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Effect of Bile Duct Flushing on Reducing the Residue of Common Bile Duct Stones

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Abstract

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is a common procedure for common bile duct (CBD) stones, because it is known to cause residual stones. Although saline irrigation has been used to reduce residual CBD stones after ERCP, the relevant evidence on the effectiveness of irrigation volume is still unclear. **Methods:** This prospective trial study was performed at the Department of Gastroenterology, Liuzhou People Hospital affiliated Guangxi Medical University between 2017 and June 2022. Patients with CBD stones were consecutively enrolled at the endoscopy center of our hospital. This study enrolled patients who underwent lithotripsy during ERCP for large CBD stones (>12 mm). Scores (Score 1: a large number of stone segments; Score 2: a small number of stone segments; Score 3: fully removed CBD without any biliary stone fragments) were accurately documented after saline irrigation with 50 mL and 100 mL, and after stone removal, respectively. **Results:** A total of 112 patients with CBD stones were enrolled. No patient had CBD clearance scores or reached scores of 3 without saline irrigation, 45 (40.2%) patients reached scores of 3 with 50 ml irrigation, and 99 (88.4%) patients reached scores of 3 with 100 ml irrigation. Multivariate analysis indicated that CBD diameter > 15 mm [odds ratio (OR) = 0.93, 95% confidence interval (CI): 0.87 - 0.98, P = 0.013] and angulation of the distal CBD140˚ (OR = 0.92, 95% CI: 0.83 - 0.98, P = 0.007) were independent risk factors for residual stones. **Conclusion:** While irrigation with 100 mL saline solution may reduce the recurrence of CBD stones, it cannot flush out all residual CBD stone fragments after mechanical lithotripsy, and additional saline irrigation may be required to clear residual stones.

Subject Areas

Gastroenterology & Hepatology, Radiology & Medical Imaging

Keywords

Saline Solution Irrigation, Common Bile Duct Stone, Intraductal

Ultrasonography, Endoscopic Retrograde Cholangiopancreatography

1. Introduction

Common bile duct (CBD) stones are among the most prevalent diseases worldwide, commonly treated with endoscopic retrograde cholangiopancreatography (ERCP), which is a relatively minimally-invasive method [1] [2]. It has been reported that 25.6% of the patients with CBD stones often experience complications, such as cholangitis, obstructive jaundice, and post-ERCP pancreatitis (PEP) [3]. Also, according to previous studies, 24.0% to 40.0% of the patients are left with residual stones after mechanical lithotripsy [4] [5] [6]. Numerous studies have indicated that a probable risk factor for the recurrence of common bile duct stones is the presence of residuum (stone or sludge) after mechanical lithotripsy during ERCP [7] [8]. Cholangiography is usually performed to examine whether the CBD stones are completely cleared; however, cholangiography-negative small stone pieces persist in 23.0% - 40.0% of cases following ERCP with mechanical lithotripsy [9]. While complete CBD clearance can prevent the recurrence of bile duct stones [1], no effective means have been established thus far.

Various trials have reported that preventive irrigation with saline solution after CBD stone removal is necessary to clear and decrease residual CBD stones [10] [11] [12]. Ang *et al.* showed that 48 ml of saline solution irrigation could clear small residual stones after the ERCP removal of CBD stones [10]. Another study revealed that solution irrigation with 100 ml saline might clear the remaining CBD stone fragments after stone extraction, thus preventing stone recurrence [9].

As currently there is no direct imaging method that could define the efficacy of irrigation after mechanical lithotripsy [13], a new imaging method is urgently needed. Intraductal ultrasound (IDUS) has become a popular diagnostic method for choledocholithiasis detection due to its being minimally invasive, highly economical, and superior to ERCP in choledocholithiasis diagnosis. There is no evidence to detect the efficacy of saline irrigation to use IDUS to examine any CBD stones. The results of no irrigation after CBD stone removal through ERCP were confirmed by IDUS and were compared to the use of saline irrigation with 50 ml or 100 ml. To further study whether saline irrigation with 100 ml is more significant in reducing residual CBD stones after lithotripsy. This prospective self-controlled study was conducted.

2. Materials and Methods

2.1. Study Design and Participants

This prospective cohort study was performed at the Department of Gastroenterology, Liuzhou People's Hospital affiliated Guangxi Medical University between

June 2017 and June 2022. The trial was approved by the Institutional Review Board of our hospital and was conducted following the Declaration of Helsinki. All researchers had access to the final data and approved the presented version of the manuscript.

The CBD stones were confirmed before ERCP by each of the following imaging methods: transabdominal ultrasonography (US), computed tomography (CT) scan, endoscopic ultrasonography (EUS), and magnetic resonance cholangiopancreatography (MRCP). Also, all patients with CBD stone size ≥ 12 mm and needing mechanical lithotripsy were asked to provide written informed consent before stone removal through ERCP. The exclusion criteria were: 1) acute suppurative cholangitis; 2) acute pancreatitis; 3) hemodynamic instability; 4) previous Billroth II gastrectomy and cholangiojejunostomy or Roux-en-Y; 5) gastrointestinal tract hemorrhage and/or perforation; 6) previous history of ERCP; 7) pregnancy or breastfeeding; 8) coagulopathy with international standardized ratio (INR) > 1.5 and low platelet count (less than 50×10^9/L) or using anticoagulation drugs; 9) septic shock; 10) biliary-duodenal fistula diagnosed before ERCP; 11) patient refusal to provide informed consent. A total of 112 patients with CBD stones were enrolled in the endoscopy center of our hospital (**Figure 1**).

2.2. Procedures

All endoscopic operations were carried out by the endoscopist with rich experience of at least 1000 pancreaticobiliary endoscopies. All patients were injected

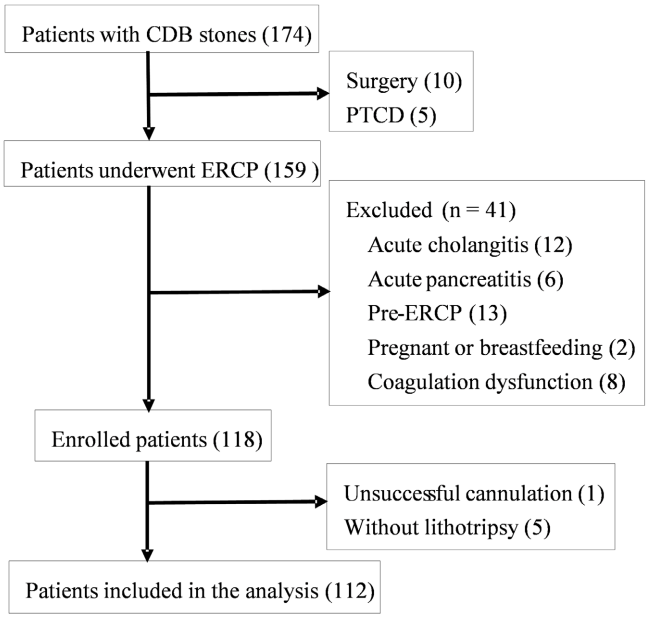

Figure 1. Flow chart of the study. CBD: Common Bile Duct, ERCP: Endoscopic Retrograde Cholangiopancreatography, PTCD: Percutaneous Transhepatic Cholangiodrainage.

with routine prophylactic antibiotics. Before ERCP, all patients were sedated with intravenous diazepam (5 mg), scopolamine butylbromide (10 - 20 mg), and meperidine (50 mg). ERCP was conducted via a typical duodenoscope (TJF-260V, Olympus, Tokyo, Japan).

During ERCP, after successful cannulation, selective CBD cannulization was carried out. In addition, cholangiography was performed to confirm the stone size (more or less than 12 mm) before mechanical lithotripsy. A standard sphincterotomy regulating the ENDO CUT mode (power setting 100 - 120 W, PSD-30, Olympus, Tokyo, Japan) followed using a controlled radial expansion balloon (10 - 12 mm in diameter, Olympus Medical Science, Tokyo, Japan). Lithotripsy was conducted using an endoscopic lithotripter-compatible basket (Boston Scientific, Natick, MA, USA; Cook Medical, Bloomington, IN, USA), after which stone extraction with a basket and a retrieval balloon was performed. Finally, using a C-arm X-ray (SIMENS Cios Alpha, Berlin, Germany), cholangiography was carried out to confirm choledocholithiasis, while the remnant stones were determined by the endoscopist and radiologist.

In order to completely assess the residual stones, the bile duct clearance score was created: Score 1: a large number of stone segments; Score 2: a small number of stone segments; Score 3: fully removed CBD without any biliary stone fragments. The scores were independently determined by two endoscopists with extensive experience and at least 500 pancreaticobiliary endoscopies between them (Figure 2).

Following confirmation by the operator that complete CBD stone removal was achieved, the clearance score was assessed by applying IDUS (GE-UE160; Olympus Optical, Tokyo, Japan) examination. If the clearance score did not reach 3, the CBD was flushed out with 50 ml of saline using a balloon or a basket intermittently. The basket or a balloon was shaken with a slight suction to

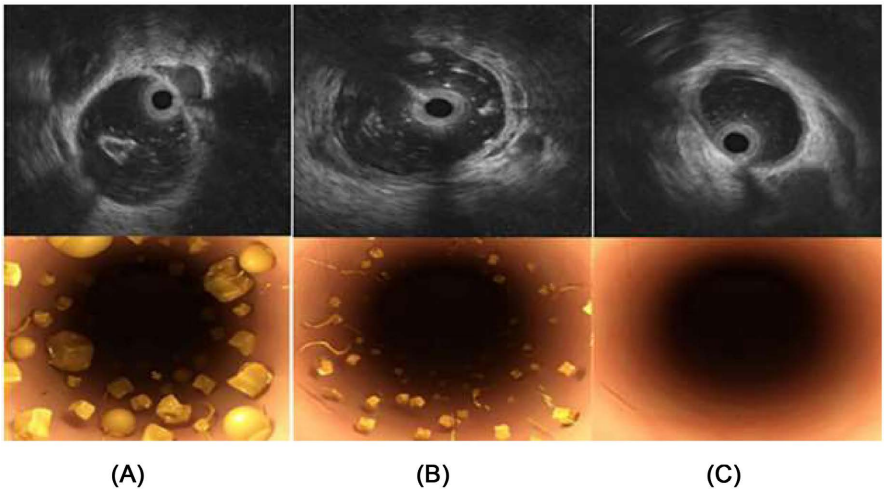

Figure 2. IDUS images and simulated diagrams of the residual stone fragments. (A)-(C) IDUS images. (A1)-(C1) and simulated diagrams (A2)-(C2). Score 1: a large number of stone fragments. Score 2: a small number of stone fragments. Score 3: completely cleared CBD without any biliary stone fragments.

promote drainage during the irrigation period, after which the bile duct was re-examined using the IDUS to detect stone fragments, and the CBD clearance score was obtained. If the CBD clearance score was still <3, irrigation was performed again using another 50 ml of saline. The final CBD clearance score was documented one more time applying IDUS examination. If there were CBD stones residuals after 100 ml saline irrigation, irrigation with saline was continued until the residual stones were fully cleared. All patients received endoscopic nasobiliary drainage (ENBD) after ERCP (**Figure 3**).

2.3. Definition for Complications

The patients were followed after the removal of CBD stones to assess the post-ERCP complications such as acute cholangitis, PEP, oozing/bleeding, and perforation based on symptoms, signs, abnormal blood tests, and imaging study

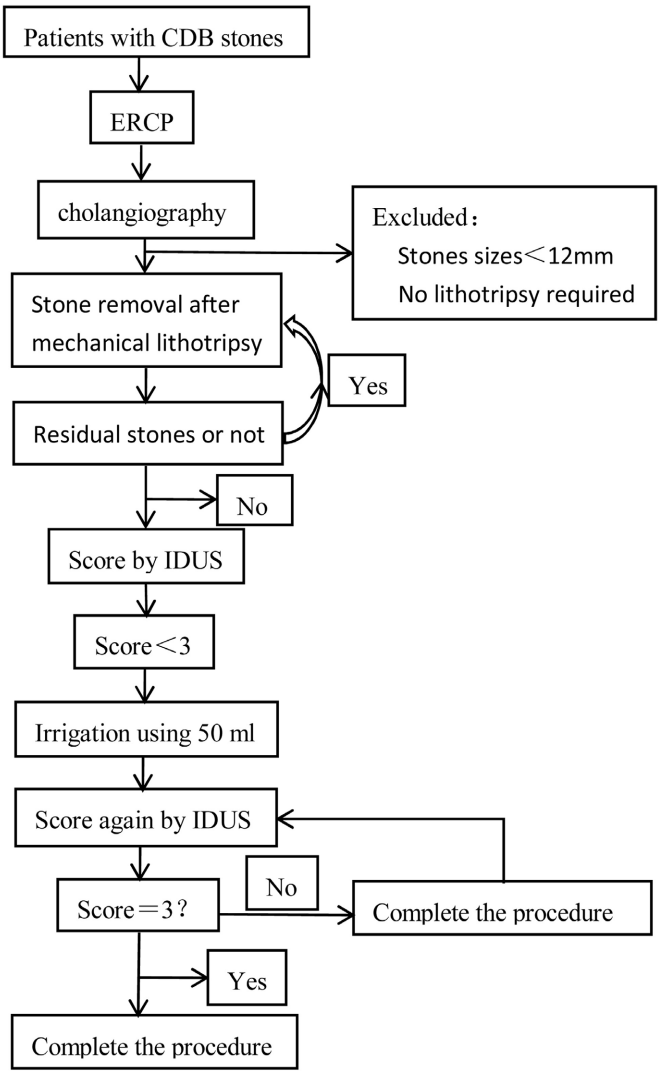

Figure 3. Protocol of evaluation and irrigation procedures. CBD: Common Bile Duct; ERCP: Endoscopic Retrograde Cholangiopancreatography; IDUS: Intraductal Ultrasound.

within 24 hours [14] [15]. Adverse events of post-ERCP were defined as follows: 1) the acute cholangitis was based on Tokyo Guidelines diagnostic criteria [15]; 2) oozing was described as slight exudation that spontaneously stopped; 3) PEP was defined as a new or worsening pain in the upper abdomen accompanied by a triple normal upper limit in serum amylase levels; 4) acute cholecystitis was an inflammation of the gallbladder wall diagnosed by the epigastrium pain along with a Murphy sign, and/or a thickened gallbladder wall; 5) perforation was confirmed as upper abdominal pain with retroperitoneal air and fluid.

2.4. Statistical Analysis

The sample size calculation depended upon a prevalence rate in order to detect the expected effect estimate. According to a previous study [16], 112 patients were needed to ensure that the study had sufficient participants. Continuous variables were presented as the mean ± Standard Deviation (SD). Continuous variables with a normal distribution were analyzed using the student's t-test or the Mann-Whitney U test. Categorical variables were compared using Pearson's Chi-square test or Fisher's exact test where appropriate. Logistic regression was used to determine the risk factors related to the complications, and the results were presented as ORs with 95.0% CIs. Variables with P-value < 0.10 in univariate analysis were included in a multiple regression model. $P < 0.05$ was considered statistically significant. SPSS version 24 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses.

3. Results

During the study period, 112 patients 48 (42.9%) men and 64 (57.1%) women with an average age of 61.2 (±16.9) years underwent endoscopic removal of CBD stones combined with irrigation. Comorbidities included coronary heart disease in 7 (6.3%) patients, hypertension in 14 (12.5%) patients, diabetes mellitus in 12 (10.7%) patients, hepatic fibrosis in 9 (8.0%) patients, and portal hypertension in 6 (5.4%) patients.

Procedure-related complications occurred in 25 (22.3%) out of 112 patients, with cholangitis in 9 (8.0%) patients, bleeding in 4 (3.6%), and PEP in 12 (10.7%) patients. In addition, no perforations or mortalities were found in our study. The mean time for ERCP was 63.43 (±15.47) min (**Table 1**).

After endoscopic CBD stone removal, cholangiography showed that CBD stones were completely removed in the subjects with ERCP. The clearance rate was calculated by IDUS before and after the irrigation of CBD with saline solution. According to IDUS, no patients scored 3 before saline irrigation of CBD. After irrigation with a saline solution containing 50 ml saline, 45 patients achieved a score of 3. After 100 ml of subsequent saline solution irrigation, the clearance rate was further improved: according to IDUS, 99 patients (88.4%) scored 3. The CBD clearance rates for no irrigation, irrigation with 50 ml saline, and irrigation with 100 ml saline were 0%, 40.2%, and 88.4%, respectively (**Table 2**).

Table 1. Clinical characteristics.

Patients	n = 112
Age (yr, mean ± SD)	61.2 ± 16.9
Male	56 (50.0%)
Multiple CBD stones	46 (41.1%)
Diameter of CBD (mm)	13.49 ± 1.71
Gallbladder stones	64 (57.1%)
Periampullary diverticulum	42 (37.5%)
Total bilirubin (μmol/L)	60.45 (19.35 - 111.55)
Comorbidities	
Coronary disease	7 (6.3%)
Hypertension	14 (12.5%)
Diabetes	12 (10.7%)
Liver cirrhosis	9 (8.0%)
Portal hypertension	6 (5.4%)
Procedure time, min (mean ± SD)	63.43 ± 15.47
Procedure-related adverse events	
Cholangitis	9 (8.0%)
Oozing	4 (3.6%)
PEP	12 (10.7%)
Cholecystitis	0
Perforation	0
Death	0

Data are expressed as the mean ± SD, median (interquartile range) or n (%), CBD: Common Bile Duct; PEP: Post-ERCP Pancreatitis.

Table 2. CBD clear score and stone clearance rate before and after saline irrigation.

Score	No Irrigation	50 ml	100 ml	P-value
Score 1	100 (89.3%)	0 (0%)	0 (0%)	
Score 2	12 (10.7%)	67 (59.8%)	13 (11.6%)	
Score 3	0 (0%)	45 (40.2%)	99 (88.4%)	<0.05

After the complete removal of the CBD stones by ERCP, 100 cases had a score of 1 before saline solution irrigation. There were 99 patients who reached a score of 3 after irrigation with 100 mL of saline solution. Multivariate analysis indicated that CBD diameter > 15 mm (OR = 0.93, 95% CI: 0.87 - 0.98; P = 0.010) and the CBD angulation (OR = 0.92, 95% CI: 0.83 - 0.98; P = 0.007) were independent risk factors for failed CBD clearance with irrigation with 100 mL saline (Table 3).

Table 3. Biliary clearance (score = 3) after 100 ml saline irrigation.

	Univariable analysis	P-value	Multivariable Analysis	P-value
	OR (95% CI)		OR (95% CI)	
Age (yr)				
≤60	1.00		-	
>60	0.78 (0.23 - 2.69)	0.700	-	-
Gender				
Male	1.00		-	
Female	0.99 (0.96 - 1.03)	0.870	-	-
CBD diameter				
≤15 mm	1.00		1.00	
>15 mm	3.86 (1.18 - 12.62)	0.026	0.93 (0.87 - 0.98)	0.013
CBD angulation				
≥140˚	1.00		1.00	
<140˚	15.63 (1.68 - 18.85)	0.001	0.92 (0.83 - 0.98)	0.007
PAD				
No	1.00		-	
Yes	3.0 (1.32 - 14.76)	0.120	-	-

CBD: Common Bile Duct; PAD: Periampullary Diverticula; CI: Confidence Interval; OR: Odds Ratio.

4. Discussion

In the present study, we showed that ERCP combined with mechanical lithotripsy was related to the recurrence of CBD stones, which is consistent with the previous study [1]. Moreover, it should be considered that saline irrigation could reduce the residual bile duct stones after mechanical lithotripsy. The present study showed the useful effect of saline irrigation on the residual bile duct stones after mechanical lithotripsy.

ERCP is a common method used to calculate the successful clearance of CBD stones [15]. However, most previous studies reported that endoscopic ultrasound could successfully identify residual biliary stones within the CBD after ERCP [13] [16]. During ERCP combined with mechanical lithotripsy, a large number of small stone fragments could act as a nidus for the stone recurrence [17] [18]. It was found that small CBD stones remain after mechanical lithotripsy and that these residual stones could be cleared using saline irrigation [19]. A previous study indicated that irrigation with an average of 48 ml of saline solution could completely remove residual CBD stones [10]. It was also reported that the irrigation saline volume was an important factor for CBD clearance rate after mechanical lithotripsy [15]. However, a series of studies have shown that at least 100 ml of saline was needed to clear the recurrence of CBD stones [1] [9]. Therefore, the efficacy of saline solution irrigation on the clearance of residual

CBD stone fragments after mechanical lithotripsy remained unclear.

The aim of the present study obviously differed from previous studies, in which all of the cases had big stones (more than 12 mm) and were treated with post-mechanical lithotripsy. This study found that after ERCP combined with mechanical lithotripsy was conducted to remove common bile duct stones, IDUS showed that most of the patients were relatively cleared despite a negative cholangiogram. The low accuracy of the cholangiography in identifying small CBD stones may result in an incomplete clearance of stones [20]. The clearance rate after 50 ml saline irrigation was 40.2%, while after 100 ml saline solution irrigation, 88.4% of the patients achieved complete clearance as confirmed by IDUS. The results demonstrated that irrigation with 100 ml of saline cannot clear the CBD residual stones. In the current study, all patients underwent mechanical lithotripsy before removing CBD stones, which generated a large number of stone fragments, thus making it difficult to clear the bile duct by ERCP. Our results showed that a larger saline irrigation volume was useful in clearing the residual stones. The clearance rate could be higher compared to those who did not undergo mechanical lithotripsy.

ERCP usually leads to residual bile duct stones, especially when combined with lithotripsy. It is assumed that small residual bile duct stones remain after ERCP and spontaneously enter the duodenum. However, many studies have shown that approximately 1/3 of cases had residual stones after ERCP using EUS [13] [21]. The existence of residual stones may be a significant reason for the CBD stones' recurrence. In addition, the EUS, which is highly operator-dependent [20], might also provide an alternative approach for treating CBD stones. The Spy Glass DS has also been applied to detect biliary stone fragments in 85.0% of cases with residual stones after ERCP before saline irrigation [16]. However, the probe is costly and can also be easily damaged. Besides, the method is very challenging. Many studies have shown that IDUS has high accuracy in detecting small stones caused by an incomplete clearance of CBD stones by standard cholangiography [16].

In the present study, the IDUS was used to document the bile duct clearance score. IDUS is an appropriate examination method with few side effects [22]. More importantly, it provides a direct image of the CBD and is more accurate in diagnosing residual CBD stones compared to other methods. Residual biliary stone fragments are considered to be the main reason for stone formation. A previous study reported that mechanical lithotripsy was significantly related to residual biliary stone fragments ($P < 0.05$) [23], which is consistent with our results. We observed that the CBD diameter >15 mm was an obvious independent risk factor for a worse CBD clearance rate. Despite the 100 ml saline solution irrigation, CBD angulation remained an independent risk factor for failed CBD clearance. Above all, these problems could be attributed to the existence of an air-filled common bile duct/acute CBD angulation that changes the distal CBD, making it difficult to flush out the CBD remained stones [24] [25]. Increasing the volume of saline irrigation could effectively improve the biliary residua

stones.

Without complete bile duct drainage, saline solution irrigation may increase the bile duct pressure, thus causing serious adverse events, such as cholangitis [26]. Specially designed drainage methods can mitigate the bile duct pressure [27]. Practically, there were no serious complications in our study. Subsequent irrigation and endoscopic suction to improve drainage can decrease the risk. There were some differences in the present study compared to previous studies: first, we studied the results of drainage with saline after mechanical lithotripsy; second, the IDUS was used to evaluate the clearance rate of the CBD stones; third, this study was a self-controlled study, which represents a great methodological advantage. Importantly, none of the cases showed residual bile duct small stones following IDUS, which demonstrated that the detection of small residual stones using IDUS was more accurate than cholangiography. If there are small residual stones in the bile duct, they would be flushed out after using extra saline until achieving the CBD clearance. In addition, the present study applied an objective method to assess small residual stones identified by IDUS.

The present study has some limitations that should be taken into consideration. This was not a randomized controlled trial and was conducted at a single institution. The sample size was small, and it is possible that the duration of the procedure might be extended by the introduction of irrigation. Future studies are needed to further confirm the clinical significance of saline irrigation.

5. Conclusions

The study indicated that mechanical lithotripsy is related to bile duct residual small stones and that subsequent saline solution of the CBD is necessary to decrease the CBD residual small stones. After irrigation with 50 ml of saline, 40.2% of the patients had relatively cleared bile ducts. After 100 ml saline irrigation, 88.4% of the patients achieved complete clearance of the bile duct. The results showed that irrigation with 100 ml of saline was not enough to clear the bile duct of residual stones.

Therefore, no less than 100 ml saline irrigation is strongly recommended to remove the residuals, especially in those cases with dilated CBD and/or with acute angulation of the distal CBD.

Data Availability Statement

The data that support the findings of this study are available upon reasonable request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Financial Disclosure

The authors declared that this study received no financial support.

Conflicts of Interest

The authors have no conflict of interest to declare.

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Abbreviations

ERCP = Endoscopic Retrograde Cholangiopancreatography; CBD = Common Bile Duct; IDUS = Intraductal Ultrasonography; US = Transabdominal Ultrasonography; CT = Computed Tomography; EUS = Endoscopic Ultrasonography; PEP = Post-ERCP Pancreatitis; INR = International Standardized Ratio; ENBD = Nasobiliary Drainage; CI = Confidence Interval; OR = Odds Ratio.