

Biliary stenting in the management of large or multiple common bile duct stones CME

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Background: Endoscopic biliary stenting with a plastic stent is often performed to prevent impaction of common bile duct (CBD) stones. The therapeutic effect of a plastic stent placement in terms of reduction in stone size and number has not been established.

Objective: The aim of this study was to study the effect of biliary stenting as therapy for CBD stones.

Design: Retrospective study.

Setting: Municipal hospital outpatients.

Interventions: Patients with large (≥ 20 mm) and/or multiple (≥ 3) stones had placement of a 7F double-pigtail plastic stent without stone extraction at the initial ERCP. Approximately 2 months later, stone removal was attempted. The number and size of CBD stones before and after stent placement, stone clearance, complications, and 180-day mortality were evaluated.

Results: Forty patients were studied. Stent placement averaged 65 days (range, 50-82 days). The median number (interquartile range) of stones per patient fell after stent placement (4.0 [3.0] before vs. 2.0 [1.0] after; $P < .0001$). Characteristically, larger stones became smaller and small stones disappeared (ie, the median stone index decreased from 4.6 [3.0] to 2.0 [1.5]; $P < .0001$). Stone clearance at the second ERCP was achieved in 37 out of 40 patients (93%). Complications included cholangitis (13%) and pancreatitis (5%) after the second ERCP. No 180-day mortality occurred.

Limitations: A retrospective, single-center study.

Conclusions: Stent placement for 2 months was associated with large and/or multiple CBD stones becoming smaller and/or disappearing without any complications. Stenting followed by a wait period may assist in difficult CBD stone removal. (Gastrointest Endosc 2010;71:1200-3.)

Cholelithiasis is one of the most common GI diseases seen in clinical therapeutic endoscopy practice. Endoscopic sphincterotomy and stone extraction is widely performed as a primary method for patients with common bile duct (CBD) stones with an 80% to 90% success rate and a complication rate of $<10\%$.¹⁻³ The technical difficulty of stone removal from CBD depends on the size and

number of stones; large stones (ie, >20 mm) often need to be fragmented by mechanical lithotripsy before removal.^{4,5} In addition, the procedure is often prolonged when it is necessary to clear many stones. Alternative approaches for these difficult stones are extracorporeal shockwave lithotripsy (ESWL),^{6,7} laser lithotripsy,⁸ and electrohydraulic lithotripsy (EHL).^{9,10}

Abbreviations: CBD, common bile duct; EHL, electrohydraulic lithotripsy; ESWL, extracorporeal shockwave lithotripsy.

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When CBD stones can not be completely removed, a plastic stent is often placed to prevent impaction.¹¹ Our experience has been that after stent placement, large stones often appeared smaller or disappeared. This experience is consistent with earlier reports that indwelling endoprostheses may affect stone size or lead to fragmentation.¹²⁻¹⁴

For the past 5 years we have placed a double-pigtail plastic stent without stone removal as primary therapy at the initial ERCP for patients with large and/or multiple stones. The aim of the present study was to retrospectively compare the number and size of CBD stones before and after 2 months of biliary stenting.

METHODS

Between January 2004 and December 2008, 674 patients underwent ERCP at Showa Inan General Hospital. Of 208 patients (31%) with CBD stones, primary stone extraction was attempted in 159 patients; successful stone clearance at the initial ERCP was 86% (137/159). Of these 159 patients, 11 had large stones (≥ 20 mm) and/or multiple stones (≥ 3) and required at least two sessions of stone removal. In 9 patients, endoscopic nasobiliary drainage tube placement was performed to improve acute suppurative cholangitis.

The remaining 40 patients (19.2%) with large (≥ 20 mm) and/or multiple (≥ 3) stones were treated by plastic stent placement without stone extraction at the initial ERCP. Stone extraction was not attempted at the initial attempt, because the patients were judged to be an increased risk (eg, elderly or taking anticoagulant and/or antiplatelet agents). In all cases, a 7F double-pigtail side-hole plastic stent (Olympus, Tokyo, Japan) was used. Patients with acute suppurative cholangitis were excluded. No oral dissolution agent was prescribed. Approximately 2 months after stent placement, sphincterotomy followed by attempted stone extraction was done by using an endoscopic mechanical lithotripter and basket/balloon catheter.

Measurement of number of CBD stones and CBD diameters

The diameters of CBD stones before and after stenting were measured on the radiographs. For patients with multiple CBD stones, all stones were measured. Also, the number of the stones was counted. The radiograph magnification was corrected by using the endoscope diameter as our reference value, and the actual stone diameter was calculated as the measured stone diameter \times the actual endoscope diameter/the measured endoscope diameter. The radiographs were reviewed independently by 2 of the authors and the measurements were averaged.

Take-home Message

- Stent placement for about 2 months resulted in large and/or multiple common bile duct stones becoming smaller and/or disappearing. No stent-related complications occurred, and there was no 180-day mortality. This method appears to be both effective and safe for the management of difficult common bile duct stones and does not require the use of any special instruments.

Measurement of the stone index

The stone index was defined as the sum of diameter in cm \times the number of stones. For example, the stone index for a patient with 3 stones of 1, 2, and 2 cm diameter is 5 ($[1 \text{ cm} \times 1] + [2 \text{ cm} \times 2]$). The stone index would estimate the stone burden and the number per patient before and after the stenting.

Statistics

Data are presented as median (interquartile range). Because the data were not normally distributed, statistical comparisons of CBD stone number and stone index were carried out by using Wilcoxon rank sum test. A value of $P < .05$ was regarded to be significant. All statistical evaluation was performed by using SPSS version 12.0J software (SPSS Japan, Tokyo, Japan).

RESULTS

There were 18 men and 22 women with a mean age of 77.8 (range, 41-89) years. Eight patients (20%) had previous cholecystectomy. Twelve patients (30%) had severe comorbid diseases, such as cerebral infarction and myocardial infarction. Six patients (15%) took anticoagulants and/or antiplatelets for the prevention of recurrence of these diseases. On admission, 27 (68%), 6 (15%), and 5 (13%) presented with cholangitis, jaundice, and abdominal pain, respectively; 27 patients who had cholangitis improved rapidly with conservative therapy and were entered. Those with classic acute suppurative cholangitis were excluded. Twenty-two patients had multiple CBD stones (>3), and 20 patients had large stones (≥ 20 mm).

As shown in Figures 1 and 2, the stent placement for 2 months alone was associated with a marked decrease in stone number. The average duration of stent placement up to the stone removal was 65 (range, 50-82) days. After biliary stenting for 2 months, 37 patients had some reductions in the stone number and/or stone size; 3 patients who had only single large stones had no significant change in the diameter of the stone. The median number (interquartile range) of stones per patient was significantly reduced after biliary stenting compared with before (4.0



Figure 1. Retrograde cholangiogram showing pigtail stent with multiple stones in the common bile duct.



Figure 2. Retrograde cholangiogram 2 months after stent placement in same patient as Figure 1, showing the reduction in size and number of stones.

[3.0] vs. 2.0 [1.0]; $P < .0001$; (Fig. 3). The median (interquartile range) stone index was also significantly decreased from 4.6 (3.0) to 2.0 (1.5) after stenting ($P < .0001$). An appendix containing detailed information about each stone in each patient is available online at www.giejournal.org.

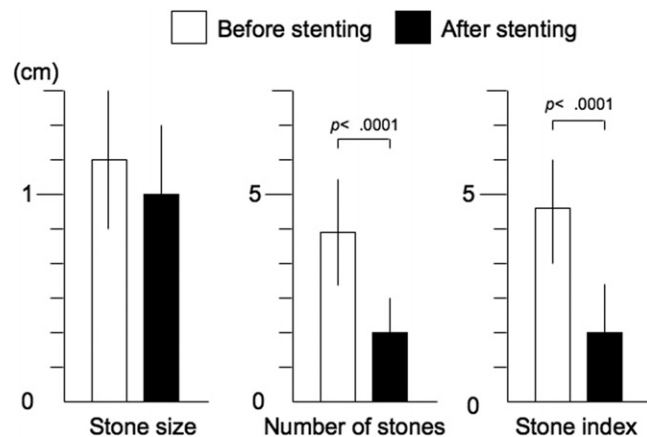


Figure 3. Comparison of size, number, and index of common bile duct stones before and after 2 months of plastic stent placement in 40 patients. Results are shown as median with interquartile range. Stone index = the sum of diameter (cm) \times the number of stones (eg, [1 cm \times 1] + [2 cm \times 2] = 5.0 for a patient with 3 stones).

DISCUSSION

We confirmed our experience and earlier reports that indwelling endoprosthesis may be associated with a decrease in stone size and stone fragmentation.¹²⁻¹⁴ Plastic stent placement for 2 months alone was associated with large and/or multiple CBD stones becoming smaller and/or disappearing, resulting in stones that could be easily removed. The reduction of the number and size of CBD stones induced by biliary stenting in the present study is similar to results reported earlier.¹²⁻¹⁴ Because large CBD stones (≥ 20 mm in diameter) can be difficult to extract by conventional techniques (basket/balloon), mechanical lithotripsy was used for stone extraction. However, the technique may fail in very large stones, multiple stones, or stones within a relatively narrow duct where there is little space to manipulate the basket. Various factors, such as presence of perampullary diverticulum, narrowing of the distal CBD, multiple CBD stones, limited sphincterotomy due to a small papilla, more acute distal CBD angulation, and a shorter length of the distal CBD arm, all may influence successful stone clearance.^{15,16} In addition, the procedure time is often prolonged when one must clear many stones. Many patients with difficult CBD stones are of older age or have severe associated diseases. For these cases, alternative methods, such as EHL or ESWL, are often used. It has been reported that peroral endoscopic EHL is an effective means of managing difficult biliary stone disease, with fragmentation rates of 96% and stone clearance rates of 90%.¹⁰ These procedures, however, are time consuming and require delicate instruments that are often not available in general institutions.

As shown in Figure 3, plastic stent placement for 2 months was generally associated with a reduction in both the number and the size of CBD stones. The stone index was developed as a novel scale designed to express changes in both the

number and the size of CBD stones. As stones fragment, the stone number can actually increase and the stone index provides a convenient method of measuring the reduction in stone burden after stenting. The mechanism of stones changing in number and size is unclear. Some possibilities include friction between the plastic stent and stones, influx of duodenal contents, or both. Because the plastic stent is thought to easily move with the body or intestinal movements, the friction between the stent and stones is expected to be much larger than that of friction between stones *in situ*. Of interest, the 3 patients who had only 1 large stone (2 cm) had no significant change in the diameter of the stone, suggesting that friction or other interactions between the stent and multiple stones may enhance the process. Possibly, placement of 2 stents would have prompted stone fragmentation. Only 3 patients failed endoscopic intervention during the second ERCP. In these patients with difficult stones, additional ERCPs were not performed, owing to the clinical condition of the patients (ie, elderly, with comorbid conditions).

According to guidelines on the management of CBD stones when endoscopic extraction is difficult, insertion of an endoscopic biliary stent is suggested to prevent stone impaction and cholangitis.¹⁶ Short-term use of a biliary stent, followed by further endoscopy or surgery, is recommended to ensure adequate biliary drainage in patients with CBD stones that have not been extracted. Use of a biliary stent as sole treatment of CBD stones has been thought to be limited to patients with limited life expectancy or prohibitive surgical risk, or both. For the first time, the present study proposes that biliary stenting could be a primary method to reduce the size and number of difficult CBD stones, thus making extraction possible. The role of adjuvants such as ursodeoxycholic acid is unclear; one study found no beneficial effect of the addition of oral ursodeoxycholic acid and stenting,¹⁷ whereas another suggested that the combination of ursodeoxycholic acid and terpene contributed to the stone reduction.¹⁸ Our approach to assessing the outcome might assist in designing additional studies to address whether dissolution therapy plus stenting provided superior results, especially for large single stones.

In the present study, biliary stenting alone was not associated with complications such as cholangitis, pancreatitis, or migration. We used a double-pigtailed stent; it is unknown whether a difference of the type of stent (ie, a straight stent) would have provided similar results. No stent migration was observed in the present study using double-pigtail stents.

The average duration of stent placement up to the stone removal was 65 (range, 50-82) days. Earlier studies have placed plastic stents for 6 months.^{13,14} The optimum duration of stenting remains unknown; however, based on our previous experiences, we suspect that at least 2 months may be needed to obtain the beneficial effect of a plastic stent placement on the fragmentation of large or multiple stones. However, future studies are needed to identify optimum timing, because the change in stone size may not

be correlated with the duration of stenting. In addition, studies are needed to examine whether oral dissolution agents would provide an additional beneficial effect. The present study also has limitations because the analyses were retrospective, there were a relatively small number of patients, and it lacked a control group so that the generalizability is unknown.

Overall, these data suggest that for patients with difficult stones that are speculated to be difficult to extract, the elderly or high-risk patients, such as those taking anticoagulant and/or antiplatelet agents, stent placement for 2 months may be an effective alternative (eg, to ESWL) for the management of difficult CBD stones.

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APPENDIX

TABLE 1. Comparison of size, number, and index of common bile duct stones before and after 2 months of a plastic stent placement in 40 patients

Patient	Stone size (cm)		No. of stones		Stone index*	
	Before	After	Before	After	Before	After
1	2, 1.8, 1.5, 1.5	1, 0.8, 0.7	4	3	6.8	2.5
2	2	2	1	1	2.0	2.0
3	2.5, 2, 1.8, 1.5	1.5, 1.7, 1	4	3	7.8	4.2
4	2, 1.5	1.5	2	1	3.5	1.5
5	1.5, 1.5, 1, 1, 0.8	1, 0.8, 0.7	5	3	5.8	2.5
6	1.4, 1, 1, 0.8	1, 0.8, 0.7	4	3	4.2	2.5
7	1.5, 1.2, 1, 1	1.2, 0.7	4	2	4.7	1.9
8	2.5	1	1	1	2.5	1.0
9	2, 1.5, 1.5, 1.2, 0.8	1, 1, 0.6	5	3	7.0	2.6
10	2, 1.5	1, 1	2	2	3.5	2.0
11	2	1, 0.5	1	2	2.0	1.5
12	2, 1.5, 1.5	1, 0.5	3	2	5.0	1.5
13	1.5, 1, 1, 1	0.7, 0.5	4	2	4.5	1.2
14	1.5, 1.3, 1	1	3	1	3.8	1.0
15	2, 1	1, 0.8	2	2	3.0	1.8
16	0.5 × 20	0.5 × 8	20	8	10	4.0
17	1.5, 1, 1	1, 1	3	2	3.5	2.0
18	1.5 × 5	1, 1	5	2	7.5	2.0
19	1 × 7	1, 1, 1, 1	7	4	7.0	4.0
20	1 × 6	1, 1, 1	6	3	6.0	3.0
21	2, 1.8, 1.5, 1.5	1, 0.8, 0.5	4	3	6.8	2.3
22	2	2	1	1	2.0	2.0
23	2.5, 2, 1.5, 1.5	2, 1, 1	4	3	7.5	4.0
24	2	2	1	1	2.0	2.0
25	1.5, 1.5, 1, 1, 1	1, 0.8, 0.7, 0.5	5	4	6.0	3.0
26	1, 1, 1, 1	1, 1	4	2	4.0	2.0
27	1.5, 1.2, 1, 1	1.2, 0.5, 0.4	4	3	4.7	2.1
28	2.5	1	1	1	2.5	1.0
29	2, 1.2, 1, 1, 0.8	1, 1, 0.5, 0.5	5	4	6.0	3.0
30	2, 1.5, 0.5	1, 1	3	2	4.0	2.0

TABLE 1 (Continued). Comparison of size, number, and index of common bile duct stones before and after 2 months of a plastic stent placement in 40 patients

Patient	Stone size (cm)		No. of stones		Stone index*	
	Before	After	Before	After	Before	After
31	2	0.5, 0.5, 0.5	1	3	2.0	1.5
32	2, 1.5, 1.5	0.8, 0.8	3	2	5.0	1.6
33	1.5, 1, 1, 0.8	0.7, 0.5	4	2	4.3	1.2
34	1.5, 1.5, 1	1	3	1	4.0	1.0
35	1, 1, 1	1, 1	3	2	3.0	2.0
36	0.7 × 15	0.8 × 6, 0.6, 0.6	15	8	10	6.0
37	1.5, 1, 1	1, 1	3	2	3.5	2.0
38	1.5 × 5	1, 1, 1	5	3	7.5	3.0
39	3, 1.5, 0.5 × 5	2, 1, 1, 0.5, 0.5	7	5	7.0	5.0
40	1 × 6	1, 1, 1, 1	6	4	6.0	4.0
Median (interquartile range)			4.0 (3.0)	2.0 (1.0)	4.6 (3.0)	2.0 (1.5)
			$P < 0.0001$		$P < .0001$	

*Stone index= the sum of diameter (cm) × the number of stones (eg, [1 cm × 1] + [2 cm × 2] = 5.0 for a patient with 3 stones).