stone basket (Wilson-Cook MWB3*6; Winston-Salem, NC, USA) was applied to extract CBD stones through the working channel of the choledochoscope. When all stones were cleared, the basket could be successfully passed through the duodenal papilla.

Next, in group B, a zebra guide wire (MTW-0.027; MTW Endoskopie, Wesel, Germany) was inserted into the CBD via an intraoperative choledochoscope and retrieved by the intraoperative ERCP (Olympus CV-260; Olympus, Tokyo, Japan). And then, under the guidance of the zebra guide wire, a nasobiliary drainage tube (Wilson-Cook 8.5F; Winston-Salem, NC, USA) was placed into the CBD, in which the head of the tube was at least 1 cm above the CBD incision and the end was dragged out from the nose. Finally, in both groups, the CBD was interruptedly or continuously closed with 4-0 Ethicon absorbable suture (Johnson & Johnson, West Somerville, NJ, USA), and a 20F silica gel drainage tube was routinely placed beside the foramen of Winslow (Fig. 1).

Outcome Definition

Postoperative morbidity was the number of complications occurring within the first 30 days after surgery, and complications were grouped according to the Dindo-Clavien classification [13]. Postoperative mortality was the number of deaths occurring during the first 30 days after surgery. Bile leakage was defined and classified according to the International Study Group of Liver Surgery [14]. A retained stone was a stone detected in the CBD during the first 2 years after surgery [15].

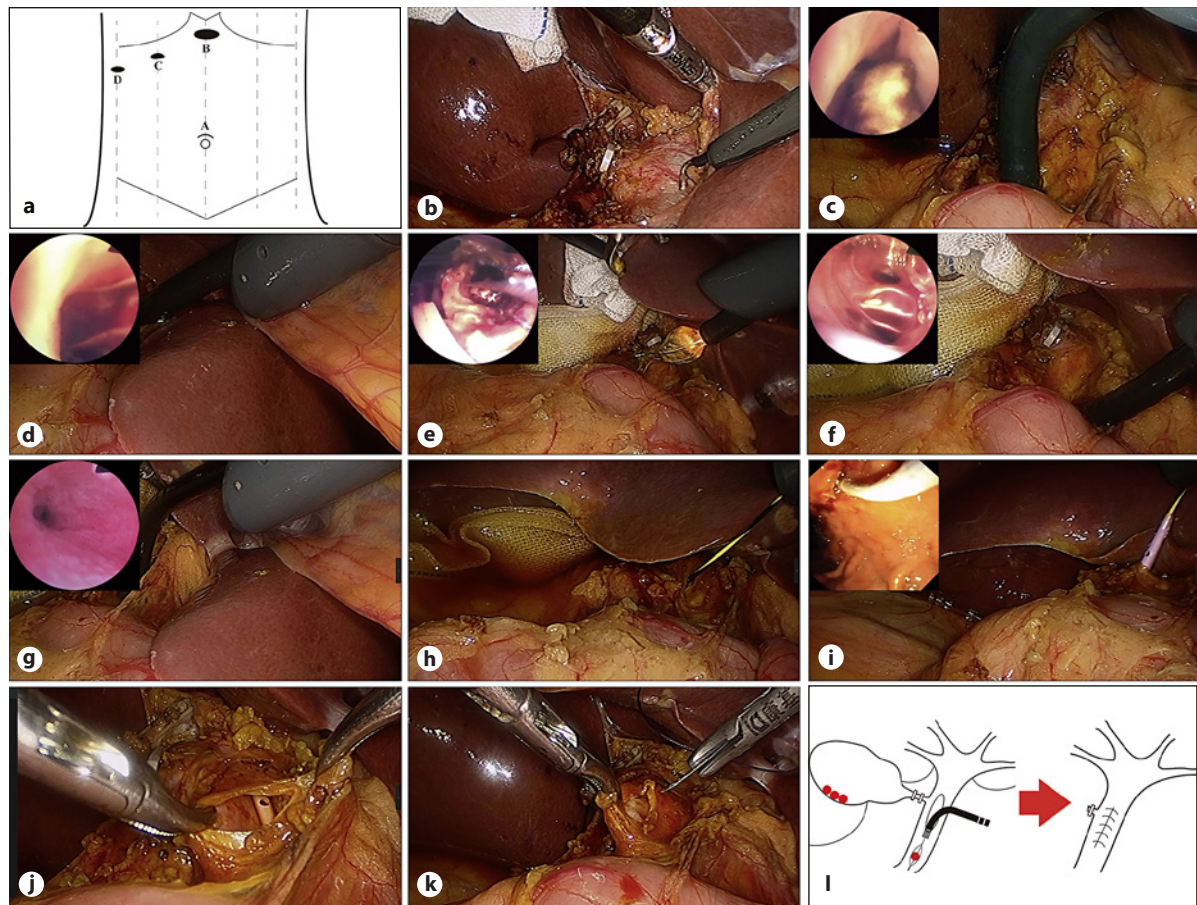


Fig. 1. Intraoperative photographs showing the surgical process of LCBDE plus PDC with or without ENBD. **a** Showing the position of trocars. **b** Choledochotomy. **c** Exploring the CBD by the choledochoscope. **d, e** Extracting the stone. **f, g** Exploring the CBD once more. **h** Inserting the guide wire. **i, j** Placing ENBD. **k** Closing the CBD at the first stage. **l** Showing LCBDE and PDC. LCBDE, laparoscopic common bile duct exploration; PDC, primary duct closure; ENBD, endoscopic nasobiliary drainage.

Statistical Analysis

Data were statistically analyzed by using the software package SPSS (version 19.0) for Windows. Measurement data with normal distribution were represented as $\bar{x} \pm \text{SD}$. Comparison between the groups was analyzed by Student's *t* test. Comparisons of count data were analyzed using the χ^2 test or Fisher exact probability. A level of $p < 0.05$ was considered statistically significant.

Results

Demographics of Cohort

From January 2016 to December 2018, a total of 164 eligible patients were undergone the surgery, and the patient characteristics are described in Table 1. Eighty-six female and 78 male patients, with a median age of 60 years (range 21–88 years), were included in this study. There were no significant differences in terms of demographic or clinical characteristics between the 2 groups ($p > 0.05$). The mean number and size of stones in the 2 groups were 1.96 ± 1.07 versus 1.65 ± 1.13 ($t = 1.819$, $p = 0.071$) and 0.87 ± 0.36 versus 0.81 ± 0.33 cm ($t = 1.125$, $p = 0.262$), respectively. The mean diameter of CBD was 1.26 ± 0.34 versus $1.17 \pm$

Table 1. Perioperative general characteristics of the 2 groups

Characteristics	Group A (n = 81)	Group B (n = 83)	χ^2/t	p values
Age, years	57.28±14.94	57.55±16.35	-0.110	0.912
Sex (male/female)	37/44	41/42	0.227 ^a	0.634
Presentations				
Fever	15 (18.52%)	25 (30.12%)	2.992 ^a	0.084
RUQ pain	73 (90.12%)	78 (93.98%)	0.834 ^a	0.361
Jaundice	39 (48.15%)	42 (50.60%)	0.099 ^a	0.753
Stone characteristics				
Stones, n	1.96±1.07	1.65±1.13	1.819	0.071
Size of stones, cm	0.87±0.36	0.81±0.33	1.125	0.262
Diameter of CBD, cm	1.26±0.34	1.17±0.35	1.703	0.090
ASA score				
1	74	72	0.892 ^a	0.345
2	7	11		
3	0	0		
4	0	0		
5	0	0		
6	0	0		
Conversion to open surgery, %	0	0		
Follow-up, months	16.52±9.30	17.64±10.30	-0.730	0.466

RUQ, right upper quadrant; WBC, white blood cell; CBD, common bile duct; ASA, American Society of Anesthesiologists. ^a χ^2 value.

Table 2. Outcomes of the 2 groups

Outcomes	Group A (n = 81)	Group B (n = 83)	χ^2/t	p values
Closure methods				
Interrupted suture	32 (39.51%)	30 (36.14%)	0.197 ^a	0.657
Continuous suture	49 (60.49%)	53 (63.86%)		
Suture materials				
Absorbable	73 (90.12%)	83 (100%)	8.618 ^a	0.003
Nonabsorbable	8 (9.88%)	0 (0%)		
Operation time, min	123.46±27.53	192.00±21.57	-17.775	0.000
Intraoperative bleeding, mL	39.94±39.39	50.14±15.22	-2.199	0.029
Postoperative first flatus, day	2.06±1.46	4.10±1.91	-7.649	0.000
Intraperitoneal drainage extubation, day	4.46±2.73	7.02±2.93	-5.807	0.000
Postoperative antibiotic therapy, day	5.95±2.64	10.39±3.44	-9.247	0.000
Postoperative hospital stay, day	6.99±2.55	11.55±3.62	-9.322	0.000
Cost (¥, ten thousand yuan)	4.84±0.83	5.72±0.86	-6.685	0.000

^a χ^2 value.

0.35 cm ($t = 1.703$, $p = 0.090$). The median follow-up was 17 months (range 7–28 months) after surgery.

Surgical Procedure

All patients successfully received laparoscopic surgical therapy without converting to open surgery, and no postoperative mortality was found in any groups. During surgery, PDC

Table 3. Perioperative complications and management of the 2 groups

Dindo-Clavien classification ¹	Complication	Group A (n = 81)	Group B (n = 83)	p value ³	Management
I	Bile leakage ²				
	Grade A	1	1	1.000	Observation
	Grade B	0	1	1.000	Observation
	Wound infection	1	1	1.000	Dressing change
II	Pneumonia	1	4	0.367	Antibiotics
	Acute pancreatitis	1	0	0.494	Octreotide
	Cholangitis	4	4	1.000	Antibiotics
	Hemobilia	1	3	0.620	Octreotide + hemostatic
III _a	Bile leakage Grade B	3	0	0.118	ERCP
III _b		0	0		
IV		0	0		

ERCP, endoscopic retrograde cholangiopancreatography. ¹ Postoperative complications were grouped according to the Dindo-Clavien classification [13]. ² The definition and classification of bile leakage as provided by the International Study Group of Liver Surgery [14]. ³ Fisher's exact test.

was performed in 39.51% (32/81) by interrupted suture and in 60.49% (49/81) by continuous suture in group A, while 36.14% (30/83) and 63.86% (53/83) in group B ($\chi^2 = 0.197$, $p = 0.657$), in addition to 90.12% (73/81) by absorbable suture in group A and 100% (83/83) in group B ($\chi^2 = 8.618$, $p = 0.003$). In both groups, the mean operation time was 123.46 ± 27.53 versus 192.00 ± 21.57 min ($t = -17.775$, $p = 0.000$) and the median intraoperative bleeding was 39.94 ± 39.39 versus 50.14 ± 15.22 mL ($t = -2.199$, $p = 0.029$) (Table 2).

Postoperative Outcomes

After surgery, the time of first flatus, intraperitoneal drainage extubation, antibiotic therapy, hospital stay, and the costs were 2.06 ± 1.46 days, 4.46 ± 2.73 days, 5.95 ± 2.64 days, 6.99 ± 2.55 days, and 4.84 ± 0.83 ten thousand yuan in group A, compared with 4.10 ± 1.91 days, 7.02 ± 2.93 days, 10.39 ± 3.44 days, 11.55 ± 3.62 days, and 5.72 ± 0.86 ten thousand yuan in group B, respectively. Statistically significant differences between the 2 groups were present in each of these parameters ($t = -7.649$, $p = 0.000$; $t = -5.807$, $p = 0.000$; $t = -9.247$, $p = 0.000$; $t = -9.322$, $p = 0.000$; $t = -6.685$, $p = 0.000$) (Table 2).

Postoperative Complications

The overall postoperative morbidity rate was 14.81% (12/81) in group A and 16.87% (14/83) in group B. The differences were not statistically significant ($\chi^2 = 0.129$, $p = 0.719$). Cases with grade A bile leakage, grade B bile leakage, cholangitis, hemobilia, acute pancreatitis, pneumonia, and wound infection were 1 (1.23%), 3 (3.70%), 4 (4.94%), 1 (1.23%), 1 (1.23%), 1 (1.23%), and 1 (1.23%) in group A, compared with 1 (1.20%), 1 (1.20%), 4 (4.82%), 3 (3.61%), 0 (0%), 4 (4.82%), and 1 (1.20%) in group B, and there was no significant difference between the 2 groups ($p > 0.05$) (Table 3). According to the Dindo-Clavien classification [13], most of the complications were grades I and II. Moreover, 3 patients with grade A or B bile leakage stopped spontaneously in 5~13 days through effective peritoneal drainage. However, in group A, there were 3 other patients with grade B bile leakage treated by ERCP and ENBD insertion. Four patients with hemobilia were detected by the peripheral blood and fecal occult

blood test and become negative after 1–3 days treated by octreotide or hemostatic drugs. Just only 1 case in group A experienced acute biliary pancreatitis on the third day after surgery and cured with octreotide. The cholangitis and pneumonia were cured with antibiotics, and the wound infection was treated by dressing change. No patients in either group developed postoperative grade C bile leakage, retained or recurrent stones, jaundice, and bile duct stricture during the follow-up period.

Discussion/Conclusion

Since LCBDE was first performed by Philips et al. in 1993 [16], the managements of the bile duct diseases have changed radically in recent years. A large multicenter randomized controlled trial indicated that one-stage laparoscopic treatment was a better option for those patients with ASA I and II [17]. In addition, a comprehensive meta-analysis demonstrates that PDC after LCBDE is feasible for choledocholithiasis because it is associated with fewer complications than T-tube placement [3]. However, Estellés Vidagany et al. [4] reported that the overall complication rate of PDC was 15% and bile leakage was 6.8%. Therefore, some scholars suggested that intraoperative ENBD should be retained after LCBDE + PDC to prevent the complications. Liao et al. [18] believed there was no significant difference in the operation time, the intraoperative blood loss, and the incidence of bile leakage between intraoperative ENBD and T-tube drainage. Furthermore, Yin et al. [19] thought that the postoperative complication rate of intraoperative ENBD was lower than that of preoperative ERCP but without significant difference (1.9 vs. 4.2%, $p = 0.29$). However, it is well known that serious complications of ENBD include acute pancreatitis, sepsis, bleeding, cholangitis, duodenal perforation, and so on [5, 6]. Moreover, multivariable regression analysis indicated that slender CBD (<0.8 cm) and inexperienced surgeons were the high-risk factors for bile leakage after PDC [20]. So, it is still controversial whether intraoperative ENBD should be applied following LCBDE + PDC for all patients [7].

Initially, the main surgery principle of choledocholithiasis is to remove stones clearly to keep the CBD unobstructed. Any factor that is likely to cause obstruction of the distal bile duct will lead to high pressure in the duct and ischemia at the suture site, resulting in the increased chances of bile leakage and duct stricture [1]. In our study, preoperative imaging and intraoperative choledochoscopy provided direct visual information about stones or distal CBD obstruction to the surgeons. Patients who met the inclusion criteria were completed the laparoscopic surgical procedure with a rate of duct clearance of 100% (Table 1), which was consistent with other published series on LCBDE (88~100%) [21–23].

The key factors to clear stones include the size and number of stones and the diameter of CBD. In our research, the cases according to the inclusion criteria were selected; that is, the size of stone must be <1.5 cm [8], the number of stones must be <5 [19], and the diameter of CBD must be >0.8 cm [1]. In group A, the mean stone size was 0.87 ± 0.36 cm, the mean number was 1.96 ± 1.07 , and the mean diameter of CBD was 1.26 ± 0.34 cm (Table 1). Multiple studies have shown that too many or too large stones may not be able to be reliably and safely removed through LCBDE. Meanwhile, the minimum diameter of 0.8 cm is essential to perform safe choledochotomy and stone removal as well as to avoid postoperative CBD stricture [3, 19, 24].

In addition, the intraoperative findings and postoperative recovery were compared between the 2 groups. Group A had the advantages of shorter operation time, less bleeding, faster recovery, and lower hospital cost ($p < 0.05$) (Table 2). The average operation time of group A was shorter because of the time saved by not having to place an ENBD. Furthermore, intraoperative ENBD through ERCP led to higher hospital cost and longer postoperative hospital stay.

The overall rate of postoperative complication and bile leakage was 14.81 and 4.94% in group A, compared with 16.87 and 2.41% in group B ($p = 0.719$; $p = 0.440$), respectively (Table 3). The differences between the 2 groups were not statistically significant. In addition, the results of this study are consistent with existing literature, which shows 15 and 6.8%, respectively [4]. Furthermore, we classified the reasons for bile leakage after PDC without ENBD as follows: (1) improper patient selection, (2) retained stones, (3) inexperience with laparoscopic suturing techniques, and (4) CBD injury. In our study, all bile leakage stopped spontaneously through interventional or conservative treatment without reoperation. Moreover, there was no severe bile leakage (grade C), recurrent stones, or bile duct stricture. These data proved that PDC without ENBD did not increase the risk of postoperative complications.

In conclusion, under the strictly screening conditions, PDC after LCBDE without ENBD has much shorter operative time, less bleeding, cheaper cost, and quicker recovery than that with ENBD, in addition to no increase in the morbidity rate of operative complications. So, PDC after LCBDE without ENBD in appropriately selected patients is safe and effective and worthy of clinical application.

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Statement of Ethics

This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The ethical approval was obtained from the First Affiliated Hospital of Hainan Medical University Ethics Committee (Grant No. 2016 [scientific research] No [3]), and written informed consents were obtained from all patients.

Conflict of Interest Statement

All authors declare that there are no conflicts of interest to disclose.

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Author Contributions

The work presented here was carried out in collaboration with all authors. Yan Yang defined the research theme and designed the research method. Yan Yang, Lin Han, and Da-Ning Lin performed the laparoscopic surgical procedures. Zeng-Ji Hu performed ERCP surgical procedures to place the ENBD. Da-Ning Lin, Wei Tu, Feng Chen, and Yong-Qiang Li were responsible for perioperative management and clinical data collection. Yan Yang and Wei Tu oversaw the statistics and analysis of clinical data. Feng Chen and Yong-Qiang Li wrote the paper. All authors have contributed to and approved the paper.

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