

## Reappraisal of endoscopic papillary balloon dilation for the management of common bile duct stones

Kwok-Hung Lai, Hoi-Hung Chan, Tzung-Jiun Tsai, Jin-Shiung Cheng, Ping-I Hsu

Kwok-Hung Lai, Hoi-Hung Chan, Tzung-Jiun Tsai, Jin-Shiung Cheng, Ping-I Hsu, Division of Gastroenterology, Department of Internal Medicine, Kaohsiung Veterans General Hospital, Kaohsiung 813, Taiwan

Kwok-Hung Lai, Hoi-Hung Chan, Ping-I Hsu, School of Medicine, National Yang-Ming University, Taipei 112, Taiwan

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Correspondence to: Kwok-Hung Lai, Professor, Division of Gastroenterology, Department of Internal Medicine, Kaohsiung Veterans General Hospital, 386 Ta-Chung 1<sup>st</sup> Road, Kaohsiung 813, Taiwan. [khlai@vghks.gov.tw](mailto:khlai@vghks.gov.tw)

Telephone: +886-7-3422121-2074

Fax: +886-7-5574361

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The indication of EPBD is now extended from removal of the small stones by using traditional balloon, to removal of large stones and avoidance of lithotripsy by using large balloon alone or after EST. According to the reports of antegrade papillary balloon dilatation, balloon dilation itself is not the cause of pancreatitis. On the contrary, adequate dilation of papillary orifice can reduce the trauma to the papilla and pancreas by the basket or lithotripter during the procedure of stone extraction. EPLBD alone is as effective as EPLBD with limited EST. Longer ballooning time may be beneficial in EPLBD alone to achieve adequate loosening of papillary orifice. The longer ballooning time does not increase the risk of pancreatitis but may reduce the bleeding episodes in patients with coagulopathy. Slowly inflation of the balloon, but not exceed the diameter of bile duct and tolerance of the patients are important to prevent the complication of perforation. EPBLD alone or with EST are not the sphincter preserved procedures, regular follow up is necessary for early detection and management of CBD stones recurrence.

**Key words:** Common bile duct stones; Complications; Endoscopic balloon dilation; Endoscopic large balloon dilation; Endoscopic sphincterotomy

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### Abstract

Although endoscopic sphincterotomy (EST) is still considered as a gold standard treatment for common bile duct (CBD) stones in western guideline, endoscopic papillary balloon dilation (EPBD) is commonly used by the endoscopists in Asia as the first-line treatment for CBD stones. Besides the advantages of a technical easy procedure, endoscopic papillary large balloon dilation (EPLBD) can facilitate the removal of large CBD stones.

**Core tip:** Indication of endoscopic papillary balloon dilation is now extended from removal of small common bile duct stones to large or difficult stones by using large balloon. Balloon dilation itself is not the cause of pancreatitis. Avoidance of unnecessary pancreatic contrast injection, use the suitable balloon and pressure, slowly balloon inflation and adequate ballooning time to achieve a widely opened papillary orifice are the important steps to perform a safe endoscopic papillary large balloon dilation and successful clearance of bile duct.

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## INTRODUCTION

In the laparoscopic era, endoscopic retrograde cholangiopancreatography (ERCP) is as efficient as laparoscopic surgery in the treatment of common bile duct (CBD) stones<sup>[1]</sup>. Since the introduction of endoscopic sphincterotomy (EST) in 1974 by Classen *et al*<sup>[2]</sup> and Kawai *et al*<sup>[3]</sup>, EST is widespread used for removal of CBD stones in the following 40 years. Although the success rate of EST is high, this procedure may cause pancreatitis, hemorrhage, perforation and other complications. In a prospective cohort study of EST in 2347 patients<sup>[4]</sup>, the overall complications of EST was 9.8%, including pancreatitis 5.4% (severe 0.4% and one patient died), hemorrhage 2% (severe 0.5% and 2 patients died), perforation 0.3% (severe 0.5%, one patient died), cholangitis 1% (severe 0.1% and one patient died), cholecystitis 0.5% (severe 0.1% and one patient died). The risk factors of pancreatitis included dysfunction of sphincter of Oddi, young age, difficulty in cannulating the bile duct, and number of pancreatic contrast injections; whereas the risk factors of hemorrhage included coagulopathy, anticoagulation therapy, cholangitis, mean case volume of endoscopist  $\leq 1/\text{week}$ , and bleeding during the procedure. Thus, the risk of complications was influenced by the technique of endoscopist in the process of bile duct cannulation and cutting the papilla<sup>[4]</sup>.

In 1981, Centola *et al*<sup>[5]</sup> presented a case with CBD stones who was successfully treated by percutaneous transhepatic balloon dilation of papilla of Vater. Staritz *et al*<sup>[6]</sup> also reported his experience by using a 15 mm diameter balloon catheter for endoscopic papillary dilation in 10 patients with CBD stones and one patient with benign papillary stenosis in the next year. Six of the ten patients were successfully cleared the bile tract soon after endoscopic papillary balloon dilation (EPBD) and four patients needed mechanical lithotripsy for stone retrieval. There were no complications in this report. For the purpose of preserving the function of sphincter of Oddi and avoidance of late complication, most endoscopists used the smaller balloon catheters (8 mm or less) to dilate the biliary sphincter for removal of the small stones, or combination use of the smaller balloon with lithotripter to treat the larger stones in the following twenty years. The success rate of EPBD was comparable with EST and reduced risk of bleeding was found<sup>[7-13]</sup>. Higher incidences of pancreatitis after EPBD by using the 8 mm balloon catheter were reported in some stud-

ies<sup>[14-16]</sup>. Although most of the patients with post-EPBD pancreatitis recovered after conservative treatment, a multi-center study from United States and Ireland disclosed two patients with fatal pancreatitis after EPBD<sup>[16]</sup>. The impact of this report discouraged the use of EPBD as the first line modality for the treatment of CBD stones by some western endoscopists, particularly in United States<sup>[17-20]</sup>. However, EPBD was still a popular procedure in Asia and parts of Europe<sup>[21]</sup>. Tsujino *et al*<sup>[22]</sup> found that 4.8% of their 1000 patients developed pancreatitis after EPBD, but all of them recovered later.

In 2003, Ersoz *et al*<sup>[23]</sup> reported their retrospective analysis for using the enteric balloon catheter (previously used for esophageal or pyloric dilation) with the diameter 12-20 mm, to treat 58 patients who had received complete endoscopic sphincterotomy but failure to clear the CBD stones. Of the 58 patients, 18 patients had tapered distal bile duct, and another 40 patients had the large, square and barrel shaped stones. Successful stone removal at the first session was 82.8%, and the other 10 patients also achieved clearance of bile duct after second dilation or mechanical lithotripsy. Complications occurred in 15.5%, including moderate bleeding in three patients (5.2%) and mild pancreatitis in two patients (3.4%). In 2004, Lin *et al*<sup>[24]</sup> from Taiwan reported a randomized controlled study comparing 51 patients receiving EPBD alone by using the enteric balloon catheter (diameter 10-12 mm) with 53 patients receiving EST for removal of CBD stones. The ballooning time was increased to 5 min to avoid the continuous blood oozing after balloon deflation. The successful bile duct clearance rates and the frequencies of mechanical lithotripsy were comparable between two groups. The minor bleeding episodes were more frequent in EST group (2% vs 26.4%,  $P < 0.001$ ), but no other adverse effects such as pancreatitis and perforation were reported. Since then, endoscopic papillary large balloon dilation alone (EPLBD) or after sphincterotomy (ESLBD) became popular use for removal the large or difficult CBD stones, the results are satisfactory and even superior to EST in most studies and literatures of meta-analysis<sup>[25-61]</sup>. Although lethal pancreatitis is rare, life-threatening complications such as perforation and bleeding have been reported after ESLBD or EPLBD<sup>[62,63]</sup>. In the era of EPLBD/ESLBD, several previous concepts about EPBD, such as the indications, methodology, short-term and long-term complications should be amended.

## INDICATIONS OF EPBD/EPLBD

Staritz *et al*<sup>[6]</sup> firstly reported the good clinical results of EPBD for removal of CBD stones by using the large balloon catheter, but most endoscopists shifted to the smaller balloon catheter (8 mm) for papillary dilation later<sup>[9-16,22]</sup>. Because of high incidence of post-procedural pancreatitis in a few studies<sup>[15,16]</sup>, the indica-

tions of EPBD was confined to the vulnerable patients (*e.g.*, coagulopathy, cirrhosis), or altered anatomy (*e.g.*, Billroth II gastrectomy, Roux-en-y anastomosis, juxtapaillary diverticulum), and the stones were lesser than 1 cm in diameter<sup>[19,20]</sup>. After ESLBD and EPLBD were widely used to remove the large or difficult stones with good results, the indications extend to the patients with large stones, tapered or stricture of distal bile duct<sup>[21,23,25,31,36,41,44,58,61]</sup>. As perforation is more likely to occur in those patients with distal bile duct stricture, some studies suggest that the target of EPLBD/ESLBD should include the patients with CBD dilation but without stricture of distal CBD<sup>[25,63]</sup>. Since stricture of distal bile duct is also a problem after EST, other studies recommend limited EST, gradually inflation of balloon and early use of lithotripter to remove the CBD stones safely<sup>[23,63-66]</sup>.

### SUCCESS RATE OF EPBD/EPLBD FOR REMOVAL OF CBD STONES

The overall success rate of EPBD by using the conventional balloon catheter was comparable (94.3% vs 96.5%) with EST in a meta-analysis of eight studies<sup>[17]</sup>, another similar analysis of thirteen studies reported that EPBD being less successful overall in regard to stone removal (90.1% vs 95.3%)<sup>[18]</sup>. Both two above studies showed that patients undergoing EPBD were more likely required mechanical lithotripsy for stone extraction (20.9% vs 14.8% and 20.0% vs 13.3%, respectively)<sup>[17,18]</sup>. The contradictory results of meta-analyses in clinical trials may be due to diverse nature of the studies in design and methods<sup>[67]</sup>. Most of the trials excluded the patients with coagulopathy, cirrhosis, distal bile duct stricture, big stones or difficult cases, the detailed methods including the ballooning time and medications were different. The heterogeneity of the trials may interfere the assessment of overall results.

The initial success rate of ESLBD was 91% (75.5% -100%), overall success rate was 98% (88.6% -100%), mechanical lithotripsy was necessary in 9.3% (0-33%)<sup>[68]</sup>. The overall success rate ESLBD was comparable with EST in most studies, but the need of mechanical lithotripsy was less frequent in ESLBD<sup>[25,31,41,44,58]</sup>. In patients received EPLBD alone, the overall success rate of CBD stones removal ranged from 92.7%-97.5%, the need for mechanical lithotripsy ranged from 15.8%-21.2%<sup>[45,51,69-72]</sup>. Minakari *et al*<sup>[69]</sup> found that there were no significant difference between the success rate of EPLBD alone and EST (97.5% vs 96.2%). Hwang *et al* reported that the overall success rate of CBD stone removal and the needs of mechanical lithotripsy were similar between the patients received EPLBD alone or ESLBD (96.8% vs 95.7% and 19.4% vs 26.1%, respectively)<sup>[57]</sup>.

### METHODS OF EPBD/EPLBD

The diameter of the balloon depends upon the injection pressure inside the balloon according to the manufacturer's instruction<sup>[24,45]</sup>. A multicenter study demonstrated the efficacy and safety of EPBD by inflating the balloon until its waist disappears, rather than inflating to a prespecified pressure<sup>[72,73]</sup>. The balloon should be slowly inflated to avoid sudden tearing of the ampullary roof. After EST, the shape of papillary orifice will be triangular and the distal CBD will be narrow in shape. In contrast, the papillary orifice will be shaped as a large round hole with cylindrical configuration without a narrowing at distal bile duct after adequate balloon dilation, the relative stiff accessory instruments such as basket and lithotripter will enter easily into bile duct for stones removal<sup>[47]</sup>. The traditional balloon catheter (8 mm in diameter, 3 cm in length) was used to remove the small CBD stones and to preserve the integrity of the sphincter<sup>[13,74]</sup>. The large balloon ( $\geq 10$  mm to 20 mm) is used to remove the big difficult stones without consideration of sphincter preservation<sup>[44]</sup>.

The choice of balloon depends on the size of the largest stones and the CBD diameter<sup>[44]</sup>. The size of balloon should not exceed the maximal diameter of bile duct. In the patients with a stricture or tapered distal bile duct, gradual dilation with smaller balloon until disappearance of the waist is suggested, and EPBD should be terminated if the patient is intolerant to the dilating procedure.

The ballooning time is heterogeneous in different reports. In several controlled studies, the short ballooning time 20-30 s had the comparable results with the ballooning time 60-120 s<sup>[55,72,75]</sup>. In the study of Choi *et al*<sup>[76]</sup> they demonstrated the favorable outcome of immediate balloon deflation method in ESLBD for the extraction of difficult CBD stones. In a randomized trial from Taiwan, Liao *et al*<sup>[77]</sup> showed that 5-min EPBD improved the efficacy of stone extraction and reduces the risk of pancreatitis in comparison with conventional 1-min EPBD. A meta-analysis also demonstrated the duration of EPBD is inversely associated with pancreatitis risk<sup>[60]</sup>. Long EPBD can result in adequate loosening of the intact sphincter and less blood oozing, the widely opened papillary orifice may facilitate the insertion of accessory instruments into bile duct, and decrease the injury of pancreas<sup>[24,45,77,78]</sup>. In the patients who received ESLBD, shorter ballooning time may be enough because the sphincter is partially severed. The longer ballooning time may probably prevent bleeding complication, particularly in the frail patients with bleeding tendency, cirrhosis, uremia or under anti-platelet therapy<sup>[37,63,65]</sup>.

Attasaranya *et al*<sup>[38]</sup> suggested that EPLBD after EST may result in separation of the pancreatic and biliary orifices and the balloon dilation forces are away

from the pancreatic duct. According to his theory, many endoscopists performed ESLBD to remove the CBD stones recently<sup>[26-30,32-35,37,39,40,42-44,46-48,53,54]</sup>. Significant bleeding was reported in 2.8% (0-8%) after ESLBD<sup>[68]</sup>. Hwang *et al*<sup>[57]</sup> conducted a study of 131 patients to compare the clinical effect of EPLBD alone and ESLBD. The successful stone removal (EPLBD 96.8%, ESLBD 95.7%), need of mechanical lithotripsy (EPLBD 19.4%, ESLBD 26.1%), postprocedural pancreatitis (EPLBD 6.5%, ESLBD 4.3%), perforation (EPLBD 0%, ESLBD 1.4%) were no significant differences between two groups<sup>[57]</sup>. The recent prospective controlled study by Kogure *et al*<sup>[77]</sup> also demonstrated the similar findings. Another two single-institution retrospective studies reported that the EPLBD alone had the overall success rate 92.7%-97.4%, required the help of mechanical lithotripsy 15.8%-21.1%, postprocedural mild pancreatitis 0-0.8%, and no major bleeding<sup>[45,71]</sup>. Therefore, EPLBD alone is a simple safe and effective method in patients with large CBD stones, precut sphincterotomy may be unnecessary except in those patients with difficult cannulation of bile duct.

## ADVERSE EVENTS AFTER EPBD/EPLBD

### Pancreatitis

EPBD is categorized as one of the important causes of pancreatitis since the report of multicenter study from Disario *et al*<sup>[16]</sup>. From the result of recent studies, pancreatitis is more frequent in the patients using the traditional balloon (8 mm) and short duration (< 3 min) than the patients using the large balloon and long duration<sup>[6,12,14-17,24,25,31,36,45,52,58,60,65,71,77,79]</sup>. In 2000, Gil *et al*<sup>[80]</sup> from Spain reported their results by using percutaneous balloon dilation of sphincter of Oddi to clear the bile duct in the 38 patients with CBD stones. The success rate was 94.7% and no patient developed pancreatitis<sup>[80]</sup>. Another study from Argentina applied similar method in 300 patients, no patients developed pancreatitis after antegrade balloon dilation of biliary sphincter with maximal diameter 20 mm<sup>[81]</sup>. A Korean retrospective study compared the efficacy and adverse event in 56 patients underwent percutaneous transhepatic papillary dilation (PTPD) with 208 patients underwent retrograde EPBD for removal of CBD stones<sup>[82]</sup>. Complete bile duct clearance was achieved in 97.1% of EPBD and 98.2% of PTPD. Fourteen (6.7%) of 208 EPBD group vs 0% of PTPD developed pancreatitis after the procedure ( $P = 0.046$ ). Hyperamylasemia occurred in 29.8% of EPBD group and 7.1% of PTPD group ( $P = 0.0005$ ). These studies disprove the previous concept of balloon dilation being the cause of pancreatitis. The balloon is innocent and the pancreatitis may actually result from the traumatic injury of major papilla or pancreatic duct at the time of selective cannulation of bile duct, or the procedures of stone extraction after

balloon dilation. In the patients with difficult cannulation, papillary edema after repeated cannulation, accidental trauma by diagnostic catheter or excessive injection of contrast medium to the pancreatic ducts are not uncommon, particularly in the patients with small papillary orifice or not widely opened orifice after inadequate balloon dilation. The pathogenesis of pancreatitis after EPBD appears multifactorial, only the superfluous injection of contrast medium into pancreatic duct is certainly considered to lead to increasing the risk of pancreatitis<sup>[83]</sup>. Once the head portion of pancreatic duct filled with contrast, we should stop the contrast medium injection immediately and withdraw the catheter in order to minimize the pancreatic injury. In addition, adequate dilation of papilla to create a large opening of bile duct may facilitate the accessory instruments enter the bile duct easily and to avoid further injury of pancreas<sup>[45]</sup>. Routine use of pancreatic stent may help for decrease the risk of pancreatitis by experienced endoscopists, but the indication and detailed methodology are not established yet<sup>[84]</sup>.

### Bleeding

Less bleeding is believed to be one of the advantages for EPBD in the treatment of CBD stones up to now. In the early meta-analysis from Baron *et al*<sup>[17]</sup>, no patients developed bleeding after EPBD in 8 controlled studies using the traditional balloon for dilation, but 2% of patients had bleeding after EST. In DiSario's study, self-limited or endoscopically controlled bleeding occurred in 27% of the patients undergoing EST and 10.5% of patients undergoing EPBD<sup>[16]</sup>. Minor oozing after EPBD commonly occurs due to microvascular rupture accompanied by stretching of the mucosa, particularly in the patients receiving EPLBD, but most of them are self-limited and does not considered as a bleeding complication in most studies<sup>[44,65]</sup>. Park *et al*<sup>[85]</sup> had conducted a study to compare the results of EPBD using traditional balloon with EST in patients with cirrhosis and coagulopathy. Significant bleeding occurred in six (30%) patients who received EST and three of them died of bleeding related complications. No bleeding episode was reported in patients received EPBD<sup>[85]</sup>. Unlike the EPBD using a traditional balloon, the bleeding episodes were ranged from 0-16.7% in patients who received the ESLBD for treatment of CBD stones<sup>[44]</sup>, one patient died of bleeding in a multi-center study who received EPLBD after a full EST<sup>[63]</sup>. Patients who received EPLBD alone had less frequent or less severe bleeding episodes in both prospective and retrospective reports<sup>[45,57-71,77]</sup>. Lin *et al*<sup>[24]</sup> prolonged the duration of balloon inflation to 5 min because of continuous oozing after short duration balloon inflation in the initial two cases. Most of published reports excluded the patients with coagulopathy in their protocols, and there is no consensus for the methodology of EPBD or EPLBD in the present

time. To prolong the duration of balloon inflation and the use of EPLBD alone may probably reduce the risk of significant bleeding to the patients with potential coagulopathy<sup>[24,65]</sup>, but it needs further controlled studies to confirm.

### Perforation

The incidence of perforation was 0-2% in patients after EPBD, 0-1.7% in patients after ESLBD<sup>[17,44]</sup>, 0-2.5% after EPLBD alone<sup>[30,45,57,71,77,86]</sup>. Mortalities after EPBD or ESLBD were also reported<sup>[7,63,86]</sup>. Distal CBD stricture and over-inflation of balloon may be responsible for the fatal perforation<sup>[63]</sup>. In the patients with stricture or tapered distal bile duct, gradual balloon dilation with a smaller balloon initially and application of lithotripter may help for safely extraction of CBD stones<sup>[23,66]</sup>. Strong resistance, persistence of notch, and intolerable pain development during balloon inflation indicated stricture of bile duct, additional pressure should not be applied to avoid perforation<sup>[63]</sup>. In such cases, it should convert to drainage procedure or other stone extraction modalities<sup>[63]</sup>.

### Infection

Incidences of infection after endoscopic treatment for CBD stones are heterogeneous in the published reports. They range from 0-8% in EST, 0-10% in EPBD, 0-3.3% in ESLBD and 0-5% in EPLBD alone<sup>[30,44,45,57,61,71,77,86,87]</sup>. Biliary infection after endoscopic treatment may relate to the concomitant disease and general condition of the patients, contamination during the procedure and incomplete drainage of bile after the procedure. However, even under strict clean and disinfection protocol, biliary infection still occurred in 0.28%<sup>[88]</sup>. Some endoscopists routinely used the prophylactic antibiotics to the patients who received endoscopic therapy, but Cotton *et al*<sup>[88]</sup> suggested that prophylactic antibiotics should restrict to patients with predictably undrainable biliary systems or likely to have infected bile (*e.g.*, immunocompromised, prior sphincterotomy, and/or stent). Besides the strict cleaning and disinfection protocol, aspiration of bile from the proximal bile duct above the obstruction level before the contrast injection and to avoid over-filling of intrahepatic ducts during the procedure may reduce disseminating infection<sup>[88]</sup>.

### Late complications

The recurrent CBD stones ranged from 0-25% in the patients using traditional EPBD<sup>[9,12,22,87,89-91]</sup>, 4.4%-21% in ESLBD<sup>[79,92-95]</sup>, 4%-14.5% in EPLBD alone<sup>[45,70,79]</sup>. Tsujino *et al*<sup>[22]</sup> reported the long term outcome of 1000 patient after traditional EPBD; the recurrence rate was 8.8%. In subgroup analysis, the recurrent rate was highest in the patients with gallbladder left *in situ* with stones (15.6%), followed by cholecystectomy before EPBD (10.8%), gallbladder left *in situ* without stone (5.9%) and elective cholecystectomy after

EPBD(2.4%)<sup>[22]</sup>. Kojima *et al*<sup>[92]</sup> and Ohashi *et al*<sup>[90]</sup> reported the highest recurrent rate of CBD stones in patients with cholecystectomy before EPBD (22%, 17.6%). The recurrent rates in other subgroups were gallbladder *in situ* with gallstones 8.9% and 0%, gallbladder *in situ* without stone 4.9% and 4.9%, cholecystectomy after EPBD 4.3% and 7.4%<sup>[90,92]</sup>. However, the incidences of acute cholecystitis in the patients with intact gallbladder and gallstones were higher than other three groups (4.5%-7.7%)<sup>[22,90]</sup>. Most of the primary CBD stones and recurrent stones from Asian patients are belonged to loose bilirubinate stone<sup>[22,50,86,90,94,96]</sup>, the small fragments of these stones missed by cholangiography may remain in the bile duct and act as nidi for early recurrent stones<sup>[90]</sup>. Poor biliary emptying is responsible to the formation of primary and recurrent stones<sup>[97]</sup>. Gallbladder contraction after meal may flush the bile duct and expel the small stone particles into duodenum. Patients with prior cholecystectomy may lose this flushing function and increase the risk of stone recurrence. In patients with an intact gallbladder and stones, the stone may migrate to cystic duct and CBD resulting to cholecystitis and recurrent CBD stones<sup>[22]</sup>.

In the recent meta-analysis by Zhao *et al*<sup>[93]</sup>, they found that the overall long-term complications were significant lower if patients were treated by EPBD rather than EST. Compared to EST, EPBD markedly decreased the incidence of acute cholecystitis. Although there were no significant difference between EPBD and EST in the incidences of acute cholangitis and recurrent CBD stones, but a study with follow-up for more than one year indicated that the stones recurrence rate decreased significantly in the EPBD group<sup>[95]</sup>. Tanaka *et al* found that the recurrent rate of CBD stones within one year was higher in EPBD than EST (25% vs 6.3%), but the incidence of recurrent CBD stones was lower in EPBD than EST after follow up for 1-6 years (6.3% vs 26.7%)<sup>[12]</sup>. Similar late complication and stone recurrence rate in patients after ESLBD and EST was reported by Kim *et al*<sup>[94]</sup>. During a median 22 mo (range, 1-56 mo) follow up, Kogure *et al*<sup>[79]</sup> found that the incidence of recurrent CBD stones was higher in patients received ESLBD than the patients received EPLBD alone (21% vs 11%).

## SPHINCTERIC FUNCTION AFTER EPBD/ EPLBD

Most endoscopists emphasized the advantage of EPBD in preservation of sphincteric function and the prevention of late complications in the last century, so the traditional balloon (8 mm) was commonly used with this purpose. Sato *et al*<sup>[74]</sup> had used the micro-transducer catheter to check the sphincter of Oddi (SO) function before and after traditional EPBD. The mean SO basal pressure dropped from 13.6 mmHg to

6.3 mmHg at one week after EPBD and increased to 9.3 mmHg after one month<sup>[74]</sup>. Yasuda *et al.*<sup>[13]</sup> used the same method as Sato *et al.*<sup>[74]</sup> and found that the preservation of SO function was not completed but remained somewhat reduced (SO basal pressure before, one week and one year after EPBD were 9 mmHg, 3.3 mmHg and 4.2 mmHg respectively)<sup>[13]</sup>. In addition, EPBD caused less pneumobilia than EST (86% vs 40%,  $P < 0.01$ ) but the incidences of recurrent CBD stones did not have significant difference between two methods<sup>[13]</sup>. Both two studies did not include the pharmacological test in manometry<sup>[98,99]</sup>, the incidences of paradoxical response after cholecystokinin or ceruletide in their patients were not known. Failure to relax the sphincter after meal or SO dysfunction may hinder the spontaneous passage of residual stones particles, resulting in recurrent stone formation<sup>[12]</sup>. In the patients who received EPLBD (> 1 cm), the SO function was not preserved<sup>[100]</sup>. The Asian patients with CBD stones are male predominant, older age, high percentage of juxtapapillary diverticulum and bilirubinate stones, their characteristics are different from the Western patients<sup>[7-10,13-16,30,35,63,83,91]</sup>. A recent retrospective study indicates that EPLBD is helpful to prevent re-recurrence of CBD stones after previous EST<sup>[101]</sup>, but further controlled studies are needed to clarify the role of sphincteric function in the Asian patients with CBD stones.

### LIMITATION OF EPBD/EPLBD

In patients with papillary stenosis, severe stricture of distal bile duct or impacted stones in papilla, it is difficult to insert the guidewire deeply into bile duct, precut sphincterotomy is necessary to assist EPBD or EPLBD. In patients with non-dilated bile duct or tapered distal bile duct, EPBD should be started with a small balloon and gradual inflation. In the patients with biliary stricture and unsuitable for surgical intervention, EPBD can be tried but the risk of perforation is high<sup>[63]</sup>. If patient feels intolerable pain during the procedure or the waist of balloon does not disappear after inflating the balloon to 75% of the maximum recommended pressure, balloon pressure should be reduced or change to other modalities<sup>[65]</sup>. Although EPBD is recommended in the patients with coagulopathy, details of the method for safely handling these high risk patients is not yet established. As non-significant bleeding is common in EPBD/EPLBD, avoid precut sphincterotomy and increased the duration of balloon dilation may be necessary to prevent the lethal bleeding complication. EPBLD alone or with EST are not the sphincter preserved procedures, the patent papillary orifice can facilitate the free drainage of small stone particles into duodenum, but also allows the reflux of duodenal content, regular follow up is necessary for early detection and management of CBD stones recurrence<sup>[102]</sup>.

### CONCLUSION

The methods in endoscopic treatment of CBD stones should be individualized. Both EST and EPBD/EPLBD can be safely used in the routine practice to remove the CBD stones by the experienced endoscopists. EPBD/EPLBD is preferred in the patients with difficult CBD stones, altered anatomy, tapered or mild stricture of distal bile duct, and coagulopathy. EST is superior to EPBD in the patients with stones impaction, difficult deep cannulation, and small CBD diameter without stricture. EPLBD is a safe procedure if it is performed according to the following steps: (1) avoidance of unnecessary pancreatic contrast injection; (2) use of suitable balloon and pressure; and (3) slowly balloon inflation and adequate ballooning time to achieve a widely opened papillary orifice. EPLBD alone is as effective as ESLBD but this point needs more controlled studies to confirm. EPLBD as well as EST is not the sphincter preserved procedure, regular follow-up may be necessary for early detection of recurrent CBD stones.

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