

# Endoscopic Papillary Balloon Dilation with Large Balloon after Limited Sphincterotomy for Retrieval of Choledocholithiasis

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Endoscopic papillary balloon dilation (EBD) for choledocholithiasis is known to be comparable to endoscopic sphincterotomy (EST) especially in cases of small stones. With larger stones, EBD with conventional balloon, which have a diameter of 6-8 mm, was reported as less effective for extraction of stones. We evaluated the efficacy and complications of EBD with large balloons (10-15 mm) after limited EST for retrieval of choledocholithiasis. From February 2005, we have performed EBD with limited EST for retrieval of common bile duct (CBD) stones. The patients who admitted with hyperamylasemia and gallstone pancreatitis were excluded. In cases without CBD dilation, EPBD with 12 mm for 40 seconds was performed. And in cases with CBD dilation, we dilated the sphincters with 15 mm sized balloon for 40 seconds. Total 22 patients (11 of male) were performed EBD with limited EST for retrieval of CBD stones. The median diameter of the stones was 10 mm (5-25 mm). Ten cases had multiple stones and 6 cases periampullary diverticuli. Successful stone removal in the initial session of ERCP with EBD was accomplished in 16 patients (72.7%). And complete retrieval of bile duct stones was achieved in all patients with repeated ERCP. In the aspect of complications, any episodes of perforation, bleeding was not developed. Only one case of mild grade of post-procedural pancreatitis was noted. However, post-procedural hyperamylasemia was developed in 16 cases (68.2%). EBD with larger balloon seems to be a feasible and safe alternative technique for conventional EST in CBD stone extraction.

**Key Words:** Choledocholithiasis, endoscopic retrograde pancreaticocholangiography, endoscopic papillary balloon dilation, endoscopic sphincterotomy

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## INTRODUCTION

Since the first description of endoscopic biliary sphincterotomy (EST) during endoscopic retrograde cholangiopancreatography (ERCP) in 1974, EST has been the standard therapy to remove bile duct stones and is often substituted for surgical exploration of the common bile duct in patients undergoing laparoscopic cholecystectomy.<sup>1-3</sup> Because it is a technically complex endoscopic procedure using electrocoagulation-cutting current, EST is related to such complications as hemorrhage, perforation, and acute pancreatitis.<sup>4,5</sup>

Endoscopic papillary balloon dilation (EBD) of the biliary sphincter has been advocated as an alternative to EST in selected patients with bile duct stones, despite a few reports of EBD having an unacceptably high risk of pancreatitis.<sup>6-11</sup> The main advantage of this technique is that it does not involve cutting the biliary sphincter. Therefore, acute complications may be less likely and the function of the biliary sphincter may be preserved.

Regardless of the theoretical merits of conventional EBD, one of the major limitations is the difficulty of removing larger stones because the biliary opening is not enlarged to the same degree as with EST. Recently, Ersoz G et al.<sup>12</sup> have reported that EBD with large balloon after conventional EST might be effective to retrieval of bile duct stones that were difficult to remove with standard methods. So, we performed dilation of the sphincter with large balloons (12-15 mm diameter) and analyzed the outcomes of EBD combined with large balloon for retrieval of bile

duct stones.

## MATERIALS AND METHODS

### Patients

From February 2005 to February 2006, a total of 22 patients were enrolled. All enrolled patients met the following selection criteria: a) referral for ERCP because of symptoms of bile duct stones, b) over 18 years of age, c) informed consent obtained before ERCP, d) bile duct stones visualized at ERCP, and e) deep cannulation of the bile duct achieved without sphincterotomy. Patients were not eligible if they had signs of acute pancreatitis (severe epigastric pain combined with serum amylase more than three times the upper normal limit), acute cholecystitis (localized pain in the right upper abdomen, fever, and a thickened gallbladder wall on ultrasonography), or a history of previous sphincterotomy, choledochoduodenal fistula, hemostatic disorders, intrahepatic stone diseases, concomitant pancreatic or biliary malignant disorders, co-existing bile leakage or choledochoduodenal fistula.

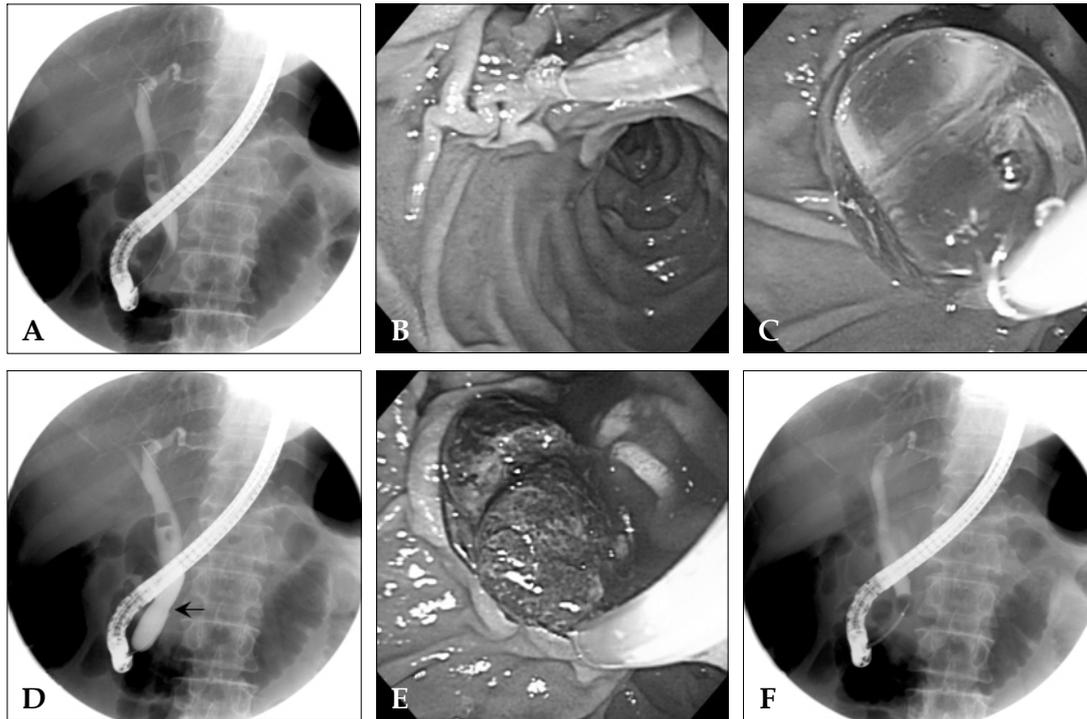
### Endoscopic procedures

The endoscopic procedure for the study was performed by single expert in ERCP. ERCP was done with Olympus TJF-240 side-viewing endoscopes (Olympus Optical Corporation, Tokyo, Japan). Patients were sedated with midazolam (3-4 mg) supplemented by an intramuscular injection of 20 mg meperidine. Prophylactic antibiotics were not routinely given. To stop duodenal peristalsis, 40 mg butylscopolamine was administered intravenously just before the start of ERCP. The major papilla was located, the bile duct was deeply cannulated with 0.035 Fr catheter (ERCP-Katheter MTW<sup>®</sup> endoskopie, Wesel, Germany), and a diagnostic cholangiogram was obtained. For further procedure, a guide wire (Hydra Jagwire<sup>™</sup> guidewire, Boston Scientific Corp. Natick, MA, USA) was passed through a diagnostic catheter into the bile duct and then the catheter was removed. Limited EST with a pull-type sphincterotome (Papillotome, MTW<sup>®</sup> endoskopie, Ger-

many) was done for easy insertion of the balloon catheter, control of the direction of balloon dilation during EBD with large balloon. A 5.5 cm, 12 mm or a 5.5 cm, 15 mm balloon catheter for pyloric dilation (CRE wire-guided dilator, Boston Scientific Corp. Natick, MA, USA) was then passed over the guide wire and positioned across the papilla. Each balloon was gradually expanded to 10 - 15 mm, depending on the maximal diameter of the CBD, measured by cholangiography. The sphincter was considered adequately dilated if the waist in the balloon had disappeared completely. The fully expanded balloon was maintained in position for 40 seconds and then deflated and removed (Fig. 1). After EBD, the stones were retrieved using a Dormia basket (Web<sup>™</sup> extraction basket, Wilson-Cook Medical Inc. Winston-Salem, North Carolina, USA) and/or a retrieval balloon catheter (Two lumen retrieval balloon catheter, Boston Scientific Corp. Natick, MA, USA). If necessary, mechanical lithotripsy (Lithotriptoren, MTW<sup>®</sup> endoskopie, Germany) was performed to fragment the stones prior to extraction from the bile duct. When the bile juice drained to the major papilla was so sticky or mixed with sludges, a 7 Fr, nasobiliary drainage catheter (ENBD-7-Liguory, Wilson-Cook Medical Inc., Winston-Salem, North Carolina, USA) was inserted. And a follow-up cholangiogram was obtained 3 days after the initial procedure. If remnant stones were found, a second ERCP with or without repeated EBD was performed for retrieval of bile duct stones.

### Measurements

Before ERCP and 1 and 3 days after ERCP, blood samples were taken for a complete blood count, liver-function tests (bilirubin, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and  $\gamma$ -glutamyl transpeptidase), measurement of serum amylase, lipase and coagulation profiles. During the initial ERCP, the stone size and number were documented on cholangiograms, taken during the initial filling of the bile duct, after optimum opacification of the biliary tree. Stone size was assessed by comparing the diameter of the stone with the tip of the endoscope, as measured on the cholangiogram.



**Fig. 1.** Endoscopic papillary balloon dilation with limited endoscopic sphincterotomy. The endoscopic retrograde cholangiography (ERC) showed two free-floating stones, one of which was measured at 15 mm diameter, (A). A pull-type sphincterotome was inserted into the major papilla, located in the lower margin of the perivater diverticulum, (B). After limited EST, EBD with a balloon catheter of 15 mm diameter was performed, (C). The ERC showed the inflated balloon and its waist by the biliary sphincter had disappeared, black arrow, (D). With a Dormia basket, two stones were retrieved through the dilated orifice of major papilla, (E). ERC after complete stone retrieval revealed no residual filling defect in the bile duct, (F).

Complete stone removal was verified either by the final cholangiogram or by the combination of initial fluoroscopic findings and the follow-up cholangiogram obtained 3 days after the initial ERCP through a nasobiliary drainage catheter.

### Outcome measures

The primary endpoint was the success rate of complete removal of stones with the initial ERCP session. Secondary outcomes measured were the number of ERCP sessions required for complete stone removal, the frequency of use of mechanical lithotripsy, and associated complications. All complications were classified and graded according to the 1991 consensus guidelines.<sup>13</sup>

### Statistical analysis

Statistical analyses were performed using statistical software (SPSS 11.5 for Windows; SPSS

Inc., Chicago, Ill, USA). Categorical and binary variables were tested by the chi-squared test with Yates' correction or Fisher's exact test if more than 20% of the cells in the frequency tables had an expected frequency below 5.

## RESULTS

Between Feb 1, 2005, and Feb 28, 2006, 22 patients gave informed consent and were enrolled in the study. Demographic data for the patients are shown in Table 1. The median diameter of the largest stone in each patient was 10 mm (range, 5-25 mm).

### Treatment outcomes

In all patients, EBD of the biliary sphincter was successful and complete retrieval of bile duct stones was achieved. Mean duration of the whole

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

Age, yrs*	63.2 ± 11.7
Gender (M/F)	11/11
Bile duct stone number	
One	12 (54.5%)
Two or more	10 (45.5%)
Median maximum diameter of the stones (range, mm)	10 (5 - 25)
Median maximum diameter of bile duct (range, mm)	13.5 (8 - 25)
Presence of perivater diverticulum	6 (27.2%)

\*Mean ± S.D.  
n = 22.

**Table 2.** Results of Endoscopic Stone Removal after EBD with a Large Balloon

Overall success in stone removal	22 (100%)
Required sessions for complete stone removal	
Single session	16 (72.7%)
Two sessions	6 (27.3%)
Mechanical lithotripsy	2 (9.1%)
Diameter of inflated balloon for EBD (mm)	
10	7 (31.8%)
12	11 (50%)
15	4 (18.2%)

EBD, Endoscopic papillary balloon dilation.  
n = 22.

procedure was  $32.9 \pm 13.7$  minutes (Table 2). Successful stone removal in the initial session of ERCP with EBD was accomplished in 16 patients (72.7%). It was not possible to achieve complete stone removal during the initial procedure in six patients. In four of these 6 cases, small-sized remnant stones, not found at the end of the initial procedure, were detected in the follow-up cholangiography through the nasobiliary drainage catheter 3 days later. In the remaining two cases, the failure to remove stones was due to severe pain and poor cooperation of patients during the initial procedure. In all 6 cases, complete stone removal was ultimately accomplished by an additional session of ERCP without further EBD or EST. Mechanical lithotripsy was necessary in only two patients.

When the patients were sub-grouped according

to stone diameter (less or greater than 10 mm) or number of stones (single or multiple), the success rate of complete stone removal after one session of ERCP for a stone < 10 mm in diameter tends to be higher than with a stone > 10 mm in diameter (87.5% vs. 64.3%, respectively). And the success rate of complete stone retrieval in a single session of ERCP for patients with a single stone seemed to be also better than in patients with multiple stones (83.3% vs. 60%, respectively) (Table 3). However, the results did not show statistical significances due to small size of sub-groups.

### Complications

With respect to complications, EBD with large balloon after minor EST proved to be very safe.

**Table 3.** Results of Endoscopic Stone Removal after EBD in Relation to Stone Size and Number

	Stone diameter < 10 mm (n = 8)	Stone diameter ≥ 10 mm (n = 14)
Complete stone removal in one session*	7 (87.5%)	9 (64.3%)
Complete stone removal after additional ERCP	1 (12.5%)	5 (35.7%)
Mechanical lithotripsy	0	2
	Single stone (n = 12)	Multiple stones (n = 10)
Complete stone removal in one session*	10 (83.3%)	6 (60%)
Complete stone removal after additional ERCP	2 (16.7%)	4 (40%)
Mechanical lithotripsy	1	1

EBD, Endoscopic papillary balloon dilation; ERCP, Endoscopic retrograde cholangiopancreatography.

\**p* value > 0.05, Fisher's exact test.

In our study group, only one patient developed mild-grade post-ERCP pancreatitis. Further, hemorrhage did not occur in any patients. In 3 cases, minor oozing that spontaneously stopped during the procedure was noted. Fatal complications such as perforation or severe pancreatitis did not occur. However, asymptomatic elevation of serum amylase/lipase was noted in 68.2% (15/22) of the patients. The elevated serum amylase/lipase usually normalized within 3 days after the procedure and did not affect the clinical course of the patients. During follow-up of at least 3 months after complete stone retrieval, any complications including recurrence of bile duct stones, cholangitis, bile duct stenosis or acute cholecystitis were documented.

## DISCUSSION

EBD has been reported to be an effective and safe method to access the bile duct for retrieval of common bile duct stones. Specifically, EBD is recommended in patients with coagulation defects such as liver cirrhosis. However, the use of conventional EBD is restricted to patients with small stones less than 10 mm of diameter, since balloon dilation does not enlarge the sphincter to the same extent as EST. Concerns surrounding EBD are primarily due to the diameter of the balloon catheter and the associated risk of pancreatitis. In this study, we performed limited sphincterotomy to control the choledochal direction during EBD

with a large balloon. With this modified EBD procedure, we can achieve greater access to the bile duct compared to conventional EBD with 8 mm of diameter. In our study group, the overall technical success of bile duct stone retrieval was 100%, although the success rate of complete stone retrieval in a single session of ERCP was comparable to previous reports.<sup>6-10</sup> Considering that the maximum diameter of the bile duct stones was larger than 10 mm in 63.6% (14/22) patients, this outcome seems clinically acceptable. Furthermore, complete stone removal was done without additional EST or EBD in all 6 cases that required additional ERCP, irrespective of the maximum diameter of the bile duct stone. In addition, mechanical lithotripsy was required in only 2 cases, both of which had stones > 10 mm in diameter (9.1%). In the aspect of relationship between the maximum diameter of bile duct stones or the number of stones and effectiveness of EBD with large balloon, large stones more than 10 mm or multiple stones may be related to the failure of complete stone retrieval on single session of EBD with large balloon. However, this suggestion should be validated with larger sized subgroups.

With respect to complications normally associated with EBD, post-procedural pancreatitis is highly disputed. Even though Disario et al.<sup>14</sup> reported that post-EBD pancreatitis developed in 14% of the patients with 2 cases of mortality, other studies have reported the post-EBD risk of pancreatitis is comparable to the risk associated with

conventional EST.<sup>6,8</sup> In theory, the risk of pancreatitis with EBD seems to be related to the pressure loaded on the orifice of the main pancreatic duct during balloon dilation. In 2003, Ersoz et al.<sup>12</sup> reported that moderate EST prior to EBD with large balloon was beneficial to prevent post-EBD pancreatitis. They suggested that EST prior to EBD could prevent pressure overload on the main pancreatic duct. In this study, we performed limited EST of bile duct to control the choledochal direction of balloon dilation and prevent pressure overload on the orifice of main pancreatic duct.

Regarding the risk of hemorrhage, conventional EBD with a small diameter balloon has been shown to be very safe. And EBD with a large balloon resulted in hemorrhage in 9% of the cases, which seems to be higher when considering the risk of hemorrhage with EST is reported to be 2-5%.<sup>5,12</sup> With the larger balloon, a higher rate of bleeding could be attributed to the moderate degree of EST. We found that if we performed limited EST prior to EBD with large balloon, we could reduce procedure-related hemorrhage. One thing to consider during EBD with large balloon is perforation of the duodenum. However, during the ballooning after limited EST, the endoscopist can watch the dilation status of the ampulla with a sideview endoscope and fluoroscope. Hence, the theoretical risk of perforation is very low.

In conclusion, the EBD with large balloon after limited EST is an effective and safe endoscopic approach to access the bile duct for retrieval of CBD stones. And the EBD with large balloon after limited EST can be an alternative for conventional EST for removal of CBD stones.

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