Clinics in Surgery

Research Article
Published: 21 Mar, 2022

Clinical Effects of Endoscopic Papillary Balloon Dilation with Different Size Balloons on Sphincter of Oddi Function for Removing Common Bile Duct Stones

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Abstract

Aim: To evaluate the clinical effects of Endoscopic Papillary Balloon Dilation (EPBD) with different-sized balloons on the function of the Sphincter of Oddi (SO) for removing Common Bile Duct (CBD) stones.

Methods: Consecutive patients with CBD stones treated successfully with EPBD from May 2010 to January 2019 were enrolled. The study patients underwent Limited Endoscopic Sphincterotomy (LEST) or EPBD with 8 mm, 10 mm, 12 mm, or 14 mm balloons for bile duct clearance. Water-soluble contrast gastrointestinal cholangiography was performed 12 months after EPBD to assess the Duodenobiliary Reflux (DBR) of the contrast agent. Abdominal imaging was performed to assess pneumobilia.

Results: A total of 1139 patients were included. The incidence of DBR was 0%, 1.5%, and 7.4% in the LEST, 8 mm to 10 mm small-balloon EPBD, and 12 mm to 14 mm large-balloon EPBD groups, respectively ($P<0.05$). The incidence of pneumobilia in each group was highest at 1 month after the procedure. The incidence of pneumobilia increased proportionately with the diameter of the balloon (57.9% in the 14 mm group and 5.6% in the 8 mm group). The incidence of pneumobilia gradually decreased with time; however, the differences among the groups were statistically significant at 1, 6, and 12 months after EPBD ($P<0.001$). The incidence of recurrent CBD stones, acute cholangitis, and acute cholecystitis among the groups was similar. No patient developed hepatic abscess or bile duct cancer during the follow-up period.

Conclusion: EPBD with a large balloon may cause greater damage to SO function than with a small balloon, leading to a higher incidence of DBR and pneumobilia. However, no obvious significant clinical effects were observed.

Keywords: Endoscopic papillary balloon dilation; Sphincter of Oddi function; Common bile duct stones; Pneumobilia; Cholangitis

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Received Date: *24 Jan 2022*
Accepted Date: *20 Feb 2022*
Published Date: *21 Mar 2022*

Citation:
Sheng-Chen, Wu Q-H, Li Q-Y, Yang-Qi, Wei-Yao, Lei-Kong, et al. Clinical Effects of Endoscopic Papillary Balloon Dilation with Different Size Balloons on Sphincter of Oddi Function for Removing Common Bile Duct Stones. Clin Surg. 2022; 7: 3459.

Introduction

Both Endoscopic Sphincterotomy (EST) and Endoscopic Papillary Balloon Dilation (EPBD) are widely used for the removal of Common Bile Duct (CBD) stones. EST is associated with complications such as bleeding, duodenal perforation, pancreatitis, and permanent loss of function in the Sphincter of Oddi (SO), leading to Duodenobiliary Reflux (DBR) [1]. The reflux of duodenal contents into the bile duct may be associated with bacterial colonization of the bile duct, recurrent bile duct stones, ascending cholangitis [2], and even bile duct cancer [3]. Compared to EST, EPBD has similar stone removal rates, a lower risk of intestinal bleeding and perforation, and a lower chance of SO dysfunction [4,5]. Hence, EPBD is being increasingly adopted worldwide as the preferred procedure for stone removal. Early studies that showed EPBD could preserve SO function were performed using small balloons with diameters of 6 mm to 10 mm [6]. However, Endoscopic Papillary Large Balloon Dilation (EPLBD) with 12 mm to 20 mm balloons is being increasingly used to remove large CBD stones [7,8]. Whether the diameter of the balloon affects the risk of SO dysfunction is unknown. Additionally, the clinical effects of SO dysfunction after EPBD such as recurrent CBD stones and cholangitis are unknown.

At our institution, we perform EPBD with balloons of different sizes based on the diameter of the largest CBD stone. Commonly used balloon diameters are 8 mm, 10 mm, 12 mm, and 14 mm

[9]. We conducted this study to determine the incidence of DBR after EPBD using different balloon sizes and the clinical impact.

Patients and Methods

This prospective study was conducted in the Department of General Surgery at Ruijin Hospital (North) Affiliated with Shanghai Jiaotong University School of Medicine. Adult patients (18 to 80 years) with CBD stones admitted between May 2010 and January 2019 who underwent EPBD with complete clearance were included in this study. The exclusion criteria were: (1) patients who developed severe post-Endoscopic Retrograde Cholangiopancreatography (ERCP) complications such as severe acute pancreatitis, intestinal perforation, or bleeding; (2) patients for whom follow-up was not possible; (2) patients with intrahepatic bile duct stones; (3) a history of Billroth II gastrectomy; (4) past history of EST or EPBD; and (5) the presence of malignant disease. Patients who did not satisfy the above criteria were included in this study after discharge and data were collected during the follow-up visits. All patients provided written informed consent for the procedure. The study was approved by the Ethics Committee of Ruijin Hospital affiliated with Shanghai Jiaotong University School of Medicine and was supported by Shanghai Municipal Health Bureau.

Endoscopic procedure

ERCP was conducted using a side-viewing endoscope (JF240; JF260V; TJF260V Olympus, Tokyo, Japan). The presence of CBD stones was confirmed by cholangiography. The tip of the endoscope was used to estimate the diameter of the largest stone. The procedure was performed according to the diameter of the stone as follows: (1) <5 mm-Limited EST (LEST) without EPBD, (2) 6 mm to 8 mm – EPBD with an 8 mm balloon (3) 8 mm to 12 mm-EPBD with a 10 mm balloon, (4) 12 mm to 14 mm-EPLBD with a 12 mm balloon, and (5) >14 mm-EPLBD with a 14 mm balloon. LEST was performed using the standard technique of pull-type sphincterotomy. The incision was made up to the mid-portion of the papilla.

For EPBD, a balloon dilation catheter (Wilson-Cook Medical Inc., NC, and United States) with the appropriate diameter was inserted and the position was confirmed by injecting diluted contrast in the bile duct. The balloon was slowly inflated until the waistline was obliterated on fluoroscopy. The balloon was kept inflated for 1 min at 6 atm or 8 atm as required. Subsequently, the balloon was deflated and the CBD stones were removed using a retrieval basket and/or balloon. For stones >14 mm in diameter on diagnostic ERCP, mechanical lithotripsy was performed to break the stones into fragments. After complete CBD clearance, a nasobiliary drainage catheter was placed in the CBD. Cholangiography was performed routinely through the nasobiliary drainage catheter before removing the catheter to confirm CBD clearance. If there were residual CBD stones, repeat ERCP was performed to remove them without EPBD.

Follow-up

All study patients were followed up in the outpatient clinic at 1 month, 6 months, and 1 year after discharge and every year thereafter. All patients were followed up for at least 1 year. At each visit, a White Blood Cell Count (WBC), liver function tests, upper abdominal Computed-Tomography (CT), and/or abdominal ultrasonography were performed. Magnetic resonance cholangiopancreatography was performed if required. If stone recurrence was suspected based on the patient' symptoms, laboratory tests, and/or radiological imaging, ERCP was performed and the recurrent stones were retrieved.

Water-soluble contrast gastrointestinal cholangiography was only performed once 1 year after discharge for all study patients. The patient was asked to drink diluted water-soluble contrast (200 ml) in an upright position under fluoroscopic guidance. If there was no contrast DBR, the patient was placed in a supine position to observe for any contrast reflux into the bile duct. If there was still no contrast reflux, the patient's abdomen was compressed with an abdominal compressor to increase the pressure on the abdominal cavity and precipitate DBR. After cholangiography, upper abdominal CT was performed immediately to determine if there was pneumobilia and/or contrast reflux into the bile duct.

One year after EPBD, the patients were contacted telephonically every 6 months. If the patients reported significant symptoms such as abdominal pain, fever, or jaundice, they were advised to visit the hospital and were evaluated to detect biliary complications if any.

Outcome measures

The primary endpoint of this study was the incidence of water-soluble contrast reflux into the bile duct on upper gastrointestinal cholangiography at 1 year after EPBD. The second endpoints were the incidence of pneumobilia, CBD stone recurrence, acute cholangitis, acute cholecystitis, and other late biliary complications such as bile duct carcinoma and liver abscess during follow-up. The diagnoses of acute cholangitis and acute cholecystitis were in accordance with the criteria in the Tokyo 2018 guidelines [10,11].

Statistical analysis

For the purpose of comparison, the patients were divided into five groups based on the procedure performed and the size of the balloon used for EPBD as follows: LEST, 8 mm, 10 mm, 12 mm, and 14 mm.

Quantitative data were presented as the mean ± Standard Deviation (SD) and compared using ANOVA. Qualitative data were expressed as the frequency (percentage) and compared using the χ^2 test or Fisher's exact test as appropriate. A P value <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 19.0 for Windows (SPSS Inc., Chicago, IL, United States).

Results

Baseline characteristics

A total of 1139 consecutive patients (634 men, 505 women) were enrolled in this study. The mean age was 63.7 ± 12.4 years and the mean follow-up duration was 5.5 ± 2.8 years (range: 1.0-10.0 years).

There was no significant difference among the groups with regards to the age, sex, presence of the gallbladder in situ, and gallstones (Table 1). The diameter of the largest CBD stone was significantly different between the groups (P<0.001).

Incidence of duodenobiliary reflux

A total of 1024 patients underwent gastrointestinal cholangiography with water-soluble contrast. During gastrointestinal cholangiography in the upright position or without abdominal compression, no DBR of the oral contrast was observed. For 18 patients (2.2%, 18/833) in the EPBD group and no patient in the LEST group, the oral contrast refluxed into the bile duct when the abdomen was compressed with an abdominal compressor in the supine position (P=0.04) (Figures 1-5). Additionally, there were significant differences in the incidence of DBR among the five groups (P<0.001) (Table 2).

Table 1: Demographic data and baseline characteristics of the study groups.

Balloon diameter	n	Sex (F/M)	Age (yr)	Diameter of largest CBD stone (mm)	Gallbladder in situ (%)	Concomitant Gallstones (%)	Periduodenal Diverticulum (%)
LEST	212	90/122	63.0 ± 13.5	5.15 ± 0.5	46 (21.7)	16 (34.8)	38 (17.9)
8 mm	478	198/280	59.3 ± 14.5	7.5 ± 1.2	99 (20.7)	43 (43.4)	86 (18.0)
10 mm	348	172/176	64.8 ± 14.9	9.6 ± 1.2	70 (20.1)	22 (31.4)	66 (19.0)
12 mm	59	27/32	66.2 ± 20.5	11.8 ± 0.6	11 (18.6)	5 (45.5)	12 (20.3)
14 mm	42	18/24	74.6 ± 12.5	13.6 ± 0.5	7 (16.7)	3 (42.9)	11 (26.2)
χ^2 or F value		5.687	2.229	181.3	0.735	1.45	1.912
P value		0.224	0.068	<0.001	0.947	0.84	0.752

Figure 1: Gastrointestinal cholangiography 1 year after EPBD with a 14 mm balloon showing reflux of the oral contrast into the intra and extra hepatic bile ducts when the abdomen was compressed.

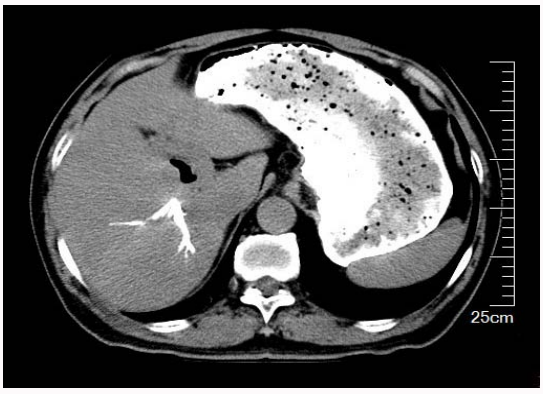

Figure 2: Abdominal CT performed immediately after gastrointestinal cholangiography showed the presence of contrast in the intrahepatic biliary system. For this patient, EPBD was performed with a 14 mm balloon 1 year before.

Figure 3: Gastrointestinal cholangiography 1 year after EPBD with a 10 mm balloon. When the abdomen was compressed in the supine position, a transient reflux of contrast from the duodenum to the distal CBD could be seen lasting for a few seconds (red arrow).

Figure 4: Abdominal CT scan performed immediately after gastrointestinal cholangiography showed the presence of oral contrast in the distal CBD (red arrow). In this patient, gastrointestinal cholangiography was performed 1 year after EPBD with an 8 mm balloon.

The contrast refluxed to the bile duct more easily and lasted longer in the 12 mm to 14 mm large balloon group than in the 8 mm to 10 mm small balloon group. Additionally, the contrast reached the intrahepatic bile ducts in the large-balloon group (Figure 1, 2), but was seen only in the distal CBD in the small-balloon group (Figure 3, 4). For patients with intestinal obstruction and increased intestinal pressure, the contrast continued to reflux into the bile duct for a long time among those who received EPBD with an 8 mm balloon, even with no external abdominal compression (Figure 5).

There were no symptoms of cholangitis such as fever, jaundice, increased WBC, or abnormal liver function in all patients with contrast reflux into the bile duct during follow-up, and no liver abscess or bile duct cancer occurred.

Incidence of pneumobilia

The incidence of pneumobilia in each group was highest at 1 month after ERCP (Table 3, Figure 6). As the diameter of the balloon increased, the incidence of pneumobilia increased, reaching 57.9% in the 14 mm group (Table 3). There was a significant difference in the incidence of pneumobilia 1 month after ERCP among the five groups (P<0.001). The incidence of pneumobilia gradually decreased with time in all groups. However, after 12 months, the difference among the groups was still statistically significant (P<0.001) (Table 3).

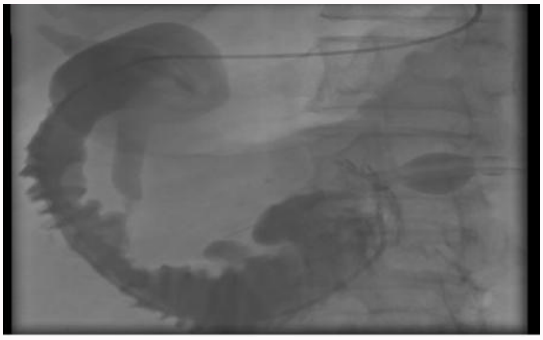

Figure 5: Gastrointestinal contrast X-ray performed 1 year after 8 mm balloon EPBD. The patient had intestinal obstruction for which a decompression catheter was placed. A contrast study through the catheter due to intestinal obstruction showed that the contrast refluxed to the CBD for a long time (red arrow).

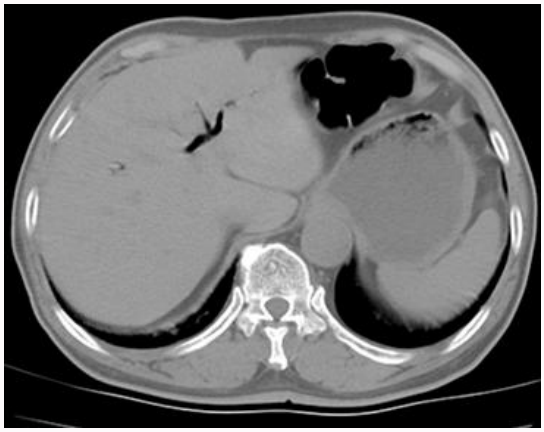

Figure 6: Abdominal CT showing pneumobilia 1 month after ERCP.

Table 2: Comparison of the incidence of duodenobiliary contrast reflux between the study groups.

Group	N	N of contrast reflux (%)
LEST	191	0 (0.0)
8 mm	426	6 (1.4)
10 mm	312	5 (1.6)
12 mm	55	3 (5.5)
14 mm	40	4 (10.0)
χ^2 value		21.799
P value		<0.001

Table 3: Comparison of the incidence of pneumobilia between the study groups in the follow-up period.

Group	N	1 month after procedure (%)	6 months after procedure (%)	12 months after procedure (%)
LEST	212	4/198 (4.5)	8/196 (4.1)	7/191 (3.7)
8 mm	478	24/431 (5.6)	35/421 (8.3)	31/426 (7.3)
10 mm	348	54/327 (16.5)	41/319 (12.9)	25/312 (8.0)
12 mm	59	23/56 (41.1)	13/53 (24.5)	13/55 (23.6)
14 mm	42	22/38 (57.9)	12/39 (30.8)	10/40 (25.0)
χ^2 value		308.524	30.46	30.934
P value		<0.001	<0.001	<0.001

Table 4: Comparison of the incidence of recurrent CBD stones between the groups.

Group	N	Recurrent CBD stones [n(%)]
LEST	212	16 (7.5)
8 mm~10 mm	826	93 (11.3)
12 mm~14 mm	101	9 (8.9)
χ^2 value		3.088
P value		0.214

Recurrence of CBD stones

A total of 118 (10.4%, 118/1139) patients developed recurrent CBD stones after LEST and EPBD. There were no significant differences in the incidence of recurrent CBD stones between the LEST, 8 mm ~ 10 mm small-balloon EPBD, and 12 mm ~ 14 mm large-balloon EPBD groups (Table 4).

Incidence of acute cholangitis

Seventy-eight patients developed acute cholangitis in the follow-up period. The cause of cholangitis was recurrent CBD stones in all cases, which were successfully treated with ERCP. No ascending cholangitis without CBD stones was observed in the follow-up period. The incidence of acute cholangitis was similar between the LEST, 8 mm ~ 10 mm small-balloon EPBD, and 12 mm ~ 14 mm large-balloon EPBD groups (P=0.214).

Incidence of acute cholecystitis

Two hundred and thirty-three patients (20.5%, 233/1139) had the gallbladder in situ and 127 patients (54.5%, 127/233) had gallstones. Forty-eight patients (20.6%, 48/233) developed acute cholecystitis during the follow-up period and 31 patients received laparoscopic cholecystectomy. There was no significant difference in the incidence of acute cholecystitis among the LEST, 8 mm ~ 10 mm small-balloon EPBD, and 12 mm ~ 14 mm large-balloon EPBD groups (P=0.203).

Other late biliary complications

No hepatic abscess or bile duct cancer was observed in any patient during the follow-up period.

Discussion

Since the first report of EPBD by Staritz for the treatment of CBD stones in 1983 [12], the effects of EPBD on SO function, especially the clinical significance such as CBD stone recurrence, reflux cholangitis, etc, have attracted much concern. Early animal experiments showed that EPBD using a cylindrical balloon with a diameter of 8 mm caused an acute transmural inflammatory response and chronic follicular hyperplasia without fibrosis or altered papillary architecture [13]. Clinical studies using endoscopic manometry showed that the SO function was preserved but somewhat reduced after EPBD and was significantly restored 1 year after EPBD. However, the function was better preserved after EPBD than after EST, which may be clinically beneficial for the prevention of later biliary complications [14,15]. In these studies, small balloons <10 mm were used. In recent years, EPLBD with large balloons (diameter ≥ 12 mm) have been used for the removal of large and multiple CBD stones. EPLBD reduces the need for mechanical lithotripsy and increases the stone removal rate [16,17]. However, the impact of EPLBD on SO function and its clinical significance are unclear. An experimental study using an *ex vivo* adult porcine model showed that large balloons could tear the bile duct wall and potentially cause SO dysfunction. The frequency of disruption and perforation increased proportionately with the diameter of the balloon [18]. There are few clinical research reports on the effect of EPLBD on SO function, especially the effects of

different sized balloons [19,20].

This clinical study compared the effects of the 8 mm ~ 10 mm small-balloon EPBD with the 12 mm ~ 14 mm large-balloon EPBD for removing CBD stones. We found that the incidence of contrast reflux into the bile duct was very low 1 year after EPBD, with 1.5% in the 8 mm ~ 10 mm small-balloon EPBD group and 7.4% in the 12 mm ~ 14 mm large-balloon EPBD group. The SO functional damage was more severe with the large balloon EPBD than with small-balloon EPBD based on the incidence of contrast bile duct reflux and pneumobilia found in this study. However, there were no obvious clinical effects of SO dysfunction such as cholangitis, cholestasis, liver abscess, or bile duct cancer during the follow-up period.

In this study, SO manometry was not performed to assess SO function due to the risk of ERCP-related complications such as acute pancreatitis. On the other hand, the clinical significance of SO manometry findings such as SO basal pressure after EPBD is unknown. Instead, in this study, water-soluble contrast was used for gastrointestinal cholangiography to directly observe the reflux of oral contract from the duodenum into the bile duct. Pneumobilia is an indirect manifestation of the functional impairment of SO. The results showed that the incidence of contrast DBR and pneumobilia was higher in the 12 mm ~ 14 mm large-balloon EPBD group than in the 8 mm ~ 10 mm small-balloon EPBD group 1 year after EPBD. The incidence of pneumobilia gradually decreased with time, suggesting the partial recovery of SO function. However, 1 year after EPBD, the differences among the groups were still statistically significant, indicating that large balloons probably because more damage to SO function.

The incidence of DBR at 1 year after EPBD, determined with gastrointestinal cholangiography, was low in this study. The most likely reason is that EPBD retained the tubular shape of the papilla, which had an anti-reflux effect. With duodenal peristalsis, the pressure in the duodenal cavity probably compressed the papilla and prevented DBR. These findings are in contrast to the free reflux of barium into the biliary tree in all patients after surgical sphincteroplasty, even 12.5 years after the procedure [3,21]. We believe that EPBD, even with 12 mm to 14 mm large balloons, can preserve the SO function and the papillary structure as seen on gastrointestinal cholangiography in this study.

It has been suggested that DBR can lead to bacterial contamination, cholangitis, bile duct stone recurrence, acute cholecystitis, and even bile duct cancer [22]. However, there are studies suggesting that as long as there is no bile duct obstruction, the intestinal content that reflux into the bile duct will flow back into the intestine without causing cholangitis and cholecystitis [23,24]. In this study, the patients with DBR had no symptoms in the absence of biliary obstruction. Additionally, all patients who developed acute cholangitis in the follow up period had biliary obstruction due to recurrent stones. Hence, we agree with the view that there is only descending cholangitis, no ascending cholangitis [21].

It has also been argued that the SO function affects the incidence of recurrent CBD stones [4,20]. In this study, there was no significant difference in the incidence of CBD stone recurrence between the 8 mm ~ 10 mm small-balloon EPBD and the 12 mm ~ 14 mm large-balloon EPBD groups despite more DBR and poor SO function in the large-balloon group. Hence, we believe that SO function has no relation with CBD stone recurrence.

There are some limitations to this study. First, gastrointestinal cholangiography was performed only once i.e. 1 year after EPBD. This was because many previous studies indicated that SO function 1 year after EPBD remains stable and does not recover further [14,19]. Second, the mean follow-up duration in this study was about 5 years. Although no bile duct carcinoma was observed during the follow-up period, longer follow-up is required to confirm the late effects of EPBD, especially in patients with contrast DBR as there is a recent report showing greater risk for the development of cholangiocarcinoma after ES/EPBD [25]. Third, this study had a small sample size with a single-center experience. Future prospective multicenter studies with long follow-up periods are required to determine the clinical effects of EPBD.

In conclusion, the results of this study showed that EPBD with 12 mm ~ 14 mm large balloons may cause greater damage to SO function than EPBD with 8 mm ~ 10 mm small balloons. However, no obvious significant clinical effects were observed with regards to the incidence of biliary complications, such as acute cholangitis, cholecystitis, recurrent CBD stone recurrence, liver abscess, or bile duct cancer in the follow-up period.

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