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Authors:
Yong Zhou, Wen-Zhang Zha, Ren-Gen Fan, Guo-qin Jiang, Xu-dong Wu

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Two-stage *versus* single-stage procedure for the management of cholecystocholedocholithiasis in elderly patients: a retrospectively cohort study

Yong Zhou[1,2], Wen-Zhang Zha[2], Ren-Gen Fan[2], Guo-qin Jiang[1] and Xu-dong Wu[3]

[1]Department of General Surgery. The Second Affiliated Hospital of Soochow University. Suzhou, Jiangsu. China. Departments of [2]General Surgery and [3]Gastroenterology. Yancheng City No. 1 People's Hospital. Yancheng, Jiangsu. China

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Correspondence: Guo-qin Jiang. Department of General Surgery. The Second Affiliated Hospital of Soochow University. 215004 Suzhou, Jiangsu. China

e-mail: xs52308@hotmail.com

Authorship: Guo-qin Jiang and Xu-dong Wu contributed equally to this work.

ABSTRACT

Background: there is an increasing incidence rate of cholecysto-choledocholithiasis associated with the increasing proportion of senile individuals.

Methods: a total of 100 elderly patients (over 80 years of age) suffering both from cholelithiasis and choledocholithiasis were retrospectively studied from January 2010 to December 2016. Patients were scheduled for either a single-stage or two-stage procedure. The LCBDE group (n = 54) included cases that underwent a single stage procedure of laparoscopic exploration of the common bile duct combined with cholecystectomy. The ERCP/EST group (n = 46) included cases that underwent a two stage procedure of preoperative endoscopic retrograde cholangiopancreaticography with endoscopic sphincterotomy followed by cholecystectomy. Comorbidity conditions, presenting symptoms, bile duct clearance,

length of hospital stay and the frequency of procedural, postoperative and long-term complications were recorded.

Results: the LCBDE group had a higher stones clearance rate than the ERCP/EST group (100.0% *vs* 89.1%, $p < 0.05$). Postoperative complications and hospitalization length were comparable in the two groups ($p > 0.05$). There were more procedural complications in the ERCP/EST group than in the LCBDE group (10.8% *vs* 0%, $p < 0.05$). Furthermore, a patient in the ERCP/EST group died due to duodenal perforation. More patients in the ERCP/EST group experienced long-term complications than those in the LCBDE group (23.9% *vs* 3.7%, $p < 0.05$) during a mean follow-up period of 28.4 months.

Conclusions: the single-stage procedure is a safe and effective technique for elderly patients with cholecysto-choledocholithiasis. LCBDE provides a good stone clearance rate with few long term complications.

Key words: Cholecysto-choledocholithiasis. Elderly patients. Laparoscopic common bile duct exploration (LCBDE). Endoscopic retrograde cholangiopancreaticography and endoscopic sphincterotomy.

INTRODUCTION

The increased proportion of senile people worldwide is accompanied by a growth in the prevalence of biliary stones (1,2). It is essential to determine a safe and effective therapeutic strategy for these patients. Aged people often have chronic diseases, which may be exacerbated by procedure-related complications. Therefore, surgical mortality in this population appears to be higher than in younger patients (3,4).

The prevalence of choledocholithiasis with concomitant cholecystolithiasis varies from 10 to 15% (5). Standard treatment usually consists of a two-stage procedure (ERCP followed by laparoscopic cholecystectomy), although a single surgical procedure via a laparoscopic common bile duct exploration (LCBDE) is also a viable alternative (6,7). Endoscopic retrograde cholangiopancreaticography with endoscopic sphincterotomy (ERCP/EST) is less invasive than surgery and has a

complication rate of 5-10% and a mortality of 0.3-0.5% in all patients, regardless of age (8-10). ERCP/EST has been widely used in old patients (2,11-13). Besides, due to the rapidly expanding skills in laparoscopic surgery, the single-stage approach of cholecisto-choledocolithiasis has gained interest. This treatment is associated with a shorter hospital stay and a lower cost compared to a two-stage procedure (14,15). An updated meta-analysis confirms that the single-stage procedure is superior to the two-stage procedure, both in perioperative safety and short and long-term postoperative efficacy. Therefore, it should be considered as an optimal treatment of choice for cholecysto-choledocholithiasis (16). However, little is known about the clinical outcomes following the two-stage or single-stage approach for the management of cholecysto-choledocholithiasis in the elderly. Accordingly, this study was performed to evaluate the efficacy and safety of these two modalities in patients aged 80 years or older.

PATIENTS AND METHODS

Patient selection

In this study, 1,260 patients referred to our institution (Yancheng City No.1 People's Hospital) due to cholecysto-choledocholithiasis were retrospectively studied from January 2010 to December 2016. One hundred elderly patients (aged ≥ 80 years), who were scheduled for a two-stage or single-stage procedure for treatment of cholecysto-choledocholithiasis, were included (Fig. 1). The LCBDE group (n = 54) included cases that underwent a single stage procedure of laparoscopic exploration of the common bile duct combined with cholecystectomy. The ERCP/EST group (n = 46) included cases that underwent a two stage procedure of preoperative endoscopic retrograde cholangiopancreaticography with endoscopic sphincterotomy followed by cholecystectomy. The exclusion criteria of the study included the following: a) previous biliary tract surgical history; b) septic shock; c) ASA score ≥ 4; d) acute pancreatitis; or e) uncorrected coagulopathy. Preoperative ultrasonography and magnetic resonance cholangiopancreatography (MRCP) were performed routinely in order to determine the presence of cholecysto-choledocholithiasis and

the diameter of the common bile duct. Patients with cholecystitis and cholangitis were given proper treatment before surgery. All patients gave written informed consent for the procedure and this study was reviewed and approved by our institutional review board. Table 1 shows the baseline characteristics of the patients. Comorbidity conditions, presenting symptoms, bile duct clearance, length of hospital stay and the frequency of postoperative, procedural and long term morbidity were recorded and studied.

Methods

The techniques of the two-stage and single-stage approach have been described previously (17,18).

ERCP/EST

ERCP was performed via a side viewing duodenoscope with a large accessory channel in a standard manner. Standard sphincterotomy was performed up to the major horizontal fold of the papilla of Vater and the stone was subsequently extracted with a basket in all the patients.

Laparoscopic cholecystectomy

The Calot's triangle was dissected and the cystic artery was clipped. Cholecystectomy was performed in the standard anterograde fashion.

Laparoscopic common bile duct exploration (LCBDE)

Common bile duct exploration was performed via a transcystic (TC) or transductal (TD) approach. Confirmation of common bile duct stones was based on cholangioscopy images (model CHFP20; Olympus, Tokyo, Japan). Stones were removed using a retrieval basket followed by repeated bile duct flushing.

Two-stage approach

ERCP/EST was performed under conscious sedation with an intravenous injection of

midazolam and pethidine. Antibiotics were administered (cefoxitin sodium 2 g/day and ornidazole 1 g/day) after ERCP/EST. Twelve hours after the procedure, laboratory tests for hemoglobin and amylase were performed. Patients underwent laparoscopic cholecystectomy the next day.

Single-stage approach

Laparoscopic cholecystectomy and common bile duct exploration was performed using a standard four-port technique with a carbon dioxide pneumoperitoneum at 14 mmHg pressure. A non-suction drain was placed in the gallbladder bed. A T-tube was inserted in the following situations: strictures of the bile duct, removal of impact stones or the need for a subsequent cholangiographic examination due to suspected residual stones.

Postoperative care and follow-up

Patients received routine care. The non-suction drain was withdrawn within 48 hours if no biliary leakage was observed. The T-tube was removed when no residual gallstones were found during the cholangiography examination three weeks later. Postoperative ultrasonography and liver function tests were performed in patients every three months.

Statistical analysis

All quantitative data are expressed as the mean ± standard deviation values. The two-tailed unpaired Student's t test, Chi-square test and Fisher's exact probability test were used to assess statistically significant differences. A $p < 0.05$ was considered to be statistically significant.

RESULTS

The two groups were clinically comparable in terms of sex, age, hepatobiliary symptoms, gallstone comorbidities and American Society of Anesthesiologists (ASA) scoring (Table 1). The stone clearance rate was 100.0% in the LCBDE group and 89.1%

in the ERCP/EST group. Three patients had to undergo surgery due to impacted stones and sedation adverse events that were non amenable to endoscopic treatment. Four patients in the ERCP/EST group suffered sedation adverse events. Two experienced hypoxemia and recovered with an increased oxygen supply and another two patients experienced chest pain and atrial fibrillation, respectively. The endoscopic procedure was terminated and they underwent surgery. One more patient in the ERCP/EST group suffered a duodenal perforation and died from the complication. The total procedural morbidity was 0% in the LCBDE group.

Biliary leakage was more frequent in the LCBDE group than in the ERCP/EST group (11.1% *vs* 0%, $p < 0.05$). Two patients had pancreatitis and one patient had a hemorrhage in the ERCP/EST group; these patients recovered with medical treatment. One case was managed using gabexate and racanisodamine hydrochloride. Two patients in the ERCP/EST group had residual stones and one required an extra ERCP/EST one week later. No patients in the LCBDE group suffered pancreatitis, hemorrhage or residual stones. However, the postoperative morbidity and hospitalization were comparable between the two groups ($p > 0.05$).

There were more long-term complications in the ERCP/EST group than in the LCBDE group during a mean follow-up period of 28.4 months (23.9% *vs* 3.7%, $p < 0.05$). Six patients (13%) in the ERCP/EST group suffered from cholangitis and recovered with a conservative management of antibiotics and ursodeoxycholic acid. No patients in the LCBDE group experienced cholangitis. Furthermore, five patients in the ERCP/EST group and two patients in LCBED group had a recurrence of common bile duct stones. Two patients underwent ERCP/EST to remove recurrent stones and only observation was performed in the rest of patients. The clinical outcomes are summarized in table 2, table 3 and figure 1.

DISCUSSION

Cholecysto-choledocholithiasis is a benign disease that is frequently encountered in the senile population (13). Procedure-associated infections such as cholangitis or cholecystitis may increase the morbidity or mortality risk in aged individuals. This is

mainly due to the fact that the competence of the immune system declines with age (19). Furthermore, surgery related complications can be catastrophic in these patients due to the high prevalence of cardiopulmonary or cerebrovascular disease. Therefore, a safe and effective therapeutic strategy for these patients is required.

ERCP/EST played an important role in the treatment of choledocholithiasis during previous decades. Since laparoscopic cholecystectomy (LC) became the gold standard for cholecystolithiasis in the past 20 years, a two-stage procedure for cholecysto-choledocholithiasis was widely accepted. Successful clearance via ERCP/EST can be achieved in most cases of common bile duct stones (over 90%) in experienced hands (20-22). Several reports have suggested that ERCP is safe in patients aged 80 years or over (11-13,23,24). However, the risk of sedation related adverse events increases in older patients compared with younger cases (25). It is worth noting that these complications may result in serious consequences. After ERCP/EST, recurrent symptomatic common bile duct stones in elderly patients are relatively common and usually require further intervention (26). Re-intervention within 90 days after the first procedure of stone extraction is associated with a 14-fold increased risk of death (27), which underlines the importance of a successful first therapeutic strategy for avoiding residual and recurrent choledocholithiasis.

Laparoscopic surgery is characterized as a less invasive procedure with a fast recovery. However, surgeons are not inclined to perform laparoscopic biliary tract surgery in senile patients with cholecysto-choledocholithiasis over the past 20 years. With the development of laparoscopic skills, single-stage treatment plays an important role in the management of choledocholithiasis when it appears with cholecystolithiasis. A series of randomized clinical trials demonstrated that a single-stage technique has the advantage of a shorter hospital stay and lower postoperative morbidity (28,29). Furthermore, LCBDE is an effective technique for choledocholithiasis with a proven safety and excellent outcome for elderly patients (30). The common bile duct exploration can be achieved via a transcystic (TC) or transductal (TD) approach. Transcystic duct exploration could be performed in 85% of patients with cholecysto-choledocholithiasis (31), with a success rate of 82.5%

(32). A modified TC approach consists in the micro-incision of the cystic duct and its confluence part, which also requires similar operative skills as the previous incision or TD approach. In experienced hands, these procedures could be achieved in 20 minutes. Although most stones can be cleared by a TC or modified approach, it may be limited by the confluence part of the cystic duct, huge choledocholithiasis, the diameter of the choledochoscope and the surgeons' expertise. As shown in our cases, a transcystic approach was the first choice for patients with an ideal dilated cystic duct and small CBD stones. Furthermore, a TC approach, with or without micro-incision of the cystic duct, was widely performed in patients with a non-dilated CBD (diameter < 10 mm) in order to avoid T-tube placement. Besides, we prefer to use the TD approach in senile patients with dilated CBD (diameter ≥ 10 mm), which can save time in complicated cases.

Procedure and postoperative morbidity plays an important role in the recovery time after choledocholithiasis extraction. In previous studies, the occurrence rate of ERCP/EST-related complications was between 4.0% and 11.2% (33-36). Pancreatitis, cholangitis, perforation, bleeding, residual stones and conversion to other procedure constitute the main complications of ERCP/EST. Most of the complications, such as pancreatitis, cholangitis, bleeding and perforation, can be treated medically. However, they can also be life-threatening, especially in elderly patients.

As shown in our study, there were three patients in the ERCP/EST group that converted to LCBDE due to sedation adverse events (two cases) and impacted stones (one case). Residual stones were found in two patients in the ERCP/EST group. The conversion rate and residual stones rate found in ERCP were much higher in our study than in previous studies (6.3% *vs* 4.1% and 4.2% *vs* 1.2%, respectively) (16). Biliary leakage and residual stones are the predominant complications of LCBDE (37,38). The occurrence rate of LCBDE-related overall complications is reported to be between 4.0% and 16% (39). However, the development of laparoscopic skills and medical materials has led to a decrease in complications. As shown in our cases, the postoperative morbidity was comparable between the two groups. Even though there was more biliary leakage in the LCBDE group than in the ERCP/EST group ($p <$

0.05), the complication resolved without any special intervention and did not prolong hospitalization.

We have to take the long-term complications into consideration for patients with benign diseases. A study of endoscopic sphincterotomy (EST) related long-term complications in 310 patients showed rates of stone recurrence, cholangitis, stenosis of the papilla and pancreatitis of 7.4%, 1.6%, 0.6% and 0.3%, respectively, after 74 months of follow-up (40). With regard to LCBDE, the rate of stones recurrence was reported to be 5.9% and no biliary stricture was observed in a study of 157 patients over a mean follow-up period of 51.9 months (41). In our study, 10.9% of cases had recurrent ductal stones and 13.0% had cholangitis in the ERCP/EST group, whereas 3.7% of cases had recurrent ductal stones in the LCBDE group. None of our patients experienced biliary stricture, stenosis of the papilla and pancreatitis. In our study, choledocholithiasis recurrence and cholangitis in the ERCP/EST group was much higher than previously reported. Reflux cholangitis could have played an important role as we always performed a large sphincterotomy.

This study had some limitations. First, it was a single-center study with a small sample size. Second, it was analyzed retrospectively and may have selection bias. There were also more male than female patients. Finally, the follow-up period of some patients was relatively short, so there was no full assessment of the long-term results. Furthermore, as a surgical department has been involved in the study, a certain bias may have occurred in favor of LCBDE as ERCP has been reported to be very safe and effective in aged patients (42).

In conclusion, a single-stage procedure is a safe and effective technique for elderly patients with cholecysto-choledocholithiasis. It can provide a good clearance rate of common bile duct stones as a consequence of the minimally invasive nature, which reduces procedure and long term complications.

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Table 1. Baseline characteristics of two groups

	ERCP/EST group (n = 46)	LCBDE group (n = 54)	p value
Age (years)	84.24 ± 2.89	83.39 ± 2.86	0.59
Gender (n)			0.84
Female	20	25	
Male	26	29	
ASA score	1.85 ± 0.66	1.80 ± 0.58	0.52
Hepatobiliary symptoms (n)			
Jaundice	5	7	1.00
Biliary symptoms	35	38	0.65
Comorbidities			
Hypertension	31	33	0.54
Diabetes mellitus	12	20	0.29
COPD	8	11	0.80

Table 2. Surgical outcomes of the two groups

	ERCP/EST group (n = 46)	LCBDE group (n = 54)	p value
Bile duct clearance (%)	89.1	100	*0.02*
Postoperative stay (days)	6.0 ± 2.1	6.2 ± 2.2	0.69
Procedural complications (%)	10.8	0	*0.02*
Duodenal perforation	2.1	0	0.46
Sedation adverse	8.4	0	*0.04*
Postoperative complications (%)	10.9	14.8	0.77
Bile leaks	0	11.1	*0.03*
Residual stones	4.2	0	0.21
Pancreatitis	4.2	0	0.21
Hemorrhage	2.1	0	0.46
T-tube related pain	0	1.9	1.0
T-tube release and peritonitis	0	1.9	1,0
Long-term complications (%)	23.9	3.7	*0.01*
Cholangitis	13.0	0	*0.01*
Stones recurrence	10.9	3.7	0.24

Table 3. Sedation adverse events of the two groups

	ERCP/EST group (n = 46)	LCBDE group (n = 54)	p value
Sedation adverse (%)	8.4	0	*0.04*
Hypoxemia	4.2	0	0.21
Chest tightness	2.1	0	0.46
Atrial fibrillation	2.1	0	0.46

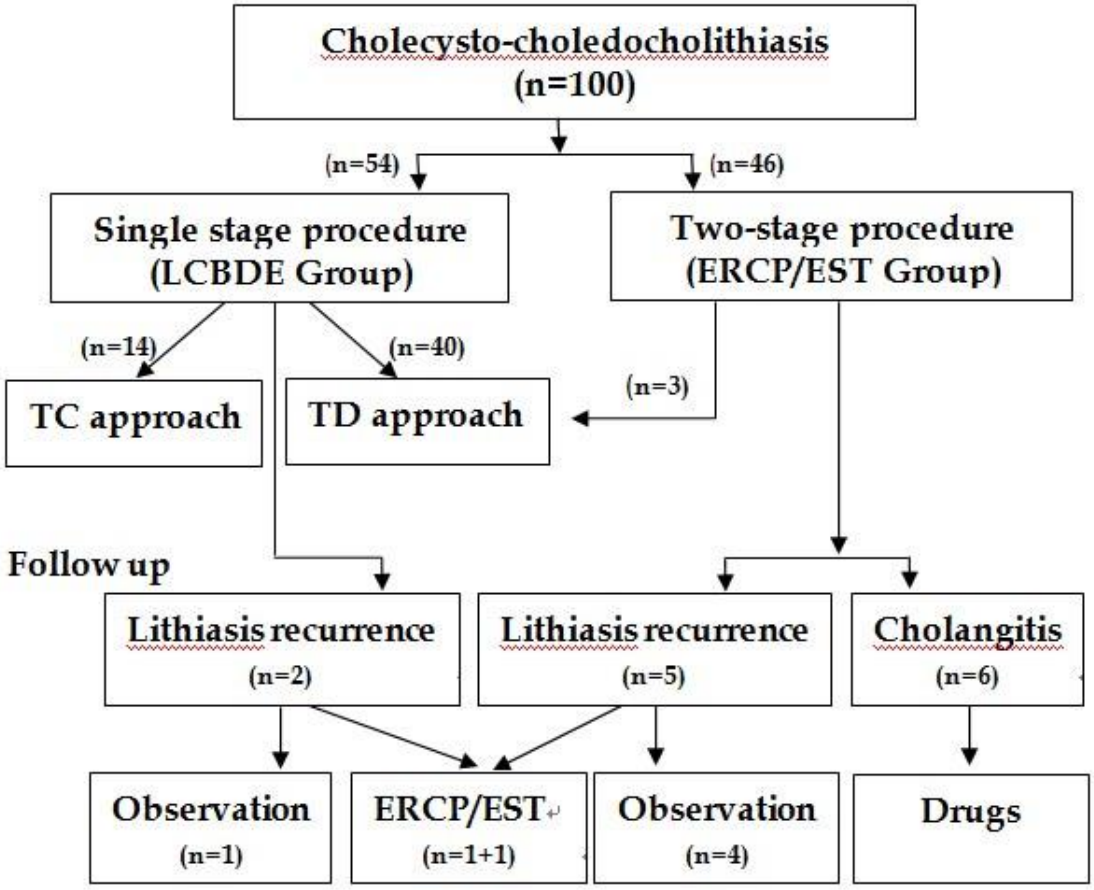

Fig. 1. Flow chart of patient enrollment and the treatment algorithm.