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ORIGINAL ARTICLE

Common bile duct stone-related parameters and their potential prognostic values for stone extraction requiring endoscopic papillary large balloon dilation

Chote Wongkanong,[*] Jayanton Patumanond,[†] Thawee Ratanachu-ek,[‡,§] Sunhawit Junrungsee[¶,‖] and Apichat Tantraworasin[†,¶,‖]

*Department of Surgery, Pattani Hospital, Pattani, †Center for Clinical Epidemiology & Clinical Statistics, Faculty of Medicine, ¶Clinical Surgical Research Center, ‖Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, ‡Surgical Endoscopy Unit, Department of Surgery, Rajavithi Hospital and §Department of Medical Services, Ministry of Public Health, Bangkok, Thailand

Key words
common bile duct calculi, endoscopic retrograde cholangiopancreatography, endoscopic sphincterotomy.

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Correspondence
Apichat Tantraworasin, Department of Surgery and Clinical Epidemiology and Clinical Statistic Center, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand.
Clinical Surgical Research Center, Chiang Mai University, 110 Intrawaroros Road, Mueang Chiang Mai, Chiang Mai 50200, Thailand.
Email: apichat.t@cmu.ac.th

The Institutional Review Board at our center approved this study. The registration number for this study is IRB # 2020-07-013. All the patients signed a written consent form for the endoscopic procedures.**Clinical trial registration**: This study was registered in the Thai clinical trials registry.
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Abstract

Background and Aim: For difficult common bile duct (CBD) stones, endoscopic sphincterotomy accompanied by endoscopic papillary large balloon dilatation (EPLBD) may be the preferred initial procedure according to the selection criteria. The purpose of this study was to determine the association between CBD stone-related parameters and their potential prognostic values for technically difficult CBD stone extraction requiring EPLBD.
Methods: We retrospectively analyzed the data of 80 patients who underwent endoscopic retrograde cholangiopancreatography (ERCP), endoscopic biliary sphincterotomy, or the aforementioned procedures combined with EPLBD, resulting in successful CBD stone extraction in the first session from January 2018 and December 2021. The association between CBD stone-related parameters and stone extraction requiring EPLBD was analyzed by multivariable risk regression analysis.
Results: In multivariable analysis, the independent predictors of CBD stone extraction that required EPLBD were CBD stones larger than distal CBD diameter by >2 mm (risk ratio [RR] 2.34, 95% CI 1.30–4.19) and the presence of shaped stones (round shape RR 1.69 [95% CI 1.05–2.73]; square shape RR 2.34 [95% CI 1.24, 4.44] *vs* oval shape).
Conclusion: Endoscopic CBD stone removal is technically difficult in patients with stones larger than 2 mm in diameter in comparison to the distal CBD diameter or round or square-shaped stones.

Junrungsee, Apichat Tantraworasin.
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Introduction

Common bile duct (CBD) stones are commonly diagnosed all over the world. Endoscopic sphincterotomy (EST) has been used to remove bile duct stones since it was first introduced over 40 years ago. EST with stone extraction is now the standard treatment method for patients with CBD stones. However, bile duct stone removal with typical biliary sphincterotomy combined with stone extraction has a 15% failure rate.[1]

In 1982, endoscopic papillary balloon dilation (EPBD) was proposed as an alternative to EST.[2] However, it is less successful than EST in removing bile duct stones because orifice dilation with EPBD is limited to 10 mm.[3] Endoscopic papillary large balloon dilation (EPLBD), which utilizes balloons with a diameter of 12–20 mm and is used in combination with EST, was introduced in 2003 to assist in the removal of large or difficult bile duct stones.[4] Since then, EPLBD with limited or large EST has gained widespread acceptance and has become increasingly popular.

The European Society of Gastroenterology and Endocrinology (ESGE) and the American Society for Gastrointestinal Endoscopy (ASGE) have recently published guidelines that recommend a combination of EST and EPLBD as a first-line treatment for CBD stones that were predicted to fail in extraction by standard biliary sphincterotomy and stone extraction.[5,6]

Previous studies have reported that factors associated with difficult CBD stone extraction included stone sizes greater than 15 mm in diameter,[7,8] the number or shape of stones, the presence of related stricture, distal CBD narrowing, the angle of the distal bile duct of less than 135°,[9] and the ratio of the stone to the common bile duct diameter greater than 1.[10]

There is limited information about the relationship between the distal bile duct diameter and the stone size and shape, which is significant for predicting the technical outcomes of endoscopic CBD stone extractions. Therefore, we examined the association between CBD stone-related parameters and their potential prognostic values for technically difficult CBD stone extraction requiring EPLBD.

Materials and Methods

Patients. This retrospective cohort study was conducted in Pattani hospital, Thailand. Between January 2018 and December 2021, 360 patients underwent endoscopic retrograde cholangiopancreatography (ERCP). Of these, 177 patients (49.1%) were diagnosed with a CBD stone by ultrasonography, computer tomography (CT), or magnetic resonance cholangiopancreatography (MRCP). The inclusion criteria for this study were patients with biliary stones with no previous ERCP treatment. Cases classified as regular or difficult CBD stones were included in the study. Only cases where the first ERCP was successfully performed were included. Cases requiring multiple ERCP procedures were excluded. Of the 132 patients (74.5%) in whom stone extractions were attempted, 60.6% resulted in successful stone clearance during the first ERCP. The 52 patients who were excluded from this study underwent multiple endoscopies until they were successfully cleared. Only patients who completed the initial attempt were included in this study. In this group of 80 patients, 50 patients had successful CBD stone clearance by EST and extraction, and 30 patients had successful CBD stone clearance by additional ELPBD combined with EST and extraction (Fig. 1).

We excluded patients with an unrecognized CBD stone on cholangiography, stricture of CBD, cancer of the periampullary and biliary tract, or an intrahepatic duct stone. In this study, the patient characteristics, the relationship between cholangiogram, CBD stone character, common bile duct size and shape, ERCP procedure details, laboratory results, and complications were thoroughly evaluated. This study evaluated stone-related factors that determined the need for EST + EPLBD in patients with difficult stone clearance. The Institutional Review Board at our center approved this study. The registration number for this study is IRB # 2020–07-013. All the patients signed a written consent form for the endoscopic procedures.

Endoscopic procedure. In this study, experienced endoscopists performed over 300 ERCP procedures. The standard treatment began with EST in all cases, systematic step-by-step assessment, and instruments to remove stones according to ESGE recommendations. If this was unsuccessful, a plastic stent was used, and subsequent ERCP sessions were performed until the stones were successfully removed. Patients assessed with a high likelihood of difficult stone removal were referred to a center with the necessary expertise, facilities, and tools.

A side-viewing duodenoscope (Olympus, TJF-Q180V) and a standard pull-type sphincterotome were used for all ERCP, EST, and stone extraction procedures. Cholangiography was performed using a 5.5-Fr standard sphincterotome that was inserted selectively. All patients underwent a partial or complete sphincterotomy with attempted stone extraction using a balloon or basket catheter, or a combination of such procedures. If stone extraction was unsuccessful, ELPBD combined with EST was attempted if there was no contraindication. Under endoscopic and fluoroscopic guidance, a balloon dilator was introduced and positioned across the papilla, which was then gradually inflated. After the diameter reached the appropriate size, which was determined by comparing the largest stone and the distal CBD diameter, the balloon dilator was typically kept inflated for 60 s during each step of dilatation. A basket and/or a balloon catheter was used to remove CBD stones.

Complete stone removal was confirmed by the absence of filling defects in the last occluded cholangiogram obtained using a balloon catheter. When the stones were not completely removed during the EPLBD session, a temporary plastic stent was inserted to prevent biliary obstruction, and endoscopic treatments were repeated until the stones were totally removed. Following the endoscopic procedure, all patients were required to be

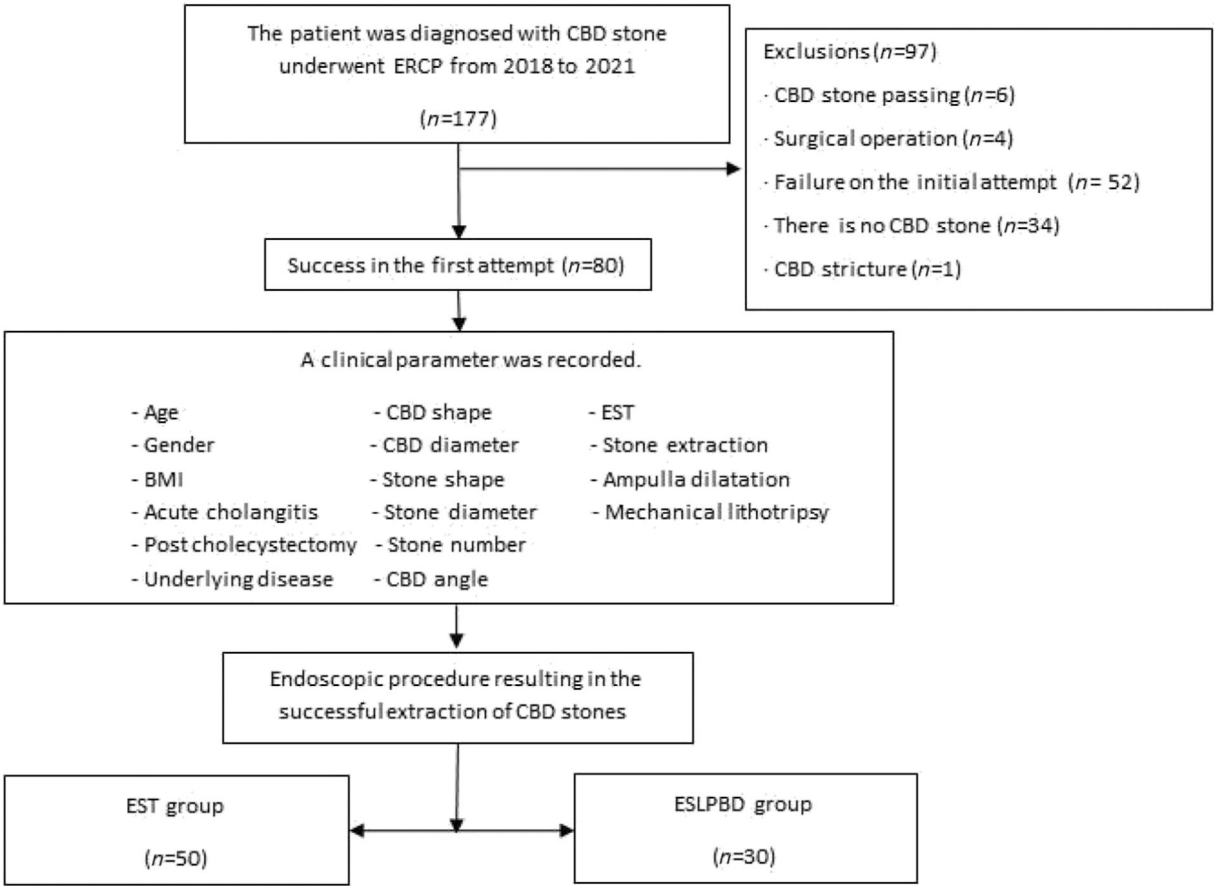

Figure 1 Flow diagram for the selection of the study participants. CBD, common bile duct; ELPBD, endoscopic large papillary balloon dilatation; ERCP, endoscopic retrograde cholangiopancreatography; ESLPBD, endoscopic sphincterotomy combined with endoscopic large papillary balloon dilatation; EST, endoscopic sphincterotomy.

admitted to the hospital for at least 24 h to monitor for any adverse events, particularly post-ERCP pancreatitis.

Definitions. CBD stones that are difficult to remove are defined by their diameter (>15 mm), the presence of multiple stones, unusual shape, or anatomical factors (bile duct narrowing distal to the stone, stone impaction, shorter length of the distal CBD, or acute distal CBD angulation [<135°]). Generally, these difficult stones cannot be removed using standard techniques; therefore, procedures and additional interventions (ELPBD, mechanical lithotripsy, cholangioscopy-assisted electro-hydraulic/laser lithotripsy, ESWL) are required.[6]

EPLBD is a procedure for performing endoscopic papillary balloon dilation with balloons ranging in diameter from 12 to 20 mm.[11]

Measurements of parameters. The size of the CBD stone and CBD diameter were corrected for radiograph magnification by multiplying the ratio of the actual and measured diameters of the duodenoscope on cholangiography and are presented as the maximum transverse diameter[12] (Fig. 2).

The distal CBD diameter was measured at 1 cm proximal to the main ampulla's orifice.[13]

The location of the stone and distal CBD measurements are reported following Sharma and Jain[14] (Fig. 3). The number and shape of CBD stones were also recorded.

The distal bile duct angle is defined as the angle formed by the CBD between 1 cm below the bifurcation and 1 cm above the papilla.[15]

Statistical analysis. Statistical analyses and estimated sample size were performed using STATA version 16 (Stata Corp., Lakeway, Texas, USA). A minimum of 10 endpoints of interest per predictor are required, according to standard recommendations,[16] to create an explanatory model with three predictors, namely stone size, stone shape, and disproportion stone and the distal CBD diameter. Hence, the sample size required for the model is 30 patients with CBD stones who underwent EST combined with ELPBD and endoscopic management. Continuous variables were described using the mean and standard deviation. Furthermore, data distribution was visualized using a histogram. For categorical data, frequency and percentages were used. Fisher's exact probability test was used to

$$\text{Actual size of the stone} = (\text{Measured size of the stone}) \times \frac{\text{(Actual size of the duodenoscope)}}{\text{(Measured size of the duodenoscope)}}$$

Figure 2 Measurement of size of CBD stone and CBD diameter.

compare the categorical variables of the different groups, while for continuous variables, an independent *t*-test and Mann–Whitney test were used for comparison as appropriate. The association between CBD stone-related parameters and stone extraction requiring EPLBD was analyzed by multivariable risk regression analysis under the Poisson working model, adjusted confounders using confounder summary score that included age, gender, underlying acute cholangitis, previous cholecystectomy, body mass index (BMI), and mechanical lithotripsy, presented as a risk ratio (RR) with the corresponding 95% confidence interval (CI). Additionally, the predictive contribution of the factor was presented with receiver operating characteristic (ROC) areas. For statistical tests, *P*-values less than 0.05 were considered significant.

Results

The study included 177 patients who were diagnosed with a CBD stone, of whom stone extraction was attempted in 132 (74.5%). The rate of successful stone clearance at the initial ERCP was 60.6% (80/132). Ninety-seven patients were excluded from the study for various reasons: 4 patients due to unsuccessful endoscopic clearance and subsequent surgical procedure, 6 patients due to stone passage, 34 patients due to no CBD stone being identified on cholangiography, and 52 patients due to the stone not being successfully removed during the first ERCP session. Successful stone extraction was done in 50 patients by EST in combination with stone extraction using a balloon catheter, a basket catheter, or a combination of the two (EST group), and in 30 patients by EPLBD combined with EST plus stone extraction (ESLPBD group).

Baseline characteristics of patients were analyzed. Gender, age, BMI, underlying disease, acute cholangitis, and previous cholecystectomy were not statistically different between the two groups, as shown in Table 1. When comparing CBD cholangiography, the ESLPBD group had a larger mid-CBD diameter than the EST group (17.0 ± 5.26 mm *vs* 13.83 ± 4.24 mm, $P = 0.008$). The difference in CBD stone to distal CBD diameter (mm) was larger in the ESLPBD group than in the EST group (2.87 ± 4.63 mm *vs* -1.86 ± 2.98 mm, $P < 0.001$). However, there was no statistical difference in the number of periampullary diverticulum, the distal CBD diameter, and the CBD angle between the two groups. The mean CBD stone diameter was larger in the ESLPBD group than in the EST group (12.1 ± 4.99 mm *vs* 7.62 ± 3.46 mm, $P = 0.001$). In terms of the shape, number of stones, and adverse events (post-ERCP pancreatitis and bleeding), there were no differences between the groups. There were also no perforations or acute cholangitis observed in this study (Table 2).

According to multivariable analysis, CBD stone diameters larger than distal CBD diameter by >2 mm, square-shaped stones, and round-shaped of stones were independent predictors of the requirement of ELPBD for stone removal (Table 2). Endoscopic large papillary balloon dilation (ELPBD) is required to remove CBD stones that are larger than the distal CBD diameter by more than 2 mm. The probability of ELPBD is 0.59 (95% CI 0.37–0.81) for a difference in diameter >2 mm and 0.25 (95% CI

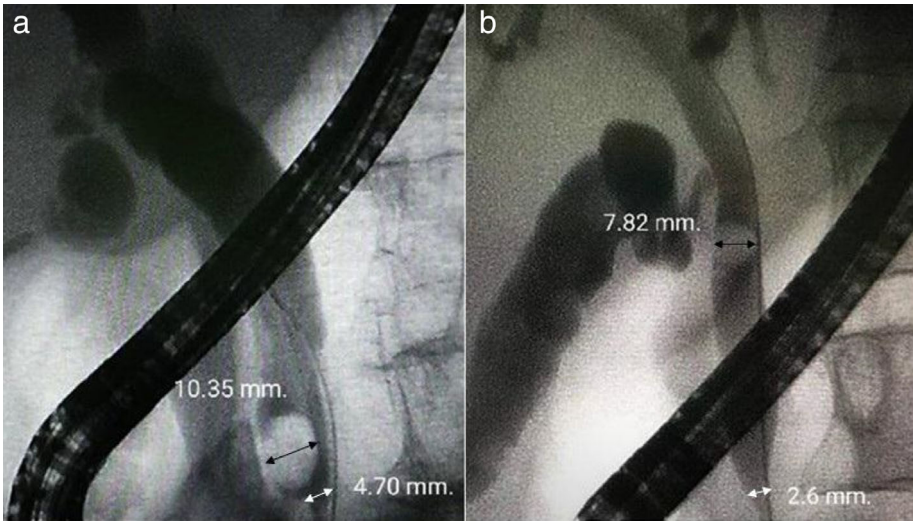

Figure 3 Cholangiography and measurement of stone (black arrow) and distal CBD (white arrow) diameter. (a) Oval-shaped CBD stone diameter 10.35 mm; distal CBD diameter 4.70 mm. (b) Round-shape CBD stone diameter 7.82 mm; distal CBD diameter 2.6 mm.

Table 1 Clinical characteristics of patients with CBD stone clearance by endoscopic sphincterotomy and stone extraction (EST) *versus* endoscopic sphincterotomy combined with endoscopic large papillary balloon dilatation (ESLPBD), endoscopic finding, cholangiographic findings, procedure, and complications

	ESLPBD ($n = 30$)		EST ($n = 50$)		
Clinical characteristics	Mean	±SD	Mean	±SD	*P*-value
Baseline characteristics					
Female (*n* %)	27	(90)	35	(70)	0.053
Age (years)	57.1	± 20.16	49.86	± 16.82	0.088
BMI (kg/m^2)	24.75	± 4.49	23.93	±4.19	0.415
Underlying disease (*n* %)	8	(26.67)	19	(38.00)	0.338
Acute cholangitis (*n* %)	11	(36.67)	16	(32.00)	0.808
Previous cholecystectomy (*n* %)	3	(10.00)	8	(16.00)	0.523
Endoscopic finding					
Periampullary diverticulum (*n* %)	8	(26.67)	8	(16.00)	0.264
Cholangiography					
CBD					
Mid-CBD diameter (mm)	17.00	±5.26	13.83	±4.24	0.008*
Distal CBD diameter (mm)	9.24	±3.97	9.49	±3.45	0.502*
CBD angle (°)	147.84	±15.76	145.93	±14.92	0.518*
CBD stone					
Number of stones median (range)	2	(1, 5)	1	(1, 6)	
Transverse diameter of stone (mm)	12.11	±4.99	7.62	±3.46	<0.001*
Difference CBD stone to distal CBD diameter (mm)†	2.87	±4.63	-1.86	±2.98	<0.001
Shape of stone					
Oval	10	(33.33)	15	(30.00)	0.806
Round	11	(36.67)	17	(34.00)	0.814
Square	3	(10.00)	2	(4.00)	0.358
Fragmented	6	(20.00)	16	(32.00)	0.306
Impacted stone	0		4	(8.00)	0.291
ERCP procedure					
Ampulla dilatation (ELPBD) (*n* %)	30	(100.0)	0		< 0.001
Mechanical lithotripsy (ML) (*n* %)	2	(6.67)	0		0.138
Complication					
Acute pancreatitis (*n* %)	6	(20.00)	3	(6.00)	0.073
Bleeding (*n* %)	3	(10.00)	1	(2.00)	0.146

**P*-value from the rank-sum test.

†Calculated by CBD stone diameter (mm) – distal CBD diameter (mm).

BMI, body mass index; CBD, common bile duct; ELPBD, endoscopic large papillary balloon dilatation; ESLPBD, endoscopic sphincterotomy combined with endoscopic large papillary balloon dilatation; EST, endoscopic sphincterotomy; ML, mechanical lithotripsy.

0.16–0.34) for a difference in diameter ≤2 mm. A square- or round-shaped stone may require ELPBD, with probabilities of success at 0.68 (95% CI 0.31, 1.03) and 0.48 (95% CI 0.31–0.67), respectively. However an oval-shaped stone may not require ELPBD, with a probability of success of 0.28 (95% CI 0.19–0.38) (Fig. 4).

Receiver operating characteristics were calculated to establish a threshold for the difference between the CBD stone and the distal CBD diameter (AUC 0.82: 95% CI 0.72–0.92) (Fig. 5). The value with the highest sensitivity and specificity was chosen as the threshold. Regarding the difference of CBD stone and distal CBD diameter, according to our results, a difference of >2 mm has a high chance of requiring ELPBD. This cut-off has a sensitivity of 56.67% (95% CI 37.43–74.54), a specificity of 98.00% (95% CI 89.35–99.95), and positive predictive value (PPV) of 94.44 (95% CI 72.71–99.86).

Discussion

Stones that do not require EPLBD can be successfully extracted by EST in resource-limited settings. Conversely, those who require EPLBD indicate that the CBD stone in question is difficult to remove,[6] requiring further procedures, equipment, or an experienced endoscopist. Our data and subsequent multivariable analysis suggest that stones larger than distal CBD exceeding 2 mm and square or round-shaped stones are good predictors of difficult CBD stones. Hence, endoscopic stone removal becomes more difficult with increasing stone size and a narrow distal CBD diameter. However, larger stones alone may not predict difficult removal; larger stones lodged within a wide distal CBD may not be difficult to remove and may not require a further procedure. In contrast, small stones lodged in a narrow distal CBD may require an additional removal procedure.

Table 2 Predictive factors associated with requiring ELPBD on successful removal of common bile duct stones

Predictors	Univariable		Multivariable[§]	
	RR (95% CI)	*P*-value	RR (95% CI)	*P*-value
Transverse diameter of largest stone (mm)[†]				
<10	(Reference)		(Reference)	
10–15	2.64 (1.17–6.00)	0.020	0.88 (0.51–1.53)	0.664
>15	4.05 (1.57–10.46)	0.004	0.80 (0.41–1.56)	0.519
Difference CBD stone to distal CBD diameter (mm)[‡]				
≤2	(Reference)		(Reference)	
>2	4.50 (2.19–9.27)	<0.001	2.34 (1.30–4.19)	0.004
Shape of stone				
Oval	(Reference)		(Reference)	
Round	0.98 (0.48–2.19)	0.942	1.69 (1.05–2.73)	0.030
Square	1.5 (0.41–5.45)	0.538	2.34 (1.24–4.44)	0.009
Fragmented	0.68 (0.25–1.87)	0.458	1.15 (0.63–2.09)	0.654

[†]Transverse diameter of the largest stone (mm) and the difference between CBD stone diameter and distal CBD diameter were categorized according to the previous study.[6,13]

[‡]Calculated from CBD stone diameter – distal CBD diameter.

[§]Multivariable risk regression under Poisson working model confounder adjusted by confounder summary scores include age, gender, BMI, underlying disease, acute cholangitis, previous cholecystectomy, periampullary diverticulum, CBD angle, mid-CBD diameter, distal common bile duct diameter, number of stones, longitudinal diameter of stone, impacted stone, and mechanical lithotripsy.

CBD, common bile duct; CI, confidence interval; ELPBD, endoscopic large papillary balloon dilatation; ERCP, endoscopic retrograde cholangiopancreatography; RR, risk ratio.

Endoscopic clearance of the CBD is difficult because of a number of stone-related variables, bile duct anatomy, and stone–bile duct relationships. However, little information is available on the relationship between stone and distal CBD diameter, which affects endoscopic CBD stone extraction in these individuals. Stone size and distal bile duct diameter are significant in predicting the technical outcomes of endoscopic CBD stone extraction. The stone size to bile duct diameter ratio of >1.0 was found to be a significant predictor of mechanical lithotripsy failure in a retrospective investigation.[17] Sharma and Jain[14] compared small stone diameters (median diameter of 8 mm [range 7–9 mm]) and narrow distal CBDs (median diameter of 3 mm [range 3–4 mm]) with large stones (median diameter 15.5 mm [range 15–20 mm]) and wide distal CBDs (median diameter of 16 mm [range 13–24 mm]) and found that the removal of small stones with narrow distal CBDs was more likely to succeed with mechanical lithotripsy, whereas the removal of large stones in wide distal CBDs was more likely to succeed with EST and basket extraction. Thus, the study concluded that any stone larger than 2 mm in diameter than the lower CBD diameter should be considered a large stone, regardless of the size. Based on this research[14] and our findings, the difference in CBD stone and distal diameter was classified into two categories, suggesting potential predictive value for difficult

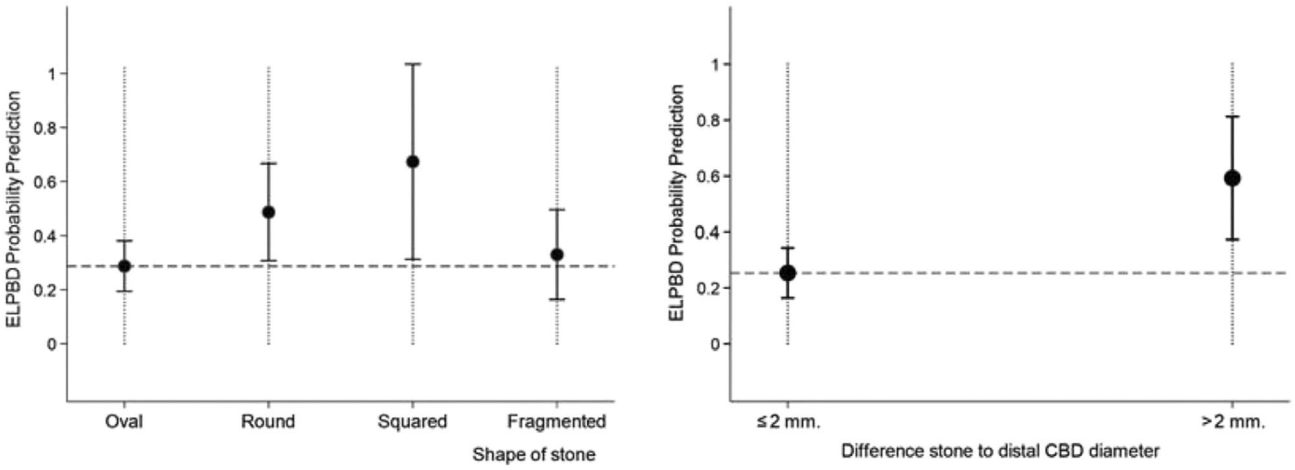

Figure 4 Prediction for the requirement of endoscopic large papillary balloon dilatation (ELPBD) for successful CBD stone extraction. Comparison of various stone morphologies (left) and comparison of the difference between CBD stone and distal CBD diameter (right).

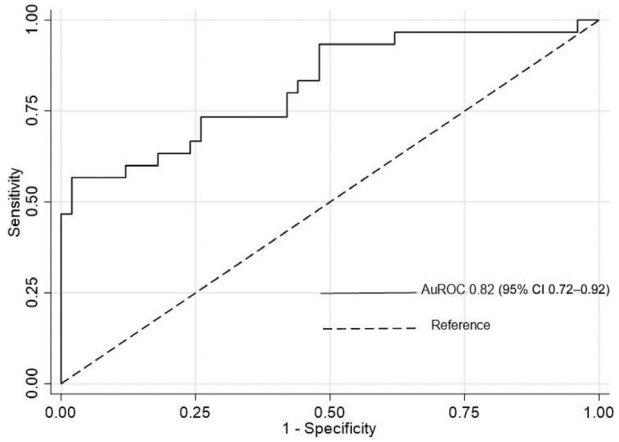

Figure 5 Area under the receiver operating characteristic curve (AuROC) of the difference between CBD stone and distal CBD diameter in discriminating CBD stone extraction requiring endoscopic large papillary balloon dilatation (ELPBD).

CBD stones requiring EPLBD. Any stone wider than a lower limit of CBD diameter exceeding 2 mm requires endoscopic techniques other than EST. Endoscopists have difficulty extracting CBD stones when the ampullary orifice or the distal CBD narrows; this may be due to insufficient relaxation of the sphincter muscles surrounding the ampulla or to a large stone compared to distal CBD.

No publication to date has examined the influence of CBD stone shape on endoscopic removal. In this study, the stone's shape (square or round) could predict the requirement for ELPBD. The univariable study for round and square-shaped stones was mainly insignificant, while the multivariable analysis was significant. These results may be explained by the fact that shape may be a variable influencing the requirement for ELPBD, but the confounding factor overshadowed its influence. However, in a multivariable analysis adjusted for confounding variables, the effect of shape was detected. Square-shaped stones may contribute to technical difficulty because their angles and equal transverse and longitudinal diameters make them difficult to pass, necessitating a large orifice. Likewise, round-shaped stones have equal transverse and longitudinal diameters, contributing to their greater difficulty passing than oval-shaped stones with smaller transverse diameters.

In this study, large stone size did not significantly predict the requirement for ELPBD. However, numerous studies have shown that stone size strongly indicates the difficulty of managing CBD stones using endoscopy. The explanations for these results are based on a relatively limited sample size. Therefore, there was no significant relationship between stone size and the necessity for ELPBD in multivariable analysis. Although many factors affect the overall success of stone extraction, these variables were adjusted as confounders in this study. In multivariable analysis, confounders were adjusted using a confounder summary score that included non-stone factors such as age, gender, underlying disease, acute cholangitis, previous cholecystectomy, BMI, and mechanical lithotripsy. Impact stones were infrequent in this study and are not a factor that requires exploration. However, the notion that the number of balloon extraction attempts during the procedure and the affected on stone consistency, whether it was rigid or fragile, may benefit from future investigations.

This study is the first to explain how the disparity between the diameters of the stone and distal CBD affects endoscopic stone removal. Additionally, this is the first study to determine that the shape of CBD stones influences the technical difficulty of endoscopic extraction. Despite our study's observational and retrospective nature, we attempted to adjust the confounding factors but were unable to accomplish this for several factors. In future, randomized controlled trials and large sample sizes should be employed. In addition, in this study stone and CBD diameter measurements during ERCP were taken in just two dimensions; this may have resulted in an underestimation of the stone's size, shape, and CBD diameter, which would have been more accurate if measured in three dimensions. Future research could correct this to improve stone and bile duct assessments.

Conclusion

In conclusion, our findings indicate that endoscopic removal of CBD stones is technically difficult in patients with specific stone-related factors, particularly with stones larger than distal CBD exceeding 2 mm and square-shaped CBD stones. Furthermore, this finding suggests that technically difficult CBD stone removal requires more complex procedures than EST and extraction.

Acknowledgment

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Data Availability Statement. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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