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Original Article

Role of endoscopic papillary balloon dilation in patients with recurrent bile duct stones after endoscopic sphincterotomy

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Abstract

Background: Endoscopic sphincterotomy (ES) is an established treatment for patients with choledocholithiasis or common bile duct stones (CBDS), but further management of patients after ES with recurrent CBDS remains controversial. Endoscopic papillary large balloon dilation (EPLBD) has been used safely and effectively for stone removal in patients after ES with recurrent CBDS. The aim of this study was to evaluate the clinical efficacy of EPLBD in patients after complete ES with recurrent CBDS.

Methods: Records of 891 patients with CBDS after complete ES from January 1991 to December 2008 were reviewed. Of 133 patients with recurrent CBDS, 122 had complete endoscopic bile duct clearance. Twenty-three patients (Group 1) underwent EPLBD and 99 (Group 2) underwent stone extraction without dilatation. Basic demographics and endoscopic findings at the first recurrence were recorded and analyzed. The primary end point was the second CBDS recurrence.

Results: No statistical differences were observed between the two groups, except for larger CBDS size in Group 1. The bile duct clearance rate was 96% in Group 1 and 91% in Group 2. No complications such as pancreatitis, perforation, and bleeding were noted in Group 1, and one patient in Group 2 suffered from bleeding after stone extraction. The rate of second recurrent CBDS after endoscopic clearance for the first recurrent CBDS was 17% in Group 1 and 60% in Group 2 ($p < 0.001$). There were two independent factors for the second recurrence, including cirrhosis (odds ratio 4.734, $p = 0.023$) and stone extraction directly without major papilla expansion (odds ratio 6.050, $p = 0.003$).

Conclusion: EPLBD is a safe and effective endoscopic treatment for recurrent CBDS in patients after ES. It can also facilitate complete clearance of CBDS and prevent further CBDS recurrence.

Keywords: endoscopic papillary large balloon dilation; endoscopic retrograde cholangiopancreatography; endoscopic sphincterotomy; recurrent common bile duct stone

1. Introduction

Endoscopic sphincterotomy (ES) is a widely used method of treatment for patients with choledocholithiasis or common bile duct stones (CBDS).[1] The actual ES procedure is technically demanding and associated with about 9.8% complications.[2] Most complications are primarily related to the indications for the procedure and the endoscopic technique.[2] Endoscopic papillary balloon dilatation (EPBD), which was

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introduced by Staritz et al[3] in 1982, is an alternative method for removing bile duct stones. It is more easily accessed and less technically demanding than ES. It also causes less hemorrhage and less perforation, and can preserve the sphincter of Oddi function.[4,5] However, EPBD is not widely used due to its associated higher risk of pancreatitis and a higher rate of using mechanical lithotripsy, as reported in some studies.[6] Endoscopic papillary large balloon dilation (EPLBD) after limited ES, which was introduced by Ersoz et al,[7] is effective in removing bile duct stones and has an acceptable complication rate.[8] Recent studies have shown that EPLBD alone is a safe and effective method for removing bile duct stones, and the procedure is also technically easy to navigate.[9,10]

Patients after ES still have the risk of recurrent CBDS, with the rate ranging from 4% to 24% over the duration of long-term follow-up.[11−14] There has been no consensus for the management of patients with recurrent CBDS after prior ES. Although most of the recurrent stones in Chinese patients are loose bilirubinate stones,[15] stone extraction is sometimes difficult, especially in patients with multiple large stones and/or papillary stenosis, even using a mechanical lithotripter. Data on the repeated use of ES for extending the previous sphincterotomy in these patients are limited and controversial. Some studies suggested that EPLBD could be used safely in these patients, with effective results.[16−18]

The aim of our study was to retrospectively evaluate the long-term clinical efficacy of EPLBD compared with direct stone extraction without balloon dilation in patients with recurrent CBDS after prior ES.

2. Methods

2.1. Patients

This study has been approved by the Institutional Review Board of Kaohsiung Veterans General Hospital (VGHKS12-CT7-02).

Consecutive patients with recurrent CBDS after complete ES in Kaohsiung General Veterans Hospital, Taiwan, from January 1991 to December 2008 were reviewed. Patients with previous biliary surgery, those with pancreatic or biliary malignant disorders, and pregnant women were excluded. We recorded the basic demographics and endoscopic findings at the first recurrence. Next, we divided the patients into two groups (Groups 1 and 2) according to the endoscopic management approach for the recurrent CBDS.

2.2. Procedures

The preparation included local anesthesia of the pharynx using 10% xylocaine, and intramuscular injection with 40 mg hyoscine-*N*-butylbromide and 25−50 mg meperidine. Endoscopic retrograde cholangiopancreatography (ERCP) was performed in the standard manner using a side-view endoscope (JF-240; Olympus Optical Corporation, Tokyo, Japan). After selective cannulation of the common bile duct using the catheter, cholangiography was performed to confirm the diagnosis of recurrent CBDS. For Group 1 patients, a 0.035-inch guidewire (Boston Scientific Corp., Marlborough, MA, USA) was then inserted into the bile duct through the catheter. EPLBD was performed by passing a dilating balloon (CRE balloon 5.5 cm in length and 1.0−1.2 cm/1.2−1.5 cm/1.5−2.0 cm in diameter; Boston Scientific Corp., MA, USA) via the prepositioned guidewire into the bile duct using fluoroscopic and endoscopic guidance. The balloon was inflated up to the optimal size ($\geq$10 mm in diameter) for 1−5 minutes according to the patients' condition and tolerance. In order to minimize the risk of perforation, the size of the balloon should not exceed the largest diameter of the CBD, and further expansion of balloon was avoided once the patient felt intolerable pain. After removal of the balloon and guidewire, the CBDS were removed using a Dormia basket or balloon-tipped catheter, with or without the aid of mechanical lithotripsy. A mechanical lithotripter (BML-4Q; Olympus Optical, Tokyo, Japan) was used to fragment the stones if the maximal stone diameter was larger than the diameter of the distal bile duct or the stones could not be removed using the Dormia basket or balloon-tipped catheter. The decision to use balloon dilation was made depending on the endoscopists' personal experiences. For Group 2 patients, direct stone extraction was performed after cholangiogram without balloon dilatation. A second attempt at stone extraction was performed within 7 days for incomplete removal of stones in the first treatment session. All patients were observed in the hospital for at least 24 hours after endoscopic treatment. Procedure-related adverse events and incidents were recorded according to the definitions and grading systems of the recent workshop held by the American Society of Gastrointestinal Endoscopy.[19] During the ERCP procedure, dimensions of the juxtapapillary diverticulum and CBD as well as size and number of stones were recorded. Stone removal was declared complete if the final cholangiogram showed no residual stones. Clinical evaluation of symptoms and serum amylase was performed the following day.

2.3. Follow up

Patients with complete clearance of the bile duct were assigned to regular follow-up after discharge at a special clinic. We followed up the patients every 2 weeks until normalization of liver function tests, and every 3 months thereafter. During each visit, a blood sample was taken routinely for liver function tests, including total serum bilirubin, albumin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase. Abdominal ultrasound was suggested every 6−12 months, or when abnormal liver function test results or clinical symptoms suggested CBDS recurrence. Endoscopic retrograde cholangiography was performed if recurrent biliary symptoms, abnormal liver function tests, or sonography suggested recurrent CBDS. When repeated endoscopic retrograde cholangiography confirmed the diagnosis of recurrent CBDS, endoscopic removal of stones (with or without further balloon dilation) was performed simultaneously in the same session, or the patient was referred to a surgeon. Telephone contact was made with patients who were unable to return to the hospital.

2.4. Statistical analysis

All statistical analyses were performed with the SPSS program (version 12.0.1C). The values were expressed as mean ± standard deviation. Categorical variables were tested by the chi-square test or using Fisher's exact test. Continuous values were analyzed by Mann–Whitney *U* test. Cumulative re-recurrence was analyzed by the Kaplan–Meier method and log rank test. A p value of <0.05 was considered significant.

3. Results

Records of 891 patients with CBDS after complete ES in Kaohsiung General Veterans Hospital from January 1991 to December 2008 were reviewed. Of the 133 (14.9%) patients having recurrent CBDS, 122 with complete bile duct clearance for the recurrent CBDS were further divided into two groups according to the endoscopic procedure: 23 patients underwent EPLBD (Group 1) and 99 stone extraction without dilatation or expansion of previous sphincterotomy (Group 2). Basic demographics and endoscopic findings at the first recurrence were recorded (Table 1), and no statistical difference was observed in age, sex, concomitant systemic disease, gallbladder status, previous ES length, common bile duct size, juxtapapillary diverticulum, and lithotripsy between the two groups. However, a larger CBD stone size was noted in Group 1, where $p = 0.024$ using the Chi-square test.

The complete bile duct clearance rate was 96% (23/24) in Group 1 and 91% (99/109) in Group 2 (Table 2). A total of 11 patients had incomplete clearance of bile duct, one in Group 1 and 10 in Group 2. Of the failed patients in Group 2, four received subsequent biliary stent insertion, four received surgical intervention, one underwent nasobiliary drainage with subsequent mortality due to sepsis, and one refused further management. Of the four patients receiving salvage stent insertion, two had subsequent surgical intervention, one was lost to follow up, and the last patient refused further management and expired due to sepsis 6 months after the stent insertion. The only patient with incomplete clearance of bile duct after EPLBD had a poor tolerance for the procedure and refused further management. The family asked to transfer the patient to another hospital, who was then lost to further follow up.

Table 1
Basic demographics and endoscopic findings.

	Group 1 (n = 24)	Group 2 (n = 109)	p
Sex (male)	67% (16/24)	65% (71/109)	0.887
Age (y)	64.3 ± 10.17	66.6 ± 10.12	0.224[a]
Juxtapapillary diverticulum	46% (11/24)	56% (61/109)	0.367
Diabetes mellitus	4% (1/24)	13% (14/109)	0.305
Hypertension	21% (5/24)	29% (32/109)	0.399
Cirrhosis	4% (1/24)	17% (19/109)	0.123
Stone size (cm)	1.7 ± 0.79	1.4 ± 0.70	0.854[a]
≥1.5	13	24	0.024[b,*]
<1.5	9	50	
Multiple stones	63% (15/24)	71% (77/109)	0.434
CBD size (cm)	1.9 ± 0.67	1.9 ± 0.63	0.524[a]
≥1.5	19	76	0.595[b]
<1.5	4	22	
Balloon size (cm)	1.5 ± 0.42	—	
Intact gallbladder	42% (10/24)	27% (29/109)	0.142
Gallstones	29% (7/24)	16% (17/109)	0.143
s/p Billroth-II anastomosis	0% (0/24)	3% (3/109)	> 0.99
Intrahepatic duct stones	17% (4/24)	20% (22/109)	> 0.99

*$p < 0.05$.
CBD = common bile duct; EPLBD = endoscopic papillary large balloon dilation; ES = endoscopic sphincterotomy.
[a] Analyzed using the Mann–Whitney *U* test.
[b] Analyzed using the Chi-square test.

Table 2
Outcomes of two groups of patients after endoscopic treatment.

	Group 1	Group 2	p
Complication	0	1% (1/99)	> 0.99
Complete bile duct clearance	96% (23/24)	91% (99/109)	0.688
Complete clearance in one session	87% (20/23)	80% (79/99)	0.561
Lithotripsy	13% (3/23)	7% (7/99)	0.397
Second recurrence of CBDS	17% (4/23)	60% (60/99)	< 0.001
Interval between two recurrence (mo)	20 ± 22.9	24 ± 28.5	0.967
Follow-up time (mo)	95 ± 58.1	90 ± 45.3	0.761

CBDS = common bile duct stones.

Most patients received only one session of endoscopic treatment (87% in Group 1 and 80% in Group 2, $p = 0.561$) for achieving complete bile duct clearance. The use of mechanical lithotripter showed no statistically significant difference between the two groups (13% in Group 1, 7% in Group 2, $p = 0.397$). No complications, including pancreatitis, perforation, and bleeding, were noted in Group 1. One patient in Group 2 suffered from intraprocedural bleeding after stone extraction, and bleeding was controlled by endoscopic injection.

Patients of Group 1 had a significantly lower rate of second recurrent CBDS than patients of Group 2 [17% (4/23) vs. 60% (60/99), $p < 0.001$, Table 2]. In Kaplan–Meier analysis, Group 1 patients had a significantly lower incidence of re-recurrent CBDS (Fig. 1, $p = 0.0017$). The interval between two recurrences in these two groups showed no statistical difference (20 months vs. 24 months, $p = 0.745$). The overall follow-up durations in both groups were also similar, as can be noted from Table 2.

Among the potential risk factors for recurrent CBDS, cirrhosis (odds ratio 4.734, 95% confidence interval 1.236–18.138, $p = 0.023$) and stone extraction directly without major papilla expansion (odds ratio 6.050, 95% confidence interval 1.880–19.469, $p = 0.003$) were two independent factors for the re-recurrence, as shown in Tables 3 and 4.

4. Discussion

Once the patients after ES had recurrent CBDS, the likelihood of a second recurrence was reportedly as high as 33%.[20] Although loss of the function of sphincter may cause ascending cholangitis in complete ES or papillary stenosis (0.5–3.9%),[21] bile stasis may also be an important factor contributing to the recurrence of bile duct stones. Further management of recurrent stones in patients after ES remains

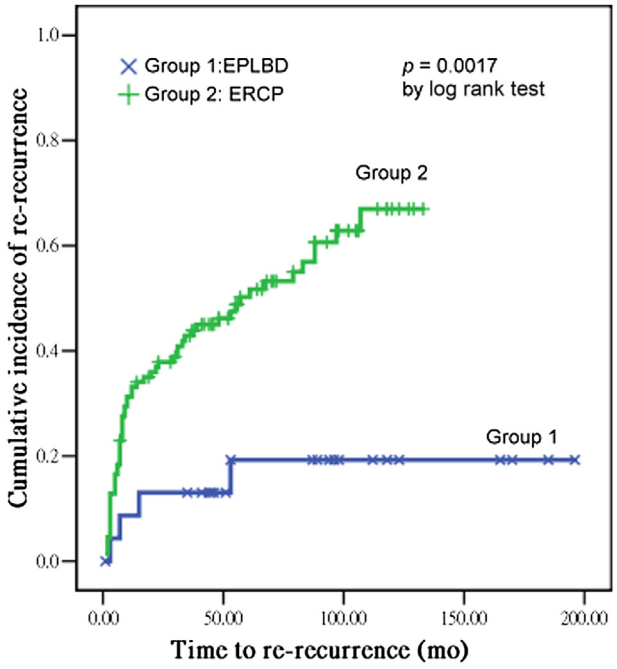

Fig. 1. Cumulative re-recurrence rate of common bile duct stones in both groups. EPLBD = endoscopic papillary large balloon dilation; ERCP = endoscopic retrograde cholangiopancreatography.

controversial. Expansion of the previous sphincterotomy is sometimes technically difficult and associated with the risks of perforation and hemorrhage.[22,23] EPLBD is a good alternative procedure because it can re-expand the papilla with safety and effectiveness. It can also treat papillary stenosis and lower bile duct stricture simultaneously.

In this study, Group 1 patients who underwent EPLBD had a significantly lower second recurrence of CBD stones (17% vs. 60%, $p < 0.001$). The literature has mentioned ES, juxtapapillary diverticulum, intact gallbladder with stones *in situ*, a large CBD diameter (>15 mm), CBD angulation, biliary stricture, papillary stenosis, and lithotripsy as possible risk factors for recurrent CBD stones.[24–29] Our previous study reported that 86% of recurrent bile duct stones were bilirubinate stones, and only 7% were pure cholesterol stones.[15] Sugiyama and Atomi[30] and Cetta[31] found that all recurrent stones were pigment stones, and suggested that bile stasis and bacterial infection might contribute to the recurrent stone formation. Most of the recurrent bilirubinate stones were loose in consistency. The conventional basket could easily to break the stones into multiple pieces, especially if the biliary outlet is not big enough for removal of the entire stone. Ten cases (3 in Group 1 and 7 in Group 2) received lithotripsy for stone fragmentation. The retained small stone fragments may become the nidus for recurrent stone growth. Therefore, by enlarging the biliary outlet, EPLBD may play an important role in biliary emptying and prevent recurrent CBDS. Cirrhosis was another independent risk factor for the re-recurrent CBDS. In our previous study, we also described that cirrhosis was an independent factor for long-term biliary complication.[24] Delayed biliary emptying with prolonged T_{max} (time required for maximal hepatic activity) and $T_{1/2max}$ (time required for peak activity to decrease by 50%) was noted in liver fibrosis and cirrhosis patients, as assessed by 99mTc-mebrofenin cholescintigraphy, compared to normal control.[32] Bile stasis may further contribute to recurrent choledocholithiasis formation.[33] We do not perform cholescintigraphy in our patients, and further prospective study is needed.

It is sometimes difficult to enlarge the papillary orifice further after previous complete sphincterotomy, particularly in patients with a large juxtapapillary diverticulum (46–56% in our series). Although Sugiyama et al,[20] Sugiyama and Atomi,[30] and Mavrogiannis et al[23] found repeated ES as safe as initial ES (complication rate 2–2.46% in repeated ES), Goodall[34] reported an increase in bleeding risk after repeated ES (1st ES, 8.2%; 2nd ES, 16.1%; and 3rd ES, 60%). In Elmi and Silverman's[35] retrospective study, 80 patients after ES and stone clearance were enrolled. Of them, 13 patients suffered from papillary stenosis and underwent repeated ES and three suffered from complications without mortality: one mild pancreatitis, one severe bleeding, and one severe duodenal

Table 3
Univariate analysis of risk factors for re-recurrent common bile duct stones.

	Re-recurrence[a]	Nonrecurrence[a]	*p*
Sex			
Male/female	44/18	35/25	0.144
Age (y)			
≥65/<65	42/20	35/25	0.282
Hypertension			
Yes/no	18/44	16/44	0.771
Type 2 DM			
Yes/no	8/54	6/54	0.615
Cirrhosis			
Yes/no	14/48	3/57	0.005*
JPD			
Yes/no	31/31	36/24	0.267
Gallstone			
Yes/no	22/40	22/40	0.803
Lithotripter			
Yes/no	5/57	5/55	> 0.99
Stone number			
≥2/single	42/20	42/18	0.788
Stone size (cm)			
≥1.5/<1.5	20/28	17/31	0.529
CBD size (cm)			
≥1.5/<1.5	49/13	46/13	0.887
Endoscopic management			
EPLBD/ERCP	4/58	19/41	<0.001*

*$p < 0.05$.
CBD = common bile duct; DM = diabetes mellitus; EPLBD = endoscopic papillary large balloon dilation; ERCP = endoscopic retrograde cholangiopancreatography; JPD = juxtapapillary diverticulum.
[a] Number of patients.

Table 4
Multivariate analysis of the risk factors for recurrent common bile duct stones.

	OR	95% CI	*p*
Cirrhosis	4.734	1.236–18.138	0.023
Endoscopic management without EPLBD	6.050	1.880–19.469	0.003

CI = confidence interval; ERCP = endoscopic retrograde cholangiopancreatography; OR = odds ratio.

perforation. Leung et al[22] found that 42.3% of patients suffered from bleeding after extension of previous sphincterotomy and showed that it was one of the independent risk factors for ES-induced bleeding. The safety of repeated ES was still in doubt. In our retrospective analysis, no patients underwent repeated ES or EPLBD after limited ES, the reason for which might be attributed to endoscopists' experiences and decision.

EPBD alone, EPLBD alone, and EPLBD after limited ES are the current balloon-based methods for CBDS management. Conventional EPBD using an 8-mm balloon was reported to be associated with a higher risk of pancreatitis and more frequent use of mechanical lithotripsy.[6] A recent meta-analysis by Liao et al[36] showed that the ballooning time of EPBD was inversely associated with pancreatitis risk, and EPBD with adequate ballooning time may be preferred to ES. EPLBD alone was also reported to be safe and effective for the removal of CBDS with innate papillary orifice in our medical center.[10] In this study, EPLBD seemed to be a good substitute for enlargement of papillary orifice from previous ES with safe and effective outcome. The large opening of the major papilla was enlarged after EPLBD and might allow complete retrieval of most of the stones without the need of crushing them, thus avoiding further nidus formation. EPLBD was easy to perform without early complications, and the re-recurrent rate was markedly decreased (17% vs. 60%, $p < 0.001$). In our previous study, we found that poor biliary emptying is a risk factor for recurrent CBD stones.[33] This was probably because the distal bile duct and whole biliary sphincter were dilated and destructed simultaneously, thus facilitating bile drainage and smooth passage of residual stone fragments or newly formed small stone particles.

The pathogenesis of ampullary stenosis is not well documented. Repeated coagulation, multiple interventions, tendency to develop excessive fibrotic reaction, bleeding, and postendoscopic hemostasis were the possible causes of ampullary stenosis.[21] Papillary stenosis is divided into two subtypes: type I means the stenosis is confined in the intraduodenal part of the sphincter, and type II means the stenosis extends into the common bile duct.[21] In type II lesions, repeated sphincterotomy is not helpful, and balloon-based methods seem to be more effective. In addition, repeated sphincterotomy for treatment of papillary stenosis may result in a higher complication rate (16–23%).[21,35] In patients undergoing EPBD, no papillary stenosis was reported after 16 months of follow-up.[37] Additionally, EPLBD seems to be more effective and is associated with a lower rate of occurrence of papillary stenosis. However, these long-term effects need further investigation.

The limitation of our study was retrospective, and patients receiving EPLBD had a typically larger stone(s) than the patients in Group 2. A large stone size is one of the risk factors for recurrent CBD stone.[38] Although patients in the EPLBD group had a larger stone size, the recurrence rate decreased after the endoscopic treatment.

Otherwise, the comparatively small number of patients who underwent EPLBD (23 vs. 99 patients) was also noted. This might be one of the biases responsible for the lower recurrence rate in the EPLBD group. Most recurrent CBDS patients underwent ERCP alone prior to 2003 and EPLBD after 2003. Selection of EPLBD as the endoscopic treatment was made depending on the personal experiences of the endoscopists. However, which condition is needed for re-expansion of the previous sphincterotomy? Should we routinely perform EPLBD on patients with recurrent CBDS, or only on patients with papillary stenosis, or those with large multiple recurrent stones and relative stricture of the distal common bile duct? These questions need further prospective research and exploration.

In conclusion, EPLBD for patients with recurrent bile duct stones after complete ES is a safe and effective treatment method. It can also facilitate complete clearance of CBDS and prevent further recurrence of CBDS.

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