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Original Article

Does preserved sphincter of Oddi function prevent common bile duct stones recurrence in patients after endoscopic papillary balloon dilation?

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Abstract

Background: Whether preserving sphincter of Oddi (SO) function by endoscopic papillary balloon dilation (EPBD) is beneficial for preventing recurrent common bile duct stone disease (CBDS) is controversial. The aim of this study was to measure sphincter of Oddi (SO) function by using SO manometry, and to evaluate the association with recurrent CBDS.
Methods: Patients with suspected CBDS who underwent successful EPBD were included. These patients underwent SO manometry at two months after EPBD with bile duct clearance. They were regularly followed for recurrent CBDS.
Results: From January 2000 to December 2009, 185 patients received EPBD and SO manometry was included. There were 64% male with mean age of 65 ± 15.6 years. Mean ballooning inflation size was 1.1 ± 0.19 cm and mean ballooning time was 4.5 ± 0.85 min 55.7% had a sphincter of Oddi basal pressure (SOBP) of 0 mmHg, 16.2% < 10 mmHg, 26.5% 10−40 mmHg, and 1.6% > 40 mmHg. In multivariate analysis, EPBD with balloon ≥1.2 cm was the only factor for loss of SO function. Moreover, patients with preserved SO function had higher stone recurrence rate (15% vs. 5%, $p = 0.034$).
Conclusion: EPBD using balloon ≥1.2 cm is a major factor for loss of SO function, which seems to reduce the risk of recurrent CBD stones.

Keywords: Common bile duct stone; Endoscopic papillary balloon dilation; Sphincter of Oddi manometry

1. Introduction

Endoscopic sphincterotomy (ES) is widely used in the treatment of patients with common bile duct stones (CBDS).[1,2] Despite improvements in this technique, ES is still associated with complications, including hemorrhage, retroperitoneal perforation, cholangitis, pancreatitis and recurrent CBDS.[3,4] Endoscopic papillary balloon dilation (EPBD) of the sphincter of Oddi (SO) was first proposed by Staritz et al.[5] and it is an alternative procedure for removal of CBDS.[6−9] However, EPBD was reported to have higher risk of post-ERCP pancreatitis[10] even if it has several advantages such as easy procedure, lower risk of procedure-related bleeding and perforation.[11−13] Thus, EPBD has been recommended only in highly selected patients with a bleeding risk or altered

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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anatomy in whom it is difficult to perform ES in Western countries. Most EPBD is performed by using a maximum ballooning size of 8 mm and inflation duration of 45−60 s in order to preserve the function of sphincter of Oddi. A recent meta-analysis reported that longer duration of balloon inflation may reduce complications.[14] Recently, endoscopic papillary large balloon dilation (EPLBD) with balloon diameter ≧ 12 mm alone or after ES has been employed to remove large or difficult stones with satisfactory results,[9,13,15−17] without increasing the risk of pancreatitis.[18,19]

EPBD may preserve SO function, although not complete and somewhat reduced,[20] but the preserved SO can prevent the spontaneous passage of stone fragments resulting in early recurrence of CBDS.[21,22] Factors, such as size of the balloon, affecting SO function after EPBD has rarely been reported. A recent study using SO manometry to evaluate the SO function after EPLBD showed that EPLBD may result in persistent or comparable loss of SO function even after one year.[23] However, there is no sufficient data to address the relationship between SO function and recurrent bile duct stones after EPLBD alone. The aim of this study was to evaluate SO function after EPBD and factors affecting stone recurrence.

2. Methods

We included patients from our previous four prospective biliary functional studies, which were approved by the Institutional Review Board of Kaohsiung Veterans General Hospital (VGHKS90-CT4-06, VGHKS91-CT4-02, VGHKS95-CT1-10, and VGHKS98-CT1-06). Not all of these patients were regularly followed up for recurrent CBDS. We retrospectively followed these patients by reviewing medical records for evaluation of recurrent CBDS after EPBD. This study was approved by Institutional Review Board of Kaohsiung Veterans General Hospital (VGHKS 12-CT8-06).

Patients who had biliary pain, with laboratory and image studies suggesting of CBDS, and who underwent successful EPBD treatment were included for follow up and SO manometry study. Patients with previous sphincterotomy or bile duct surgery, pregnancy, bile duct stricture, intrahepatic stones, and pancreatic or biliary malignancy were excluded. Coagulopathy was corrected, and prophylactic antibiotics with broad-spectrum coverage were prescribed before endoscopic retrograde cholangiopancreatography (ERCP). Informed consent was obtained before the ERCP and SO manometry.

2.1. Endoscopic procedure

Local anesthesia of the pharynx using 10% xylocaine and intramuscular injection with 40 mg hyoscine-N-butylbromide and 25−50 mg meperidine were done before the procedure. ERCP was performed in the standard manner using a side-viewing endoscope (JF-240, JF1T-30, Olympus, Optical Corporation, Tokyo, Japan). After selective cannulation of the common bile duct, cholangiography was performed to confirm the diagnosis of CBDS. Then a 0.035-inch guide wire was inserted into the bile duct through the catheter. A balloon dilator (CRE balloon, 8-9-10 mm, 10-11-12 mm, 12-13.5-15 mm, 15-16.5-18 mm, 18-19-20 mm, Boston Scientific Corporation, Marlboro, MA, USA) was passed over the guide wire into the bile duct; the balloon was inflated to the desired diameter according to the maximal diameter of the CBD and stones, as well as the tolerance of patients. The maximal diameter of the balloon inflation should not exceed the maximal diameter of CBD. The duration of balloon inflation was 1−5 min according to the tolerance of patients. The stones in the CBD were then removed using a Dormia basket or retrieval balloon catheter after EPBD. Mechanical lithotripsy (BML-4Q, Olympus Optical, Tokyo, Japan) was employed to crush the stones if they were larger than the diameter of the distal bile duct or difficult to be removed by the Dormia basket. All patients were observed in hospital for at least 24 h after endoscopic treatment.

During ERCP, juxtapapillary diverticulum, maximal diameter of CBD, size and number of stones, and the diameter of balloon during EPBD were recorded. Stone removal was defined as complete if the final cholangiogram showed no residual stones.

2.2. Clinical follow-up

Patients were followed-up initially every two weeks after discharge until normalization of liver function. They were then regularly followed-up with liver function tests (serum alanine aminotransferase, aspartate aminotransferase, *r*-glutamyl transpeptidase), and abdominal sonography every 3−6 months or any time with recurrent symptoms. Patients were also assigned for SO manometry after normalization of liver biochemistries at least 2 months after EPBD.

2.3. Sphincter of Oddi manometry

The initial preparation of SO manometry was the same as ERCP, except injection of hyoscine-N-butylbromide, which might affect the sphincter of Oddi motor function. Side-viewing endoscope was used and advance it to the major papilla. The gross appearance of the papilla was recorded. SO manometry for the measurement of sphincter of Oddi basal pressure (SOBP)[24] was performed using a triple lumen polyethylene catheter of 1.7 mm outer diameter(Lehman sphincter manometry catheter; Cook Endoscopy, Winston−Salem, NC, USA), which was introduced through the biopsy channel of a duodenoscope (Olympus JF 1T 20, Tokyo, Japan). The catheter was perfused with sterile distilled water at a rate of 0.25 ml/min by a pneumohydraulic capillary pump (Arndorfer Medical Specialties, Greendale, Wisconsin, USA). No premedication except local pharyngeal anesthetic was given during SO manometry. The pressure on the catheter in the duodenal lumen was calibrated to zero before cannulation into the bile duct. After deep cannulation, bile was aspirated from one lumen of the catheter to confirm the correct position of the catheter. Pressure was measured from the CBD, SO and duodenum sequentially by using the station pull-through technique. A basal pressure of SO (SOBP) below 10 mm Hg, in

addition to a wide opening of the major papilla, was defined as a complete ablation of SO.[25] Cholangiography was also performed after manometry to confirm absence of residual stones.

2.4. Statistical analyses

Continuous variables such as age, stone size, CBD size were expressed as mean ± SD. Continuous variables were compared by Student's *t* test. Categorical and binary variables such as sex, gallbladder status, presence of juxtapapillary diverticulum, were tested by the Chi-square test or Fisher's exact test. Those variables were subsequently assessed by a logistic regression method for multivariate analysis. A p value < 0.05 was considered significant.

3. Results

Between January 2000 and December 2009, 185 patients were enrolled into this study. There mean age was 65 years and 64% were male. The mean CBD diameter was 1.4 ± 0.50 cm, and stone size was 1.1 ± 0.49 cm. There were 40% of multiple stones, 30% of single stones, and 30% of no observable stones (probably small sandy stone particles, and which had been passed out). 50% had an intact gallbladder, 30% had gallbladder stones, and 52% had juxtapapillary diverticulum. The balloon inflation size was 1.1 ± 0.19 cm (range 0.8−2.0 cm), and the mean balloon inflation time was 4.5 ± 0.85 min (range 1−5 min) (Table 1).

SO manometry showed that 103 patients (55.7%) had a SOBP of 0 mmHg, 30 patients (16.2%) had a SOBP of less than 10 mmHg, 49 patients (26.5%) had a SOBP between 10 and 40 mmHg, and three patients (1.6%) had a SOBP of more than 40 mmHg (Table 2). Overall 28.1% patients receiving EPBD had preserved sphincter of Oddi function (≥10 mmHg) and 71.9% of patients had a loss their function with SOBP less than 10 mmHg. In univariate analysis, male gender, presence of juxtapapillary diverticulum and diameter of balloon dilation ≥1.2 cm were the factors leading to loss of SO function after EPBD (Table 3). In multivariate analysis, balloon size ≥1.2 cm was the only risk factor for loss of SO function (OR 4.2, 95% CI 1.816−9.800, $p = 0.001$).

In addition, 15 patients (8.1%) were found to have recurrent CBDS, with a mean interval of 26.1 months (6−62 months). Patients with preserved SO function had significantly higher recurrent rate compared with those having loss of function, which is similar to the post-sphincterotomy state (15% vs. 5%, $p = 0.034$, Table 4). Other factors, such as gender, age, size of CBD, gallbladder status, juxta-papillary diverticulum, balloon size or duration of inflation, uses of lithotripter were not associated with recurrent CBDS. All patients with recurrent CBDS were successfully treated by endoscopic procedure. No patients suffered from ERCP-related complication during and after SO manometry examination.

Table 1
Patients' characteristics (n = 185).

Parameter	N (%)
Sex (M/F)	118/67 (64/36)
Age (years)	65.0 ± 15.6
No. of stones (no stone/single/multiple)	56/56/73 (30/30/40)
Stone size (cm)	1.1 ± 0.49
CBD size (cm)	1.4 ± 0.50
Balloon size (cm)	1.1 ± 0.19 (0.8−2.0)
Male	1.1 ± 0.17
Female	1.1 ± 0.21
Ballooning time (minutes)	4.5 ± 0.85 (1−5)
Presence of JPD	97 (52)
Intact gallbladder	92 (50)
Intact gallbladder with stones	58 (31)

N= No. of cases.
CBD = common bile duct.
JPD = juxtapapillary diverticulum.

Table 2
SOBP in patients after EPBD (n = 185).

SOBP (mmHg)	No. of cases (%)
0	103 (55.7)
1−9	30 (16.2)
10−40	49 (26.5)
>40	3 (1.6)

SOBP = sphincter of Oddi basal pressure.

4. Discussion

In previous research, SO function was significantly reduced within one week after balloon dilation, and it recovered gradually after one month.[26] In this study, manometry was performed two months after EPBD when the SO function was supposed to have recovered. In the studies of both Sato and Yasuda, the recovery of SO function after EPBD with the 8 mm balloon dilator was not complete even after one year.[20,26] It is well known that EPLBD could ablate the SO function, but no insufficient data was noted, especially the manometry aspect.[27] Our study could apply some clinical

Table 3
Factors affecting function of sphincter of Oddi after EPBD in univariate analysis.

	SOBP		*p*
	<10 mmHg	≥10 mmHg	
Gender (M/F)	91/42	27/25	0.036[a]
Age (<65 years/≧ 65 years)	53/80	21/31	0.947
CBD size (<1/≥ 1 cm)	19/114	9/43	0.606
Intact gallbladder (+/−)	67/66	25/27	0.779
Gallstones (+/−)[b]	43/90	15/37	0.646
JPD (+/−)	76/57	21/31	0.040[a]
Balloon size (<1.0/≧ 1.0 cm)	7/126	6/46	0.197
Balloon size (<1.2/≧ 1.2 cm)	73/60	44/8	<0.001[a]
Ballooning time (≦3mins/>3mins)	30/103	18/34	0.093

EPBD = endoscopic papillary balloon dilation.
SOBP = sphincter of Oddi basal pressure.
CBD = common bile duct.
JPD = juxtapapillary diverticulum.
[a] $p < 0.05$.
[b] Gallstone +: patients with GB stones without cholecystectomy, Gallstone −: patients without GB stones or with cholecystectomy.

Table 4
Factors affecting recurrent CBD stones after EPBD in univariate analysis.

	Recurrence (%)	*p*
Gender		0.750
Male	9/118 (8)	
Female	6/67 (9)	
Age		0.099
< 65 years	3/74 (4)	
≥ 65 years	12/111 (11)	
CBD size		0.432
<1 cm	0/28 (0)	
≥ 1 cm	15/157 (10)	
Intact gallbladder		0.432
+	6/92 (7)	
−	9/93 (10)	
Gallstones		0.152
+	2/58 (3)	
−	13/127 (10)	
JPD		0.091
+	11/97 (11)	
−	4/88 (5)	
Balloon size		0.398
<1.2 cm	11/117 (9)	
≧1.2 cm	4/68 (6)	
Ballooning time		0.542
≦ 3mins	5/48 (10)	
>3mins	10/137 (7)	
Lithotriptor		0.452
+	1/7 (14)	
−	14/178 (8)	
SOBP		0.034[a]
<10 mmHg	7/133 (5)	
≥10 mmHg	8/52 (15)	

[a] $p < 0.05$.

evidence that EPLBD could ablate the SO function. The current study showed that 71.9% patients had SOBP of less than 10 mmHg after EPBD, which is probably attributable to the use of larger balloons, since balloon inflation size ≥12 mm was the significant factor accounting for ablation of SO function. A widely patent biliary orifice may facilitate biliary emptying, but the loss of sphincter function is associated with bacterial colonization of the bile duct which can cause stone formation.[28] We used EPBD for preserved SO function (may be partially) and such preservation was believed to be a mandatory process for prevention of stone recurrence.[20]

Whether maintenance of an intact SO is beneficial or not remains controversial.[29,30] However, this study showed significantly higher rates of recurrent CBDS among patients with preserved sphincter basal pressure compared with those having loss of sphincter function (15% *vs*. 5%, $p = 0.034$). Since biliary emptying is abnormal even after complete ablation of SO,[31] intact sphincter function after EPBD may further hinder the spontaneous passage of stone fragments left in the bile duct.[21,32] Several risk factors are associated with recurrent CBDS, including dilated bile duct, large stone, presence of juxta-papillary diverticulum, gallstones, brown pigmented stones, uses of lithotripter, ES, pneumobilia after ES, longer ballooning time, etc.[13,17,33–35] However, in our study, SOBP of less than 10 mmHg was the only factor contributing to the less recurrent CBDS. Significantly higher rate of preserved sphincter function was found in female patients (37%) than in male patients (23%), $p = 0.036$.

Cholecystectomy for gallbladder stones is an important factor for recurrent CBD stones. A large scale study from healthcare database in Taiwan showed that cholecystectomy decreased the recurrent cholangitis and all-cause mortality in patients with successful endoscopic clearance of bile duct.[36] In our study, patients with gallbladder stones without cholecystectomy is not a risk, which might be due to insufficient sample size, and retrospective study.

The limitations are that 1) not all patients were regularly follow up in our clinic after EPBD, and the sample size of complete follow-up was small, and many risk factors of recurrent bile duct stone were not significant in this study; 2) SO manometry was not performed before EPBD and sphincter of Oddi function was evaluated by SOBP without pharmacological stimulation, such as cholecystokinin (CCK) provocation,[37] and 3) Manometry was performed once only in patients after normalization of liver biochemistries. Certain degree of changes of SO may still occur afterwards. Some authors recommended that SO manometry should be done again one year after EPBD.[20] Longer duration of investigation may help to evaluate the permanent change of sphincter function.

In conclusion, endoscopic papillary balloon dilation with balloon ≥12 mm is a major factor for loss of SO function, which seems to reduce the risk of recurrent CBD stones. However, further large scale prospective studies are needed to clarify the issue in the world.

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