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Factors Predicting Difficult Biliary Cannulation during Endoscopic Retrograde Cholangiopancreatography for Common Bile Duct Stones

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Background/Aims: Difficult biliary cannulation is an important risk factor for post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP). Therefore, this study aimed to identify the factors that predict difficult cannulation for common bile duct stones (CBDS) to reduce the risk for PEP.

Methods: This multicenter retrospective study included 1,406 consecutive patients with native papillae who underwent ERCP for CBDS. Factors predicting difficult cannulation for CBDS were identified using univariate and multivariate analyses.

Results: Univariate analysis showed that six factors significantly predicted difficult cannulation: ERCP performed by non-expert endoscopists, low-volume center, absence of acute cholangitis, normal serum bilirubin, intradiverticular papilla, and type of major duodenal papilla. Multivariate analysis identified ERCP performed by non-expert endoscopists (odds ratio [OR], 2.5; $p < 0.001$), low-volume center (OR, 1.6; $p < 0.001$), intradiverticular papilla (OR, 1.3; $p = 0.007$), normal serum bilirubin (OR, 1.3; $p = 0.038$), and absence of acute cholangitis (OR, 1.3; $p = 0.049$) as factors significantly predicting difficult cannulation for CBDS.

Conclusions: Initial cannulation by an experienced endoscopist, early rescue cannulation, or early takeover by an experienced endoscopist should be considered when performing ERCP for CBDS in the presence of factors predicting difficult cannulation. **Clin Endosc 2022;55:263-269**

Key Words: Common bile duct stone; Cannulation; Endoscopic retrograde cholangiopancreatography; Factor

INTRODUCTION

Common bile duct stones (CBDS) are common worldwide in the field of gastroenterology. Although endoscopic retrograde cholangiopancreatography (ERCP) is considered the

standard treatment for CBDS, it is a technically challenging procedure. Moreover, post-ERCP pancreatitis (PEP), which is closely related to difficult biliary cannulation, has been identified as the most common and serious post-ERCP complication, with an incidence rate of 3%–10%.¹⁻³

Difficult biliary cannulation is a well-known risk factor for PEP.¹⁻³ Given the benign nature of CBDS, identifying factors predicting difficult biliary cannulation for CBDS is essential in reducing the risk of PEP. Although many studies have examined factors associated with difficult biliary cannulation for pancreatobiliary diseases,⁴⁻⁹ only a few have focused on CBDS.

Accordingly, prospective studies have shown that biliary cannulation lasting >5 min was a significant risk factor for the incidence of PEP.^{10,11} Despite the various definitions for difficult biliary cannulation based on duration, the European

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Society of Gastrointestinal Endoscopy (ESGE) guideline for papillary cannulation defines difficult biliary cannulation as that which exceeds > 5 min.¹²

The current study examined the factors predicting difficult biliary cannulation for CBDS based on the ESGE guidelines' definition of difficult biliary cannulation.

METHODS

Study design

This multicenter retrospective study reviewed the electronic medical records of 1,406 consecutive patients with native papilla who had received therapeutic ERCP for CBDS between April 2012 and February 2020 at the Kumamoto Chuo Hospital, Saiseikai Kumamoto Hospital, and Kumamoto City Hospital in Japan. Patients with a history of Billroth-II gastrectomy or Roux-en-Y reconstruction, with biliary pancreatitis, whose CBDS was not identified during ERCP, and whose major duodenal papilla were not visible using a side-viewing duodenoscope were excluded. Approval was obtained from the institutional review boards of each participating institution. This study was performed in accordance with the Declaration of Helsinki. Consent was obtained using an opt-out approach. We selected possible predictive factors for difficult biliary cannulation with reference to the ESGE guidelines and previous literature.^{4-9,12-15}

Study definitions

Difficult biliary cannulation was defined as that which exceeded 5 min after visualization of the major duodenal papilla, based on the ESGE guideline for papillary cannulation¹² or unsuccessful biliary cannulation. Non-expert endoscopists were defined as those who had experienced < 200 ERCP procedures throughout their careers.^{16,17} The reference value for serum bilirubin utilities was set to < 25.7 $\mu\text{mol/L}$, which is the upper normal limit used in our institutions. The appearance of the major duodenal papilla can be classified into the following four types based on the classification proposed by Haraldsson et al.: regular (type 1), small (type 2) (i.e., diameter < 3 mm), protruding or pendulous (type 3), and creased or ridged (type 4).¹⁸ Acute cholangitis was diagnosed according to the revised Tokyo Guidelines (2018),¹⁹ and patients who satisfied the definitive diagnostic criteria were included in this study. A low-volume center was defined as an institution that performed < 250 ERCP procedures annually. Among the three participating institutions included in this study, two were low-volume centers, and one was a high-volume center with > 1,000 performed ERCP.

Method of biliary cannulation

After reaching the major duodenal papilla using a side-viewing duodenoscope (JF-260 or TJF-260; Olympus Medical Systems, Tokyo, Japan) under appropriate sedation, the major duodenal papilla type and presence of periampullary diverticulum were determined. In this study, guidewire- or contrast-assisted cannulation using a wire-loaded type injection catheter (MTW Endoskopie, Wesel, Germany) and a 0.025-inch guidewire (VisiGlide2; Olympus, Tokyo, Japan/Jagwire; Boston Scientific, Marlborough, MA, USA) was the first choice for primary biliary cannulation. For difficult biliary cannulations, rescue cannulation techniques, such as pancreatic guidewire-assisted biliary cannulation and/or precut sphincterotomy, were performed based on the surgeon's discretion.

Among the 38 different endoscopists included in this study, 18 were non-expert endoscopists who had performed < 200 ERCP procedures. When a non-expert endoscopist performed the ERCP procedure, an experienced endoscopist who had performed > 500 ERCP procedures assisted to ensure procedural safety. The standard duration for takeover by an experienced endoscopist after attempting initial biliary cannulation in difficult cases at our institution was 10 min.

Statistical analysis

One-to-one propensity score matching with a caliper of 0.2 was performed to examine the association between difficult biliary cannulation and the incidence of PEP. Univariate analysis using the chi-square or Fisher's exact test for categorical data and Welch's *t*-test for continuous data were performed to identify potential factors predicting difficult biliary cannulation. Significant factors ($p < 0.10$) from univariate analyses were subjected to multivariate logistic regression analysis.

All statistical analyses were performed using EZR (version 1.53; Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (version 4.1.0; The R Foundation for Statistical Computing, Vienna, Austria),²⁰ with two-sided *p*-values < 0.05 indicating statistical significance.

RESULTS

Baseline characteristics

Among the 1,406 patients, there were 738 (52.5%) men and 668 (47.5%) women, with a mean age of 74.9 years. Indications for ERCP included acute cholangitis (925 patients, 65.8%), obstructive jaundice without cholangitis (298 patients, 21.2%), and asymptomatic CBDS (183 patients, 13.0%). A total of 574 patients (40.8%) had non-dilated common bile duct (< 10

mm). The incidence rate of intradiverticular papilla was 4.3% (60/1,406). Types 1, 2, 3, and 4 major duodenal papillae occurred in 623 (44.3%), 618 (44.0%), 100 (7.1%), and 65 (4.6%) patients, respectively. A total of 220 patients (15.7%) underwent ERCP by non-expert endoscopists, whereas 310 patients (22.1%) underwent ERCP in a low-volume center. The current study obtained a final successful cannulation rate of 98.9% (1,391/1,406).

The baseline characteristics associated with PEP development for all patients and the propensity score-matched patients with and without difficult biliary cannulation are detailed in Table 1. The baseline characteristics were well-balanced among the propensity score-matched patients.

Association between difficult biliary cannulation and PEP incidence

The rates of PEP in all patients and propensity score-matched patients with and without difficult biliary cannulation are detailed in Table 2. Difficult biliary cannulation was a significant factor associated with the development of PEP after one-to-one propensity score-matching adjustment for confounding factors.

Factors predicting difficult biliary cannulation

The results of the univariate analysis for factors predicting difficult biliary cannulation are detailed in Table 3. Accordingly, absence of acute cholangitis, normal serum bilirubin, intradiverticular papilla, types of major duodenal papilla, ERCP performed by non-expert endoscopists, and low-volume center were identified as significant factors predicting difficult biliary cannulation.

The multivariate analysis results of the potential factors predicting difficult cannulation are outlined in Table 4. Accordingly, ERCP performed by non-expert endoscopists (odds ratio [OR], 2.5; 95% confidence interval [CI], 1.9–3.5; $p < 0.001$), low-volume center (OR, 1.6; 95% CI, 1.2–2.1; $p < 0.001$), intradiverticular papilla (OR, 1.3; 95% CI, 1.1–1.5; $p = 0.007$), normal serum bilirubin (OR, 1.3; 95% CI, 1.01–1.7; $p = 0.038$), and absence of acute cholangitis (OR, 1.3; 95% CI, 1.00–1.7; $p = 0.049$) were identified as significant factors predicting difficult biliary cannulation.

Successful biliary cannulation after rescue cannulation

Among patients who underwent rescue cannulation within 5 and 5–10 min after initial cannulation, 33/45 (73.3%) and 56/71 (78.9%) achieved successful biliary cannulation within 5 min after the rescue technique, respectively.

All patients who underwent rescue cannulation within 5

min after the initial cannulation underwent pancreatic guidewire-assisted cannulation. In addition, 65 (91.5%) and 6 (8.5%) of the 71 patients who underwent rescue cannulation within 5–10 min after initial cannulation underwent pancreatic guidewire-assisted cannulation and precut sphincterotomy, respectively.

DISCUSSION

This study aimed to identify factors predicting difficult biliary cannulation for CBDS. Our results revealed that ERCP performed by non-expert endoscopists, low-volume centers, intradiverticular papilla, normal serum bilirubin, and absence of acute cholangitis were significant factors predicting difficult biliary cannulation for CBDS.

Successful biliary cannulation is considered the first step in successful ERCP. Furthermore, difficult biliary cannulation has been identified as an important risk factor for the incidence of PEP;^{2,3} the most common and serious post-ERCP complication. In this study, difficult biliary cannulation was associated with the development of PEP after adjusting for confounding factors. Therefore, identifying factors that predict difficult biliary cannulation during ERCP may help reduce the incidence of PEP in patients with CBDS. Although previous reports have revealed that malignant biliary strictures are a risk factor for difficult cannulation,^{21,22} only a few studies have focused on factors predicting difficult biliary cannulation in patients with CBDS.

The ESGE guideline for papillary cannulation states that surgical experience and patient factors influence the likelihood of successful biliary cannulation.¹² This present study found that normal serum bilirubin and absence of acute cholangitis were significant factors predicting difficult cannulation. Difficult biliary cannulation in patients with normal serum bilirubin or without acute cholangitis might be attributed to a tighter sphincter of Oddi, thereby reducing the lower bile duct pressure, than that in patients with elevated serum bilirubin or with acute cholangitis.

Asymptomatic CBDS is representative of normal serum bilirubin levels and the absence of acute cholangitis. Recently, several studies have revealed that asymptomatic CBDS was a risk factor for the incidence of PEP.^{13,14,23–27} The results obtained in the present study may explain why asymptomatic CBDS was associated with a high PEP risk. As such, experienced endoscopists may promote better outcomes in patients with asymptomatic CBDS.

Balance should be maintained between training non-expert endoscopists and ensuring the safety and success of initial

Table 1. Baseline Characteristics

	All patients			Propensity score-matched patients		
	With difficult cannulation (n=600)	Without difficult cannulation (n=806)	p-value	With difficult cannulation (n=221)	Without difficult cannulation (n=221)	p-value
Age (mean, [SD]) (years)	75.2 (13.8)	74.6 (14.0)	0.39	74.1 (14.3)	74.5 (14.8)	0.82
Age less than 60 years (5%)	89 (14.8)	124 (15.4)	0.82	40 (18.1)	40 (18.1)	1.0
Female gender (%)	297 (49.5)	371 (46.0)	0.21	113 (51.1)	103 (46.6)	0.39
Bilroth-I reconstruction (%)	21 (3.5)	19 (2.4)	0.26	9 (4.1)	8 (3.6)	1.0
Performance status 3 or 4 (%)	105 (17.5)	152 (18.9)	0.53	39 (17.6)	37 (16.7)	0.90
End-stage renal failure requiring dialysis (%)	20 (3.3)	22 (2.7)	0.53	10 (4.5)	5 (2.3)	0.29
Normal serum bilirubin (%)	299 (49.8)	331 (41.1)	0.001	104 (47.1)	97 (43.9)	0.57
Nondilated CBD (<10 mm) (%)	243 (40.5)	331 (41.1)	0.87	85 (38.5)	88 (39.8)	0.85
Large CBD stones (>10 mm) (%)	106 (17.7)	148 (18.4)	0.78	40 (18.1)	42 (19.0)	0.90
Multiple CBD stones (≥2 stones) (%)	232 (38.7)	345 (42.8)	0.13	91 (41.2)	84 (38.0)	0.56
Intradiverticular papilla (%)	35 (5.8)	25 (3.1)	0.016	12 (5.4)	14 (6.3)	0.84
ERCP performed by non-expert endoscopists	141 (23.5)	79 (9.8)	<0.001	44 (19.9)	51 (23.1)	0.49
Contrast-assisted cannulation (%)	274 (45.7)	731 (90.7)	<0.001	176 (79.6)	176 (79.6)	1.0
PGW-assisted cannulation (%)	182 (30.3)	4 (0.5)	<0.001	9 (4.1)	4 (1.8)	0.26
Wire-guided cannulation (%)	69 (11.5)	71 (8.8)	0.11	31 (14.0)	41 (18.6)	0.25
Pancreatic injection (%)	428 (71.3)	199 (24.7)	<0.001	107 (48.4)	110 (49.8)	0.85
EST (%)	512 (85.3)	714 (88.6)	0.076	194 (87.8)	191 (86.4)	0.78
EPBD (%)	74 (12.3)	89 (11.0)	0.50	25 (11.3)	29 (13.1)	0.66
EPLBD (%)	79 (13.2)	134 (16.6)	0.084	38 (17.2)	37 (16.7)	1.0
Precut sphincterotomy (%)	75 (12.5)	0 (0.0)	<0.001	5 (2.3)	0 (0.0)	0.061
Attempted stone removal (%)	560 (93.3)	785 (97.4)	<0.001	211 (95.5)	209 (94.6)	0.83
Balloon (%)	474 (79.0)	650 (80.6)	0.46	179 (81.0)	182 (82.4)	0.81
Basket (%)	255 (42.5)	384 (47.6)	0.058	98 (44.3)	99 (44.8)	1.0
Mechanical lithotripsy (%)	110 (18.3)	112 (13.9)	0.027	42 (19.0)	44 (19.9)	0.90
Biliary stent placement (%)	513 (85.5)	686 (85.1)	0.88	194 (87.8)	188 (85.1)	0.49
Prophylactic pancreatic stent placement (%)	153 (25.5)	38 (4.7)	<0.001	24 (10.9)	23 (10.4)	1.0
Complete stone removal (%)	555 (92.5)	783 (97.1)	<0.001	210 (95.0)	208 (94.1)	0.83
Rectal NSAIDs (%)	57 (9.5)	71 (8.8)	0.71	23 (10.4)	26 (11.8)	0.76
Protease inhibitor (%)	247 (41.2)	235 (29.2)	<0.001	104 (47.1)	87 (39.4)	0.12
Prolonged procedure time (>30 min) (%)	321 (53.5)	76 (9.4)	<0.001	63 (28.5)	61 (27.6)	0.92
Procedure time (mean, [SD]) (min)	36.6 (16.5)	19.5 (9.4)	<0.001	27.6 (9.4)	27.0 (12.4)	0.63

CBD, common bile duct; EPBD, endoscopic papillary balloon dilation; EPLBD, endoscopic papillary large balloon dilation; ERCP, endoscopic retrograde cholangiopancreatography; EST, endoscopic sphincterotomy; NSAIDs, nonsteroidal anti-inflammatory drugs; PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis; PGW, pancreatic guidewire; SD, standard deviation.

Table 2. Rate of post-ERCP Pancreatitis

	All patients			Propensity score-matched patients		
	With difficult cannulation (n=600)	Without difficult cannulation (n=806)	p-value	With difficult cannulation (n=221)	Without difficult cannulation (n=221)	p-value
PEP (%)	50 (8.3%)	13 (1.6%)	<0.001	12 (5.4%)	3 (1.4%)	0.032

ERCP, endoscopic retrograde cholangiopancreatography; PEP, post-endoscopic retrograde cholangiopancreatography pancreatitis.

Table 3. Univariate Analysis for Factors Predicting Difficult Biliary Cannulation

	With difficult cannulation (n=600)	Without difficult cannulation (n=806)	p-value
Age (mean, [SD]) (years)	75.2 (13.8)	74.6 (14.0)	0.39
Female gender (%)	297 (49.5)	371 (46.0)	0.21
Absence of acute cholangitis (%)	238 (39.7)	243 (30.1)	<0.001
Normal serum bilirubin (%)	299 (49.8)	331 (41.1)	0.001
Nondilated CBD (<10 mm) (%)	243 (40.5)	331 (41.1)	0.87
Performance status 3 or 4 (%)	105 (17.5)	152 (18.9)	0.53
Bilroth-1 reconstruction (%)	21 (3.5)	19 (2.4)	0.26
Intradiverticular papilla (%)	35 (5.8)	25 (3.1)	0.016
Appearance of the major duodenal papilla (%)			0.002
Type 1	265 (44.2)	358 (44.4)	
Type 2	276 (46.0)	342 (42.4)	
Type 3	26 (4.3)	74 (9.2)	
Type 4	33 (5.5)	32 (4.0)	
ERCP performed by non-expert endoscopists	141 (23.5)	79 (9.8)	<0.001
Low-volume center (%)	170 (28.3)	140 (17.4)	<0.001
Multiple CBD stones (≥2 stones) (%)	232 (38.7)	345 (42.8)	0.13
Large CBD stones (>10 mm) (%)	106 (17.7)	148 (18.4)	0.78
History of cholecystectomy (%)	59 (9.8)	97 (12.0)	0.20
Presence of gallstones (%)	386 (64.3)	495 (61.4)	0.27

CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography; SD, standard deviation.

Table 4. Multivariate Analysis for Factors Predicting Difficult Biliary Cannulation

	OR	95% CI	p-value
ERCP performed by nonexpert endoscopists	2.5	1.9–3.5	<0.001
Low-volume center	1.6	1.2–2.1	<0.001
Intradiverticular papilla	1.3	1.1–1.5	0.007
Normal serum bilirubin	1.3	1.01–1.7	0.038
Absence of acute cholangitis	1.3	1.00–1.7	0.049
Appearance of the major duodenal papilla	0.98	0.85–1.1	0.77

CI, confidence interval; ERCP, Endoscopic retrograde cholangiopancreatography; OR, odds ratio.

biliary cannulation. If a non-expert endoscopist experiences any difficulty in biliary cannulation, an experienced endoscopist should be available to ensure the success of secondary ERCP with minimal additional time for biliary cannulation. A prospective study revealed that non-expert endoscopist involvement did not impair biliary cannulation success or prolong subsequent attempts by an experienced endoscopist after an initial unsuccessful cannulation under the training protocol, which allowed non-expert endoscopists to perform 6 min of supervised biliary cannulation attempts after reaching the major duodenal papilla. After an experienced endoscopist took over following the allotted 6 min, an average of 3 min was required for successful biliary cannulation.²⁸ Given that cannulations exceeding 10 min have been reported to be a risk factor for PEP,¹⁰ the definition of difficult cannulation (i.e., cannulation exceeding 5 min) proposed by the ESGE guideline may be useful for determining the optimal timing at which an experienced endoscopist should take over.

In cases of difficult biliary cannulation, rescue techniques, such as pancreatic guidewire-assisted cannulation or precut sphincterotomy are suitable in achieving biliary cannulation.²⁹ Reports have shown that rescue techniques are useful for patients with periampullary diverticulum.¹² In the current study, approximately three-fourths of the patients who underwent rescue techniques, including pancreatic guidewire-assisted cannulation and precut sphincterotomy within 5–10 min after initial cannulation, achieved successful selective cannulation within 5 min following the rescue technique. As such, the definition of difficult cannulation proposed by the ESGE guideline may be useful for determining the optimal timing in attempting a rescue technique.³⁰ Difficult biliary cannulation is an important risk factor for PEP. Patients with factors predicting difficult biliary cannulation should receive aggressive prophylaxis, including the use of rectal nonsteroidal anti-inflammatory drugs.^{2,3}

This study has several limitations. First, this was a retrospective study. Second, some residual confounding factors, such as the orientation of the major duodenal papilla, may have been present.

In conclusion, the current study revealed that ERCP performed by non-expert endoscopists, a low-volume center, intradiverticular papilla, normal serum bilirubin, and absence of acute cholangitis were significant factors predicting difficult biliary cannulation for CBDS. When performing ERCP among patients who exhibit the aforementioned predictive factors, initial cannulation attempts by an experienced endoscopist, early utilization of rescue techniques (e.g., pancreatic guidewire-assisted cannulation and precut sphincterotomy), and early takeover by an experienced endoscopist should be considered.

Conflicts of Interest

The authors have no potential conflicts of interest.

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