

Original Article

Comparison of endoscopic papillary balloon dilatation with conventional endoscopic sphincterotomy for peripapillary choledochoduodenal fistula with bile duct stones

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Abstract: Background: Peripapillary choledochoduodenal fistula (PCDF) is occasionally detected during endoscopic retrograde cholangiopancreatography. This study was designed to compare perioperative outcomes of the peripapillary choledochoduodenal fistula with bile duct stones via endoscopic papillary balloon dilatation and conventional endoscopic sphincterotomy. Methods: We retrospectively reviewed 28 patients in whom a diagnosis was made with ERCP of benign peripapillary choledochoduodenal fistula between January 2009 and August 2014. Endoscopic sphincterotomy was performed in 10 patients and endoscopic papillary balloon dilatation was performed in 18 patients. All clinical data were analyzed retrospectively. Results: The median operating time was significantly shorter in the EPBD group with a median of 19.78±4 mins versus 42.2±11.6 mins in the EST group ($P<0.05$). Postoperative complications occurred in five (50%) versus one (5.5%) patients in the EST and EPBD groups respectively. There were significant differences in postoperative complication rates. The rates of post-ERCP pancreatitis and perforation were not significantly different between the EPBD and EST groups [1/10 (10%) vs 2/18 (11%), $P=0.7$; 0% vs 0%; respectively]. There were 2 (20%) bleeding cases in EST group, and no bleeding cases in EPBD group. Conclusion: EPBD appear to be safe and effective modalities for common bile duct stone removal in patients with PCDF.

Keywords: Peripapillary choledochoduodenal fistula, endoscopic sphincterotomy, endoscopic papillary balloon dilatation

Introduction

Before the introduction of endoscopic retrograde cholangiopancreatography (ERCP), peripapillary choledochoduodenal fistula (PCDF) was considered relatively rare [1]. As ERCP has become more widely used, these fistulas have been diagnosed more frequently. Peripapillary choledochoduodenal fistula is a known complication of a number of disorders, including common bile duct stones (CBDS), duodenal ulcers, periampullary tumors, papillitis and pancreatitis. Currently, most patients with a peripapillary choledochoduodenal fistula undergo endoscopic sphincterotomy (EST) for the treatment of bile duct stones rather than operative procedures such as transduodenal papillotomy or pupilloplasty [2, 3]. However, it still runs the risk of various adverse events, such as bleeding, perforation, pancreatitis and cholangitis [4-6],

and large bile duct stones may require endoscopic mechanical lithotripsy (EML) as an adjunctive procedure to facilitate stone clearance [7, 8]. Endoscopic papillary balloon dilatation (EPBD) was first proposed as an alternative to EST in 1982 [9]. Initially it was widely performed in the belief that it had more advantages over EST such as the reduction of bleeding and perforation risks and functional preservation of the biliary sphincter.

The aim of this study was to undertake a comparison between EPBD and EST. Clinical outcomes were analyzed to assess any differences between the EPBD and EST groups.

Methods

We retrospectively reviewed 28 patients in whom a diagnosis was made with ERCP of

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Table 1. Comparison of clinical demographics of patients in EST group and EPBD group

clinical variables	EST (n=10)	EPBD (n=18)	P value
Age (years)	57.20±11.46	63.00±11.24	0.27
Sex (Female/Male)	7/3	9/9	0.32
Mean diameter of stone (cm)	1.30±0.40	1.54±0.22	0.1
Mean diameter of common bile duct (cm)	2.0 ± 0.45	1.9 ± 0.5	0.4
Median operating time (mins)	19.78±4	42.2 ±11.6	0.007

Table 2. Comparison of adverse events among EST group and EPBD group

	EST (n=10)	EPBD (n=18)	P value
No. of patients	10	18	0.013
Pancreatitis (n, %)	2 (20)	1 (5.6)	
Bleeding (n, %)	2 (20)	0 (0)	
Perforation (n, %)	0 (0)	0 (0)	
Other adverse events (n, %)	1 (10)	0 (0)	

low-up cholangiogram through a nasobiliary tube.

Follow-up data were obtained from outpatient records or telephone call, interview, or ERCP when indicated. All the patients were asked about the presence and timing of certain symptoms: abdominal pain, fever, jaundice, and dark

benign peripapillary choledochoduodenal fistula between January 2009 and August 2014. In all 28 patients, bile duct stones were present. Patients were divided into 2 groups according to the treatment performed; group 1 underwent removing bile duct stones by EST, and group 2 received EPBD for bile duct stones. All procedures were performed using side-viewing endoscopes (TJF-260; Olympus Optical Corporation, Tokyo, Japan). Endoscopic retrograde cholangiopancreatography (ERCP) was performed by experienced endoscopists at a single center. Cannulation was attempted using an ERCP catheter or a pull-type sphincterotome. When conventional cannulation failed, a pre-cut technique using a needle knife was applied. EPBD was performed using a dilating balloon catheter (CRE balloon, Boston Scientific Cork, Ireland) positioned at the center of the balloon across the ampullary orifice (**Figure 1**). Dilating balloon catheters with a diameter of 12-20 mm were used. Ballooning size was determined based on stone sizes and common bile duct diameter, but should not exceed 2 mm of the diameter of the distal common bile duct. Balloons were inflated with caution until balloon notches disappeared. Mechanical lithotripsy was attempted when stones were too difficult to remove intact. When incomplete stone removal was suspected, a nasobiliary tube or a plastic stent was placed to prevent cholangitis. Complete stone removal was confirmed either by cholangiogram at the end of each procedure or by fol-

urine. The presence of residual stones was confirmed by ERCP at the completion of treatment. Recurrent stones were defined as stones that developed after extraction and completion of treatment. The incidence and frequency of late complications such as stone recurrence, cholangitis were compared between groups 1 and 2.

Statistical analysis

All results are expressed as median and range values. Continuous variables were analyzed using Mann-Whitney U test, whereas categorical variables were analyzed using the Chi squared and or Fisher's exact test. A *p* value of <0.05 was considered significant. All statistical analyses were performed using SPSS software for Windows (version 18; SPSS, Inc., Chicago, IL).

Results

Demographic characteristics of the 28 patients (12 men, 16 women) are presented in **Table 1**. The mean stone(s) and common bile duct diameters were not significantly different between the EST and EPBD groups (13±4 mm vs 15.4±2.2 mm, *P*=0.1; and 20.0±4.5 mm vs 19±5 mm, *P*=0.4, respectively). The median operating time was significantly shorter in the EPBD group with a median of 19.78±4 mins versus 42.2±11.6 mins in the EST group (*P*<0.05). Postoperative complications occurred

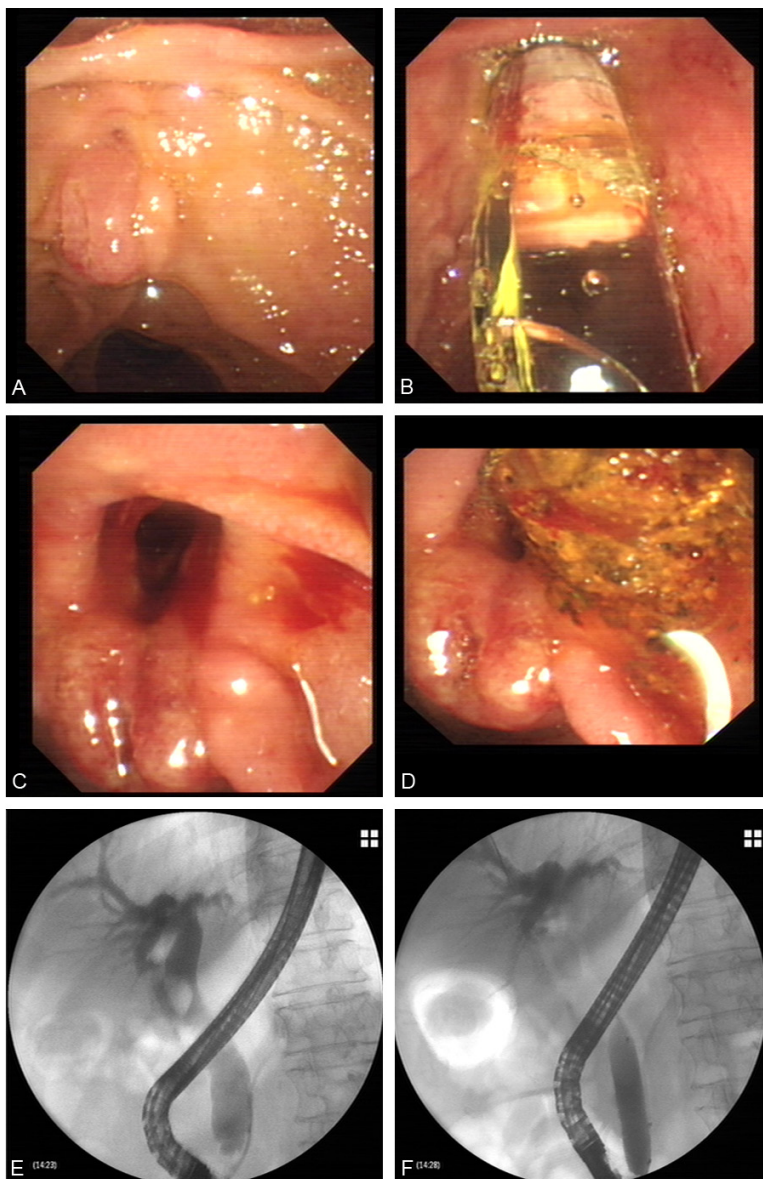


Figure 1. A. Duodenal papilla and PCDF. B. Papillary balloon dilatation from PCDF. C. PCDF after dilatation. D. The stone from the PCDF. E. The cholangiogram. F. EPBD through the PCDF.

in five (50%) versus one (5.5%) patients in the EST and EPBD groups respectively. There were significant differences in postoperative complication rates. The rates of post-ERCP pancreatitis and perforation were not significantly different between the EPBD and EST groups [1/10 (10%) vs 2/18 (11%), $P=0.7$; 0% vs 0%; respectively]. All cases of pancreatitis were mild and they were treated conservatively. There were 2 (20%) bleeding cases in EST group, and no bleeding cases in EPBD group (Table 2).

During a median period of 38 months (range 3 months to 48 months), 8 patients (28.5%)

developed late complications including recurrence of bile duct stones (4 patients, 14.2%) and acute cholangitis (4 patients, 14.2%). The incidence of stone recurrence was not statistically significant difference. All recurrent bile duct stones were bilirubinate and easily treated again by endoscopy. Three patients had stone recurrence 2 to 4 times. Acute cholangitis associated with recurrent stones occurred in 6 patients.

Discussion

Choledochoduodenal fistulas are classified as distal and proximal types. The distal form connects to the duodenum in the distal 2 cm of the common bile duct, and the fistula orifice can be observed during ERCP. The incidence of PCDF in regions of the world where cholelithiasis is endemic is greater than the incidence in non-endemic areas. Spontaneous biliodigestive fistulas are detected in 1-2% of patients after gall bladder resection; in 70% of these cases, the defects are choledochoduodenal. EST has been considered the standard for treatment of fistula if bile duct stones are present because both removal of the stones and fistulotomy are achieved nonoperatively. Although some

investigators have described the effectiveness of enlarging the fistula in a cephalad direction through the fistula orifice with the standard EST technique, an incision of excessive length results in an increased risk of hemorrhage and perforation. In addition, an incision positioned well proximal may predispose a patient to biliary sump syndrome. Currently, EPBD is regarded as an effective modality for treating difficult common bile duct stones. Complications, such as, hemorrhage and perforation, have been reported to be less frequent in EPBD than in standard EST. Furthermore, mechanical lithotripsy is less required during EPBD, because it

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provides spacious ampullary opening, and thus, facilitates complete bile duct stone removal. More recently, it has been suggested that EPBD is as safe and effective as EST for the removal of large bile duct stones.

In the two groups we studied, postoperative complications occurred more frequently in EST group than in EPBD group. Bleeding is one of the most serious complications associated with EST. Theoretically, bleeding risk can be increased if EST is performed. Previous studies have reported incidences of bleeding after EST ranging from 0% to 9% [10]. In the present study, we experienced one episode of major bleeding after EST in the EST group.

In conclusion, EPBD appear to be safe and effective modalities for common bile duct stone removal in patients with PCDF. Furthermore, an incidental finding of PCDF presents no additional technical challenge to the achievement of successful EPBD. This result complements those of previous studies on the management of common bile duct stones in patients with PCDF. Nevertheless, because the present study is limited by its retrospective nature and a relatively small cohort, a large prospective study is needed to analyze the clinical feasibility of EPBD in patients with PCDF.

Disclosure of conflict of interest

None.

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