Predictors of Technical and Clinical Success of ERCP in Patients with Biliary Obstruction: A Study from a Tertiary Referral Center in Indonesia

Tony Darmadi*, Achmad Fauzi, Dadang Makmun, Hamzah Shatri, Djoa Theadora Rebecca Santoso

Division of Gastroenterology, Pancreatobiliary, and Digestive Endoscopy, Department of Internal Medicine, Faculty of Medicine, Universitas Indonesia-Dr. Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia.

Corresponding author:
Tony Darmadi, MD. Division of Gastroenterology and Hepatobiliary, Department of Internal Medicine, Faculty of Medicine, Universitas Indonesia - Dr. Cipto Mangunkusumo National General Hospital. Jl. Diponegoro no. 71, Jakarta 10430, Indonesia. Email: tonydarmadi25@gmail.com

ABSTRACT

Background: *Endoscopic retrograde cholangiopancreatography (ERCP) is a primary therapeutic modality for managing malignant and benign biliary obstruction. Technical success (TS) and clinical success (CS) of modality are essential indicators of procedural efficacy, which is influenced by various patient- and procedure-related factors. Therefore, this study aims to evaluate the TS and CS rates of ERCP and identify their predictors in patients with biliary obstruction at a tertiary referral center in Indonesia.* ***Methods:*** *A retrospective analysis was conducted on patients with biliary obstruction who underwent therapeutic ERCP at Cipto Mangunkusumo Hospital between January 2022 and December 2024. Patients with diagnostic ERCP or prehepatic/parenchymal jaundice were excluded.* ***Results:*** *A total of 259 patients were included (49.4% female, mean age 50.6 years) in this study. The results show that the TS rate is 96.5%, with multivariate analysis identifying ulcerative fragile papillary mass (AOR 0.075; P=0.001) as an independent negative predictor. Meanwhile, the CS rate is 88%, with pre-ERCP bilirubin ≥3 mg/dL (AOR 8.545; P<0.001) and previous ERCP stenting/pre-cutting (AOR 0.330; P=0.037) being independent predictors. Distal malignant obstruction causes a higher pre-ERCP bilirubin level (P=0.025) of ≥3 mg/dL (OR 6.116; P=0.011).* ***Conclusion:*** *ERCP showed high technical and clinical success rates in managing biliary obstructions. TS was negatively predicted by ulcerative fragile papillary mass. CS was positively predicted by pre-ERCP bilirubin ≥3 mg/dL and negatively by prior stenting or pre-cutting. These findings should be taken into consideration when planning and delivering ERCP to achieve better outcomes.*

Keywords*: biliary obstruction, ERCP, technical success, clinical success, predictive factors.*

INTRODUCTION

Biliary obstruction is a condition where bile flow from the liver to the duodenum is blocked by malignant or benign causes, originating within or outside the bile ducts.[1,2] Common benign etiologies include choledocholithiasis, which affects approximately 5 in 1,000 people. Other etiologies include benign strictures caused by various conditions, such as primary sclerosing cholangitis (PSC), Mirizzi syndrome, Lemmel syndrome, or post-traumatic injury.[1,3] Malignant obstructions, estimated at 15 per 100,000 people, are often caused by pancreatic adenocarcinoma, cholangiocarcinoma, ampullary/duodenal cancer, gallbladder carcinoma, lymphoma, or nodal metastases.[4]

Endoscopic retrograde cholangiopancreatography (ERCP) is a primary therapeutic modality for biliary obstruction. A duodenoscope is inserted into the duodenum, allowing direct visualization and access to the biliary and pancreatic ducts for therapeutic interventions, such as stone extraction in choledocholithiasis or stent placement in biliary strictures.[5,6] The overall effectiveness of the modality can be evaluated through technical success (TS) and clinical success (CS). TS refers to successful biliary cannulation and the completion of intended therapeutic procedures.[6] Meanwhile, CS is a ≥30% reduction in total bilirubin within 2 weeks following a technically successful procedure.[7–9]

Although TS rates are generally high, CS tends to vary more.[6,8,9] This variability shows the importance of identifying patient- and procedure-related factors that may influence both outcomes. However, current evidence often focuses on either malignant or benign etiologies alone and remains limited in developing countries, such as Indonesia. Therefore, this study aims to evaluate the TS and CS rates of ERCP and identify their predictors in patients with biliary obstruction at a high-volume tertiary referral center in Indonesia. The results are expected to provide essential insights for improving ERCP outcomes in similar resource-limited settings.

METHODS

Data were collected retrospectively, including patients over 18 years with biliary obstruction who underwent therapeutic ERCP at Cipto Mangunkusumo National General Hospital between January 2022 and December 2024. The exclusion criteria were patients who had incomplete medical records, underwent diagnostic ERCP, or had prehepatic or parenchymal jaundice. Only cases with confirmed TS were included to analyze CS predictors to ensure outcomes that reflected clinical factors independently.

Ethical Approval

The study was conducted by the Declaration of Helsinki and approved by the institutional ethics committee (Approval No. KET- 73/UN2. F1/ETIK/PPM.00.02/2025).

Data Collection and Definitions

Clinical data were retrospectively collected from electronic medical records, such as patient demographics (age, sex), comorbidities (diabetes mellitus, hypertension), body mass index (BMI), smoking history, history of gastrointestinal surgery, prior ERCP, and pre-ERCP total bilirubin levels. In addition, procedural data extracted from ERCP reports included papilla morphology, use of pre-cut sphincterotomy, stent type, operator experience, obstruction site, etiology of biliary obstruction, and procedural difficulty. Post-ERCP bilirubin levels were also recorded within 2 weeks and compared to baseline values.

BMI was classified according to WHO Asia-Pacific guidelines, namely underweight (<18.5 kg/m2), normal (18.5–22.9 kg/m2), overweight (23–24.9 kg/m2), obesity grade I (25–29.9 kg/m2), and obesity grade II (≥30 kg/m2). Pre-ERCP bilirubin levels were dichotomized at 3 mg/dL, a threshold associated with clinically evident jaundice. Papilla morphology was categorized using the Haraldsson classification, namely type I (normal), type II (small, <3 mm, 9 fr), type III (bulging/pedunculated), type IV (ridged), and additional morphologies including peridiverticular (type D), previous ERCP stenting, or pre-cutting, and ulcerative/fragile masses.[10,11] Pre-cut sphincterotomy refers to a papillary incision performed after failed standard cannulation.[12] Operator experience was categorized as junior (<6 years) or senior (≥6 years). Several stents were used in this study, namely plastic (cotton-leung, single/double pigtail, tannenbaum), metallic (self-expandable metallic stent), or biodegradable stent. Biliary obstruction level was classified as perihilar, common bile duct (CBD), or multilevel. Non-malignant etiology consisted of choledocholithiasis, passing stones, and benign strictures, while malignant etiology comprised pancreatic cancer, ampullary cancer, and cholangiocarcinoma. Procedural difficulty was assessed using the complexity grading system of the American Society for Gastrointestinal Endoscopy (ASGE).[6]

The primary outcomes of this study were predictors of ERCP TS and CS. TS was defined as successful biliary cannulation and therapeutic intervention, while CS was defined as ≥30% reduction in total bilirubin level within 2 weeks post-technically successful ERCP.[6–9] The secondary outcomes were the TS and CS rates, and the association of obstruction location and etiology with pre-ERCP bilirubin levels.

Statistical Analysis

Categorical variables were presented as frequencies (n) and percentages (%), while continuous variables were presented as mean ± standard deviation (SD). Bivariate analysis was performed using Pearson's Chi-square or Fisher's exact test for categorical variables and an independent t-test or Mann-Whitney U for continuous variables. Variables with a *P*-value <0.25 in bivariate analysis were included in multivariate analysis, which was carried out using stepwise logistic regression. Collinearity assumptions were assessed, with tolerance values >0.01 and variance inflation factors <10, indicating no multicollinearity. A *P*-value <0.05 was considered statistically significant, and the statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA).

RESULTS

Patients Characteristics

A total of 259 patients with biliary obstruction undergoing ERCP were enrolled in this study.

Table 1. Baseline characteristics of patients undergoing ERCP admitted to this study.

Characteristics	Values (N = 259)
Patient-related	
Age (years)	50.6 ± 13.3
Gender, male/female	131 (50.6%)/ 128 (49.4%)
Body Mass Index (kg/m^2)	22.9 ± 6.0
Underweight	52 (20.1%)
Normoweight	93 (35.9%)
Overweight	43 (16.6%)
Obesity grade I	53 (20.5%)
Obesity grade II	18 (6.9%)
Diabetes mellitus	41 (15.8%)
Hypertension	83 (32%)
Cigarette smoking	60 (23.2%)
History of previous ERCP	45 (17.4%)
History of gastrointestinal surgery	22 (8.5%)
Cholecystectomy	20 (7.7%)
Adhesiolysis	2 (0.77%)
Pre-ERCP bilirubin (mg/dL)	15.1 ± 11.1
Procedure-related (n, (%))	
Type I papilla morphology	135 (52.1%)
Type III papilla morphology	37 (14.3%)
Type D papilla morphology	23 (8.9%)
Previous ERCP stenting or pre-cutting	31 (12%)
Ulcerative fragile papillary mass	33 (12.7%)
Pre-cut sphincterotomy	23 (8.9%)
Junior operator (<6 years of expertise)	165 (63.7%)
Senior operator (≥6 years of expertise)	94 (36.3%)
Plastic stent	180 (69%)
Metallic stent	3 (1.2%)
Biodegradable stent	2 (0.77%)
Perihilar obstruction	33 (12.7%)
Common bile duct obstruction	202 (78%)
Multilevel obstruction	24 (9.3%)
Choledocholithiasis	114 (44.8%)
Single stone	72 (27.8%)
Multiple stone	42 (16.2%)
Stone diameter < 15 mm	75 (29%)
Stone diameter ≥ 15 mm	39 (15%)
Passing stone	74 (28.2%)
Benign stricture	10 (3.9%)
Primary sclerosing cholangitis	5 (1.9%)
Mirizzi syndrome	1 (0.3%)
Lemmel syndrome	2 (0.8%)
Others	2 (0.8%)
Pancreatic cancer	29 (11.6%)
Stage I	6 (2.3%)
Stage II	4 (1.5%)
Stage III	5 (1.9%)
Stage IV	14 (5.4%)
Ampullary cancer	18 (6.2%)
Stage I	5 (1.9%)
Stage II	3 (1.1%)
Stage III	9 (3.5%)
Stage IV	1 (0.3%)
Cholangiocarcinoma	14 (5.4%)
Stage I	2 (0.8%)
Stage II	4 (1.5%)
Stage III	4 (1.5%)
Stage IV	4 (1.5%)
ASGE grade I	23 (8.9%)
ASGE grade II	145 (56%)
ASGE grade III	91 (35.1%)
ASGE grade IV	0 (0%)
ERCP success rate (%)	
Technical success	96.5%
Clinical success	88%
Complications	
Bleeding	29 (11.2%)
Post-ERCP pancreatitis	21 (8.11%)

ERCP: endoscopic retrograde cholangiopancreatography; ASGE: American Society for Gastrointestinal Endoscopy.

Table 1 presents the general characteristics of the study sample.

Most of the patients were classified as being in the normal BMI category (35.9%). Hypertension emerged as the most frequently observed comorbidity. A total of 8.5% of patients underwent gastrointestinal surgery, including cholecystectomy and adhesiolysis. The most common papilla vateri morphology observed during ERCP was type I (normal), while types II and IV were not detected. In addition, the most prevalent stent used to manage obstructions was a plastic stent. Most obstructions occurred in the CBD, with the most common etiology being choledocholithiasis. Based on the result of this study, the cases were predominantly classified as ASGE grade II, comprising bile duct stone extraction <10 mm and the management of both benign and malignant extrahepatic strictures. The complexity level of ASGE I included deep cannulation of the duct of interest, central papilla, sampling, and biliary stent removal/exchange, while ASGE III included biliary stone extraction >10 mm, intraductal imaging and biopsy, treatment of hilar tumors, treatment of benign biliary strictures, and hilum. In this study, TS was observed in 96.5% of ERCP cases. The failure was attributed to unsuccessful cannulation of the biliary duct. Meanwhile, CS was achieved in 84.9% of cases.

The complications associated with ERCP procedures included bleeding manifesting as hematemesis, melena, and anemia, as well as post-ERCP pancreatitis.

Predictors of ERCP Technical Success for Biliary Obstruction

Higher TS rates were observed in patients aged 18 to 59 years, male, without diabetes, with hypertension, obesity grade II, smokers, prior ERCP, no gastrointestinal surgery, and pre-ERCP bilirubin <3 mg/dL. Others included type D and previous ERCP stenting or pre-cutting papillary morphology, no pre-cutting sphincterotomy, junior operator, multilevel obstruction, malignant etiology, perihilar malignant obstruction, and ASGE grade I. However, bivariate analysis observed only papillary morphology to be significantly associated with TS (P=0.007), with the lowest success in ulcerative fragile papillary

Table 2. Technical success of therapeutic ERCP based on each characteristic of patients with biliary obstruction.

Characteristics	Technical failure, n (%) (N=9)	Technical success n (%) (N=250)	Technical success Rate, n (%)	or (95% CI)	*P*-value
Age					
18-59 years	6 (66.7%)	191 (76.4%)	97	0.618	0.451
≥60 years	3 (33.3%)	59 (23.6%)	95.2	(0.150–2.547)	
Gender					
Male	3 (33.3%)	128 (51.2%)	97.7	0.477	0.330
Female	6 (66.7%)	122 (48.8%)	95.3	(0.117–1.948)	
Diabetes mellitus					
No	7 (77.8%)	211 (84.4%)	96.8	0.647	0.431
Yes	2 (22.2%)	39 (15.6%)	95.1	(0.130– 3.231)	
Hypertension					
No	7 (77.8%)	169 (67.6%)	96	1.678	0.723
Yes	2 (22.2%)	81 (32.4%)	97.6	(0.341–8.256)	
BMI Categories					
Underweight	2 (22.2%)	50 (20%)	96.2		
Normoweight	3 (33.3%)	90 (36%)	89.8		
Overweight	1 (11.1%)	42 (16.8%)	97.7	-	0.920
Obesity grade I	3 (33.3%)	50 (20%)	94.3		
Obesity grade II	0 (0%)	18 (7.2%)	100		
Cigarette smoking					
No	7 (77.8%)	192 (76.8%)	96.5	1.057	1.000
Yes	2 (22.2%)	58 (23.2%)	96.7	(0.214–5.230)	
History of previous ERCP					
No	9 (100%)	205 (82%)	95.8	0.958	0.366
Yes	0 (0%)	45 (18%)	100	(0.931–0.985)	

History of GI surgery					
No	8 (88.9%)	229 (91.6%)	96.6	0.734 (0.088–6.151)	0.556
Yes	1 (11.1%)	21 (8.4%)	95.5		
Pra-ERCP bilirubin					
<3 mg/dL	0 (0%)	36 (14.4%)	100	1.042 (1.014–1.070)	0.617
≥3 mg/dL	9 (100%)	214 (85.6%)	96		
Papila morphology					
Type I	2 (22.2%)	133 (53.2%)	98.5		
Type III	2 (22.2%)	35 (14%)	94.6		
Type D	0 (0%)	23 (9.2%)	100	-	0.007
Previous ERCP stenting or pre-cutting	0 (0%)	31 (12.4%)	100		
Ulcerative fragile mass	5 (55.6%)	28 (11.2%)	84.8		
Pre-cut sphincterotomy					
No	7 (77.8%)	229 (91.6%)	97	0.321 (0.063–1.644)	0.185
Yes	2 (22.2%)	21 (8.4%)	91.3		
Operator					
Junior (experience <6 years)	5 (55.6%)	160 (64%)	97	0.703 (0.184–2.685)	0.727
Senior (experience ≥6 years)	4 (44.4%)	90 (36%)	95.7		
Obstruction level					
Perihilar	1 (11.1%)	32 (12.8%)	97	-	1.000
CBD	8 (88.9%)	194 (77.6%)	96		
Multilevel	0 (0%)	24 (9.6%)	100		
Obstruction etiology				1.081	1.000
Non-malignant	7 (77.8%)	191 (76.4%)	96.5	(0.219–5.346)	
Malignant	2 (22.2%)	59 (23.6%)	96.7		
Obstruction level - etiology					
Perihilar non-malignant	1 (11.1%)	22 (8.8%)	95.7	0.957	1.000
Perihilar malignant	0 (0%)	10 (4%)	100	(0.877–1.044)	
CBD non-malignant	6 (66.7%)	145 (58%)	96	1.014	1.000
CBD malignant	2 (22.2%)	49 (19.6%)	96,1	(0.198–5.189)	
ASGE complexity grading				-	0.497
Grade I	0 (0%)	23 (9.2%)	100		
Grade II	7 (77.8%)	138 (55.2%)	95.2		
Grade III	2 (22.2%)	89 (35.6%)	97.8		

ERCP: endoscopic retrograde cholangiopancreatography; ASGE: American Society for Gastrointestinal Endoscopy; GI: gastrointestinal; CBD: common bile duct; OR: odds ratio; 95% CI: 95% confidence interval.

masses (**Table 2**). The TS rate of native papilla cannulation was 96.1% in this study.

The multivariate analysis included papillary morphology (with type I as a reference) and previous sphincterotomy. There was no collinearity between variables. In the multivariate regression model (**Table 3**), ulcerative fragile papillary masses were the only independent predictors of ERCP TS, significantly associated with a lower probability of TS (AOR 0.075 [95% CI 0.017-0.337]; *P*=0.001).

Predictors of ERCP clinical success for biliary obstruction

Higher CS rates were observed in patients aged 18 to 59 years, female, with diabetes, without hypertension, obesity grade II, smokers, without a history of previous ERCP, with a history of gastrointestinal surgery, and pre-

Table 3. Multivariate analysis of predictors for ERCP technical success in biliary obstruction.

Variables	B	AOR (95% CI)	P-value
Ulcerative fragile papillary mass	-2.584	0.075 (0.017–0.337)	0.001
Pre-cut sphincterotomy	-1.782	0.168 (0.027–1.065)	0.058

AOR: adjusted odds ratio; 95% CI: 95% confidence interval.

ERCP bilirubin ≥3 mg/dL. Others included type III papillary morphology, no pre-cutting sphincterotomy, usage of biodegradable stent, junior operator, CBD obstruction, malignant etiology, perihilar malignant obstruction, and ASGE grade II. Bivariate analysis showed that each of these characteristics was associated with CS, namely history of previous ERCP (*P*=0.010), pre-ERCP bilirubin ≥ 3 mg/dL (*P*<0.001), and papillary morphology (*P*=0.049). Other characteristics were not significantly associated with CS (**Table 4**).

Multivariate analysis was conducted with characteristics of age, BMI categories (normal weight as reference), cigarette smoking, history of previous ERCP, pre-ERCP bilirubin, papillary morphology (type I as reference), stent types (without stent as reference), operator, obstruction level (multilevel as reference), and ASGE complexity grading (grade I as reference). No collinearity was observed between variables in this study. The analysis showed that the independent predictors of CS were pre-ERCP bilirubin ≥ 3 mg/dL (AOR 8.545 [95%CI 3.252–22.452]; *P*<0.001) and papilla with previous ERCP stenting or pre-cutting (AOR 0.330 [95% CI 0.116–0.936]; *P*=0.037). Higher bilirubin categories were more likely to achieve CS. Meanwhile, papilla with previous ERCP stenting or pre-cutting had a lower probability of CS (**Table 5**).

Association of obstruction location and etiology with pre-ERCP bilirubin levels

The association between each obstruction location and etiology with pre-ERCP bilirubin levels was assessed as a secondary outcome (**Table 6**). A significant difference between pre-ERCP bilirubin levels among obstruction locations was observed (*P*=0.022), where perihilar obstruction showed the highest

Table 4. Clinical success of therapeutic ERCP based on each characteristic of patients with biliary obstruction

Characteristics	Clinical failure n (%) (N=30)	Clinical success n (%) (N=220)	Clinical Success Rate (%)	OR (95% CI)	P-Value
Age					
18-59 years	6 (66.7%)	191 (76.4%)	97	0.482 (0.215–1.082)	0.072
≥60 years	3 (33.3%)	59 (23.6%)	95.2		
Gender					
Male	3 (33.3%)	128 (51.2%)	97.7	1.102 (0.513–2.367)	0.803
Female	6 (66.7%)	122 (48.8%)	95.3		
Diabetes mellitus					
No	7 (77.8%)	211 (84.4%)	96.8	1.230 (0.404–3.742)	1.000
Yes	2 (22.2%)	39 (15.6%)	95.1		
Hypertension					
No	7 (77.8%)	169 (67.6%)	96	0.806 (0.364–1.785)	0.595
Yes	2 (22.2%)	81 (32.4%)	97.6		
BMI Categories					
Underweight	2 (22.2%)	50 (20%)	96.2	-	0.099
Normoweight	3 (33.3%)	90 (36%)	89.8		
Overweight	1 (11.1%)	42 (16.8%)	97.7		
Obesity grade I	3 (33.3%)	50 (20%)	94.3		
Obesity grade II	0 (0%)	18 (7.2%)	100		
Cigarette smoking					
No	7 (77.8%)	192 (76.8%)	96.5	3.000 (0.876– 10.276)	0.111
Yes	2 (22.2%)	58 (23.2%)	96.7		
History of previous ERCP					
No	9 (100%)	205 (82%)	95.8	0.316 (0.138-0.722)	0.010
Yes	0 (0%)	45 (18%)	100		
History of GI surgery					
No	8 (88.9%)	229 (91.6%)	96.6	1.323 (0.292–5.989)	1.000
Yes	1 (11.1%)	21 (8.4%)	95.5		
Pra-ERCP bilirubin					
<3 mg/dL	0 (0%)	36 (14.4%)	100	6.550 (2.824–15.193)	<0.001
≥3 mg/dL	9 (100%)	214 (85.6%)	96		

Papila morphology				-	0.049
Type I	2 (22.2%)	133 (53.2%)	98.5		
Type III	2 (22.2%)	35 (14%)	94.6		
Type D	0 (0%)	23 (9.2%)	100		
Previous ERCP stenting or pre-cutting	0 (0%)	31 (12.4%)	100		
Ulcerative fragile mass	5 (55.6%)	28 (11.2%)	84.8		
Pre-cut sphinctereotomy				0.802	0.725
No	7 (77.8%)	229 (91.6%)	97	(0.222–2.903)	
Yes	2 (22.2%)	21 (8.4%)	91.3		
Stent types					
Without stent	7 (23.3%)	58 (26.4%)	89.2		
Plastic stent	21 (70%)	159 (72.3%)	88.3	-	0.094
Metallic stent	2 (6.7%)	1 (0.45%)	33.3		
Biodegradable stent	0 (0%)	2 (0.9%)	100		
Operator					
Junior (experience <6 years)	5 (55.6%)	160 (64%)	97	0.603	0.194
Senior (experience ≥6 years)	4 (44.4%)	90 (36%)	95.7	(0.279–1.302)	
Obstruction level					
Perihilar	1 (11.1%)	32 (12.8%)	97	-	0.224
CBD	8 (88.9%)	194 (77.6%)	96		
Multilevel	0 (0%)	24 (9.6%)	100		
Obstruction etiology					
Non-malignant	7 (77.8%)	191 (76.4%)	96.5	1.269 (0.493–3.271)	0.621
Malignant	2 (22.2%)	59 (23.6%)	96.7		
Obstruction level - etiology					
Perihilar non-malignant	1 (11.1%)	22 (8.8%)	95.7	2.000 (0.194–20.614)	1.000
Perihilar malignant	0 (0%)	10 (4%)	100		
CBD non-malignant	6 (66.7%)	145 (58%)	96	1.015 (0.349–2.955)	1.000
CBD malignant	2 (22.2%)	49 (19.6%)	96.1		
ASGE complexity grading					
Grade I	0 (0%)	23 (9.2%)	100		
Grade II	7 (77.8%)	138 (55.2%)	95.2		
Grade III	2 (22.2%)	89 (35.6%)	97.8		

ERCP: endoscopic retrograde cholangiopancreatography; ASGE: American Society for Gastrointestinal Endoscopy; GI: gastrointestinal; CBD: common bile duct; OR: odds ratio; 95% CI: 95% confidence interval.

Table 5. Multivariate analysis of predictors for ERCP clinical success in biliary obstruction

Variables	B	AOR (95% CI)	P-value
Obesity grade II	19.057	infinity (0.0–infinity)	0.998
Age ≥60 years	-0.921	0.398 (0.156–1.018)	0.054
Pre-ERCP bilirubin level ≥3 mg/dL	2.145	8.545 (3.252–22.452)	<0.001
Previous ERCP stenting or pre-cutting	-1.109	0.330 (0.116–0.936)	0.037
Metallic stent	-2.188	0.112 (0.008–1.625)	0.109
Senior operator	-0.806	0.447 (0.184–1.085)	0.075

ERCP: endoscopic retrograde cholangiopancreatography; AOR: adjusted odds ratio; 95% CI: 95% confidence interval.

bilirubin levels. For obstruction etiology, malignant etiology indicated a significantly higher pre-ERCP bilirubin level than non-malignant etiology (P=0.041). In addition, it was also noted that there was a correlation between obstruction etiology and pre-ERCP level, in which malignant etiology was more likely to have pre-ERCP bilirubin level >3 mg/dL or clinically jaundice (OR 6.116 [95% CI 1.425–26.250]; P = 0.011).

Analysis of biliary obstruction etiology based on its location showed that malignant distal obstruction had a significantly higher pre-ERCP bilirubin level (*P*=0.025) and was attributed to a higher probability of having pre-ERCP bilirubin >3 mg/dL (OR 10.4 [95% CI 11.374– 78.717]; *P* = 0.011) than non-malignant distal obstruction. Meanwhile, analysis of the biliary obstruction location based on its etiology showed that non-malignant perihilar obstruction had significantly higher pre-ERCP bilirubin level (*P*=0.007) than non-malignant distal obstruction. No association with the categorical bilirubin level was observed, as presented in **Table 6.**

DISCUSSION

As a primary therapeutic modality for biliary obstruction, ERCP technical and clinical success, and its predictors must be assessed to ensure optimal therapy. However, current evidence often focuses on either malignant or benign etiologies alone. In this study, the TS rate of ERCP for biliary obstruction therapy reached 96.5% and was higher than each category of ASGE recommendation (Table 2).[13] TS rate of 3.5% was entirely due to failure to cannulate the targeted biliary duct. Therefore, it reflected the success of cannulation during therapeutic ERCP. Selective cannulation was the most challenging and risky part of the procedure and generally revealed the overall success of the ERCP procedure. The results of this study showed TS and cannulation rates comparable to those reported in previous studies.[13,14]

The morphology of the papilla vateri was the only variable significantly associated with TS. Anatomical variations of the papilla vateri affected visualization, positioning, and the ability of the sphincterotomy or catheter to cannulate the bile duct, thereby increasing cannulation difficulty.[15] Multivariate analysis also showed that ulcerative fragile papillary masses were the only independent predictor of ERCP TS. This was significantly associated with a lower probability of TS. The presence of ulcerative fragile papillary masses complicated access to the papilla and cannulation. These findings supported previous studies reporting duodenal

Table 6. Comparison of obstruction, location and etiology with pre-ERCP bilirubin levels

Variables	Pre-ERCP Bilirubin level (mean ± SD)	P-value	Pre-ERCP bilirubin level (n (%))		OR (95% CI)	*P*-value
			<3 mg/dL	≥3 mg/dL		
Obstruction location						
Perihilar	20.90 ± 13.36	0.022	3 (8.3%)	30 13.5%)		0.220
CBD	14.43 ± 10.62		27 (75%)	175 (78.5%)	-	
Multilevel Obstruction etiology						
Non-malignant	14.37 ± 10.94	0.041	34 (94.4%)	164 (73.5%)	6.116	0.011
Malignant	17.55 ± 11.33		2 (5.6%)	59 (26.5%)	(1.425 –26.250)	
Obstruction location + etiology Perihilar obstruction						
Non-malignant	21.56 ± 13.33	0.583	2 (66.7%)	21 (70%)	0.857	1.000
Malignant	19.38 ± 14.02		1 (33.3%)	9 (30%)	(0.069 –10.699)	
CBD (distal) obstruction						
Non-malignant	13.56 ± 10.40	0.025	26 (96.3%)	125 (71.4%)	10.400	0.011
Malignant	17.19 ± 10.86		1 (3.7%)	50 (28.6%)	(1.374 – 78.717)	
Obstruction etiology + location Non-malignant						
Perihilar	21.56 ± 13.33	0.007	2 (7.1%)	21 (14.4%)	0.458	0.378
CBD (distal)	13.56 ± 10.40		26 (92.9%)	125 (85.6%)	(0.101 – 2.074)	
Malignant						
Perihilar	19.38 ± 14.02	0.736	1 (50%)	9 (15.3%)	5.556	0.303
CBD	17.19 ± 10.86		1 (50%)	50 (84.7%)	(0.318 – 97.127)	

or ampullary tumors, papillary oedema, and ulceration as significant factors influencing cannulation difficulty.[15,16] Although not a predictor of TS, among the 4 Haraldsson papilla types, the highest success rate was observed in type I morphology, consistent with previous studies.[11] Although peridiverticular papillae could increase cannulation difficulty, all patients with peridiverticular papillae were successfully cannulated in this study.[10]

Patient characteristics in this study were not associated with the TS rate, which was lower in females than in males, consistent with other studies indicating that biliary cannulation tended to be more difficult in females. However, the 2 variables were not associated in multivariate analysis.[17] Studies on the relationship between TS and BMI, diabetes mellitus, hypertension, and smoking were limited and primarily focused on post-ERCP complications. Unlike previous studies reporting that the history of cholecystectomy was an independent risk factor for difficulty, no significant association was found between the 2 in this study.[18]

ERCP TS was higher in bilirubin levels <3 Mg/dL, consistent with previous studies reporting higher cannulation success rates in patients with bilirubin levels <2 mg/dL without significant intervariable associations.[17,19] This was also supported by the results of secondary outcome analyses, indicating that bilirubin levels were associated with the location and etiology of obstruction. The probability of bilirubin levels ≥3 mg/dL was 10.4 times higher in distal malignant obstruction. Pressure, invasion, or obstruction in the distal biliary tract could complicate cannulation, which was consistent with the causes of technical failure in this study.[20] In addition, TS in CBD obstruction was lower compared to other obstruction locations.

Regarding procedure-related factors, the TS rate of pre-cut sphincterotomy reached 91.3%, like other studies reporting a success rate of 91.7%.[6] This study had no association between the operator and ERCP TS. A meta-analysis reported that ERCP success rates increased with increasing ERCP volume.[21] However, the TS rate for junior operators was 97% and 95.7% for senior operators. This result could be influenced by bias, where senior operators tended to handle more challenging cases.

TS in CBD obstruction was lower compared to other obstruction locations, suggesting greater difficulty in cannulation when the distal biliary tract was involved. Based on complexity levels, the highest TS rates were found in ASGE grades I, III, and II, respectively. In previous studies, cannulation success rates decreased with increasing ASGE grade. However, the decrease was not statistically significant.[6]

In this study, the CS rate of therapeutic ERCP for biliary obstruction reached 84.9%. CS rates of ERCP tended to be more variable and limited to specific etiologies. In addition, there were no nationally or internationally established standards for CS. TS was preferred as an indicator of ERCP quality because CS alone was insufficient to assess the quality of the ERCP procedure and was influenced by various factors that were difficult to control.[22]

The analysis showed that the predictor of CS, defined as a minimal 30% reduction in bilirubin level within 2 weeks, was pre-ERCP bilirubin level and papilla with previous ERCP stenting or pre-cutting. Pre-ERCP bilirubin ≥3 mg/dL was 8.5 times more likely to achieve CS, consistent with other studies reporting higher CS rates at higher pre-ERCP bilirubin levels.[9] In this study, high pre-ERCP bilirubin levels were more commonly found in malignant obstruction and distal malignant obstruction. However, no significant association was observed between the location and etiology of obstruction and CS. This relationship likely reflected the impact of severe obstruction on bile drainage, where higher pre-ERCP bilirubin levels indicated more extensive biliary blockages that, once relieved, resulted in more pronounced clinical improvement.

Papillae with a history of ERCP stenting or pre-cutting had a lower probability of ERCP CS. Although cannulation was easier to perform, patients who had previously undergone stenting or pre-cut sphincterotomy demonstrated disease recurrence and more complex procedures and cases, whether due to malignant biliary obstruction or recurrent gallstones. These findings were supported by the association between ERCP history and lower CS rates,

although the relationship was not significant in multivariate analysis. Previous studies on the relationship between papilla vateri morphology and CS were limited and primarily focused on TS and cannulation.

Patient characteristics such as age and gender did not show significant associations and varied across studies. This was likely due to demographic differences and risk factors specific to each ERCP indication, and further study was needed. Data on the association between CS and comorbidities, BMI category, smoking, history of gastrointestinal surgery, and pre-cut sphincterotomy were limited and primarily focused on ERCP complications and mortality.

Procedural factors, namely stent use, showed the highest CS rate with biodegradable and the lowest with metallic stents, without a significant association. This contradicts other studies stating that metallic stents were more commonly used in patients with clinical success and vice versa for plastic stents.[23,24] This difference was due to this study's limited use of metallic stents (1.2%). Like TS, CS in junior operators was higher in this study, although no significant association was found. Studies on operators and CS were still limited and more focused on TS.

This study found the highest CS in the CBD, followed by perihilar and multilevel, without a significant association. ERCP was a promising approach for treating distal extrahepatic bile duct obstruction. Meanwhile, stent placement or perihilar obstruction management was more challenging and a complex endoscopic procedure. Multilevel obstruction required more extensive intervention and carried a higher risk of inadequate bilirubin drainage.[8,25] The most common etiology of obstruction was choledocholithiasis (45.2%), and its proportion was like other studies.[26] No significant association was observed between etiology and CS. The obstruction location in relation to its location also showed no significant correlation. This study showed the highest CS by ASGE II, followed by ASGE I, and lastly ASGE III, and did not follow a linear trend of ASGE complexity grading and CS, indicating the need for further investigation.

Strengths and Limitations

This study is the first to comprehensively analyze patient-related and procedural factors as predictors of technical and clinical success in biliary obstruction without being restricted to specific factors or etiologies. However, as a retrospective study, many cases were excluded from the sample due to incomplete data. Therefore, a prospective study with a larger sample is needed to analyze the relationship between the identified factors and technical and clinical outcomes. In addition, patients with pre-hepatic and parenchymal jaundice were excluded from the study, and the results obtained could not be applied to this population.

CONCLUSION

This study demonstrates high technical and clinical success rates of ERCP in managing biliary obstructions at a tertiary referral center in Indonesia, aligning with ASGE recommendations. An ulcerative fragile papillary mass was the predictor of lower ERCP technical success, highlighting the need for cautious planning and endoscopic handling in such cases. Clinical success was independently predicted by pre-ERCP bilirubin levels ≥3 mg/dL,

which significantly increased the likelihood of success, and by a history of prior ERCP stenting or pre-cutting, which was associated with decreased success. These findings should be taken into consideration during the planning and delivery of ERCP to achieve better outcomes. Routine measurement of total bilirubin levels before and within two weeks after ERCP is recommended as an objective parameter for evaluating clinical success.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

REFERENCES

1. Coucke EM, Akbar H, Kahloon A, Lopez PP. Biliary Obstruction [Internet]. StatPearls.2025.
2. Sugiharto S, Budianto A, Siswardana DR, Sulistyo H. Penyakit-penyakit pada kantong empedu dan salurannya. 1st ed. In: Sugiharto S, Pratama AJ, editors. Malang: Litnus; 2024.

3. Yusmaidi, Rafie R, Permatasari A. Karakteristik pasien ikterus obstruktif et causa batu saluran empedu. J Ilm Kesehat Sandi Husada. 2020;11(1):328–4563.
4. Pu LZCT, Singh R, Loong CK, De Moura EGH. Malignant biliary obstruction: Evidence for best practice. Gastroenterol Res Pract. 2016;2016.
5. Chandrasekhara V, Khashab MA, Muthusamy VR, et al. Adverse events associated with ERCP. Gastrointest Endosc [Internet]. 2017;85(1):32–47.
6. Demir T, Ustaoglu M. Evaluation of the success and complication rates of endoscopic retrograde cholangiography according to the difficulty of the procedure. Precis Med Sci. 2023;12(1):4–9.
7. Rizqiansyah CY, Awatara PID, Amar N, Lesmana CRA, Mustika S. Efficacy and safety of endoscopic ultrasonography (EUS) hepaticogastrostomy (HGS) versus choledochoduodenostomy (CDS) in ERCP-failed malignant biliary obstruction: A systematic review and META-analysis. JGH Open. 2024;8(10):1–9.
8. Pausawasdi N, Termsinsuk P, Charatcharoenwitthaya P, Limsrivilai J, Kaosombatwattana U. Development and validation of a risk score for predicting clinical success after endobiliary stenting for malignant biliary obstruction. PLoS One [Internet]. 2022;17(8 August):1–15.
9. Jaroensri C, Eurboonyanun C, Titapun A, Srisuk T, Eurboonyanun K, Ruangwannasak S. Predicting factors for clinical success of endoscopic retrograde cholangiopancreatography with biliary drainage in unresectable perihilar cholangiocarcinoma. Diagnostic Interv Endosc. 2023;2(3):75–9.
10. Mohamed R, Lethebe BC, Gonzalez-Moreno E, et al. Morphology of the major papilla predicts ERCP procedural outcomes and adverse events. Surg Endosc. 2022;35(12):6455–65.
11. Tari E, Gagyi EB, Rancz A, et al. Morphology of the papilla can predict procedural safety and efficacy of ERCP — a systematic review and meta-analysis. Sci Rep [Internet]. 2024;1–12.
12. Rejeski J, Hines M, Jones J, et al. Outcomes of precut sphincterotomy techniques in cases of difficult biliary access. Frontline Gastroenterol [Internet]. 2021 Mar 1;12(2):113 LP – 117.
13. Sharma ZD, Puri R. Quality indicators in endoscopic retrograde cholangiopancreatography: a brief review of established guidelines. Clin Endosc. 2023;56(3):290–7.
14. Barakat MT, Girotra M, Thosani N, Kothari S, Banerjee S. Escalating complexity of endoscopic retrograde cholangiopancreatography over the last decade with increasing reliance on advanced cannulation techniques. World J Gastroenterol [Internet]. 2020 Nov 7;26(41):6391–401.
15. Fung BM, Pitea TC, Tabibian JH. Difficult biliary cannulation in endoscopic retrograde cholangiopancreatography: Definitions, risk factors, and implications. 2021;(August):64–72.
16. Liu Y, Liu W, Hong J, et al. Causes and countermeasures of difficult selective biliary cannulation: A large sample size retrospective study. Surg Laparosc Endosc Percutan Tech. 2021 Feb;31(5):533–8.
17. Cáceres-escobar D, Muñoz-velandia OM, Vargas-rubio R. Factors associated with difficult biliary cannulation in a training center for endoscopic intervention of the biliary tract. 2022;29–34.
18. Cheng Y, Feng J, Chen X, Lin J, Wang H. Endoscopic retrograde cholangiopancreatography consultation after digestive tract reconstruction and risk factors for complications. Eur J Med Res [Internet]. 2025.
19. Khan D, Ullah I, Kashif M. Analysis of the effectiveness of second attempt endoscopic retrograde cholangiopancreatography (ERCP) 24 hours (second day) after primary failure. Cureus. 2024;16(2):1–8.
20. Sheppard DP, Craddock SJ, Warner BD, Wilkinson ML. ERCP cannulation success benchmarking: implications for certification and validation. Frontline Gastroenterol. 2015 Apr;6(2):141–6.
21. Keswani RN, Qumseya BJ, O'Dwyer LC, Wani S. Association between endoscopist and center endoscopic retrograde cholangiopancreatography volume with procedure success and adverse outcomes: A systematic review and meta-analysis. Clin Gastroenterol Hepatol [Internet]. 2017;15(12):1866-1875.e3.
22. Sharma ZD, Puri R. Quality indicators in endoscopic retrograde cholangiopancreatography: a brief review of established guidelines. Clin Endosc [Internet]. 2023 May 30;56(3):290–7.
23. Lee SH, Kim YS, Kim EJ, et al. Long-term outcomes of fully covered self-expandable metal stents versus plastic stents in chronic pancreatitis. Sci Rep [Internet]. 2021;11(1):1–8.
24. Jang S, Stevens T, Parsi MA, Bhatt A, Kichler A, Vargo JJ. Superiority of self-expandable metallic stents over plastic stents in treatment of malignant distal biliary strictures. Clin Gastroenterol Hepatol [Internet]. 2022;20(2):e182–95.
25. Ninalowo HA, Adenigba PT, Oluyemi AO. Overcoming tight perihilar malignant biliary obstructions during percutaneous biliary intervention in Nigerian patients : case reports. Egypt J Radiol Nucl Med [Internet]. 2024;
26. Joseph D, Muraleedharanpillai R, Kolassery S, Sebastian S. Clinical profiles and outcomes of patients undergoing endoscopic retrograde cholangiopancreatography in a tertiary care center. Cureus. 2024 Feb;16(2):e55065.