

## Retrospective Study

# Endoscopic papillary large balloon dilation for bile duct stones in elderly patients

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## Abstract

**AIM:** To investigate whether endoscopic papillary large balloon dilation (EPLBD) can be safely and effectively performed in patients aged  $\geq 80$  years.

**METHODS:** Lithotomy by EPLBD was conducted in 106 patients with bile duct stones  $\geq 13$  mm in size or with three or more bile duct stones  $\geq 10$  mm. The patients were divided into group A ( $< 80$  years) and group B ( $\geq 80$  years). Procedure success rate, number of endoscopic retrograde cholangiopancreatographies (ERCP), and incidence of complications were examined in both groups.

**RESULTS:** Group B tended to include significantly more patients with peripapillary diverticulum, hypertension, hyperlipemia, cerebrovascular disease/dementia, respiratory disease/cardiac disease, and patients administered an anticoagulant or antiplatelet agent ( $P < 0.05$ ). The success rate of the initial lithotomy was 88.7 (94/106)%. The final lithotomy rate was 100 (106/106)%. Complications due to treatment procedure occurred in 4.72 (5/106)% of the patients. There was no significant difference in procedure success rate, number of ERCP, or incidence of complications between group A and group B.

**CONCLUSION:** EPLBD can be safely performed in elderly patients, the same as in younger patients.

**Key words:** Elderly patients; Endoscopic papillary large balloon dilation; Endoscopic sphincterotomy; Large bile duct stones; Choledocholithiasis

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**Core tip:** Endoscopic treatment by papillary large balloon

dilation for large stones can be safely performed in elderly patients, the same as in younger patients.

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## INTRODUCTION

The number of elderly patients with common bile duct stones has been increasing associated with the global prolongation of life expectancy<sup>[1]</sup>. Endoscopic retrograde cholangiopancreatography (ERCP) has been recognized as a treatment with less risk and lower mortality than surgery<sup>[2]</sup>. Endoscopic treatment for choledocholithiasis should be attempted as the first choice of treatment because of its high success rate in addition to its low invasiveness and low incidence of complications<sup>[3]</sup>. Although a report indicated that ERCP related procedures may be hazardous for patients with common bile duct stones as well as in elderly patients aged  $\geq 80$  years<sup>[4]</sup>, it is often reported that this procedure can be useful and safely performed even in elderly patients<sup>[5-20]</sup>. The usefulness of endoscopic treatment using endoscopic papillary large balloon dilation (EPLBD) which is a new papillary treatment using a balloon of large diameter for large bile duct stones or multiple bile duct stones has been recently reported. Most of the reports described the procedure as safe and useful<sup>[20-34]</sup>. However, there have been some cases of death<sup>[35]</sup>. Since elderly patients often have an underlying disease, they may follow a fatal course, thus they require special attention<sup>[4]</sup>. There are few reports on the usefulness of this procedure in elderly patients<sup>[20]</sup>, and it has not been examined sufficiently. This report examined usefulness of EPLBD in patients aged  $\geq 80$  years.

## MATERIALS AND METHODS

The study involved 106 patients (A) with bile duct stones  $\geq 13$  mm in their short diameter, or (B) multiple ( $\geq 3$ ) bile duct stones with the smallest more than 10 mm in the shortest diameter, but without confluence stones. These patients were selected from among those with bile duct stones visiting our hospital or our affiliated hospitals from November 2009 to June 2014. Inclusion criteria were patients who could undergo endoscopic sphincterotomy (EST), and who gave their informed consent to the procedure. Exclusion criteria were coagulopathy (international normalized ratio  $> 1.5$ ), marked thrombocytopenia

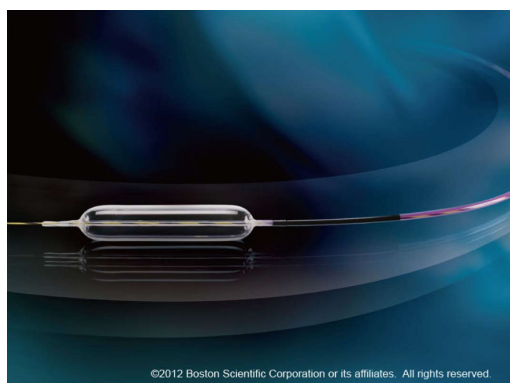
(platelet count  $< 50000/\text{mL}$ ), patients who could not discontinue the administration of an anticoagulant or antiplatelet agent, patients for whom endoscopic biliary drainage was difficult (Billroth-II or Roux-en-Y), patients with the papilla within the diverticulum, patients with stenosis of the intrapancreatic bile duct, stone diameter  $> 30$  mm (shortest diameter), and patients who do not give their informed consent.

We selected 79 patients with new bile duct stones and 27 with recurrent stones. All cases of recurrent stones were those after EST. We performed EST in 65 patients and it had been already performed in 41 patients. Fourteen patients whose stones were not recurrent and EST had been already performed were difficult cases referred to our hospital for a lithotomy. The average diameter of the stones was 14.29 (10-28) mm, the number of stones was 5.73 (1-30) and the diameter of the bile duct was 16.97 (10-28) mm. As for the gall bladder, 77 patients were calculous, one was acalculous and 28 had undergone cholecystectomy. Parapapillary diverticulum was noted in 50 patients. The patients were divided into group A ( $< 80$  years) and group B ( $\geq 80$  years). The clinical background of patients in these 2 groups is shown in Table 1. Patients in group B tended to have significantly more frequently peripapillary diverticulum, hypertension, hyperlipemia, cerebrovascular disease/dementia, respiratory/cardiac disease, or were taking an anticoagulant or antiplatelet agent. There was no significant difference in other factors between group A and group B. One session of treatment lasted up to 60 min after inserting the endoscope. The condition of the patients was observed, and if the patient showed much discomfort, the procedure was completed after inserting the drainage, even while in the process of treatment. Before ERCP, all patients were given a standard premedication consisting of intravenous administration of midazolam (3 to 10 mg), and the dose depended on age and tolerance. Scopolamine butylbromide or glucagon was used for duodenal relaxation. During ERCP, arterial oxygen saturation was continuously monitored using a pulse oximeter. Patients were kept fasting after the procedure for at least 24 h with drip infusion of 2000 mL and remained hospitalized for at least 72 h. For cannulation, catheters PR-104Q, R110Q-1 and PR233Q were used. A 0.025-inch or 0.035-inch guidewire (Jagwire: Microvasive, Boston Scientific Corp., Natick, MA; Revo Wave: PIOLAX, or VisiGlide: Olympus Corp.) was used. The endoscopes used were JF240, JF260V, TJF260V (Olympus Corp.), backward side-viewing endoscope, for patients with no history of gastric resection and patients of Billroth-I. After cholangiography, a guidewire was placed in the bile duct to conduct EST. Clever-Cut3V (Olympus Corp.) was used as the knife for EST. EST was conducted using a single electrosurgical current generator (PSD-20, Olympus Corp.) at a power of 25 watts. For those in which an incision had been already

Table 1 Patient background

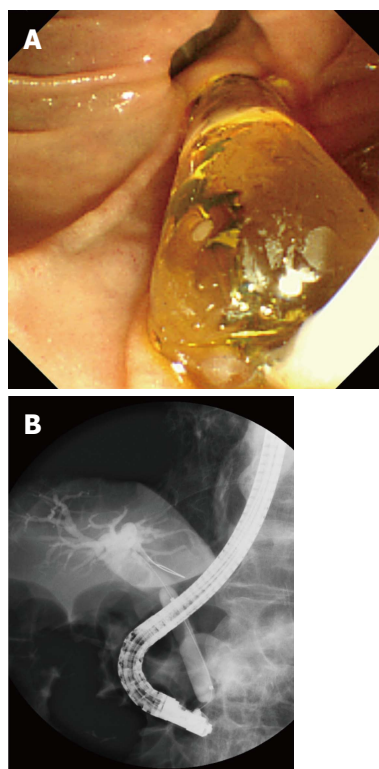
	< 80 yr old (Group A)	≥ 80 yr old (Group B)	P-value
Number of patients	59	47	
Male	36	20	NS
Female	23	27	NS
Choledocholith			
Number of stones	5.24 ± 5.52 (1-30)	6.44 ± 6.98 (1-25)	NS
Stone diameter (mm)	14.03 ± 3.00 (10-28)	14.52 ± 4.48 (10-25)	NS
Common bile duct diameter (mm)	16.62 ± 3.52 (10-28)	17.44 ± 3.93 (10-25)	NS
Gallbladder			
Calculous	43	34	NS
Acalculous	0	1	NS
Cholecystectomy	15	13	NS
Primary case	43	36	NS
Recurrence	17	10	NS
Endoscopic sphincterotomy	36	29	NS
Post endoscopic sphincterotomy	23	18	NS
Diverticulum	15	35	< 0.05
Hypertension	23	37	< 0.05
Hyperlipidemia	9	21	< 0.05
Diabetes mellitus	10	8	NS
Chronic respiratory disease	0	5	< 0.05
Cardiac disease	8	18	< 0.05
Chronic liver disease	1	0	NS
Chronic kidney disease	2	3	< 0.05
Anticoagulant/antiplatelet	9	23	< 0.05

NS: Not significant.



**Figure 1 Endoscopic papillary large balloon dilation.** CRE 12-20 mm (Wire-guided type 5.5 cm, Boston Scientific Corp., Natick, MA).

made, a guidewire was placed in the bile duct after cholangiography to perform EPLBD. In performing EPLBD, CRE 12-20 mm (Fixed wire type 8 cm or Wire-guided type 5.5 cm: Boston Scientific Corp.) was used depending on the diameter of the bile duct (Figure 1). For balloon dilation, a contrast agent mixed with saline solution at a volume ratio of 1:1 was used to slowly inflate it. Inflation was performed until the notch on the balloon disappeared (Figure 2). However, regardless of the disappearance of the notch, 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



**Figure 2 The papilla.** 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).

deflated. When we considered it necessary to perform lithotripsy of the stone, we did it without hesitation.

The basket catheter used for lithotripsy was LBGT-7245S (ZEON Medical) or BML-V237QR-30 (Olympus Corp.). Peroral cholangioscopy (POCSL) was performed by mother-baby system using CHF-B260 (Olympus Corp.) as the cholangioscope and Autholith (Northgate) as the electrohydraulic lithotripsy probe. The basket catheter used for collecting stones was FG-22Q or FG-V416Q (Olympus Corp.), LBGT-7245S (ZEON Medical) or BML-V237QR-30 (Olympus Corp.). The balloon catheter used was EXP718200 (ZEON Medical) or FS-QEB-XL-B (COOK). No drainage tube was inserted when lithotomy was successful, while it was inserted when we thought a stone still remained.

Iatrogenic morbidity was assessed according to the criteria of Cotton *et al.*<sup>[36]</sup>. The observation period was 30 d after the procedure and any coincidental event noted during the period was considered as an early coincidental event. All the treatment procedures were performed after obtaining the informed consent from the patients in writing. This study was conducted after the study protocol was approved by the ethics committee of Chiba University.

### Statistical analysis

Pearson  $\chi^2$  test with Yates correction and Fisher's exact test, when appropriate, were used for statistical analysis of categorical variables. Data were analyzed using SPSS software version 11 (SPSS, Chicago, IL). Differences with a *P* value of < 0.05 were considered statistically significant.

## RESULTS

The success rate of lithotomy in the initial treatment was 88.7 (94/106)%. The final lithotomy rate was 100 (106/106)%. The time necessary to perform lithotomy was 39.4 (10-128) min and the mean treatment frequency was 1.21 (1-4) times. Lithotripsy was needed in 11.3 (12/106)% of the patients. Among the patients requiring lithotripsy, 6 had a highly tortuous bile duct and 6 had significantly large bile duct stones. For lithotripsy, endoscopic mechanical lithotripsy was performed in 10 patients and POCSL in 2. Complications due to the treatment procedure were observed in 4.7 (5/106)% of the patients, including bleeding in 1.9 (2/106)%, perforation in 0.9 (1/106)%, pneumonia in 0.9 (1/106)%, and acute cholangitis in 0.9 (1/106)%. Patients were classified into group A or group B for the analysis of data (Tables 2 and 3). The lithotomy success rate was 88.1 (52/59)% in group A, and 89.4 (42/47)% in group B and that for final lithotomy was 100%, both in group A (59/59)% and in group B (47/47). The lithotripsy rate was 10.2 (6/59)% in group A, and 12.8 (6/47)% in group B. Operation time was  $37.59 \pm 26.94$  (12-125) min in group A, and  $42.02 \pm 27.12$  (10-128) min in group B. The number of ERCP was  $1.24 \pm 0.683$  (1-4) in group A, and  $1.17 \pm 0.529$  (1-4) in group B. The incidence

of complications was 6.8 (4/59)% in group A and 2.1 (1/47)% in group B, and there was no significant difference between group A and group B, regarding other parameters.

## DISCUSSION

This study showed that elderly patients aged  $\geq 80$  years often have underlying diseases, however, results of treatment for large bile duct stones or multiple bile duct stones using EPLBD lithotomy were equivalent to those aged < 80 years in terms of success rate, lithotripsy rate, procedure time, number of ERCP, and complications caused by the procedure. EPLBD is the endoscopic treatment for bile duct stones reported by Ersoz *et al.*<sup>[21]</sup> in 2003. Recently, the reports on the results of treatment for choledocholithiasis using EPLBD have been increasing<sup>[20-35]</sup>. Ordinary endoscopic papillary balloon dilation (EPBD) employs a balloon 4-10 mm in diameter for papillary dilation, whereas EPLBD is performed using a balloon 12-20 mm in diameter. Before this procedure was reported, lithotomy of large bile duct stones or multiple bile duct stones was difficult without lithotripsy of the stone. This procedure has the advantage that compared with EPBD or EST a larger papillary aperture can be obtained. It is reported in randomized controlled trials and meta-analyses that the larger papillary aperture enables easy insertion of the device as well as lithotomy of stones the same size as that of the dilated balloon without lithotripsy of the stones in many patients<sup>[34,37,38]</sup>, which may be advantageous because the duration of the procedure would be shortened<sup>[26]</sup>. In this study many patients were cured after one session of treatment. There are many reports describing that in the nature of things, elderly patients have many underlying diseases, whereas the comparison of patients aged 80 years or greater with those aged less than 80 years showed the similar tendency<sup>[11,19]</sup>. Shorter treatment time is naturally an advantage even in young patients, and this study confirmed that a shorter treatment time was desirable for elderly patients because many of them have underlying diseases such as respiratory disease. Shorter treatment time is beneficial for elderly patients. There was no difference in the success rate of the procedure itself, however, many patients aged  $\geq 80$  years have peripapillary diverticulum according to a past report<sup>[19]</sup>, and this study also showed elderly patients tended to develop it, thus when performing the procedure, it may be necessary to pay attention to perforation. The presence of peripapillary diverticulum may cause deviation of the course of the bile duct leading to difficulty in cannulation<sup>[39]</sup>. However, this study revealed that there was no difference in the success rate of the procedure between the two groups. The reason may be due to recent advancement of the endoscope and its related treatment instruments. In this study, EPLBD was performed after EST. There are past reports describing

**Table 2** Lithotomy by endoscopic papillary large balloon dilation

ERCP procedures	< 80 yr old (Group A; n = 59)	≥ 80 yr old (Group B; n = 47)	P-value
Lithotomy success rate			
Initial	52 (88.1%)	42 (89.4%)	NS
Final	59 (100%)	47 (100%)	NS
Lithotripsy	6 (10.2%)	6 (12.8%)	NS
Procedure time: min	37.59 ± 26.94 (12-125)	42.02 ± 27.12 (10-128)	NS
Number of ERCP	1.24 ± 0.683 (1-4)	1.17 ± 0.529 (1-4)	NS

ERCP: Endoscopic retrograde cholangiopancreatography; NS: Not significant.

that it is possible to safely perform EPLBD without performing EST<sup>[35]</sup>. According to this study many elderly patients not only have peripapillary diverticulum but also are taking an anticoagulant or antiplatelet agent, thus if it were possible to safely perform EPLBD without performing EST, the procedure time would be shortened even further and the risk of perforation or bleeding would also be reduced.

Although a shorter procedure time and success of the procedure are very important for elderly patients, a low rate of complications derived from the procedure is also required. Past reports showed that complications caused by this procedure occurred at a low rate<sup>[20-35]</sup>. In the present study, complications occurred at a low rate and there was no difference between the two groups, suggesting it is possible to safely perform EPLBD even in elderly patients. The most problematic complications among ERCP related procedures is pancreatitis. Although it is reported that pancreatitis is less likely to occur in elderly patients because of their reduced pancreatic function<sup>[40]</sup>, this study revealed there were no such results at all, suggesting that safety of the procedure is not only ensured for elderly patients but also that of the procedure itself is ensured. Reports describing usefulness and safety of EPLBD in elderly patients are currently limited to retrospective studies, thus a prospective study is necessary to confirm our findings.

EPLBD can be safely performed in elderly patients the same as in younger patients.

## COMMENTS

### Background

The usefulness of endoscopic treatment using endoscopic papillary large balloon dilation (EPLBD), which is a new papillary treatment using a large diameter balloon for large bile duct stones or multiple bile duct stones has been recently reported. Most of the reports have described this procedure is safe and useful. However, there are some cases of death. Since elderly patients are often complicated with underlying diseases, they may follow a fatal course after EPLBD, thus they require special attention. There are only a few reports on the usefulness of this procedure in elderly patients, and sufficient examination has not been conducted. This report examined the usefulness of EPLBD in patients aged ≥ 80 years.

### Research frontiers

The results of EPLBD in patients with bile duct stones ≥ 13 mm in their short diameter or patients with three or more bile duct stones ≥ 10 mm in their short

**Table 3** Complications after endoscopic papillary large balloon dilation

Related complications	< 80 yr old (Group A; n = 59)	≥ 80 yr old (Group B; n = 47)	P-value
Pancreatitis	0	0	
Perforation	1 (mild)	0	NS
Bleeding	2 (mild)	0	NS
Cholangitis	0	1 (mild)	NS
Cholecystitis	0	0	
Others	1	0	NS
Total	4	1	NS

NS: Not significant.

diameter were examined.

### Innovations and breakthroughs

EPLBD for bile duct stones was reported by Ersoz *et al* in 2003. Recently, its indication has widened. The reports describing the usefulness and safety of EPLBD in elderly patients are currently limited to retrospective studies. A prospective study is necessary to confirm our findings.

### Applications

In patients with large common bile duct stones, endoscopic sphincterotomy (EST) + EPLBD is 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. Endoscopic treatment by papillary large balloon dilation can be safely performed in elderly patients the same as in younger patients.

### Terminology

Treatment by EPLBD, which is lithotomy without lithotripsy for large stones by dilating the papilla using a large balloon, after performing EST has been reported. Endoscopic treatment by papillary large balloon dilation can be safely performed in elderly patients the same as in younger patients.

### Peer-review

This is a retrospective study evaluating whether EPLBD can be safely and effectively performed in elderly patients. This study may be of interest to the readers.

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