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TOPIC HIGHLIGHT

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Large balloon dilation post endoscopic sphincterotomy in removal of difficult common bile duct stones: A literature review

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Abstract

Endoscopic sphincterotomy (ES) is the standard therapy in common bile duct (CBD) stones extraction. Large stones (≥ 12 mm) or multiple stones extraction may be challenging after ES alone. Endoscopic sphincterotomy followed by large balloon dilation (ESLBD) has been described as an alternative to ES in these indications. Efficacy, safety, cost-effectiveness and technical aspects of the procedure have been here reviewed. PubMed and Google Scholar search resulted in forty-one articles dealing with CBD stone extraction with 12 mm or more dilation balloons after ES. ESLBD is at least as effective as ES, and reduces the need for additional mechanical lithotripsy. Adverse events rates are not statistically different after ESLBD compared to ES for pancreatitis, bleeding and perforation. However, particular attention should be paid in patients with CBD strictures, which is identified as a risk factor of perforation. ESLBD is slightly cost-effective compared to ES. A small sphincterotomy is usually performed, and may reduce bleeding rates compared to full sphincterotomy. Dilation is performed with 12-20 mm enteral balloons. Optimal inflation time is yet to be determined. The procedure can be performed safely even in patients with peri-ampullary diverticula and surgically altered anatomy. ESLBD is effective and safe in the removal of large CBD stones, however, small sphincterotomy might be preferred and CBD strictures should be considered as a relative contraindication.

Key words: Bile duct stone; Endoscopic papillary large balloon dilation; Endoscopic sphincterotomy; Endoscopic retrograde cholangiopancreatography; Mechanical lithotripsy

Core tip: Endoscopic sphincterotomy followed by large balloon dilation is actually routinely performed in difficult stones extraction. The efficacy and safety of this procedure has been evaluated in thirty-two original studies published in English. Severe adverse events have been reported. This review describes indications, efficacy, morbidity and technical aspects of this procedure and tries to provide helpful data to the endoscopists in order to improve patient outcomes.

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INTRODUCTION

Endoscopic sphincterotomy (ES), introduced in 1974, is the standard therapy in common bile duct (CBD) stone extraction[1,2]. The rate of successful CBD stone clear-

ance after ES approaches 90%[3]. Endoscopic papillary balloon dilation with biliary balloons has been proposed as an alternative to ES, with similar CBD clearance rate, but is associated with an increased risk of pancreatitis[4]. Large CBD stones or multiple stones may be difficult to remove after ES alone. In case of failure of stone extraction after ES, lithotripsy techniques are used, especially mechanical lithotripsy (ML)[5]. However, ML is often technically difficult to perform and time-consuming. Recently, several teams evaluated large balloon dilation ($\geqslant$ 12 mm) without previous sphincterotomy[6-8] for extraction of large CBD stones, but data are very limited. Endoscopic sphincterotomy followed by large balloon dilation (ESLBD) was introduced by Ersoz *et al*[9] in 2004 in removal of difficult CBD stones. Further studies tend to confirm its effectiveness and safety in more than 1700 patients. In this article, indications, results and technical aspects of ESLBD will be reviewed.

LITERATURE REVIEW

A search was performed using the following key words: endoscopic sphincterotomy, bile duct stones, and balloon dilation. The databases included PubMed and Google Scholar Search. A search in the references of the articles was also performed (2003-September 2013). Only full-text articles published in English were recorded. Studies in which balloon dilation diameter was less than 12 mm were excluded of global analysis. Overall, 41 fully published articles including 32 original studies were selected.

ESLBD INDICATIONS

ESLBD is mainly performed in endoscopic removal of difficult extra-hepatic stones, such as stones larger than 12 or 13 mm, or multiple stones, and always used in patients with dilated CBD. Case reports demonstrated also the successful use of ESLBD to treat basket impaction[10] and Mirizzi syndrome[11].

PATIENT OUTCOMES

Patient outcomes are summarized in Table 1. After ESLBD, CBD stone clearance rates at index ERCP ranges from 72.7%[12] to 100%[13]. Three retrospective controlled studies[14-16] and four prospective randomized controlled trials[17-20] compared ESLBD to ES. Only two of the retrospective studies report a significantly higher rate of stone removal after ESLBD than after ES at index ERCP (84.2% *vs* 44.2%, $P < 0.001$[14] and 87.5% *vs* 74.0%, $P = 0.036$[16]). None of the five other studies describes a significant difference on this outcome. Only Rosa *et al*[14] report a significantly higher overall stone removal rate after ESLBD compared to after ES (95% *vs* 70%, $P < 0.001$) but such a low rate of CBD clearance after ES alone is surprising when compared to literature.

In most studies, the need for additional mechanical lithotripsy is reduced when using ESLBD compared to ES[21]. A randomized controlled trial reports a significant decrease in the need of using ML in the ESLBD group *vs* ES group (28.8% *vs* 46.2%, $P = 0.028$), in particular for stones larger than 15 mm (58.1% *vs* 90.9%, $P = 0.002$). In this trial, ES alone was identified as an independent risk factor for ML in multivariate logistic regression analysis[18]. The meta-analysis by Feng *et al*[22] also mention a decrease in use of ML after ESLBD compared to ES (OR = 0.51, 95%CI: 0.30-0.86, $P = 0.01$), but the difference was not significant in the large stone sub-group, maybe due to the small number of patients. Use of ML was correlated with larger stone size in a large retrospective series; ML rates were 17.6%, 43.4% and 62% for 10-14 mm, 15-19 mm and $\geqslant$ 20 mm stones respectively ($P < 0.01$)[23].

Considering long term outcomes, Kim *et al*[24] report no significant difference for CBD stone recurrence after ES and ESLBD (13.6% *vs* 11%, $P = 0.546$) with a 30-mo follow-up. Nevertheless, cumulative recurrence rate in two years on Kaplan-Meier curve in patients who un-

Table 1 Patient outcomes after endoscopic sphincterotomy combined with large balloon dilation

Ref.	Study type	No. patients ESLBD	Dilating balloon diamete (mm)	Success at index ERCP (%)	ML (%)
Ersoz *et al*[9]	R	58	12-20	82.8	6.9
Bang *et al*[12]	P	22	12-15	72.7	9.1
Espinel *et al*[55]	P	22	12-20	100	3.2
Lee *et al*[13]	R	55	15-20	100	5.5
Minami *et al*[28]	R	88	20	99	1
Maydeo *et al*[34]	P	60	15	95	5
Heo *et al*[20]	RCT	100	12-20	83	8
Kim *et al*[51]	R	9	12-18	55	11
Attasaranya *et al*[29]	R	103	12-18	95	27
Misra *et al*[35]	R	50	15-20	100	10
Itoi *et al*[15]	RA	53	15-20	96	5.6
Park *et al*[44]	R	6	12-15	33	50
Kim *et al*[19]	RCT	27	15-18	85	33
Itoi *et al*[27]	R	18	15-18	94	22
Kim *et al*[42]	R	70	12-18	97	1.4
Itoi *et al*[52]	R	11	15-20	100	18.2
Kurita *et al*[43]	R	24	15-20	96	4.2
Youn *et al*[32]	R	101	15-20	92	6.9
Kim *et al*[53]	R	16	12-18	94	6.3
Itoi *et al*[54]	R	15	15-20	100	6.7
Stefanidis *et al*[17]	RCT	45	15-20	98	0
Kim *et al*[16]	RA	72	12-20	88	17.9
Rosa *et al*[14]	R	30	12-18	84	20
Paspatis *et al*[48]	RCT	124	15-20	86	3.2
Sakai *et al*[47]	R	59	12-20	83.1	13.6
Yang *et al*[23]	R	169	12-18	95.3	38.6
Poincloux *et al*[45]	R	62	15-20	95	3.2
Harada *et al*[25]	R	30	15-20	97	10
Yoon *et al*[41]	R	52	12-20	ND	23
Teoh *et al*[18]	RCT	73	13-15	89	28.8
Hwang *et al*[56]	RCT	69	12-20	94	26.1
Rosa *et al*[14]	RA	68	12-18	82.4	14.7

ESLBD: Endoscopic sphincterotomy combined with large balloon dilation; ERCP: Endoscopic retrograde cholangiopancreatography; ML: Mechanical lithotripsy; R: Retrospective series; P: Prospective series; RCT: Randomized: controlled trial; RA: Retrospective analysis; ND: Not determined.

Table 2 Rates of adverse events after endoscopic sphincterotomy combined with large balloon dilation *n* (%)

Ref.	No. patients ESLBD	PEP	Bleeding	Perforation	Cholangitis	Miscellaneous	Overall AEs
Ersoz *et al*[9]	58	2 (3.4)	5 (8.6)	0	2 (3.4)	0	9 (15.5)
Bang *et al*[12]	22	1 (4.5)	0	0	0	0	1 (4.5)
Espinel *et al*[55]	22	0	0	0	0	0	0
Lee *et al*[13]	55	0	0	0	0	0	0
Minami *et al*[28]	88	1 (1.1)	1 (1.1)	0	1 (1.1)	12 (13.6)	15 (17.0)
Maydeo *et al*[34]	60	0	5 (8.3)	0	0	0	5 (8.3)
Heo *et al*[20]	100	4 (4.0)	0	0	0	1 (1.0)	5 (5.0)
Kim *et al*[51]	9	0	0	0	0	0	0
Attasaranya *et al*[29]	103	0	2 (1.9)	1 (1.0)	0	3 (2.9)	6 (5.8)
Misra *et al*[35]	50	4 (8.0)	3 (6.0)	0	0	0	7 (14.0)
Itoi *et al*[15]	53	1 (1.9)	0	0	1 (1.9)	0	2 (3.8)
Park *et al*[44]	6	0	1 (16.7)	0	0	0	1 (16.7)
Kim *et al*[19]	27	0	0	0	0	0	0
Itoi *et al*[27]	18	0	0	0	0	0	0
Kim *et al*[42]	70	1 (1.4)	0	0	0	0	1 (1.4)
Itoi *et al*[52]	11	0	0	0	0	0	0
Kurita *et al*[43]	24	0	0	0	0	0	0
Youn *et al*[32]	101	5 (5.0)	2 (2.0)	1 (1.0)	0	2 (2.0)	10 (9.9)
Kim *et al*[53]	16	0	1 (6.3)	0	0	0	1 (6.3)
Itoi *et al*[54]	15	0	0	0	0	0	0
Stefanidis *et al*[17]	45	1 (2.2)	1 (2.2)	0	0	0	4,4
Kim *et al*[16]	72	5 (6.9)	0	0	1 (1.3)	0	6 (8.3)
Rosa *et al*[14]	30	1 (3.3)	0	0	0	0	1 (3.3)
Paspatis *et al*[48]	124	4 (3.2)	6 (4.8)	2 (1.6)	5 (4.0)	0	17 (13.7)
Sakai *et al*[47]	59	0	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)	4 (6.8)
Yang *et al*[23]	169	2 (1.2)	4 (2.4)	1 (0.6)	1 (0.6)	0	8 (4.7)
Poincloux *et al*[45]	62	2 (3.2)	5 (8.0)	0	2 (3.2)	0	9 (14.5)
Harada *et al*[25]	30	0	0	0	0	0	1 (3.3)
Yoon *et al*[41]	52	0	0	0	0	0	0
Teoh *et al*[18]	73	2 (2.7)	1 (1.4)	0	1 (1.4)	1 (1.4)	5 (6.8)
Hwang *et al*[56]	69	3 (4.3)	0	1 (1.4)	0	1 (1.4)	5 (7.2)
Rosa *et al*[14]	68	9 (13.2)	0	0	1 (1.5)	0	10 (14.7)

ESLBD: Endoscopic sphincterotomy combined with large balloon dilation; PEP: Post-endoscopic retrograde cholangiopancreatography pancreatitis; AE: Adverse event.

derwent large balloon dilation for recurrent CBD stones after previous ES was lower than in those who didn't (P = 0.039), but the statistical power of this study is limited since only thirty patients were included[25].

ADVERSE EVENTS

Adverse events are summarized in Table 2. Regarding Cotton's consensual criteria[26], rates of overall adverse events (AEs), pancreatitis, and bleeding after ESLBD range from 0% to 17%[27,28], 0% to 13.2%[14,29] and 0% to 8.6%[9,16] respectively after ESLBD, when these rates are established respectively at 10.3%, 4.3% and 2% after ES alone[30]. However, the latter data are from a meta-analysis of CBD stones of all size, therefore results are not directly comparable. Among the four randomized controlled studies comparing ESLBD to ES[17-20], no significant difference in overall AEs, pancreatitis, bleeding and perforation was reported in all of them but one: Stefanidis *et al*[17] identified less overall AEs after ESLBD than after ES (4.4% *vs* 20%, P = 0.049).

The most serious AE after ESLBD is perforation. Fortunately, this complication is rare: 7 perforations (0.4%) have been described among 1761 patients in 32 original studies. Most cases were described as mild to moderate and have been treated conservatively[31,32]. However, a retrospective multicenter study[33] investigating 946 patients reports 9 perforations (0.95%), of which 3 resulted in death. Distal CBD stricture was found to be an independent risk factor of perforation in multivariate analysis (OR = 17.083; 95%CI: 3.936-74.132, P < 0.001), and could be considered as a relative contraindication to ESLBD.

One of the most common AE remains bleeding. Self-limiting oozing during ESLBD is common and usually not considered as a complication. Most of bleeding episodes are described as mild to moderate and managed conservatively, with blood transfusion, or endoscopic intervention[34]. But severe arterial bleeding, sometimes delayed, has been described and required aggressive therapy such as angiographic intervention[29] or surgery[35,36]. Park *et al*[33] have reported a death after massive delayed hemorrhage despite angiographic intervention. In this study, cirrhosis (OR = 8.028; 95%CI: 2.022-31.883, P = 0.003), full ES (OR = 6.222; 95%CI: 2.374-16.307, P = 0.001), and stone size ⩾ 16 mm (OR =3.996; 95%CI: 1.978-8.074, P = 0.001) were identified as predictive factors of bleeding.

Acute cholangitis is an exceptional and usually mild complication[33], severe acute cholangitis have neverthe-

less been described[37,38].

PROCEDURE AND FLUOROSCOPY TIMES, COST

In the retrospective analysis of 101 patients, Itoi *et al*[15] reported significantly shorter total procedure time (32 min *vs* 40 min, $P < 0.05$) and fluoroscopy time (13 min *vs* 22 min, $P < 0.05$) in the ESLBD group than in the ES group. Procedure time was recorded by Teoh *et al*[18] in a randomized controlled trial, and no difference was found between ES and ESLBD. In stone recurrence after previous ES, procedure time was shorter when using large balloon dilation (19 min *vs* 28 min, $P < 0.001$)[25]. Teoh *et al*[18] reported a reduction in direct cost of the procedures in the ESLBD group compared to ES group (US $5025 *vs* US $6005, $P = 0.034$), although no precisions are given on this secondary endpoint.

TECHNICAL ASPECTS

Size of the endoscopic sphincterotomy

Most of specialized endoscopists perform small or mid-size ES (*i.e.*, 1/3 to 1/2 of the distance to the papillary roof) before large balloon dilation. This step is suspected to reduce complication rates, especially regarding bleeding risk[33]. However, some retrospective studies describe normal ES before large balloon dilation with comparable outcomes[34]. On the other hand, these studies present a weaker level of evidence due to a small number of patients. Therefore, normal ES should be used more carefully than small or mid-size ES. In case of failure of stone removal after full ES, ESLBD could be used as a rescue procedure to complete stone extraction without ML[35,39], keeping in mind that bleeding risk may be increased.

Stone recurrence

In case of stone recurrence after ES, repeating ES is associated with a higher risk of complication, such as bleeding[40]. Four studies evaluated large balloon dilation in case of CBD stone recurrence in patients with previous ES[25,41-43]. ES was not repeated before dilation. Among 176 patients, only one mild pancreatitis was reported[42]. In three of these studies, CBD clearance after the first procedure was achieved in 97% and additional ML was required in 2.4% cases. Unfortunately, the fourth study did not present the clearance outcome after the first procedure[41].

Fistulotomy

Only few data are available about large balloon dilation after fistulotomy. A case series about 6 patients[44] who underwent 12-15 mm large balloon dilation after fistulotomy in case of failure of transpapillary biliary cannulation reports 100% stone extraction with no acute pancreatitis or perforation. One of six patients presented with minor delayed bleeding. In another retrospective study, no perforation occurred during seven 18 mm large balloon dilations following fistulotomy[45].

Balloon size and inflation time

Enteral dilation wire-guided balloons are used, ranging from 12 to 20 mm in diameter. The choice of the diameter depends on the size of the largest stone and on the CBD diameter. Some authors limit balloon size to 15 mm because of the apprehension of perforation. Hisatomi *et al*[46], in an *ex-vivo* porcine model with non-dilated CBD, showed that distal CBD lesions are correlated with balloon size: perforation was observed only with 15 mm or larger balloons. However, one large retrospective study showed that dilation with balloons larger than 15 mm in 101 patients had a complication rate similar to what is described in literature with smaller balloons[32]. The smallest balloon should always be chosen depending on stone size and CBD diameter.

The ideal balloon inflation time remains yet controversial, as studies are heterogeneous regarding this parameter. The major endpoint is the disappearance of the notch on the balloon under fluoroscopic guidance. Balloon is then kept inflated for different times. When mentioned, inflation time ranges from 0 s to 2 min[45,47]. This is yet not known if a shorter inflation time is associated with a higher risk of bleeding. One study compared prospectively 30 and 60 s dilation times, and did not show any significant difference for CBD clearance or adverse events[48], which is consistent with the meta-analysis by Feng *et al*[22].

Persistence of the notch or continued resistance during balloon inflation could correspond to occult stricture with a subsequent risk of perforation. Although they were not identified statistically as risk factors, 3 perforations were reported after ESLBD in these two situations, and led to death. Lee *et al*[49] suggested that a persistent notch or continued resistance during balloon inflation at 75% of the manufacturer's maximum recommended pressure may be considered as contraindication to ESLBD.

Specific conditions

In most studies, demographic characteristics describe a large proportion of periampullary diverticula (PAD), up to 57%[16]. No study highlighted an increased risk of AEs in patients with PAD, in particular for perforation. A case-control study compared ESLBD with 10-20 mm balloons in 73 patients with PAD to 66 patients without PAD, and found no significant difference in terms of stone removal or complication rates[50].

Surgically altered anatomy can make CBD stone extraction challenging. Three series evaluated ESLBD in 36 patients after ES or needle-knife papillotomy in case of Billroth-Ⅱ gastrectomy[51-53]. CBD clearance was achieved in a single procedure in 34 patients, and only one case of minor bleeding was reported. In 15 patients with Roux-en-Y anastomosis, Itoi *et al*[54] used single or double-balloon enteroscopy to reach the papilla before introducing

a conventional endoscope through the overtube to perform ESLBD. Stone clearance was achieved in all cases with no complication.

CONCLUSION

ESLBD has been widely evaluated for the endoscopic removal of large stones, in dilated CBD. This procedure is at least as effective as ES in this indication and reduces the need for additional ML. This technique is safe, but should be used with caution in case of CBD stricture or after full ES, due to perforation and bleeding risks.

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