

## Endoscopic papillary balloon dilation for bile duct stones in patients on hemodialysis

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### Abstract

**Background** Endoscopic papillary balloon dilation (EPBD) is a less hazardous alternative to endoscopic sphincterotomy for managing bile duct stones in patients with a coagulopathy. However, little information on EPBD is available for patients with bile duct stones who are undergoing hemodialysis (HD). We aimed to evaluate the safety and efficacy of EPBD for such patients.

**Patients** This was a retrospective cohort study with prospectively collected data for 37 consecutive patients with bile duct stones who were undergoing HD and who also underwent EPBD between December 1995 and April 2010 at four institutions in Tokyo, Japan. The main outcome was the safety and efficacy of EPBD for managing bile duct stones in patients undergoing HD.

**Results** The bile duct stones were completely removed in one session in 24 patients (64.8%). Overall success was achieved using EPBD alone in all patients. Complications occurred in five patients (13.5%), including two with hemorrhage (5.4%). No hemorrhage developed in any of the 33 patients who had no additional bleeding risk except for HD. Pancreatitis and perforation developed in two (5.4%) and one (2.7%) patient, respectively.

**Conclusions** EPBD seems to be a safe and effective treatment to extract bile duct stones in patients undergoing HD. However, EPBD should be performed carefully in patients with additional bleeding risk factors, such as Child–Pugh class C liver cirrhosis and those taking anti-platelet agents at the time of EPBD.

**Keywords** Bile duct stone · Endoscopic retrograde cholangiopancreatography · Endoscopic papillary balloon dilation · Hemodialysis

### Abbreviations

HD Hemodialysis  
ERCP Endoscopic retrograde cholangiopancreatography  
EPBD Endoscopic papillary balloon dilation  
EST Endoscopic sphincterotomy

### Introduction

Gallstones are one of the most common and costly digestive conditions [1]. Bile duct stones occur in 15–20% of patients with symptomatic gallstones [2, 3]. The prevalence of gallstones in patients with end-stage renal disease on hemodialysis (HD) is higher than that in the general population [4, 5]. Thus, we sometimes encounter patients with bile duct stones who are undergoing HD. In patients

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undergoing HD, procedure-related adverse events may be exacerbated because of their concomitant diseases, so safety is the most important factor in determining a therapeutic strategy.

Endoscopic sphincterotomy (EST) is widely accepted as the standard procedure for managing common bile duct stones [6, 7]. However, early complications after EST, such as bleeding, pancreatitis, and perforation, are not uncommon [8]. The frequency of bleeding after EST in previous reports is in the range of 0.76–2%, and various predictive factors for post-EST bleeding have been identified [8–11]. Patients on HD are recognized as a high-risk bleeding group after EST; the incidence of bleeding in these patients is as high as 25% in previous reports [11, 12].

Endoscopic papillary balloon dilation (EPBD) has been developed as an alternative to EST for bile duct stones [13–15]. Compared with EST, bleeding rarely occurs after EPBD, even in patients with a coagulopathy [16–18]. Thus, EPBD may be preferable to EST for preventing bleeding. However, no study has reported on EPBD in patients who are undergoing HD. Thus, we conducted this retrospective study to evaluate the efficacy and safety of EPBD for managing bile duct stones in patients who are undergoing HD.

## Patients and methods

This retrospective study was conducted at four institutions in Tokyo, Japan, and was carried out in accordance with the ethical principles of the Helsinki Declaration. The study was approved by the ethics committee at each institution. Written informed consent was obtained from each patient before endoscopic retrograde cholangiopancreatography (ERCP) and EPBD were conducted.

### Patient selection

A prospectively collected ERCP database (Microsoft Access; Microsoft, Redmond, WA, USA) was searched for data on all patients with bile duct stones who were on HD and who had undergone EPBD for naïve papilla between January 1995 and April 2010. Inclusion criteria were as follows: (1) patients with end-stage renal disease on HD (i.e., chronic kidney disease stage 5D, defined as a glomerular filtration rate of  $<15$  ml/min/1.73 m<sup>2</sup> with HD [19]); (2) bile duct stones detected by computed tomography, magnetic resonance cholangiopancreatography, or endoscopic ultrasound; and (3) a history of fever or abdominal complaint due to bile duct stones. Exclusion criteria were associated with primary intrahepatic stones.

### Evaluation

The success rate of bile duct stone removal using EPBD, and early complications after EPBD, were evaluated retrospectively. Medical records of the identified patients were reviewed using a standardized data entry form. Data on physical examinations, medical history, and regular medication were obtained, as were data on blood examinations, including complete blood counts, serum amylase, biochemical tests of liver function, and the coagulation profile before the procedures.

### Endoscopic procedure

All procedures were performed by experienced endoscopists with experience of more than 1000 therapeutic ERCP procedures. ERCP was usually performed with a side-viewing duodenoscope, whereas a forward-viewing endoscope was used when performing ERCP in patients with a prior Billroth II gastrectomy.

Currently, in patients with cholangitis, regardless of its severity, we insert biliary drainage at the first urgent session, followed by EPBD at the second, elective, session. However, in the past, in patients with mild cholangitis, we used to complete all procedures in one session.

A protease inhibitor (gabexate or ulinastatin) and antibiotics (cefazolin sodium or cefotiam hydrochloride) were administered routinely before the procedure. Patients were sedated with diazepam (5–10 mg) and pethidine hydrochloride (17.5–35 mg) as needed. Duodenal relaxation was obtained with scopolamine butylbromide or glucagon.

After a guidewire was inserted deeply into the bile duct, a balloon-tipped catheter (Eliminator; Bard Interventional Products, Billerica, MA, USA; Hurricane RX; Boston Scientific, Natick, MA, USA) was passed over the guidewire and placed across the papilla. In the period from 1995 to 1999, the balloon was inflated with diluted contrast medium at 8 atm for 2 min. From 2000 to 2010, the balloon was inflated slowly (1–2 min) with diluted contrast medium until the waist disappeared from the balloon contour, and the pressure was then maintained for 15 s [20]. An 8-mm balloon was used routinely, whereas a 6-mm balloon was used when the bile duct was smaller than 8 mm in diameter. The balloon was selected on the basis of the bile duct diameter, which was measured from the cholangiogram on the X-ray monitor during ERCP.

After the dilation catheter was removed, stones were subsequently extracted with a conventional four-wire basket or retrieval balloon catheter. We chose devices to extract stones according to the diameter of the stones and bile duct. Four-wire basket catheters were used when the diameter of the stone was similar to that of the bile duct. An eight-wire or spiral basket catheter was used only when

the stone was much smaller than the diameter of the bile duct. After stone removal, the retrieval balloon was used to clear residual sludge. Endoscopic mechanical lithotripsy was used to crush stones larger than 10 mm in diameter before retrieval. A biliary stent or a nasobiliary catheter was inserted when complete stone removal was not achieved within 1 h. Residual stones were removed at the next session without repeating the EPBD. Complete stone removal was defined as the absence of bile duct stones confirmed by a balloon-occluded cholangiogram or intraductal ultrasonography at the end of ERCP.

In patients who received anti-platelet agents, we discussed the thromboembolic risk for each patient's comorbidities with the prescribing non-gastroenterological specialist physicians. As a general rule, antithrombotic agents were discontinued at least 5 days before an elective procedure if possible. However, in urgent cases of cholangitis, these principles did not necessarily apply. In patients in whom discontinuation of anti-platelet agents was deemed inappropriate, a continuous intravenous infusion of heparin was given for 7 days before the EPBD. Heparin was stopped 6 h before the procedure and restarted when a procedure-related hemorrhage did not occur. HD was usually conducted with heparin until the day before the EPBD. HD was restarted using nafamostat mesilate instead of heparin as a hemodialytic anti-coagulant until 1 week after the EPBD [21].

#### Follow up and definitions

All patients were hospitalized for at least 1 day after EPBD and stone removal. A protease inhibitor (gabexate or ulinastatin) and antibiotics (cefazolin sodium or cefotiam hydrochloride) were administered routinely before and after the procedure. Blood was obtained for liver function tests and determination of pancreatic enzymes 18–24 h after the EPBD. Second-look endoscopy to check for hemorrhage was not performed unless tarry stool occurred or there was a change in laboratory data such as decrease of hemoglobin level or elevation of blood urea nitrogen. Early complications were defined and graded according to the criteria of Cotton et al. [22]. Severe hemorrhage was defined as one requiring a blood transfusion or an endoscopic stytic procedure [22].

## Results

#### Patient characteristics

From December 1995 to April 2010, 37 consecutive patients with bile duct stones who were undergoing HD also underwent EPBD as initial treatment at our institutions. The

**Table 1** Baseline characteristics of patients

	<i>N</i> = 37
Age (years)	71 (49–88) <sup>a</sup>
Sex (male/female)	25/12
Periampullary diverticulum	6 (16.2%) <sup>b</sup>
Previous gastrectomy	2 (5.4%) <sup>b</sup>
Previous cholecystectomy	3 (8.1%) <sup>b</sup>
Gallbladder stones in situ	27 (73.0%) <sup>b</sup>
Stone diameter (mm)	8.1 ± 7.2 <sup>c</sup>
Stone number	2.2 ± 1.6 <sup>c</sup>
Bile duct diameter (mm)	10.0 ± 3.5 <sup>c</sup>
Serum creatinine (mg/dl)	7.9 ± 2.3 <sup>c</sup>
Duration of hemodialysis (years)	5.1 (0.03–14.8) <sup>a</sup>
Risk factors for hemorrhage	
Cirrhosis (Child–Pugh A/B/C)	4/1/1
Use of antiplatelet agents	3

<sup>a</sup> Median, (range)

<sup>b</sup> *N* (%)

<sup>c</sup> Mean ± SD

baseline characteristics of the patients are shown in Table 1. The patients consisted of 25 males and 12 females, with a median age of 71 years (range 49–88). The median period of HD was 5.1 years (range 0.03–14.8). There were no cases of impacted stones at the papilla of Vater in this study. Three patients had previously undergone a cholecystectomy, and 27 patients had gallbladder stones in situ. Six patients had liver cirrhosis (four with Child–Pugh class A and one each with Child–Pugh class B and C). Two patients had had a previous gastrectomy with Billroth II reconstruction. Of 12 patients who had used anti-platelet agents for concomitant cardiovascular disease, three received urgent EPBD and stone extraction without cessation of the anti-platelet agents, at the discretion of the endoscopist. Eight patients underwent EPBD and stone removal after severe cholangitis subsided consequent to endoscopic biliary drainage. No pancreatic stents were inserted in this study.

#### Stone removal

Bile duct stones were completely removed by EPBD alone in all patients. Deep cannulation into the bile duct was achieved without a precut EST or rendezvous technique in all patients. Stones ranged from 1 to 38 mm (mean 8.1 ± 7.2 mm) in size and from 1 to 8 (mean 2.2 ± 1.6) in number. The median number of endoscopic sessions required for complete bile duct clearance was 1.0 (range 1–5). Mechanical lithotripsy was performed in seven patients (24 %). The success rates at the first session in patients with small ( $\leq 9$  mm) ( $n = 29$ ) and large ( $\geq 10$  mm) stones ( $n = 8$ ) were 76 and 25%, respectively.

**Table 2** Bile duct clearance and early complications

	<i>N</i> (%)
Bile duct clearance by endoscopic papillary balloon dilation (EPBD) alone	37 (100%)
Number of endoscopic sessions	
1	24 (64.9%)
2	10 (27.0%)
3 or more	3 (8.1%)
Use of lithotripsy	8 (21.6%)
Early complications	
Overall	5 (13.5%)
Hemorrhage	2 (5.4%)
Pancreatitis	2 (5.4%)
Cholangitis	1 (2.7%)
Perforation	1 (2.7%)

### Early complications

Complications occurred in five patients (14%) after EPBD (Table 2). Two patients (5%) had severe hemorrhage. One patient, who had received aspirin at the time of EPBD because of concomitant ischemic heart disease, developed bleeding requiring six units of blood, but the bleeding was controlled conservatively. The other patient with a hemorrhage had concomitant Child–Pugh C liver cirrhosis and required four units of blood. Because of refractory cholangitis caused by hemobilia, he also underwent multiple sessions of endoscopic therapy for hemostasis and the control of cholangitis. Balloon tamponade, epinephrine injection, and clipping techniques were performed to stop the bleeding. No hemorrhage developed in any of the 33 patients who had no additional bleeding risk except for HD.

Post-EPBD pancreatitis occurred in two patients (5%), but it was graded as mild. No relationship was found between post-EPBD pancreatitis and a history of pancreatitis. One of the two patients with post-EPBD pancreatitis had cholangitis simultaneously, which might have been caused by papillary edema after the EPBD and stone extraction. A duodenal microperforation was seen in one patient with a Billroth II gastrectomy. It was diagnosed by computed tomography after the procedure, being shown by the presence of a small amount of retroperitoneal air bubbles. Because it took a considerable amount of time to achieve the procedure, compression by the scope could cause the mucosal injury, which led to perforation. Fortunately, with conservative treatment, the patient recovered without sequelae, although he required 10 days of fasting. Thus, the perforation was graded as mild. None of the patients with gallbladder stones developed acute cholecystitis within 30 days after EPBD. No death occurred that was related to EPBD.

### Discussion

Patients undergoing HD have been regarded as being at high-risk for post-EST bleeding because of platelet dysfunction and activated fibrinolysis [23, 24]. Reported rates of post-EST bleeding range up to 28.6% [11, 12]. Post-EPBD bleeding was observed in two patients (5%) in our study. No bleeding developed in any of the 33 patients undergoing HD without additional bleeding risk factors. Two of the four patients (50%) who had additional bleeding risk factors did develop severe bleeding (one patient was taking anti-platelet agents at the time of EPBD, and the other had Child–Pugh class C liver cirrhosis). Cardiovascular comorbidities are frequent in patients undergoing HD, and anti-platelet agents are often administered to HD patients [25, 26]. In three patients in our study, EPBD was performed without cessation of anti-platelet agents in an emergent, though two-step procedure (i.e., insertion of biliary drainage at the first urgent session, followed by EPBD at a second, elective, session), and such a procedure might be the one of choice to extract bile duct stones safely. EPBD should be performed very carefully in any patients who are undergoing HD and especially in HD patients with Child–Pugh class C liver cirrhosis, because they are at high risk for bleeding [18, 22, 27]. Administering fresh-frozen plasma might be an option to prevent post-EPBD bleeding in patients with Child–Pugh class C liver cirrhosis who are undergoing HD [28].

In the present study successful stone removal at the first session was achieved in 76% of the patients with small (<9 mm) stones. This result was comparable to that in our previous report [15], which described successful stone removal at the first session being achieved in 79.8% of non-HD-patients with small ( $\leq 9$  mm) stones. This suggests that undergoing HD may not affect the success rate of stone removal. Although multiple sessions were required with EPBD, this procedure, because of its low incidence of hemorrhage, is indicated especially for patients with the need for hemostasis, such as those with liver cirrhosis and those with HD.

The risk of pancreatitis after EPBD remains a controversial but serious issue. In previous randomized controlled trials (RCTs) in a “non-HD” setting, the incidence of pancreatitis was reported to be 0–20% [29–31]. The result of our present study was comparable to the previous data, because pancreatitis occurred in 5.4% of the patients. The pathogenesis of pancreatitis after EPBD remains unresolved, but papillary edema or spasm after balloon dilation is likely to play an important role. Our previous study identified pancreatography as the only risk factor for post-EPBD pancreatitis [32]. Unintentional pancreatography was performed in only two patients (5.4%). The exact reason for the low number of pancreatographies is not

clear, but the relatively low incidence of pancreatitis in the present study might be attributable to the low number of pancreatographies.

Our study has some limitations. This was a retrospective cohort study with prospectively collected data in consecutive patients and included a limited number of cases. Further investigation, in multicenter prospective settings, is needed to confirm the safety of EPBD in patients undergoing HD.

In conclusion, EPBD seems to be a safe procedure for extracting bile duct stones in patients who are undergoing HD. However, further attention should be paid to bleeding, particularly in patients with additional risk factors, such as Child–Pugh class C liver cirrhosis or those taking antiplatelet agents at the time of the EPBD.

**Conflict of interest** The authors declare that they have no conflict of interest.

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