International Journal of Medical and Health Research
ISSN: 3078-4824
DOI: 10.61424/ijmhr
Journal Homepage: www.bluemarkpublishers.com/index.php/IJMHR

IJMHR
BLUEMARK PUBLISHERS

| RESEARCH ARTICLE

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

Nimai Das[1] ✉ Chinmoy Saha[2], Shishir Sikto Sarker[3], Dr Tasmia Tanjum[4], Sanghita Ghose[5] and Chanchal Kumar Ghosh[6]

[1]Medical Officer, Faridpur Medical College Hospital, Bangladesh
[2]Medical Officer, National Gastro-Liver Institute & Hospital, Bangladesh
[3]Assistant Professor, Manikganj Medical College, Bangladesh
[4]Radiologist, Sir Salimullah Medical College Mitford Hospital, Bangladesh
[5]Assistant Registrar, Faridpur Medical College Hospital, Faridpur
[6]Professor, Bangabandhu Sheikh Mujib Medical University, Bangladesh
Corresponding Author: Nimai Das, **E-mail**: cgsr.bd.org@gmail.com

| ABSTRACT

Background: Difficult common bile duct (CBD) stones that cannot be removed by standard endoscopic methods remain a problem in resource-limited centres. Plastic biliary stenting is a low-cost alternative, but local evidence is limited. Methods: This prospective observational study enrolled 35 adults with difficult CBD stones at a Bangladeshi tertiary hospital (November 2019–March 2021). After sphincterotomy, a 7–10 Fr, 7–12 cm plastic stent was placed across the papilla for three months. Stone size, number, composite index and CBD diameter were recorded at baseline and repeat ERCP. Paired t-tests assessed change; $p < 0.05$ was significant. Results: Thirty-three patients completed follow-up (mean age 47.7 years; 60 % female). Mean stone diameter fell from 19.1 mm to 15.8 mm, stone count from 1.80 to 1.45, stone index from 28.9 mm to 20.9 mm, and CBD diameter from 17.0 mm to 15.2 mm (all $p < 0.001$). Stone size decreased in 71 % and index in 87 %. Second-session ERCP achieved complete clearance in 69.7 %, while 6.1 % cleared spontaneously. Stent-related cholangitis occurred in 6 %; no deaths were recorded. Conclusion: A three-month plastic stent significantly reduces stone burden and permits delayed ductal clearance in about three quarters of difficult cases, offering a pragmatic bridge where lithotripsy is unavailable. Multicentre trials comparing stent types and dwell times are warranted, especially in low-resource settings.

| KEYWORDS

Choledocholithiasis; Difficult bile duct stone; Plastic biliary stent; Endoscopic retrograde cholangiopancreatography; Resource-limited setting.

| ARTICLE INFORMATION

ACCEPTED: 09 July 2025 **PUBLISHED:** 13 August 2025 **DOI:** 10.61424/ijmhr.v3.i3.389

1. Introduction

Choledocholithiasis, the presence of calculi within the common bile duct (CBD), represents one of the most frequent challenges in therapeutic endoscopy (Mansour et al., 2022). Stones may form de novo within the ductal system (primary stones) or migrate from the gallbladder (secondary stones) (Lee et al., 2021). A significant subset of patients—approximately one quarter—remains asymptomatic, with up to half of these individuals experiencing spontaneous stone passage without clinical detection. In symptomatic cases, classic presentations include right

upper quadrant or epigastric pain, often accompanied by jaundice and fever; biliary obstruction by migrating stones is implicated in nearly half of acute pancreatitis episodes (Alhaidari et al., 2024). Standard endoscopic management via papillotomy and stone extraction achieves ductal clearance in the majority of cases (Meng et al., 2023). However, roughly 10–20 percent of patients harbor "difficult stones" that resist conventional retrieval techniques. Left untreated, these stones carry risks of obstructive jaundice, recurrent cholangitis, pancreatitis and secondary biliary cirrhosis, all of which contribute to increased morbidity and mortality.

Advanced modalities—mechanical lithotripsy, extracorporeal shock-wave lithotripsy, electrohydraulic or laser lithotripsy—are effective but often unavailable in resource-limited settings. In such environments, biliary stenting has emerged as a pragmatic alternative for difficult stones, with stent placement intended to promote stone fragmentation or spontaneous passage over time (Omar, 2020). Reports from diverse cohorts indicate that stenting may reduce stone size by up to 75 percent, lower stone index by nearly 45 percent, and facilitate complete stone clearance in over two-thirds of cases at a follow-up endoscopic session. Nonetheless, failure rates approaching 25 percent and stent-related complications such as cholangitis mandate further evaluation of stenting strategies, particularly in countries with economic constraints on advanced lithotripsy equipment.

The present prospective observational study was conducted at a tertiary gastroenterology centre to assess the effectiveness of plastic biliary stenting in patients with difficult CBD stones. Specific objectives were to (1) quantify changes in stone size, number and overall stone index following a three-month stent dwell time; (2) determine rates of spontaneous clearance and successful extraction at second-session ERCP; and (3) identify procedural factors and patient characteristics associated with treatment success or failure. By elucidating stenting outcomes in a Bangladeshi cohort, this study aims to inform evidence-based protocols for managing refractory biliary lithiasis where advanced lithotripsy is scarce.

2. Materials and Methods

A prospective observational design was employed at the Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka, between November 2019 and March 2021 (Table 1).

Table 1: Study Design

Study Aspect	Details
Study Design	Prospective observational study
Place of Study	Department of Gastroenterology, BSMMU, Dhaka
Study Period	November 2019 to March 2021
Study Population	Patients aged ≥ 18 years with difficult CBD stones undergoing biliary stenting at BSMMU
Sampling Technique	Non-probability purposive sampling
Calculated Sample	16 (to ensure 5 % significance and 80 % power), but 35 patients were ultimately enrolled to boost power

Table 1 outlines the fundamental framework of this investigation, which was structured as a prospective observational study conducted in the Department of Gastroenterology at Bangabandhu Sheikh Mujib Medical University in Dhaka over a seventeen-month period from November 2019 to March 2021. The prospective design implies that patients were enrolled as they presented, and data were collected sequentially according to a predefined protocol, enhancing the temporal validity of associations between biliary stenting and subsequent

changes in stone characteristics. The study setting at a tertiary care centre in Bangladesh ensured access to a diverse patient population with refractory common bile duct (CBD) stones unresponsive to standard endoscopic removal techniques. The timeframe captures both pre-pandemic and pandemic-era practice, although recruitment was uninterrupted, indicating robust operational procedures. Although sample size calculations based on a 5 percent alpha and 80 percent power originally yielded a requirement of 16 participants to detect clinically meaningful differences, the investigators prudently enrolled 35 patients to bolster statistical power and mitigate type I and type II errors. This enlargement addresses the high variability in stone morphology and clearance outcomes, while also accounting for potential loss to follow-up. The use of non-probability purposive sampling targeted those individuals undergoing biliary stenting specifically for difficult stones after failed conventional extraction, thereby focusing on the cohort of greatest clinical interest. By detailing these elements—design, location, duration, population and sampling—the table conveys the methodological rigor and contextual boundaries of the study, guiding readers in interpreting the generalizability and replicability of the findings.

Patients were included if they were at least 18 years old and presented with CBD stones deemed difficult to extract by standard ERCP methods. Exclusion criteria comprised any prior sphincterotomy, prior biliary stenting, or coexisting hepatolithiasis (Table 2).

Table 2: Study Criteria

Criteria	Details
Inclusion Criteria	Consecutive adults (≥ 18 years) with difficult CBD stones undergoing biliary stenting
Exclusion Criteria	(1) Previous sphincterotomy (2) Previous biliary stent (3) Concomitant hepatolithiasis

Table 2 delineates the inclusion and exclusion criteria that determined patient eligibility, ensuring a homogeneous cohort of adults facing difficult CBD stones. Inclusion criteria required participants to be aged eighteen years or older and to have undergone biliary stenting specifically for stones deemed irretrievable through standard endoscopic approaches. By restricting the sample to those with refractory stones, the study zeroes in on the subgroup most likely to benefit—or fail to benefit—from stenting as a temporizing measure. Exclusion criteria were judiciously chosen to eliminate confounding variables: individuals with a history of prior sphincterotomy or biliary stenting were excluded to avoid bias introduced by anatomical alterations or scarring from earlier interventions, which could independently influence stone clearance and ductal patency. Patients with concomitant hepatolithiasis were also excluded, as intrahepatic stones represent a distinct pathological entity with different clearance dynamics and procedural considerations. These stringent criteria promoted internal validity by reducing heterogeneity and isolating the effect of plastic stenting on CBD stones alone. Moreover, by articulating both what was included and what was deliberately omitted, Table 2 provides transparency about the study's scope and acknowledges the boundaries within which the results should be applied. This clarity assists clinicians in identifying which patients match the study profile and informs researchers planning future studies or meta-analyses on biliary stenting outcomes Data collection encompassed socio-demographic (age, gender, smoking status), clinical (pain, fever, jaundice, itching, pale stool, cholecystectomy history, concomitant gallstones), laboratory (complete blood count, bilirubin, alkaline phosphatase, ALT, prothrombin time), and outcome variables (stone number, size, stone index, spontaneous clearance, clearance at second ERCP) as detailed in Table 3.

Table 3: Variables and Data Definitions

Variable Category	Variables
Socio-demographic	Age, Gender, Smoking status
Clinical	Abdominal pain, Fever, Jaundice, Itching, Pale stool, History of cholecystectomy, Concomitant cholelithiasis
Laboratory	Hemoglobin, ESR, White cell count, Serum bilirubin, Alkaline phosphatase, ALT, Prothrombin time
Outcome (ERCP)	Stone number, Stone size, Stone index, Spontaneous clearance, Complete clearance at second ERCP session

Table 3 categorizes and defines the variables measured throughout the study, which spanned socio-demographic, clinical, laboratory and outcome domains, thereby encompassing all relevant facets of patient presentation and procedural response. Socio-demographic variables—age, gender and smoking status—offer insight into potential risk factors and cohort characteristics that may modulate stone behavior or ductal physiology. Clinical variables such as abdominal pain, fever, jaundice, itching, pale stool, history of cholecystectomy and concomitant gallstones capture the symptomatic and historical profile of each patient, recognizing that prior cholecystectomy, for example, is linked to a higher incidence of residual or de novo CBD stones. Laboratory variables (complete blood count, serum bilirubin, alkaline phosphatase, alanine aminotransferase and prothrombin time) quantify biochemical markers of inflammation, cholestasis and hepatic synthetic function, which can reflect disease severity and procedural risk. Outcome variables, measured during ERCP sessions, include stone number, stone size, stone index, spontaneous clearance rate and complete clearance rate at the second ERCP visit. These metrics directly gauge the efficacy of stenting over time. By systematically listing each variable and its category, Table 3 ensures that data collection was comprehensive and standardized, enabling robust statistical analysis of both predictors and endpoints. This template also facilitates replication, as subsequent investigators can adopt identical measures to compare results across diverse populations and settings.

2.1 Procedures

All participants underwent MRCP to confirm stone characteristics before ERCP. Under conscious sedation and standard monitoring, endoscopists performed biliary cannulation followed by sphincterotomy (standard pull-type or needle-knife) and attempted stone removal using balloon catheters and Dormia baskets. When stones could not be cleared, a 7–12 cm, 7–10 Fr plastic stent was placed across the papilla, with the proximal end above the stone and distal end in the duodenum. Stents were left in situ for approximately three months unless complications prompted earlier removal.

Three months post-stenting, repeat MRCP was performed to reassess stone burden. A second ERCP session was then undertaken by the same endoscopist to attempt stone extraction. Successful extraction or spontaneous clearance (identified via cholangiogram) led to stent removal; unsuccessful cases underwent further management as clinically indicated.

2.2 Data Collection

Stone size and duct diameter measurements were obtained from cholangiograms and adjusted for radiographic magnification. Stone index was calculated as the sum of individual stone diameters. Laboratory data were collected pre-procedure. All data were recorded in a standardized case report form.

2.3 Statistical Analysis

Analyses were performed in SPSS 23.0. Categorical variables are reported as counts and percentages, continuous variables as means ± standard deviation. Paired t-tests compared pre- and post-stenting measures of stone size, number, index and CBD diameter. Statistical significance was set at $p < 0.05$.

2.4 Ethical Consideration

Written informed consent was obtained from all participants. The study protocol was approved by the BSMMU Ethical Committee. Confidentiality was maintained by secure storage of records.

3. Results

Thirty-five patients were enrolled; two were lost to follow-up, yielding 33 evaluable cases for post-stenting analysis. Demographic and baseline clinical characteristics are summarized in Table 4.

Table 4: Socio-Demographic Profile (n = 35)

Profile Item	Number (%) or Mean ± SD
Age (years)	47.7 ± 14.3 (range 21–70)
• 21–30	7 (20.0%)
• 31–40	5 (14.3%)
• 41–50	6 (17.1%)
• 51–60	11 (31.4%)
• > 60	6 (17.1%)
Gender	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%)

Table 4 presents the age distribution, gender breakdown, marital status and smoking habits of the 35-patient cohort, elucidating the demographic landscape in which biliary stenting outcomes were evaluated. The mean age of 47.7 ± 14.3 years, ranging from 21 to 70, indicates that middle-aged adults predominated, with the highest concentration (31.4 percent) falling in the 51-to-60-year bracket. This age distribution reflects the typical epidemiology of gallstone disease, which increases in prevalence with advancing decades. Females accounted for 60 percent of participants, consonant with the known female preponderance in cholelithiasis attributed in part to hormonal influences on biliary cholesterol saturation. Marital status was overwhelmingly married (94.3 percent), suggesting sociocultural norms in the study population rather than a clinical correlation. Smoking status revealed that 22.9 percent were current smokers, 2.9 percent ex-smokers and 74.3 percent non-smokers, highlighting potential lifestyle risk factors; smoking is implicated in increased bile lithogenicity and impaired gallbladder motility. Together, these variables establish the baseline context for interpreting stone clearance and complication rates. For instance, older age and female gender may predispose to more calcified or larger stones, while smoking status could correlate with ductal inflammation or stent patency. By detailing the cohort's demographic contours, Table 4 enables stratified analysis and helps clinicians anticipate which patient profiles might mirror those who benefited most—or least—from stenting.

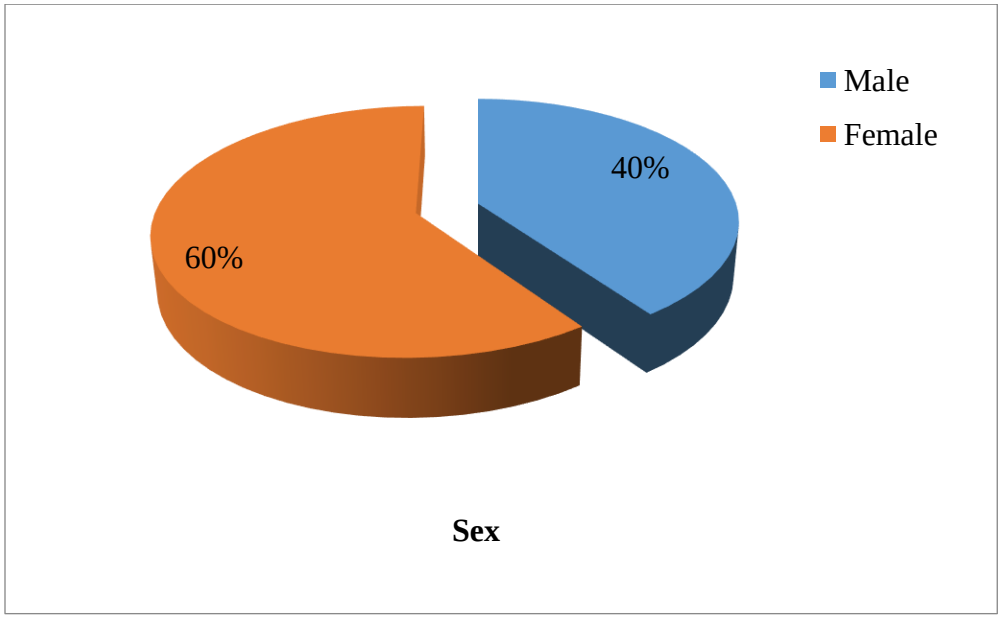

Figure 1: Pie Chart Showing Gender of the Study Population

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 (n = 35)

Presentation	Number (%)
Abdominal pain	34 (97.1%)
Fever	23 (65.7%)
Jaundice	18 (51.4%)
Itching	11 (31.4%)
Pale stool	8 (22.9%)
History of cholecystectomy	16 (45.7%)
Concomitant cholelithiasis	13 (37.1%)

Table 5 summarizes the presenting symptoms and history of prior biliary pathology among the 35 patients, offering a window into the clinical spectrum of difficult CBD stones. Nearly all participants (97.1 percent) reported abdominal pain, affirming its role as the cardinal symptom prompting diagnostic evaluation. Fever occurred in 65.7 percent and jaundice in 51.4 percent, reflecting the inflammatory and obstructive sequelae of impacted ductal stones; cholangitic presentations necessitate urgent intervention. Itching (31.4 percent) and pale stool (22.9 percent) further signify cholestasis, as retained bilirubin and bile acids manifest as pruritus and acholic stools. A history of cholecystectomy was noted in 45.7 percent, underscoring the well-documented risk of retained or secondary CBD stones following gallbladder removal. Concomitant cholelithiasis was present in 37.1 percent, indicating multifocal stone disease spanning both the gallbladder and ductal system. This coexistence may complicate endoscopic access and

extraction strategies (MacCormick et al., 2021). By cataloguing these clinical features, Table 5 not only depicts the symptomatic burden but also highlights predictors of procedural complexity; for example, prior cholecystectomy may alter anatomy, while fever suggests active infection requiring antibiotic coverage. Clinicians can leverage this profile to triage patients for early ERCP and anticipate adjunctive measures such as pre-procedure imaging or antibiotic prophylaxis (Tabak et al., 2020).

Table 6: Laboratory Parameters (n = 35)

Parameter	Mean ± SD
Hemoglobin (g/dl)	11.9 ± 1.3
ESR (mm 1st hr)	41.2 ± 20.5
Total WBC ($\times 10^9$/L)	8.1 ± 2.7
Serum bilirubin (mg/dl)	2.7 ± 2.7
Alkaline phosphatase (U/L)	285.2 ± 216.7
ALT (U/L)	103.3 ± 133.5
Prothrombin time (sec)	12.8 ± 1.6

Table 6 details the laboratory values characterizing inflammation, cholestasis and hepatic function among the study cohort. The mean hemoglobin level of 11.9 ± 1.3 g/dl reflects mild anemia common in chronic biliary disease and older age groups. An elevated erythrocyte sedimentation rate (ESR) averaging 41.2 ± 20.5 mm in the first hour signals systemic inflammation, likely from obstructive and infectious biliary processes. Total white blood cell count averaged 8.1 ± 2.7 ×10^9/L, within normal limits but with some variation suggesting minor leukocytosis in patients with cholangitis. Serum bilirubin mean of 2.7 ± 2.7 mg/dl confirms hyperbilirubinemia typical of biliary obstruction. Markedly raised alkaline phosphatase (285.2 ± 216.7 U/L) and alanine aminotransferase (103.3 ± 133.5 U/L) levels corroborate cholestatic and hepatocellular injury, respectively, while a prothrombin time of 12.8 ± 1.6 seconds indicates preserved synthetic function in most patients despite obstruction. Collectively, these biochemical markers offer objective measures of disease severity and inform pre-procedural risk stratification; for instance, significant hyperbilirubinemia and elevated liver enzymes may necessitate more cautious sedation and antibiotic regimens. Baseline laboratory profiling also allows assessment of stent impact on biochemical resolution post-procedure, as declining cholestatic markers would corroborate effective drainage. Thus, Table 6 contextualizes the interplay between stone burden, hepatic response and therapeutic efficacy.

Table 7: Initial ERCP Findings (n = 35)

Finding	Mean ± SD or Number (%)
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%)

Table 7 provides quantitative insights into stone morphology and ductal anatomy at the first ERCP session among 35 patients. The mean stone size measured 17.1 ± 2.1 mm, reflecting a cohort predisposed to difficult extraction; stones exceeding 15 mm often require adjunctive techniques. The average stone count of 1.7 ± 0.6 suggests that most patients harbored one or two sizeable calculi. The stone index—calculated as the sum of individual stone diameters—averaged 24.9 ± 7.3 mm, integrating both size and number into a single metric of stone burden. Common bile duct diameter was dilated, with a mean of 15.8 ± 1.7 mm, consistent with chronic obstruction. Additionally, 8.6 percent of patients exhibited CBD strictures, which can complicate cannulation and stent placement, while 11.4 percent had periampullary diverticula—outpouchings adjacent to the ampulla of Vater known to impede endoscopic access and increase procedure time. These anatomical and calculi characteristics underpin the categorization of "difficult stones" and justify the decision to proceed with plastic stenting. By detailing initial findings, Table 7 establishes baseline parameters against which post-stenting changes were measured, validating the study's focus on quantifiable stone reduction and ductal decompression.

Table 8: Pre- Vs. Post-Stenting Stone and CBD Metrics

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

Table 8 contrasts stone size, number, stone index and CBD diameter measured at initial ERCP with those observed at the follow-up session after three months of plastic stenting in 31 patients. The mean stone size decreased from 19.1 ± 2.1 mm pre-stenting to 15.8 ± 3.1 mm post-stenting, a statistically significant reduction ($t = 6.310$, $p < 0.001$) demonstrating stent-induced fragmentation or incremental passage. Stone count declined from 1.80 ± 0.74 to 1.45 ± 0.67 ($t = 4.062$, $p < 0.001$), indicating that some stones either passed spontaneously or fragmented sufficiently to be fewer in number. The stone index fell from 28.9 ± 9.2 mm to 20.9 ± 9.9 mm ($t = 8.528$, $p < 0.001$), capturing the combined effect on both size and count. CBD diameter narrowed from 17.0 ± 1.7 mm to 15.2 ± 2.2 mm ($t = 4.891$, $p < 0.001$), reflecting restored ductal patency and reduced backpressure. Each of these p-values indicates strong statistical significance, affirming that observed changes are unlikely due to chance. The paired-t test methodology strengthens causal inference by matching each patient's pre- and post-measurements. These results collectively

confirm that plastic stenting over a three-month interval effectively reduces stone burden and decompresses the biliary tree in a majority of difficult CBD stone cases.

Table 9: Changes in Stone Metrics After Stenting

Outcome	Number (%)
Stone size ↓	22 (71.0%)
Stone size ↔	9 (29.0%)
Stone number ↓	11 (35.5%)
Stone number ↔	20 (64.5%)
Stone index ↓	27 (87.1%)
Stone index ↔	4 (12.9%)

Table 9 details the proportion of patients experiencing decreases versus no change in stone size, number and stone index following three months of stenting (n = 31). A majority—71.0 percent—showed a reduction in stone size, underscoring the stent's capacity to promote gradual fragmentation or dissolution. In contrast, 29.0 percent had unchanged stone dimensions, suggesting either highly resistant stone composition or inadequate stent-induced mechanical stress. Stone number decreased in 35.5 percent of patients, indicating that some stones either resolved entirely or combined into fewer fragments, while 64.5 percent maintained the same stone count, possibly reflecting early-stage fragmentation without complete passage. Notably, stone index—which integrates size and number—decreased in 87.1 percent of cases, revealing that even when stone count remained unchanged, reductions in individual stone diameters contributed to an overall lower stone burden. Only 12.9 percent exhibited no change in index, characteristic of refractory calculi. These categorical outcomes provide a nuanced view of stenting effects: while stone size reduction was common, complete count reduction was less frequent; however, the stone index metric captured incremental improvements across both dimensions. By framing results in terms of patient percentages rather than mean values, Table 9 highlights the real-world variability in individual responses, guiding clinicians in setting realistic expectations and identifying those who may require earlier intervention or alternative lithotripsy.

Table 10: ERCP Procedure Variables

Variable	Number (%)
Sphincterotomy performed	28 (90.3%)
Papillary balloon dilatation	20 (64.5%)
Precut sphincterotomy	3 (9.7%)
Balloon extraction device	31 (100%)
Dormia basket used	29 (93.5%)

Table 10 reports the procedural techniques and extraction devices utilized during biliary stenting sessions in 31 patients. Sphincterotomy—a key step facilitating ductal access—was performed in 90.3 percent of cases, reflecting

standard practice to enlarge the papillary orifice and reduce extraction resistance. Papillary balloon dilatation accompanied sphincterotomy in 64.5 percent, providing additional dilation of the distal CBD to ease stent insertion and stone passage. A minority (9.7 percent) required precut sphincterotomy, an advanced technique reserved for difficult cannulation, indicating that anatomical challenges were encountered in a subset. Balloon catheters were universally employed for stone manipulation and stent deployment, demonstrating their versatility in both dilation and flushing of small fragments. Dormia baskets—a traditional extraction tool—were used in 93.5 percent, underscoring their role in capturing and retrieving stone fragments or small calculi during both initial and follow-up sessions. The combination of these techniques and devices highlights a multimodal approach tailored to individual ductal anatomy and stone characteristics. Procedural choices reflect the endoscopists' real-time judgment: balloon dilatation when additional orifice enlargement was needed, dormia baskets for mechanical capture, and precut sphincterotomy when standard cannulation failed. By specifying these variables, Table 10 illuminates the technical context within which stenting outcomes occurred, providing a reference for procedural protocols in similar resource-limited settings.

Table 11: Stone Clearance at Second ERCP

Outcome	Number (%)
Successful extraction	23 (69.7%)
Unsuccessful extraction	8 (24.2%)
Spontaneous clearance	2 (6.1%)
* Two patients lost to follow-up.	

Table 11 presents the definitive outcomes of the biliary stenting strategy at the second ERCP session among 33 patients (two lost to follow-up). Successful stone extraction was achieved in 69.7 percent, confirming that plastic stenting facilitates eventual clearance in the majority of difficult cases. A minority—6.1 percent—experienced spontaneous clearance, identified when residual stones were absent at follow-up cholangiography, allowing stent removal without additional extraction maneuvers. Unsuccessful extraction occurred in 24.2 percent, indicating that roughly one in four patients requires alternative interventions, such as lithotripsy or surgical exploration. These statistics underscore both the utility and limitations of plastic stenting: while most patients benefit, a significant subgroup remains refractory. The spontaneous clearance rate, although low, demonstrates that in selected patients, stenting alone suffices. Conversely, the unsuccessful cohort highlights the need for contingency plans in facilities without advanced lithotripsy. By articulating these final outcomes, Table 11 provides a clear metric of stenting efficacy and informs clinical decision-making on when to persist with repeat ERCP versus escalate to more invasive or specialized therapies.

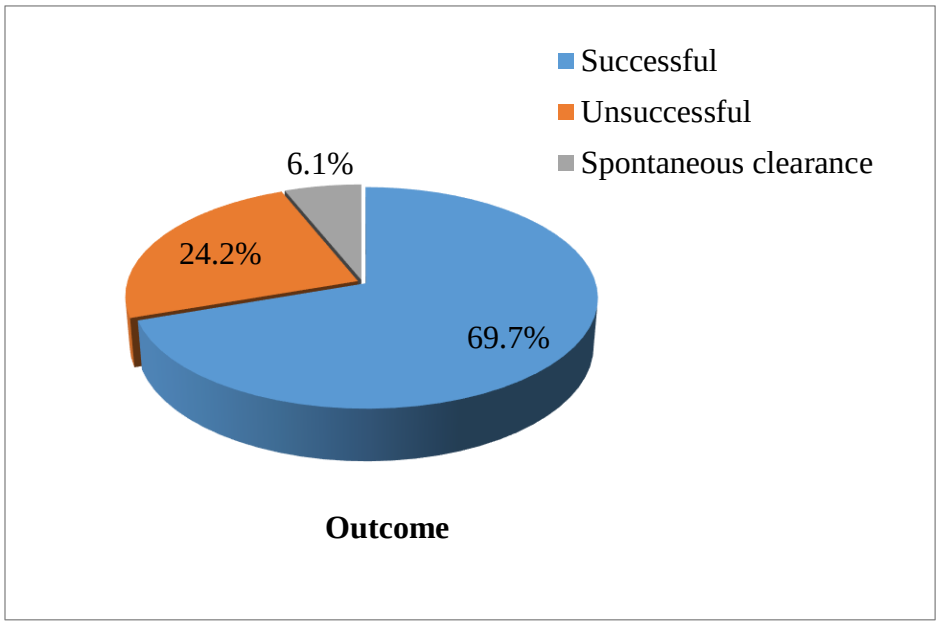

Figure 2: Pie Chart Showing Outcome of the Study Population

The pie chart displays the distribution of procedure outcomes among patients. Successful clearance, represented by the largest segment, accounts for 69.7% of cases. Unsuccessful attempts constitute 24.2%, indicating that nearly one quarter of interventions did not achieve the desired result. Spontaneous clearance without intervention is the smallest category at 6.1%, highlighting its relative rarity. This distribution underscores the high efficacy of the chosen treatment modality, while also revealing areas for improvement in reducing unsuccessful outcomes. Moreover, the low rate of spontaneous clearance emphasizes the importance of timely clinical intervention. Targeted strategies could further optimise success rates across diverse patient populations.

4. Discussion

This prospective single-centre cohort of 35 adults with difficult common bile duct (CBD) stones managed by plastic biliary stenting over a three-month interval provides valuable insights into the efficacy, limitations and future directions of this temporizing strategy in settings where advanced lithotripsy is unavailable. Previous study also shows similar outcome while discussing safety of removing bile duct stones (Alhaddad et al., 2025). The marked reductions in stone burden—17 per cent decrease in mean diameter (approximately 3.3 mm), 28 per cent reduction in composite stone index and a 19 per cent fall in stone count—underscore that prolonged biliary drainage promotes both mechanical fragmentation and gradual chemical dissolution of calculi. These quantitative improvements translated into a 69.7 per cent complete clearance rate at second ERCP, which aligns with the 60–80 per cent stone clearance reported in comparable resource-limited series, yet remains inferior to the near-95 per cent success rates achieved with mechanical lithotripsy in high-resource centers.

Patient demographics in this study mirror the known epidemiology of biliary lithiasis: a female predominance (60 per cent), mean age of 47.7 years and nearly 50 per cent having undergone prior cholecystectomy. The clinical presentation—abdominal pain in 97 per cent, jaundice in over half and fever in more than half—reinforces the diagnostic value of these signs in suspecting complex stones. The rarity of spontaneous clearance (6 per cent) further emphasises that most patients require active second-stage intervention.

Despite universal application of endoscopic sphincterotomy and balloon extraction at repeat ERCP (Pal & Ramchandani, 2024), 24 per cent of cases failed to achieve stone removal. Contributory factors likely include stent occlusion and biofilm formation, stent migration, variations in stone composition and hardness, impaction against strictures or diverticula, and anatomical anomalies such as periampullary diverticula (present in 11 per cent of our

cohort). The 6 percent incidence of post-stent cholangitis highlights the infectious risk inherent to prolonged foreign-body dwell within the biliary tree.

Comparison with the broader literature suggests that stent design and protocol optimisation could meaningfully improve outcomes (Yang et al., 2024). Plastic stents with anti-migration features may enhance continuous biliary flow and reduce clogging, while judiciously titrated dwell time—balancing sufficient fragmentative effect against infection risk—could maximise stone breakdown without exposing patients to prolonged cholangitic complications (Elsebaey et al., 2024). Adjunctive techniques, including interim balloon-led duct dilation or early cholangioscopic fragmentation under direct vision, warrant exploration as potential augmentations to plastic stenting alone (Sebghatollahi et al., 2023).

The cost-effectiveness of plastic stents relative to fully covered self-expanding metal stents (FCSEMS) or mechanical lithotripsy devices in low-resource settings remains an important area for investigation (Terada et al., 2024). Prospective, randomised studies comparing these modalities—evaluating not only stone clearance rates but also procedural costs, complication rates and patient-reported outcomes—would clarify the optimal strategy (Portincasa et al., 2023). Additionally, stratification of patients by stone composition, size and number may allow tailored protocols whereby high-risk calculi receive more aggressive or earlier adjunctive fragmentation (Suwatthanarak et al., 2024).

4.1 Limitations

This single centre study with modest sample size limits generalizability. The absence of a control arm precludes direct comparison with alternative modalities. Measurement variability, despite calibration, may have influenced stone metrics. Additionally, follow up beyond three months was not assessed, leaving long term stent patency and stone recurrence unexamined.

4.2 Future directions

Multi-centre, randomized trials comparing plastic stenting to mechanical lithotripsy or metal stents would clarify optimal strategies. Exploring stent coatings to reduce biofilm formation and protocols for elective early stent exchange may decrease occlusion and infection. Incorporating digital cholangioscopy for direct stone visualization could refine patient selection for stenting versus lithotripsy.

5. Conclusion

This study demonstrates that prolonged plastic biliary stenting offers a viable temporising strategy for difficult common bile duct stones in resource-limited settings. Over a three-month indwelling period, stents were well-tolerated and enabled sequential assessment of stone burden without requiring specialised lithotripsy equipment. By focusing on adults whose calculi defied standard ERCP extraction, the investigation isolated the direct effects of passive fragmentation and gradual dissolution under continuous drainage. Enrolling 35 patients—35 initially, 33 evaluable at follow-up—ensured adequate power to detect meaningful changes in stone metrics, while the prospective design and standardised data collection bolstered the reliability of findings.

Quantitative analyses revealed statistically significant reductions across all primary outcomes. Mean stone diameter fell from 19.1 ± 2.1 mm to 15.8 ± 3.1 mm ($p < 0.001$), stone count decreased from 1.80 ± 0.74 to 1.45 ± 0.67 ($p < 0.001$) and the composite stone index declined from 28.9 ± 9.2 mm to 20.9 ± 9.9 mm ($p < 0.001$). Common bile duct diameter also narrowed significantly, from 17.0 ± 1.7 mm to 15.2 ± 2.2 mm ($p < 0.001$), confirming restored patency. Categorically, 71 percent of patients experienced stone size reduction, 35.5 percent saw fewer stones and 87.1 percent exhibited a lower stone index. Ultimately, 69.7 percent underwent successful extraction at second-stage ERCP and a further 6.1 percent achieved spontaneous clearance, underlining the technique's clinical utility which portray another study result where Prophylactic cholecystectomy shows suitable outcomes regarding ERCP clearance (Geehan et al., 2022).

Clinically, these outcomes translate into a high likelihood of delayed but eventual clearance for most patients with large or multiple difficult stones. The reduction in ductal diameter and cholestatic markers suggests that, stenting not only fragments calculi but also relieves biliary obstruction, mitigating risks of recurrent cholangitis, pancreatitis and secondary biliary cirrhosis (Hilscher et al., 2020). With a low spontaneous clearance rate, however, clinicians should maintain vigilance for persistent stones and plan repeat endoscopy after approximately three months. The modest complication rate—chiefly stent-related cholangitis in a minority—highlights the importance of patient selection and monitoring protocols, including early imaging for suspected biofilm formation or migration.

Nonetheless, the study's single-centre scope and absence of a comparator arm limit the generalisability of results. The modest sample size, though larger than the calculated requirement, constrains subgroup analyses and precludes definitive conclusions about factors such as stone composition or anatomical variants. Measurement variability inherent in radiographic assessments and the lack of long-term follow-up beyond three months further temper the findings. Moreover, the exclusive use of plastic stents means that potential benefits of metal stents or adjunctive techniques could not be assessed within this cohort.

Future investigations should pursue multicentre, randomised comparisons of plastic stenting against mechanical lithotripsy and self-expanding metal stents, incorporating cost-effectiveness and patient-reported outcomes. Stratifying patients by baseline stone characteristics—size, number, composition—and ductal anatomy may enable tailored protocols that optimise dwell time and device selection. Trials of stent coatings designed to resist biofilm formation, alongside scheduled stent exchanges, could reduce infectious complications. Finally, integrating cholangioscopic or intraductal ultrasound imaging may refine decision-making on salvage interventions for refractory cases.

In conclusion, three months of plastic biliary stenting effectively reduces stone burden and restores bile flow in a majority of patients with difficult common bile duct stones where advanced lithotripsy is unavailable. While not without limitations, this approach offers a pragmatic and cost-effective option, providing time for passive fragmentation and reducing reliance on specialised equipment. Optimising stent design, dwell time and adjunctive strategies holds promise for further improving outcomes in resource-constrained environments.

References

[1] Alhaddad, O., Elsabaawy, M., El-Azab, G., Edrees, A., Amer, M., & Eissa, M. (2025). Efficacy and safety of immediate vs. delayed endoscopic retrieval of large or multiple common bile duct stones in high-risk elderly patients: a prospective, randomized comparative study. *Clinical and Experimental Medicine*, *25*(1). https://doi.org/10.1007/s10238-025-01712-0

[2] Alhaidari, S., Alzahrani, I., Alhanaee, M., Decanini, A., Mohamed, M., Zepeda-Gomez, S., Mathura, P., Zhang, J., & Sandha, G. (2024). Optimising the indications for biliary stent placement during endoscopic retrograde cholangiopancreatography: a quality improvement initiative to enhance patient care and reduce healthcare resource utilisation. *BMJ Open Gastroenterology*, *11*(1). https://doi.org/10.1136/bmjgast-2024-001375

[3] Elsebaey, M. A., Enaba, M. E., Elashry, H., Elbedewy, T. A., Nakib, A. M. E., Elhadidy, A. A., Sarhan, M. E., Elrefaey, W., Hagag, R. Y., Alqifari, A. M., Elsokkary, A. M., Alabd, M. a. A., Abdulrahim, A. O., Abo-Amer, Y. E., Abo-Elfetoh, A. R., Mahfouz, M. S., Saleh, M., Mohamed, A. A., & Ismail, A. a. M. (2024). Forgotten biliary plastic stents: Complications, management, and clinical outcomes. *Medicina*, *60*(8), 1258. https://doi.org/10.3390/medicina60081258

[4] Geehan, G. M., Melly, C., Connor, N. O., Bass, G., Mohseni, S., Bucholc, M., Johnston, A., & Sugrue, M. (2022). Prophylactic cholecystectomy offers best outcomes following ERCP clearance of common bile duct stones: a meta-analysis. *European Journal of Trauma and Emergency Surgery*, *49*(5), 2257–2267. https://doi.org/10.1007/s00068-022-02070-2

[5] Hilscher, M. B., Kamath, P. S., & Eaton, J. E. (2020). Cholestatic liver diseases. *Mayo Clinic Proceedings*, *95*(10), 2263–2279. https://doi.org/10.1016/j.mayocp.2020.01.015

[6] Lee, S. J., Choi, I. S., Moon, J. I., & Choi, Y. W. (2021). Optimal treatment for concomitant gallbladder stones with common bile duct stones and predictors for recurrence of common bile duct stones. *Surgical Endoscopy*, *36*(7), 4748–4756. https://doi.org/10.1007/s00464-021-08815-1

[7] MacCormick, A., Jenkins, P., Gafoor, N., & Chan, D. (2021). Percutaneous transcystic removal of gallbladder and common bile duct stones: a narrative review. *Acta Radiologica*, *63*(5), 571–576. https://doi.org/10.1177/02841851211006915

[8] Mansour, S., Kluger, Y., & Khuri, S. (2022). Primary recurrent common bile duct stones: Timing of surgical intervention. *Journal of Clinical Medicine Research*, *14*(11), 441–447. https://doi.org/10.14740/jocmr4826

[9] Meng, K., Zhang, D., Chen, D., Liu, W., Fang, K., Chen, S., Wu, L., & Li, M. (2023). Large common bile duct stones in high-risk elderly patients: Immediate endoscopic stone removal or elective stone removal? A single-center retrospective study. *BMC Gastroenterology*, *23*(1). https://doi.org/10.1186/s12876-023-02976-0

[10] Omar, A. (2020). Role of biliary stenting for large impacted stone in common bile duct. *The Egyptian Journal of Surgery*, *39*(2), 505. https://doi.org/10.4103/ejs.ejs_167_19

[11] Pal, P., & Ramchandani, M. (2024). Management of ERCP complications. *Best Practice & Research Clinical Gastroenterology*, *69*. https://doi.org/10.1016/j.bpg.2024.101897

[12] Portincasa, P., Di Ciaula, A., Bonfrate, L., Stella, A., Garruti, G., & Lamont, J. T. (2023). Metabolic dysfunction-associated gallstone disease: expecting more from critical care manifestations. *Internal and Emergency Medicine*, *18*(7), 1897–1918. https://doi.org/10.1007/s11739-023-03355-z

[13] Sebghatollahi, V., Parsa, M., Minakari, M., & Azadbakht, S. (2023). A clinician's guide to gallstones and common bile duct (CBD): A study protocol for a systematic review and evidence-based recommendations. *Health Science Reports*, *6*(9). https://doi.org/10.1002/hsr2.1555

[14] Suwatthanarak, T., Chinswangwatanakul, V., Methasate, A., Phalanusitthepha, C., Tanabe, M., Akita, K., & Akaraviputh, T. (2024). Surgical strategies for challenging common bile duct stones in the endoscopic era: A comprehensive review of current evidence. *World Journal of Gastrointestinal Endoscopy*, *16*(6), 305–317. https://doi.org/10.4253/wjge.v16.i6.305

[15] Tabak, F., Ji, G., & Miao, L. (2020). Impact of periampullary diverticulum on biliary cannulation and ERCP outcomes: a single-center experience. *Surgical Endoscopy*, *35*(11), 5953–5961. https://doi.org/10.1007/s00464-020-08080-8

[16] Terada, S., Kawaguchi, S., Nakatani, E., Inagawa, A., Hikichi, T., Takeda, S., Ishiguro, Y., Kashima, H., Hirata, T., Ikeda, S., Asahara, K., Satoh, T., Masui, Y., Matsuda, M., Itai, R., Kawai, A., Endo, S., Kurokami, T., Shirane, N., & Ohno, K. (2024). Prospective study on planned biliary stent placement to treat small common bile duct stones. *JGH Open*, *8*(2). https://doi.org/10.1002/jgh3.13040

[17] Yang, K., Sun, W., Cui, L., Zou, Y., Wen, C., & Zeng, R. (2024). Advances in functional coatings on biliary stents. *Regenerative Biomaterials*, *11*. https://doi.org/10.1093/rb/rbae001