

## Original Article

# Effectiveness of one-step ERCP procedure in treating patients with non-severe acute calculous cholangitis

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**Abstract:** This study aimed to evaluate the efficiency of one-step endoscopic retrograde cholangiopancreatography (ERCP) for treatment of patients with non-severe acute calculous cholangitis. A total of 105 patients, between 2014 and 2016, were randomly assigned into an emergency lithotomy group (EL group, 44) and selective lithotomy group (SL group, 61). All patients were treated with intravenous antibiotics after each ERCP procedure. Indicators, such as age and gender of the patients, number of CBD stones, diameter of the largest CBD stone, diameter of the CBD, sum operation time of ERCP performance, papilla disposal techniques, interval to WBC normalization, ERCP-related complication rate, and length of stay (LOS) in hospital, were compared between the two groups. Preoperative diagnosis and severity assessment of cholangitis was performed according to criteria recommended in the 2013 Tokyo Guidelines. Results showed no significant differences between the EL and SL group regarding the following variables, mean age, gender proportion, diameter of the largest stone and CBD, pre-ERCP WBC levels, percentage of cases with unstable hemodynamics, percentage of cases with papilla stone impaction, percentage of lithotripsy, and incidence of complications. However, a lower percentage of cases with a single stone (24.6% vs. 43.2%), longer duration of ERCP procedure ( $40.5 \pm 9.8$  vs.  $36.3 \pm 6.5$  min), interval to WBC normalization ( $5.9 \pm 3.4$  vs.  $3.9 \pm 2.4$  d), and LOS ( $9.1 \pm 3.6$  vs.  $7.3 \pm 2.2$  d) were found in the SL group than the EL group. Diameter of the largest stone and CBD were statistically correlated with time of ERCP procedure ( $R=0.61$ ,  $P<0.001$ ;  $R=0.56$ ,  $P<0.001$ ). Application of lithotripsy significantly prolonged the duration of ERCP procedure (lithotripsy vs. not:  $47.8 \pm 10.3$ ,  $36.7 \pm 7.0$  min,  $P<0.05$ ), while the diameter of the largest stone was the only statistical factor affecting duration of the ERCP procedure. One-step ERCP shortened recovery times, hospital stays, and operation duration. This was suitable for patients with non-severe acute calculous cholangitis, especially in patients with single relatively small stones.

**Keywords:** Endoscopic retrograde cholangiopancreatography, cholangitis, common bile duct stone

## Introduction

Acute cholangitis is an emergent condition characterized by acute inflammation and infection in the bile duct. It can be fatal unless appropriate and prompt medical care is provided. Prompt biliary drainage is the most important therapeutic method, accepted worldwide, especially for severe acute cholangitis. If treatment is delayed, mortality in high-risk patients reaches to 17%-40% [1-3]. Elective drainage procedures contribute to favorable effects on the reduction of mortality rates caused by acute cholangitis. However, endoscopic retrograde cholangiopancreatography (ERCP) has

been associated with procedure-related complications and risk of cannulation failure, thus the timing of drainage for non-severe acute cholangitis remains controversial [4].

Choledocholithiasis is the most frequent cause of benign biliary obstruction, inducing occurrence of acute cholangitis. Lithotomy by ERCP is performed together with duodenal papilla disposal and stone extraction after cannulation. Lithotripsy and biliary balloon cleaning may also be necessary. Therefore, the risks of ERCP-related complications are increased, leading to longer procedures in an emergency setting. Urgent endoscopic biliary drainage me-

thods include endoscopic sphincterotomy (EST) alone, EST followed by lithotomy, and endoscopic nasobiliary drainage (ENBD) with or without EST. Suggestions in the Tokyo Guidelines regarding method selection are not clearly specified due to the lack of RCTs (randomized controlled trials), except in critically ill patients, for whom one-stage choledocholithotomy with EST is not recommended [4-6]. Therefore, the impact of ERCP methods on patients with moderate acute cholangitis has not been clearly determined.

This study aimed to evaluate the therapeutic value of urgent biliary drainage, compare the efficiency and effectiveness with different lithotomy modes of urgent ERCP procedures, and provide insight for clinical selection in a cohort of patients with moderate acute cholangitis.

### Patients and methods

#### *Patients*

From January 1, 2014 to June 30, 2016, a total of 105 enrolled patients were diagnosed with non-severe acute cholangitis caused by choledocholithiasis. They underwent urgent ERCP treatment. Patients were randomly assigned into two groups according to the specific ERCP treatment modality: emergency lithotomy with ENBD drainage (emergency lithotomy group, EL group) and emergency ENBD drainage with selective lithotomy (selective lithotomy group, SL group). All patients in the SL group underwent at least two operations.

Indicators, including age and gender of the patients, number of CBD stones, diameter of the largest CBD stone, diameter of the CBD, pre-ERCP level of WBC (white blood cells), proportion of unstable hemodynamics (hypotension with/without tachycardia) and papilla stone impaction cases, percentage of lithotripsy, sum operation time of ERCP performance, papilla disposal techniques, interval to WBC normalization, ERCP-related complication rate, and length of stays (LOS) in the hospital, were compared between the two groups. All patients with unstable hemodynamics received rapid fluid infusions with physiologic saline to maintain normal blood pressure before or/and during the ERCP procedure.

Preoperative diagnosis and severity assessment of cholangitis was performed according to criteria recommended in the 2013 Tokyo Guidelines, including evidence of an inflammatory response, cholestatic status presented by abnormal liver function tests (alkaline phosphatase, gamma-glutamyl transferase, aspartate aminotransferase, or/and alanine aminotransferase  $\geq 1.5$  of the upper normal limit), total bilirubin  $\geq 34.2 \mu\text{mol/L}$ , and dilatation of the CBD  $> 6 \text{ mm}$  visualized by transabdominal ultrasonography. Moderate acute cholangitis has been associated with any two of the following conditions: abnormal WBC count ( $> 12,000/\text{mm}^3$ ,  $< 4,000/\text{mm}^3$ ), high fever ( $\geq 39^\circ\text{C}$ ), old age ( $\geq 75$  years), hyperbilirubinemia (total bilirubin  $\geq 85.5 \mu\text{mol/L}$ ), and hypoalbuminemia ( $< \text{STD} \times 0.7$ ). Patients that were not associated with onset of dysfunction in any one of the organs/systems (cardiovascular, respiratory, renal, hepatic or hematological) were diagnosed as severe acute cholangitis and excluded. Biliary pancreatitis was diagnosed when two of the following revised Atlanta 2012 criteria were required: characteristic abdominal pain, serum amylase level  $> 3$  over the upper limit of normal, and characteristic findings of acute pancreatitis on radiological examinations. The interval to WBC normalization in the SL group was calculated as the sum of recovery time after the first emergency ENBD process and the delayed lithotomy process.

#### *ERCP and medicinal treatment*

All ERCPs were performed within 24 hours after the definite diagnosis of acute cholangitis by experienced endoscopists. Midazolam and meperidine were used for patient conscious sedation and ERCPs were performed using a duodenoscope (TJF-260V or JF-260V, Olympus, Japan), according to standard procedures. After successful cannulation of the CBD through the duodenal papilla, a low-osmolar contrast medium (ioversol) was injected to confirm the size and number of stones, as well as the diameter of the CBD. The papilla was disposed by the sphincterotome to complete the EST procedure and/or by the plastic balloon to complete the EPBD procedure. Patients underwent the ENBD procedure by cannulation with a nasobiliary catheter (straight or pigtail nasal catheter, 7F, Wilson Cook Medical, Inc., USA). All patients were treated with intravenous antibiotics after

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**Table 1.** Baseline characteristics of the patients

Age (y)	60.6±16.0
Gender (male/female)	52/53
Diameter of CBD (mm)	13.4±3.8
Diameter of largest CBD stone (mm)	11.6±3.2
Percentage of single stone case %	32.4
Pre-ERCP WBC count (*10 <sup>9</sup> /L)	11.8±4.5
Duodenal papilla disposal techniques (EST/EPBD/both)	16/63/26
Percentage of unstable hemodynamics case %	17.1
Percentage of stone impaction case %	10.5
Mean sum duration of the ERCP procedure (min)	38.7±8.8
Percentage of lithotripsy %	18.1
Mean interval to WBC normalization (d)	5.1±3.2
Percentage of complications %	6.7
Mean LOS (d)	8.3±3.2

each ERCP procedure. Somatostatin was used only for patients whose amylases were elevated 3 hours and 12 hours after ERCP to treat post-ERCP pancreatitis or hyperamylasemia. The nasobiliary catheter was aspirated continuously to drain the infected bile in the following days. If the patient underwent emergency ENBD without lithotomy, a selective endoscopic lithotomy was adopted when inflammation subsided after antibiotic administration.

### *Strategy of papilla disposal techniques*

Papilla disposal techniques were selected mainly by the size of maximum CBD stone and CBD diameter, especially the diameter of distal part of CBD under the stones. Regarding stones with maximum diameters smaller than 1.2 cm without distal CBD (under the stone) stricture, EST alone or EPBD alone was chosen. For stones with diameters larger than ( $\geq 1.2$  cm) with dilated CBD at the distal part, EPLBD (endoscopic papillary large balloon dilatation) alone or minor to moderate scale EST followed by EPLBD was the first choice. If the papilla was not a naïve one, EPBD or EPLBD alone was the only choice.

The method of EPBD in this study included normal size EPBD (0.8 to  $<1.2$  cm) and large size EPBD, i.e. EPLBD ( $\geq 1.2$  cm). Larger stones ( $\geq 1.2$  cm) were extracted after two types of papilla disposal techniques: EPLBD alone or EST followed by EPLBD. EPLBD was not applied in patients with smaller stones regardless of the diameter of CBD. Lithotripsy was applied

when the diameter of the maximum CBD stone was larger than 1.5 cm, whether it was single or one of the multiple ones.

### *Case exclusion criteria*

If the endoscopist failed to totally clear the CBD stone in the delayed procedure of lithotomy in the SL group, biliary drainage with the plastic stent or operations were performed.

If the distal part of CBD was smaller than the stone or CBD stricture formed under the stone, stone extraction was not applied and ERBD (Endoscopic retrograde biliary drainage) with the plastic stent or operations were chosen.

Patients needing vasoactive agents to increase blood pressure were excluded.

### *Statistical analysis*

All statistical analyses were performed with SPSS 19.0 statistical software (IBM, Armonk, NY, USA). Student's *t*-test was used to analyze numerical data. Categorical data were analyzed with Fisher's exact test. Pearson's bivariate correlation test was applied to analyze the correlation between two continuous variables. Multivariate logistic regression, using a stepwise procedure, was applied to identify factors that were independently and significantly associated with differences between groups. Multivariate linear regression was applied to confirm variables affecting the duration of the ERCP procedure and the interval to WBC normalization. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. A *p* value  $<0.05$  is considered statistically significant.

## **Results**

### *Clinical features and comparison of variables between the EL and SL group*

There was a total of 105 patients enrolled in the present study, with demographic data shown in **Table 1**. In all patients, the ERCP procedure was successfully performed and complete extraction of bile duct stones was

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**Table 2.** Univariate analysis of EL and SL groups

Variables	EL group (n=44)		SL group (n=61)		P	
	Single (19)	Multiple (25)	Single (15)	Multiple (46)	S	M
Age (y)	59.9±14.3		61.1±17.1		>0.05	
	60.0±12.8	59.8±15.6	56.2±15.0	62.6±17.7		
Gender (male/female)	19/25		33/28		>0.05	
	8/11	11/14	8/7	25/21		
Diameter of the largest stone (mm)	11.0±3.2		12.1±3.1		>0.05	
	11.1±3.3	10.8±3.3	12.1±2.0	12.1±3.4		
Pre-ERCP WBC (*10 <sup>9</sup> /L)	11.2±4.4		12.3±4.5		>0.05	
	10.5±4.0	11.7±4.7	12.4±3.9	12.3±4.8		
Percentage of unstable hemodynamics cases %	6.8		13.1		>0.05	
	10.5	4.0	0	17.4		
Percentage of stone impaction cases %	11.4		21.3		>0.05	
	15.8	8.0	26.7	19.6		
Percentage of lithotripsy %	18.2		18.0		>0.05	
	21.1	16.0	6.7	21.7		
Diameter of the CBD (mm)	12.7±4.0		13.9±3.6		>0.05	
	13.1±4.2	12.4±4.0	14.1±2.5	13.9±3.9		
Percentage of single stone cases %	43.2		24.6		<0.05 <sup>▲</sup>	
Sum duration of ERCP procedure (min)	36.3±6.5		40.5±9.8		<0.05 <sup>▲</sup>	
	34.2±4.5	38.0±7.3	40.1±11.3	40.6±9.4	<0.05 <sup>#</sup>	>0.05
Interval to WBC normalization (d)	3.9±2.4		5.9±3.4		<0.05 <sup>▲</sup>	
	3.8±2.1	4.0±2.6	6.7±1.7	5.7±3.8	<0.05 <sup>#</sup>	<0.05 <sup>*</sup>
Percentage of complications %	6.8		6.6		>0.05	
	5.3	8.0	0	8.7		
LOS (d)	7.3±2.2		9.1±3.6		<0.05 <sup>▲</sup>	
	7.0±2.0	7.6±2.3	9.1±2.6	9.1±3.9	<0.05 <sup>#</sup>	<0.05 <sup>*</sup>

▲: Significant differences between EL and SL group; #: Significant differences between EL and SL subgroup with single CBD stone; \*: Significant differences between EL and SL subgroup with multiple CBD stones; S: single stone; M: multiple stones.

**Table 3.** Multivariate analysis: independent predictors affecting selection of emergency or selective lithotomy (logistic regression)

Variables	β-Coefficient	OR	95% CI	P
Interval to WBC normalization	0.990	2.691	1.101; 6.576	0.030
Percentage of single stone cases	0.259	1.295	1.009; 1.526	0.002

achieved. None of the patients died from acute cholangitis or ERCP-related complications, such as post-ERCP pancreatitis (3.8%) or bleeding (2.9%).

The number of cases in the EL group and SL group was 44 and 61, respectively. There were no significant differences between the EL and SL group for the following variables, mean age, gender proportion, diameter of the largest stone and CBD, pre-ERCP WBC level, percentage of cases with unstable hemodynamics, percentage of cases with papilla stone impaction,

percentage of lithotripsy, and incidence of complications. Of note, the percentage of cases with a single stone was significantly lower in the SL group than the EL group (24.6% vs. 43.2%). Significantly longer duration of ERCP procedure was found in the SL group than the EL group (40.5±9.8 vs. 36.3±6.5 min). The interval to WBC normalization and LOS in the SL group were relatively longer than the EL group (5.9±3.4 vs. 3.9±2.4 d; 9.1±3.6 vs. 7.3±2.2 d) (Table 2).

Multivariate analysis indicated the most significant factors associated with differences between the ERCP modality of emergency or selective lithotomy were the percentage of cases with a single stone and the interval to

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**Table 4.** Multivariate analysis: independent predictors affecting duration of the ERCP procedure (linear regression)

Variables	Coefficient	OR	P
Diameter of the largest stone	1.667	0.612	<0.001

**Table 5.** Multivariate analysis: independent predictors affecting the interval to WBC normalization (linear regression)

Variables	Coefficient	OR	P
Pre-ERCP WBC	0.435	0.619	<0.001
EL or SL	1.488	0.233	0.001
Application of lithotripsy	1.454	0.178	0.010

WBC normalization (**Table 3**). Additionally, linear regression analysis showed that the significant factor affecting the duration of the ERCP procedure was the variable of diameter of the largest stone, while statistical influencing factors for interval to WBC normalization were pre-ERCP WBC levels, emergent lithotomy or selective one, and application of lithotripsy (**Tables 4, 5**).

### *Comparison between the EL and SL group according to number of CBD stones*

To eliminate bias caused by the number of CBD stones, all cases were divided again into four subgroups for further comparison: EL with a single stone (ELs), EL with multiple stones (ELm), SL with a single stone (SLs), and SL with multiple stones (SLm). The number of cases in each subgroup was 19, 25, 15, and 46, respectively. In the subgroups with a single stone, the ELs subgroup was characterized by a shorter time of ERCP procedure, interval to WBC normalization, and LOS, compared to SLs. Likewise, similar results were also observed in comparisons between the ELm and SLm subgroups, except for the difference of duration of ERCP procedure (**Table 2**).

### *Factors affecting the duration of ERCP procedure*

Univariate analysis demonstrated that duration of the ERCP procedure was affected by certain factors. Except for significant differences mentioned above between the EL and SL group, diameter of the largest stone and CBD was correlated with time of ERCP procedure ( $R=$

$0.61, P<0.001; R=0.56, P<0.001$ ) (**Table 4**). Application of lithotripsy dramatically prolonged the duration of ERCP procedure (lithotripsy vs. not:  $47.8\pm 10.3, 36.7\pm 7.0$  min,  $P<0.05$ ). However, the diameter of the largest stone was the only statistical factor affecting duration of the ERCP procedure, based on multivariate analysis with linear regression, while factors, such as the number of stones, occurrence of papilla impaction, and duodenal papilla disposal method (EST or EPBD), had no correlation with duration of the ERCP procedure.

## Discussion

Cholangitis can be life-threatening and has been regarded as a medical emergency. Symptoms of cholangitis vary and range from yellow discoloration of the skin or whites of the eyes, fever, abdominal pain, to severe manifestation of low blood pressure and confusion. [7] Cholangitis generally requires admission to the hospital where initial treatment is provided, including administration of intravenous fluids and antibiotics. However, under circumstances of gallstones or narrowing in the bile duct, endoscopic retrograde cholangiopancreatography (ERCP) is the most common approach in relieving obstructions of the bile duct [8]. ERCP combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems in the biliary or pancreatic ductal systems. For example, it can be performed for diagnosis and therapy of gallstones [9]. However, potential risks of ERCP still exist, while the impact of ERCP on non-severe acute cholangitis caused by choledocholithiasis requires further evaluation.

Recent findings have indicated that timing, urgent ERCP is required in patients with acute cholangitis, and delays in performing ERCP, along with adverse events, increase 30-day readmission risks [10, 11]. In the present study, ERCP treatment was applied for patients diagnosed with non-severe acute cholangitis caused by choledocholithiasis. It has been demonstrated that percutaneous transhepatic cholecystoscopic lithotomy is a rescue therapy for removal of bile duct stones in Billroth II gastrectomy patients, in which ERCP is difficult to perform [12]. Lithotomies have been utilized for removal of calculi, stones formed inside the gallbladder. This study compared the effects

between emergency lithotomy with ENBD drainage (EL) and emergency ENBD drainage with selective lithotomy (SL), finding that the percentage of cases with a single stone was significantly lower than in the EL group. Moreover, significantly longer duration of ERCP procedure, interval to WBC normalization, and LOS were found in the SL group, compared to the EL group. Interestingly, in agreement with previous studies that indicate a significant cost and time reduction with implementation of the one-step treatment of calculous biliary disease, present data on patients with either a single stone or multiple stones indicate that emergency lithotomy significantly shortened the time of ERCP procedure, interval to WBC normalization and LOS. Results also indicated that the one-step ERCP procedure was effective in treating patients with non-severe acute calculous cholangitis [13, 14]. Further investigation is still required to determine the clinical effects of one-step ERCP within a larger cohort.

### Conclusion

The present study demonstrated shorter recovery times, hospital stays, and operation duration using one-step ERCP rather than two-step. No significant correlation between duration of ERCP and nipple treatment or gravel was found, but size of the stone was a key factor. Therefore, one-step ERCP is proposed for patients with non severe acute calculous cholangitis, especially in patients with a single relatively small stone.

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### Disclosure of conflict of interest

None.

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