

# The Increase in Balloon Size to Over 15 mm Does Not Affect the Development of Pancreatitis After Endoscopic Papillary Large Balloon Dilatation for Bile Duct Stone Removal

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## Abstract

**Background** Endoscopic papillary large balloon dilatation (EPLBD) after endoscopic sphincterotomy (EST) has recently become widely used for common bile duct (CBD) stone removal, but many clinicians remain concerned about post-procedural pancreatitis with increasing the balloon size to over 15 mm.

**Aims** We aimed to evaluate the safety and efficacy of EPLBD with a relatively large balloon (15–20 mm) after EST and to evaluate the factors related to post-EPLBD pancreatitis.

**Methods** A retrospective review was undertaken of the endoscopic database of 101 patients with CBD stones who underwent EPLBD using a larger balloon size of over 15 mm (15–20 mm). Clinical parameters, endoscopic data, and outcomes were analyzed.

**Results** The mean age of the subjects was 69 years. All patients had a dilated CBD of over 11 mm (mean = 22.6 mm). The mean size of balloon used in EPLBD was  $17.1 \pm 1.9$  mm (range 15–20 mm). Mechanical lithotripsy was required in seven patients (6.9%). The rate of complete stone removal in the first session was 92.1%. Post-procedural pancreatitis developed in five cases (5.4%), but none were graded as severe. The smaller dilatation of the CBD, longer cannulation time, and longer time for stone removal

were associated with post-procedural pancreatitis, but larger size of balloon did not affect the development of post-EPLBD pancreatitis.

**Conclusions** EPLBD with a large balloon of over 15 mm with EST is an effective and safe procedure with a very low probability of severe post-procedural pancreatitis. Post-EPLBD pancreatitis was not associated with larger balloon size, but was associated with longer procedure time and smaller dilatation of the CBD.

**Keywords** Common bile duct (CBD) stone · Endoscopic papillary large balloon dilatation (EPLBD) · Large balloon · Post-EPLBD pancreatitis

## Introduction

Endoscopic papillary balloon dilation (EPBD) using a small-diameter balloon catheter (5–10 mm) was introduced in 1982 as an alternative to endoscopic sphincterotomy (EST), and is considered to have advantages in preserving the sphincter function and decreasing bleeding complications of EST [1, 2]. So, EPBD has frequently been performed, and many trials have compared the efficacy and safety of EPBD with EST for the removal of bile duct stones [3–5]. However, EPBD has been reported to have a higher risk of pancreatitis than EST in some studies, and there are still debates over the use of EPBD and the risk of developing pancreatitis following the procedure [6–8]. Moreover, for the extraction of large bile duct stones, both EST and EPBD have limitations because of the frequent additional need for mechanical lithotripsy (ML). Therefore, as an alternative to conventional EPBD using a small balloon of less than 10 mm in size, the technique of endoscopic papillary large balloon dilatation (EPLBD) using a balloon larger than

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12 mm after mid-incision EST was introduced for the removal of large common bile duct (CBD) stones [9]. Despite concerns about serious complications such as severe pancreatitis and bile duct perforations caused by large balloon inflation, recent data has suggested that EPLBD is an effective procedure that does not cause complications if performed under strictly established guidelines [10–14]. However, many clinicians remain concerned about post-procedural pancreatitis with increasing balloon size, especially those over 15 mm. The aims of this study were to investigate whether increasing the size of the inflating balloon is a risk factor for pancreatitis, to evaluate the efficacy and safety of EPLBD with a relatively large balloon (15–20 mm) after EST, and to evaluate the clinical factors related to post-EPLBD pancreatitis.

## Methods

### Patients

The study participants included 101 consecutive patients with CBD stones who underwent EST and EPLBD using a balloon larger than 15 mm at Gangnam Severance Hospital from November 2004 to November 2008. The medical records and endoscopic database of the patients were reviewed retrospectively. The criteria for selecting patients were a sufficiently dilated CBD ( $>10$  mm) and a large or multiple bile duct stones ( $\geq 13$  mm or  $\geq 3$  stones). Exclusion criteria included CBD with stricture and CBD with no dilatation ( $\leq 10$  mm). We routinely applied the EPLBD procedure during the study period on most of the patients who met the above criteria. All patients were fully informed about the methods and possible complications of the procedure and were recruited after written consent had been obtained.

### Endoscopic Procedure

All endoscopic procedures were performed under conscious sedation with intravenous midazolam, meperidine hydrochloride, and/or propofol. Protease inhibitors, which might affect the incidence of procedure-associated pancreatitis, were not administered routinely either before or after endoscopic retrograde cholangiopancreatography (ERCP).

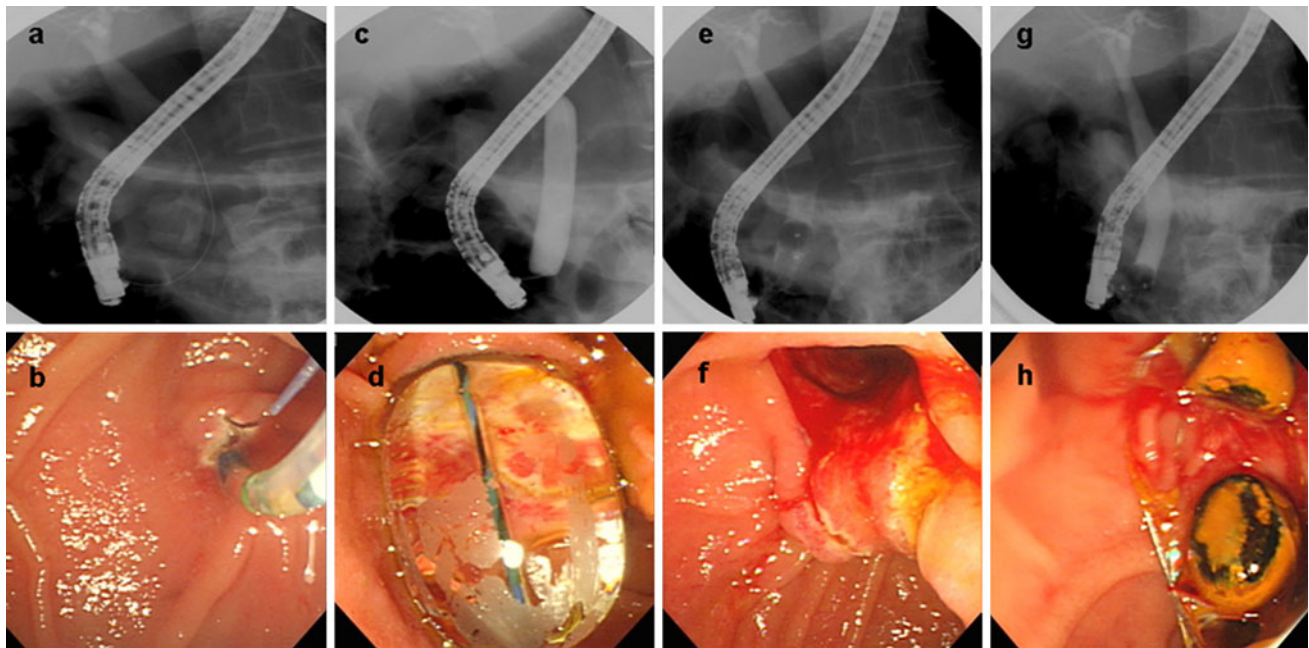
Two expert endoscopists performed the ERCP using a standard duodenoscope (JF-240, TJF-240; Olympus Optical Co. Ltd., Tokyo, Japan). Contrast medium (60% amidotrizoate sodium meglumine, Schering, Osaka, Japan) was used at a 1:1 dilution. A 0.035 Fr catheter (ERCP-Kat-heter; MTW<sup>®</sup> Endoskopie, Wesel, Germany) and a guide-wire (0.035-inch, Boston Scientific Corporation, Natick, MA, USA) were used for diagnostic cholangiograms.

Mid-incision EST with pull-type sphincterotome (Papillo-tome, MTW<sup>®</sup> Endoskopie, Wesel, Germany) was performed and extended beyond the top of the transverse fold or the superior margin of the papilla bulge. Pre-cut sphincterotomy was performed for the cannulation of inaccessible bile ducts. A generator with an automatically controlled cut-out system (Endocut mode, ICC200, ERBE Elektromedizin GmbH, Tübingen, Germany) was used for EST. A 5 Fr over-the-guidewire type of hydrostatic balloon catheter (controlled radial expansion [CRE] dilation balloon; esophageal/pyloric; maximum diameter 15, 18, or 20 mm; length 5 cm; Micro-vasive, Boston Scientific Corporation) was inserted over the guidewire and positioned across the main duodenal papilla. The maximum diameter of balloon was chosen during ERCP among the sizes 15, 18, or 20 mm, not exceeding 2–3 mm over the dilatation of the distal CBD.

The balloon was then gradually inflated to 15–20 mm with diluted contrast using an inflation device (Indeflator<sup>®</sup>; Abbott, Santa Clara, CA, USA). The sphincter was considered to be adequately dilated if the waist in the balloon had disappeared completely on fluoroscopic examination, and then the fully dilated balloon was maintained for 30–60 s. If the waist of the balloon could not be resolved even with near-maximal pressure (6–8 atm) or if longitudinally extensive narrowing of the balloon was recognized, the pressure of inflation was not increased further to avoid perforation. The bile duct stones were extracted using a Dormia basket (Web<sup>®</sup> extraction basket; Wilson-Cook Medical Inc., Winston-Salem, NC, USA) and/or a retrieval balloon catheter (Boston Scientific Corporation) (Fig. 1). A mechanical lithotripter (Lithotriptoren; MTW<sup>®</sup> Endoskopie) was used to crush the stones when extraction could not be achieved by basket or retrieval balloon even after EPLBD with EST. If remnant stones were suspected, a second session of ERCP with or without repeated EPLBD was performed.

### Measurement of Outcomes

For the close monitoring and early handling of possible complications, abdominal X-rays and blood sample analyses for complete blood count, liver-function tests, concentration of serum amylase and lipase, and coagulation profiles were routinely performed on the day of the ERCP procedure and on the following day in all patients. The size and number of bile duct stones and the diameter of the CBD was assessed using an initial diagnostic cholangiogram by comparing the diameter of the stone and CBD with the tip of the endoscope, with correction for magnification of the external diameter of the distal end of the duodenoscope (13.5 mm). The angle of the distal CBD with the horizontal plane was measured using the angle between the inflated balloon and the horizontal plane of the



**Fig. 1a–h** Endoscopic papillary large balloon dilatation (EPLBD) procedure. **a** Cholangiogram shows a large dilated common bile duct (CBD) and multiple bile duct stones. **b** Endoscopic sphincterotomy is performed. **c, d** Papillary dilation with a 20-mm large balloon.

**e–g** Large bile duct stones were removed without crushing, by balloon retrieval and Dormia basket. **h** Large biliary orifice after the procedure

vertebra (Fig. 2), and was also analyzed for possible association with complications. The technical success of the procedure was defined as complete removal of all CBD stones. The number of sessions required for complete stone removal, the frequency of use of ML, and associated complications such as pancreatitis, hyperamylasemia, bleeding, and perforation were classified and graded

according to the consensus guidelines [15]. The severity of pancreatitis was graded according to Ueno's modification of the Cotton criteria: minimal (complaint of abdominal pain persisting 12–24 h with at least threefold elevation of serum amylase concentration); mild (clinical pancreatitis with at least threefold elevation of serum amylase concentration, requiring 1–3 days of treatment); moderate (requiring 4–10 days of treatment); and severe (requiring more than 10 days of medication, or percutaneous or surgical intervention) [16].

#### Data Management and Statistical Analysis

Statistical analyses were performed using statistical software (SPSS 12.0 for Windows; SPSS Inc., Chicago, IL, USA). Quantitative data are presented as the mean  $\pm$  standard deviation (SD). The Mann–Whitney test, Chi-square test, and independent sample *t*-test were used to compare variables between the complication group and the no-complication group, and logistic regression analysis was used for the independency test of the variables. A *P*-value  $<0.05$  was considered to be significant.

#### Results

The baseline characteristics and demographic data are shown in Table 1.



**Fig. 2** The angle of the distal common bile duct (CBD) with the horizontal plane. The angle of the distal CBD was measured as the angle between the inflated balloon at the ampulla and the horizontal plane of the vertebra (*black lines*)

**Table 1** Demographic data and baseline characteristics of the patients

Age (years)	69.1 ± 11.7 (range 36–92)
Gender (M:F)	40:61
Body mass index (BMI)	22.7 ± 3.2 (range 17.8–36.2)
Prior history of acute pancreatitis	10 (10.0%)
Previous gastric surgery	
Billroth I	2 (2.0%)
Billroth II	3 (3.0%)
Hyperbilirubinemia (total bilirubin > 1.3 mg/dL)	41 (40.6%)
Periampullary diverticulum	12 (11.9%)
Diabetes mellitus	5 (5.0%)
Liver cirrhosis	2 (2.0%)

**Table 2** Characteristics of choledocholithiasis and the results of stone clearance with EPLBD

Number of CBD stones	
Single	39 (38.6%)
Multiple	62 (61.4%)
Mean size of CBD stone (mm)	21.8 ± 8.5 (range 7–52)
CBD diameter (mm)	22.6 ± 5.7 (range 11–45)
Size of balloon (mm)	17.1 ± 1.9 (range 15–20)
Overall success in stone removal	101 (100%)
Sessions required for complete stone removal	
Single session	93 (92.1%)
Two sessions	8 (7.9%)
Mechanical lithotripsy	7 (6.9%)

*EPLBD* endoscopic papillary large balloon dilatation, *CBD* common bile duct

In all patients, the EPLBD with EST procedures were successful, and complete retrievals of bile duct stones were achieved. The majority of patients had multiple bile duct stones, and all patients had a dilated CBD >11 mm. Successful stone removal in the initial session of ERCP with EPLBD was accomplished in 93 patients (92.1%), and ML was required in seven patients (6.9%). The size of the balloon used in EPLBD was 17.1 ± 1.9 mm (range 15–20 mm). The characteristics of choledocholithiasis and the results of stone removal with EPLBD are summarized in Table 2.

With respect to complications, there were five cases (5.0%) of post-procedural pancreatitis (three minimal, one mild, and one moderate), two cases (2.0%) of bleeding and intramural dissection, and one case (1%) of perforation (Table 3). Post-ERCP hyperamylasemia, defined as the elevation of serum amylase concentration to threefold greater than the normal upper limit without clinical pancreatitis, was noted in three patients (3.0%). There was no

**Table 3** Complications associated with EPLBD

Post-EPBD pancreatitis	5 (5.0%)
Minimal	3 (3.0%)
Mild	1 (1.0%)
Moderate	1 (1.0%)
Bleeding, mild	2 (2.0%)
Intramural dissection	2 (2%)
Microperforation	1 (1.0%)

*EPLBD* endoscopic papillary large balloon dilatation, *CBD* common bile duct

patient who received pancreatic stent to prevent pancreatitis after EPLBD; however, there were no cases of severe pancreatitis related to EPLBD. Two cases of bleeding were controlled with a combination of epinephrine injection, electrical coagulation, and balloon tamponade, and one case of microperforation was treated by conservative management with intravenous antibiotics and NPO.

When clinical and endoscopic parameters were compared according to the development of post-procedural pancreatitis, no significant associations were found for age, body mass index, gender, size or the number of CBD stones, periampullary diverticulum, usage of mechanical lithotripsy, usage of pre-cut EST, incomplete inflation (notching during inflation), previous history of pancreatitis, cholangitis and gastric surgery, or the presence of jaundice and other comorbid medical conditions. The angle of the distal CBD with the horizontal plane and the size of the balloon used in EPLBD also did not affect the development of post-procedural pancreatitis. However, we did find that smaller dilatation of the CBD, longer cannulation time, and longer stone removal time were significantly associated with the development of post-procedural pancreatitis, and these three factors were also shown to independently affect the risk of pancreatitis in the logistic regression analysis (Table 4).

## Discussion

EPBD with a small balloon of size <10 mm might have advantages on preserving sphincter function [17–19], but there have been serious issues concerning the risk of pancreatitis in EPBD following two cases of mortality due to severe pancreatitis in middle-aged patients during a randomized trial in the United States [6]. However, EPLBD introduced a different concept, results in the rupture of the orifice and permanent loss of the sphincter, and simplifies the retrieval of a large stone [9]. Several studies on EPLBD have demonstrated a relatively high technical success rate, ranging from 74 to 99% without ML for the removal of large bile duct stones, which are similar to our data (93.1%



**Table 4** Clinical and endoscopic parameters associated with post-EPLBD pancreatitis

	No post-EPLBD pancreatitis ( <i>n</i> = 96)	Patients with post-EPLBD pancreatitis ( <i>n</i> = 5)	<i>P</i> -value	<i>P</i> -value by logistic regression
Age (years)	69.6 ± 11.5	62.3 ± 13.1	0.11	
History of prior pancreatitis	9/96 (9.4%)	1/5 (20.0%)	0.41	
Mechanical lithotripsy	7/96 (7.3%)	0/5 (0%)	1.00	
Pre-cut EST	6/96 (6.3%)	0/5 (0%)	1.00	
Size of EPLBD balloon (mm)	17.1 ± 1.9	17.0 ± 2.4	0.94	
Angle of the distal CBD with the horizontal plane (°)	89.5 ± 16.3	92.5 ± 12.5	0.68	
CBD diameter (mm)	23.0 ± 5.4	17.6 ± 6.7	0.02	0.05
Cannulation time (min)	4.5 ± 2.8	10.4 ± 6.1	0.01	0.01
Stone removal time (min)	17.4 ± 13.4	30.0 ± 3.5	0.01	0.04

without ML), and relatively low rates of pancreatitis [9–14]. Because EPLBD shares a similar method of ballooning to that of EPBD, there are still some concerns about the risk of pancreatitis.

The mechanisms underlying post-EPBD or post-EPLBD pancreatitis seem to be multifactorial, and suggested mechanisms were that (1) the direct physical compression effect of the balloon on the papilla, pancreatic duct orifice, or parenchyme may induce peripapillary edema or spasm of the sphincter, or that (2) repeated bile duct cannulation or transpapillary manipulation due to difficulty in cannulation or stone extraction may induce edema or spasm and, in turn, obstruct the flow of pancreatic juice and, eventually, induce pancreatitis [4, 20–22]. However, it is unclear whether the major factor in the induction of pancreatitis is the ballooning itself (and is, therefore, related to the balloon size) or to problems in selective cannulation and transpapillary manipulation. So, many clinicians still have concerns and hesitate to use larger balloons over 15 mm in size. We analyzed the cases involving especially large balloons ( $\geq 15$  mm), to investigate whether or not the increase in balloon size is a possible cause of pancreatitis. In our results, the frequency of pancreatitis after EPLBD using balloons over 15 mm in size was only 5% (with no cases of severe pancreatitis), and was not higher than the findings of most previous EPLBD series [9–14] using smaller balloons (12–15 mm) than our study. Our data support the proposal that increased balloon size and direct physical compression effects by the balloon itself are not a major cause of post-procedural pancreatitis.

To date, there have been a few studies on the risk factors of post-EPBD pancreatitis. Bergman et al. [22] found no predictive factors for post-EPBD hyperamylasemia or pancreatitis in their multivariate analysis, whereas Sugiyama et al. [23, 24] reported four independent risk factors for hyperamylasemia: age  $\leq 60$  years, previous pancreatitis, bile duct diameter  $\leq 9$  mm, and difficult bile duct cannulation. The present study also showed three

independent risk factors predictive of pancreatitis after EPLBD: smaller degree of CBD dilatation, prolonged time required for cannulation, and longer time of stone removal.

In patients with smaller degrees of CBD dilatation, EPLBD is not a suitable procedure because of the risk for perforation and pancreatitis as well. The finding of our study that a lesser degree of CBD dilatation is a risk factor for post-EPLBD pancreatitis is in good agreement with many authors who speculate that an appropriately dilated CBD might be very important when EPLBD is applied.

Our data also showed an independently increased risk for pancreatitis in cases with prolonged time required for cannulation and a longer time for stone removal. These findings suggest that the most important factor influencing post-EPLBD pancreatitis might be the papillary and transpapillary manipulation times. When applied to an appropriately dilated CBD, sufficient dilation of the papilla using a large-diameter balloon might both facilitate easier and faster stone extraction and reduce trauma to papilla during stone extraction, thus, having a beneficial effect on the outcome. In our present study, the application of ML did not affect the risk of pancreatitis, whereas the total time for stone removal independently affected the occurrence of pancreatitis. Based on these findings, the quicker stone extraction by sufficiently large dilation of the papilla and an earlier decision to use ML (if needed) in cases of difficult stone retrieval might be beneficial.

The history of previous pancreatitis and younger age ( $\leq 60$  years) have also been reported as risk factors for post-EPBD hyperamylasemia [23, 24], but they were not significant in our data. These factors might have been underestimated in the present study because the number of patients with history of pancreatitis and the number of younger patients were relatively small.

The main limitation of our study was its retrospective nature and non-comparative one-arm treatment analysis in single center. In addition, the study included many older patients, whose risk of pancreatitis might be small.

In conclusion, the application of a larger balloon over 15 mm in size by EPLBD is an effective and safe procedure with respect to pancreatitis in patients with a sufficiently dilated CBD. Post-EPLBD pancreatitis is associated with longer procedure time, including cannulation time and stone removal time, rather than larger balloon size. Finally, to reduce the risk of post-EPLBD pancreatitis, the selection of patients with sufficient CBD dilatation and the avoidance of excessive papillary manipulation appears to be important.

**Conflicts of interest** The authors report no other conflicts of interest.

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