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Effectiveness and safety of biliary stenting in the management of difficult common bile duct stones in elderly patients

BILIARY

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Original Article

ABSTRACT

Background/Aims: To investigate the efficacy and safety of endoscopic biliary stenting for difficult common bile duct (CBD) stones in elderly patients.

Materials and Methods: Elderly patients (≥65 years) with large (≥20 mm) or multiple (≥3) CBD stones were studied. The patients underwent placement of single (n=34, group A) or double (n=30, group B) plastic stents at the time of initial endoscopic retrograde cholangiopancreatography (ERCP). Approximately 3 months later, stone removal was attempted at the second ERCP. The reduction of stone size and number before and after biliary stenting, complete stone removal, 3-month stent patency rate, and complications were compared.

Results: The mean size (longitudinal/transverse diameter) of the CBD stones was significantly reduced after biliary stenting in both groups (p<0.001). Complete stone removal at the second ERCP was 94.1% in group A and 100% in group B (p=0.494). Kaplan–Meier analysis indicated that group B had a higher 3-month stent patency rate than group A (p=0.008).

Conclusion: Endoscopic biliary stenting is safe and feasible for the management of difficult CBD stones in elderly patients, while double biliary stenting is superior to single stenting in maintaining higher stent patency rates.

Keywords: Common bile duct stone, stent, endoscopic retrograde cholangiopancreatography, elderly

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) with biliary sphincterotomy is widely accepted as a conventional method of extracting common bile duct (CBD) stones (1-3). However, managing CBD stones in approximately 10–15% of patients can be formidable despite an adequate sphincterotomy, with the complete stone clearance rate being even lower in elderly patients (4,5). Large (≥20 mm in diameter) or multiple (≥3) stones, distal CBD variants, the presence of periampullary diverticula, and past procedures on the biliary tract, stomach, and duodenum all decrease the possibility of successful stone extraction (6). Alternative techniques include mechanical, extracorporeal, electrohydraulic, or laser lithotripsy as well as chemical dissolution (7). Although these interventions have been considered as effective therapeutic methods for removing CBD stones, they are time-consuming and unavailable in some institutions (7,8). In addition, elderly patients, particularly those with severe comorbidities, cannot tolerate invasive endoscopic procedures of a long duration (8-10).

Temporary plastic biliary stenting is a useful alternative when extraction techniques have failed to remove CBD stones completely, particularly in frail, elderly, and high-risk patients (11-13). Importantly, short-term use of biliary stenting has been shown to be associated with reduction in stone size or fragmentation and serves as a bridge treatment to secondary intervention, thereby leading to easier stone removal at follow-up endoscopy (14-17). Although several studies have reported that therapeutic ERCP plus stent placement is safe and effective for the elderly (18,19), data on the effectiveness and safety of this technique in elderly patients with difficult CBD stones is still limited.

For the past several years, we placed either single or double stents without attempting extraction as the pri-

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mary intervention at the initial ERCP for elderly patients with difficult CBD stones. Our study aimed to retrospectively compare the efficacy and safety of short-term biliary stenting with either single or double stents for the treatment of difficult CBD stones in elderly patients with unacceptably high surgical risks or comorbidities.

MATERIALS AND METHODS

Patients

Data of patients who underwent therapeutic ERCP for CBD stones from March 2004 to July 2013 were collected. Patients meeting the following inclusion criteria were included: (1) 65 years of age or older; (2) large (≥20 mm) and/or multiple (≥3) CBD stones that could not be extracted by conventional methods; (3) high risk of surgical complications or serious comorbidities (cerebrovascular or cardiopulmonary diseases); (4) classification of the American Society of Anesthesiologists (ASA) of III. Patients with acute suppurative cholangitis were excluded. This retrospective study was a single-center study and was approved by the Ethics Committee of our hospital; informed consent was obtained from each patient.

Endoscopic procedure and follow-up

All procedures were performed collaboratively by two experienced endoscopists, and the whole process was performed under the supervision of our chief endoscopist. Each patient underwent ERCP with a standard side-viewing duodenoscope (TJF 160; Olympus, Tokyo, Japan) in the prone or lateral decubitus position after sedation with propofol (0.5 mg/kg). Prophylactic antibiotics and analgesics were routinely used. Endoscopic sphincterotomy was performed in patients with bile duct enlargement, and single (8.5 French (Fr); group A) or double (7 or 8.5 FR; group B) plastic stents (Wilson Cook Medical Inc.; Winston-Salem, NC, USA) were then inserted into the bile duct over a guidewire *via* a standard technique, with the proximal end above the stone and the distal end of the duodenum (20). The use of single or double stents was based on the severity of the condition (age, patient's tolerance, number and size of stones, comorbidity, etc) by reaching a consensus between two endoscopists. The chief endoscopist was not involved in patient grouping, but only supervised the whole operation procedure. No oral dissolution agent was prescribed. All patients were requested to return for a second ERCP 3 months after stenting and were suggested to contact our department if indications for a second ERCP (abdominal pain, appearance of jaundice, and/or derangement of liver function tests) occurred earlier. At the second ERCP, these patients underwent standard techniques for CBD stone removal (basket, extraction balloon, and mechanical lithotripsy).

Outcome variables

The following data were collected for each patient: age, gender, history of chronic concomitant conditions (19), clinical features, complications (ERCP-related (21) and stent-related), 3-month stent patency rate, and complete stone removal rate. The diameters (longitudinal/transverse) of the CBD stones for each patient before and after stenting were measured on the radiographs. For multiple stones, the diameter of the largest stone was calculated (15), and the number of the stones was also counted. The actual CBD stone size was adjusted for radiograph magnification by multiplying the ratio of the actual and measured diameters of the endoscope on the cholangiogram. The radiographs were reviewed independently by two investigators and the results were averaged.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 15.0 (SPSS Inc.; Chicago, IL, United States). Mean and standard deviation (SD) were used to summarize the data for continuous variables and the percentages for categorical variables. A Shapiro–Wilk test was performed to assess if the continuous data was normally distributed. Based on the results of the Shapiro–Wilk test, statistical comparisons of continuous variables were performed using Student's t-test or the Wilcoxon rank sum test. Categorical parameters were analyzed by χ^2 test or Fisher's exact test. Kaplan–Meier analysis was applied for the estimation of the 3-month stent patency rate. $P<0.05$ was considered statistically significant.

RESULTS

Sixty-four patients were enrolled in this study. There were 42 men and 22 women with ages ranging from 65 to 88 years (mean age 73 years). In total, 34 (53.13%) patients underwent single stent placement and were included in group A. Group B included 30 (46.88%) patients who underwent double stent placement. In total, 17, 34, and 56 patients presented with cholangitis, jaundice, and abdominal pain on admission, respectively. Seventeen patients with cholangitis recovered rapidly with conservative treatment and were included. The baseline characteristics of the two groups are shown in Table 1. There were no statistical differences between the two groups with respect to age, gender, clinical features, comorbidities, and surgical history.

The median duration of stenting was 133 [interquartile range (IQR), 105–148] days in group A and 143 (IQR, 118–179) days in group B ($p>0.05$). The mean size (longitudinal/transverse diameter, mean±SD) of CBD stones before stenting was 19.15±5.78 / 17.41±5.64 mm in group A and 17.03±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 ($p<0.001$; Table 2, Figure 1). We also analyzed data in patients aged 80 or older. There were six and four patients whose ages were greater than 80 years in group A and B, respectively. Similarly, stone size also dramatically decreased ($p<0.05$; Table 2). Also, the median number of stones significantly decreased (group A, 4 [2, 5.25] versus 3 [2, 3], $P<0.05$; group B, 4.5 [4, 7] versus 3 [2, 3.25], $p<0.001$; Table 2), whereas this was not observed in patients aged 80 or older (group A, 3

Table 1. Baseline characteristics of patients

	Group A	Group B	p
No. of patients	34	30	
Gender (male/female)	24 / 10	18 / 12	0.373
Age (years) mean±SD (range)	73.4±6.2 (65-88)	72.6±5.1 (65-84)	0.571
Concomitant disease			
Cardiovascular	19	22	0.147
Cerebrovascular	13	10	0.683
Distal CBD stricture	4	1	0.360
Diabetes mellitus	2	4	0.407
Renal	1	0	NA
Surgical history			
Billroth II gastrectomy	1	1	1.000
Previous cholecystectomy	14	9	0.352
Combination of stones			
Large stones only (n≤2)	9	3	0.117
Multiple stones only	14	19	0.077
Large and multiple stones	11	8	0.405
Clinical symptoms			
Cholangitis	11	6	0.264
Jaundice	14	20	0.041
Abdominal pain	30	26	1.000
Stone size before stenting (mm, Mean±SD)			
Longitudinal	19.15±5.78	17.03±4.85	0.121
Transverse	17.41±5.64	16.63±4.71	0.554

Group A: single-stent placement, group B: double-stent placement.
SD: standard deviation; CBD: common bile duct; NA: not available

[1, 5.5] versus 1.5 [0.75, 4], p=0.416; group B, 4 [2.5, 5.5] versus 4 [3.75, 6.25], p=0.593; Table 2). The laboratorial data, including bilirubin and gamma glutamyltransferase levels, significantly decreased after biliary stenting in both groups (Table 2). However, there was no significant difference in the reduction of stone size and number between the two groups (p>0.05; Table 3). Using only the basket and retrieval balloon catheter, complete stone removal was achieved in 27 patients in group A and 26 in group B. An additional endoscopic sphincterotomy or mechanical lithotripsy only was performed for complete stone removal in three patients in group A and two patients in group B. Four patients in group B received an additional endoscopic sphincterotomy only to achieve complete stone removal. The stone size of two patients in group A remained unchanged, and a second stent was placed for long-term treatment. Therefore, total CBD stone clearance was achieved in 32 patients (94.1%) in group A and 30 patients (100%) in group B (p=0.494; Table 3). In patients aged 80 or older, complete stone removal was also achieved in 5 patients (83.3%) in group A and 4 patients (100%) in group B (p=1.000; Table 3). Kaplan–Meier analysis indicated that group B had a higher three-month stent patency rate than group A (p=0.008; Figure 2). Nonetheless, the three-month stent patency rate was not significantly different in patients aged 80 or older between the two groups (p=0.694; Figure 3).

Three patients (10%) developed mild pancreatitis in group B 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. Neither mental deterioration nor mortality was observed in either group.

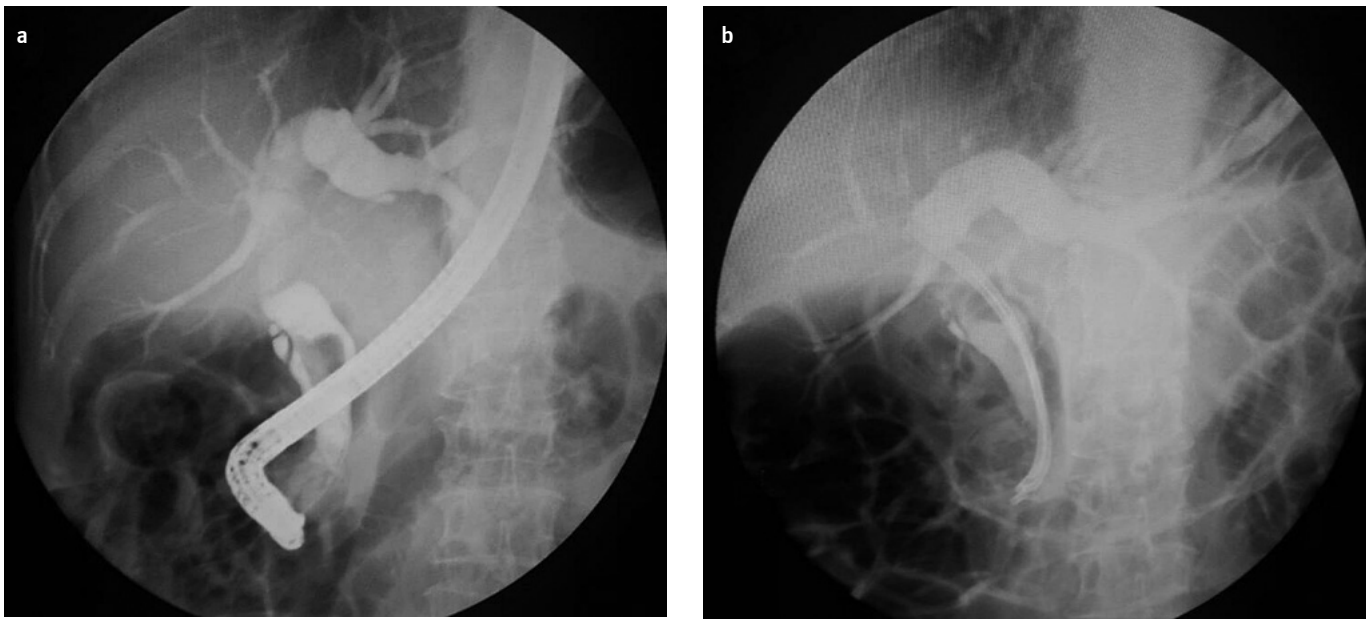

Figure 1. a, b. Retrograde cholangiograms showing stone change before (a) and after (b) biliary stenting.

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

	Group A			Group B		
	Before	After	p	Before	After	p
Stone size (mm) in patients aged 65 or older[1]						
Longitudinal	19.15±5.78	10.85±4.38	<0.001	17.03±4.85	8.57±3.65	<0.001
Transverse	17.41±5.64	9.38±4.14	<0.001	16.63±4.71	6.63±3.02	<0.001
Stone number[2]	4 (2, 5.25)	3 (2, 3)	0.01	4.5 (4, 7)	3 (2, 3.25)	<0.001
Stone size (mm) in patients aged 80 or older[1]						
Longitudinal	17.00±4.47	9.33±6.41	0.007	19.25±3.40	9.50±2.38	0.025
Transverse	15.5±4.32	8.00±5.404	0.003	18.50±2.65	10.75±1.50	0.016
Stone number in patients aged 80 years or older[2]	3 (1, 5.5)	1.5 (0.75, 4)	0.416	4 (2.5, 5.5)	4 (3.75, 6.25)	0.593
Laboratory data[1]						
Bilirubin (µmol/L)	56.85±72.20	25.62±27.30	0.002	60.13±73.81	22.83±27.25	0.002
GGT (U/L)	418.26±321.24	265.97±175.86	0.005	477.83±243.00	142.47±108.69	0.001

[1]Data were presented as mean±standard deviation.
[2]Data were presented as median (interquartile range).
Group A, single stent; Group B, double stents.
GGT: gamma glutamyltransferase

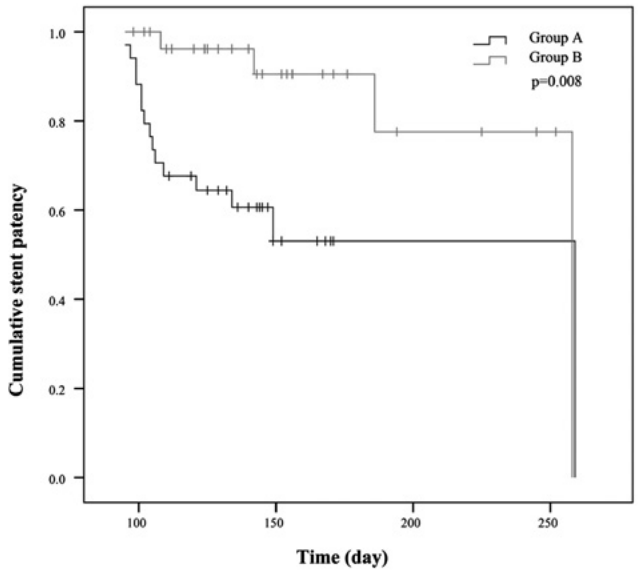

Figure 2. Kaplan–Meier's curve comparing groups A and B with respect to cumulative stent patency rate.

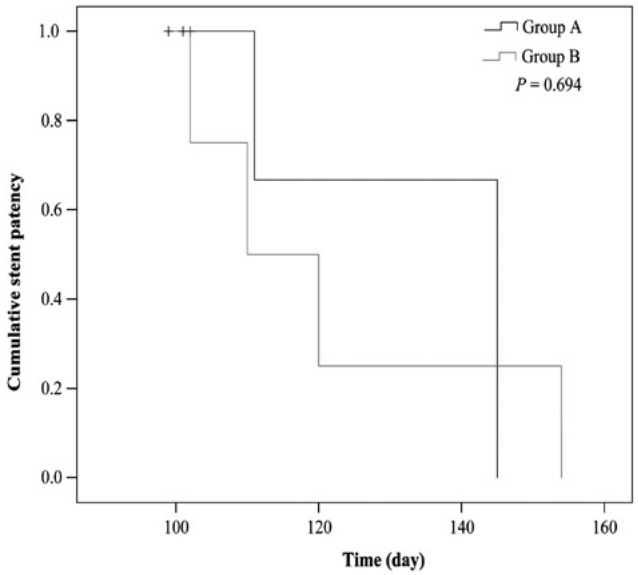

Figure 3. Kaplan–Meier's curve comparing patients aged 80 years or older in groups A and B with respect to cumulative stent patency rate.

DISCUSSION

Conventional methods, including balloon or basket techniques, are often problematic when extracting large and/or multiple CBD stones (6,8). The rate of successful removal declines with increasing sizes of the stone (22). Moreover, many patients with difficult CBD stones are of an older age (≥65 years) and/or have severe associated diseases. These patients have a high incidence of complications and are unable to undergo surgery because of the existence of comorbid cardiopulmonary and cerebrovascular conditions. Furthermore, a more prolonged procedure duration may be necessary to completely remove large/multiple stones in these frail, elderly patients. In such individuals, temporary biliary stenting is a safe and effective alternative (11-16,18,19). In the present study, we confirmed our previous experience and earlier reports that biliary stenting might be associated with a decrease in stone size and stone fragmentation (14-16) and also that indwelling double stents are superior to a single stent in maintaining the 3-month stent patency rate.

As shown in Table 2, short-term (approximately 3 months) biliary stenting was generally associated with a reduction in both the size and number of CBD stones. This result is consistent with previous reports (14-17). The reduction of stone size and num-

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Table 3. Baseline characteristics of patients

Parameter	Age	Group A	Group B	p
Complete stone removal	≥65	94.1% (32/34)	100% (30/30)	0.494
	≥80	83.3% (5/6)	100% (4/4)	1.000
Reduction in stone size (mm)[1]	≥65	8.29±4.20/ 8.03±4.00	8.57±3.65/ 9.03±3.05	0.855/ 0.171
	≥80	7.67±4.23/ 7.50±3.45	8.50±4.04/ 9.00±3.65	0.764/ 0.528
Reduction in stone number[2]	≥65	1 (0, 3)	1 (1, 2)	0.128
	≥80	0 (-1.50, 2.25)	1 (1, 2)	0.388

[1]Longitudinal/transverse diameter, data were presented as mean ± standard deviation.
[2]Data were presented as median (interquartile range).
Group A, single stent; Group B, double stents.

ber was remarkable after stenting in both groups, with greater, but non-significant changes in group B patients (Table 3). Furthermore, there was a tendency towards a higher rate of complete stone removal in the double-stent group. However, these differences were not statistically significant. The mechanism by which the stones change in number and size is still obscure. Primarily, respiration and intestinal movements cause friction between the stents and stones, thus inducing fragmentation and facilitating removal. Also, prevention of stone impaction at the ampulla of Vater facilitates drainage after biliary stenting. Furthermore, polygonal stones may become more rounded after a period of friction and achieve a higher possibility of spontaneous passage (22). Indeed, no stones were detected in one patient in each group at the second ERCP. Other studies also showed similar results (16,20,22).

Stent occlusion often occurs after a short period of time, thus requiring frequent stent exchanges (14,23). The exact mechanisms of occlusion are not well understood. It may be attributed to the adhesion of bacteria to the stent surface and the formation of insoluble calcium bilirubinate, which is precipitated within the stent (24). The present study showed that our 3-month cumulative stent patency rate was significantly higher in group B than in group A (p=0.008), suggesting that double stent placement may provide more efficient and continuous drainage. Our data also showed that a relatively higher successful rate of stone removal was achieved in group B, although this difference was not significant. The possible reasons may be as follows: primarily, insertion of double stents would increase surface friction between the stents and prompt more stone fragmentation than a single stent. Also, even if stent occlusion occurs, stents may still maintain continuous drainage of the bile duct via a "wicking" phenomenon, with bile flowing around and between the stents (8). Furthermore, the more efficient drainage caused by the insertion of double stents could reduce duodenobiliary reflux and prevent calcium bilirubinate from precipitating in the stents.

As shown in the present study, we used biliary stenting without attempting to extract difficult stones as the primary therapy; one of the advantages of this modality is that it can shorten the procedure time and reduce the possibility of multiple cannulation attempts to decrease the incidence of post-ERCP complications. In terms of complications, three group B patients developed mild pancreatitis at the initial ERCP, whereas Horiuchi et al. (17) reported that the incidence of post-ERCP pancreatitis was 5%. Cholangitis occurred in two patients in group A and was controlled after removal of the stones and administration of intravenous antibiotics. Stent migration was discovered at the second ERCP in four and three patients in groups A and B, respectively. Of the seven patients with stent migration, six had significant reduction in stone size and achieved complete stone removal at the second ERCP, except for one failure in group A, indicating the efficacy of stenting. Therefore, we considered that the results might be only slightly affected by stent migration. It is postulated that movements of the stone in the dilated duct promote the extrusion of the stent into the duodenum (22,25). The optimal type of stent has not yet been ascertained, although previous studies demonstrated that a pigtail stent may provide a lower risk of migration, cholangitis and perforation (16,17). A pigtail stent emerges from the bile duct with its duodenal orifice at an angle, maintaining the meatus open more efficiently and allowing bile to flow around the stone and stent. Our data provided similar results to previous studies (16,17). Further studies are necessary to analyze and compare these different stents in future studies.

By its very nature, there are limitations to our study. The analyses were retrospective and may have produced population bias. Moreover, the selection of single or double stents was made at the discretion of two endoscopists. Relatively more patients with multiple stones and jaundice were allocated to group B, thereby inducing selection bias. This bias might be expected to mask some of the beneficial effects of double stenting. However, the majority of the baseline characteristics of the patients showed no significant difference, implying that selection bias had been largely reduced. Still, we could not draw clinically explicit conclusions from this study only. Also, there was a relatively small sample size in this study because eligible candidate patients are very rare, although there are approximately 700 cases of ERCP performed at our center per year. In the present study, double-stent placement in the treatment of difficult CBD stones did not show its superiority statistically except for a higher 3-month stent patency rate. However, there was a trend towards a higher rate of successful stone clearance at the second ERCP and reduction of stone size and number in the double-stent group. We consider that this calculation of sample size does not have sufficient statistical power. Perhaps enlarging the sample size could lead us to find more remarkable and statistically significant differences between the groups. Furthermore, our data represent the experience at a single center, and the generalizability is unknown. Therefore, a larger, multicenter study may provide significant results. An-

other limitation is that we did not apply larger stents. There is a belief among endoscopic physicians that once an adequate endoscopic sphincterotomy is performed, stent size is irrelevant to continued patency (26). Theoretically, a large stent offers better drainage and a lower rate of stent occlusion than a small stent. However, previous studies showed no significant stent occlusion for both a 10 FR stent and a 6–7 FR stent (27,28). The other reasons considered in selecting 7 and 8.5 FR stents were easy operation and reduced trauma to the bile duct, particularly for elderly, fragile patients. Stents are known to block, and typically, bile duct patency is maintained by passing around the stent. However, it seems to be promising that larger stents (i.e., 10 FR) may improve outcomes. This issue may be addressed by further study.

Overall, these data suggest that for CBD stones that are speculated to be difficult to remove in elderly, fragile patients with comorbidities, biliary stenting may be a safe and effective method for the management of difficult CBD stones, while double-stent placement is superior to a single stent for the 3-month patency rate. Our data also showed a relatively higher success rate of complete stone clearance and a greater reduction of stone size in the double-stent group. A larger, multicenter study is warranted before definite conclusions can be drawn.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Wenzhou Medical University.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - X.C.S.; Design - X.H.Y., X.C.S.; Supervision - X.H.Y, X.C.S.; Resource - X.C.S.; Materials - X.C.S.; Data Collection and/or Processing - X.H.Y., J.P.H.; Analysis and/or Interpretation - X.H.Y., J.P.H.; Literature Search - X.H.Y., J.P.H.; Writing - X.H.Y., J.P.H.; Critical Reviews - X.H.Y., X.C.S.

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