TECHNICAL REVIEW

International consensus guidelines for endoscopic papillary large-balloon dilation

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Common bile duct stones are frequently diagnosed throughout the world. Endoscopic sphincterotomy (EST) has been used for the removal of bile duct stones for the past 40 years. The purpose of EST is to provide an opening to allow bile duct stone extraction. However, adverse events such as bleeding, perforation, pancreatitis, and cholangitis occur in 5% to 10% of patients who undergo EST.[1-4] Additionally, endoscopic mechanical lithotripsy (EML) may be required as an adjunctive procedure in patients with large bile duct stones to facilitate clearance.[5-9] Endoscopic papillary balloon dilation (EPBD) was first proposed as an alternative to EST in 1982.[10] Because the extent of orifice dilation with EPBD is limited to a diameter of $\leq$10 mm, it is less successful than EST in removing bile duct stones.[11,12] Endoscopic papillary large balloon dilation (EPLBD) combined with EST was introduced in 2003 to facilitate the removal of large or difficult bile duct stones,[13] and the size of the large-diameter balloons used was 12 to 20 mm. Since then, EPLBD with limited or large EST has become rapidly and widely adopted, mainly in Asia. As an alternative method, EPLBD without a preceding EST was introduced as a simplified technique in 2009.[14] Several studies have reported that this technique is safe and effective in patients with large bile duct stones without an increased risk of severe pancreatitis or bile duct perforation. Nevertheless, it is difficult to precisely analyze the outcomes of EPLBD because the techniques and definitions are used differently among studies. To date, there is no published consensus of guidelines on the techniques and indications for EPLBD. The consensus guidelines in this report will help provide a framework to improve the outcome of EPLBD.

Abbreviations: CI, confidence interval; EML, endoscopic mechanical lithotripsy; EPBD, endoscopic papillary balloon dilation; EPLBD, endoscopic papillary large-balloon dilation; EST, endoscopic sphincterotomy; OR, odds ratio; PAD, periampullary diverticulum.

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METHOD FOR PREPARING THE GUIDELINES

The literature on EPLBD was initially reviewed by searching titles and abstracts with the search terms "large balloon," "balloon dilation," "sphincteroplasty," and "endoscopic papillary large balloon dilation" in MEDLINE, the Cochrane Library, and Embase. After reviewing the corresponding abstracts of the retrieved articles, the full text of the articles relevant to this review were downloaded. Additional articles were then searched by reviewing the references of these articles.

Before the consensus meeting, the Korean co-authors created first draft statements. The statements for EPLBD were divided into the following topics: definition, indication, technique, outcomes, adverse events, and specific cases such as periampullary diverticulum, surgically altered anatomy, and previous EST. These topics were determined according to their perceived clinical importance. These statements were provided by e-mail to the consensus group panel. A face-to-face meeting of the consensus group was held on February 14, 2014, in Seoul, Republic of Korea, to review and discuss the evidence for all statements. All statements were revised and finally agreed on at the concluding plenary session. Thereafter, the evidence level and recommendation grade were rated using the evidence leveling system of Scottish Intercollegiate Guidelines Network Grading Review Group (Table 1),[15] and the voting system used was a 5-point Likert scale (Table 2). The first vote was conducted in this meeting, and the second voting was conducted electronically by e-mail. Consensus was considered to be achieved when 80% or more of voting members indicated "accept completely" or "accept with some reservation." A statement was refused when 80% or more of voting members "reject completely" or "reject with some reservation" (Table 2). Commentaries on statements

TABLE 1. Definitions of categories for evidence levels and recommendation grades used in these guidelines[15]

Evidence level:

- 1++: High-quality meta-analyses; systematic reviews of randomized, controlled trials; or randomized, controlled trials with a very low risk of bias
- 1+: Well-conducted meta-analyses; systematic reviews of randomized, controlled trials; or randomized, controlled trials with a low risk of bias
- 1−: Meta-analyses, systematic reviews, or randomized, controlled trials with a high risk of bias
- 2++: High-quality systematic reviews of case-control or cohort studies; high-quality case-control studies or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
- 2+: Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
- 2−: Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
- 3: Nonanalytic studies (eg, case reports, case series)
- 4: Expert opinion

Recommendation grade:

- A: At least 1 meta-analysis, systematic review, or randomized, controlled trial rated as 1++ and directly applicable to the target population or a systematic review of randomized, controlled trials or a body of evidence consisting principally of studies rated 1+ directly applicable to the target population and demonstrating overall consistency of results
- B: A body of evidence including studies rated 2++ directly applicable to the target population and demonstrating overall consistency of results or extrapolated evidence from studies rated 1++ or 1+
- C: A body of evidence including studies rated 1− or 2+ directly applicable to the target population and demonstrating overall consistency of results or extrapolated evidence from studies rated 2++
- D: Evidence level 2−, 3, or 4 or extrapolated evidence from studies rated 2+

were written by T.H. Kim and J.H. Kim and all co-authors were involved in the final editing of the commentaries.

In this report, we first discuss the definition, indication, and technique of EPLBD with or without EST. We then focus on the best indications, followed by a discussion of safe techniques and outcomes of EPLBD. Each section of this report includes the key recommendations related to the section topic followed by a summary of the supporting evidence (Table 3).

1. DEFINITION

1.1. EPLBD is used to dilate the biliary orifice with a large-diameter balloon (≥12 mm) and can be performed with or without EST.

EPBD involves dilation of the biliary sphincter with a small-diameter balloon (≤10 mm) and is usually performed without EST. When large bile duct stones are extracted by using EPBD, a great number of EMLs is needed because of the small biliary opening created after EPBD. EPLBD is an extension of EPBD, which is used to create a larger biliary opening with a large diameter balloon (≥12 mm). The intended purpose of EPLBD is to simplify removing large or difficult bile duct stones without additional adverse events of EST alone or EPBD alone. EST has been generally recommended before EPLBD because it was believed to be associated with a decreased risk of postprocedure pancreatitis.[16,17] EPLBD was initially performed when the standard balloon and basket extraction techniques failed after large EST, but recently it has been performed after limited EST or sometimes without EST to minimize the risk of adverse events of large EST, even before attempting trials of the standard extraction techniques. A recent systematic review of EPLBD concluded that EPLBD with EST has similar outcomes in terms of stone clearance and the advantage of a lower risk of overall adverse events and pancreatitis compared with EST alone.[18] As an alternative method, Jeong et al[14] reported that avoiding EST during EPLBD can simplify the procedure and that this technique is safe and effective for managing large bile duct stones without increasing the risk of pancreatitis. Although the initial success rate of EPLBD without EST was significantly lower than that of EPLBD with EST, there were no significant differences in the overall success rates in the systematic review.[18] However, only a few reports regarding EPLBD without EST have been published. Accordingly, large-scale prospective, multicenter studies would be ideal to verify the effectiveness of EPLBD without EST.

TABLE 2. Voting on recommendation

- A: Accept completely
- B: Accept with some reservation
- C: Accept with major reservation
- D: Reject with reservation
- E: Reject completely

2. INDICATION

2.1. In the removal of large or difficult bile duct stones, EPLBD can be used as an alternative to EML.

Evidence level: 1+

Recommendation level: B

Level of agreement: A, 70.6%; B, 29.4%; C, 0%; D, 0%; E, 0%

Bile duct stones may be difficult to remove endoscopically by using standard balloon and basket extraction