

## Difficult Common Bile Duct Cannulation Factors in Endoscopic Retrograde Cholangiopancreatography Procedure

Shirly Elisa Tedjasaputra<sup>1</sup>, Marcellus Simadibrata<sup>2</sup>, Irsan Hasan<sup>3</sup>, Cleopas Martin Rumende<sup>4</sup>

1 Department of Internal Medicine, Tarakan General Hospital Jakarta, Indonesia;

2 Gastroenterology Division Department of Internal Medicine, Cipto Mangunkusumo General Hospital, Medical Faculty University of Indonesia, Jakarta, Indonesia;

3 Hepatology Division Department of Internal Medicine, Cipto Mangunkusumo General Hospital, Medical Faculty University of Indonesia, Jakarta, Indonesia;

4 Pulmonology Division Department of Internal Medicine, Cipto Mangunkusumo General Hospital, Medical Faculty University of Indonesia, Jakarta, Indonesia.

**Conflict-of-interest statement:** The authors declare that there is no conflict of interest regarding the publication of this paper.

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**Correspondence to:** Shirly Elisa Tedjasaputra, MD, Internist, Internal Medicine Tarakan General Hospital, Jl. Rawa Kepa IV No 692 B, Tomang, Jakarta Barat 11440, DKI Jakarta, Indonesia.  
Email: [shirly\\_elisa@yahoo.com](mailto:shirly_elisa@yahoo.com)  
Telephone: +6285659090303

Received: May 16, 2021

Revised: May 23, 2021

Accepted: May 25, 2021

Published online: June 21, 2021

### ABSTRACT

**BACKGROUND:** Endoscopic Retrograde Cholangiopancreatography (ERCP) is the standard procedure for diagnosis and treatment of pancreatobiliary disease. Successful biliary cannulation will determine the next procedure. Selective biliary cannulation with a standard ERCP catheter or sphincterotome reportedly fails in 15-35 % cases.

The factors associated with difficult biliary cannulation of ERCP procedure should be identified to prevent ERCP complications. The aim of this study was to determine the prevalence of difficult biliary cannulation and the factors associated to difficult biliary cannulation in ERCP procedure.

**METHODS:** This research was conducted with cross sectional study in Gastrointestinal Endoscopy Center and Medical Record Unit Cipto Mangunkusumo General Hospital, using medical records data of subjects who underwent ERCP from 2018-2020. Bivariate and multivariate analysis were performed for the factors that associated with difficult biliary cannulation.

**RESULTS:** There were 194 subjects enrolled in this study. The prevalence of difficult biliary cannulation was 26.3% (51/194) cases. The prevalent of biliary obstructions were; (1) Non-malignant 57.2%; (2) Non-distal common bile duct (CBD) stricture 73.7%; (3) Non-periampullary diverticle 91.8%. The experience's ERCP operator was 53.1%. The prevalence of multiple choledocholithiasis was 16% and cholangiocarcinoma was 20.1%. Difficult CBD cannulation correlated significantly to the age, direct bilirubin level and ERCP operator's experience. There was correlation, although non-significant, with malignancy and distal CBD stricture. There was no correlation with comorbid and periampullary diverticle.

**CONCLUSIONS:** The prevalence of difficult biliary cannulation in ERCP procedure was 26.3%. Age, direct bilirubin level, and operator experience were factors associated with difficult biliary cannulation in ERCP procedure. There was also related between difficult CBD cannulation and malignancy and distal CBD stricture, although not significant.

**Key words:** Endoscopic Retrograde Cholangiopancreatography (ERCP); Difficult biliary cannulation

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Tedjasaputra SE, Simadibrata M, Hasan I, Rumende CM. Difficult Common Bile Duct Cannulation Factors in Endoscopic Retrograde Cholangiopancreatography Procedure. *Journal of Gastroenterology and Hepatology Research* 2021; **10(3)**: 3510-3515 Available from: URL: <http://www.ghrnet.org/index.php/joghr/article/view/3122>

## INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is the standard procedure for diagnosis and treatment of pancreatobiliary disease, technically varies from a simple to a highly complex diagnostic and therapeutic procedure. A recent survey in the UK showed wide range of endoscopists success rates from 76% to 95% and the serious complications from 0% to 16%<sup>[1]</sup>. Success and complications depend not only on the endoscopist's skill and experience but also on the technical difficulty. Selective biliary cannulation with a standard ERCP catheter or sphincterotome reportedly fails in 15-35 % cases. A difficult cannulation alone has been shown to carry an inherent risk for a post-ERCP complication<sup>[2-4]</sup>. Difficult cannulation is defined as a situation where the endoscopist, using his/her regularly used cannulation technique, fails within a certain time limit or after a certain number of unsuccessful attempts. Unsuccessful cannulation occurred in 20% cases and correlated with the higher risk of post ERCP pancreatitis, bleeding and perforation<sup>[5]</sup>. Pancreatitis is the most frequent complication after a difficult cannulation compared with a standard cannulation that increased from 4.3% to 11.3%.

Originally scale the ERCP difficulty grading scale ranged from 1 to 5, with 1 being a relatively easy ERCP procedure and 5 being a difficult ERCP procedure. A few years later, a committee from the American Society for Gastrointestinal Endoscopy (ASGE) eliminated 2 of the grades, making the scale range from grade 1 to grade 3. The grade is an indicator of difficulty over the course of many ERCP procedures. Grade 1 ERCP procedures are relatively easy while grade 3 ERCP procedures are harder to complete successfully.

The factors associated with difficult biliary cannulation of ERCP procedure should be identified to anticipate the ERCP difficulty and complications<sup>[3,8]</sup>.

The aim of this study was to determine the prevalence of difficult biliary cannulation and the factors associated with difficult biliary cannulation in ERCP procedure such as age, comorbid diseases, history of gastric operation (Billroth II, Roux-en-Y), difficult papilla Vater position, little and tortuous papilla Vater, periampullary diverticula, distal CBD stricture, malignancy infiltration of papilla Vater and other distorted caused of biliary obstruction like pancreatic malignancy, also the operator experience and laboratory result.

## MATERIALS AND METHODS

### Study Design

There was a cross-sectional study was enrolled on 194 subjects of biliary obstruction who underwent ERCP from 2018-2020. This study was conducted from October - December 2020 in Gastrointestinal Endoscopy Centre - Cipto Mangunkusumo General Hospital.

The non-probability consecutive sample to determine prevalence of difficult biliary cannulation. Bivariate analysis of the related variable (age, comorbid, history of gastric operation, bilirubin level, cause of biliary obstruction, distal CBD stricture, periampullary diverticula and operator experience) and difficult cannulation were conducted by Chi-Square test. Multivariate logistic regression models to assess the scoring factor. *P* value was two-tailed and considered statistically significant at < 0.05 and 95% confidence interval (CI).

### Subject enrollment

All subject with biliary obstruction underwent ERCP in Gastrointestinal Endoscopy Centre - Cipto Mangunkusumo General Hospital. The data was taken from the medical record Cipto Mangunkusumo General Hospital. Protocol was approved

by Health Research Ethic Committee University of Indonesia - Cipto Mangunkusumo General Hospital No. 1108/UN2.F1/ETIK/PPM.00.02/2020.

**The inclusion criteria were:** (1) The first time ERCP was done; (2) All biliary obstruction patients who underwent ERCP more than 18 years old.

**Subject were excluded if:** (1) Medical record data was not complete; (2) The insertion of duodenoscope was failed to reached the Papilla Vater for selective biliary cannulation. (3) Serious systemic disease that unavailable for ERCP procedure.

## RESULTS

There were 194 subjects enrolled in this study. The basic characteristics of subject and prevalence of difficult biliary cannulation are showed in Table 1. The mean age of subject was  $50.82 \pm 14.73$  years old (71.6% was  $\leq$  60-year-old). There was no significant difference between male and female (51% and 49%). Most of subject has  $\leq$  1 (90.2%) comorbid. No gastric operation history was happened in all subject. The difficult CBD cannulation was 26.3% (51/194) cases.

The prevalence of biliary obstructions were; (1) Non-malignant 57.2%; (2) Non-distal common bile duct (CBD) stricture 73.7%; (3) Non-periampullary diverticle 91.8%. The experience's ERCP operator was 53.1%. The prevalence of multiple choledocholitis was 16% and cholangiocarcinoma was 20.1%.

Laboratory result of bilirubin, SGOT and SGPT level showed in table 2.

Bivariate analysis (correlation between difficult cannulation and the variables of age, comorbid, gastric operation history, direct bilirubin level, cause of biliary obstruction, distal CBD stricture, periampullary diverticula and operator experience) was showed in table 3.

Difficult CBD cannulation correlated significantly to the age, direct bilirubin level and ERCP operator's experience. There was correlation, although non-significant, with malignancy and distal CBD stricture. There was no correlation with comorbid and periampullary diverticle.

### Logistic regression Difficult CBD cannulation

**Equation Difficult CBD cannulation:** Scoring difficult CBD cannulation =  $-1.981 + 0.849$  (age >60 y.o.) +  $0.833$  (direct bilirubin level >5 mg/dL) +  $1.119$  (less operator experience).

AUC 0.691 with  $p < 0.001$  CI 95% (0.613-0.770).

Hosmer-Lemeshow Calibration scoring system  $p = 0.292$  (Significance Hosmer-Lemeshow  $p > 0.05$ ). The model is fit for difficult CBD cannulation difficulty.

The optimal cut off point sensitivity 54.90% and specificity 70.63%, Likelihood Ratio (LR) 1.87 (cut off point 3), probability 65.15% for difficult CBD cannulation.

## DISCUSSION

Endoscopic retrograde cholangiopancreatography (ERCP) is the most technically challenging procedure performed by endoscopists. ERCP cannulation requires the insertion of a catheter through a tiny orifice. After successful cannulation of the common bile duct, the complete ERCP procedure could be proceeded (sphincterotomy, stone extraction, stent placement etc.). Selective biliary cannulation is all the more exacting due to the occasional anatomic challenge or wayward catheter. Serious complications can occur, even in the hands of the most gifted and facile endoscopists.

The prevalence of difficult CBD cannulation in this research was 26.3% (51/197). Abdullah et al (2008-2018) reported the prevalence of difficult CBD cannulation was 18%<sup>[9]</sup>, and Tabak et al (2016-2018) reported 22.2% of difficult cannulation<sup>[10]</sup>. There was increased the difficult case of ERCP cannulation.

Considering the cannulation difficulty, age more than 60 years old was noted to be a significant correlation with difficult cannulation which happened in 36.4% subject, with the OR 2.33,  $p = 0.021$  (Table 3 and Table 4). Tabak et al (2016-2018) reported that the difficult cannulation was not associated with an increased overall adverse events rate while age  $\geq 80$  years. The malignancy and

**Table 1** Subject Characteristics and Prevalence.

Variable	Total [ n=194 (100%)]
<b>Age (Year)</b>	
≤60	139 (71.6)
>60	55 (28.4)
<b>Gender</b>	
Female	95 (49.0)
Male	99 (51.0)
<b>Comorbid</b>	
≤1	175 (90.2)
>1	19 (9.8)
<b>History of gastric operation</b>	
No	194 (100.0)
Yes	0 (0.0)
<b>Etiology of biliary obstruction</b>	
Non-malignancy	111 (57.2)
Malignancy	83 (42.8)
<b>Distal CBD stricture</b>	
No	143 (73.7)
Yes	51 (26.3)
<b>Periampullary Diverticula</b>	
No	178 (91.8)
Yes	16 (8.2)
<b>Operator ERCP experience</b>	
≤100 procedures / year	91 (46.9)
>100 procedures /year	103 (53.1)
<b>Specific cause of Biliary Obstruction</b>	
n (%)	
Cholangiocarcinoma	39 (20.1)
Multiple choledocholitis	31 (16.0)
Simple choledocholitis	28 (14.4)
Caput pancreas carcinoma	23 (11.9)
Papilla Vater carcinoma	19 (9.8)
Giant CBD stone	18 (9.3)
Sludge CBD	13 (6.7)
Impacted CBD stone	3 (1.5)
Mirizzi syndrome	3 (1.5)
Bile leakage CBD	3 (1.5)
Multiple pancreatic stone	2 (1)
Sphincter Oddi dysfunction	2 (1)
Biloma	2 (1)
*Other causes	8 (4.3)
<b>Difficult Biliary Canulation</b>	
No	143 (73.7)
Yes	51 (26.3)

\*Multiple pancreatic stone, Choledochal cyst, Lemmel syndrome, Pancreatic pseudocyst, Gall bladder tumor.

periampullary diverticulum were noted to be the cause of difficult cannulation in the elderly group. In contrast, distal stricture or impacted stone was the most frequent cause of difficult cannulation in younger patients<sup>[4]</sup>.

Most of the subject of biliary obstruction was less than 60 years old, no significant different between male and female. (Table 1). This was the same finding by Abdullah et al (2008-2010)<sup>[9]</sup>. Tabak et al in 2016-2018 showed the median age was 68 years old<sup>[4]</sup>.

Funes et al (2001-2002) reported the significant difference successful ERCP procedure between the age of < 65 years old and > 65 years old, but no significant differences of the complication and mortality between both of age<sup>[11]</sup>.

The comorbid diseases should be evaluated before ERCP procedure, working to control these factors can avoid negative outcomes of morbidity and mortality, high patient cost and length of hospitals stay. These factors including infection control, acute or chronic kidney failure, acute or chronic liver disease, congestive

**Table 2** Laboratory Finding of Subject.

Variabel	Median (min-max)
Total bilirubin (mg/dL)	13.79 (4.49-22.0)
Direct bilirubin (mg/dL)	10.23 (3.04-14.72)
AST / SGOT (U/L)	76.50 (44.75-123.25)
ALT / SGPT (U/L)	73.50 (39.00-114.00)

Not normal distribution numeric variable show in median (min-max)

**Table 3** Bivariant Analysis (Correlation between difficult cannulation and The Age, Comorbid, History of gastric operation, Bilirubin Level, Malignancy, Distal CBD Stricture, Periampullary Diverticula and Operator Experience)

Variable	Difficult Cannulation [n (%)]	Not difficult Cannulation [n (%)]	OR (CI 95 %)	p
<b>Age</b>				
> 60 y.o.	20 (36.4)	35 (63.6)	1.630 (1.022-2.602)	0.045
≤ 60 y.o.	31 (22.3)	108 (77.7)		
<b>Comorbid</b>				
> 1	5 (26.3)	14 (73.7)	1.001 (0.453-2.211)	1.000*
≤ 1	46 (26.3)	129 (73.7)		
<b>History of gastric operation</b>				
Yes	0 (0.0)	0 (0.0)	-	-
No	51 (26.3)	143 (73.7)		
<b>Direct bilirubin level</b>				
> 5 mg/dL	41 (30.6)	93 (69.4)	2.204 (1.019-4.770)	0.042
≤ 5 mg/dL	10 (16.7)	50 (83.3)		
<b>Etiology of biliary obstruction</b>				
Malignant	27 (32.5)	56 (67.5)	1.505 (0.940-2.409)	0.088
Non-malignant	24 (21.6)	87 (78.4)		
<b>Distal CBD stricture</b>				
Yes	18 (35.3)	33 (64.7)	1.529 (0.949-2.465)	0.089
No	33 (23.1)	110 (76.9)		
<b>Periampullary diverticula</b>				
Yes	5 (31.2)	11 (68.8)	1.209 (0.561-2.607)	0.767
No	46 (25.8)	132 (74.2)		
<b>Operator experience</b>				
< 100 procedures/year	33 (36.3)	58 (63.7)	2.075 (1.258-3.422)	0.003
≥ 100 procedures/year	18 (17.5)	85 (82.5)		

Chi square test, n %, OR (CI 95%), and p Value, \*Fisher's exact test, n (%), OR (CI 95%), p Value.

heart failure, chronic lung disease, cerebrovascular disease (CVD), diabetes mellitus with complications, a coagulopathy disorder, anaemia and malignancy. Gordon V et al, (2012-2015) reported a significant correlation of comorbid diseases in the elderly patient (80 years old) and the worse patient outcomes. The significant comorbid correlation were hypertension, ischemic heart disease, CVD and dementia, COPD/asthma, malignancy and periampullary diverticulum. *Charlson Comorbidity Index* (CCI)  $\geq 2$  was significant correlated to overall ERCP complication ( $p = 0.045$ )<sup>[4]</sup>. Tabak et al (2016-2018) reported CCI  $\geq 2$  was not correlated to difficult CBD cannulation in ERCP procedure (OR 1.221,  $p = 0.433$ )<sup>[4]</sup>.

Most of the research's subject (90.2%) has less than one disease comorbid. No history of gastric operation in all subject. Subjects with difficult insertion of duodenoscope failed to reached the Papilla Vater for selective biliary cannulation were excluded. Most of the ERCP subject in this research had less than one comorbid under control. Analysis of the comorbid was not correlated with the difficulty of CBD cannulation (Table 3). All the ERCP's patient had been selected of special examination for anesthesia toleration and selected by ASA (American Society of Anesthesiologists) criteria.

History of gastric operation Billroth II or Roux-en-Y causes

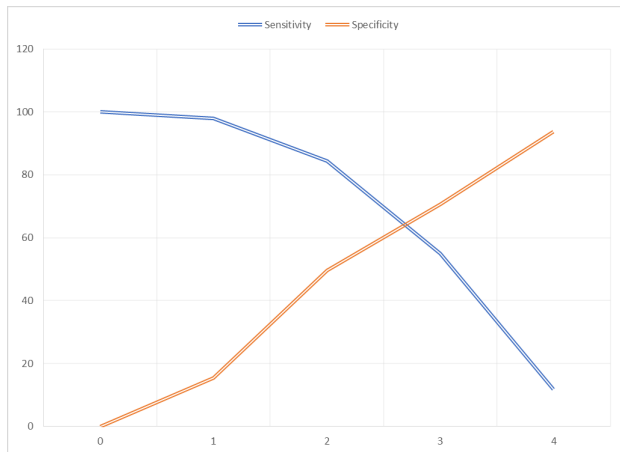


Figure 1 ROC curve (Receiving Operator Characteristics) and cut off point scoring system test.

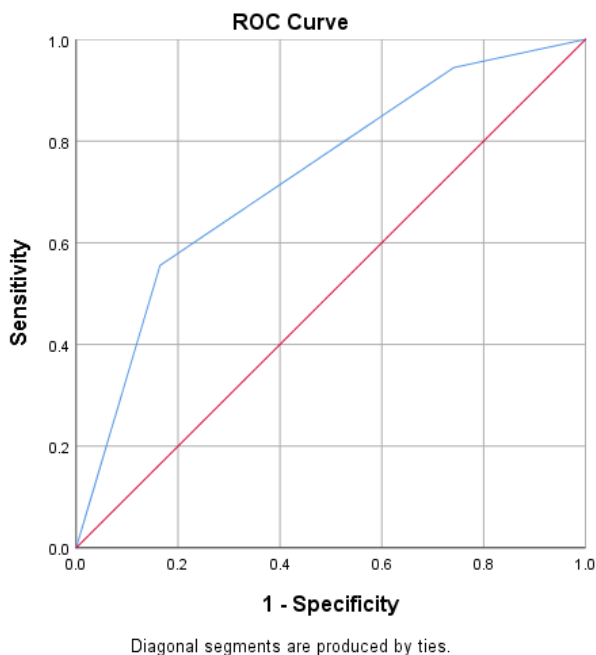


Figure 2 Cut off point sensitivity and specificity.

the difficulty of CBD cannulation while the papilla position was changed. Cicek et al (2002-2005) reported the successful rate of ERCP procedure in Billroth II operation compare to Roux-en-Y operation was 83% dan 29%<sup>[12]</sup>. Bove et al (1982-2012) in Billroth II gastrectomy showed successful CBD cannulation was 93,8%<sup>[13]</sup>. ERCP procedure in anatomical changing was correlated with perforation risk, especially in the a limb (*afferent limb*). Perforation risk happened in 0.6 -11% caused by duodenoscope looping<sup>[5,122]</sup>. No history of gastric operation subjects in this research.

Laboratory finding of all subject showed normal limit of ALT and AST. The total bilirubin and direct bilirubin level were increased in all subject. The bilirubin level was significant correlated with CBD cannulation difficulty. The CBD cannulation more difficult in the higher bilirubin level. The result was the same as Uskudar et al reported the bilirubin level was correlated with CBD cannulation difficulty. The ALT and AST were not correlated with CBD cannulation difficulty<sup>[14]</sup>. The bilirubin level, especially direct bilirubin ( $> 5$  mg/dL), was significantly correlated with difficult CBD cannulation (OR 2.299,  $p = 0.042$ ) (Table 3 and Table 4). The severity and length duration of obstruction will influence the bilirubin level. Sultan et al (2015-2017) reported the increasing bilirubin level caused by malignancy obstructions decreases the success rate ERCP from 76.9% to 71% and the duration jaundice decreased successful ERCP from 83% to 75%<sup>[15]</sup>. Zheng et al. (2013-2017) reported total bilirubin level was not significant correlated with successful CBD cannulation<sup>[16]</sup>.

Table 4A Multivariat Analysis Difficult CBD Cannulation.

Variable	OR (c.i. 95 %)	p
Step 1		
Age >60 y.o.	2.221 (1.052-4.689)	0.036
Direct bilirubin level >5 mg/dL	1.987 (0.827-4.776)	0.125
Cause of biliary obstruction	1.312 (0.604-2.850)	0.492
Distal CBD stricture	1.730 (0.824-3.634)	0.148
Operator experience	3.194 (1.570-6.497)	0.001
Step 2		
Age >60 y.o.	2.362 (1.142-4.889)	0.021
Direct bilirubin level >5 mg/dL	2.240 (0.999-5.021)	0.05
Distal CBD stricture	1.801 (0.867-3.745)	0.115
Operator experience	3.086 (1.531-6.218)	0.002
Step 3		
Age >60 y.o.	2.337 (1.136-4.808)	0.021
Bilirubin level >5 mg/dL	2.299 (1.033-5.119)	0.042
Operator experience	3.061 (1.528-6.133)	0.002

Table 4B Multivariat Analysis Difficult CBD Canulation

Variable	B	SE	B/SE	Score	Final score
Age	0.849	0.368	2.305	1.131	1
Direct bilirubin level >5 mg/dL	0.833	0.408	2.038	1.000	1
Operator experience	1.119	0.355	3.155	1.548	2

Table 4 C Probability score predictor difficult CBD canulation

Variable	Catagoric	Score
Age >60 y.o.	Yes	1
	No	0
Direct bilirubin level >5 mg/dL	Yes	1
	No	0
Less operator experience	Yes	2
	No	0
Total score		4

The biliary obstruction caused by malignancy showed correlation to difficult CBD cannulation although there was not significant (OR 1.505  $p = 0.088$ ). (Table 3 and Table 4). The hole for cannulation is difficult to identify while the infiltration of tumor covers the surface of lumen, or distorted of CBD by the tumor mass either pancreatic tumor, duodenal tumor or cholangiocarcinoma. The malignant mass is fragile, bleeds easily and swollen when the cannulation was done. The stage of malignancy is also influencing the successful of cannulation<sup>[5,15,17]</sup>.

The stricture of distal CBD is one of the causes of difficult CBD cannulation. The stricture could be caused by tumor compression, tumor infiltration, and inflammation. Primary distal CBD stricture, abnormal papilla Vater and difficult positioning of duodenoscope cause the difficulty of guidewire insertion. Our research showed non-significant correlation of distal CBD stricture with difficulty of CBD cannulation. (OR 1.53,  $p = 0.089$ ) (Table 3 and Table 4).

Periampullary diverticulum was herniation of mucosa or submucosa by muscle layer defect. Periampullary diverticulum (PAD) is frequently come upon during endoscopic retrograde cholangiopancreatography (ERCP), especially in elderly patients.<sup>4</sup> There were 3 type of periampullary diverticula. Type I, Papilla intra-diverticula, major papilla located inside the diverticula, Type II, located on the edge of diverticula, Type 3, located near diverticula. The prevalence's were 50%, 30% and 20%<sup>[2,18]</sup>. Major Papilla located 2 cm from diverticula was diverticulum juxta papillar<sup>[19]</sup>. The difficulty of CBD cannulation in periampullary diverticulum is caused by difficulty to find the orifice of papilla Vater lumen and the axis of cannulation<sup>[5,20]</sup>. Our research showed the periampullary diverticulum prevalence was 8.2% (16/194) subject and no correlation with difficult cannulation. Boix et al, (2001-2002) showed no correlation between cannulation difficulty and periampullary diverticula<sup>[18,21]</sup>. Sfarti et al, Zoepf et al. and Rajnakova et al showed significant correlation between difficult cannulation and periampullary diverticula<sup>[20,22,23]</sup>. Lobo et al. showed successful cannulation 62.4% vs 92.7% in periampullary diverticulum and no diverticulum. Periampullary intra-diverticulum cannulation was more difficult than juxta-diverticulum (38.1% vs 77.6%). PAD was associated with longer cannulation time and increase in the cannulation difficulty, especially with PAD type 1<sup>[4]</sup>.

Berry R et al, reported that successful cannulation happened in experience operators after doing 350-400 ERCP procedures<sup>[5]</sup>. Verma et al (2002-2003) reported for 80% successful CBD cannulation by ERCP trainee should minimal 180-200 procedures by supervising, and successful cannulation > 96% after the trainee do 300 procedures without supervision after finish the training<sup>[24]</sup>. Zheng et al (2013-2017) showed successful cannulation of distal CBD stricture was 31% by trainee and 46.7% by supervisor<sup>[16]</sup>. This research showed a significant correlation between operator experience (more or less than 100 procedures/year) and difficult cannulation (OR 3,061,  $p = 0.002$ ).

## CONCLUSIONS

Difficult CBD cannulation was happened in 26.3% cases. Difficult CBD cannulation correlated with age, direct bilirubin level, and operator experience. Increased the age and direct bilirubin level decreased the success rate of ERCP procedure. The operator's experience influenced the successful rate of biliary cannulation. There was correlation between difficult CBD cannulation and distal CBD stricture and malignancy, although there were not significant. No correlation between difficult CBD cannulation and comorbid and periampullary diverticula.

## Limitation

The limitation of this research was not detail analysis of parameter, such as the detail of comorbid, etiology of the malignancy and stricture, experience and operator situation, type of periampullary diverticula. In the future it should explain more detail about the difficulty of CBD cannulation.

## Author contributions

Study concept and design: S.E.T., M.S. Data acquisition: S.E.T. Data analysis and interpretation: S.E.T. Drafting of the manuscript: S.E.T., M.S. Critical revision of the manuscript for important intellectual content: M.S., I.H., C.M.R. Statistical analysis: S.E.T., C.M.R. Obtained funding: S.E.T. Administrative, technical, or material support; study supervision: M.S., I.H., C.M.R.

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