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ROLE OF BILIARY STENTING IN THE MANAGEMENT OF LARGE OR MULTIPLE COMMON BILE DUCT STONES

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Abstract

Background:
Difficult common bile duct (CBD) stones, characterized by large size (≥15 mm), multiplicity, or impaction, present significant challenges to endoscopic clearance. Advanced lithotripsy techniques are effective but remain costly and limited in availability in resource-constrained settings. Biliary stenting has been proposed as an interim or adjunctive approach to facilitate subsequent clearance.

Objective: *This study aimed to evaluate the efficacy and safety of biliary stenting in reducing stone burden and improving clearance rates in patients with large or multiple CBD stones.*

Methods:
A prospective observational study was conducted at Faisalabad Teaching Hospital over six months after ethical approval from the institute and department ((Dec to May 2025) (enrolling 60 patients with difficult CBD stones in whom complete clearance was not feasible during the index ERCP. Patients underwent placement of a 7–10 Fr plastic biliary stent, followed by repeat ERCP after three months . Stone characteristics, reduction in stone size and number (stone index), clearance rates, and procedure-related complications were recorded. Statistical analyses included paired t-tests, chi-square tests, and logistic regression.

Results: *The mean age of patients was 48.7 ± 11.9 years, with 53.3% males. Large stones were present in 36 patients (60%), while 24 (40%) had multiple stones. The median largest stone diameter decreased from 17 mm to 9 mm post-stenting ($p < 0.001$), with a significant reduction in stone number as well ($p < 0.001$). Definitive clearance without further intervention was achieved in 61.7% of patients, while 38.3% required additional ERCP or surgery. Complication rates were low and not statistically different between groups.*

Conclusion:
Biliary stenting is a safe and effective strategy for managing large or multiple CBD stones, significantly reducing stone burden and facilitating subsequent clearance.

INTRODUCTION

Common bile duct (CBD) stones, or choledocholithiasis, are among the most prevalent biliary tract disorders, with an estimated incidence of 10–15% in patients undergoing cholecystectomy for symptomatic gallstones (1). They can lead to serious complications such as biliary obstruction, acutecholangitis, and pancreatitis if not managed

effectively (2). Endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and stone extraction is considered the standard of care, achieving high clearance rates in routine cases (3, 4). However, removal becomes challenging in "difficult stones," typically defined as stones ≥15–20 mm, multiple stones (≥3), impacted stones, or stones associated with a dilated bile duct (5). In such scenarios, complete clearance at the first ERCP attempt is often unsuccessful, and repeated interventions may be required. Studies suggest that approximately 10–15% of patients with difficult CBD stones cannot achieve clearance with standard endoscopic techniques. Advanced modalities such as mechanical lithotripsy, laser lithotripsy, or cholangioscopy-guided interventions have improved outcomes but remain limited in availability and cost, particularly in resource-constrained settings(6).

Biliary stenting has gained recognition as an effective interim or adjunctive measure in managing these complex cases. Placement of a plastic biliary stent ensures continuous drainage, reduces biliary pressure, and facilitates gradual stone fragmentation or size reduction through mechanical friction and changes in bile flow(7). Evidence suggests that this approach enhances stone clearance during subsequent ERCP sessions, reduces the incidence of cholangitis, and improves patient safety(8).

In elderly or high-risk surgical patients, temporary stenting provides a safer bridge until definitive therapy, while in others, it minimizes the need for surgical exploration and its associated morbidity(7). Furthermore, multiple studies report that stenting not only reduces stone size but also improves duct clearance rates at follow-up ERCP, often exceeding 90% success(9). Despite this, gaps remain regarding the optimal stent type, number, and replacement interval, as well as predictors of treatment failure. Given the limited regional data, particularly from South Asia, further evaluation of stenting as a strategy for large or multiple CBD stones is essential. This study aims to provide evidence on its efficacy in reducing stone burden and improving clearance outcomes, thereby informing local clinical practice and contributing to guideline development.

METHODOLOGY:

This study was designed as a prospective observational analysis and conducted in the Department of Gastroenterology at Faisalabad Teaching Hospital following ethical approval from the institutional review board (letter no. 48/ERC/FMU/2024-25/05. The duration of the study was six months from the date of approval (Dec to May 2025). A total of 60 patients were enrolled, with the sample size calculated using the WHO calculator by assuming an anticipated prevalence of CBD stones of 10%, a margin of error of 8%, and a 95% confidence interval.

All adult patients presenting with difficult common bile duct stones were screened for eligibility. The inclusion criteria were consisted of patients with large stones, defined as a diameter of ≥15 mm, or multiple stones, defined as three or more, in whom complete clearance during the index ERCP session was not feasible. Patients undergoing plastic biliary stent placement without stone extraction at the first ERCP were included. Those with uncorrectable coagulopathy, altered gastrointestinal anatomy precluding ERCP, major cardiorespiratory compromise, or other contraindications to endoscopic intervention were excluded.

The procedure was started with an initial ERCP under standard sedation, during which biliary cannulation and sphincterotomy was attempted. If stone extraction is unsuccessful due to size, number, or impaction, a 7–10 Fr plastic biliary stent was deployed to maintain ductal drainage. The stent was left in situ for approximately three months, during which patients were monitored for symptoms such as jaundice, abdominal pain, or cholangitis. Routine laboratory tests and imaging studies were performed when clinically indicated.

At the end of the stenting period, patients underwent a second ERCP. During this session, attempts were

made to achieve complete clearance of stones using standard endoscopic techniques such as balloon or basket extraction and mechanical lithotripsy if required. The number and size of stones was documented before and after stenting using fluoroscopic cholangiography. The "stone index" was calculated as the sum of diameters (in centimeters) multiplied by the number of stones for each patient, both before and after stenting, to objectively measure changes in stone burden.

Data was collected on demographic variables (age, sex), clinical features, stone characteristics, type and size of stent, interval between procedures, and occurrence of procedure-related or stent-related complications such as cholangitis, pancreatitis, stent migration, or occlusion. The primary outcome was the reduction in stone index following biliary stenting. Secondary outcomes include the rate of complete duct clearance, the number of ERCP sessions required, the need for surgical intervention, and the incidence of adverse events.

Data entry and statistical analysis was performed using SPSS version 25. Continuous variables such as age, stone size, and stone index was expressed as mean ± standard deviation, while categorical variables such as sex, stone clearance are summarized as frequencies and percentages. Mann Whitney U test was be used to compare changes in the stone index before and after stenting. Chi-square test was applied for categorical outcomes. Logistic regression was conducted to identify independent predictors of stone clearance or stent failure. A p-value of less than 0.05 was considered statistically significant.

RESULTS:

A total of 60 patients were included in the study, with a mean age of 48.7 ± 11.9 years (range: 30–69 years). The cohort comprised 32 males (53.3%) and 28 females (46.7%). Large stones were identified in 36 patients (60.0%), while 24 patients (40.0%) had multiple stones. The median largest stone diameter before stenting was 17 mm (IQR: 15–19 mm), which reduced to 9 mm (IQR: 7–11 mm) following stenting. Similarly, the median number of stones per patient decreased from 1 (IQR: 1–3) pre-stenting to 1 (IQR: 1–2) post-stenting. Further intervention in the form of ERCP or surgery was required in 23 patients (38.3%), whereas 37 patients (61.7%) achieved clearance without additional procedures.

The median largest stone diameter decreased significantly from 17 mm (IQR: 15–19 mm) pre-stenting to 9 mm (IQR: 7–11 mm) post-stenting ($p < 0.001$). Similarly, the median number of stones per patient was reduced from 1 (IQR: 1–3) before stenting to 1 (IQR: 1–2) after stenting ($p < 0.001$). These findings indicate a substantial reduction in both stone size and number following stent placement. Definitive clearance without further intervention was achieved in 24 of 36 patients (66.7%) with large stones and 13 of 24 patients (54.2%) with multiple stones; however, this difference was not statistically significant ($p = 0.48$). Patients with multiple stones exhibited a greater reduction in stone number (median reduction of 2.2 vs. 0.3 in the large stone group, $p = 0.01$), while mean reduction in stone size was similar between the groups. Overall, both groups benefited from stenting, although multiple stones were associated with a higher tendency to require further intervention. Patients who required additional ERCP or surgery tended to be younger (45.7 ± 12.3 vs. 50.6 ± 11.5 years), although this was not statistically significant ($p = 0.13$). Gender distribution and stone type were comparable across both groups. Mean stone size reduction was slightly lower among patients requiring further intervention (6.5 mm vs. 8.2 mm), but this difference also failed to reach statistical significance. Complication rates were higher in the intervention group (13.0% vs. 5.4%), though not statistically significant. These results suggest that age and stone reduction trends may influence outcomes, but no strong predictors were identified. None of the assessed variables including age, gender, stone type, or stone size reduction emerged as significant predictors of the need for additional procedures. Although younger age

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and multiple stones showed a trend toward higher risk, these associations did not reach statistical significance. This suggests that the efficacy of CBD stenting is generally consistent across patient subgroups in this sample.

Table 1. Baseline demographic and clinical characteristics (n = 60)

Variable		Value
Age (years)	Mean ± SD	48.7 ± 11.9
Gender	Male	32 (53.3%)
	Female	28 (46.7%)
Stone type	Large	36 (60.0%)
	Multiple	24 (40.0%)
Further intervention	Yes	23 (38.3%)
	No	37 (61.7%)

Table 2. Stone characteristics pre- and post-stenting

Parameter	Pre-stenting	Post-stenting	p-value
Number of stones per patient	1 (1–3)	1 (1–2)	<0.001
Largest stone diameter (mm)	17 (15–19)	9 (7–11)	<0.001

Table 3. Comparative outcomes by stone type

Outcome	Large stones (n=36)	Multiple stones (n=24)	p-value
Definitive clearance (no further intervention)	24 (66.7%)	13 (54.2%)	0.48
Required further intervention	12 (33.3%)	11 (45.8%)	
Mean reduction in largest stone size (mm)	7.9	5.4	0.21
Mean reduction in number of stones	−0.3	−2.2	0.01

Table 4. Comparative outcomes by intervention requirement

Variable	No further intervention (n=37)	Further intervention (n=23)	p-value
Age (years, mean ± SD)	50.6 ± 11.5	45.7 ± 12.3	0.13
Gender (M/F)	20/17	12/11	1.00
Stone type (Large/Multiple)	24/13	12/11	0.48
Mean stone size reduction (mm)	8.2	6.5	0.19

Table 5. Logistic regression: predictors of further intervention

Predictor	Adjusted OR	95% CI (Lower–Upper)	p-value
Age (per year increase)	0.97	0.92 – 1.02	0.14
Male gender	1.01	0.37 – 2.78	0.99
Stone type (Multiple vs Large)	1.46	0.50 – 4.23	0.48
Stone size reduction (per mm)	0.88	0.71 – 1.07	0.18

DISCUSSION:

The present study demonstrates that biliary stenting is an effective strategy in the management of difficult common bile duct (CBD) stones, particularly when stones are large or multiple. Stenting resulted in a significant reduction in stone size, with the median largest diameter decreasing from 17 mm to 9 mm, and also reduced the number of stones per patient. Clearance was achieved in more than 60% of cases without the need for additional intervention. These findings highlight the value of stenting as both a bridging and definitive measure in clinical practice(1, 3).

The reduction in stone burden following stenting is likely explained by the combined effects of continuous bile flow, mechanical friction, and alterations in ductal pressure, which facilitate fragmentation and dissolution of calculi. Similar mechanisms have been described in prior studies, where the remodeling effect of stents resulted in improved stone retrievability at subsequent ERCP (10, 11).

Subgroup analysis showed that patients with multiple stones achieved greater numerical reduction in calculi, whereas those with large stones demonstrated higher clearance rates at follow-up(12). Although definitive clearance was slightly better in the large stone group (66.7%) compared with the multiple stone group (54.2%), this difference was not statistically significant. These results resonate with findings by Amaral et al., who observed that cholangioscopy-guided lithotripsy offered superior clearance for multiple stones, but emphasized that stenting still played a pivotal role where advanced modalities were unavailable(9).

The study provides important regional evidence from Pakistan, where data on stenting outcomes are limited despite the high prevalence of gallstone disease. Similar challenges in North India, with up to 20% of ERCP procedures involving difficult stones (5, 13). In both contexts, limited access to advanced devices such as cholangioscopes and laser lithotripters underscores the value of stenting as a widely available, cost-effective, and pragmatic alternative.

Interestingly, the present study did not identify significant predictors of stenting success or the need for further intervention. While younger patients and those with multiple stones showed a trend toward higher risk of repeat procedures, logistic regression did not confirm these associations. This contrasts with Fujita et al., who emphasized stone size and multiplicity as independent predictors of failure(2). Similar observations were made in a European multicenter registry by Masciangelo et al, which showed that large stone size (>20 mm) was the strongest predictor of failed clearance at first ERCP(14).

The safety profile observed was favorable, with only modest complication rates. Patients requiring further interventions had slightly higher rates of cholangitis and stent-related issues, but these differences were not statistically significant. Lyu et al similarly reported low complication rates, supporting the safety of stenting as an interim strategy, especially in elderly or high-risk patients for whom immediate stone extraction poses greater risks (15).

When compared with newer technologies, biliary stenting offers lower absolute clearance rates but superior accessibility. Cholangioscopy-guided laser or

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electrohydraulic lithotripsy, as reported by Putri et al., achieves clearance rates above 95% in expert centers, but the cost and technical demands limit widespread adoption(16). In contrast, plastic stenting is inexpensive, simple to perform, and effective in most patients, making it particularly valuable in resource-limited healthcare systems such as South Asia (17).

The study utilized plastic biliary stents, which are commonly preferred for their affordability and availability. However, evidence suggests that fully covered self-expanding metal stents (FCSEMS) may provide superior duct clearance by exerting stronger radial force, though at the expense of higher migration rates and costs (7). Recent work by García et al. has shown that FCSEMS facilitated duct clearance in up to 92% of patients with refractory stones, supporting their selective use(18). Moreover, while three months of stenting was effective in this cohort, the optimal duration remains uncertain, with most guidelines recommending stent exchange at 3–6 months to minimize occlusion risk(2).

When aligned with international findings, the present clearance rate of 61.7% without further intervention is somewhat lower than the 70–80% reported in Western cohorts (6, 8). This may reflect differences in patient selection, operator expertise, and access to ancillary devices. Nonetheless, the observed reduction in stone size from 17 mm to 9 mm mirrors the early findings of Cipolletta et al, indicating that the core mechanism of stenting has remained effective across decades and diverse populations(6).

Present study reinforces the role of biliary stenting as a safe and effective strategy for difficult CBD stones, especially in settings where advanced lithotripsy is unavailable. The findings are consistent with recent international work, though they highlight slightly lower clearance rates in regional practice. Future research should explore optimization of stent type, number, and replacement interval, as well as cost-effectiveness analyses tailored to resource-constrained environments(17). Collectively, this evidence supports incorporating stenting not merely as a rescue measure but as a proactive strategy in the management algorithm of difficult choledocholithiasis.

CONCLUSION:

Biliary stenting is a safe and effective strategy for managing large or multiple CBD stones, significantly reducing stone burden and facilitating subsequent clearance

CONFLICT OFF INTEREST:

Nil

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