

TO STUDY THE SAFETY AND EFFICACY OF ERCP AND BILIARY STENTING IN THE MANAGEMENT OF DIFFICULT COMMON BILE DUCT (CBD) STONES IN ELDERLY PATIENTS

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Abstract

Background: CBD stones are commonly managed using endoscopic retrograde cholangiopancreatography (ERCP) along with sphincterotomy. It is acknowledged as the gold standard for treating common bile duct (CBD) stones. **Aims:** To study the safety and efficacy of ERCP and biliary stenting in the management of difficult common bile duct (CBD) stones in elderly patients. **Materials and Methods:** Geriatric patients with choledocholithiasis (male/female) of age (≥ 65 years) and stones of large size (≥ 15 mm) and multiple (≥ 3) CBD stones were studied. The patients underwent ERCP & placement of single stent in CBD (n=30, group A) or double (n=24 group B) plastic CBD stents; ERCP at 10-12 weeks later for stone removal was attempted. Decrease in the size and number of stones before and after ERCP; Stent patency and stone clearance rates, and other complications were compared. **Results:** The mean size of the stone (longitudinal/transverse diameter) was significantly reduced after biliary stenting in both groups ($p < 0.001$). Complete stone removal at the second ERCP was 92.1% in group A and 100% in group B ($p = 0.494$). Statistical analysis indicated that group B had a higher 3-month stent patency rate than group A ($p = 0.008$). **Conclusions:** Endoscopic biliary stenting in elderly patients is safe and feasible for the management of difficult CBD stones; double CBD stenting has a better patency rate as compared to single stenting.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy is widely used in the management of CBD stones. It is accepted as a gold standard method of common bile duct (CBD) stone management.^[1-3] However, stone clearance of the biliary tree is not possible in all cases. Approximately 10–15% of patients procedure can be very formidable despite an adequate sphincterotomy; CBD stone clearance rates are even lower in geriatric patients.^[4,5] Large stones (≥ 15 mm in diameter) or multiple stones (≥ 3) stones, the presence of periampullary diverticula in elderly, and past procedures on the biliary tract, stomach, and duodenum all reduce the possibility of successful CBD clearance.^[6] Other techniques of CBD stone removal include mechanical breakdown of stone, extracorporeal shockwaves, electrohydraulic, or laser lithotripsy and chemical dissolution.^[7] These methods are time consuming and are not readily available every time and elderly patients, particularly those with severe co-

morbidities, cannot tolerate invasive endoscopic procedures of a longer duration.^[7-10]

Temporary biliary stenting with plastic stents is a useful alternative when complete stone clearance is not possible particularly in elderly, frail and high risk patients.^[11-13] The short-term uses of biliary stenting have been shown to be associated with advantages like reduction in stone size or stone fragmentation and serves as a bridge treatment to secondary intervention and easier stone removal at follow-up ERCP procedures.^[14-17] Several studies have reported that therapeutic ERCP with stent placement is safe and effective for CBD stones in the elderly population.^[18,19] Clinical data on the effectiveness and safety of this technique in elderly patients with difficult CBD stones is still limited. This study is aimed to compare the safety and efficacy of short-term biliary stenting with either a single or double CBD stents for the treatment of difficult CBD stones in elderly patients with co-morbidities and higher surgical risks.

MATERIALS AND METHODS

Patients

Patients with CBD stones who underwent therapeutic ERCP and stenting from Feb 2008 to Feb 2022 were studied. Inclusion criteria for the study was: (1) Elderly patients of 65 years or older I,^[2] Higher stone size (≥ 15 mm) ; multiple CBD stones (≥ 3) that could not be extracted by conventional methods,^[3] serious comorbidities (cerebrovascular or cardiopulmonary diseases and high risks of surgical complications),^[4] American Society of Anesthesiology “ ASA “ grade of III. Patients with acute suppurative cholangitis were excluded.

ERCP procedure was carried out in prone position with the standard side viewing endoscope under light sedation (propofol and Medazolam). Prophylactic antibiotics and analgesics were routinely used. Endoscopic sphincterotomy was performed in patients under vision. A single (7x10 French stent (Fr); group A) or double (7X10FR; group B) plastic stents were placed in the bile duct.^[20] The use of single or double stents was based on the severity of the condition (number and size of stones, CBD diameter, age, co morbidity and patient's tolerance. No oral dissolution agent was prescribed. All patients were subjected to a second ERCP 12 weeks after stenting. At the second ERCP; CBD stones removal was done by various methods like retrieval baskets and extraction balloon.

Outcome variables

Clinical parameters like age, sex, co morbidity,^[19] procedure related complications,^[21] patency rate, and complete stone extraction rate. The size of the stones were measured radiologically (longitudinal/transverse diameters before and after stenting. In case of multiple stones the size of the largest stone was taken into account.^[15]

Statistical analysis.

The Statistical Package for the Social Sciences (SPSS 15.0) was used. Mean and standard deviation (SD) were used to summarize the data for continuous variables and the percentages for categorical variables. Based on the results of the Shapiro–Wilk test (Used to assess the distribution of continuous data), statistical comparisons of continuous variables were performed using Student's t-test or the Wilcoxon rank sum test was applied for the estimation of the 12 week stent patency rate. $P < 0.05$ was considered statistically significant.

54 patients were enrolled in this study. There were 36 men and 18 women with ages ranging from 65 to 90 years (mean age 74 years). In total, 30 (55.55%) patients underwent single stent placement and were included in group A. Group B included 24 (45.34%) patients who underwent multiple (double) stent placements. Pain abdomen and Jaundice were the most common symptoms. Patients who recovered from cholangitis with conservative treatment were also included. Table 1 shows the baseline characteristics of our series. There were no statistical differences between the two groups with respect to age, gender, clinical features, co morbidities, and surgical history.

The median duration of stenting was 120 [Range 100–152] days in group A and 133 (R, 108–169) days in group B ($p > 0.05$). The mean size of CBD stones (longitudinal/transverse diameter before stenting was 17.15 ± 5.78 / 17.41 ± 5.64 mm in group A and 19.03 ± 4.85 / 16.63 ± 4.71 mm in group B (Table 2). Stone size reduced significantly to 10.85 ± 4.38 / 9.38 ± 4.14 mm in group A and 8.57 ± 3.65 / 6.63 ± 3.02 mm in group B after biliary stenting ($p < 0.001$); Liver function tests including bilirubin and gamma glutamyltransferase levels, significantly decreased after biliary stenting in both groups (Table 2). Balloon catheters and retrieval Baskets achieved complete stone removal 24 patients in group A and 20 in group B. Additional procedures of endoscopic sphincterotomy or mechanical lithotripsy was performed for complete stone removal in three patients in group A and two patients in group B. 3 Patients in group A remained unchanged, and a second stent was placed for long-term treatment. Therefore, total CBD stone clearance was achieved in 28 patients (94.1%) in group A and 24 patients (100%) in group B ($p = 0.494$; Figure 2). The three-month stent patency rate was not significantly different in patients aged 78 or older between the two groups ($p = 0.694$; Figure 3). Three patients (10%) developed mild pancreatitis in group A at initial ERCP and were treated with conservative therapy. Potential life-threatening complications such as perforation and bleeding did not develop in any patient. No complications related to biliary stenting were recorded. During follow-up, cholangitis occurred in two patients at day 95 and day 102 in group A. Stent migration developed in four patients in group A and three in group B. No mortality was observed in either group.

Table 1:

	Group A	Group B	P
No. of patients	30	24	
Gender (male/female)	20/30	16/24	0.37
Age (years) mean (Range)	65-90	65-88	0.57
<i>Concomitant disease</i>			
Cardiovascular	19	18	0.69

Cerebrovascular	15	14	0.78
CBD Stricture	4	1	0.56
DM	12	14	0.81
Renal Disease	2	1	0.66
Combination of stones			
Large stones only	9	6	0.13
Multiple stones	16	19	0.56
Clinical symptoms			
Jaundice	24	17	0.9
Pain	20	12	0.21
Cholangitis	4	6	
Stone size before stenting			
Longitudinal	16.8	17.9	0.11
transverse	14.2	15.1	0.16

Table 2: Change of stone size, number and laboratorial data before and after biliary stenting in two groups

Group AGroup B						
Prior to stentafter stentpPrior to stentafter stentp						
Stone size (mm) patients aged 65 or olde	16.8	8.2	Less than 0.001	17.9	7.6	0.001
Stone number	3	1	0.001	4	2	0.001
Laboratory data1						
Bilirubin(mg/dl)	8	2	0.001	10	3.4	0.001
GGT	398	210	0.001	426	250	0.001

Table 3: Baseline characteristics of patients

Parameter	Group A	Group Bp	
Complete stone removal	90	100	0.009
Reduction in stone size	8.2/16.8	7.6/17.9	0.067
Reduction in stone number	1/3	2/4	0.31

DISCUSSION

Multiple and larger CBD stone management frequently requires balloon or ERC basket technique for retrieval. These techniques are often associated with certain complications. With increase in the size of the stone the rate of clearance of the bile duct decreases.^[20-22] Older patients having difficult CBD stones are often associated with multiple clinical morbidities. These patients have a high incidence of complications and are unable to undergo surgery because of the existence of cardiopulmonary and cerebrovascular co morbid conditions. ERCP procedure requires IV sedation or general sedation. It is a procedure requiring prolonged duration and large and multiple stones and fragile patients further complicate the problem in the elderly patients. In such individuals, temporary biliary stenting is a safe and effective alternative.^[21-25] This study confirmed the previous experience and reports that biliary stenting is associated with a decrease in stone size and stone fragmentation and that multiple stents are superior to a single stent in maintaining the 12 weeks stent patency rate.

As shown in Table 2, short-term (approximately 12 weeks) biliary stenting was generally associated with a reduction in both the size and number of CBD stones. This result is consistent with previous published reports.^[14-17] The decrease in the size and number of stones was remarkable after stenting in both groups, with greater, but non-significant changes in group B patients (Table 3). Multiple stenting was associated with higher stone clearance

rates. However, these differences were not statistically significant. The mechanism by which the stones change in number and size is still not understood completely. The Respiratory movements and intestinal movements cause friction between the stents and stones, thus inducing fragmentation and facilitating their removal. Patency at the Ampulla facilitates clearance after biliary stenting. Multifaceted stones may become more and more rounded after a period of friction and achieve a higher possibility of spontaneous passage through the Ampulla.^[26] No stones were detected in FEW patient in each group at the second ERCP. Similar results have been reported by multiple investigators. CBD stent occlusion is not uncommon & often occurs after a short period of time, thus requiring frequent CBD stent exchanges.^[25-26] Stent occlusion is attributed to the adhesion of bacteria to the stent surface and the formation of insoluble calcium bilirubinate, which is precipitated within the stent leading to blockage.^[27] The present study showed that our 12 week cumulative stent patency rate was significantly higher in group 'A' than in group 'B' (p=0.008), suggesting that double stent placement may provide more efficient and continuous drainage. Present data also showed that a relatively higher successful rate of stone removal was achieved in group B, although this difference was not statically significant. The probable reasons for the findings are that multiple stents increase friction and stone fragmentation, further multiple stents reduce duodenobiliary reflux and decreases formation of calcium bilirubinate and stent occlusion. Occluded stents still maintain bile around

and between stents by the wicking phenomena. In the present study, we used biliary stenting without attempting to extract difficult stones as the primary therapy which resulted in not only decrease in the procedure time but also reduced the chances of multiple cannulations and thus decreased the procedure related complication. Complications seen the study included pancreatitis at the initialercp in group A patient (3 patients). Other complications included cholangitis and it was managed with adequate hydration and parental antibiotics. Migration of the CBD stent was discovered at the second ERCP in four and three patients in groups A and B groups respectively. Stent migration was shown associated with decrease in the size of the stones and was associated with higher duct clearance at second ERCP indicating the efficacy of stenting. The movements of the stones in the dilated bile ducts promote the expulsion of the stent into the duodenum.^[25-27] The stent configuration does have a bearing on the stent behavior and previous studies demonstrated that a pigtail stent may provide a lower risk of migration, cholangitis and perforation. In this study pig tail (single and double) were associated with lower migration and stent related complication. However, further studies are necessary to analyze and compare these different stents in future studies. The sample size of the study was small due to lower number of cases as the disease in study is not commonly seen in the population. Data analysis showed that double stent placement had a significant higher 12-week stent patency rate as compared to single one and a higher stone clearance of the biliary tract at second ERCP and a decrease in the size of the stones over the period. Furthermore, our data represent the experience at a single center and Therefore, a larger, multicenter study may provide significant results. Our study include elderly patient with co morbidities not fit for prolonged procedures and endoscopic maneuvering so smaller stent size 7X7 Fr were more frequently used. Large stents presumably will have a higher stent patency ;However it has been demonstrated conclusively that with adequate sphincterotomy stent size is immaterial in mantling patency and preventing migration.^[26,27,28] Stents are known to block, and typically, bile duct patency is maintained by bile flow passing around the stent(wick effect). However, it seems to be promising that larger stents (i.e., 10 FR) may improve outcomes. This issue may be addressed by further studies. Perhaps increasing the sample size could lead us to find more remarkable and statistically significant differences between the groups.

CONCLUSION

In conclusion, we can state that CBD stones in elderly population who are frequently associated with other co morbidities biliary stenting may be a

safe and effective method in the stone management of difficult cbd stones and our data has shown a higher rates of complete duct clearance and a grater reduction in the size of the stones in the multiple stenting, however a larger multi-centre study may be required before a definitive conclusion are drawn.

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