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Endoscopic papillary large-balloon dilation with sphincterotomy for difficult common bile duct stones ≤12 mm: a prospective study

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Abstract

Background Stone recurrence is a significant complication following endoscopic bile duct clearance. Endoscopic papillary large-balloon dilation (EPLBD) with biliary sphincterotomy (EBS) has shown satisfactory results in preventing recurrence of "large" common bile duct stones (CBDS). However, data on outcomes after EPLBD+EBS for CBDS ≤12 mm remain scarce. The present study prospectively evaluated the mid- and long-term efficacy of EPLBD+EBS for CBDS recurrence among this group of patients.

Methods Consecutive patients with CBDS ranging from 8-12 mm, treated with EPLBD+EBS from June 2018 through June 2020, were prospectively followed-up for at least 36 months. CBDS recurrence was defined as recurrent stones confirmed by endoscopic retrograde cholangiopancreatography (ERCP) during the follow-up period.

Results Overall, 72 patients (mean age: 67 years, 52.8% male) were included, of whom 22 (30.5%) had multiple (≥3) CBDS, 23 (31.9%) had a history of cholecystectomy, 13 (18.1%) had a periampullary diverticulum and 22 (30.5%) had a previous EBS. The mean CBD diameter was 11.6±1 mm, while a tapered duct was noted in 7 (9.7%). Post-procedural bleeding and cholangitis occurred in 1 and 2 cases respectively. No cases of perforation and post-ERCP pancreatitis were observed. During a mean follow up of 46.4±6.2 months (range 37-60), no mid-term recurrence was observed, whereas CBDS recurred in 2/72 (2.7%) in the long term.

Conclusions EPLBD+EBS in patients with CBDS ≤12 mm was associated with a very low rate of mid- and long-term CBDS recurrence. Our results need to be further investigated with randomized controlled trials.

Keywords Balloon dilation, bile duct stones

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Introduction

It has been 2 decades since Ersoz *et al* [1] pioneered the use of endoscopic papillary large-balloon dilation (EPLBD) along with endoscopic biliary sphincterotomy (EBS) in order to widen the pre-papillary portion of the common bile duct (CBD) and facilitate the extraction of CBD stones (CBDS). Since then, the existing literature and endoscopic societies recommend the combination of EBS with EPLBD for "difficult" CBDS, or when the stone extraction is considered challenging because of the anatomy of the papilla and the distal CBD [2,3]. Accumulating evidence has confirmed EPLBD+EBS as an effective and safe endoscopic approach in patients with difficult-to-treat CBDS, including cases with large or multiple stones, and tortuosity or tapering of the distal CBD [4-8]. Acute complications of this technique are rare and can be managed conservatively in most cases [9].

CBDS recurrence constitutes a significant long-term complication following endoscopic bile duct clearance,

affecting both the patient and healthcare expenditures. Even after complete clearance of the CBD, recurrent CBDS are not rare, and recurrence rates of 17% have been reported after EBS [10]. The risk of stone recurrence after endoscopic extraction sharply increases to 23.4% after a first recurrence and 33.4% after a second recurrence [11,12]. Repeated ERCPs significantly increase the risk of intervention and prolong hospitalization stays. However, it remains unclear which technique is useful for the prevention of CBDS recurrence.

Previous studies have demonstrated a significantly lower rate of recurrence for "large" CBDS treated with EPLBD+EBS compared with EBS alone [13-16]. Although EBS is very effective for the endoscopic treatment of "non-large" CBDS, it remains unclear whether EPLBD could reduce the recurrence rate in this group of patients. We hypothesized that EPLBD might be associated with a lower rate of CBDS recurrence than conventional treatment; however, data have never been reported. In this study, we conducted a prospective trial to evaluate the mid- and long-term effects of EPLBD+EBS for CBDS sized ≤12 mm. The primary aim was to evaluate the CBDS recurrence rate in patients followed for a minimum duration of 3 years. Secondary outcomes included the recurrence time and ERCP-related adverse events.

Patients and methods

Patients

This observational, prospective study was conducted in Venizeleion General Hospital (Heraklion-Crete, Greece) from June 2018 through June 2020. We included consecutive patients with CBDS ranging from 8-12 mm successfully treated with EPLBD+EBS and followed-up for at least 36 months. The inclusion criteria for the study were patients with CBDS sized 8-12 mm (transverse diameter) that were difficult to remove based on cholangiographic findings: tapered distal bile duct [17], bile duct narrowing distal to the stone, stone impaction, CBD morphology of S type [18], multiple and/or unusually shaped stones. A tapered distal bile duct was defined when the lower part of the biliary tract was <8 mm in diameter and >15 mm in length, measured by cholangiography [17]. Exclusion criteria included the following: (i) unrecognized CBDS on cholangiogram; (ii) need for needle knife pre-cutting; (iii) selective bile duct cannulation achieved after more than 2 accidental pancreatograms or more than 5 insertions of the guidewire in the pancreatic duct; (iv) benign or malignant CBD stricture; (v) presence of intrahepatic bile duct stones; (vi) coagulopathy with international normalized ratio >1.3 or platelets <50,000/μL; (vii) prior gastrointestinal reconstruction surgery, such as Billroth II and Roux-en-Y; (viii) hemodynamic instability; and (ix) life expectancy ≤3 years. For each patient, baseline data collected at the time of the EPLBD+EBS procedure included age and sex, diameter of the largest CBD stone, number of stones, CBD diameter, history of cholecystectomy, the American Society of Anesthesiologists (ASA) score, presence of periampullary diverticulum, history of previous EBS and presence of a tapered or S-type duct. The study protocol was approved by the local Institutional Review Board and registered with ClinicalTrials.gov (NCT05191693). All the patients signed a written consent form for the endoscopic procedures and the extended follow up.

Endoscopic procedures

After deep bile duct cannulation, an initial cholangiogram was obtained to confirm the diagnosis of CBDS and assess CBD morphology. The CBD diameter and the diameter of the largest stone were measured on the fluoroscopic image using electronic calipers. ELPBD was attempted if CBDS met the inclusion criteria and there was no contraindication. A guidewire was passed into the CBD and all patients underwent EBS, limited to one-third of the distance to the papillary roof. A generator with an automatically controlled cutout system (Endocut mode, ICC200, Erbe Elektromedizin GmbH, Tubingen, Germany) was used. In cases with previous sphincterotomy, minor EBS toward the 11 o'clock position was performed to adjust the direction of papilla tearing before balloon dilation. ELPBD was performed using a wire-guided dilating balloon (CRE Esophageal/Pyloric, maximum diameter 12 or 15 mm, Boston Scientific, Marlborough, MA) placed across the papilla orifice. The size of the balloon was chosen according to the diameter of the stone and did not exceed the diameter of the distal CBD. The balloon was then filled gradually with diluted contrast medium under endoscopic and fluoroscopic guidance to observe the gradual disappearance of the waist in the balloon. Once the waist disappeared, the balloon remained inflated for 30 sec [19]. In cases where the waist had not completely disappeared, we terminated the procedure without the full disappearance of the waist. The CBDS were then retrieved with a basket, balloon, or a combination. Complete stone removal was defined as the absence of any filling defect during a final occlusion cholangiogram. All ERCP procedures were performed using side-viewing endoscopes (TJF-160 or 190; Olympus Optical, Tokyo, Japan), under deep propofol sedation provided by an anaesthetist, and were carried out by 2 experienced pancreaticobiliary endoscopists (GP and EV; each one with experience of >1000 ERCPs at the initiation of the study).

The blood amylase and blood routine of each patient were monitored 6 h after ERCP and the morning after the procedure. Complications and clinical outcomes were evaluated according to the standards established by Cotton [20], as follows:

(a) bleeding: clinical evidence of bleeding, such as melena or hematemesis, with an associated decrease of at least 2 g/dL in haemoglobin concentration or the need for a blood transfusion;
(b) post-ERCP pancreatitis (PEP): persistent epigastric pain for >24 h with a more than 3-fold elevation in serum amylase levels after the procedure;
(c) cholangitis: fever >38°C >24 h and liver biochemistry suggestive of biliary obstruction.

Long-term follow up

Following endoscopic bile duct clearance, all patients were included in an extended follow-up protocol in order to investigate the early (<15 days), mid-term (<1 year), and long-term (1-3 years) post-procedure outcomes. They were prospectively followed-up with regular appointments in the outpatient clinics (scheduled at 6-month intervals) to assess the occurrence of biliary events. The follow-up assessment involved laboratory analysis for all patients, along with imaging for symptomatic individuals or those manifesting abnormal laboratory results. Data were analyzed until July 2023 and no patient was lost to follow up. An ERCP was performed in those who became symptomatic during the follow-up period (cholangitis, jaundice) and in whom the presence of CBDS was confirmed on laboratory and imaging studies. To exclude retained stones, recurrent CBDS were defined as those detected more than 6 months following index ERCP with complete duct clearance. The dates of CBDS recurrence were defined as the date on which an imaging test produced evidence of CBDS, (including abdominal ultrasound, computerized tomography, magnetic resonance cholangiopancreatography, or endoscopic ultrasound).

Statistical analysis

Categorical data are expressed as percentages, whereas continuous data are reported as means with standard deviation. Categorical variables were compared using the corrected χ^2 or 2-sided Fisher's exact test. Continuous data were compared with unpaired Student's *t* or Mann-Whitney *U* tests, as appropriate. Time-to-recurrence analysis was conducted by the Kaplan-Meier method. The statistical analyses were performed using SPSS statistics version 22 (SPSS, IBM, Chicago, IL, USA). All analyses were 2-sided and P-values <0.05 were considered statistically significant.

Results

Overall, 72 consecutive patients met the eligibility criteria (mean age: 67 years, 52.8% male) and were included in the study. Multiple CBDS (≥3) were observed in 22 patients (30.5%), 23 patients (31.9%) had a history of cholecystectomy, 13 (18.1%) had a periampullary diverticulum, and 22 (30.5%) had a previous EBS. CBDS measuring 10-12 mm were identified in 48.6% of the patient cohort (35 of 72 individuals). Additionally, in terms of CBD diameter, 70 of 72 patients demonstrated a diameter of ≥10 mm. The mean CBD diameter was 11.6±1 mm, while a tapered CBD was noted in 7 (9.7%) and S-type in 5 cases (6.9%). In 5 cases (6.9%) the balloon waist did not completely disappear during balloon inflation and the dilation was terminated. Complete stone clearance was achieved in all cases. ERCP-related bleeding occurred in 1 case, successfully treated with a fully covered self-expandable metal stent. Mild cholangitis occurred in 2 cases and both were treated with antibiotics without complications. No cases of perforation or PEP were observed.

During a mean follow up of 46.4±6.2 months (range 37-60), CBDS recurred in 2/72 (2.7%). Recurrences were observed during the 33rd and 36th month of the follow-up period, and both patients presented with cholangitis. The time-to-recurrence Kaplan-Meier curve is presented in Fig. 1. The mean time to recurrence was 59.3 months (95% confidence interval 58.3-60.3). Recurrent CBDS were sized <10 mm and they were easily removed with a balloon catheter, without the need for an additional EBS or EPLBD. Both cases had a tapered CBD. The baseline characteristics in the recurrence and non-recurrence groups are shown in Table 1. The presence of a tapered CBD was associated with stone recurrence (P=0.008). Given that the number of recurrent events was only 2, no further analyses (univariate or multivariate) could be performed.

Discussion

In this prospective study of patients with CBDS ≤12 mm treated with EPLBD+EBS, we found an overall recurrence rate of 2.7% within a minimum follow-up duration of 3 years. No episodes of mid-term recurrence occurred, and long-term recurrence was observed during the 3rd year of the follow-up period. ERCP-related bleeding and cholangitis incidence rates were 1.3% and 2.7%, respectively, while no cases of perforation or PEP were noted.

The available knowledge about the role of EPLBD+EBS in preventing CBDS recurrence has focused on "large" stones. Data on mid- and long-term recurrence rates after EPLBD+EBS for "non-large" CBDS remain limited, since the latter are routinely removed with EBS. This report is the first study to examine the recurrence rate for "non-large" stones that were treated with EPLBD+EBS because of risk factors predicting difficult endoscopic extraction. There is no consensus in the literature regarding the definition of a "large" stone: most authors use a cutoff between 10 and 15 mm [21]. Based on this heterogeneity, "non-large" stones in this study were defined as those with a maximal diameter of 12 mm. The minimum diameter was defined to be 8 mm.

Compared with EBS alone, EPLBD can result in a larger papillary orifice. The distal CBD can also be dilated. Therefore,

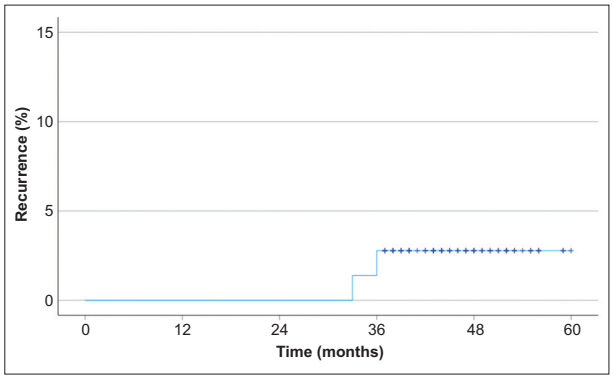

Figure 1 Kaplan-Meier time-to-recurrence curve

Table 1 Baseline characteristics compared between the recurrence and non-recurrence groups

Characteristics	Patients without recurrence (n=70)	Patients with recurrence (n=2)	P-value
Age, years	67.21±15.27	59.5±10.67	0.5
Male sex	38	0	0.2
Periampullary diverticulum	13	0	>0.99
Largest bile duct stone size, mm	9.63±1.01	9.50±0.70	0.9
Mean number of stones	2.46±2.01	3.0±1.41	0.7
Prior sphincterotomy	22	0	>0.99
Size of common bile duct, mm	11.57±1.09	12.50±0.70	0.3
Disappearance of the waist	65	2	>0.99
Tapered duct	5	2	0.008
S type duct	4	1	0.1
Cholecystectomy	23	0	>0.99
American Society of Anesthesiologists score			0.2
I	20	0	
II	45	1	
III	5	1	
IV	0	0	

EPLBD facilitates the extraction of large CBDS, as shown in previous studies [22,23]. The combined technique of EPLBD+EBS cuts the intramural portion of the sphincter of Oddi to shorten the stone extraction tunnel, while also dilating the ductal portion of the distal CBD, maximizing the papillary opening [24]. In the present study, the controlled radial expansion balloon used had a length of 5 cm, of which approximately half was positioned in the distal CBD. Thus, part of the terminal and distal CBD could be dilated simultaneously. The success rate of stone removal was 100%. There were no overt perforations at the level of the papilla, which suggests that the initial sphincterotomy incision, followed by the stretching of the forcible dilation, is a safe way to provide the largest exit route for stones. Moreover, in 5 cases where the disappearance of the waist needed marginally increased pressure—which would, however, exceed the diameter of the distal CBD—we terminated the procedure. Although the question of whether it is risky to inflate the balloon beyond the level of the distal CBD remains legitimate [17], we are in line with most scientific societies, which recommend that the maximal inflated diameter of the balloon should not exceed the diameter of the distal CBD, to prevent the risk of perforation due to balloon over-inflation [2,6].

Another important safety consideration in the current study is the absence of PEP. We suppose that the initial separation of the bile- and pancreatic-duct orifices by the EBS may allow dilating forces to be exerted without injuring the pancreatic component of the sphincteric complex. This finding is consistent with previous meta-analyses that demonstrated no significant differences in the rate of PEP between EPLBD+EBS and EBS [25-27]. Apart from ERCP-related pancreatitis, EPLBD+EBS tended to be superior to EBS in terms of the risk of bleeding or perforation [27].

We found no mid-term recurrence events, while the overall long-term risk of recurrent CBDS was 2.7%. Many earlier studies have investigated CBDS recurrence among patients who underwent ERCP with EBS. An Australian retrospective study with 573 cases reported a recurrence rate of 8.9%, with a mean time to recurrence of 3.3 years [28]. Two decades ago, Costamagna *et al* demonstrated a recurrence rate of 11.1% among 458 patients treated with EBS; 65% of recurrence episodes were observed more than 2 years after the index ERCP [29]. A similar study included 614 cases with a mean stone diameter of 9.7 mm. The recurrence rate was found to be 19% over a mean follow-up duration of 3.3 years [30]. In a recent retrospective study from Japan, Takimoto *et al* investigated the relation between EBS incision size and CBDS recurrence, enrolling 243 cases with a mean stone diameter <10 mm. Recurrence episodes were observed in 13.6% of all patients [10]. Although the present study cannot be compared precisely to the previous investigations, since CBDS were treated with EPLBD+EBS rather than EBS alone, our recurrence rate was significantly lower than the above-mentioned rates, including those for CBDS <10 mm.

On the other hand, EPLBD+EBS has been employed to reduce the recurrence rate of CBDS >10 mm with satisfactory results. We have previously shown, with prospectively collected data, that EPLBD+EBS is associated with a low rate of long-term CBDS recurrence in patients with CBDS ≥12 mm [31]. Similarly, earlier reported investigations demonstrated a significantly lower rate of mid- and long-term recurrence for CBDS >10 mm, while EPLBD was recently shown to reduce the risk of further recurrence in patients with recurrent CBDS [13-16].

This study implicated a tapered duct as a potential risk factor for recurrence. No significance was found for other parameters that have been reported as risk factors, such as the presence of periampullary diverticulum. Although the recurrent patients were only 2, this finding might be attributable to the fact that the bile flow, as happens with the angle of CBD, may be inversely proportional to the distal CBD diameter. The prolonged biliary drainage time might

cause bile concentration, thus leading to the increase of cholesterol saturation and the decrease of bile duct systolic function, creating conditions for the recurrence of CBDS [32].

There were several limitations to our study. First, it was a single-center study; therefore, the results cannot be generalized. However, the patients were followed-up continuously in outpatient clinics or via regular phone appointments, minimizing the possibility of underestimating the cases of recurrent CBDS requiring treatment. Second, decisions whether to perform EPLBD relied on the subjective judgement of the treating endoscopist, which may have introduced bias. Third, the present study was not randomized. Despite the fact that our results showed that EPLBD+EBS might result in a lower recurrence for CBDS ≤12 mm, we do not suggest that patients should routinely undergo EPLBD to prevent CBDS recurrence. However, examining whether EPLBD+EBS could be used as an initial approach, rather than after a failed conventional extraction, is an extremely important issue, since, in terms of safety, EPLBD+EBS appears to be at least as safe as EBS. While acknowledging the higher cost associated with EPLBD+EBS compared to EBS alone, we posit that the reduction in stone recurrence rates, leading to fewer hospitalizations due to a need for repeat ERCP, could justify the expenditure and be ultimately cost-effective.

In conclusion, EPLBD+EBS was a safe and effective method for the extraction of CBDS ≤12 mm, while the mid- and long-term follow up showed that CBDS recurrence was very low and easily treated endoscopically. The results of our current study deserve to be further investigated by large randomized controlled studies, to better define the best approach for avoiding CBDS recurrence.

Summary Box

What is already known:

- Stone recurrence is a significant complication following endoscopic bile duct clearance
- Endoscopic papillary large-balloon dilation (EPLBD) with biliary sphincterotomy (EBS) has shown satisfactory results in preventing recurrence for "large" common bile duct stones (CBDS)
- Accumulating evidence has confirmed EPLBD+EBS as an effective and safe endoscopic approach in patients with difficult-to-treat CBDS

What the new findings are:

- EPLBD+EBS in patients with CBDS ≤12 mm was associated with a very low rate of mid- and long-term recurrence
- The long-term recurrence rate observed in the current study was lower than the recurrence rates reported in the literature following EBS alone
- EPLBD+EBS was a safe and effective method for the extraction of CBDS ≤12 mm

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