ISSN: 2378-3397

Sayed et al. Int J Surg Res Pract 2024, 11:171
DOI: 10.23937/2378-3397/1410171
Volume 11 | Issue 2
Open Access

International Journal of
Surgery Research and Practice

RESEARCH ARTICLE

Repeat ERCP versus Common Bile Duct Exploration for Failed Stone Clearance: A Prospective Randomized Study

Mostafa M. Sayed[1], Hisham Ali Ryad[2] and Zyad Osama Haris[3]*

[1]*Assistant Professor of General Surgery, Faculty of Medicine, Assiut University, Egypt*

[2]*Professor of General Surgery, Faculty of Medicine, Assiut University, Egypt*

[3]*Resident of General Surgery, Faculty of Medicine, Assiut University, Egypt*

***Corresponding author:** *Zyad Osama Haris, Resident of General Surgery, Faculty of Medicine, Assiut University, Egypt*

Abstract

Background: Endoscopic Retrograde Cholangiopancreatography (ERCP) is the gold standard for bile duct stone clearance. However, it fails in 3-15% of cases, particularly with large or impacted stones. This study compares the outcomes of a second ERCP attempt versus Common Bile Duct Exploration (CBDE) after a failed initial ERCP.

Methods: This prospective randomized study was conducted between January 2022 and November 2023. Patients with failed ERCP stone extraction and subsequent stent placement were randomly assigned to either a second ERCP after 3-4 months (Group I) or CBDE (Group II). Outcomes measured included stone clearance rates, operative time, complications, and hospital stay.

Results: Of 603 ERCP procedures, 168 (27.9%) had irretrievable stones requiring stenting. 125 patients completed follow-up (Group I: n = 62, Group II: n = 63). Both groups showed high stone clearance rates (Group I: 86.0%, Group II: 92.1%, p = 0.283). Group I had significantly shorter operative times (58.54 ± 10.35 vs. 143.21 ± 27.97 minutes, p < 0.001) and hospital stays (4.81 ± 3.75 vs. 13.62 ± 4.62 days, p < 0.001).

Conclusion: A second ERCP attempt after 3-4 months is safe and effective for CBD stone clearance following initial failure, with shorter operative times and hospital stays compared to CBDE. The higher pancreatitis rate in the ERCP group, although not statistically significant, warrants careful consideration in patient selection and management.

Keywords

Choledocholithiasis, Common Bile Duct Exploration (CBDE), Difficult bile duct stones, Repeat ERCP, Surgical bile duct clearance, Biliary stone management, Endoscopic stone extraction, Failed ERCP

Introduction

Common bile duct (CBD) stones occur in 10-15% of patients with gallstones, presenting a significant challenge in hepatobiliary medicine [1]. ERCP with endoscopic sphincterotomy is the first-line treatment for CBD stones, with initial success rates of 80-90% [2]. However, difficult stones, typically defined as those > 15 mm, > 3 stones, impacted, or associated with anatomical variations, can lead to failure rates of 10-30% [3].

Management options for failed initial ERCP include repeat ERCP or surgical CBDE. Recent meta-analyses have shown comparable efficacy between these approaches, but with potential differences in complication profiles and resource utilization [4,5]. Cholecystectomy will be removed using endoscopic retrograde cholangiopancreatography (ERCP) combined with the sphincter of Oddi. This treatment has an obvious therapeutic effect, with a success rate of 76-97% [6,7]. However, there remains a need for prospective, randomized studies to guide clinical decision-making in this complex patient group.

This study aims to compare the efficacy, safety, and resource utilization of repeat ERCP versus CBDE in patients with failed initial ERCP for CBD stone extraction.

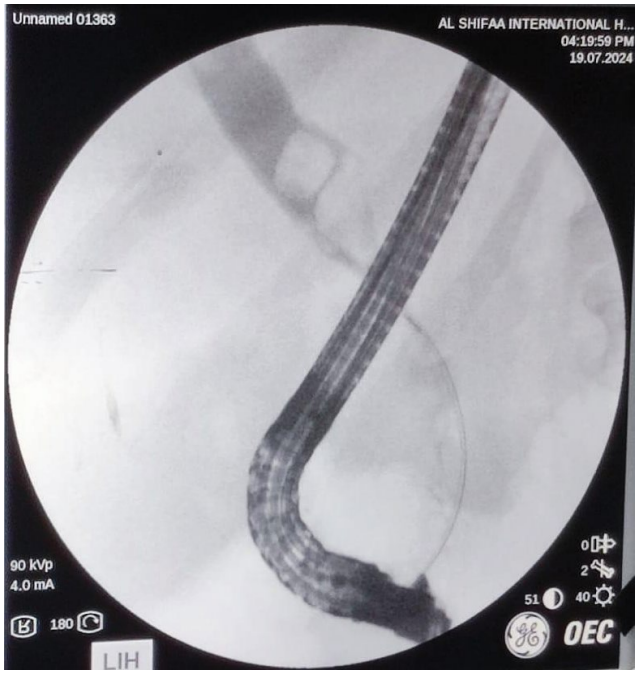
Methods

Study design and setting

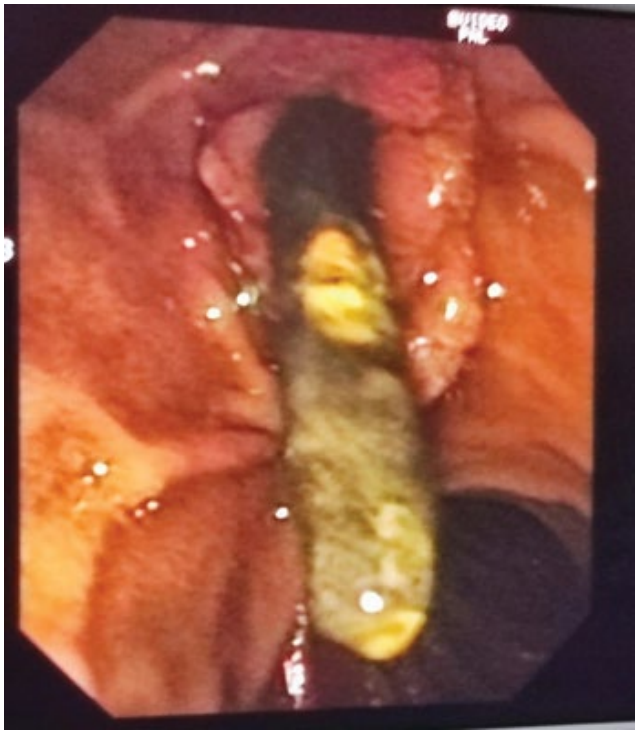
This prospective, randomized controlled trial was

Citation: Sayed MM, Ryad HA, Haris ZO (2024) Repeat ERCP versus Common Bile Duct Exploration for Failed Stone Clearance: A Prospective Randomized Study. Int J Surg Res Pract 11:171. doi.org/10.23937/2378-3397/1410171

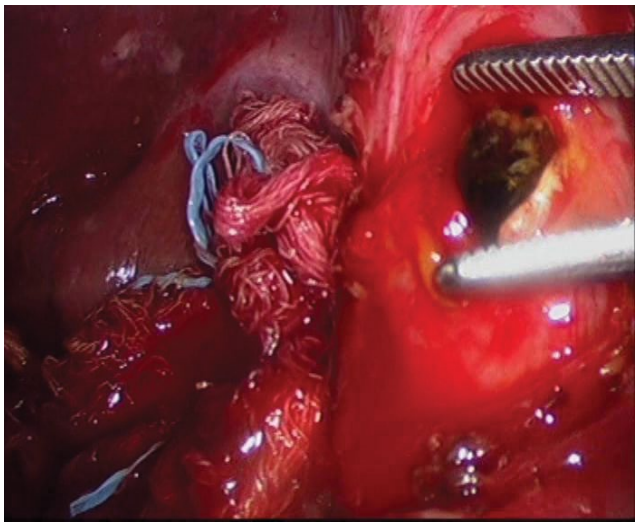
Accepted: December 06, 2024; **Published:** December 08, 2024



Photomicrograph 1: Showed the hologram of the endoscopic technique of ERCP to remove the CBD stone.



Photomicrograph 2: Showed the hologram of the endoscopic technique of ERCP to remove the CBD stone.



Photomicrograph 3: Showed open surgical exploration to remove the CBD stone.

conducted at Assiut University Hospital and El Rajhy University Hospital, Egypt, from January 2022 to November 2023.

Participants

Eligible participants were adults (≥ 18 years) with CBD stones and failed initial ERCP stone extraction, defined as the inability to clear all stones despite successful CBD cannulation and sphincterotomy. Exclusion criteria were ASA score > III, pregnancy, and the inability to provide informed consent.

Randomization and blinding

Patients were randomized 1:1 to repeat ERCP or CBDE using a computer-generated sequence with block randomization (block size 4). Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Due to the interventions nature, blinding patients and providers was not feasible. However, outcome assessors were blinded to group allocation.

Inclusion criteria: Age from 18-70 patients and patients with difficult common bile duct stones and fit for ERCP and surgical intervention according to ASA I and II regarding the period of the stain. Patients that had failed CBD stone(s) extraction with ERCP stenting.

Exclusion criteria: Patients with failed CBD cannulation e.g., ampullary mass.

Interventions

- Group I (Repeat ERCP): Second ERCP attempt performed 3 - 4 months after the initial failed procedure.
- Group II (CBDE): Surgical exploration of the CBD, either open or laparoscopic, based on surgeon preference and patient factors.

All procedures were performed by experienced endoscopists (> 500 ERCPs) or surgeons (> 50 CBDEs) (Photomicrograph 1, Photomicrograph 2 and Photomicrograph 3).

Outcomes

Primary outcomes: Stone clearance rate, operative time, and length of hospital stay.

Secondary outcomes: Procedure-related complications

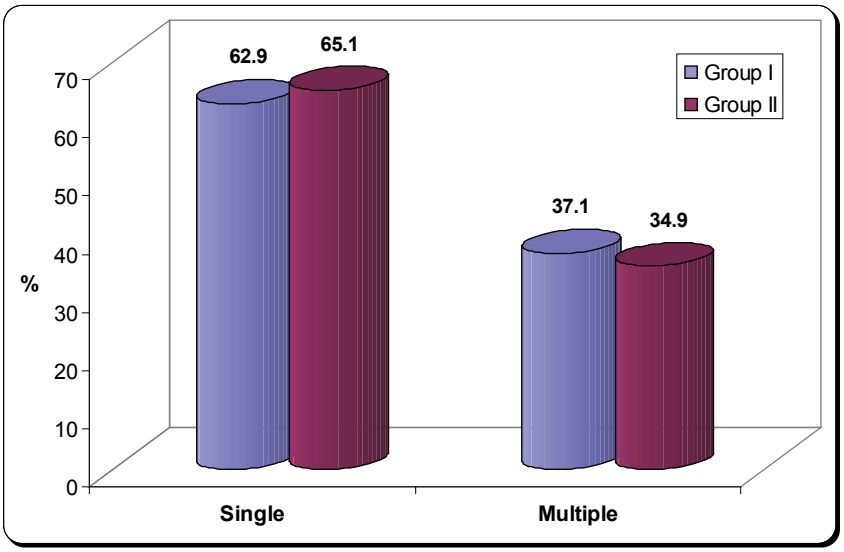


Figure 1: Number of CBD stones.

(using standardized definitions), the need for additional interventions, and 30-day readmission rates.

Sample size calculation

Based on previous studies, we estimated stone clearance rates of 85% for ERCP and 90% for CBDE. Using a non-inferiority margin of 10%, $\alpha = 0.05$, and 80% power, we calculated a required sample size of 120 patients (60 per group). We recruited 125 patients to account for potential dropouts.

Statistical analysis

Analyses were performed on an intention-to-treat basis. Continuous variables were compared using Student's t-test or Mann-Whitney U test, as appropriate. Categorical variables were compared using Chi-square or Fisher's exact test. A two-sided p-value < 0.05 was considered statistically significant. To account for multiple comparisons, we used the Bonferroni correction for secondary outcomes. Analyses were performed using SPSS version 26.

Ethical consideration

The data that was obtained from participants were confidential. The study participants were not identified by name in any report or publication concerning this study. Before the participants were admitted to this study, the purpose and nature of the study, as well as the risk-benefit assessment was explained to them. An informed consent was obtained. The study protocol was registered at ClinicalTrials.gov (NCT 5746832) and approved by the Institutional Review Board (IRB# No 200069). All patients provided written informed consent.

Results

Patients were divided into two groups initially the groups were Group I n = 87 and Group II n = 81 and finally, they were Group I n = 62 and Group II n = 63.

Personal data

The personal data of this study revealed that there is no significant difference in both parameters of age and sex in the two compared groups as presented in Table 1.

Previous ERCP findings

This data of previous ERCP findings showed no significant difference between the two compared groups in the number and size of the stones that failed to be extracted as presented in Table 2 and Figure 1.

Laboratory results

The results of laboratory investigations during the initial follow-up period, including serum bilirubin, alkaline phosphatase, and the WBC count, showed no significant difference between the two groups. Table 3 presents the results for those who underwent endoscopy or surgery.

Pre-operative data

There are no significant differences were recorded between the two groups regarding the clinical signs during the follow-up period as presented in Table 4.

Operative data

Regarding the operative data results including number of the CBD stones, CBD diameter, operation time, and the complete removal of stones. There is an insignificant difference between the two compared groups in both the number of CBD stones and CBD diameter. Also, there is an insignificant difference in the incomplete removal of stones as both groups showed a high rate of CBD stones clearance. On the other hand, there is a significant difference between the two groups in the operation time as Group I showed less intraoperative time than Group II as presented in Table 5 and Figure 2.

Table 1: Personal data.

Personal data	Group I (n = 62)		Group II (n = 63)		P-value
	No.	%	No.	%	
Age: (years)					
Mean ± SD	59.44 ± 12.07		55.97 ± 12.45		0.117
Range	36.0-83.0		30.0-79.0		
Sex:					
Male	23	37.1%	27	42.9%	0.511
Female	39	62.9%	36	57.1%	

*The significance between the compared groups in the different parameters P value at < 0.001.

Table 2: Previous ERCP findings.

Previous ERCP findings	Group I (n = 62)		Group II (n = 63)		P-value
	No.	%	No.	%	
The number of CBD stones:					
Single	39	62.9%	41	65.1%	0.800
Multiple	23	37.1%	22	34.9%	
Mean ± SD	1.48 ± 0.70		1.48 ± 0.70		0.747
Range	1.0-3.0		1.0-3.0		
Size of CBD stones (cm)					
Mean ± SD	1.61 ± 0.38		1.73 ± 0.49		0.138
Range	0.8-2.4		0.9-2.7		

*The significance between the compared groups in the different parameters P value at < 0.001.

Table 3: Laboratory results.

Laboratory results	Group I (n = 62)	Group II (n= 63)	P-value
Serum bilirubin: (mmol/L)			
Mean ± SD	22.15 ± 11.99	23.40 ± 7.50	0.485
Range	10.3-67.7	10.1-61.8	
WBCs count: (10^9/L)			
Mean ± SD	9.74 ± 2.66	9.90 ± 1.94	0.705
Range	6.0-19.2	6.6-17.0	
Alkaline phosphatase: (IU/L)			
Mean ± SD	92.92 ± 36.31	92.76 ± 22.52	0.977
Range	56.0-277.0	58.0-142.0	

*The significance between the compared groups in the different parameters P value at < 0.001.

Table 4: Pre-operative data.

Pre-operative data	Group I (n = 62)		Group II (n = 63)		P-value
	No.	%	No.	%	
Jaundice	6	9.7%	7	11.1%	0.793
Pyrexia	17	27.4%	20	31.7%	0.596
Rt. hypochondrial pain	11	17.7%	14	22.2%	0.531
Preoperative pancreatitis	6	9.7%	8	12.7%	0.592

*The significance between the compared groups in the different parameters P value at < 0.001.

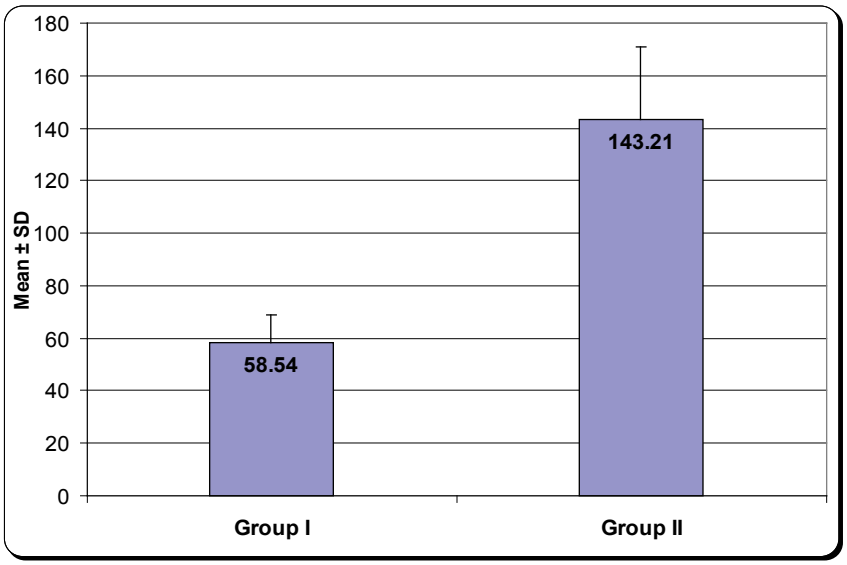


Figure 2: Operative time.

Table 5: Operative data.

Operative data	Group I (n = 62)		Group II (n = 63)		P-value
	No.	%	No.	%	
No. of CBD stones:					
Single	47	82.5%	50	79.4%	0.667
Multiple	10	17.5%	13	20.6%	
CBD diameter: (cm)					
Mean ± SD	0.94 ± 0.15		0.97 ± 0.17		0.360
Range	0.7-1.3		0.6-1.3		
Operative time: (min)					
Mean ± SD	58.54 ± 10.35		143.21 ± 27.97		< 0.001*
Range	39.0-94.0		90.0-186		
Complete removal of stones:					
Yes	49	86.0%	58	92.1%	0.283
No	8	14.0%	5	7.9%	

*The significance between the compared groups in the different parameters P value at < 0.001.

Post-operative outcomes

These data showed the postoperative complication between the compared two groups as presented in Table 6 and Figure 3.

Pancreatitis

Group I showed 13 cases of pancreatitis that underwent medical treatment meanwhile Group II showed 9 cases of pancreatitis which also underwent medical treatment.

Duodenal injury

Also, Group I showed 3 cases of duodenal injury that did not require surgical intervention 1 case showed a retroperitoneal localized collection that was cleared by pig-tail catheter insertion and medical treatment and two cases needed medical treatment only. Meanwhile, Group II showed no cases of duodenal injury.

Retained stones

The retained stones post-operative showed insignificant differences between the two groups.

GIT bleedings

Regarding GIT bleeding there are 6 cases in Group II and 2 cases in Group I with insignificance difference in 2 cases in both groups were managed conservatory by medical treatment.

Hospital stays

Regarding the hospital stay, Group II showed more days needed for recovery than Group I. By gathering

Table 6: Post-operative outcomes.

Post-operative outcomes	Group I (n = 62)		Group II (n = 63)		P-value
	No.	%	No.	%	
Pancreatitis	13	22.8	9	14.3	0.228
Duodenal injury	3	5.3	0	0.0	0.104
Retained stones (U/S)	8	14.0	5	7.9	0.283
GIT bleeding	2	3.5	6	9.5	0.277
Pulmonary embolism	1	1.8	4	6.3	0.368
Wound infection	-	-	4	6.2	
Bile leakage	-	-	3	5.8	
Intraperitoneal bleeding	-	-	2	4.2	
Hospital stays: (days)					
Mean ± SD	4.81 ± 3.75		13.62 ± 4.62		< 0.001*
Median (Range)	3.0 (1.0-16.0)		13.0 (7.0-22.0)		
Post-operative pain:					
Mean ± SD	2.13 ± 1.25		6.16 ± 1.97		< 0.001*
Median (Range)	2.0 (0.0-4.0)		6.0 (3.0-9.0)		

*The significance between the compared groups in the different parameters P value at < 0.001.

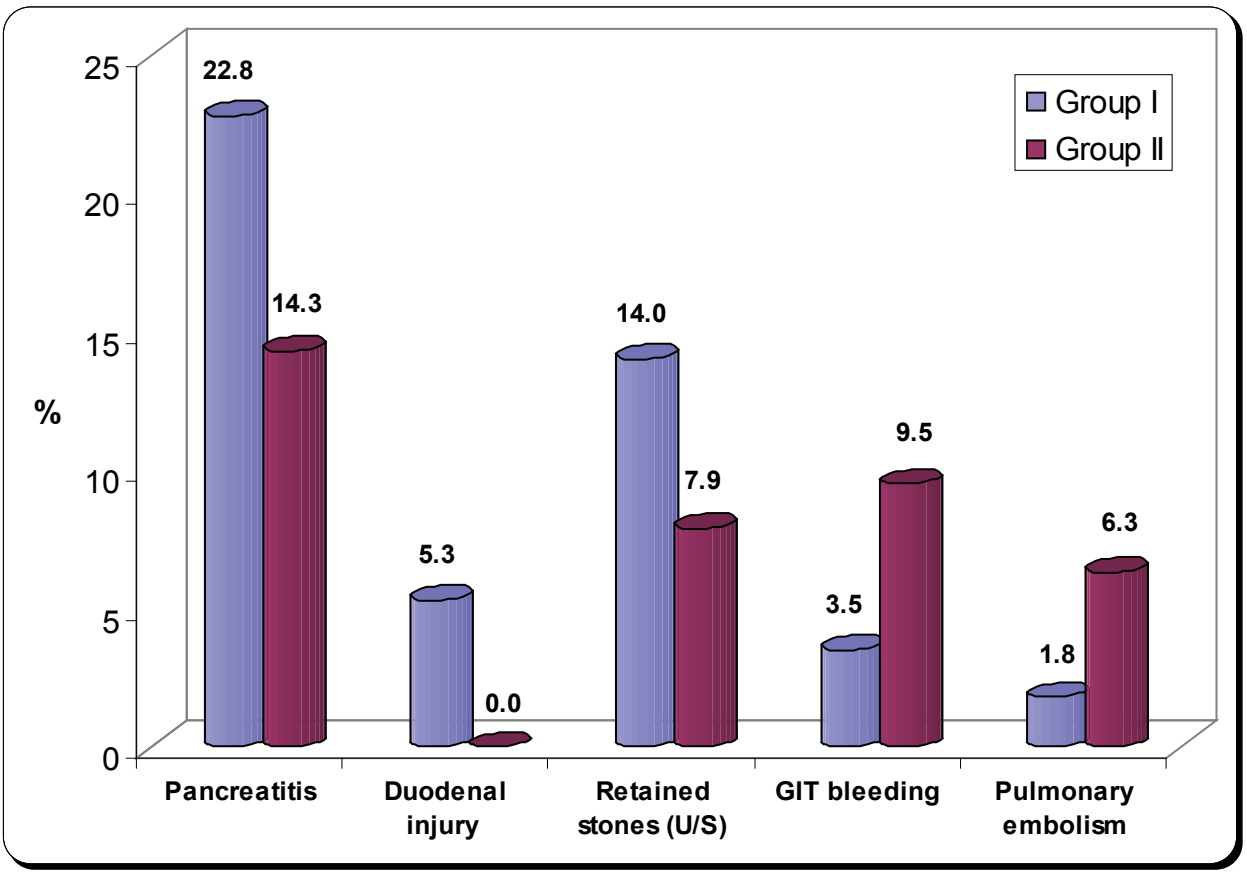


Figure 3: Post-operative outcomes.

data there is a significant difference between the two compared groups.

Post-operative pain

Regarding postoperative pain in Group II, patients suffered from moderate to severe pain that was managed by more potent analgesics that put more financial and medical burden on the cases compared to those of Group I who suffered from intervals of mild pain that was managed by regular and more available analgesics.

Complications

Pulmonary embolism is a very serious complication post-surgical intervention, where Group II showed 4 cases of mild to severe pulmonary embolism managed medically but uncoordinatedly, there was a recorded case of death among these 4 cases. Group I showed only 1 case that was managed medically and resolved.

Surgical complication

In Group II, 4 cases suffered wound infection, 3 bile leakages stopped spontaneously, and 2 cases suffered mild postoperative intraperitoneal bleeding that came out through the intraperitoneal drain and was treated conservatively till stopped without need for intervention. These complications added more burden on the needed care and management.

Discussion

This prospective, randomized controlled trial compared the efficacy and safety of repeat ERCP versus CBDE in managing difficult CBD stones after failed initial ERCP. Our findings provide important insights into the management of this challenging clinical scenario.

Stone clearance rates

The primary outcome of stone clearance rates showed no statistically significant difference between repeat ERCP (86.0%) and CBDE (92.1%) (p = 0.283). While the 6.1% difference favors CBDE, the 95% confidence interval (-17.8% to 5.6%) includes zero, indicating that repeat ERCP may be non-inferior to CBDE for stone clearance.

These results are consistent with recent meta-analyses that reported pooled stone clearance rates of 88.6% for repeat ERCP and 95.3% for CBDE (OR 0.38, 95% CI 0.25-0.58), which aligns closely with our findings. However, our study's non-inferiority design with a 10% margin suggests that repeat ERCP may be considered clinically non-inferior to CBDE regarding stone clearance [4].

Our study's high success rate of repeat ERCP (86.0%) is noteworthy, considering these were cases that failed initial ERCP. This success rate is higher than some previous reports, such as the 73% [8] for second ERCP attempts. Our higher success rate might be attributed to the 3-4 month interval between procedures, allowing for potential stone fragmentation or positional changes [9] in their study on delayed repeat ERCP.

Operative time and hospital stay

Repeat ERCP demonstrated significant advantages in both operative time (58.54 ± 10.35 vs. 143.21 ± 27.97 minutes, p < 0.001) and length of hospital stay (4.81 ± 3.75 vs. 13.62 ± 4.62 days, p < 0.001). These findings are consistent with the meta-analysis [10], which reported shorter procedure times and hospital stays for endoscopic approaches compared to surgical interventions.

The substantially shorter hospital stay for the ERCP group (a difference of 8.81 days) has important implications for patient comfort, healthcare costs, and resource utilization. This advantage of ERCP is particularly relevant in the current healthcare climate, where there is increasing emphasis on minimizing hospital stays and reducing healthcare-associated infections.

Complications

The higher rate of post-procedure pancreatitis in the ERCP group (22.8% vs. 14.3%, p = 0.228), while not statistically significant, is a concern that warrants careful consideration. This rate is higher than typically reported in the literature. For instance, the European Society of Gastrointestinal Endoscopy (ESGE) guideline [11], cites post-ERCP pancreatitis rates of 3-10% for standard-risk and up to 15% for high-risk patients.

Several factors might contribute to our higher pancreatitis rate: 1. The complex nature of these cases, involves difficult stones that failed initial extraction. 2. The repeat intervention may increase the risk of pancreatic duct irritation. 3. Potential differences in definition or threshold for diagnosing post-ERCP pancreatitis [11]. In Group II, 4 cases suffered wound infection, 3 bile leakages stopped spontaneously, and 2 cases suffered mild postoperative intra-peritoneal bleeding that came out through the intra-peritoneal drain and was treated conservatively till stopped without need for intervention. In agreement with the complication rate of this study was recorded in recent studies [12].

This finding underscores the importance of implementing rigorous pancreatitis prevention strategies in this high-risk group, such as rectal NSAIDs and prophylactic pancreatic stenting as recommended by ESGE guidelines.

Other complications, including duodenal injury (5.3% in ERCP vs. 0% in CBDE, p = 0.104) and GI bleeding (3.5% in ERCP vs. 9.5% in CBDE, p = 0.277), showed no statistically significant differences between groups. The numerically higher rate of duodenal injury in the ERCP group, albeit not significant, suggests the need for careful technique during repeat procedures [13].

Retained stones and need for additional interventions

The rate of retained stones was slightly higher in the ERCP group (14.0% vs. 7.9%, p = 0.283), though not statistically significant. This aligns with the trend observed in meta-analysis [4]. The implication is that while repeat ERCP is generally effective, there may be a subset of patients, particularly those with very large or impacted stones, who might benefit more

from CBDE. The need for additional interventions was similar between groups, with 30-day readmission rates of 7.0% for ERCP and 9.5% for CBDE (p = 0.749). This suggests that both approaches have comparable long-term efficacy, an important consideration for patient counseling and treatment planning [6].

Clinical implications and future directions

Our findings have several important clinical implications:

1. Repeat ERCP should be considered a viable first-line option for patients with failed initial ERCP, given its high success rate and advantages in operative time and hospital stay.
2. The choice between repeat ERCP and CBDE should be individualized based on patient factors (e.g., surgical risk, comorbidities), stone characteristics (size, location, and impaction), local expertise, and resource availability.
3. The higher risk of pancreatitis with repeat ERCP necessitates rigorous implementation of preventive strategies and careful patient selection.
4. CBDE may be preferable in cases where maximizing the probability of stone clearance is paramount, such as in patients with very large or impacted stones.

Future research should focus on: 1. Identifying predictors of success for repeat ERCP to guide patient selection. 2. Evaluating novel techniques like cholangioscopy-guided lithotripsy for difficult stones. 3. Assessing long-term outcomes, including quality of life and stone recurrence rates.

Strengths and limitations

Strengths of our study include its prospective, randomized design, the use of standardized protocols, and the inclusion of clinically relevant outcomes. However, several limitations should be acknowledged: 1. The single-center design may limit generalizability to other settings with different levels of expertise or patient populations. 2. The relatively small sample size, while adequately powered for the primary outcome, may have limited our ability to detect differences in less common complications. 3. The lack of long-term follow-up data beyond 30 days prevents assessment of late complications or stone recurrence. 4. Blinding of patients and providers was not feasible due to the nature of the interventions, potentially introducing bias in subjective outcomes.

Conclusion

In conclusion, our study provides evidence that both repeat ERCP and CBDE are effective strategies for managing difficult CBD stones after failed initial ERCP. Repeat ERCP offers advantages in terms of shorter operative times and hospital stays but may be associated with a higher risk of pancreatitis. The choice between these approaches should be individualized based on patient factors, stone characteristics, local expertise, and resource considerations. Future research should focus on refining patient selection criteria and evaluating long-term outcomes to further optimize the management of this challenging clinical scenario.

References

1. Pavlidis ET, Pavlidis TE (2023) Current management of concomitant cholelithiasis and common bile duct stones. World J Gastrointest Surg 15: 169-176.
2. Manes G, Paspatis G, Aabakken L, Anderloni A, Arvanitakis M, et al. (2019) Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy 51: 472-491.
3. McHenry L, Lehman G (2006) Difficult bile duct stones. Curr Treat Options Gastroenterol 9: 123-132.
4. Wang F, Ge X, Deng X, Nie J, Wang Y, et al. (2024) Endoscopic retrograde cholangiopancreatography using a pediatric colonoscope in patients with Roux-en-Y gastrectomy and an intact major duodenal papilla. Exp Ther Med 28: 390.
5. Zhang N, Li G (2024) Comparing sedation protocols for endoscopic retrograde cholangiopancreatography (ERCP): A retrospective study. Heliyon 10: e27447.
6. Liu S, Fang C, Tan J, Chen W (2020) A comparison of the relative safety and efficacy of Laparoscopic Choledochotomy with Primary Closure and Endoscopic treatment for bile Duct Stones in patients with Cholelithiasis. J Laparoendosc Adv Surg Tech A 30: 742-748.
7. Bhardwaj AM, Trehan KK, Sharma V (2022) Laparoscopic common bile duct exploration after failed endoscopic retrograde cholangio-pancreatography: Our patient series over a period of 10 years. J Minim Access Surg 18: 533-538.
8. Cahyadi O, Tehami N, de-Madaria E, Siau K (2022) Post-ERCP Pancreatitis: Prevention, Diagnosis and Management. Medicina (Kaunas) 58: 1261.
9. Everett Simon M, Ahmed W, Dobson C, Haworth E, Jarvis M, et al. (2024) British Society of Gastroenterology Endoscopic Retrograde Cholangiopancreatography (ERCP) quality improvement programme: Minimum service standards and good practice statements. Frontline Gastroenterol 15: 445-471.
10. Zhang Y, Liang Y, Feng Y (2022) An insight on pharmacological and mechanical preventive measures of post-ercp pancreatitis (PEP)-A Review. Gastroenterol Insights 13: 387-403.
11. Dumonceau JM, Andriulli A, Deviere J, Mariani A, Rigaux J, et al. (2010) European Society of Gastrointestinal Endoscopy. European Society of Gastrointestinal Endoscopy (ESGE) Guideline: Prophylaxis of post-ERCP pancreatitis. Endoscopy 42: 503-515.
12. González JE, Peña RT, Torres JR, Alfonso MÁ, Quintanilla RB, et al. (2016) Endoscopic versus laparoscopic treatment for choledocholithiasis: a prospective randomized controlled trial. Endosc Int Open 4: E1188-E1193.
13. A Alghamdi BS, Sind OA, Rajab WH, Alzahrani SH, T Alrayes HA, et al. (2017) Open surgery versus endoscopic intervention in the management of bile duct stones. Egypt J Hosp Med 67: 705-712.