

Recurrence of Bile Duct Stones after Endoscopic Papillary Large Balloon Dilation Combined with Limited Sphincterotomy: Long-Term Follow-Up Study

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Background/Aims: Endoscopic papillary large-balloon dilation combined with limited endoscopic sphincterotomy (EPLBD+ES) is promising for the treatment of common bile duct (CBD) stones. The aim of this study was to clarify the recurrence rate and the risk factors for CBD stones after EPLBD+ES. **Methods:** In total, 100 patients who underwent EPLBD+ES from 2006 to 2007 were evaluated retrospectively. One hundred and nine patients who were treated with endoscopic sphincterotomy (ES) from 2004 to 2005 were set as the historical control group. Various risk factors for the recurrence of bile duct stones were analyzed. **Results:** Of the 209 patients, the duration of follow-up was 32.5±4.5 months in the EPLBD+ES group and 31.8±6.0 months in the ES group. The recurrence rate of CBD stones was 11.0% (11/100) in the EPLBD+ES group and 13.8% (15/109) in the ES group ($p=0.546$). The cumulative recurrence rate of stones was not significantly different between the EPLBD+ES and ES groups (log rank, $p=0.537$). Univariate analysis showed that the diameter of the CBD (≥ 22 mm) was the only predictive variable that could differentiate recurrence from nonrecurrence in the EPLBD+ES group. Multivariate analysis revealed that the diameter of the bile duct was the only risk factor for stone recurrence ($p=0.022$; odds ratio, 1.175; 95% confidence interval, 1.023 to 1.348). **Conclusions:** The recurrence rate of CBD stones after EPLBD+ES is comparable to that of the ES group, and a dilated CBD appears to increase the risk of bile duct stone recurrence. (**Gut Liver 2012;6:107-112**)

Key Words: Endoscopic sphincterotomy; Endoscopic papillary large balloon dilation; Common bile duct stone

INTRODUCTION

Since introduction of endoscopic sphincterotomy (ES) by Classen and Demling¹ and Kawai *et al.*² in 1974, ES has been the standard therapy for treatment of various cholangiopancreatic diseases. Although ES has many advantages, substantial complications associated with ES have been reported. Acute pancreatitis, hemorrhage, duodenal perforation, and acute cholangitis are known to be short-term complications, and recurrence of stones and papillary stenosis are known to be long-term complications of ES.³⁻⁵

Endoscopic papillary balloon dilation (EPBD) was first described by Staritz *et al.*⁶ and has been advocated as an alternative to ES for facilitation of common bile duct (CBD) stone removal. The potential advantage of EPBD over ES is that it preserves the function of the biliary sphincter and possibly reduces the long-term sequelae of ES. However, due to certain limitations in the clinical setting in that the biliary opening is not enlarged to the same degree as with ES, mechanical lithotripsy is more frequently required for management of large stones.⁷⁻⁹ In addition, there have been a number of reports that EPBD was associated with a higher rate of post-procedure pancreatitis.¹⁰

Meanwhile, Ersoz *et al.*¹¹ have suggested that EPBD with a large balloon following conventional ES might be a very effective method for retrieval of bile duct stones that were difficult to extract by a standard procedure. According to a few recent reports, endoscopic papillary large balloon dilatation (EPLBD) combined with limited ES (EPLBD+ES) has a similar therapeutic effect and is relatively safe in terms of complications for treatment of CBD stones.^{12,13} Complications, such as hemorrhage and perforation, were less frequent in EPLBD+ES, compared with conventional ES.¹⁴⁻¹⁶

Long-term study has shown that the incidence of recurrence

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of choledocholithiasis after ES is 5.8% to 24%.¹⁷⁻²¹ There are many descriptions of short-term results of EPLBD+ES; however, little is known about mid-term or long-term complications, such as recurrence of choledocholithiasis after EPLBD+ES.^{12-14,16} We conducted this study in order to evaluate the recurrence rate of CBD stones between the EPLBD+ES group and the ES group, and to determine the risk factors associated with recurrence of bile duct stones after EPLBD+ES.

MATERIALS AND METHODS

A total of 100 patients with bile duct stones larger than 1 cm in diameter (51 men, 49 women; mean age, 70.9±10.3 years) who underwent EPLBD+ES from May 2006 to December 2007 were studied retrospectively. A total of 109 patients with bile duct stones larger than 1 cm in diameter (48 men, 61 women; mean age, 71.9±12.9 years), who were treated with ES using a sphincterotome in a conventional manner from January 2004 to August 2005, were set as a historical control group. Patients were followed up until December 2009 in the EPLBD+ES group and until May 2007 in the ES group, to match the duration of follow-up between the two groups. Recurrence of CBD stones is defined as recurrence after 6 months of treatment with EPLBD+ES or ES. Exclusion criteria for this study were as follows: 1) patients with hepatolithiasis; and 2) patients with recurrent bile duct stones which were detected less than 6 months after EPLBD+ES or ES.

All endoscopic retrograde cholangiopancreatography (ERCP) procedures were performed using side-viewing endoscopes (TJF-240; Olympus Optical Co., Tokyo, Japan). These ERCPs were carried out by experienced endoscopists. Precutting with a needle knife or guide wire technique was applied in cases of difficult CBD cannulation. In the EPLBD+ES group, EPLBD was performed with a balloon dilator after small or medium ES. Once ES was completed, a guide wire was left in the biliary tree and a balloon dilator (CRE balloon; Boston Scientific Microvasive, Cork, Ireland) was advanced over the guide wire, positioning the middle portion of the balloon across the ampullary orifice. Under endoscopic and fluoroscopic guidance, the balloon was then inflated gradually with diluted contrast media until the notch on the balloon disappeared. Once the notch disappeared, inflation of the balloon was maintained for 30 to 60 seconds. A balloon dilator between 12 to 20 mm in diameter was used and the diameter of the balloon was determined according to the size of the stones. In the ES group, medium or large-sized ES with a pull-type sphincterotome was performed according to the size of CBD stones. The size of sphincterotomy was categorized as large (to the upper margin of the papillary roof), medium (below the upper margin), or small. For stones that were too large for removal in one session, an endoscopic mechanical lithotripsy was attempted in order to fragment the stones. When incomplete stone removal was suspected at the end of the procedure,

an endoscopic nasobiliary drainage or plastic stent was inserted in order to prevent cholangitis.

The size and number of stones were documented on the cholangiogram after optimum opacification of the bile duct. Stone size was measured manually with the removed stone or assessed by comparison of the diameter of the stone with the shaft of the endoscope on the cholangiogram. In the same way, other factors including diameter and angulation were measured from the cholangiogram using PACS program (Infinit, Seoul, Korea). The angulation was measured at the first angle from the ampullary orifice along the CBD. Complete stone removal was confirmed either by final cholangiogram just after ERCP or by follow-up cholangiogram through the nasobiliary drainage catheter. All recurrent CBD stones were confirmed by ERCP. Risk factors for recurrence of bile duct stones and mean intervals between the time of initial treatment and the time of recurrence of CBD stones were analyzed. The protocol was approved by the Institutional Review Board of our hospital.

Statistical analysis was performed using the Student's t-test and the chi-square test using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA). Potential risk factors were assessed by univariate analysis on logistic regression and then a multivariate logistic regression model. Cumulative recurrence rates of bile duct stones during the follow-up intervals were compared using the Kaplan-Meier method. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Demographic characteristics of the 209 patients are shown in Table 1. The gender ratio was similar in the two groups. The mean age was 70.9±10.3 years in the EPLBD+ES group and

Table 1. Characteristics of Patients between the EPLBD+ES Group and the ES Group at the Time of the Initial ERCP

Characteristic	EPLBD+ES (n=100)	ES (n=109)	p-value
Mean age, yr	70.9±10.3	71.9±12.9	0.544
Sex, M/F	51/49	48/61	0.314
Previous cholecystectomy	22 (22.0)	25 (22.9)	0.871
Periampullary diverticulum	35 (47.3)	36 (33.0)	0.052
Bilroth II gastrectomy	8 (8.0)	1 (0.9)	0.012
Mean number of stones	2.2±1.3	1.7±0.9	0.003
Mean diameter of stone, mm	16.4±6.7	14.0±4.6	0.003
Mean diameter of CBD, mm	21.1±5.7	19.6±5.6	0.060
Type of stones, brown/black	85/15	88/19	0.593

Values are presented as mean±SD or number (%).

EPLBD+ES, endoscopic papillary large balloon dilation combined with limited endoscopic sphincterotomy; ES, endoscopic sphincterotomy; ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct.

71.9±12.9 years in the ES group. Billroth II gastrectomy was documented in 8 patients (8.0%) in the EPLBD+ES group and one patient (0.9%) in the ES group ($p=0.012$). The mean number of stones was 2.2 ± 1.3 in the EPLBD+ES group and 1.7 ± 0.9 in the ES group ($p=0.003$). The mean diameter of stones was 16.4 ± 6.7 mm in the EPLBD+ES group and 14.0 ± 4.6 mm in the ES group ($p=0.003$). No significant differences in age, sex, previous cholecystectomy or periampullary diverticulum were observed between the EPLBD+ES and ES groups. The diameter of the CBD was 21.1 ± 5.7 mm in the EPLBD+ES group and 19.6 ± 5.6 mm in the ES group; however, the difference between the two groups was not significant ($p=0.060$).

The duration of follow-up was 32.5 ± 4.5 months (range, 22 to 40 months) in the EPLBD+ES group and 31.8 ± 6.0 months (range, 22 to 41 months) in the ES group. Of the 209 patients who underwent ERCP for choledocholithiasis, recurrent CBD stones appeared in 26 patients, with an overall recurrence rate of 12.4% during the follow-up period. The recurrence rate of

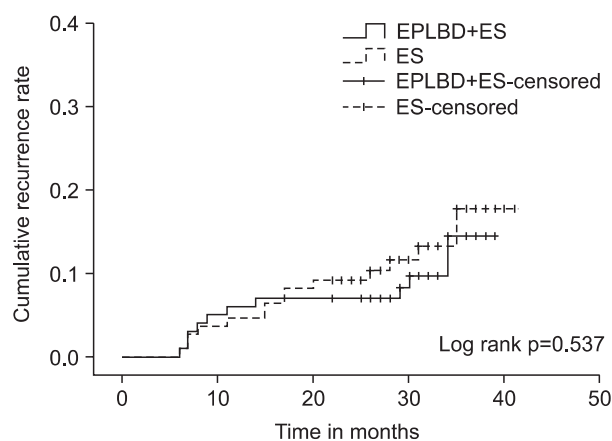


Fig. 1. Kaplan-Meier plot for the cumulative recurrence rate of common bile duct stones in a total of 209 patients between the EPLBD+ES group and the ES group. No statistically significant difference was observed between the two groups ($p=0.537$, log-rank test). EPLBD+ES, endoscopic papillary large-balloon dilation combined with limited endoscopic sphincterotomy; ES, endoscopic sphincterotomy.

Table 2. Comparison of Patients with Recurrent Bile Duct Stones between the EPLBD+ES and the ES Groups at Follow-Up ERCP

Variable	EPLBD+ES (n=100)	ES (n=109)	p-value
Recurrence of CBD stones	11 (11.0)	15 (13.8)	0.546
Duration of follow-up, mo	32.5 ± 4.5 (22-40)	31.8 ± 6.0 (22-41)	0.334
Time interval between ERCP and stone recurrence, mo	17.2 ± 11.8 (6-34)	18.5 ± 10.2 (6-35)	0.758

Values are presented as the mean±SD (range) or number (%). EPLBD+ES, endoscopic papillary large-balloon dilation combined with limited endoscopic sphincterotomy; ES, endoscopic sphincterotomy; ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct.

CBD stones in the EPLBD+ES group was lower than that of the ES group; however, the difference was not significant (11.0% vs 13.8%, $p=0.546$) (Table 2). The mean interval between stone removal and stone recurrence in the EPLBD+ES and ES group was 17.2 ± 11.8 months (range, 6 to 34 months) and 18.5 ± 10.2 months (range, 6 to 35 months), respectively ($p=0.758$). Kaplan-Meier analysis revealed that the cumulative recurrence rate of bile duct stones between the EPLBD+ES group and the ES group was not significantly different (log rank, $p=0.537$) (Fig. 1).

A variety of possible risk factors associated with recurrence of bile duct stones, including age, sex, previous cholecystectomy, periampullary diverticulum, Billroth II gastrectomy, the size of the bile duct, angulation of bile duct, dilating balloon size, the number, size, and type of stones, and mechanical lithotripsy are listed in Table 3. On univariate analysis, the diameter of the CBD was found to be the only predictive variable that could differentiate the recurrence group from the nonrecurrence group: the mean diameter of the CBD in the recurrence group was 25.0 ± 6.0 mm (range, 14.3 to 34 mm), whereas that of the nonrecurrence group was 20.6 ± 5.6 mm (range, 10.9 to 35.5 mm) ($p=0.022$). The diameter of the CBD ≥ 22 mm was identified to be the predictive factor for the recurrence of stones. Multivariate analysis determined that the diameter of the CBD was the single risk factor to distinguish the recurrence group from the nonrecurrence group ($p=0.022$; odds ratio, 1.175; 95% confidence interval, 1.023 to 1.348). None of the variables previously men-

Table 3. Univariate Analysis of Risk Factors for Recurrent Bile Duct Stones after EPLBD+ES

Variable	Patients with recurrence (n=11)	Patients with non-recurrence (n=89)	p-value
Mean age, yr	72.6 ± 12.2	70.7 ± 10.1	0.572
Sex, M/F	5/6	46/43	0.697
Previous cholecystectomy	2 (18.2)	20 (22.5)	0.746
Periampullary diverticulum	4 (36.4)	30 (50.0)	0.409
Billroth II gastrectomy	1 (9.1)	7 (7.9)	0.888
Mean number of stones	2.0 ± 1.3	2.2 ± 1.3	0.674
Mean diameter of stone, mm	18.4 ± 5.8	16.3 ± 6.8	0.326
Mean diameter of CBD, mm	25.0 ± 6.0	20.6 ± 5.6	0.022
CBD diameter			
≥ 22 mm	8 (72.7)	33 (37.9)	0.039
< 22 mm	3 (27.3)	54 (62.1)	
Distal CBD angulation, degree	139.6 ± 21.1	142.9 ± 18.4	0.602
Dilating balloon size, mm	16.6 ± 1.6	17.3 ± 1.6	0.227
Mechanical lithotripsy	1 (9.1)	3 (3.4)	0.381
Type of stones, brown/black	8/3 (72.7/27.3)	77/12 (86.5/13.5)	0.238

Values are presented as mean±SD or number (%). EPLBD+ES, endoscopic papillary large-balloon dilation combined with limited endoscopic sphincterotomy; CBD, common bile duct.

tioned as not significant were able to provide any improvement to the final model.

DISCUSSION

Since introduction of endoscopic papillary large balloon dilatation combined with limited ES (EPLBD+ES), many studies of the effectiveness of sequential ES and EPBD have been published.^{9,11-16} Currently, there are many descriptions of long-term complications after ES, including cholangitis, recurrent bile duct stones, and biliary pancreatitis.^{3,19,22} Reported incidence of recurrent choledocholithiasis after ES was 6% to 24%, and most recurrences occurred within the first 2 or 3 years after stone removal.^{17,19-21} Meanwhile, EPBD demonstrated a similar rate of recurrence.^{7,17,18} However, few studies on long-term follow-up results after EPLBD+ES have been reported.

Causes of recurrence of bile duct stones after ES are multifactorial: bile stasis, bacterial infection of the bile duct, and duodenocholedochal reflux are known to play crucial roles in pathogenesis of recurrent stone formation.^{23,24} After ES, bile duct is susceptible to bacterial infection due to loss of sphincter function. Other studies have demonstrated that some bacterial species, e.g., *E. coli*, produce β -glucuronidase, which is a key enzyme in formation of brown pigment stones after sphincterotomy.^{25,26} In our study, recurrent bile duct stones in the EPLBD+ES group, as well as the ES group, were mainly brown pigment stones, indicating that secondary bacterial infection of the bile duct via the patulous ampullary opening plays a major role in the process of stone recurrence.

We postulated that, because EPLBD+ES could provide sufficient enlargement for complete removal of bile duct stones compared with ES, recurrence of choledocholithiasis is expected to be reduced. In our study, the recurrence rate of CBD stones in the EPLBD+ES group was lower than that of the ES group, although not statistically significant. In the present study, univariate and multivariate analysis determined that the diameter of the CBD was the only key factor accounting for the increased rate of recurrence of stones in the EPLBD+ES group.

A higher stone recurrence was reported in the gallbladder *in situ* with stones in the EPBD group (14%) and a very low recurrence rate after cholecystectomy.²⁷ However, in our study, previous cholecystectomy was not associated with risk factors for recurrence. This finding is largely explained by the fact that recurrent stones in our cases were mostly brown stones, which were formed in the bile duct, rather than migrated from the gallbladder; thus, presence or absence of gallbladder appeared not to be associated with the risk of recurrence. Mechanical lithotripsy is frequently required for crushing large stones and is likely to increase the risk of recurrence because even a few missed tiny stone fragments may act as a nidus for stone re-accumulation.²¹ However, lithotripsy was not a significant risk factor for recurrence in the present study. The reasons might be as

follows: First, use of mechanical lithotripsy was rarely required in EPLBD+ES, because the papillary orifice can be fully opened. Second, more complete clearance of stone debris might be achieved after stone fragmentation, owing to wider enlargement of the ampullary opening. Periampullary diverticula compress the distal CBD anatomically, leading to bile stasis, and, subsequently, cause bacterial infection of the bile duct via the Oddi orifice.²⁸ However, in our study, periampullary diverticulum was not found to be a risk factor for recurrent stones.

The degree of angulation along the course of CBD may contribute to the bile stasis and thus cause recurrence of stones. A study have reported that an angulation (≤ 145 degree) of CBD is a risk factor for the recurrence of stones.²⁹ Meanwhile, other investigations demonstrated that distal angulation (≤ 135 degree) of bile duct was not associated with the recurrence of stones though it was a significant contributing factor to the technical difficulty of stone clearance.^{30,31} In this study, the angulation of the CBD was not a significant risk factor for recurrence. In fact, the exact measurement of angulation has a technical limitation in patients with anatomical variation of bile duct on a 2-dimensional plane. Balloon dilators, mainly 15 or 18 mm, were used to dilate the ampullary orifice. However, the size of balloons did not show a significant difference between the two groups. Size of the CBD is already known as an important predictor for recurrence of CBD stones. In the present study, the diameter of the CBD (≥ 22 mm) appears to be a risk factor for recurrent choledocholithiasis in the EPLBD+ES group. Costamagna *et al.*²⁰ demonstrated that a bile duct diameter ≥ 22 mm was a prognostic factor for choledocholithiasis. Some authors have identified bile duct size >15 mm as a risk factor for recurrent stones.^{18,21,32} A dilated CBD is likely to lead to bile stasis and bacterial infection, which play central roles in the mechanism of stone formation.^{20,24,33} There are some possibilities of small fragmented stones missed by cholangiogram in patients with a large bile duct.

In conclusion, although statistical significance was not observed between the EPLBD+ES group and the ES group in terms of the recurrence rate, in our experience, the frequency of recurrent bile duct stones in the EPLBD+ES group was lower than that of the ES group. Large size of the CBD was identified as the only significant predictive factor for increasing the recurrence rate of bile duct stones in the EPLBD+ES group. This study, however, has the limitation of retrospective data; therefore, further study is needed for investigation of the long-term outcome of EPLBD+ES.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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