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Endoscopic Papillary Large Balloon Dilation Versus Endoscopic Sphincterotomy for Treatment of Bile Duct Stones

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Abbreviations *CBD* Common bile duct · *ERCP* Endoscopic retrograde cholangiopancreatography · *EPBD* Endoscopic papillary balloon dilation · *EPLBD* Endoscopic papillary large balloon dilation · *EST* Endoscopic sphincterotomy · *EUS* Endoscopic ultrasound · *PAD* Peri-ampullary diverticulum

Abstract

Purpose of review To review the current literature focusing on the indications, efficacy, and safety of endoscopic papillary balloon dilation (EPBD) and endoscopic papillary large balloon dilation (EPLBD) with or without endoscopic sphincterotomy (EST) in the treatment of bile duct stones.

Summary/recent findings

- EPBD without EST is associated with a higher risk of post-procedural pancreatitis and lower rate of stone clearance than EST alone.
- EPBD without EST should be at least 2 min in duration, and placement of a pancreatic stent and other measures to reduce pancreatitis risk should be considered.
- EPBD without EST is most useful to reduce risk of bleeding in patients with coagulopathy.
- EPLBD combined with EST can be used as an alternative or adjunct to mechanical lithotripsy in the removal of large or difficult bile duct stones.

- EPLBD combined with EST results in fewer complications than EST alone for removal of bile duct stones.

Introduction

Common bile duct (CBD) stone disease is the most common indication for endoscopic retrograde cholangiopancreatography (ERCP) in the USA and remains the primary treatment modality [1]. More than 90% of the stone disease is treated with conventional methods using balloon/basket-assisted extraction after an endoscopic sphincterotomy (EST) [2].

Failure of conventional extraction methods can be broadly categorized based on (1) patient factors: age > 65, use of anti-thrombotics, presence of periampullary diverticulum (PAD), post-surgical anatomy, duodenal stricture, tapering of the bile duct or biliary stricture. (2) Stone-related factors: stones > 15 mm in size, multiple stones, hard consistency of stones, or non-rounded stones [3, 4]. There are different endoscopic techniques over the last two decades for extraction of such difficult bile duct stones with or without EST. Techniques of mechanical lithotripsy and cholangioscopy-guided lithotripsy have been widely studied for the management of difficult stones and are not discussed in this chapter [5–7].

After the advent of EST in 1974, endoscopic papillary balloon dilation (EPBD) was a proposed alternative to EST in 1982 [8]. Endoscopic papillary large balloon dilation (EPLBD) was later proposed in 2003 to help with the removal of large stones after EST [9]. In 2009, EPLBD alone without EST was applied for large stone extraction and widely adopted as a simplified technique mostly in Asia [10].

Definitions

Full or large endoscopic sphincterotomy: sphincterotomy anywhere between two-thirds of the total length of the ampulla and up until the major horizontal fold crossing the intramural portion of the bile duct.

Limited endoscopic sphincterotomy: sphincterotomy limited to one-third to one-half the size of the ampulla.

Endoscopic papillary balloon dilation (EPBD): dilation of the papillary orifice with a balloon diameter of ≤ 10 mm.

Endoscopic papillary large balloon dilation (EPLBD): dilation of the papillary orifice with a balloon diameter of > 10 mm (11 mm to 20 mm).

Endoscopic sphincterotomy

Biliary sphincterotomy, though considered standard for the removal of bile duct stones, is not without risk of complications. ERCP has associated risk of pancreatitis, perforation, and bleeding [11•, 12]. Long-term risks include structuring papillary stenosis, cholangitis, and stone recurrence [13, 14]. Overall complication rates of 5% or less after EST done for stone disease are not unusual, even in rigorously conducted prospective studies [15]. The need for full EST vs limited or no EST along with papillary balloon dilation remains a topic of ongoing debate.

Endoscopic papillary balloon dilation

EST along with balloon/basket retrieval has > 90% success in ≤ 10-mm bile duct stones [16, 17]. Since the introduction of EST by Kawai et al. in 1974, sphincterotomy for bile stone extraction has become a gold standard [18]. EPBD was later introduced by Staritz et al. in 1982 [8] and gained popularity initially in Japan. Komatsu et al. published the first case series of 226 patients showing effectiveness of papillary balloon dilation in bile duct stones [19]. A landmark US 2004 multicenter randomized study comparing EPBD with EST up to 8 mm (dilated for 1 min) was stopped early due to rates of pancreatitis (15.4% vs 0.8%) and deaths (1.7% vs 0%) attributed to pancreatitis in balloon dilation arm [15]. After this study, EPBD in the Western countries has taken a back seat and limited to patients with liver cirrhosis, those on anti-coagulants, and those on dialysis.

Over the last decade, EPBD has widely gained popularity in Asia. EPBD has theoretical benefit of preserved sphincter and decreased in recurrence of choledocholithiasis from duodeno-biliary reflux. The overall success of stone extraction with EPBD is almost comparable with that of EST; EPBD has also shown to lower the risk of 2% post-ERCP bleeding [20], halve the rate of long-term stone recurrence [21] and better success with altered anatomy [22]. In a meta-analysis of randomized

controlled studies by Zhao et al. [21] comparing EPBD to EST, the total stone clearance in the EPBD group decreased (OR = 0.64, 95% CI 0.42 to 0.96, $p = 0.03$), the use of stone extraction baskets significantly increased (OR = 1.91, 95% CI 1.41 to 2.59, $p < 0.01$), and the incidence of pancreatitis significantly increased (OR = 2.79, 95% CI 1.74 to 4.45, $p < 0.0001$). The incidence of bleeding (OR = 0.12, 95% CI 0.04 to 0.34, $p < 0.01$) and cholecystitis (OR = 0.41, 95% CI 0.20 to 0.84, $p = 0.02$) significantly decreased. Based on these findings, and especially reinforced by the US randomized trial [15] which showed a dramatically higher risk of post-ERCP pancreatitis (PEP), including two deaths, there remains great concern about the benefits of EPBD and the raised risk of post-ERCP pancreatitis. Few of the studies, the majority of which are from East Asia, include placement of pancreatic stents or other measures to lower risk.

The European Society of Gastrointestinal Endoscopy in 2016 [11•] published a clinical guideline recommending placement of pancreatic stents in patients undergoing EPBD: They also recommend EPBD as an alternative to EST for extracting CBD stones < 8 mm in patients without anatomical or clinical contraindications, especially in the presence of coagulopathy or altered anatomy. An 8-mm-diameter balloon is recommended irrespective of the CBD diameter, and papillary dilation following waist disappearance should last for a minimum of 2 min. Choosing a single balloon size despite stone and bile duct diameter was a paradigm shift proposed in these guidelines. This is based on multiple studies using single balloon diameter in all patients despite stone/duct size and no difference in PEP rates.

The long-term outcomes associated with EPBD have not been studied and impact endoscopists' decision to adapt this technique vs mechanical lithotripsy. A retrospective cohort study with a median follow-up of 92 months showed lower incidence of recurrent choledocholithiasis after EPBD vs EST [23]. A recent prospective study of 170 patients looked at long-term outcomes after EPBD. The median follow-up period was 7 years. The study population had balloon dilation times of either 1 min or 5 min at the time of initial ERCP, showing no difference in recurrence of choledocholithiasis or acute cholangitis (15% vs 12%, p 0.352) [24•]. Notably, mechanical lithotripsy at initial ERCP in this study quadrupled the risk of recurrent choledocholithiasis or acute cholangitis (attributable hazard ratio 4.55, p 0.008). This outlines the importance of extracting stone in one piece whenever possible as remnant stones and sludge may act as nidus for recurrent stone disease.

Endoscopic papillary large balloon dilation

EPLBD was first described by Ersoz et al. in 2003 and used a 12–20-mm esophageal dilation balloon with 90% success in removing large stones [9]. The comparative efficacy of these procedures remains controversial. Traditionally, EPLBD is usually preceded by a EST to decrease the perceived risk of PEP [25] (Fig. 1). A 2009 study by Jeong et al. [10] recommended simplification of procedure by avoiding EST altogether but showed a low success rate (65%). However, a 2013 systematic review of 32 EPLBD studies showed no significant difference in overall success rates. In this study, higher procedural bleeding was noted with large EST compared to limited EST (OR 3.3, $p < 0.001$) or no EST (OR 2.2, $p < 0.04$) [26]. A 2014 meta-analysis of five randomized studies comparing EST to EPLBD for extraction of > 10-mm stones showed similar stone extraction rates (93% vs 94%) with no differences in complications including bleeding, pancreatitis, and perforation [27]. A 2016 study by Park et al. for EPLBD without EST for large bile duct stones showed a 1% overall complication rate of pancreatitis and minor bleeding [28]. For large bile duct clearance, recent studies continued to show overall success of EPLBD with or without EST is comparable to EST alone [29].

Should EPLBD be used if a conservative approach fails as an alternative to mechanical lithotripsy? Traditionally, mechanical lithotripsy is used when convention EST + balloon/basket technique fails. Mechanical lithotripsy is associated with a high risk of adverse events ranging from 6 to 13% and recurrence of stones [24•, 30, 31]. A recent 2017 multicenter randomized controlled study comparing EST + EPLBD with EST alone for large stones (diameter ≥ 13 mm) showed superiority of EPLBD + EST for primary endpoint of single endoscopy session stone clearance (96% vs 74%, $p < 0.001$). Complete sphincterotomy was performed in both the groups. Although this study was not powered to analyze adverse events, there were no differences in short-term procedural complications, duration, and cost. The main advantage of EPLBD appears to be from reduced need for mechanical lithotripsy and related complications when the conventional approach fails [32•].

A 2018 prospective, multicenter study from South Korea of 200 patients with bile duct stones ≥ 10-mm diameter (median 13.6 mm) showed that there was no difference in adverse events in the EPLBD group compared to EPLBD with limited EST. The overall success

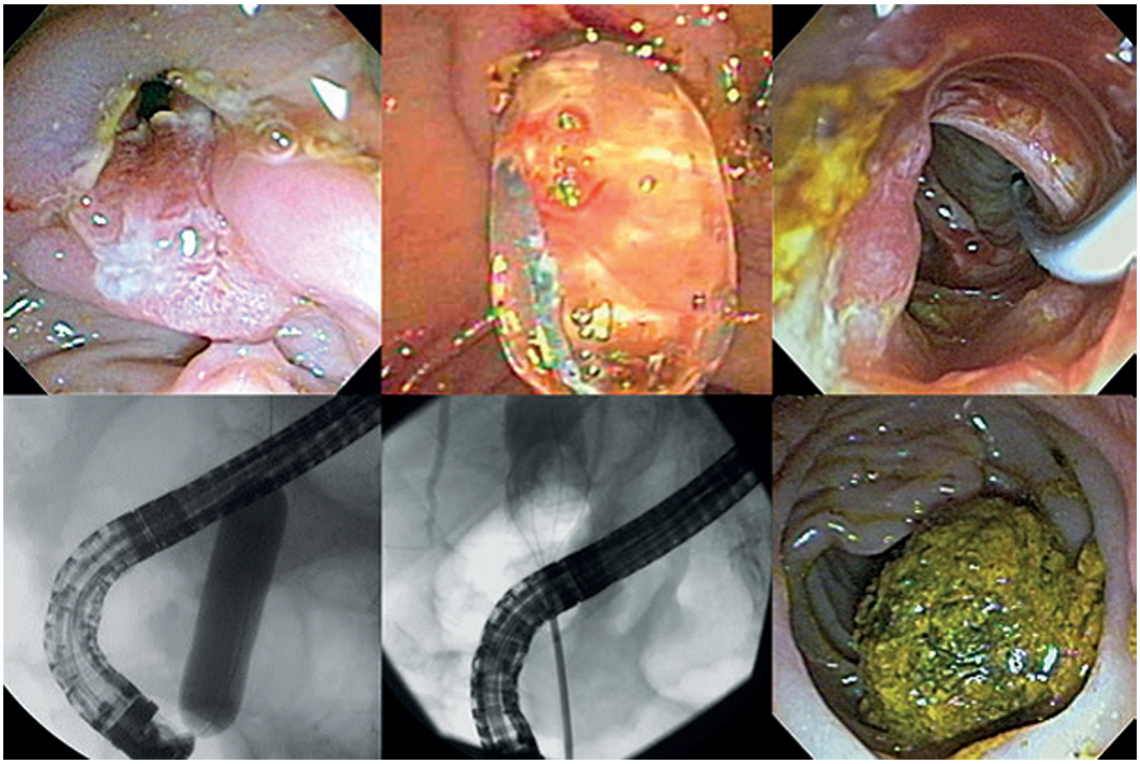

Fig. 1. Endoscopic papillary large balloon dilatation combined with endoscopic sphincterotomy for the removal of a large bile duct stone. **a** After ample sphincterotomy. **b** Large balloon (15 mm) dilatation. **c** Very large papillary orifice enabling a view up the duct. **d** Fluoroscopic view of large balloon dilation. **e** Basket capture of stone. **f** After removal of intact stone into the duodenum.

(92% vs 88%, *p* 0.35), pancreatitis (1% vs 3%, *p* 0.28), and need for mechanical lithotripsy (6.5% vs 9%, *p* 0.39) are reported [33]. The authors hypothesize that the higher prevalence of the sphincter of Oddi dysfunction and hard cholesterol stones in Western populations may be playing a role in elevated PEP after balloon dilation.

In 2016, international consensus guidelines for EPLBD were published based on 30 EPLBD studies with 6 randomized controlled trails included [32•]. These guidelines propose (1) the use of EPLBD as an alternative or adjunct to mechanical lithotripsy in the removal of large or difficult bile duct stones and (2) use EPLBD with EST in most indications, but limiting use of EPLBD without EST to patients with coagulopathy.

Duration of balloon dilation—seconds vs minute vs minutes?

It is proposed that EPBD only transiently stretches the ampullary and biliary sphincters without completely disrupting them, thereby increasing the likelihood of compartment syndrome of the ampulla leading to an elevated risk of post-ERCP pancreatitis (PEP). In the systematic review of studies on EPLBD with EST, balloon dilation time was reported from 10 to 180 s [26]. A meta-analysis by Feng et al. [34] showed no difference in rates of duct clearance when EPLBD was performed for < 1 min vs ≥ 1 min.

A 2010 study by Liao et al. took 170 patients undergoing ERCP for routine bile duct stone extraction and randomized to intact sphincter dilation with a 10-mm balloon for a duration of either 1 min or 5 min. The primary endpoints were successful complete stone removal and post-ERCP pancreatitis favoring the 5-min dilation group compared to the 1-min group with better success at stone extraction (93% vs 80%) and post-ERCP pancreatitis (15% vs 5%) [35]. This study was followed by a meta-analysis by the same group comparing EST vs short-duration EPBD vs long-duration EPBD. This study reported that short-duration EPBD had a higher risk for pancreatitis (OR, 3.9) but longer duration EPBD did not pose a higher risk of pancreatitis (OR, 1.1) when compared with EST. Every 1-min increase in the duration of the dilation up to 3 min was associated with close to

50% reduction in the odds ratio for PEP [36]. Of note, a randomized controlled study in the USA that was stopped due to death from pancreatitis used 1-min EPDB and had similar PEP rates (15.4%) [15]. Further confirming safety of longer (> 1 min) dilation, Kuo et al. performed a prospective study of 170 patients who underwent ERCP for suspected choledocholithiasis and randomized to either short-duration EPBD over 1 min or long-duration EPBD over 5 min, using a 10-mm dilating balloon irrespective of bile duct size. There was no significant difference between groups in the rate of recurrent choledocholithiasis or cholangitis (primary outcome) [24•]. A randomized controlled study of EPBD with EST compared to 30-s dilation to 60-s dilation showed no difference in adverse events like perforation, pancreatitis, and bleeding [37]. Another 2017 retrospective, multicenter study of 607 patients compared 5-min EPBD with 15-s EPBD showed no difference in PEP among the groups (8.3% vs 8.9%, p 0.87) but 5-min EPBD facilitated complete stone removal with decreased need for mechanical lithotripsy [38]. Despite accumulating evidence for longer duration of EPBD to prevent PEP, the optimal timing of dilation remains controversial. In summary, after EST, duration of dilation is not important, but without EST, longer duration of dilation appears to be critical.

Balloon size vs duct size

In the study by Liao et al., despite variable CBD diameter from 5 to 22 mm, there were no perforations with 10-mm balloon dilation. ESGE guidelines now state for EPBD "balloon size should not be selected based on the diameter of the CBD or stone" [11•] (Tables 1, 2, and 3). This does not apply for EPLBD when dilating to a diameter > 12 mm. In a study of 946 patients by Park et al. who underwent EPLBD when the inflated balloon diameter was larger than the distal duct, two fatal perforations were seen [39].

Complications after EPBD and EPLBD

Post-procedure pancreatitis

The compartment syndrome of the ampulla theory leading to an elevated risk, especially without concomitant EST, is proposed. Meta-analyses show

Table 1. Treatment algorithm summarizing steps for different stone sizes (based on ESGE guidelines [11] and international consensus guidelines [32] and personal experience)

1. Stones < 8 mm:
- EST plus balloon dilation to 8 mm for most
  - Without acute cholangitis or pancreatitis
- Balloon dilation without EST primarily for patients with
  - Coagulopathy
  - Altered anatomy
- Balloon dilation > 2 min beyond waist disappearance.

2. Stones > 8–10 mm, multiple or difficult:
- EST plus large balloon (> 10 mm)
  - Not to exceed the diameter of the distal bile duct
  - Slow dilation, up to 1 min
- Large balloon dilation without EST primarily for patients with
  - Coagulopathy
  - Altered anatomy

Pancreatic stent is recommended:
- After cannulation involving deep pancreatic guidewire placement.
- For balloon dilation without sphincterotomy.

Table 2. Tips and tricks (based on personal experience)

1. Decide on need for balloon dilation prior to attempting removal, based on size and complexity of stone disease.
2. Perform ample sphincterotomy prior to balloon dilation for bile duct stones.
   a. Especially if a pancreatic stent is not to be placed.
3. Use balloon diameter somewhat smaller than the distal bile duct at first.
4. Perform balloon dilation before attempting conventional techniques such as stone, basket, or mechanical lithotripsy.
   a. Failed balloon extraction of stones may result in impaction of the stone in the duct and further complicate removal, especially with soft stones.

substantially higher risk of PEP after EPBD without EST [21]. Recognizing this higher risk of PEP with balloon dilation [5, 39, 40], ESGE guidelines propose placement of a prophylactic pancreatic stents when performing EPBD [41], as well as other measures including rectal NSAID and IV fluids. The risk of pancreatitis and the need for prophylactic measures such as pancreatic stents are less clear for EPBLD after EST [32•].

Bleeding

Immediate or delayed bleeding from balloon dilation maneuvers ranges from 0 to 8% [42, 43]. In a multicenter study of 946 patients by Park et al., the rate of bleeding was 6% [39]. Bleeding in this study was associated with full-length EST, stone size ≥ 16 mm, and underlying cirrhosis. Full-length EST when compared to limited EST was shown to have higher bleeding risk despite similar rates of stone clearance [44]. To summarize, decreased risk of bleeding, which is now rare in patients without coagulopathy, seems to be the main advantage of EPBD without EST.

Perforation

Unlike EPBD, EPLBD is considered an independent risk factor for perforation (OR 17, $p < 0.001$) especially in the presence of distal bile duct stricture and is contraindicated in patients with bile duct stricture and a non-dilated duct [39]. The ASGE guidelines recommend that the maximal diameter of the balloon should not exceed the diameter of the distal bile duct, and especially with biliary strictures, to reduce risk of perforation [32•].

Table 3. Areas for future research

1. Need for pancreatic stents to reduce post-ERCP pancreatitis risk in patients undergoing balloon dilation, with or without EST.
2. Role of alternative strategies to reduce risk of post-ERCP pancreatitis in patients undergoing balloon dilation.
3. Threshold for coagulopathy or how long to withhold anticoagulation in order to reduce bleeding risk.

Effectiveness of EPBD and EPLBD in a spectrum of community practices.

Special populations

Uncorrectable coagulopathy

EST is associated with risk of bleeding in patients with coagulopathy [12]. EPBD with balloon ≤ 10 mm is shown to reduce the risk of bleeding in such a population compared to EST [15, 45]. There are few data regarding EPLBD in coagulopathy. Extrapolating data from systematic reviews of EPLBD studies showing excess bleeding after EST, it is recommended to consider EPLBD without EST in patients with coagulopathy when planned [26, 39].

Peri-ampullary diverticulum

PAD increases the difficulty of sphincterotomy due to duodenal distortion and dislocation of the sphincter. There are no data comparing EST with EPBD in the presence of PAD. A 2018 study in patients with PAD showed EPLBD to be effective and safe avoiding the need of other techniques [46]. Based on the limited studies, EPLBD without EST should be considered in a setting of PAD to avoid bleeding and perforation.

Altered anatomy

Biliary stone extraction remains challenging in patients with surgically altered anatomy such as Billroth II. Various cannulation methods including balloon enteroscopy, laparoscopy-assisted transgastric ERCP, and EUS-guided access have been studied [47–49]. The inverted approach to the papilla in Billroth II anatomy makes sphincterotomy and stone extraction challenging [50]. Case series in patients with Billroth II gastrectomy showed stone clearance of > 96% with EPLBD after limited EST [51]. A single-center study of 40 patients by Jang et al. [52] reported EPLBD without EST was successful in the removal of large bile duct stones in all patients with no serious adverse events. EPLBD is considered as a safe and effective procedure in patients with altered anatomy after EST.

Compliance with Ethical Standards

Conflict of Interest

Abdul Haseeb declares that he has no conflict of interest. Martin L. Freeman declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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