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Endoscopic papillary balloon dilation: Revival of the old technique

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Abstract

Radiologists first described the removal of bile duct stones using balloon dilation in the early 1980s. Recently, there has been renewed interest in endoscopic balloon dilation with a small balloon to avoid the complications of endoscopic sphincterotomy (EST) in young patients undergoing laparoscopic cholecystectomy. However, there is a disparity in using endoscopic balloon papillary dilation (EPBD) between the East and the West, depending on the origin of the studies. In the early 2000s, EST followed by endoscopic balloon dilation with a large balloon was introduced to treat large or difficult biliary stones. Endoscopic balloon dilation with a large balloon has generally been recognized as an effective and safe method, unlike EPBD. However, fatal complications have occurred in patients with endoscopic papillary large balloon dilation (EPLBD). The safety of endoscopic balloon dilation is still a debatable issue. Moreover, guidelines of indications and techniques have not been established in performing endoscopic balloon dilation with a small balloon or a large balloon. In this article, we discuss the issue of conventional and large balloon endoscopic dilation. We also suggest the indications and optimal techniques of EPBD and EPLBD.

Key words: Endoscopic papillary balloon dilation; Endoscopic papillary large balloon dilation; Common bile duct stone; Endoscopic sphincterotomy; Mechanical lithotripsy

Core tip: Endoscopic papillary dilation with a dilating balloon is technically simple and effective. However, there is still debate regarding safety, and there is no guideline or consensus of detailed techniques. Because the procedure is performed to treat a common benign condition, it is important to ensure that there are no lethal procedure-related complications. It, however, can lead to potential morbidity and even death. As the foremost priority is patient safety, it should be performed with appropriate techniques in selected patients. Therefore, we suggest the optimal indications and tips for avoiding severe complications of endoscopic papillary balloon dilation with a small balloon or a large balloon.

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INTRODUCTION

A common bile duct (CBD) stone is one of the most

common indications of endoscopic retrograde cholangiopancreatography (ERCP). In 1974, endoscopic sphincterotomy (EST) was introduced to remove CBD stones[1]. It has since become established as the standard treatment for widening the biliary orifice. Although the success rate of ERCP with EST is more than 90%, EST accounts for a major portion of the morbidity and mortality associated with ERCP[2,3].

To avoid complications of EST, endoscopic papillary balloon dilation with a small balloon (EPBD) was introduced as an alternative to EST. Before the development of EPBD, interventional radiologists originally introduced the transpapillary elimination of CBD stones through dilation of the sphincter with a 6 mm balloon in 1981[4]. In 1983, Staritz *et al*[5] applied this technique to endoscopy during an ERCP procedure. However, EPBD had not been routinely used for the removal of CBD stones in those days because of frequent complications, mainly acute pancreatitis (in patients with sphincter of Oddi dysfunction)[6]. Nevertheless, there was renewed interest in EPBD to preserve the function of the biliary sphincter.

As time passed on, various studies reported on the safety, effectiveness, and advantages of EPBD in the East. In contrast, Western studies showed more frequent lethal complications of EPBD compared with EST[7,8]. This disparity has led to the different current practices between East and West. Balloon dilation of the intact papilla is rarely used in most Western countries whereas this technique is popularly used in Eastern countries.

Recently, EST followed by endoscopic papillary balloon dilation with a large balloon (EPLBD) was introduced[9]. This review discusses conventional EPBD and EPLBD separately, because the concept, potential advantage, indication, and main purpose of EPBD may differ from those of EPLBD, which utilizes a larger balloon. EPBD may be technically simple and easy to use, but there is still debate regarding safety. The aim of this review is to address the concept, outcomes, safety, techniques and advantages of EPBD and EPLBD. In addition, we suggest indications and technical tips for EPBD and EPLBD individually.

DEFINITIONS AND CONCEPTS

EPBD involves the dilation of the biliary sphincter with a dilating balloon, and is usually performed without EST by using a small-diameter dilating balloon (≤ 10 mm) (Figure 1). The potential advantages of the EPBD over EST are to avoid short-term complications of bleeding and perforation, to preserve the biliary sphincter, and possibly to reduce long-term sequelae of EST[8,10,11]. EPLBD is usually defined as the use of a dilating balloon with a diameter of 12 mm or larger in order to remove large stones that require a larger opening of the CBD[12,13]. The potential advantages of EPLBD are to reduce the use of mechanical lithotripsy (ML) and to reduce the complications related to full EST in removing large or difficult CBD stones[14].

In EPLBD, EST is generally recommended before balloon dilation, because the preceding EST may shift the expansile force toward the CBD rather than the pancreatic orifice. When this combined approach is used, a large endoscopic sphincterotomy is not required. As a result, EPLBD can enlarge the biliary orifice to a greater extent than a standard full EST and create a large biliary orifice (Figure 2). EPLBD may have the advantages of a lower risk of bleeding and perforation over a routine full EST[14]. Although EST is generally used at the start of the EPLBD procedure, the safety of large balloon dilation alone without a preceding EST is reported in some studies[15,16]. In contrast to EPLBD, the biliary orifice after EPBD is usually less wide than after a full EST. The target stones of EPBD are small- to moderate-sized in minimally dilated CBDs, whereas those of EPLBD are large stones in considerably dilated CBDs (Table 1).

OUTCOMES

Outcome of EPBD compared with that of EST for extraction of bile duct stones

In a Japanese randomized controlled trial (RCT), EPBD and EST had similar outcomes in the successful removal of bile duct stones (99.3% *vs* 100%) and overall complications (14.5% *vs* 11.8%)[2]. In contrast, RCTs from Western countries did not show the same results. In a German RCT, EPBD was inferior to EST in terms of stone removal during the first attempt (77% *vs* 100%)[7]. The overall complication rate of EPBD was also higher than that of EST (30.0% *vs* 5.0%). Although the bleeding rate was lower in the EPBD group, cholangitis and pancreatitis developed more frequently than in the EST group. Severe pancreatitis with pancreatic necrosis occurred only in the EPBD group (6.7%). This study was terminated early due to this complication in the EPBD group. Another well-known RCT from the United States reported 2 deaths due to severe pancreatitis developing after EPBD[8]. This study was also terminated at the first interim analysis.

Two meta-analyses evaluating the outcome of EPBD compared with EST are available by Baron *et al*[3] (8 studies analyzed) and Weinberg *et al*[17] (15 studies analyzed). Baron *et al*[3] showed that EST and EPBD had comparable overall success rates of stone removal (94.3% *vs* 96.5%). However, in the first attempt without EST, the initial success rate of stone removal was lower in the EBPD group than in the EST group (70.0% *vs* 79.8%). Furthermore, the use of ML was also more prevalent in the EPBD group than in the EST group (20.9% *vs* 14.8%). Overall complication rates were similar in both the EPBD and EST groups (10.5% *vs* 10.3%). However, the rate of pancreatitis was significantly higher in the EPBD group than in the EST group (7.4% *vs* 4.3%) while the rate of bleeding was lower in the EPBD group than in the EST group (0% *vs* 2.0%). Rates of cholangitis and perforation were similar in both groups.

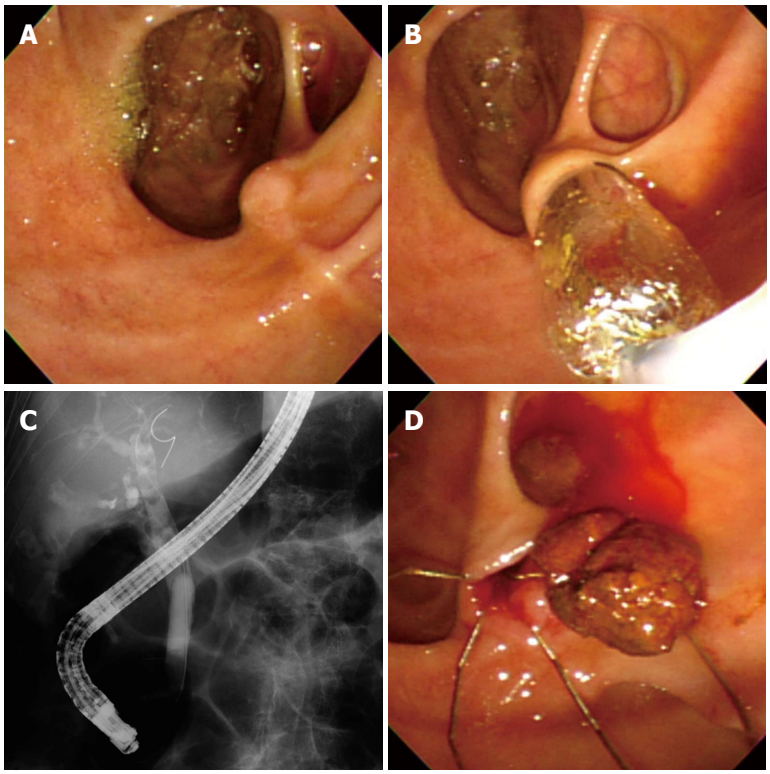

Figure 1 Endoscopic papillary balloon dilation with a small dilating balloon. A: Huge periampullary diverticulos were noted near the ampulla; B: The 8 mm sized small balloon is gradually inflated with diluted contrast material; inflation is maintained for 30 s; C: Fluoroscopy during balloon dilation shows complete disappearance of the sphincter waist; D: A common bile duct stone was removed by basket through the enlarged biliary orifice.

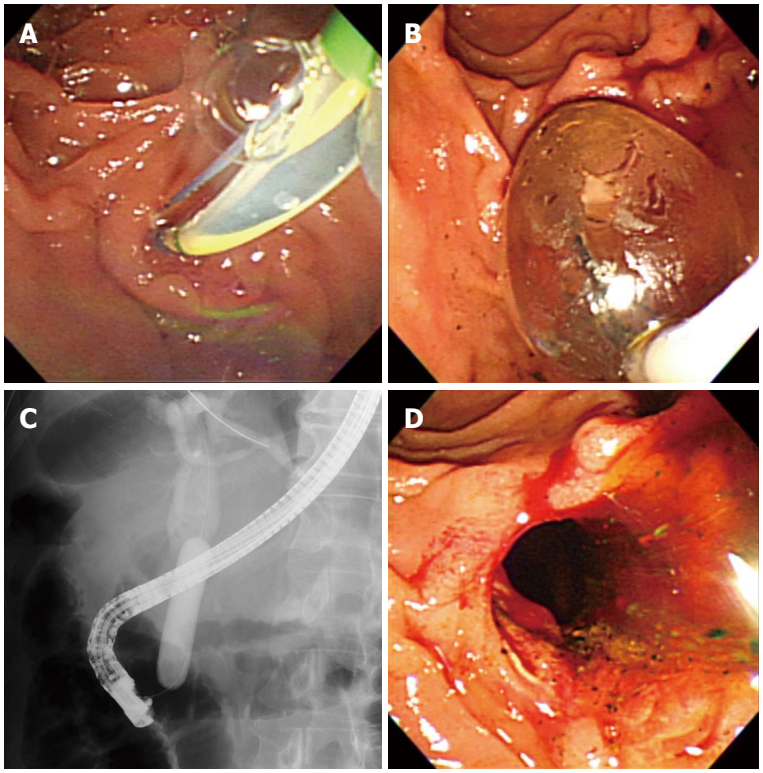

Figure 2 Endoscopic papillary large balloon dilation with minor sphincterotomy. A: A minor incision of up to one-third of the papilla was performed over a guidewire; B: The 15 mm sized large balloon is gradually inflated with diluted contrast material; inflation is maintained for 30 s; C: Fluoroscopy during balloon dilation shows complete disappearance of the sphincter waist; D: A large biliary orifice can be seen after balloon dilation.

Weinberg *et al*[17] reported that EPBD was statistically less successful for extraction of the stone at the first attempt than EST (73.5% *vs* 80.9%), and the overall success rate of EPBD was slightly lower than that of EST (90.1% *vs* 95.3%). There was no significant difference in short-term complications between the EPBD and EST groups (12.1% *vs* 12.7%). Incidences of bleeding and short-term infections were significantly lower in the EPBD group than in the EST group. The incidence of perforation was not different between the 2 groups. While many of the complications were similar or lower in the EPBD group than in the EST group, this meta-analysis showed that the incidence of pancreatitis was significantly higher in the EPBD group than in the EST group (8.6% *vs* 4.3%).

Table 1 Comparison of endoscopic balloon dilation methods according to balloon diameter

	Small-balloon EPBD	Large-balloon EPBD
Balloon diameter used	≤ 10 mm (6-10 mm)	≥ 12 mm (12-20 mm)
Target stone	Small to moderate sized stones in no or minimally dilated CBD	Large stones in considerably dilated CBD
Endoscopic biliary sphincterotomy	Not performed	Mostly, in conjunction with a small EST[1]

[1]Preceding small-endoscopic biliary sphincterotomy (EST) use may shift the expansile force more toward the common bile duct (CBD) rather than the pancreatic orifice. EPBD: Endoscopic papillary balloon dilation.

Furthermore, in the subgroup analysis, the risk of pancreatitis was higher in younger patients of the EPBD group. These meta-analyses consistently showed that, while EPBD and EST had similar overall success rates for stone removal, acute pancreatitis occurred more frequently in the EPBD group than in the EST group.

Outcomes of EPLBD

EPLBD with EST: In the first introduction of EPLBD by Ersoz *et al*[9], stone clearance was successful without using ML in patients with large stones (> 15 mm). After this retrospective study, many studies showed that EPLBD could be a useful alternative technique in patients with large CBD stones that were difficult to remove with standard EST.

Recent studies showed that complete stone removal in the first session of EPLBD was accomplished in 89.3% of procedures, and ML was required in 9.5% of patients (including 6 retrospective and 1 prospective trials involving 496 patients)[14,18-23]. Overall success of stone removal was 97.6%. Only 8.5% of patients had documented complications, such as bleeding and perforation. Pancreatitis developed in 1.6% of patients. Severe pancreatitis was not reported, contrary to that seen with EPBD.

In a retrospective comparison of EPLBD (with EST) and EST alone (2 studies involving 250 patients)[24,25], EPLBD showed similar outcomes to EST in overall successful stone removal (98.4% *vs* 96.0%) and complications (4% *vs* 6%). However, ML was required significantly more often in the EST group than in the EPLBD group (21.6% *vs* 7.2%). Total procedure time was shorter in the EPLBD group due to less use of ML (13 min *vs* 22 min)[24]. Moreover, EPLBD was an effective and safe method for removal of CBD stones in patients with Billroth Ⅱ gastrectomy, prior biliary sphincterotomy, and periampullary diverticulum[14,26,27].

In prospective randomized comparison studies (2 studies involving 255 patients)[28,29], EPLBD showed similar outcomes to EST for overall success rate of bile duct stones (97.0% *vs* 98.0%) and stone removal at the first attempt (83.5% *vs* 85.9%). Overall use of ML was not different in the EPLBD group and in the EST group (13.4% *vs* 14.1%). The prevalence of overall complications was similar in the EPLBD and EST groups (7.1% *vs* 7.0%). Moreover, no significant difference was seen in the frequency of pancreatitis, perforation, hemorrhage or cholangitis. In another prospective randomized comparison of EPLBD with EST and ML with EST (involving 90 patients), EPLBD had a similar success rate of stone removal as ML with EST (97.7% *vs* 91.1%), whereas the complication rate was lower in the EPLBD group than in the ML with EST group (4.4% *vs* 20.0%)[30]. Cholangitis was less frequent in the EPLBD group than in the ML with EST group (0% *vs* 13.3%). Rates of pancreatitis were similar between the 2 groups.

EPLBD without a preceding EST: Although EST is generally used at the start of the EPLBD procedure, only large balloon dilation without a preceding EST is performed for removal of large CBD stones in some studies. In a retrospective study, the overall success rate of EPLBD without a preceding EST was 97.4%, and complete duct clearance with EPLBD alone was performed in 76.3% of patients[16]. ML was used in 21.1% of patients. Procedure-related pancreatitis was observed in only one patient (2.6%) and there were no other complications, such as bleeding, perforation, or cholangitis. This study suggested that EPLBD without a preceding EST might be as simple, effective, and safe in patients with large bile duct stones, as EPLBD with a preceding EST. However, the study had a limitation in that there was no comparison of EPLBD without a preceding EST and EPLBD with a preceding EST. Therefore, EPLBD without a preceding EST was not regarded as a routine technique for the removal of large bile duct stones, though it could be an alternative treatment.

POTENTIAL ADVANTAGES OF EPBD

Avoidance of bleeding

An important advantage of EPBD over EST is the avoidance of sphincterotomy-induced bleeding. Patients with coagulopathy and those who take anticoagulation medication have a higher risk of EST-induced bleeding[31,32]. Several RCTs showed that EPBD might significantly reduce the risk of bleeding compared with EST[2,8,33]. In a comparison of bleeding risk in patients with liver cirrhosis and coagulopathy, it was reported that the rate of EST-related hemorrhaging was 30%, whereas the hemorrhagic rate of EPBD was 0%[34]. Moreover, a meta-analysis commented that the occurrence of major bleeding was significantly lower in patients treated with EPBD than those treated with EST[17]. EPBD is currently regarded as an alternative method to EST in patients with coagulopathy to avoid sphincterotomy-induced bleeding.

EPLBD

The rate of bleeding after EPLBD was reported as various rates, approximately 0%-8.3%[23,29,35]. According to a recent report, severe bleeding occurred less frequently in patients with EPLBD than with EST, though minor bleeding and bleeding in patients with coagulopathy were

excluded[36]. However, the rate of bleeding was not significantly different between EPLBD and EST in comparison studies[28,30]. Moreover, several reports mentioned that serious massive bleeding had occurred after EPLBD[37,38]. Severe bleeding may be caused by the large balloon, and it may lead to surgical intervention or even mortality. These results suggest that EPLBD is not superior to EST with regard to ERCP-related bleeding, unlike EPBD.

Preservation of sphincter of Oddi function

Until now, EST has been widely accepted as an effective and standard technique for the removal of CBD stones; however, EST causes permanent loss of sphincter of Oddi (SO) function. Pneumobilia and duodenal biliary reflux were observed in approximately 50% of patients after EST and almost 100% of patients developed bactericholia and chronic inflammation of the biliary system[39,40]. Because laparoscopic cholecystectomy (LC) has been widely performed, preservation of the SO function is needed to avoid complications in young patients undergoing LC[41].

Since EST disrupts the SO function for a long period of time, it is hoped that EPBD reduces damage to SO function compared with EST. Based on an anatomic study in pigs, EPBD showed no rupture of SO smooth muscle, and it was expected to preserve papillary smooth muscle integrity in humans[42]. In a manometric study of the SO function[43], EPBD seemed to depress SO function for at least 1 wk. However, 1 mo after EPBD, SO peak pressure and frequency of SO contraction increased significantly, and SO basal and CBD pressure tended to increase compared with the first week's values. These results suggested at least partial recovery of SO function in 1 month after EPBD. In another manometric comparison study of SO function between EPBD with EST, SO basal and peak pressures partially recovered at 1 year, although these values still remained lower than those before EPBD[44]. The risk of long-term complications and pneumobilia were also lower in the EPBD group than in the EST group. This study suggested that SO function was preserved to a greater degree than after EST. However, there were studies with different results of preservation of the SO function after EST or EPBD.

In a comparison study, SO function was estimated by measurement of pancreatic enzyme activity in bile aspirated from the CBD[45]. According to this study, there were no significant differences in pancreatic enzyme levels from before the procedure *vs* 1 year after the procedure in both EPBD and EST groups. In another prospective study, bacterial cultures of bile were used to evaluate bacterial contamination of the biliary tract after EPBD or EST[46]. There was no significant difference in the bacterial cultures at 6 mo or 2 years after the procedures between the EPBD and EST groups. As a result, it is not clear whether the preservation of SO function with EPBD was superior to that of EST, although several studies showed that damaged SO function after EPBD was substantially recovered over time.

Although the preservation of SO function is incomplete, EPBD is still an attractive method, especially in younger patients, to avoid long-term complications. However, young age is an important risk factor for acute pancreatitis, and acute pancreatitis is more frequent after EPBD. Furthermore, a meta-analysis showed that the pancreatitis risk was higher in younger patients than in older patients in the EPBD group[17]. Although EPBD was performed to preserve SO function in younger patients, it is ironic that post-EPBD pancreatitis was more evident in the younger patients.

EPLBD

The preservation of SO function after EPLBD is not clear. Because the acquirement of the large CBD opening after ballooning was the aim of EPLBD, preservation of SO function was not regarded as an important factor in EPLBD. Theoretically, SO function is permanently ablated after EPLBD. From our experience, it is found that SO function does not recover after EPLBD regardless of EST.

POTENTIAL ADVANTAGES OF EPLBD

ML

ML has been commonly used for the management of large CBD stones. EPLBD was developed to reduce the complications related to full EST and to avoid the use of ML for removal of large bile duct stones. In a prospective study of 60 patients, only 3 patients (5%) required adjuvant ML for stone extraction after EPLBD[23]. In another RCT, ML was required significantly more often in the EST group than in EPLBD group (25% *vs* 6%)[24]. Contrary to previous reports, EPLBD compared with EST alone resulted in similar outcomes in terms of overall successful large CBD stone removal (94.4% *vs* 96.7%) and the use of ML (8.0% *vs* 9.0%) in another RCT[28]. Furthermore, there was no difference in the use of ML for large-sized CBD stones in a recent meta-analysis[47], although the overall rate of ML use for various sized stones was less frequent in the EPLBD group than in the EST group. A few discrepancies in the use of ML for removal of large CBD stones have been seen, although many studies report that ML has been used less often in the EPLBD group compared with the EST group. Because the outcomes of the use of ML were not consistent, the choice of EPLBD only to reduce the use of ML in the removal of large CBD stones should be carefully considered.

EPBD

A reduction in the use of ML is not the main purpose of EPBD, unlike EPLBD. Most studies, including 2 meta-analyses, reported that the use of ML was more prevalent in EPBD groups than in EST groups[3,17,48].

SAFETY ISSUES

EPBD and EPLBD are technically simple and effective, but safety is still a debatable issue. As the procedures are performed to treat a common benign condition, it is important to ensure that there are no lethal procedure-

Table 2 Techniques and outcomes of small balloon-endoscopic papillary balloon dilation in randomized controlled trials

Ref.	Patients (*n*)	Balloon diameter (mm)	Maximum pressure of inflation (atm)	Time of inflation (s)	duration of maximal dilation (s)	Number of ballooning	Overall success rate	Post-EPBD pancreatitis	Bleeding	Perforation	Infection	Death (*n*)
Arnold *et al*[7]	30	8	10	60		2	77%	20%	0%	0%	10%	0
Bergman *et al*[49]	101	8	Waist	60-120	45-60	1	89%	7%	0%	2%	4%	1 for perforation
DiSario *et al*[8]	117	8 or less		60		1	97.4%	15.4%	10.5%	0%	1%	2 for pancreatitis
Fujita *et al*[2]	138	4-8	Waist	180	15	1	99%	10.8%	0%	0%	2.9%	0
Lin *et al*[53]	51	8-12	8-12		120/300	1	94.1%	0%	2%	0%	0%	0
Natsui *et al*[58]	41	8	3		120	1	93%	5%	0%	0%	2%	0
Ochi *et al*[11]	51	8	60-80 mmHg	60		3	93%	0%	0%	0%	2%	0
Tanaka *et al*[59]	16	8	8	120		1	100%	19%	0%	0%	0%	0
Vlavianos *et al*[60]	103	10	12	30 or more		Repeated until satisfaction	87.4%	4.8%	0%	0%	1.9%	0
Yasuda *et al*[44]	35	8	6		60	2	100%	5.7%	0%	0%	0%	0

EPBD: Endoscopic papillary balloon dilation

related complications. Although adequate procedural techniques may reduce complications, optimal techniques do not always prevent all complications.

Acute pancreatitis is the most common severe complication of EPBD. In a United States RCT, 2 patients with post-EPBD pancreatitis died[8]. Another study reported that one patient died of retroperitoneal perforation after EPBD[49], although perforations are usually rare in EPBD. EPLBD has been regarded as a safe and effective method, regardless of a preceding EST. However, massive bleeding and perforation were occasionally reported in some studies. Life-threatening hemorrhage following EPLBD with a preceding EST was reported, and it was treated with angiographic embolization[37]. Four patients died due to EPLBD-related complications in a Korean and Japanese multicenter study[50]. Of these 4 patients, 3 died as a result of perforation, and the other died due to delayed massive bleeding. Perforation was a more frequent severe complication of EPLBD, although some patients died due to both bleeding and perforation.

For EPBD, serious pancreatitis has been reported in several studies, although it was showed that discrepancy of complications between East and West. Therefore, the choice of EPBD (in the young patients with CBD stone) only to preserve SO function should be carefully considered. The reason is that the long-term effect from the preservation of SO functions has not proven, until now. For EPLBD, although EPLBD is reported as an effective method in many studies, several reports showed procedure-related deaths due to perforation and delayed bleeding. Therefore, the choice of EPLBD only to reduce the use of ML should be carefully considered. In terms of safety issue, to avoid serious complications, strict selection of patients is of utmost importance in both EPBD and EPLBD.

TECHNICAL ISSUES

EPBD

It is not clear why small balloon EPBD has been shown to have a high risk compared with EST in the United States while it is relatively safe in South Korea and Japan. A recent study showed that post-EPBD pancreatitis was more frequent in an EPBD group than in a group with percutaneous transhepatic papillary balloon dilation[25]. This suggests that post-EPBD pancreatitis may be associated with detailed procedure protocols, rather than balloon dilation itself. Differences in the detailed methodology might lead to differences in outcome, although there are several possible reasons for the differences in outcome. The EPBD techniques in various RCTs are summarized along with procedure-related complications in Table 2. Technical factors that may be related to the outcomes include balloon diameter, dilation pressure, and dilation time.

Among these technical factors, selection of the optimal balloon diameter is important. Generally, a balloon smaller than the diameter of the CBD is recommended to reduce the damage to the SO and pancreatic orifice[51]. If a large CBD stone exceeding the diameter of the papillary orifice remains after EPBD, additional treatment, such as

Table 3 Techniques and outcomes of endoscopic papillary large balloon dilation in various studies

Ref.	Patients (*n*)	Extent of EST	Balloon diameter (mm)	duration of balloon dilation (s)	Overall success rate	Use of ML	Post-EPBD pancreatitis	Bleeding	Perforation	Infection	Death (*n*)
Ersoz *et al*[9]	58	Full	12-20	20-45	100%	6.9%	3%	9%	0%	3%	0
Bang *et al*[21]	22	small	10-15	40	100%	9.1%	4.5%	0%	0%	0%	0
Heo *et al*[28]	100	small	12-20	60	97%	8%	4%	0%	0%	1%	0
García-Cano *et al*[35]	30	Variable	10-18	60	94.5%		10%	10%	0%	3.3%	0
Stefanidis *et al*[30]	44	full	15-20	10-12	97.7%	0%	2.2%	2.2%	0%	0%	0
Attasaranya *et al*[20]	103	Full	12-18		95%	27.2%	0%	2%	1%	0%	0
Kochhar *et al*[18]	74	small	10-18	60	91.9%	2.7%	2.7%	8.1%	0%	0%	0
Lee *et al*[14]	55	small	15-20	30-60	100%	5.5%	0%	3.6%	0%	0%	0
Misra *et al*[22]	50	Full	15-20	30-45	100%	10%	8%	6%	0%	0%	0
Minami *et al*[61]	88	small	20		98.9%	1%	1%	1%	0%	1%	0
Maydeo *et al*[23]	60	Full	12-15	30	100%	5%	0%	8.3%	0%	0%	0
Itoi *et al*[24]	53	Full	15-20	15-30	100%	5.6%	1.9%	0%	0%	1.9%	0
Park *et al*[50]	946	Variable	12-20	30-180	96.9%	10.0%	2.5%	5.9%	0.9%	0.6%	4 (1 for bleeding, 3 for perforation)
Jeong *et al*[16]	38	Without EST	15-18	10-60	97.4%	21.1%	2.6%	0%	0%	0%	0

ML: Mechanical lithotripsy; EPBD: Endoscopic papillary balloon dilation; EST: Endoscopic biliary sphincterotomy.

EST or ML, is often needed.

Other techniques, such as balloon inflation and duration of balloon dilation, were also analyzed in several studies. Techniques of balloon inflation were divided into 2 categories in a recent study[52]. In the ungraded inflation method, the balloon was gradually inflated to the target pressure during a fixed time (approximately 30-60 s). In the graded inflation method, the balloon was slowly inflated until the disappearance of the balloon's waist, and then the pressure was maintained for 15 s. In the graded inflation group, the incidence of post-EPBD pancreatitis was significantly lower than in the ungraded inflation group. The result suggested that lower pressure and shorter duration was less traumatic to the papilla, resulting in fewer complications.

Until recently, the optimal duration of balloon dilation had not been established. In most studies and during actual practice, the dilation of EPBD was performed for a short duration of 1 min or less. However, some studies examined a longer duration of balloon dilation and the results showed adequate outcomes with no post-EPBD pancreatitis[43,53]. A 5-min EPBD improved the efficacy of stone removal and reduced the risk of post-EPBD pancreatitis, compared with a 1-min EPBD[54]. In addition, the duration of EPBD was inversely associated with pancreatitis risk in a meta-analysis, with less than 1-min dilations actually increasing acute pancreatitis[55]. Another 2 studies explained that a long duration of balloon dilation served to loosen the SO sufficiently and to resolve compartment syndrome, which involved intramucosal hemorrhaging and edema at the papilla. They suggested that an inadequately loosened SO surrounding the common channel may cause a compartment phenomenon that compresses pancreatic flow and increases the risk of post-EPBD pancreatitis[3,42]. Therefore, a long duration (5 min) of EPBD might be preferred over a short duration (less than 1 min) to reduce the risk of post-EPBD pancreatitis.

EPLBD

There are not many analyses of EPLBD technique, although EPLBD has been accepted to be an effective and safe method for large CBD stone removal. The EPLBD techniques of several studies are summarized with procedure-related complications in Table 3. In contrast to EPBD, the important complications of EPLBD are not post-EPBD pancreatitis, but perforation and bleeding. Therefore, the techniques of concern are different from that of EPBD.

Regarding the techniques related to EPLBD, the extent of EST, diameter of the balloon, and the method of balloon inflation are considered the most important. The size

Table 4 Indications for endoscopic balloon dilation according to balloon diameter

	Small-balloon EPBD	Large-balloon EPBD
Absolute indication	Patients with coagulopathy and need for anticoagulation to avoid sphincterotomy-induced bleeding	No indication
Relative indication	Patients with anatomical abnormalities including gastric bypass surgery (Billroth Ⅱ gastrectomy) or periampullary diverticulum	Patients with altered anatomy, such as gastric bypass surgery (Billroth Ⅱ gastrectomy), periampullary diverticulum and prior biliary sphincterotomy
Possible indication	To preserve SO functions	To reduce the use of ML for removal of large CBD stones To avoid full EST-induced bleeding

SO: Sphincter of Oddi; EPBD: Endoscopic papillary balloon dilation; CBD: Common bile duct.

Table 5 Tips for avoiding severe complications of endoscopic papillary balloon dilation

EPBD	EPLBD
1. A balloon smaller than the diameter of the CBD is recommended to reduce damage to the SO and pancreatic orifice.	1. Maximal inflated diameter of balloon should not exceed the CBD diameter.
2. Graded balloon inflation may significantly reduce the incidence of post-EPBD pancreatitis.	2. A small extent of EST followed by large balloon dilation may be recommended, rather than large balloon dilation without EST.
3. If the balloon's waist remains after 2–3 s at maximal balloon inflation, balloon dilation must be stopped immediately.	3. The balloon should be inflated gradually to avoid perforation and bleeding.
	4. If the balloon's waist remains at 80% of the maximum inflation capacity, balloon dilation must be stopped immediately and change to alternative procedures, such as EST and ML.
	5. Close monitoring must be necessary after EPLBD to detect the delayed complications, such as perforation and delayed bleeding.

SO: Sphincter of Oddi; EPBD: Endoscopic papillary balloon dilation; CBD: Common bile duct; EST: Endoscopic biliary sphincterotomy; ML: Mechanical lithotripsy; EPLBD: Endoscopic papillary large balloon dilation.

of the CBD stone and diameter of the dilated CBD are significant factors for the selection of balloon size. Among these factors, the diameter of the CBD is regarded more important, because excessive balloon dilation over the CBD diameter might increase the risk of perforation. Therefore, the maximal inflated diameter of balloon should not exceed the diameter of the proximally dilated CBD. Generally, a small EST is recommended to reduce the risk of bleeding, because full EST increases the damage of the large vessel at the papillary roof. A small EST also lowers the risk of perforation, because direct observation of ampullary tearing is possible during balloon dilation.

In a South Korean study, the techniques of larger balloon dilation were recommended to avoid severe complications, such as perforation and massive bleeding[56]. If the balloon waist remained at 80% of the maximum inflation capacity, it meant that significant stricture existed in the distal CBD. Excessive inflation for distal CBD stricture could cause a perforation. Therefore, the balloon should be inflated gradually to avoid perforation, with observation of disappearance of the balloon waist at the distal CBD. Unlike EPBD, the duration of ballooning was regarded to be of no importance in the EPLBD, because the small EST might prevent acute pancreatitis[15]. In EPLBD, bleeding is not uncommon; however, the bleeding site could be invisible endoscopically. If hemostasis could not be completed by local therapy, the insertion of a fully covered biliary metal stent should be considered for a tamponade effect[57].

CONCLUSION

Endoscopic papillary dilation with a dilating balloon is an old technique. However, it seems that there is no guideline or consensus on detailed techniques. According to various studies, EPBD and EPLBD for the removal of CBD stones are useful and effective methods. To clinicians, these methods are very attractive because they are very easy to perform, technically simple, and have a short learning curve. Although EPBD and EPLBD are generally safe, clinicians must remain aware that they can lead to potential morbidity and even death. The foremost priority is the patient's safety, so these methods should not be use indiscriminately, but be performed carefully in selected patients. In addition, doctors should be prepared to use EST or ML if the initial treatment fails. When EPBD and EPLBD are used for the correct indications (Table 4), according to the technical guideline (Table 5), an effective and safe outcome should be expected.

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