

The Ballooning Time in Endoscopic Papillary Balloon Dilatation for the Treatment of Bile Duct Stones

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Background/Aims: Endoscopic papillary balloon dilatation (EPBD) is a safe and effective method for the treatment of choledocholithiasis, but previous studies have rarely reported the appropriate ballooning time (BT). We prospectively evaluated the safety and efficacy of EPBD according to BT in patients undergoing bile duct stone removal.

Methods: Seventy consecutive patients with bile duct stones were randomly assigned to receive EPBD with either conventional (n = 35, 60 seconds) or short (n = 35, 20 seconds) BT.

Results: EPBD alone achieved complete bile duct clearance in 67 patients (long BT, n = 33, 94.3%; short BT, n = 34, 97.1%; $p = 0.808$). We also found no significant difference in the rate of complete duct clearance, including procedures that used mechanical lithotripsy, between the long and short BT groups (97.1% vs. 100%; $p = 0.811$). Mild pancreatitis was noted in four (11.4%) patients in the long BT group and two (5.7%) patients in the short BT group, but this incidence was not significantly different.

Conclusions: The study showed that EPBD using both 20-sec and 60-sec BTs is safe and effective for the treatment of bile duct stones. Short and long BTs produced comparable outcomes. (**Korean J Intern Med 2010;25:239-245**)

Keywords: Endoscopic papillary balloon dilatation; Choledocholithiasis; Pancreatitis

INTRODUCTION

Endoscopic papillary balloon dilatation (EPBD) has been suggested as an alternative to endoscopic sphincterotomy (EST) for the treatment of choledocholithiasis [1,2], despite its possible association with an unacceptably high risk of pancreatitis [3]. Because this technique dilates the biliary sphincter without requiring surgical incision, acute complications such as hemorrhage and perforation are less likely [2,4,5] and biliary sphincter function is preserved [6-8]. Despite the frequent use of EPBD, studies have rarely reported the appropriate ballooning time (BT). A single recent EPBD study demonstrated a decreased tendency for post-procedural pancreatitis with a short BT

(vs. long BT), with no differences in the efficacy of bile duct stone extraction [9]. Because patients experience pain during an EPBD despite adequate pre-procedural medication, the reduction in BT is desirable if the outcome is not affected. We therefore evaluated the safety and efficacy of EPBD performed with short and long BTs.

METHODS

Patients and study design

From September 2005 to July 2007, 70 consecutive patients who had been diagnosed with common bile duct (CBD) stones were randomly allocated to a long or short

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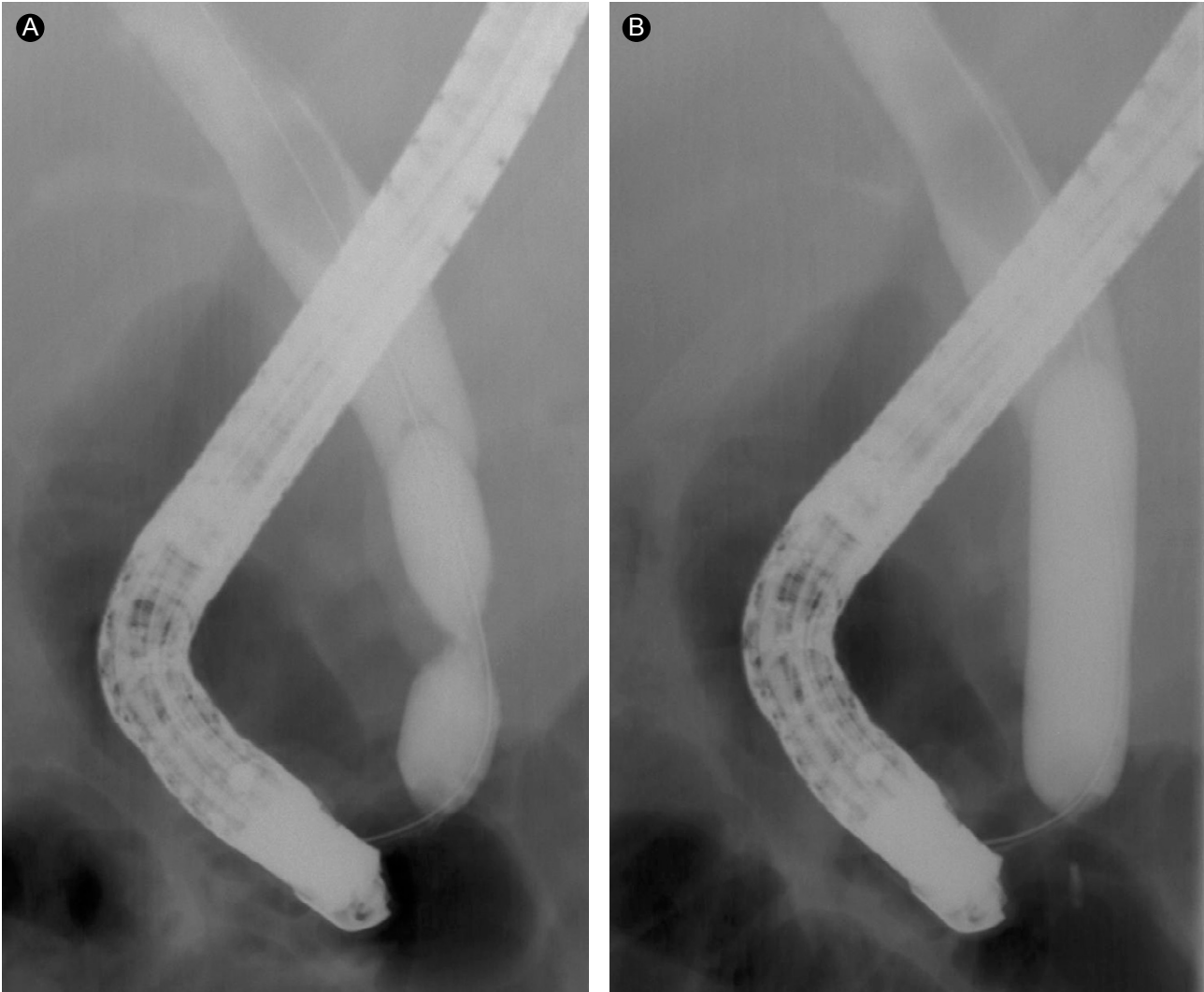


Figure 1. Cholangiogram showing endoscopic papillary balloon dilation. (A) The biliary sphincter is visible as a 'waist' during balloon inflation. (B) The biliary sphincter is adequately dilated when the balloon's waist has completely disappeared.

BT group. Patients were excluded if they had a history of previous EST or EPBD, choledochoduodenal fistula, benign bile duct stricture, previous precut papillotomy, or concomitant pancreatic or biliary malignancies. This study was approved by the institutional review board of our institution, and all patients provided written informed consent before enrolling in the study.

The initial diagnostic endoscopic retrograde cholangiopancreatography (ERCP) provided measurements of the CBD diameter, number of stones, and maximal transverse diameter of the largest stone. The technical success of the EPBD procedure was defined as the complete removal of all CBD stones, with or without the use of mechanical lithotripsy. Physical examination, abdominal radiography, and measurement of serum amylase and lipase, total bilirubin, alkaline phosphatase, and complete

blood counts were performed the morning after the ERCP to detect early complications such as acute pancreatitis, acute cholangitis, perforation, or bleeding. Major complications associated with the ERCP were diagnosed and their severity was graded according to modified Cotton's criteria [10]. Bleeding that was controlled during the procedure without clinical evidence was not considered a complication. Post-procedural pancreatitis was defined as epigastric pain persisting for at least 24 hours with a serum amylase level exceeding three times the normal level. The pancreatitis was considered mild if hospitalization was extended for 2 to 3 days, moderate if hospitalization lasted 4 to 10 days, and severe when hospitalization time was prolonged for more than 10 days. Post-procedural hyperamylasemia was defined as a serum amylase concentration that exceeded three times the upper limit of normal levels.

Table 1. Patient demographics and procedural findings

	Long BT group (n = 35)	Short BT group (n = 35)	<i>p</i> value
Sex (M/F)	19/16	16/19	0.473
Age, yr	66.2 ± 17.4	63.3 ± 13.6	0.443
Stone number			
Single	16 (45.7)	21 (60.0)	0.231
2 to 4	8 (22.9)	7 (20.0)	0.771
Over 5	11 (31.4)	7 (20.0)	0.243
Maximum stone size, mm	8.1 ± 3.5	8.2 ± 3.3	0.969
CBD diameter, mm	12.3 ± 3.1	13.1 ± 4.2	0.369
Balloon diameter, mm	9.7 ± 2.6	9.6 ± 2.4	0.904
Prior cholecystectomy	5 (14.2)	6 (17.1)	0.743

Values are presented as number (%) or mean ± SD.
BT, ballooning time; CBD, common bile duct.

Endoscopic procedure

The ERCP was performed with a side-viewing duodenoscope (TJF-240, Olympus Optical Corp. Ltd., Tokyo, Japan) under sedation with 3 to 5 mg midazolam and 25 mg meperidine hydrochloride. Duodenal peristalsis was suppressed with 20 mg scopolamine butylbromide. After selective cannulation of the CBD with a 0.035-inch cholangiography catheter (ERCP-Katheter, MTW® Endoskopie, Wesel, Germany), an initial cholangiogram was performed and the maximal transverse diameter of the CBD and the largest stone was measured. The measurements were corrected for magnification effects using the external diameter of the distal end of the duodenoscope as a reference. The catheter was then removed while the guide wire was left in place, and a balloon-tipped catheter (CRE balloon®, Boston Scientific Corp., Natick, MA, USA) was passed over the guide wire and placed across the papilla. Under endoscopic and fluoroscopic control, the balloon was gradually inflated with diluted radiopaque contrast medium to the target diameter using an inflation device (Indeflator®, Abbott, Santa Clara, CA, USA). The target diameter was based on the CBD and stone diameters.

We defined BT as the period between attainment of the target diameter (Fig. 1) and deflation of the balloon. Short BT in this study was 20 seconds in duration, and long BT was 60 seconds. After dilation of the papilla, the balloon was deflated and the balloon catheter and guide wire were removed. CBD stones were removed with Dormia baskets (Web® extraction basket, Wilson-Cook Medical Inc., Winston-Salem, NC, USA) and/or retrieval balloon catheters (two-lumen retrieval balloon catheter, Boston

Scientific Corp.). Mechanical lithotripsy was performed when the stone extraction could not be achieved with EPBD alone. A balloon-occlusion cholangiogram was obtained at the end of the procedure to ensure complete stone removal.

Statistical analysis

All continuous variables are expressed as means ± standard deviation (SD). Student's *t* test was used to compare mean values between the two groups. Categorical and binary variables were analyzed using chi-square tests. A *p* value of less than 0.05 was considered statistically significant. All analyses were performed using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

The conventional, long BT group included 35 patients (19 men, 16 women; mean age, 66.2 ± 17.4 years), as did the short BT group (16 men, 19 women; mean age, 63.3 ± 13.6 years). No significant differences were found in bile duct diameter, stone number or size, or previous cholecystectomy between groups (Table 1). The EPBDs of three patients (8.5%) in each group used a large (> 15 mm diameter) balloon catheter.

EPBD achieved complete duct clearance in 33 patients (94.3%) in the long BT group and 34 patients (97.1%) in the short BT group; this difference was not significant (*p* = 0.808). All CBD stones were completely retrieved during the initial EPBD in 32 patients (91.4%) in the long BT group and 31 patients (88.6%) in the short BT group (*p* =

Table 2. Efficacy of stone extraction after endoscopic papillary balloon dilation

	Long BT group (n = 35)	Short BT group (n = 35)	p value
Complete duct clearance with/without mechanical lithotripsy	34 (97.1)	35 (100.0)	0.811
Complete duct clearance by EPBD	33 (94.3)	34 (97.1)	0.808
Sessions required for complete duct clearance by EPBD			
1	32 (91.4)	31 (88.6)	0.478
2	1 (2.9)	3 (8.6)	0.174
Procedures including mechanical lithotripsy	1 (2.9)	1 (2.9)	1.000

Values are presented as number (%).

BT, ballooning time; EPBD, endoscopic papillary balloon dilation.

0.478). Complete stone removal was achieved during the second EPBD in one patient (2.9%) in the long BT group and two patients (5.7%) in the short BT group ($p = 0.174$). The mean numbers of sessions required for complete duct clearance were 1.2 and 1.1, respectively, for the long and short BT groups. No significant difference was observed in the rate of complete bile duct clearance between groups, independent of the use of mechanical lithotripsy (long BT, 97.1% vs. short BT, 100%; $p = 0.811$). One patient (2.9%) in each group required mechanical lithotripsy (Table 2); in these cases, the dilated biliary outlet was unexpectedly smaller than the largest stone after EPBD, preventing extraction. The stone of one patient in the long BT group could not be extracted because it was impacted in the CBD lumen, and the basket could not open properly. This stone was extracted using peroral transpapillary cholangioscopy with electrohydraulic lithotripsy.

Pancreatitis was noted in four patients (11.4%) in the long BT group and two patients (5.7%) in the short BT group ($p = 0.393$). All post-ERCP pancreatitis observed in this study was mild and resolved without complications. Asymptomatic hyperamylasemia was present in four

patients (11.4%) in the long BT group and three patients (8.6%) in the short BT group ($p = 0.690$). No other complications, such as hemorrhage, perforation, or cholangitis, occurred in either group. Serum amylase levels measured the morning after ERCP were 346.8 ± 55.6 IU/L in the long BT group and 198.2 ± 39.5 IU/L in the short BT group; this difference was significant ($p = 0.037$) (Table 3).

DISCUSSION

EPBD is technically easy and can be readily performed by endoscopists trained in standard therapeutic ERCP techniques [11]. Concerns regarding the increased incidence of ascending cholangitis and the possible recurrence of bile duct stones after EST [12,13], especially in younger patients, have led to the revival of EPBD. However, no agreement has been reached on the appropriate BT, which has been determined primarily by the operator's experience with the procedure. Balloon dilation has been used on the strictures of the esophagus, pylorus, and colon. BT must

Table 3. Early complications after endoscopic papillary balloon dilation

	Long BT group (n = 35)	Short BT group (n = 35)	p value
Pancreatitis	4 (11.4)	2 (5.7)	0.393
Cholangitis	0 (0.0)	0 (0.0)	NA
Perforation	0 (0.0)	0 (0.0)	NA
Hemorrhage	0 (0.0)	0 (0.0)	NA
Hyperamylasemia	4 (11.4)	3 (8.6)	0.690
Serum amylase, IU/L	346.8 ± 55.6	198.2 ± 39.5	0.037

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

BT, ballooning time; NA, not available.

Table 4. Safety and efficacy of bile duct stone extraction of previously reported endoscopic papillary balloon dilation according to ballooning time

	Natsui et al. [11]	Seo [15]	Viavianos et al. [16]	Ochi et al. [17]	Watanabe et al. [18]	Bergman et al. [19]	Mac Mathuna et al. [20]
Number	70	42	103	55	90	101	100
BT, sec	120	60-120	30	60 × 3	120	45-60	45-60 × 2
Balloon size, mm	8	NA	10	8	8	8	< 8
Overall complications	6 (8.6)	6 (14.3)	7 (6.8)	2 (3.6)	12 (13.3)	17 (16.8)	5 (5.0)
Pancreatitis	4 (5.7)	3 (7.1)	5 (4.9)	2 (3.6)	9 (10.0)	7 (7.0)	5 (5.0)
Cholangitis	2 (2.9)	3 (7.1)	2 (1.9)	0 (0.0)	3 (3.3)	4 (4)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Overall success	65 (92.9)	34 (80.9)	90 (87)	51 (92.7)	78 (86)	90 (89)	82 (82.0)
No. of session	NA	1.5	NA	NA	1.6	NA	NA
First session	41 (58.7)	NA	65 (63)	40 (78.4)	65 (72)	81 (80)	78 (78)
Second session or more	NA	NA	NA	NA	13 (14.5)	NA	4 (4)
ML or ESWL	29 (41.4)	19 (45.2)	7 (6.8)	7 (13.7)	76 (84)	31 (31)	16 (16)

Values are presented as number (%).

BT, ballooning time; NA, not available; ML, mechanical lithotripsy; ESWL, extracorporeal shock wave lithotripsy.

be sufficient for the dilation of the stricture and the reduction of restenosis risk. However, the papilla is a physiologically narrow area and should lack fibrosis unless a benign or malignant biliary stricture is also present. Reduction in BT may therefore help to preserve the physiological function of the papilla after EPBD, and may also reduce the risk of post-ERCP pancreatitis by curtailing the obstruction time of the pancreatic duct orifice. The sphincter is thought to be adequately dilated when the waist of the balloon disappears completely. In our experience, the waist disappeared within 20 seconds of achieving the target diameter in most EPBD procedures. We therefore found it reasonable to determine the effective minimum BT as the time required for the waist to disappear (20 seconds), and further believed that this minimum BT would be sufficient to dilate the papilla.

Patients may experience abdominal pain during EPBD, and the procedure has been associated with an increased risk of pancreatitis. Longer BTs further exacerbate these disadvantages [14]; BT reduction may conversely help alleviate these problems. Previous studies have reported BTs ranging from 30 to 120 seconds, with most operators using a 60-second BT [11,15-20]. The present study found comparable outcomes in the short and long BT groups, measured by the overall technical success of stone removal. Our results suggest that BT may be reduced when EPBD is performed.

This study found lower rates of post-procedural pancreatitis and hyperamylasemia in the short BT group than

in the long BT group, but these differences were not significant. Post-procedural serum amylase levels were significantly lower in the short BT group than in the long BT group. The compression of the papilla or the pancreatic duct orifice by ballooning may cause papillary edema or a sphincter of Oddi spasm during the EPBD procedure, which obstructs the flow of pancreatic juice and eventually results in a pancreatic insult [21-23]. Many factors may act independently or in concert to cause post-ERCP pancreatitis [24-26]; high-risk predictors include suspected sphincter of Oddi dysfunction (SOD), young age, history of post-ERCP pancreatitis, number of contrast injections into the pancreatic duct, and experience of the endoscopist. This study did not assess risk factors for post-ERCP pancreatitis, but our data suggest that a shorter BT may reduce the frequency of pancreatic insults during an EPBD, thus leading to a lower incidence of pancreatitis. A review of eight EPBD studies in which BT was specified (Table 4) found that BT ranged from 30 to 120 seconds, based on the operator's personal experience, and that a single EPBD was performed in most cases [11,15-20]. Two or three EPBDs were performed in two studies [17,20]. A comparison of efficacy and early complications according to BT showed no significant differences in the results of previous studies. Several confounding variables, however, prevented us from ruling out the possibility of correlations. These variables included the endoscopist's experience and the number of pancreatic duct cannulations.

Tsujino et al. [27] reported immediate and long-term complications associated with EPBD in 1000 patients; they initially inflated the balloon with air or diluted contrast material for 2 minutes, but reduced BT after one patient developed severe post-procedural pancreatitis. In the modified procedure, the balloon was inflated slowly for 1 to 2 minutes with diluted contrast, until the waist disappeared. The pressure was maintained for 15 seconds and they achieved complete removal of CBD stones with EPBD. The results of this study suggested that a short BT was sufficient for the removal of CBD stones, and that the ballooning speed may have been an important factor associated with complications; a slowly inflated balloon appeared to be less harmful to the ampulla of Vater, as it decreased post-procedural complications.

In conclusion, this study found that EPBD with a short, 20-second BT was safe and effective. The outcomes of procedures using a short BT were comparable to those using a conventional, 60-second BT for the treatment of bile duct stones. In addition, a short BT tended to be associated with a decreased incidence of post-ERCP pancreatitis and hyperamylasemia. Large prospective population studies are required to confirm the safety and efficacy of EPBD with a short BT, and to empirically define the appropriate BT for EPBD.

Conflict of interest

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

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