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CLINICAL TRIALS STUDY

Endoscopic papillary large balloon dilation for removal of bile duct stones

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Abstract

AIM: To investigate the efficacy and outcomes of endoscopic papillary large balloon dilation (EPLBD) for bile duct stones in a multicenter prospective study.

METHODS: Lithotomy by EPLBD was conducted in 124 patients with bile duct stones ⩾ 13 mm in size or with three or more bile duct stones ⩾ 10 mm. After endoscopic sphincterotomy, the papilla was dilated using balloons 12-20 mm in diameter fitting the bile duct diameter.

RESULTS: The success rate of first-time lithotomy was 86.3% (107/124) and the final lithotomy success rate was 100% (124/124). Lithotripsy was needed in 10 of the 124 (13.6%) patients. Adverse events due to the treatment procedure occurred in 6 (4.8%) patients, all of which were mild. Performing large balloon dilation after endoscopic sphincterotomy in patients with large stones or multiple stones in the bile duct is considered to ensure the safety of treatment and to reduce the need for lithotripsy.

CONCLUSION: It is suggested that treatment by EPLBD for large bile duct stones may be safe and useful.

Key words: Endoscopic retrograde cholangiopancreatography; Endoscopic sphincterotomy; Endoscopic papillary large balloon dilation; Large bile duct stones; Multiple bile duct stones

Core tip: Endoscopic treatment by papillary large balloon dilation for large stones or multiple stones may be safe and useful.

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INTRODUCTION

For common bile duct stones, endoscopic treatment is the less invasive method and the procedure that should be primarily tried. Recently, endoscopic treatment has made remarkable progress and it can be performed in most patients diagnosed with common bile duct stones[1]. As for the papilla, endoscopic sphincterotomy (EST) was first reported by Kawai *et al*[2] and Classen *et al*[3] in 1974. EST is the gold standard procedure in current endoscopic treatment. However, sometimes endoscopic papillary balloon dilation (EPBD) is performed because the procedure can be used in patients with a bleeding tendency, in those who have been subjected to Billroth-Ⅱ reconstruction or surgery, and in patients in whom it is necessary to preserve papillary sphincter muscle function[4]. Although these procedures are useful to treat bile duct stones, it is difficult to perform lithotomy in patients with stones ⩾ 15 mm or with multiple stones. Thus, it is reported that many patients require a lithotripsy procedure such as mechanical lithotripsy (ML) or electrohydraulic or laser lithotripsy[5-7]. Currently, endoscopic papillary large balloon dilation (EPLBD), which consists of lithotomy without lithotripsy and dilation of the papilla using a large balloon, has been reported for large stones or multiple stones after performing EST[8-22]. Yet, many of those reports refer to retrospective studies in a single facility, with reports of multicenter prospective studies numbering only a few[17,21]. Therefore, it is difficult to state positively that the procedure has been sufficiently reviewed. In this study, we examined the usefulness of EPLBD for large stones or multiple stones in a multicenter prospective study.

MATERIALS AND METHODS

We evaluated the outcomes of patients with bile duct stones ⩾ 13 mm at the shortest diameter or patients with three or more bile duct stones ⩾ 10 mm at the shortest diameter, who were operated on in the trial facilities between July 2012 and March 2014. The inclusion criteria were (1) informed consent in writing for endoscopic retrograde cholangiopancreatography (ERCP) obtained before endoscopic treatment; (2) patients aged 20 years or older; (3) patients with stones ⩾ 13 mm at shortest diameter or with three or more stones ⩾ 10 mm; (4) patients admitted and followed-up on the day ERCP is performed; and (5) a balloon 5.5 cm long for dilating the papilla must be used. Exclusion criteria included (1) patients subjected to Billroth-Ⅱ surgery and patients with the stomach reconstructed by a Roux-en-Y anastomosis; (2) patients in whom EST cannot be performed; (3) patients with a papillary lesion in the diverticulum; (4) patients with stenosis of the middle and distal bile duct; and (5) patients for whom the procedure is determined to be inappropriate by the attending physician. One hundred and twenty-four patients were examined. Mean patient age was 78.3 (47-98) years. There were 64 males and 60 females. Three patients had a stomach reconstructed by Billroth-I method, and other patients were not treated with surgery. Eighty-five patients had a primary bile duct stone, and 39 had recurrent stones. All of the recurrent stones occurred in patients who had been subjected to EST. EST was performed in 75 patients and it had been already performed in 49 patients. Ten patients with no recurrent stones who had already undergone EST were introduced as patients with difficult lithotomy. The mean diameter of stones was 14.0 (10-25) mm, the mean number of stones was 3.9 (1-20), and the mean diameter of the bile duct was 15.4 (10-25) mm. As for the state of the gallbladder, 82 patients had gallbladder stones, 18 patients had no gallbladder stones, and in 24 patients the gallbladder had been removed. Parapapillary diverticulum was observed in 69 patients. One session of treatment lasted up to 60 min after inserting an endoscope. The status of the patients was observed, and if the patient moved violently, the procedure was ended after inserting the drainage, even during the process of treatment. During ERCP, arterial oxygen saturation was continuously monitored employing a pulse oximeter. EPLBD was conducted as follows. The endoscopes used were JF240, JF260V, or TJF260V (Olympus Corp.) backward side-viewing endoscopes. After cholangiography, the guidewire was placed within the bile duct and EST was started. Clever-Cut 3V (Olympus Corp.) was used as the knife for EST. The selected incision range was small- to medium-sized so that the bile duct and the pancreatic duct had a separate aperture. In patients who had an incision already made, the guidewire was inserted within the bile duct after cholangiography, and EPLBD was performed. In performing EPLBD, a controlled radial expansion (CRE) 12-20 mm wire-guided type balloon 5.5 cm (Boston Scientific Corp., Natick, MA) was used depending on diameter of the bile duct (Figure 1). For balloon dilation, the balloon was gradually inflated using a mixture of contrast medium and physiological saline (Figure 2A and B), until the notch on the balloon disappeared. However, in patients in whom the notch on the balloon did not disappear, balloon dilation was completed when the papilla was dilated enough for stone removal. The balloon was dilated in a position where it was possible to confirm the tip of the balloon in the papillary side on the endoscopic image, and the position was maintained. After the notch on the balloon disappeared, the balloon was promptly deflated. When we considered it was necessary to perform lithotripsy of the stone, we performed it without hesitation.

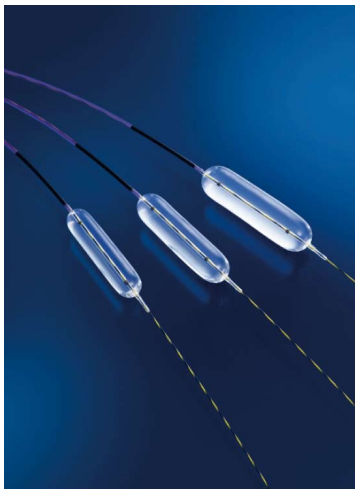

Figure 1 Endoscopic papillary large balloon dilation: Controlled Radial Expansion 12-20 mm wire-guided type balloon 5.5 cm (Boston Scientific Corp., Natick, MA).

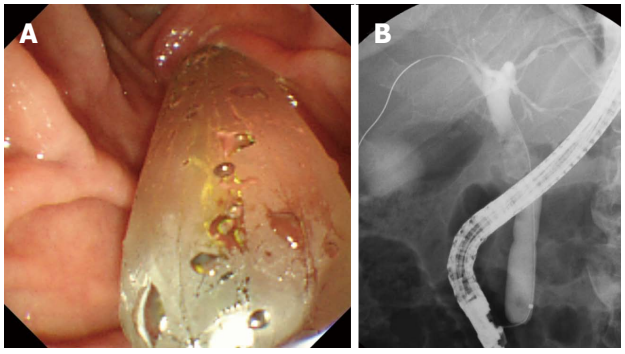

Figure 2 View of papilla gradually dilated. A: The papilla was gradually dilated using a large balloon. Dilation was continued until the notch on the balloon disappeared (endoscopic image); B: The papilla was gradually dilated until the notch on the balloon disappeared (fluoroscopic image).

When lithotomy was successful, no drainage tube was inserted, whereas when we judged there were remaining stones, a drainage tube was inserted. Iatrogenic morbidity was assessed according to the criteria of Cotton *et al*[23]. Patients were followed up for 30 d after the treatment, and adverse events presenting during that period were examined. All treatment procedures were performed after obtaining a written informed consent from the patients. This study was performed after approval of the ethical committee of each institution, and registered at UMIN Clinical Trial Registry (UMIN000008275-ESLBD study).

RESULTS

The results of EPLBD in this study and the existing reports are shown in Tables 1, 2, and 3. The success rate of lithotomy in the initial treatment was 86.3% (107/124). The final lithotomy rate was 100% (124/124). The time necessary to perform lithotomy was 36 (10-128) min and mean treatment frequency was 1.15 (1-3) times. Lithotripsy was needed in 10 of the 124 patients (13.6%). As for type of lithotripsy, ML was performed in 8 patients, and extracorporeal shock wave lithotripsy (ESWL) in 2 patients. Two patients who underwent ESWL had Mirizzi syndrome type Ⅱ. Adverse events due to the treatment procedure occurred in 6 patients (4.8%), including bleeding in 3 (2.4%), pneumonia in 2 (1.6%), and pancreatitis in 1 patient (0.8%). All these adverse events were mild, and were treated conservatively. In the ten patients who failed to be cured by the initial treatment, a tube stent was inserted in five and endoscopic nasobiliary drainage (ENBD) was inserted in the other five patients. In patients who were successfully treated with lithotomy initially, no drainage tube was inserted.

DISCUSSION

EPLBD is a treatment for bile duct stones reported by Ersoz *et al*[8] in 2003. The results of this multicenter prospective study are similar to those of existing reports[8-22]. We think, on the basis of our results, that this maneuver is effective and safe. Ordinary EPBD employs balloons 4-10 mm in diameter for papillary dilation, whereas EPLBD is performed using balloons 12-20 mm in diameter. Before this procedure was reported, lithotomy of large stones or multiple stones was difficult without previous lithotripsy of the stones. This procedure allows a papillary aperture larger than that obtained with EPBD or EST (Figure 3A-C). The larger papillary aperture enables easy insertion of the device as well as lithotomy of stones with a diameter equal to that of the dilated balloon without requiring lithotripsy of the stones in many patients[21,24,25]; this is a great advantage because it shortens the procedure time[13]. Furthermore, even in patients who are difficult to treat, stones can be removed in one session and thus hospital stay of the patients is also shortened. Nevertheless, this does not mean that lithotripsy is not required in all the patients. In patients with strong flexion of the bile duct due to postoperative sequelae, it is difficult for the balloon to closely contact the bile duct, and dilation of the papilla may be insufficient because the balloon is longer than that used in ordinary EPBD. In such patients, lithotripsy may be needed, and even if dilation is achieved with the balloon, it may be probably necessary to physically crush the stones larger than the diameter of the balloon. In this study we even treated patients with Mirizzi syndrome type Ⅱ who were in a progressive state of the inflammatory process and presented pressure necrosis of the septum between the cystic and common hepatic ducts with intrusion of the stone into the common hepatic duct and a resultant cholecysto-choledochal fistula. In these patients it was difficult to insert not only the lithotripsy tool but also the balloon and basket to collect the stones at the hepatic side. Therefore, there may be a number of patients who require peroral cholangioscopic lithotripsy or radiographic ESWL after inserting the ENBD prior to the lithotomy.

Another advantage is the low rate of early adverse events[8-22], although there have previously been reports

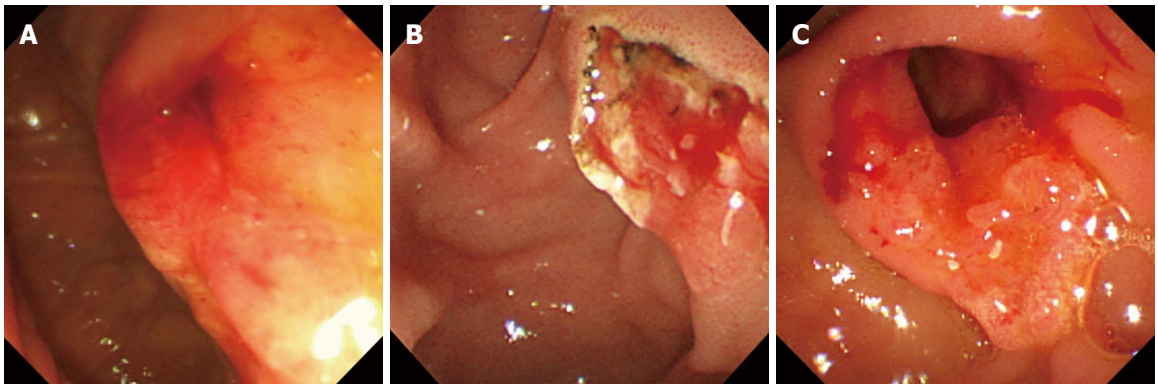

Figure 3 Duodenal papilla after endoscopic procedure. A: Papillary balloon dilation; B: The duodenal papilla after endoscopic sphincterotomy; C: The duodenal papilla after endoscopic papillary large balloon dilation.

Table 1 Results of endoscopic papillary large balloon dilation

Ref.	*n*	Study design	Mean stone size (range, mm)	Mean number of stones (range)	Success in first/final session (%)	Use of lithotripsy (%)
Ersoz *et al*[8]	58	Retrospective study	NA	NA	83/100	7
Minami *et al*[9]	88	Retrospective study	14 (NA)	2.5 (1-25)	99/99	1
Maydeo *et al*[10]	60	Retrospective study	16 (12-20)	1 (median 43%)	96	5
Heo *et al*[11]	100	Retrospective study	16 (NA)	2.7 (NA)	83/97	8
Attasaranya *et al*[12]	107	Retrospective study	13 (10-30)	NA	95/95	27
Itoi *et al*[13]	57	Retrospective study	15 (10-28)	3.2 (1-11)	96/100	6
Kim *et al*[14]	70	Retrospective study	13 (5-30)	NA	95/100	2
Kurita *et al*[15]	24	Retrospective study	17 (10-39)	NA	96/96	4
Kim *et al*[16]	72	Retrospective study	18 (11-25)	NA	88/97	8
Stefanidis *et al*[17]	45	RCT	17	NA	98/98	2
Kim *et al*[18]	139	Retrospective study	NA	NA	76/100	13
Itoi *et al*[19]	11	Retrospective study	14 (7-30)	5 (1-26)	100/100	18
Sakai *et al*[20]	59	Retrospective study	15 (10-28)	7.5 (1-30)	83/100	14
Teoh *et al*[21]	73	RCT	12.5 (5-35)	NA	89/97	29
Park *et al*[22]	946	Retrospective study	14.6 (12-20)	2.5 (1-15)	Final 97	22
Our study	124	Prospective study	14.0 (10-25)	3.9 (1-20)	86/100	14

EPLBD: Endoscopic papillary large balloon dilation; NA: Not available; RCT: Randomized controlled trial.

Table 2 Adverse events after endoscopic papillary large balloon dilation

Ref.	Complications	Bleeding	Pancreatitis	Perforation	Others
Ersoz *et al*[8]	16%	9%	3%	0%	3%
Minami *et al*[9]	6%	1%	1%	0%	4%
Maydeo *et al*[10]	8%	8%	0%	0%	0%
Heo *et al*[11]	8%	5%	4%	0%	0%
Attasaranya *et al*[12]	6%	2%	0%	1%	3%
Itoi *et al*[13]	2%	0%	1%	0%	1%
Kim *et al*[14]	2%	0%	2%	0%	0%
Kurita *et al*[15]	4%	0%	0%	0%	4%
Kim *et al*[16]	10%	0%	2%	0%	7%
Stefanidis *et al*[17]	4%	2%	2%	0%	0%
Kim *et al*[18]	7%	1%	6%	0%	0%
Itoi *et al*[19]	0%	0%	0%	0%	0%
Sakai *et al*[20]	7%	2%	0%	2%	3%
Teoh *et al*[21]	7%	1%	3%	0%	3%
Park *et al*[22]	10%	6%	3%	0.5%	0.5%
Our study	5%	2%	1%	0%	2%

of death due to the procedure[22]. In particular, when the treatment for large stones was carried out using EPLBD or ML, the incidence of cholangitis was reported to be significantly low in the EPLBD group[21]. The reason may be that in EPLBD, the papilla is markedly opened, thus small stones which cannot be confirmed by cholangi-

Table 3 Diameter of the balloon used

Balloon size	*n*	Percent
10-12 mm	40	32.3%
12-15 mm	61	49.2%
15-18 mm	20	16.1%
18-20 mm	3	2.4%

ography may be eliminated spontaneously. In addition, when ML is performed in patients who have undergone EST, although the papillary opening is incised, the opening is not as large as in EPLBD, thus the fragments resulting from lithotripsy or biliary sludge may cause bile stasis within the bile duct and will likely cause cholangitis. As for other adverse events, if there is no bleeding after EST, the risk of bleeding may be even less if the papilla and the endoscope are correctly positioned and the balloon is gradually dilated. However, according to past reports, liver cirrhosis, large incision at the time of papillary incision, and stones ≥ 16 mm are risk factors for bleeding[22]. As for pancreatitis, which is the most problematic adverse event after ERCP-related procedures, it is widely known that conventional EPBD is associated with a high incidence of pancreatitis[26]. Yet, in EPLBD, endoscopic sphincterotomy is performed first and after making a separate opening for the bile duct and pancreatic duct, dilation using the balloon is performed, thus the damage to the pancreatic duct is minor. Furthermore, since in lithotomy taking the treatment tools in and out is easy, damage to the papilla may also be small. Consequently, the incidence of pancreatitis in the past reports was low[8-22]. Although early adverse events may occur less frequently, the task hereafter will be to assess the long term prognosis including bile duct stone recurrence. Comparison of EPBD and EST revealed that recurrence rate after EPBD is significantly low[27]. The reason may be that the papillary sphincter muscle function is preserved and the possibility of retrograde infection is low. It is generally considered that in EPLBD the papillary sphincter muscle function is almost eliminated. If we consider only this factor, the stone recurrence rate would increase. Regarding the long term prognosis after EST, pneumobilia and lithotripsy are considered to be risk factors for stone recurrence[28]; however, in EPLBD the papillary opening is wider than in EST and the number of patients with pneumobilia may increase. Since the papillary opening is wider, the rate of lithotripsy can be decreased, leading to the possibility of spontaneous elimination of small stones or fragments from lithotripsy, thus an increase in recurrence rate is not always expected. Actually, Harada *et al*[29] reported that the stone recurrence rate after EPLBD was significantly lower than that after ML because the treatment is performed without lithotripsy. Hereinafter, it would be desirable to have reports of trials, including RCTs, on the long term prognosis after EPLBD.

In many reports EPLBD was performed for large stones or multiple stones after EST. In addition, recently there have been reports describing EPLBD performed on the site where a pre-cut was made in patients with difficulty in cannulation[30], or describing that the papilla was dilated using a large balloon without adding EST[31,32]. According to the latter reports, the incidence of pancreatitis after ERCP without adding EST is not different from that when EST is added. Because the sample size is still small, it is necessary to carefully review the results before reaching a conclusion. However, such results can be expected because certainly there is papilledema caused by pancreatography or difficulties in cannulation other than direct papilledema caused by the balloon as the cause of pancreatitis after EPBD. However, the sample size is small; indeed, it is necessary to review these findings based on sufficient sample size. In this study we did not perform EPLBD in patients with a papillary lesion in the diverticulum or patients who had undergone Billroth-Ⅱ reconstruction; however, there are reports describing that it is possible to perform EPLBD in patients with a papillary lesion in the diverticulum[18], or Billroth-Ⅱ reconstruction[19].

There is no definite opinion regarding the tools used in EPLBD. Although the balloon used in this study was 5.5 cm in length, balloons of 4 cm in length[33] or 8 cm in length[1,20] have also been used and it is necessary to examine which length of the balloon is most appropriate. As for the time for papilla dilation, there is no definite opinion either[33]. It is necessary to further review EPLBD in order to perform the procedure more safely and efficiently.

In conclusion, we consider that performing large balloon dilation after EST in patients with large stones or multiple stones in the bile duct ensures the safety of treatment and reduces the need for lithotripsy.

COMMENTS

Background

Endoscopic papillary large balloon dilation (EPLBD) for large or multiple stones after performing endoscopic sphincterotomy (EST) has been previously reported. However, many of those reports correspond to retrospective studies in a single facility. The authors have examined the usefulness of EPLBD for large stones or multiple stones in a multicenter prospective study.

Research frontiers

The results of EPLBD in patients with bile duct stones ≥ 13 mm at their shortest diameter or patients with three or more bile duct stones ≥ 10 mm at their shortest diameter were examined.

Innovations and breakthroughs

EPLBD for bile duct stones was reported by Ersoz *et al* in 2003. Recently, its indication has widened, and there have been reports describing EPLBD performed on the site where a pre-cut was made in patients with difficulty in cannulation, or describing that the papilla was dilated using a large balloon without adding EST. Hereinafter, it would be desirable to have reports of trials, including randomized controlled trials, on the long term prognosis.

Applications

In patients with large common bile duct stones, EST + EPLBD are a good alternative to conventional EST. Before this procedure was reported, lithotomy of large stones or multiple stones was difficult without lithotripsy of the stones. Compared with EST, this procedure has the advantage that a larger papillary aperture can be obtained. Furthermore, it may reduce treatment to one session even in patients who are difficult to treat and thereby shortens the hospital stay.

Terminology

Treatment by EPLBD, which is lithotomy without lithotripsy for large stones by

dilating the papilla using a large balloon, performed after EST, has been reported.

Peer review

Performing large balloon dilation after EST in patients with large stones or multiple stones in the bile duct is considered by the authors to ensure a safe treatment with less chance of lithotripsy. This paper could be a valuable reference for other researchers.

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