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Outcome of the Endoscopic Biliary Stenting for Irretrievable Common Bile Duct Stones in an Academic Hospital – A Prospective Study

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ABSTRACT

***Background*: Choledocholithiasis is characterized by the existence of a stone in the common bile duct. Based on findings published in the Medical Clinics of North America, around 10-15% of individuals with gallstones experience the development of choledocholithiasis. Presently, the established approach for addressing common bile duct stones involves the implementation of endoscopic papillotomy and stone extraction. The combined utilization of Dormia basket, balloon catheter, and lithotripsy achieves a success rate of approximately 90%. In cases where traditional endoscopic removal methods prove ineffective, biliary stenting plays a crucial role in the conservative management of CBD stones.**

***Objectives*: The main goal of the study was to evaluate the outcome of biliary stenting in irretrievable common bile duct stones.**

***Materials and Methods*: This observational study took place at the Department of Gastroenterology, Dhaka Medical College and Hospital, Dhaka, from January 2018 to December 2018. The study included consecutive patients who were 18 years or older and diagnosed with common bile duct stones. These patients underwent endoscopic retrograde cholangiopancreatography (ERCP) for stone extraction. The study specifically focused on patients who received biliary stenting for irretrievable common bile duct stones, and they were enrolled as participants in the study.**

***Results*: Out of the 83 patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) for stone extraction, 29 patients (35%) were deemed as having irretrievable stones, necessitating the implementation of stenting. Among these irretrievable stone cases, the average age was 46.69, and there was a predominance of females with 17 patients (58.6%). Of the 29 cases, 22 patients completed the follow-up. During the follow-up ERCP, a significant reduction was observed in both the average number of stones (3.14 vs. 1.9; P=0.002) and their size (16.32 vs. 12.4; P=0.005). Successful stone extraction was achieved in 14 patients (63.64%) during the second ERCP. In one patient (4.55%), spontaneous clearance of the stone occurred, while in 7 patients (31.81%), stone extraction was not possible during the second ERCP. The reduction in mean stone size was the only significant factor affecting the success of the second ERCP. However, there was no correlation found between the duration of stenting and the reduction in stone size (r=-0.193, p=0.401).**

***Conclusion*: Our study shows that repeat ERCP can successfully extract stones regardless of stenting duration. Unlike Western data, we emphasize the effectiveness of endoscopic biliary stenting in a context with limited access to advanced techniques, where initial stone extraction rates are lower. This approach is particularly beneficial for patients with stone sizes over 15 mm, avoiding the need for complex surgical procedures.**

Keywords: Biliary Stenting, Common Bile Duct Stones, Irretrievable.

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I. Introduction

Choledocholithiasis refers to the presence of stones in the common bile duct. Research published in the Medical Clinics of North America suggests that approximately 10-15% of individuals with gallstones develop choledocholithiasis [1]. There are two classifications of choledocholithiasis: primary, where stones form in the bile ducts, and secondary, where

stones originate in the gallbladder and pass into the bile ducts. The natural progression of common bile duct (CBD) stones is not fully understood, but around 25% of patients are asymptomatic, and a significant portion of them (30% to 50%) will eventually pass the stones spontaneously and without symptoms [1]. CBD stones can lead to various complications such as biliary colic, partial or complete biliary obstruction, cholangitis, hepatic abscesses, pancreatitis, and even chronic obstruction resulting in secondary biliary cirrhosis and portal hypertension [2]. Clinical indications for investigating CBD stones include epigastric or right upper quadrant pain, particularly if accompanied by jaundice and/or fever [3]. Additionally, CBD stones should be considered as a potential cause of acute pancreatitis, with gallstones migrating to the common bile duct estimated to contribute to 50% of cases [4]. The management of bile duct stones has significantly evolved in recent years, shifting from open surgery to per-oral endoscopic procedures. Endoscopic retrograde cholangiopancreatography (ERCP) is now the preferred approach worldwide for the management of extrahepatic bile duct stones, surpassing surgical or percutaneous methods, although it can present challenges in some cases [5]. Endoscopic therapy is a commonly used method for extracting bile duct stones. It involves performing endoscopic biliary sphincterotomy followed by conventional stone retrieval techniques using devices such as balloon catheters, Dormia baskets, and mechanical lithotripters. Over the past thirty years, endoscopic biliary sphincterotomy (EST) has become the established approach for extracting bile duct stones, and conventional techniques have proven successful in the majority of cases. The standard treatment for common bile duct stones is currently endoscopic papillotomy and stone extraction [6]. The combined use of Dormia baskets, balloon catheters, and lithotripsy achieves a success rate of approximately 90% [7]. However, in 10%-20% of patients with CBD stones, standard techniques may not be effective, leading to the classification of these stones as "difficult stones." Difficult stones are characterized by larger size (>1.5 cm), a high number of stones (>3), the presence of periampullary diverticula, stone impaction, and narrowing of the biliary duct distal to the stone [8, 9]. Untreated CBD stones can result in increased morbidity and mortality due to conditions such as obstructive jaundice, recurrent cholangitis, pancreatitis, and secondary biliary cirrhosis. Studies have shown successful removal of CBD stones using standard techniques in a significant proportion of cases, ranging from 78.5% to 86.4% [10, 11]. The situation in Bangladesh differs from the global scenario when it comes to the extraction of bile duct stones. In Bangladesh, the commonly used methods include endoscopic biliary sphincterotomy (EST), balloon catheter, and Dormia basket, while lithotripsy is rarely utilized. Economic constraints lead to the reuse of devices, and there is also variability in endoscopic settings and expertise. Consequently, the stone removal rate in our setup is slightly lower compared to rates reported in other studies, despite data showing that conventional methods can remove 80-90% of CBD stones. When stone removal is unsuccessful, stenting is performed with the hope that the stone will either pass spontaneously or become more retrievable in subsequent sessions. However, there is limited data available regarding the outcomes of biliary stenting for irretrievable common bile duct stones in our country. Therefore, this study was conducted to examine the outcomes of endoscopic biliary stenting in cases of irretrievable CBD stones.

II. Objectives

A. General Objective

To evaluate the outcome of biliary stenting in irretrievable common bile duct stones.

B. Specific Objective

To assess the difference in stone numbers before and after stent placement.

To measure the difference in stone size before and after stent placement.

To find out the frequency of spontaneous clearance of CBD stones after stenting.

To determine the complete clearance rate of stone extraction at 2nd session of ERCP.

III. Materials and Methods

A. Study Design

Observational study.

B. Place of Study

Gastroenterology Department of Dhaka Medical College and Hospital.

C. Study Period

January 2018 to December 2018.

D. Study Population

All patients of 18 years. or above with CBD stones who underwent ERCP.

E. Sampling Technique

Nonprobability purposive sampling.

F. Sample size Determination

$$n = \frac{P_1(1-P_1)+P_2(1-P_2)}{(P_1-P_2)^2} x\left(Z_\alpha + Z_\beta\right)^2$$

where

Z_α represents the Z value at a specific level of significance, such as 1.96 at a 5% level of significance.

Z_β represents the Z value at a specific power, for example, 0.84 at 80% power when β is 0.2.

P_1 denotes the efficacy of biliary stenting based on a previous study, which is 60.0% (0.60).

P_2 represents the expected efficacy of biliary stenting in our setup, estimated to be 30.0% (0.30).

The values for Z_α and Z_β are 1.96 and 0.84, respectively.

$$n = \frac{0.60(1-0.60)+0.30(1-0.30)}{(0.60-0.30)^2} \times (1.96+0.84)^2$$

$$n = \frac{0.60x0.40+0.30x0.70}{(0.30)^2} \times (2.8)^2$$

n= 39.2
n= 39(estimated sample size)

So total sample size will be 39, but due to time constraints, we took 29 cases of irretrievable stones.

G. Inclusion Criteria

We included consecutive patients aged 18 years or above with common bile duct (CBD) stones. Specifically, patients with CBD stone sizes less than 2.5 cm, as determined by magnetic resonance cholangiopancreatography (MRCP), were eligible for the study. Additionally, patients who underwent biliary stenting for irretrievable CBD stones were included.

H. Exclusion Criteria

Patients who had previously undergone sphincterotomy or biliary stenting, as well as those with concomitant hepaticolithiasis, were excluded from the study.

I. Data Collection Procedure

Data was collected using a predefined data sheet that captured patients' medical history, clinical information, and laboratory investigations. Upon admission, patients and their legal guardians were provided with a detailed explanation of the study's objectives, potential risks and benefits, their freedom to participate, and the assurance of confidentiality. Informed consent was obtained from interested patients or their guardians. Data collected for the study included clinical history, laboratory test results, imaging findings from relevant studies, and observations made during endoscopic retrograde cholangiopancreatography (ERCP).

J. Data Processing and Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 22.0. Categorical data were presented as numbers and percentages, while numerical data were expressed as mean and standard deviation. Stone sizes, CBD diameters, stone numbers, and differences were analyzed using the unpaired t-test and chi-square test. Statistical significance was defined as $p < 0.05$.

Ethical considerations: Informed written consent was obtained from each patient or their guardian, ensuring that they were fully informed about the treatment procedure, expected outcomes, potential advantages, disadvantages, and possible complications while taking into account ethical considerations. Confidentiality was maintained through verbal and documentary means, including the use of separate lockers and computer passwords. The study protocol was approved by the ethical committee of Dhaka Medical College & Hospital.

IV. Result and Observation

A total of 90 patients were enrolled at the initial screening. After excluding 5 patients (1 had previous H/O ERCP, 2 patients have hepatolithiasis, 2 patients had stone size >2.5 cm.) 85 patients were selected for ERCP but in 83 (in 1 patient cannulation was not successful and in 1 patient incidentally periampullary growth was found) patients ERCP could be completed. Out of 83 patients in 29 patients initially, stone extraction was not possible and biliary stenting was done. Out of 29 patients, 22 patients completed FU ERCP.

Table I shows the demographic profile of patients with irretrievable stones. It was observed that 58 % of the patients with irretrievable stones were female 20% had H/O smoking and 35% patients had H/O Cholecystectomy.

TABLE I: Demographic Profile of Patients with Irretrievable Stones

Demographic Profile	Irretrievable Stones (n=29)
Age (in years)	
Range	18-78
Mean±SD	46.69±14.68
Sex	
Male	12 (41.4%)
Female	17 (58.6%)
H/O Smoking	6 (20.7%)
Cholelithiasis	16 (55.2%)
H/O Cholecystectomy	10 (34.5%)

Table II shows the presenting complaints of irretrievable stone cases. It was observed that 100% of patients with irretrievable stones presented with abdominal pain and one-third of patients had jaundice.

TABLE II: Presenting Complaints of Irretrievable Stone Cases

Presenting complaints	Irretrievable Stone Cases (n=29)	
	n	%
Abdominal pain	29	100.0
Jaundice	18	62.1
Fever	8	27.6
Itching	5	17.2

Table III shows ERCP findings of the patients with irretrievable stones. It was observed that in cases of irretrievable stones mean the stone number was 2.86±1.4, the mean stone size was 16.07±4.52, and 17.9% of patients had diverticula.

TABLE III: ERCP Findings of the Patients with Irretrievable stones

Initial ERCP	Irretrievable Stone Cases (n=29) Mean±SD	n (%)
Stone Number	2.86±1.46	
Stone size (mm)	16.07±4.52	
CBD diameter (mm)	13.92±3.8	
CBD stricture		5 (17.9%)
Diverticuli		5 (17.9%)

This study compares the number and size of common bile duct (CBD) stones, as well as the CBD diameter, before and after the placement of biliary stents in 21 patients. The results indicate a significant reduction in the median number of stones per patient after biliary stenting compared to before (3.14 vs 1.9; P = 0.002). Similarly, the median size of the stones showed a significant decrease after biliary stenting compared to before (16.32 vs 12.4; P = 0.005). Although there was a decrease in the CBD diameter after stenting compared to before (13.9 vs 13.28), this difference was not statistically significant (P = 0.611).

TABLE IV: Comparison of Number and Size of CBD Stones and CBD Diameter before and after Stent Placement in 21 Patients

F/U ERCP	Prestenting Mean±SD	Poststenting Mean±SD	P-value
Stone number	3.14±1.49	1.9±0.89	0.002[s]
Stone size (mm)	16.32±4.76	12.4±3.83	0.005[s]
CBD diameter (mm)	13.9±3.98	13.28±3.87	0.611[ns]

s= significant, ns= not significant, p-value reached from paired t-test.

Table V shows the change in stone number and size after biliary stenting of irretrievable CBD stones. After biliary stenting 71.4% of patient's stone number was decreased and stone size was decreased in 90% of patients.

TABLE V: CHANGE OF STONE NUMBER AND SIZE AFTER BILIARY STENTING IN IRRETRIEVABLE CBD STONES

Outcome	Number	Percentage
Stone Number		
Decreased	15	71.4%
Increased	0	00%
Unchanged	6	28.57%
Stone size		
Decreased	19	90.48%
Increased	2	9.52%
Unchanged	0	00%

Fig. 1 shows the stone clearance rate at the 2nd ERCP. It was observed that stone could be extracted in two-thirds of the patients (63.64) at follow-up ERCP, in 1 patient (4.55%) there was spontaneous clearance of stone but in 7 patients (31.81%) stone extraction was unsuccessful at repeat ERCP.

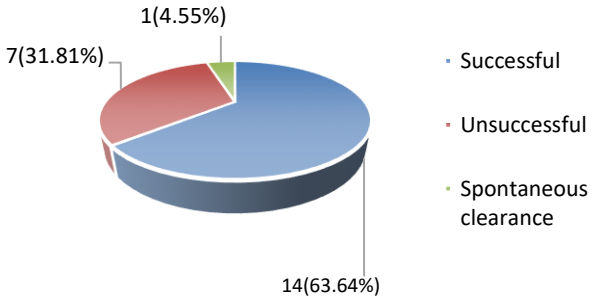

Fig. 1. Stone clearance rate at 2nd ERCP.

Table VI shows complications of biliary stenting in the study population (n=22). In our study, 2 patients (9%) patients developed cholangitis after biliary stenting.

TABLE VI: COMPLICATION OF BILIARY STENTING IN THE STUDY POPULATION (N=22)

Complication	Number (%)
Cholangitis	2 (9%)
Abdominal pain	1 (4.5%)
Jaundice	1 (4.5%)

Table VII shows factors affecting endoscopic success in repeat ERCP, it was observed that mean stone size reduction is the only significant factor that affects ERCP success in 2nd ERCP. Cholecystectomy, duration of stenting, and mean stone number reduction does not affect repeat ERCP outcome.

Fig. 2 shows a Scatter diagram to see the correlation between the duration of stenting with stone size reduction. It shows there is no correlation between the duration of stenting and stone size reduction. (r=-0.193, *p*=0.401).

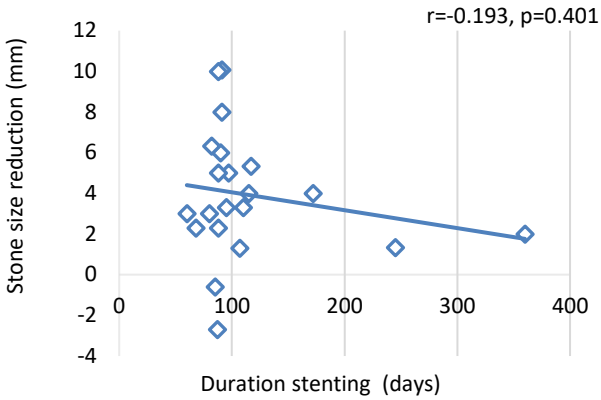

Fig. 2. Scatter diagram shows the correlation between duration of stenting with stone size reduction.

V. DISCUSSION

The management of bile duct stones has undergone significant changes in recent years, with a shift from open surgery to per-oral endoscopic procedures. This study aimed to evaluate the outcomes of biliary stenting in patients with irretrievable common bile duct stones. A total of 83 patients underwent endoscopic retrograde cholangiopancreatography (ERCP) for stone extraction. Stone extraction was successful during the initial ERCP in 54 patients (65.06%), while in 29 patients (34.93%), the extraction was unsuccessful. This failure rate is higher compared to previous studies due to the unavailability of newer techniques like ESWL and lithotripter in our setting, as well as the reuse of equipment due to economic constraints. The mean age of patients with irretrievable CBD stones was 46.69±14.68, with 58.6% of them being female and 34.5% having a history of cholecystectomy. These findings are consistent with the results reported by Aslan *et al*. [12]. Periampullary diverticula were observed in 5-32% of the patients undergoing duodenoscopy, which is in line with existing literature [13]–[15].

In our study, 11 patients (13.25%) were found to have duodenal diverticuli. The impact of periampullary diverticula on successful cannulation and procedural outcomes during ERCP has been a subject of debate for years. However, recent publications have supported the notion that these diverticula do not significantly affect the success of endoscopic treatments (OR = 0.529, p = 0.052). Our study also revealed that patients with irretrievable CBD stones had an average stone size greater than 15 mm (mean 16.07±4.52). Similar findings were reported by Silvis *et al*. [16], who observed that stones larger than 20 mm exceeded the safe limit for sphincterotomy. Some studies have suggested that stenting is necessary for stones larger than 15 mm [17]. Additionally, our study found that when the stone number exceeded 2

TABLE VII: FACTORS AFFECTING ENDOSCOPIC SUCCESS IN REPEAT ERCP

Variables	Successful (n=14)	Unsuccessful (n=7)	OR	P-value
Cholecystectomy	4(28.57%)	1(14.28%)	2.40(0.16-71.29)	[a]0.445[ns]
Mean duration between ERCP	103.79±42.77	139.71±103.06		[b]0.267[ns]
Mean stone number reduction	1.21±0.69	1.14±0.53		[b]0.817[ns]
Mean stone size reduction	5.12±1.78	1.7±0.63		[b]0.001[s]

s = significant, ns = not significant, [a]p value reached from Chi-square test, [b]p value reached from Unpaired t-test.

(mean 2.86±1.46), ERCP alone was insufficient for stone removal. Similar observations were made by Ramakrishnan *et al*. [10, 18], who found that stone retrieval may not be possible during the initial procedure when the stone number exceeds 3. In cases where CBD stones cannot be removed using standard methods, temporary plastic stenting may be considered to prevent impaction [19].

It has been reported in previous studies that biliary stenting not only facilitates biliary drainage but also causes fragmentation of large CBD stones [17], [18], [20], [21]. Our study found a statistically significant decrease in both the mean number of stones (3.14 vs 1.9; P=0.002) and the mean stone size (16.32 vs 12.4; P=0.005) after biliary stenting, which aligns with earlier research. After an average period of 114.5 days, the stone number decreased in 15 patients (68%) and the stone size decreased in 19 patients (86%). However, in 6 patients (32%), the stone number remained unchanged, and in 2 patients (14%), the stone size increased. These findings are consistent with the findings of Chan *et al.* [18]. The mean duration following stenting in our study was 114.5 days, whereas it was 63 days in Chan *et al*.'s study [18] and 180 days in Jain *et al*.'s study [17]. Despite the differences in stenting duration, the mean reduction in stone size and success rate were similar across these studies, indicating that the change in stone size is not significantly correlated with the duration of stenting. Scatter diagram analysis of mean stone size reduction against stenting duration revealed no correlation (r=-0.193, p=0.401), which is consistent with Chan *et al*. findings (18). In our study, 9% of patients developed cholangitis after biliary stenting, which is comparable to the 6.25% reported by Aslan *et al*. [12]. Out of 22 patients, stone extraction during the second ERCP was successful in 14 patients (63.64%). Additionally, one patient (4.55%) experienced spontaneous stone clearance, while stone extraction was not possible in 7 patients (31.81%) during the second ERCP. Similar to our findings, Aslan *et al*. [12] reported a 9.4% rate of spontaneous clearance and successful stone extraction in 62.5% of cases during repeat ERCP. Although we initially expected a lower stone clearance rate during repeat ERCP compared to international standards, our study showed a slightly higher rate. This discrepancy may be attributed to the fact that we could not utilize newer stone extraction techniques during the initial ERCP, resulting in some cases where stones were not technically difficult but still required stenting. When the findings are analyzed based on the outcomes of the second ERCP, no statistical differences were observed in terms of stone number (1.86 vs. 2.0, P=0.816) and stone size (11.4 vs. 14.41). However, successful cases demonstrated a higher mean reduction in stone size compared to unsuccessful cases (5.02 vs 1.7, P=0.001), which is consistent with the study conducted by Chan *et al*. [18]. In conclusion, our study demonstrates that biliary stenting significantly reduces stone size and enables subsequent stone retrieval during ERCP. However, the reduction in stone size is not influenced by the duration of stenting.

VI. Limitations of the Study

The sample size was small, so the result may not indicate a true scenario. The study was done in a single center. So, it does not reflect the whole population of the country. As newer techniques were not used in the initial ERCP the failure rate was high and stenting was done in stone which may not have been difficult if there were modern techniques were implied.

VII. Conclusions

In summary, our study demonstrates that endoscopic stenting is an effective alternative approach with favorable outcomes for patients with challenging stones. Biliary stenting not only facilitates biliary drainage but also reduces the number and size of stones, making them retrievable during subsequent ERCP procedures. We observed a high success rate in stone extraction during repeat ERCP. However, the reduction in stone size is not influenced by the duration of stenting. While Western data suggest that biliary stenting is suitable for elderly or high-risk patients, in our setting where the initial ERCP stone extraction rate is lower than standard due to the unavailability of modern techniques, endoscopic biliary stenting can be an effective alternative, particularly for patients with stones larger than 15 mm, thus avoiding the need for complex surgical CBD exploration.

VIII. Recommendations

A multi-center study with a large sample size may be undertaken to make a representation of the whole country's population. A multi-center study in a well-equipped center may be done so that truly difficult stones can be enrolled. National-level guidelines should be made regarding the management of difficult CBD stone patients within our available resources.

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