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Research Paper

Role of Endoscopic Biliary Stenting in the Management of Difficult Common Bile Duct Stones

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Abstract

Removing large or multiple common bile duct stones that cannot be cleared at first endoscopic retrograde cholangiopancreatography (ERCP) is difficult in resource-limited settings. This study assessed whether temporary plastic stenting promotes subsequent clearance of these "difficult" stones. In a prospective observational study at Bangabandhu Sheikh Mujib Medical University, Dhaka (November 2019 – March 2021), 35 adults with difficult common bile duct stones underwent endoscopic sphincterotomy followed by placement of a 7–10 Fr plastic stent. Stone size, number, index, and duct diameter were measured before stenting and at repeat ERCP three months later. Clearance rates and stent-related adverse events were recorded. Thirty-one patients completed follow-up. Mean stone size fell from 19.1 ± 2.1 mm to 15.8 ± 3.1 mm; mean stone number from 1.80 ± 0.74 to 1.45 ± 0.67; and mean stone index from 28.9 ± 9.2 mm to 20.9 ± 9.9 mm (all $p < 0.001$). Complete bile duct clearance at second-session ERCP was achieved in 69.7%, while 6.1% showed spontaneous passage. Complications were limited to stent migration (6%), occlusion (9%), and cholangitis (6%), with no procedure-related mortality. Short-term endoscopic biliary stenting safely reduces stone burden and enables successful second-session extraction in most patients with difficult common bile duct stones. It offers an effective bridge therapy where advanced lithotripsy techniques are unavailable.

Keywords: *Common Bile Duct Stones, Biliary Stenting, ERCP, Lithiasis.*

INTRODUCTION

Choledocholithiasis is defined as the presence of a stone within the common bile duct (CBD). Choledocholithiasis is one of the most common gastrointestinal diseases seen in clinical therapeutic endoscopy practice (Fujita et al., 2023). Choledocholithiasis can be primary, forming initially in the bile ducts, or secondary, originating in the gallbladder and passing into the bile ducts (Portincasa et al., 2023).

Approximately 25% of patients with CBD stones are asymptomatic, and a substantial number of these (30% to 50%) will eventually pass their CBD stone spontaneously and silently (Cianci & Restini, 2021). According to Sebghatollahi et al. (2023), many patients with gallstones develop choledocholithiasis. The natural history of CBD stones is not as fully understood as that of stones in the gallbladder (Sebghatollahi et al., 2023).

Clinical presentations of CBD stone include epigastric or right upper quadrant pain, especially if associated with jaundice and/or fever (Hilscher et al., 2020). CBD stone should also be considered in patients with acute pancreatitis, where gallstones migrating to the CBD are estimated to be a causal factor in up to 50% of cases (Cianci & Restini, 2021).

Currently, the standard treatment for CBD stones is endoscopic papillotomy and stone extraction (Lee et al., 2021). However, in approximately 10%-20% of patients with CBD stones,

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clearance of the biliary system cannot be obtained using these standard techniques and these kinds of stones are termed "difficult stones" (Suwatthanarak et al., 2024).

Meng et al. (2023) found that CBD stones were successfully removed in 75.3% (262) cases with the standard technique at ERCP. CBD stones were successfully removed with standard techniques at the ERCP session in a maximum of 89.5% cases (Meng et al., 2023). If CBD stones are left untreated, they may cause increases in morbidity and mortality due to several conditions, including obstructive jaundice, repeated attacks of cholangitis, pancreatitis, and secondary biliary cirrhosis (Geehan et al., 2022).

When CBD stones cannot be removed by conventional methods, newer techniques such as mechanical lithotripsy (ML), extracorporeal shock wave lithotripsy (ESWL), electrohydraulic lithotripsy (EHL), or laser lithotripsy and chemical dissolution can be used as therapeutic interventions (Seoane et al., 2024). Of the various modalities, biliary stenting has an important role in the conservative management of CBD stones refractory to conventional endoscopic removal (Lee et al., 2021).

Alhaddad et al. (2025) in their study found that there was a significant reduction in stone size, number, and stone index, with the availability of stone removal in the second session of ERCP. Choi et al. (2020) in their study found that the median number and size of stones significantly reduced after biliary stenting. Mansour et al. (2022) reported that in 95% cases, complete clearance of CBD stones occurred following an ERCP at an early stage. In 25% of patients, the stones had become smaller, were fragmented, and could be easily extracted (Mansour et al., 2022).

Tiwari et al. (2022) have reported that stone clearance was possible in 65% of a series of 107 patients with large (>20mm) and/or multiple (>3) large stones. A study carried out by MacCormick et al. (2021) stated that CBD stone extraction from 118 out of 139 patients is 84.9% and gallbladder stone extraction success rate from 97 out of 114 patients is 85.0% (MacCormick et al., 2021). Terada et al. (2024) in their series found that 73.6% of stones were either reduced in size or had fragmented after biliary stenting. In a study conducted by Omar (2020), plastic biliary stents were placed in 46 patients whose CBD stones could not be removed during the first ERCP session. However, during the next ERCP session, 63.04% of these patients had either successful removal of their stones or decreased stone size.

Although there are several methods for the extraction of bile duct stones but in Bangladesh, EST, balloon catheter, and dormie basket are commonly used, and lithotripsy is rarely used. Moreover, due to economic constraints, newer techniques such as mechanical lithotripsy (ML), extracorporeal shock wave lithotripsy (ESWL), electrohydraulic lithotripsy (EHL), or laser lithotripsy are not widely available in our country to remove difficult CBD stones. When a stone cannot be removed, biliary stenting is done with the idea that the stone will either pass spontaneously or will be removable in the next setting (Yang et al., 2024).

The research questions of this study are: (1) What are the outcomes of biliary stenting in patients with difficult CBD stones? and (2) How effective is biliary stenting in reducing stone size and facilitating subsequent removal? The research objectives are to evaluate the success rate of stone removal after biliary stenting and to assess the clinical implications of this intervention. Furthermore, the findings contribute to clinical practice and healthcare policy by providing insights into optimal management strategies for CBD stones, particularly in settings with limited access to advanced lithotripsy techniques.

RESEARCH METHOD

Table 1. Study Design and Setting

Study Aspect	Details
Study Design	Prospective observational study
Place of Study	Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka
Study Period	November 2019 to March 2021
Study Population	All patients aged 18 years or above with common bile duct (CBD) stones who underwent biliary stenting for difficult CBD stones at the Department of Gastroenterology, BSMMU, Dhaka

Source: Created by the Author 2025

The study used non-probability purposive sampling with an estimated sample size of 16, calculated using the formula based on a 5% significance level ($Z\alpha = 1.96$) and 80% power ($Z\beta = 0.84$). In this study, 35 patients were included despite the initial calculation of 16 participants based on the sample size formula. By increasing the sample size, the study mitigates the risk of Type I and Type II errors, providing greater statistical power to detect meaningful differences in stone characteristics and post-procedure outcomes.

Table 2. Selection criteria

Criteria	Details
Inclusion Criteria	Consecutive patients aged 18 years or above with CBD stones who underwent biliary stenting for difficult common bile duct stones.
Exclusion Criteria	1. Previous history of sphincterotomy. 2. Previous history of biliary stenting. 3. Concomitant hepatolithiasis.

Source: Created by the Author 2025

Table 3. Variables

Variable Category	Variables
Socio-demographic variables	- Age - Gender - Smoking
Clinical variables	- Abdominal pain - Fever - Jaundice - Itching - Pale stool - Concomitant cholelithiasis - History of cholecystectomy
Laboratory variables	- Complete Blood Count (CBC) - Serum bilirubin - Serum alkaline phosphatase - Serum ALT - Prothrombin time
Outcome variables (by ERCP)	- Stone number - Stone size - Stone index - Spontaneous stone clearance rate - Complete stone clearance rate at second session ERCP

Source: Created by the Author 2025

Study procedure

The patients diagnosed with CBD stones through Magnetic Resonance Cholangiopancreatography (MRCP) were treated with ERCP for stone removal. MRCP was used in this study because it is a non-invasive imaging method that provides detailed visualization of the bile ducts, making it preferable over other methods such as CT scan or ERCP (Lee et al., 2021). Informed consent was obtained, and all procedures were performed by experienced endoscopists. The study was approved by the Ethical Committee of Bangabandhu Sheikh Mujib Medical University. During ERCP, sphincterotomy was performed using either a standard pull-type or

needle-knife technique for precut papillotomy.

The size, number, and index of stones, as well as CBD diameter, were measured from the cholangiogram. Stone and CBD measurements were adjusted for radiograph magnification using a formula. After stone removal, a follow-up cholangiogram confirmed CBD clearance.

Antibiotics were routinely given before and after every procedure. Heart rate and peripheral oxygen saturation were continuously monitored. All patients received oxygen via a nasal cannula at 2 L/min during the procedure. All procedures were performed under general anesthesia by an anesthetist. In patients with difficult stones, a plastic 7–12 cm long, 7–10 Fr stent was inserted into the bile duct over a guidewire using standard technique, with the proximal end above the top of the CBD stone and the distal end left in the duodenal lumen. The stent was left in place for 3 months unless complications occurred earlier.

After three months, the CBD stones were reassessed by MRCP, and stone removal was attempted by ERCP. In cases of spontaneous clearance of stones, only the stent was removed after three months. The second ERCP was done by the same endoscopist. The number and size of CBD stones, stone index, stone clearance rate, as well as CBD diameter before and after stent placement, were evaluated.

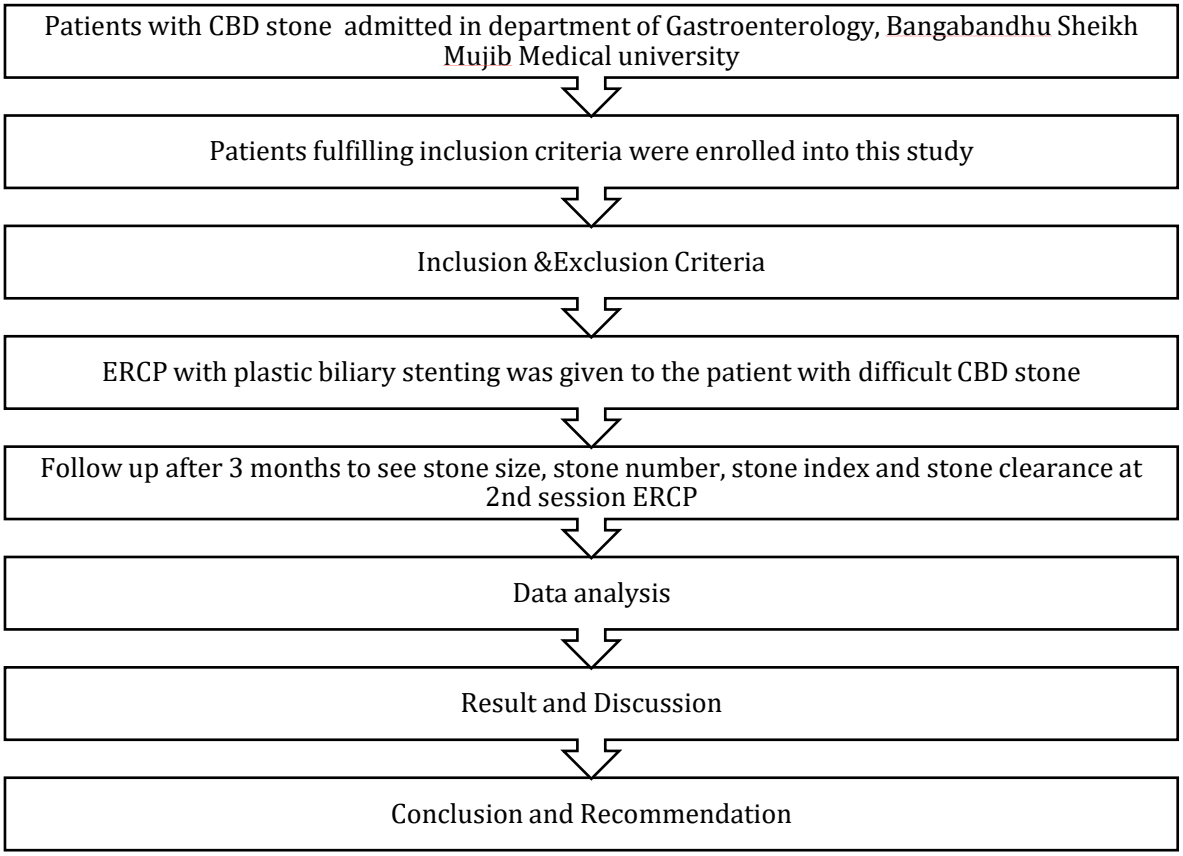

Figure 1. Study flow chart
Source: Created by the Author 2025

Data collection procedure

The data collection process for assessing stone characteristics, such as stone size, number, and index, was carried out using standardized procedures during the ERCP (Endoscopic Retrograde Cholangiopancreatography). Stone measurements were taken directly from the cholangiogram and adjusted for radiographic magnification using a specified formula. This ensured that the data

collected were accurate and reproducible. Furthermore, the study employed MRCP (Magnetic Resonance Cholangiopancreatography) both before and after stenting to provide a non-invasive method for confirming stone characteristics. This dual approach, combining ERCP and MRCP, allowed for comprehensive evaluation, ensuring reliable assessments of the stone size, number, and clearance status at follow-up sessions.

Data processing and analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 23.0 (SPSS Inc.; Chicago, IL, United States). Categorical data were presented as numbers and percentages. Numerical data were presented as mean and standard deviation. Stone sizes, stone number, stone index, and diameters of CBDs differences were analyzed with the paired t-test. Statistical significance was defined as $p < 0.05$.

Validity and Reliability Checks

To ensure data reliability, experienced endoscopists followed standardized protocols for ERCP procedures, minimizing variability in stone measurements. Imaging equipment was calibrated regularly to ensure accurate and consistent measurements. Stone characteristics were assessed at multiple stages, allowing for cross-validation. Statistical analysis using paired t-tests in SPSS confirmed the significance of pre- and post-stenting outcomes, ensuring that observed differences were meaningful and statistically valid.

Ethical consideration

Informed written consent was taken, and confidentiality was maintained both verbally and documentarily by using a separate locker and computer password. The protocol was approved by the ethical committee of Bangabandhu Sheikh Mujib Medical University, Dhaka.

The study followed established ERCP guidelines, ensuring consistency with best gastroenterology practices. Procedures like sphincterotomy and stent placement adhered to medical standards, with post-procedure care including antibiotics and oxygenation. Inclusion criteria matched established guidelines for difficult CBD stones, ensuring the study population was representative of typical clinical cases in gastroenterology departments.

Results and observations

This was a prospective observational study conducted in the Department of Gastroenterology, BSMMU, Bangladesh, during the period of November 2019 to March 2021. A total of 35 patients were included in this study. The results were as follows:

Table 4. Socio-demographic profile of the study population (n=35)

Socio-demographic profile	Number of patients	Percentage
Age (years)		
21-30	7	20.0
31-40	5	14.3
41-50	6	17.1
51-60	11	31.4
>60	6	17.1
Mean ±SD	47.7	±14.3
Range (min-max)	21	-70
Sex		

Male	14	40.0
Female	21	60.0
Marital status		
Married	33	94.3
Unmarried	2	5.7
Smoking status		
Smoker	8	22.9
Ex-smoker	1	2.9
Non smoker	26	74.3

Source: Created by the Author 2025

Table 4 shows that the mean age was found to be 47.7±14.3 years with a range from 21 to 70 years. 11 (31.4%) patients belonged to the age group 51-60 years, 21(60.0%) were female, 33(94.3%) were married, and 8(22.9%) patients were smokers.

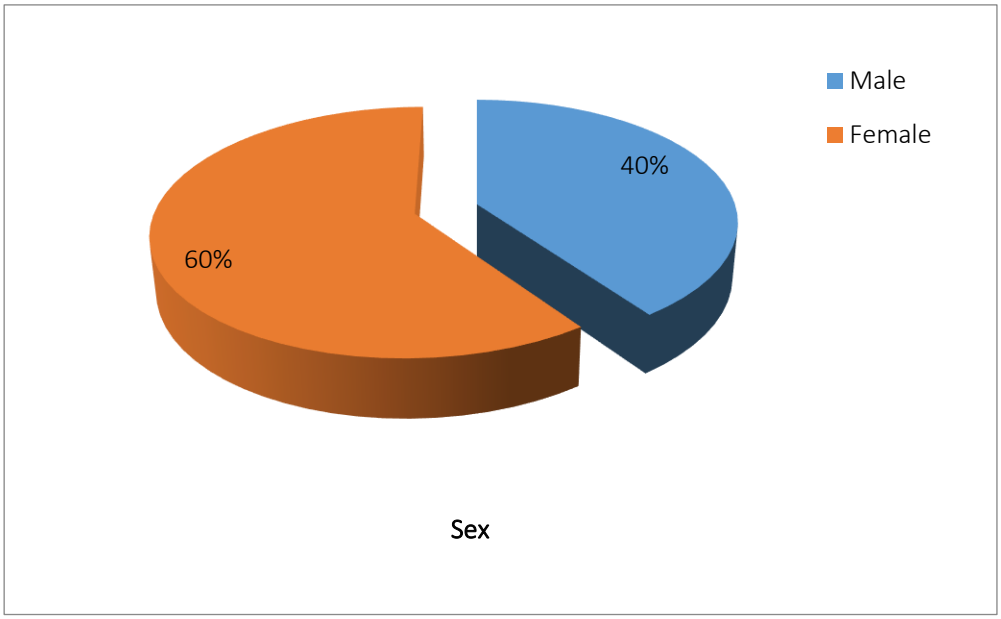

Figure 2. Pie chart showing the gender of the study population
Source: Created by the Author 2025

The pie chart illustrates the gender distribution of the study population. Females represent 60% of the total participants, while males make up 40%. This indicates a higher proportion of female participants compared to males in the study. The chart visually emphasizes the female majority with a larger orange segment, contrasted against the smaller blue segment for males.

Table 5. Clinical presentation of the study population (n=35)

Clinical presentation	Number of patients	Percentage
Abdominal pain	34	97.1
Fever	23	65.7
Jaundice	18	51.4
Itching	11	31.4
Pale stool	8	22.9
H/O cholecystectomy	16	45.7
Concomitant cholelithiasis	13	37.1

Source: Created by the Author 2025

Table 5, shows that 34(97.1%) patients had abdominal pain followed by 23(65.7%) had fever, 18(51.4%) had jaundice, 11(31.4%) had itching, 8(22.9%) had pale stool 16(45.7%) had H/O cholecystectomy and 13(37.1%) had concomitant cholelithiasis.

Table 6. Laboratory parameters of the study population (n=35)

Laboratory parameters	**Mean**	**±SD**
Hemoglobin (gm/dl)	11.9	±1.3
ESR (mm in 1st hour)	41.2	±20.5
TWBC (x10^9/L)	8.1	±2.7
Serum Bilirubin (mg/dl)	2.7	±2.7
Serum Alkaline phosphatase (U/L)	285.2	±216.7
Serum ALT (U/L)	103.3	±133.5
Prothrombin time (sec)	12.8	±1.6

Source: Created by the Author 2025

Table 6 shows that the mean hemoglobin was 11.9±1.3 gm/dl, ESR was 41.2±20.5 mm in 1st hour, TWBC was 8.1±2.7 x10^9/L, Serum Bilirubin was 2.7±2.7 mg/dl, Serum Alkaline phosphatase was 285.2±216.7 U/L, Serum ALT was 103.3±133.5 U/L, and Prothrombin time was 12.8±1.6 seconds.

Table 7. Initial ERCP findings of the study population (n=35)

Initial ERCP	**Mean±SD**
Stone size (mm)	17.1±2.1
Stone number	1.7±0.6
Stone index (mm)	24.9±7.3
CBD diameter (mm)	15.8±1.7
CBD stricture	3 (8.6%)
Periampullary diverticula	4 (11.4%)

Source: Created by the Author 2025

In initial ERCP, the mean stone size was found to be 17.1±2.1 mm, the mean stone number was 1.7±0.6, the mean stone index was 24.9±7.3 mm, the mean CBD diameter was 15.8±1.7 mm, 3(8.6%) patients had CBD stricture, and 4(11.4%) had periampullary diverticula.

Table 8. Comparison of size, number, and index of CBD stones and CBD diameter before and after stent placement in 31 patients.

ERCP	**Pre-stenting**	**Post-stenting**	**t-value**	**p value**
	Mean±SD	**Mean±SD**		
Stone size (mm)	19.1±2.1	15.8±3.1	6.310	0.001s
Stone number	1.80±0.74	1.45±0.67	4.062	0.001s
Stone index (mm)	28.9±9.2	20.9±9.9	8.528	0.001s
CBD diameter (mm)	17.0±1.7	15.2±2.2	4.891	0.001s

Source: Created by the Author 2025
s= significant
p-value reached from paired t-test

Table 8 shows that the mean stone size was 19.1±2.1 mm in pre-stenting and 15.8±3.1 mm in post-stenting. The mean stone number was 1.80±0.74 in pre-stenting and 1.45±0.67 in post-stenting. The mean stone index was 28.9±9.2 mm in pre-stenting and 20.9±9.9 mm in post-stenting. The mean CBD diameter was 17.0±1.7 mm in pre-stenting and 15.2±2.2 mm in post-stenting. The differences were statistically significant ($p<0.05$) between the two groups.

Table 9. Changes in stone size, number, and index after biliary stenting (n=31)

	Number of patients	**Percentage**
Stone size		
Decreased	22	71.0
Unchanged	9	29.0
Stone number		
Decreased	11	35.5
Unchanged	20	64.5
Stone index		
Decreased	27	87.1
Unchanged	4	12.9

Source: Created by the Author 2025

Table 9 shows that after biliary stenting, stone size was decreased in 71.0% patients, stone number was decreased in 35.5% patients, and stone index was decreased in 87.1% patients.

Table 10. ERCP procedure-related variables of biliary stenting in the study population (n=31)

ERCP procedure-related variables	**Number of patients**	**Percentage**
Method used		
Sphincterotomy	28	90.3
Papillary balloon dilatation	20	64.5
Precut done	3	9.7
Device used for stone extraction		
Balloon	31	100.0
Dormia basket	29	93.5

Source: Created by the Author 2025

Table 10 shows that 28(90.3%) patients used the sphincterotomy method, 31(100.0%) used a balloon for stone extraction, and 29(93.5%) used a Dormia basket for stone extraction.

Table 11. Stone clearance rate at 2nd session of ERCP (n=33)*

Outcome	**Number of patients**	**Percentage**
Successful	23	69.7
Unsuccessful	8	24.2
Spontaneous clearance	2	6.1

Source: Created by the Author 2025

***Note: Two patients dropped dropout due to loss of follow-up.**

Table 11 shows that stone could be extracted in 23(69.7) patients at follow-up ERCP, in 2(6.1%) patients, there was spontaneous clearance of stone, and in 8(24.2%) patients, stone extraction was unsuccessful at repeat ERCP.

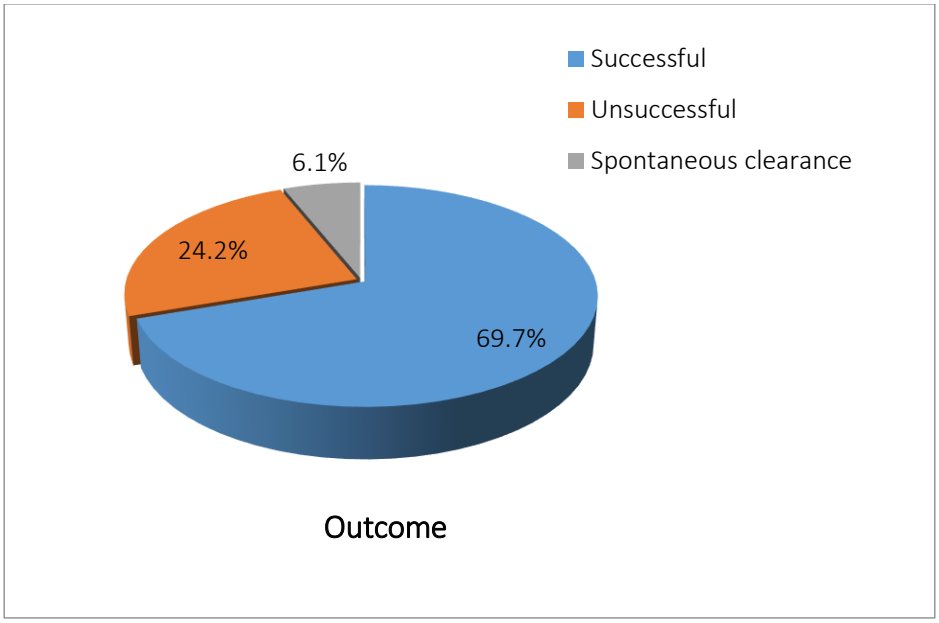

Figure 3. Pie chart showing the outcome of the study population
Source: Source: Created by the Author 2025

The pie chart illustrates the study population outcomes: 69.7% were successful, 24.2% unsuccessful, and 6.1% experienced spontaneous clearance, highlighting that most cases achieved success in the study.

RESULTS AND DISCUSSION

In this study, 35 patients with difficult CBD stones were included, with a mean age of 47.7 ± 14.3 years, and a predominance of females (60%). The demographic data showed that 74.3% of patients were non-smokers, which may correlate with a lower incidence of CBD stone complications related to smoking, as smoking is a known risk factor for biliary diseases. The clinical presentation indicated that abdominal pain was the most common symptom (97.1%), followed by fever (65.7%), jaundice (51.4%), and itching (31.4%). These symptoms are consistent with previous studies, such as those by Mortensen et al. (2021), who also observed similar symptom distributions in their cohorts, suggesting that these clinical signs are highly predictive of difficult CBD stones. Additionally, 45.7% of the patients had a history of cholecystectomy, which aligns with findings from Choe et al. (2021), where of patients had a prior cholecystectomy. This information is clinically relevant, as it highlights the high prevalence of post-cholecystectomy CBD stones, which often require advanced procedures like biliary stenting.

As part of the treatment, biliary stenting was used in cases where standard methods were unsuccessful. The study observed a high rate of stone clearance at the second ERCP session, with 69.7% of patients successfully having their stones removed. However, the rate of unsuccessful outcomes (24.2%) during the second ERCP warrants further exploration. It is possible that factors such as stent migration or occlusion contributed to this relatively high failure rate. Furthermore, cholangitis was observed in 6.0% of the patients after stenting, indicating the need for better management strategies to prevent infection. These complications might be attributed to the duration of stenting, the characteristics of the stones, or anatomical variations, such as periampullary diverticula, which were found in 11.4% of our patients. Periampullary diverticula have been reported to complicate ERCP procedures by affecting cannulation success, a factor that could contribute to the higher failure rate (Tabak et al., 2020).

In terms of clinical relevance, our findings highlight the importance of considering patient

demographics and anatomical factors when predicting outcomes of biliary stenting in difficult CBD stones. For instance, the significant reduction in stone size, number, and index observed post-stenting (71.0%, 35.5%, and 87.1%, respectively) suggests that biliary stenting can effectively reduce the burden of CBD stones in most patients. The reduction in stone size and index also aligns with findings from Elsebaey et al. (2024), who reported similar outcomes in their cohort. However, it is important to note that despite the reduction in stone size, a substantial proportion of patients (24.2%) did not experience successful stone removal at the second ERCP. This discrepancy may indicate underlying issues related to the stone characteristics, such as hardness or impaction, that are not entirely addressed by stenting alone. Adding effect sizes or confidence intervals in future studies would provide a more robust interpretation of these results, enhance the clarity of the findings, and better inform clinical practice.

Practically, our study suggests that while biliary stenting is an effective intervention for difficult CBD stones, the relatively high rate of unsuccessful outcomes at any stage of ERCP calls for a reevaluation of stent duration and post-procedure management (Pal & Ramchandani, 2024). In resource-limited settings, where advanced interventions may not always be available, optimizing the use of stents, enhancing training for endoscopists, and introducing protocols for managing stent-related complications could improve patient outcomes (Alhaidari et al., 2024). Additionally, the study's findings underscore the need for further research into the long-term effects of stenting, especially in terms of stent migration and occlusion, which may help refine future clinical guidelines and improve patient care.

In conclusion, while the study provides valuable insights into the effectiveness of biliary stenting for managing difficult CBD stones, there are several areas for improvement. The high rate of unsuccessful outcomes during the second ERCP warrants further investigation into the potential causes of stent migration and occlusion. Addressing these issues and expanding research into multi-center studies with larger sample sizes could enhance the practical applicability of these findings and contribute to more effective patient management strategies in the treatment of CBD stones.

CONCLUSION

This study demonstrates the effectiveness of biliary stenting in the management of difficult CBD stones, highlighting significant reductions in stone size, number, and index following stenting. The main findings of this study successfully fulfill the research objectives, confirming that biliary stenting is effective in reducing stone size and facilitating subsequent stone removal. Despite a high rate of successful stone clearance in the second ERCP (69.7%), a notable percentage of patients (24.2%) experienced unsuccessful outcomes, which suggests complications such as stent migration and occlusion. The study's limitations include a single-center design and a relatively small sample size, which may affect the generalizability of the findings. Future research should focus on multi-center studies with larger sample sizes to better understand the long-term effects of stenting and refine clinical guidelines. Additionally, addressing the limitations of current techniques and resource constraints could further improve patient outcomes. Furthermore, this study contributes to clinical practice by providing evidence-based guidance for the management of difficult CBD stones and informs healthcare policy regarding the availability and use of advanced lithotripsy techniques.

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