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# Late Complications and Stone Recurrence Rates after Bile Duct Stone Removal by Endoscopic Sphincterotomy and Large Balloon Dilation are Similar to Those after Endoscopic Sphincterotomy Alone

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**Background/Aims:** Between endoscopic sphincterotomy (ES) alone and combined endoscopic sphincterotomy and large balloon dilation (ES-LBD) groups, efficacy and long-term complications, difference in biliary stone recurrence rate, and risk factors of stone recurrence were compared.

**Methods:** Medical records of 222 patients who underwent ERCP for biliary stone removal were retrospectively reviewed. Patients with dilated CBD  $\geq 11$  mm and follow-up longer than 6 months were included.

**Results:** There were 101 patients in ES-LBD group and 121 patients in ES group. Mean follow-up duration was 25.0 (6-48) months and 13.0 (6-43) months, respectively ( $p=0.001$ ). There was no difference in number of ERCP sessions, brown pigment stones, angle between mid and distal common bile duct (CBD angle)  $<135^\circ$ , and lithotripsy rate. Complete retrieval success rate was excellent in both groups (100% vs. 99%). Early complication rate of ES-LBD and ES alone group was 4 and 4.1%, respectively ( $p=1.000$ ). One patient in ES-LBD group died from delayed bleeding. Late complication rate was 5.9 and 3.3%, respectively ( $p=1.000$ ). Stone recurrence rate was 6.9% and 5.8%, respectively ( $p=0.984$ ). The only Independent risk factor of stone recurrence was presence of periampullary diverticulum.

**Conclusions:** Late complication and stone recurrence rates were similar between ES-LBD and ES alone groups.

**Key Words:** Common bile duct stone; Sphincterotomy, endoscopic; Endoscopic large balloon dilation; Stone recurrence; Late complication

## INTRODUCTION

Since the introduction of endoscopic sphincterotomy followed by endoscopic papillary balloon dilation (ES-EPBD) in 2003,<sup>1</sup> immediate and acute complications of this procedure have been well studied.<sup>2,3</sup> Long-term outcome after ES-EPBD with a  $\leq 8$  mm balloon is also known.<sup>4,5</sup> However, long-term outcome after ES followed by large balloon dilation (ES-

LBD,  $\geq 12$  mm) has not been established yet. Since the results of an *ex vivo* animal study showed that ES-LBD can damage the bile duct wall and cause potential impairment of sphincter of Oddi function and overdilation of extrahepatic bile ducts,<sup>6</sup> long-term outcome after ES-LBD may be different from that of ES-EPBD using a balloon with smaller diameter. The aim of this study was to retrospectively compare ES alone and ES-LBD groups in regard to efficacy and late complications, difference in bile duct stone recurrence rate, and risk factors of stone recurrence.

## MATERIALS AND METHODS

### Patient selection

From December 2004 to March 2009, patients who underwent endoscopic retrograde cholangiopancreatography (ERCP)

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for bile duct stone removal were included if they met all of the following criteria: 1) age >18 years, 2) first trial of ERCP (virgin papilla), 3) dilated common bile duct (CBD) with a diameter of  $\geq 11$  mm on a cholangiogram, and 4) follow-up period of  $\geq 6$  months either by review of medical records or by phone calls. Patients were excluded if they met any of the following criteria: 1) previous ES, 2) precut or infundibulotomy, 3) previous Billroth II operation, or 4) uncorrected coagulopathy. All patients gave written informed consent before undergoing ERCP for bile duct stone removal.

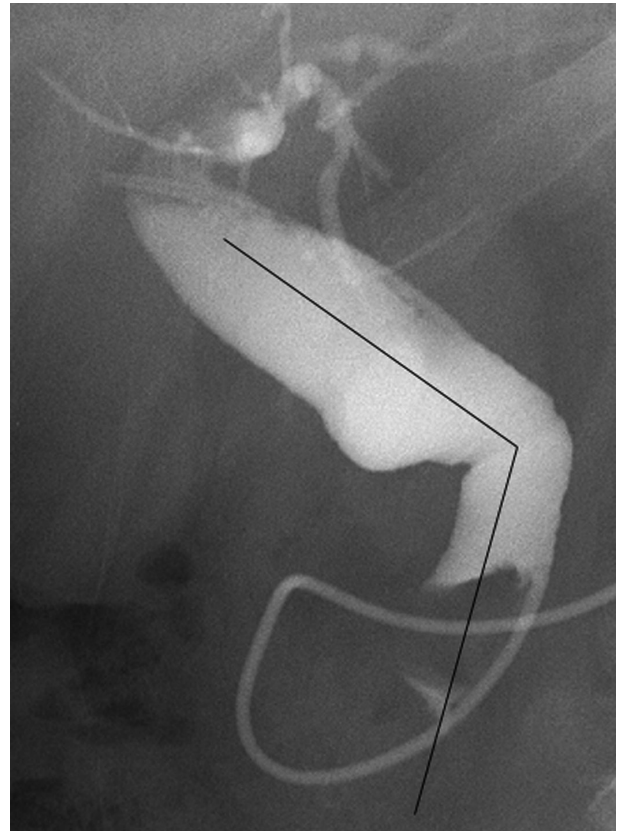
### Endoscopic procedures

All ERCP procedures were performed under conscious sedation after intravenous injection of midazolam and pethidine. An Olympus EVIS system, JF-V, or TJF 200 series (Olympus, Tokyo, Japan) was used for ERCP. A generator with an automatically controlled cutout system (Endocut mode) was used for all ES. Selective bile duct cannulation was performed, and cholangiogram was obtained. After the assessment of number and size of bile duct stones and diameter of the bile duct, either ES alone or ES-LBD was chosen at discretion of the endoscopist. A pull-type papillotome (Autotome RX44; Boston Scientific Corp., Natick, MA, USA) was used for sphincterotomy. In the ES-alone group, ES was performed up to the major horizontal fold of the major duodenal papilla. In the ES-LBD group, ES was performed up to the mid-portion of the major duodenal papilla. Then, a wire-guided balloon dilation catheter with a diameter of  $\geq 12$  mm was used for LBD (CRE™ Wireguided; Boston Scientific Corp., Natick, MA, USA). Bile duct stones were removed with a basket or a retrieval balloon. A mechanical lithotripter was used when stones could not be retrieved after either maximal ES (in the ES-alone group) or balloon dilation after ES (in the ES-LBD group). After removal of bile duct stones, a 7 Fr nasobiliary catheter (Nagaraja Nasal Biliary Drainage; Wilson-Cook Medical Inc., Winston-Salem, NC, USA) was placed. Cholangiogram through a nasobiliary catheter was obtained one or two days later.

### Outcome parameters

The following parameters were assessed and compared between the two groups:

- Patient characteristics
- Bile duct stone characteristics: number, maximal diameter of the largest stone, type, requirement for lithotripsy
- Complication rate: bleeding, hyperamylasemia, pancreatitis, perforation
- Stone recurrence rate
- Risk factors of stone recurrence: CBD angle (Fig. 1), periampullary diverticulum, intrahepatic duct stone, common he-



**Fig. 1.** Measurement of the common bile duct angle. The first angulation from the ampullary orifice is measured on a cholangiogram obtained in the prone position.

patic duct stricture, history of cholecystectomy, gallbladder stones left *in situ*, mechanical lithotripsy, CBD diameter after stone extraction

### Definitions

Definitions of complications related to ES and ES-LBD were similar to those of Cotton et al.<sup>7</sup> Minor bleeding was defined as a decrease of at least 2 g/dL in the hemoglobin concentration and achievement of hemostasis during the same procedure. Major bleeding was defined as interruption of the procedure, clinical evidence of bleeding such as melena or hematemesis with a decrease of at least 2 g/dL in hemoglobin concentration, or the need for at least two units of packed red blood cell transfusion. Delayed bleeding was defined as bleeding that developed after the procedure. Procedure-induced hyperamylasemia was defined as an increase in the serum amylase level  $\geq 3$  times that of the upper normal limit without pancreatic pain and normalized serum amylase level within 2 days. Procedure-induced pancreatitis was defined as the development of pancreatic pain with an increase in the serum amylase level  $\geq 3$  times that of the upper normal limit lasting over 2 days. Early complication was defined as complication that developed within 72 hours after the procedure and in-

cluded bleeding, hyperamylasemia, post-ERCP pancreatitis, perforation, and death. Late complication was defined as complication that occurred more than 72 hours after the procedure and included recurrent cholangitis, biliary pancreatitis, bile duct stricture, and cholecystitis. CBD angle was defined as the first angulation from the ampullary orifice along the course of CBD, and measured on the cholangiogram (Fig. 1).<sup>8</sup> Bile duct stone recurrence was defined as presence of biliary pain and abnormal liver function test results and/or bile duct stone detected on an abdominal computed tomography scan.

### Statistical analysis

Statistical analysis was performed with SPSS version 14.0 software for Windows (SPSS Inc., Chicago, IL, USA). Values were presented as median with range. Potentially relevant risk factors were assessed by univariate analysis with the chi-square statistic for categorical variables and simple logistic regression for continuous variables. Significant factors ( $p < 0.1$ ) from univariate analysis were included in a forward, stepwise multiple logistic regression model to identify the risk factors for recurrent bile duct stones. A  $p < 0.05$  was considered statistically significant.

## RESULTS

### Patients

There were 101 patients in the ES-LBD group and 121 patients in the ES-alone group. Baseline characteristics of the patients are summarized in Table 1. There was no significant difference between the two groups except for age, presence of gallbladder stone and periampullary diverticulum, and follow-up duration.

### Bile duct stones

Bile duct stones in the ES-LBD group were greater in num-

ber and larger in maximal diameter than those in the ES alone group (1.0 [1 to  $\geq 5$ ] vs. 2.0 [1 to  $\geq 5$ ],  $p = 0.001$ ; 10.0 [2 to 20] vs. 12.0 [3 to 25] mm,  $p = 0.000$ , respectively). However, there was no significant difference between the ES-LBD and ES-alone groups regarding number of ERCP sessions for removal, number of patients with brown pigment stones, use of lithotripsy, and complete removal rate (1.0 [1 to 3] vs. 1.0 [1 to 4],  $p = 0.149$ ; 80 [79.2%] vs. 94 [75.2%],  $p = 0.870$ ; 25 [24.8%] vs. 33 [27.3%],  $p = 0.759$ ; 100 [99%] vs. 121 [100%],  $p = 0.455$ , respectively).

### Complications

Complications related to ES and ES-LBD are summarized in Table 2. The most common early complication in both groups was minor bleeding (15/121 vs. 15/101;  $p = 0.580$ ). One death occurred in the ES-LBD group from delayed major bleeding and rapid development of hypovolemic shock that did not respond to resuscitation and intervention. The most common late complication in both groups was recurrent cholangitis (2/121 vs. 4/101;  $p = 0.413$ ). Acute cholecystitis occurred in two patients of each group ( $p = 1.000$ ).

### Bile duct stone recurrence

Bile duct stone recurred in seven patients from the ES-alone group and seven patients from the ES-LBD group (5.8% vs. 6.9%;  $p = 0.786$ ). Between the two groups, there was no significant difference in sex and age of the patients with bile duct stone recurrence (5 males vs. 2 males,  $p = 0.286$ ; 79.0 [46 to 83] years vs. 75.0 [51 to 87] years,  $p = 0.932$ , respectively). Also, there was no significant difference in maximal bile duct diameter, maximal stone diameter, and number of bile duct stones (14.0 [10 to 17] mm vs. 14 [12 to 15] mm,  $p = 0.788$ ; 11.0 [6 to 15] mm vs. 14.0 [3 to 21] mm,  $p = 0.289$ ; 2.0 [1 to  $\geq 5$ ] vs. 5.0 [1 to  $\geq 5$ ],  $p = 0.052$ , respectively). Presence of periampullary diverticulum was not different between the two groups (1/7 vs.

**Table 1.** Baseline Characteristics of the Patients

Characteristic	ES alone ( $n=121$ )	ES-LBD ( $n=101$ )	$p$ -value
Sex, male:female	65:56	47:54	0.345
Age, yr	69.0 (37–89)	74.0 (37–92)	0.002
Diagnosis			
Cholangitis	98 (81.0)	75 (73.3)	0.257
Biliary pancreatitis	15 (12.4)	17 (16.8)	0.443
Previous cholecystectomy	18 (14.9)	21 (20.8)	0.289
Gallbladder stone	61 (50.4)	37 (36.6)	0.043
Gallbladder <i>in situ</i> after initial ERCP	20 (16.5)	20 (19.8)	0.998
Periampullary diverticulum	55 (45.5)	68 (67.3)	0.001
Follow-up duration, mo	25.0 (6–48)	13.0 (6–43)	0.001

Values are presented as median (range) or number (%).

ES, endoscopic sphincterotomy; LBD, large balloon dilation; ERCP, endoscopic retrograde cholangiopancreatography.

**Table 2.** Complications Related to Common Bile Duct Stone Removal and Bile Duct Stone Recurrence

	ES alone (n=121)	ES-LBD (n=101)	p-value
Early complications			
Bleeding			
Minor	15 (12.4)	15 (14.9)	0.580
Major	2 (1.7)	2 (2.0)	0.580
Hyperamylasemia	7 (5.8)	4 (4.0)	0.758
Pancreatitis	2	1	1.000
Perforation	1	0	1.000
Death	0	1 <sup>a)</sup>	1.000
Overall rate	27 (22.3)	22 (21.8)	1.000
Significant overall rate <sup>b)</sup>	5 (4.1)	4 (4.0)	1.000
Late complications			
Recurrent cholangitis	2 (1.7)	4 (4.0)	0.413
Biliary pancreatitis	0	0	
Bile duct stricture	0	0	
Cholecystitis	2 (1.7)	2 (2.0)	1.000
Overall rate	4 (3.3)	6 (5.9)	1.000

Values are presented as number (%).

ES, endoscopic sphincterotomy; LBD, large balloon dilation.

<sup>a)</sup>Cause of death was delayed major bleeding; <sup>b)</sup>Significant overall rate, excluding minor bleeding and hyperamylasemia.

2/7;  $p=0.515$ ). Mechanical lithotripsy was performed in three patients of the ES-alone group and five patients of the ES-LBD group ( $p=0.280$ ). Patients with recurrent bile duct stones had gallbladder stones left *in situ* in two patients from the ES-alone group and two from the ES-LBD group ( $p=1.000$ ). CBD angle did not show significant difference between patients with recurrent bile duct stones from the ES-alone and ES-LBD groups ( $<90^\circ$ , 1 vs. 1,  $p=0.409$ ;  $90^\circ$  to  $135^\circ$ , 3 vs. 4,  $p=1.000$ ;  $135^\circ$  to  $180^\circ$ , 3 vs. 2,  $p=0.181$ , respectively). Time to recurrence and follow-up duration of patients with recurrent bile duct stones from each group did not show significant difference (16.0 [10 to 42] months vs. 14.0 [1 to 35] months,  $p=0.395$ ; 36 [13 to 44] months vs. 20.0 [6 to 42] months,  $p=0.202$ , respectively).

### Risk factors for bile duct stone recurrence

Because there was no significant difference between the ES-alone and ES-LBD groups in respect to potential risk factors for bile duct stone recurrence, risk factors for bile duct stone recurrence in the entire study subjects were investigated. In univariate analysis, the risk factors for bile duct stone recurrence were number of ERCP sessions to clear CBD stones, CBD angle of  $<135^\circ$ , need for mechanical lithotripsy, and presence of periampullary diverticulum (Table 3). Multivariate analysis showed that presence of periampullary diverticulum was the only independent risk factor for bile duct stone recurrence (odds ratio, 7.85; 95% confidence interval, 1.68 to 36.69;  $p=0.009$ ) (Table 4).

## DISCUSSION

In this study, the long-term outcome of ES-LBD in patients with CBD stones was not significantly different from that of ES alone with regard to recurrent cholangitis, cholecystitis, and bile duct stone recurrence. This finding may be explained by possible permanent disruption of sphincter function by ES-LBD. Preservation of sphincter function is a well-known advantage of EPBD<sup>9,10</sup> and has been the basis for lower rate of late biliary complications after EPBD. However, an *ex vivo* animal study demonstrated that balloons with diameters of  $\geq 12$  mm disrupt integrity of the bile duct wall and sphincter function.<sup>6</sup> Because of differences between the *ex vivo* animal model and humans in clinical practice (i.e., compliance of the bile duct, thickness of the fibromuscular layer, and different anatomy), findings of the animal study may not be directly applicable to clinical practice.<sup>6</sup> Nevertheless, irreversible loss of sphincter function by ES-LBD may result in duodenobiliary reflux similar to that by ES alone. This reflux of duodenal contents into the biliary system may be associated with bacterial colonization and can cause recurrent bile duct stones, ascending cholangitis, and acute cholecystitis.<sup>11</sup> Also, long-term outcome of ES-LBD may have been affected by older age and greater prevalence of gallbladder stone and periampullary diverticulum in this group. Older age and periampullary diverticulum are known risk factors of bile duct stone recurrence.<sup>12,13</sup> On the other hand, these factors may prompt the use of ES-LBD for stone removal. Gallbladder stone is a known

**Table 3.** Univariate Analysis of the Risk Factors for Bile Duct Stone Recurrence

	Nonrecurrence (n=208)	Recurrence (n=14)	p-value	95% CI
ERCP session no.	1.0 (1–4)	2.0 (1–2)	0.016	1.18–5.24
Angle of CBD <135°	66 (31.7)	8 (57.1)	0.026	0.09–0.86
Previous procedure, ES:ES-LBD	114:94	7:7	0.984	0.33–2.94
Sex, male:female	105:103	7:7	0.888	0.31–2.75
Age, yr	71.0 (37–92)	77.0 (46–87)	0.173	0.98–1.09
Brown pigment stone	164 (78.8)	10 (71.4)	0.559	0.43–4.83
Mechanical lithotripsy	51 (24.5)	7 (50)	0.020	1.24–11.36
History of cholecystectomy	37 (17.8)	12 (85.7)	0.272	0.04–2.48
Gallbladder with stones <i>in situ</i>	90 (43.3)	8 (57.1)	0.396	0.50–5.73
Periampullary diverticulum	118 (56.7)	6 (42.9)	0.024	0.06–0.82
No. of stone	2.0 (1–≥5)	2.5 (1–≥5)	0.150	0.92–1.75
Maximum diameter of stone, mm	10.0 (2–25)	11.5 (3–21)	0.143	0.97–1.26
CBD diameter after stone extraction, mm	13.0 (10–18)	14.0 (10–17)	0.078	0.97–1.77

Values are presented as median (range) or number (%).

CI, confidence interval; ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct; ES, endoscopic sphincterotomy; LBD, large balloon dilation.

**Table 4.** Multivariate Analysis of the Risk Factors for Bile Duct Stone Recurrence

	Odds ratio	95% Confidence interval	p-value
ERCP session no.	2.34	0.74–7.39	0.146
Angle of CBD <135°	4.39	0.98–19.70	0.053
Mechanical lithotripsy	1.67	0.35–7.94	0.518
Periampullary diverticulum	7.85	1.68–36.69	0.009

ERCP, endoscopic retrograde cholangiopancreatography; CBD, common bile duct.

risk factor for bile duct stone recurrence.<sup>14,15</sup> Cholecystectomy is usually recommended to prevent bile duct stone recurrence. However, the bile duct stone recurrence rate did not differ between the ES-alone and ES-LBD groups with regard to the presence of gallbladder or gallbladder stones. This may result from predominance of brown pigment stones in the study subjects. Also, there have been concerns about papillary stricture in ES-LBD.<sup>16</sup> In this study, there was no papillary stricture during the follow-up.

Bile duct stone recurrence rate after ES-LBD was 6.9%, which was similar to that of previous studies that evaluated ES-EPBD or EPBD alone.<sup>4,5,14</sup> There was no significant difference in potential risk factors for bile duct stone recurrence between the ES alone and the ES-LBD group. Therefore, the risk factors for bile duct stone recurrence in the entire study subjects were evaluated. Multivariate analysis showed that presence of periampullary diverticulum was the only independent risk factor for bile duct stone recurrence. This finding was not much different from known risk factors. A previous study showed that the risk factors for CBD stone recurrence after ES only include older age, dilation of the CBD ( $\geq 13$  mm), previous open or laparoscopic cholecystectomy, presence of periampullary diverticulum, and more acute CBD angulation

( $\leq 145^\circ$ ).<sup>17</sup> Known risk factors for recurrent stones after ES and EPBD vary from study to study and include presence of a periampullary diverticulum, gallbladder stones left *in situ*, dilated CBD, previous cholecystectomy, no confirmation of a clean duct on intraductal ultrasonography, and mechanical lithotripsy.<sup>5,14,15,18</sup> Risk factors for recurrent stones after ES-LBD are less well studied. One recent study reported that a dilated bile duct ( $\geq 22$  mm) predicted stone recurrence in patients who underwent ES-LBD.<sup>19</sup> Although acute CBD angle did not reach statistical significance in multivariate analysis, this may result in bile stasis and stone recurrence. The number of ERCP sessions needed to clear CBD stones implies multiplicity and difficulty in removing all the stones. To decrease the number of ERCP sessions needed to clear bile duct stones and prevent stone recurrence, intraductal ultrasonography, or direct peroral cholangioscopy may be useful for documenting the complete clearance of bile duct stones, but it is not universally available.<sup>20–22</sup> On the other hand, the presence of periampullary diverticulum and an acute CBD angle are risk factors that cannot be modified. Still, these are useful in predicting bile duct stone recurrence and in educating patients at high risk.

Limitations of this study are its retrospective, single-center



design and the small number of patients with bile duct stone recurrence. Further prospective, randomized controlled studies with a longer follow-up period and a greater number of patients are needed to overcome these limitations.

In conclusion, ES-LBD for bile duct stones showed similar complete stone removal rate, long-term complication rate, and stone recurrence rate compared with ES alone. The independent risk factor for stone recurrence was presence of periampullary diverticulum.

### Conflicts of Interest

The authors have no financial conflicts of interest.

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