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ORIGINAL ARTICLE

Prospective Study

Is endoscopic papillary large balloon dilatation without endoscopic sphincterotomy effective?

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Abstract

AIM: To evaluate the safety and efficacy of endoscopic papillary large balloon dilatation (EPLBD) without endoscopic sphincterotomy in a prospective study.

METHODS: From July 2011 to August 2013, we performed EPLBD on 41 patients with naïve papillae prospectively. For sphincteroplasty of EPLBD, endoscopic sphincterotomy (EST) was not performed, and balloon diameter selection was based on the distal common bile duct diameter. The balloon was inflated to the desired pressure. If the balloon waist did not disappear, and the desired pressure was satisfied, we judged the dilatation as complete. We used a retrieval balloon catheter or mechanical lithotripter (ML) to remove stones and assessed the rates of complete stone removal, number of sessions, use of ML and adverse events. Furthermore, we compared the presence or absence of balloon waist disappearance with clinical characteristics and endoscopic outcome.

RESULTS: The mean diameters of the distal and maximum common bile duct were 13.5 ± 2.4 mm and 16.4 ± 3.1 mm, respectively. The mean maximum transverse-diameter of the stones was 13.4 ± 3.4 mm, and the mean number of stones was 3.0 ± 2.4. Complete stone removal was achieved in 97.5% (40/41) of cases, and ML was used in 12.2% (5/41) of cases. The mean number of sessions required was 1.2 ± 0.62. Pancreatitis developed in two patients and perforation in one. The rate of balloon waist disappearance was 73.1% (30/41). No significant differences were noted in procedure time, rate of complete stone removal (100% *vs* 100%), number of sessions (1.1 *vs* 1.3, P = 0.22), application of ML (13% *vs* 9%, P = 0.71), or occurrence of pancreatitis (3.3% *vs* 9.1%, P =

0.45) between cases with and without balloon waist disappearance.

CONCLUSION: EST before sphincteroplasty may be unnecessary in EPLBD. Further investigations are needed to verify the relationship between the presence or absence of balloon waist disappearance.

Key words: Endoscopic papillary large balloon dilatation; Difficult bile duct stone; Endoscopic sphincterotomy; Distal common bile duct; Perforation

Core tip: Optimal approaches to sphincteroplasty of endoscopic papillary large balloon dilatation (EPLBD) remain controversial. We evaluated sphincteroplasty in EPLBD. Forty-one patients with naïve papillae received EPLBD. During sphincteroplasty of EPLBD, endoscopic sphincterotomy (EST) was not performed. Complete stone removal, number of sessions, use of mechanical lithotripter (ML), and adverse events were assessed. Complete stone removal was achieved in 97.5% of cases, and ML was used in 12.2% of cases. The mean number of sessions required was 1.2 ± 0.62. Pancreatitis developed in two patients and perforation in one. EST before sphincteroplasty may be unnecessary in EPLBD.

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INTRODUCTION

Endoscopic sphincterotomy (EST) and endoscopic papillary balloon dilatation (EPBD) are well-established therapies to treat bile duct stones[1-6]. However, the removal of multiple stones; large stones; barrel-shaped or tapering stones; or retrieving any size or shape of stone through a tortuous distal common bile duct, remains difficult[7]. Ersoz *et al*[8] first reported the utility of endoscopic papillary large balloon dilation (EPLBD) to remove large bile duct stones, with a number of subsequent studies reporting the efficacy and safety of the procedure[8-26]. However, opinions differ on whether or not to use an EST incision and the degree of such an incision (small, moderate or large). Meanwhile balloon selection and dilation techniques have been widely discussed[8-11,13-18,22-26]. For example, Jeong *et al*[16] reported that EPLBD using a large size balloon (15-18 mm) without EST was both effective and safe. However, given that few other studies have been conducted to verifying the utility of this technique[16,23,25,26], we sought to corroborate the results. In the present study, during sphincteroplasty of EPLBD, EST was not performed. Furthermore, we improved the dilatation technique to make it as minimal as possible.

MATERIALS AND METHODS

Patients

The study participants comprised 41 consecutive patients who underwent EPLBD at Toho University Ohashi Medical Center from July 2011 to September 2013. The inclusion criteria were as follows: successful selective biliary cannulation; distal common bile duct ⩾ 11 mm in diameter or large bile duct stones (⩾ 10 mm in diameter); multiple stones (n > 2); and post-gastric reconstruction (Billroth Ⅰ or Ⅱ or Roux-en-Y).

The exclusion criteria were as follows: coagulopathy (international normalized ratio ⩾ 1.5; marked thrombocytopenia (platelets < 50000/mL); need for precutting to achieve selective biliary cannulation; acute cholangitis or pancreatitis; previous EST; distal common bile duct > 21 mm in diameter; benign or malignant biliary stricture; or failure to give informed consent to the procedure.

All anticoagulant and antiplatelet drugs were discontinued before the procedure, with temporary heparin substitution as necessary. All patients were sedated *via* intravenous administration of midazolam (5-10 mg). Scopolamine butyl bromide (20 mg) or glucagon (1 mg) was injected intravenously to inhibit gastrointestinal peristalsis, and each patient received nafamostatmesilate (20 mg/d) for one day before endoscopic retrograde cholangiopancreatography (ERCP). Blood samples collected 2 h after ERCP were used to determine complete blood counts and serum amylase levels; those collected 18-24 h after were used to measure hepatobiliary enzymes and C-reactive protein. We did not place a pancreatic duct stent to prevent pancreatitis.

The protocol adhered to the Helsinki Declaration and was approved in advance by the Institutional Ethical Review Board. The trial was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN0000011533). All participants gave written, informed consent beforehand.

Endoscopic procedure

EPLBD was performed using endoscopes (JF-260V™; Olympus, Tokyo, Japan, or ED-530XT8™; Fujinon, Tokyo, Japan), and balloons of 5.5 cm in length and 10-12, 12-15, 15-18, or 18-20 mm in diameter (CRE esophageal/pyloric balloon™; Boston Scientific, Natick, MA, United States) were used for dilatation. The pressure was 10-11-12 mm: 3-5-8 atm, 12-13.5-15 mm: 3-4.5-8 atm, 15-16.5-18 mm: 3-4.5-7 atm,

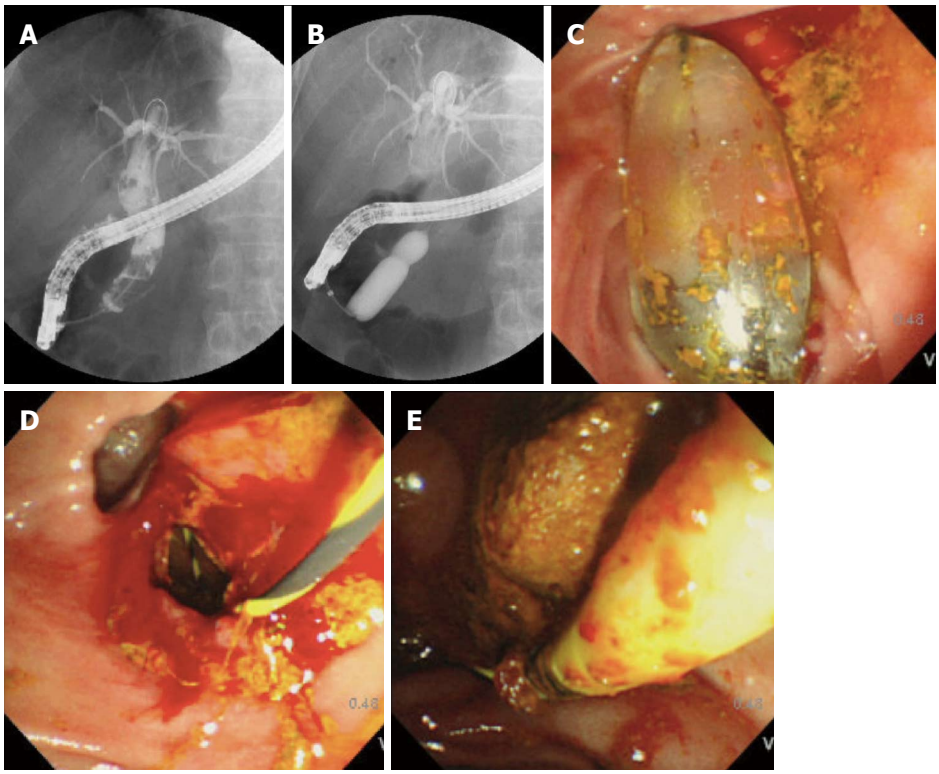

Figure 1 Fluoroscopic and endoscopic view of a bile duct. A: Multiple large bile duct stones and marked dilation of the common bile duct; B: Endoscopic papillary dilatation with a large (15-18 mm) balloon. Endoscopic sphincterotomy was not performed before balloon sphincteroplasty. This case features incomplete disappearance of the waist; C: An inflated balloon; D: A large biliary orifice was obtained; E: Large stones extraction using a retrieval balloon.

18-19-20 mm: 3-4.5-6 atm, respectively. All ERCPs were performed by an endoscopist with career experience of over 500 ERCPs (Maetani I, Shigoka H or Omuta S). After accessing the major papilla, the bile duct was cannulated by a wire-guided cannulation technique using a catheter (Tandem XL™, Boston Scientific, Natick MA, United States). A cholangiogram was obtained and used to measure the diameter of the distal common bile duct and stones, correcting for magnification with the external diameter of the distal end of the duodenoscope (JF 260V: 11.3 mm/ED-530XT8: 11.5 mm) as a reference (Figure 1).

Balloon diameter selection was determined based on previously described distal common bile duct diameter. For example, for 15-mm, we selected a 15-18 mm balloon to obtain a larger opening of the orifice. After removal of the catheter, the balloon was passed over the guidewire and positioned across the major papilla. An assisting endoscopist gradually performed dilatation under endoscopic and fluoroscopic guidance, using diluted contrast to inflate the balloon.

Inflation of the balloon was done until the desired pressure was achieved. If the balloon waist did not disappear, and the desired pressure was satisfied, we judged the dilatation as complete.

When possible, stones were removed using a retrieval balloon (Fusion Quattro™, Cook Medical, Tokyo Japan). When stone removal was not possible with a retrieval balloon, a mechanical lithotripter (ML) (Trapezoid™; Boston Scientific) was used to crush and capture the stones. Within a few days of initial EPLBD, a follow-up cholangiogram was obtained to assess the presence of residual stones. If residual stones were detected, a second ERCP session was performed to remove them without an additional sphincteroplasty. Each ERCP session was finished within 60 min.

Evaluation

The primary study endpoint was the rate of complete stone removal. Secondary endpoints were number of ERCP sessions needed, rate of application of ML, and adverse events, such as post-ERCP pancreatitis (PEP), bleeding, cholangitis or perforation within 72 h after EPLBD.

For subgroup analysis, we compared the presence or absence of balloon waist disappearance with clinical characteristics and endoscopic outcome. Complete stone removal was defined as the absence of any filling defect during a final cholangiogram performed endoscopically or through a nasobiliary drainage catheter. PEP was defined as continued abdominal pain $\geqslant$ 24 h after ERCP, with a serum amylase level more than three times the upper limit of normal[27]. Bleeding was defined as either or both hematemesis or a melena or a hemoglobin drop exceeding 2g[27]. Cholangitis was defined as increased temperature (over 38 ℃ for > 24 h) with cholestasis[27]. Perforation was defined as evidence of air or luminal contents outside

Table 1 Baseline characteristics of patients (*n* = 41) *n* (%)

Age (yr)	**77.7 ± 10.8**
Gender ratio (M:F)	19:22
Periampullary diverticulum	28 (68.3)
Previous gastric surgery	3 (7.3)
Billroth Ⅱ/Roux-en-Y reconstruction, *n*	2/1
Previous cholecystectomy	12 (29.2)
Gallbladder stone	18 (43.9)
Anticoagulant or antiplatelet therapy	19 (46.3)
Diabetes mellitus	3 (7.3)
CBD diameter (distal/maximum) (mm)	13.5 ± 2.4/16.4 ± 3.1
CBD stone diameter (maximum transverse) (mm)	13.4 ± 3.4
Number of stones	3.0 ± 2.4

CBD: Common bile duct; M: Male; F: Female.

Table 2 Outcome of endoscopic papillary large balloon dilation (*n* = 41) *n* (%)

Balloon size	
10-12 mm/12-15 mm/15-18 mm/18-20 mm	10/20/8/3
Distal CBD (balloon diameter)/CBD stone ratio	1.03 ± 0.15
Maximum CBD/CBD stone ratio	1.25 ± 0.19
Waist disappearance	30/41 (73.1)
Procedure time (min)	44.5 ± 21.2
Complete stone removal	40/41 (97.5)
Sessions required for complete stone removal	1.2 ± 0.62
Application of ML	5/41 (12.2)
Amylase after EPLBD (IU/L)	427 ± 695

CBD: Common bile duct; ML: Mechanical lithotripsy.

Table 3 Early adverse events of endoscopic papillary large balloon dilation (*n* = 41) *n* (%)

Early (< 72 h)	
Asymptomatic hyperamylasemia	2/41 (4.9)
Acute pancreatitis	2/41 (4.9)
Mild/moderate/severe	2/0/0
Bleeding	0/41 (0)
Acute cholangitis	0/41 (0)
Perforation	1/41 (2.4)

Table 4 Waist disappearance *vs* waist non-disappearance

Variables	Waist disappearance (*n* = 30)	Waist non-disappearance (*n* = 11)	*P* value
Age (yr)	77.7 ± 10.8	77.5 ± 11.4	NS
Gender (M:F)	15:15	4:7	NS
Periampullary diverticulum	70% (21/30)	63.6% (7/11)	NS
Distal CBD diameter (mm)	13.0 ± 2.1	14.8 ± 2.9	NS
Distal CBD diameter/stone ratio	1.05 ± 0.13	1.00 ± 0.21	NS
Number of stones	2.8 ± 2.2	3.6 ± 2.7	NS
Procedure time (min)	43 ± 20	49 ± 24	NS
Sessions required for complete stone clearance	1.1 ± 0.86	1.3 ± 0.43	NS
Application of ML	13.3% (4/30)	9.1% (1/11)	NS
Acute pancreatitis	3.3% (1/30)	9.1% (1/11)	NS

NS: Not significant; CBD: Common bile duct; ML: Mechanical lithotripsy.

the gastrointestinal tract[27]. Each adverse event was graded based on values set by the American Society for Gastrointestinal Endoscopy (ASGE)[27].

Statistical analysis

Data were presented as mean ± SD with ranges. In subgroup analyses, the χ^2 test or Fisher's exact test were used for noncontinuous variables and Student's *t*-test was used for continuous variable comparison between two groups. Analyses were performed using SPSS 19.0 (SPSS Inc., Chicago IL, United States). A *P* value less than 0.05 was considered statistically significant.

RESULTS

Baseline characteristics and indications of the 41 consecutive patients enrolled in this study are summarized in Table 1. The EPLBD procedure was successfully performed in all patients. Two post-gastric reconstruction patients had undergone a Billroth-Ⅱ, and one had undergone a Roux-en-Y. A periampullary diverticulum was observed 68.3% (28/41). The mean diameter of the distal/maximum common bile duct was 13.5 ± 2.4 mm/16.4 ± 3.1 mm. The mean maximum transverse-diameter of the stones was 13.4 ± 3.4 mm, and the mean number of stones was 3.0 ± 2.4. Endoscopic outcomes are summarized in Table 2. Complete stone removal was achieved in 97.5% of patients (40/41), with a successful stone removal rate during the initial EPLBD of 87.8% (36/41). Thirteen patients required a second session, and one patient required a third session. The mean number of sessions required for complete stone removal was 1.2 ± 0.62. The rate of application of ML was 12.2% (5/41), and the rate of balloon waist disappearance was 73.1% (30/41).

Adverse events are shown in Table 3. Mild PEP occurred in two patients (4.9%): both were managed successfully with conservative treatment. Perforation developed in one patient who had undergone post-gastric reconstruction (Billroth-Ⅱ) and did not have a stricture of the distal common bile duct; the balloon waist s disappeared immediately during balloon dilatation. The patient required emergency surgery and stayed in the hospital for six months. After the patient's condition improved, complete stone removal was achieved using only a retrieval balloon catheter without an additional sphincteroplasty.

On comparing clinical characteristics and endoscopic outcomes with the presence or absence of balloon waist disappearance (Table 4), no significant differences were noted for distal common bile duct diameter, procedure time, mean number of sessions required for complete stone removal, application of ML or occurrence of PEP.

Table 5 Summary of published series of endoscopic papillary large-balloon dilatation for the removal of common bile duct stones *n* (%)

Ref.	Design	No. of cases	CBD stone diameter (mm)	Degree of EST	Balloon size (mm)	Complete stone removal overall, *n* (%)	Complete stone romoval initial, *n* (%)	No. sessions, mean	Application of ML, *n* (%)	PEP, *n* (%)	Bleeding, *n* (%)	Cholangitis, *n* (%)	Perforation, *n* (%)
Ersoz *et al*[8], 2003	Retrospective	58	16/18, mean	Moderate	12-20, range	58/58 (100)	48/58 (82.8)	1.2	4/58 (6.9)	2/58 (3.4)	3/58 (5.2)	2/58 (3.4)	0/58 (0)
Maydeo *et al*[9], 2007	Prospective	60	16, mean	Large	12-15, mean	60/60 (100)	57/60 (95)	1.0	3/60 (5)	0/60 (0)	1/60 (1.7)	0/60 (0)	0/60 (0)
Heo *et al*[10], 2007	Randmized controlled trial	100	16, mean	Moderate	12-20, range	97/100 (97)	83/100 (83)	1.1	8/100 (8)	4/100 (4)	0/100 (0)	0/100 (0)	0/100 (0)
Minami *et al*[11], 2007	Retrospective	88	14, mean	Small	12-20, range	87/88 (98.9)	87/88 (98.9)	1.0	1/88 (1.1)	1/88 (1.1)	1/88 (1.1)	1/88 (1.1)	0/88 (0)
Misra *et al*[13], 2008	Retrospective	50	15-25, range	Adequate	12-20, range	NA	NA	NA	5/50 (10)	4/50 (8)	2/50 (4)	0/50 (0)	0/50 (0)
Attasaranya *et al*[14], 2008	Retrospective	103	13, median	Discretion of endoscopist	13.5, median	102/107 (95.1)	102/107 (95.1)	1.0	28/103 (27.2)	0/103 (0)	2/103 (1.9)	0/103 (0)	1/103 (1)
Itoi *et al*[15], 2009	Retrospective	53	14.8, mean	Moderate	12-20, range	53/53 (100)	51/53 (96.2)	1	3/53 (5.7)	1/53 (1.9)	0/53 (0)	1/53 (1.9)	0/53 (0)
Jeong *et al*[16], 2009	Retrospective	38	17.7, mean	Not performed	15-18, range	37/38 (97.4)	25/37 (65.8)	NA	8/38 (21.1)	1/38 (2.6)	0/38 (0)	0/38 (0)	0/38 (0)
Draganov *et al*[17], 2009	Retrospective	44	12.7, mean	Large	10-15, range	42/44 (95)	37/44 (84)	1.1	2/44 (4.5)	0/44 (0)	2/44 (4.5)	1/44 (2.2)	0/44 (0)
Kim *et al*[18], 2009	Randmized controlled trial	27	20.8, mean	Small	15-18, range	27/27 (100)	23/27 (85.2)	1.3	9/27 (33.3)	0/27 (0)	0/27 (0)	0/27 (0)	0/27 (0)
Stefanidis *et al*[22], 2011	Randmized controlled trial	45	12-20, range	Large	12-20, range	44/45 (97.8)	44/45 (97.8)	1.0	0/45 (0)	1/45 (2.2)	1/45 (2.2)	0/45 (0)	0/45 (0)
Chan *et al*[23], 2011	Retrospective	247	16.4, mean	Not performed	11-20, range	229/247 (92.7)	202/247 (81.8)	1.2	39/247 (15.8)	2/247 (0.8)	6/247 (2.4)	1/247 (0.4)	0/247 (0)
Kim *et al*[24], 2011	Retrospective	72	17.5, mean	Small	12-20, range	70/72 (97.2)	63/72 (87.5)	1.1	6/72 (8.3)	5/72 (6.9)	1/72 (1.3)	0/72 (0)	0/72 (0)
Jang *et al*[25], 2013	Retrospective	40	10.5, median	Not performed	10-17, range	40/40 (100)	37/40 (92.5)	1.1	1/40 (2.5)	2/40 (5.0)	0/40 (0)	0/40 (0)	0/40 (0)
Kogure *et al*[26], 2014	Retrospective	28	14, mean	Not performed	12-18, range	27/28 (96)	25/28 (89)	1.1	3/28 (11)	1/28 (4)	0/28 (0)	0/28 (0)	1/28 (4)
Present study	Prospective	41	13.4 mean	Not performed	11-20, range	40/41 (97.5)	36/41 (87.8)	1.2	5/41 (12.2)	2/41 (4.9)	0/41 (0)	0/41 (0)	1/41 (2.4)

Results are described as large balloon biliary sphinteroplasty alone. NA: Not available; CBD: Common bile duct; ML: Mechanical lithotripsy; PEP: Post-retrograde cholangiopancreatography pancreatitis.

DISCUSSION

Ersoz *et al*[8] first reported the use of endoscopic sphincterotomy followed by large balloon dilation as an alternative for managing difficult bile duct stones. Their reported overall complete stone removal rate was 100%, with ML application used in 7% and an overall adverse event rate of 15%, including a 3% PEP rate. EPLBD without preceding EST was described in 2009 by Jeong *et al*[16], who reported an overall complete stone removal rate of 97%, with a 21% rate of ML application and a 2.6% PEP rate. A summary of the English-language literature published on EPLBD is shown in Table 5. We conducted research on PubMed/MEDLINE from 2003 to October 2014. A search strategy was used to identify reports of randomized controlled trials, retrospective studies and prospective case series in EPLBD, with a combination of controlled vocabulary and text words related to (1) endoscopic papillary large balloon dilatation; (2) difficult common bile duct stones; and (3) endoscopic sphincterotomy. Fifteen full papers were identified, comprising eleven retrospective studies, three controlled trials and one prospective case series[8-11,13-18,22-26].

In the present study, the rates of complete stone removal in the initial session and overall were 87.8% and 97.5%, respectively. The mean number of sessions required for complete stone removal was 1.2, and the rate of ML application was 12.2%. Our endoscopic outcome was compared with those performed with preceding EST (small to large) in Table 5[8-11,13-15,17,18,22,24]. The rates of complete stone removal in the initial session and overall ranged from 83% to 99% and 95% to 100%, respectively, and the number of sessions required for complete stone removal and rate of ML application ranged from 1.1 to 1.3 and 0% to 27%, respectively. Thus, our endoscopic outcomes were equivalent to those in other studies. In the studies of balloon dilatation without preceding EST, including our study, the initial and overall complete stone removal rates ranged from 66% to 93% and 93% to 100%, respectively (Table 5)[16,23,25,26], and the number of sessions required for complete stone removal and the rate of ML application ranged from 1.1 to 1.2, and 2.5% to 21%, respectively. Thus, the efficacy data suggest that EPLBD without preceding EST was a

satisfactory outcome.

PEP occurred in 4.9% of patients in our study. EPBD has been reported to be associated with more frequent and severe PEP than EST[28-30]. PEP is believed to occur as a reaction to the direct physical compression effect of the balloon on the papilla, the pancreatic duct orifice or the pancreatic parenchyma, and stone removal might induce peripapillary edema or spasm of the sphincter[21]. We hypothesized that the relatively low PEP rates seen in the present study may be because the balloon dilatation was minimized, thereby reducing the severity of the trauma to the papilla. In addition, we used a 15-18 mm balloon rather than a 12-15 mm one when the distal common bile duct was 15 mm, thereby reducing inflation time. Using a larger balloon provided adequate dilatation of the papilla, facilitating stone removal at the orifice. Sugiyama *et al*[31] reported that age < 60 years and bile duct diameter < 9 mm were independent risk factors for PEP, although we noted no such correspondence in the present study. Attasaranya *et al*[14] reported low rates of PEP because the pancreatic duct orifice was separated from the biliary orifice after EST and noted that balloon dilatation forces are directed away from the pancreatic duct. However, their evidence was insufficient to support the hypothesis[16]. While PEP occurrence has been found to range from 0% to 7% in cases with preceding EST[8-11,13-15,17,18,22,24], rates ranged from 0.8% to 5.0% in cases without preceding EST[16,23,25,26], including the present study (Table 5). Therefore, we suggest that the efficacy of EST could not be judged based on the rate of occurrence of PEP.

Bleeding occurred less frequently with EPBD than EST (EPBD 0% *vs* EST 2.0%, $P = 0.001$)[7]. While the rate of bleeding occurrence has been found to range from 0% to 5% in procedures performed after EST[8-11,13-15,17,18,22,24], rates ranged from 0% to 2% in procedures performed without EST[16,23,25,26], including the present study. Based on these findings, we question the propriety of EST in EPLBD.

Perforation is considered the most serious adverse events of EPLBD. Park *et al*[32] reported that stricture of the distal common bile duct was an independent factor predictive of perforation and that, if strong resistance was encountered during balloon inflation, additional pressure should not be applied. EPLBD has been reported to be safe in Billroth Ⅱ patients[25,33]. Perforation is understood to be caused by looping of the scope, not by the tip of the endoscope itself[34]. When surgery was performed in one patient in the present study, a very small stone was found in the retroperitoneal region of the dorsal side of the ampulla. This case with Billroth Ⅱ had no stricture, no resistance on balloon dilatation and the progress of the scope to the ampulla of Vater did not meet with any difficulties. Regarding the endoscopic procedure, balloon pressure was 3 atm, balloon size was 15-18 mm and the dilatation time was 125 s (from starting inflation to finishing deflation). Upon review of this case, we considered that the endoscopic procedure was not performed incorrectly, and subsequent surgical investigation confirmed that the very small stone was pressed into the duct wall during balloon dilatation, resulting in perforation. Therefore, it is important that we should confirm not only the configuration of the distal bile duct but also the presence of very small stones before EPLBD.

We collected the blood, and performed magnetic resonance cholangiopancreatography and/or abdominal ultrasound to recognize common bile duct stone every three months during follow-up. During the median follow-up period of 487 d, no cases of recurrence were noted in our study. One patient died of aspiration pneumonia 156 d after complete stone removal.

We encountered cases where the balloon waist did not disappear during dilatation. Lee *et al*[12] reported a series of endoscopic lithotomies with 100% complete stone removal in spite of a balloon waist disappearance rate of only 69%. In the present study, we noted no significant differences in complete stone removal, number of sessions, rate of application of ML, or rate of PEP between cases with and without balloon waist disappearance. Given the relatively small number of cases involved in the present study, further studies in a larger number of patients are needed to validate these findings.

Lee *et al*[12] speculated that it was caused by scar change of the incised orifice; however, this speculation has not been verified.

The present study was subject to several limitations. Our sample size was small and from a single center, with no control cases. Endoscopic outcomes were analyzed retrospectively with respect to balloon waist disappearance. Regarding the degree of the waist disappearance, although we did not establish a definition, we observed a disappearance rate of more than 80% among the cases. In particular, further investigations are needed to verify the relationship between the presence or absence of balloon waist disappearance and outcome. Based on these findings, EST before sphincteroplasty may be unnecessary in EPLBD. Furthermore, a randomized controlled study is needed to evaluate any differences between prior EST and no prior EST.

COMMENTS

Background

Ersoz *et al* first reported on the utility of endoscopic papillary large balloon dilation (EPLBD) to remove large bile duct stones, and a number of subsequent studies further reported on the efficacy and safety of the procedure. However, opinions differ on whether or not to use an endoscopic sphincterotomy (EST) incision and the degree of such an incision (small, moderate or large).

Research frontiers

Jeong *et al* reported that EPLBD using a large size balloon (15-18 mm) without EST was both effective and safe. However, few studies have been conducted to verify the utility of this technique.

Innovations and breakthroughs

Balloon diameter selection was determined based on the previously described

distal common bile duct diameter. For example, for 15-mm, a 15-18 mm balloon was selected to obtain a larger opening of the orifice, and inflation of the balloon to the desired pressure was performed until the desired pressure was achieved. When the balloon waist did not disappear and the desired pressure was satisfied, the dilatation was judged as complete. The presence or absence of waist disappearance with clinical characteristics and endoscopic outcome were compared.

Applications

Complete stone removal was achieved in 97.5% of patients (40/41); the mean number of sessions required for complete stone removal was 1.2 ± 0.62. The rate of application of mechanical lithotripter (ML) was 12.2% (5/41), and the rate of waist disappearance was 73.1% (30/41). Mild post-endoscopic retrograde cholangiopancreatography pancreatitis occurred in two patients (4.9%). No significant differences were noted in procedure time, rate of complete stone removal, number of sessions, application of ML or occurrence of pancreatitis between cases with and without waist disappearance.

Terminology

EST before sphincteroplasty may be unnecessary in EPLBD. A randomized controlled study is needed to evaluate any differences between prior EST and no prior EST. Further investigations are needed to verify the relationship between the presence or absence of balloon waist disappearance and outcome.

Peer-review

In this paper, the authors investigated the efficacy and safety of EPLBD without EST. The topic of this study is interesting.

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