Digestive and Liver Disease 47 (2015) 401–404

Contents lists available at ScienceDirect

Digestive and Liver Disease

journal homepage: www.elsevier.com/locate/dld

Digestive Endoscopy

Efficacy and safety of double-balloon endoscopy-assisted endoscopic papillary large-balloon dilatation for common bile duct stone removal

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ARTICLE INFO

Article history:
Received 15 November 2014
Accepted 10 February 2015
Available online 20 February 2015

Keywords:
Double-balloon endoscopy
Endoscopic papillary large-balloon dilatation
Endoscopic retrograde cholangiopancreatography
Roux-en-Y reconstruction

ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography is difficult to perform in patients with gastrointestinal tract reconstruction.
Aims: To evaluate the efficacy and safety of double-balloon endoscopy-assisted endoscopic papillary large-balloon dilatation for common bile duct stones in patients with gastrointestinal tract reconstruction.
Methods: We conducted a retrospective case series with a comparison to historical controls. During the period 2009–2013, 11 postoperative patients underwent endoscopic papillary large-balloon dilatation (Group A). Procedure efficacy and safety were compared with patients who underwent endoscopic sphincterotomy without endoscopic papillary large-balloon dilatation, who served as historical controls (Group B).
Results: Group A consisted of 11 patients (63.6% males, mean age 78 ± 10 years), and Group B consisted of 32 patients (78.1% males, mean age 75 ± 7 years). The stone clearance rate was significantly higher in Group A than in Group B (100% vs. 65.6%, respectively; $p < 0.05$). Median procedure time was significantly shorter in Group A than in Group B (54 min vs. 102 min, respectively; $p < 0.05$), and the complication rate was not significantly different between groups (18% vs. 15.6%, respectively; $p = 0.586$).
Conclusion: Endoscopic papillary large-balloon dilatation may be an effective and safe treatment procedure in patients with gastrointestinal tract reconstruction.

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a difficult procedure to perform in patients with gastrointestinal (GI) tract reconstruction, because in those patients the endoscope cannot easily reach the duodenal papilla. The use of double-balloon endoscopy (DBE), which was developed and introduced for hepatobiliary disorders by Yamamoto et al. [1] in 2001, enabled the approach to the duodenal papilla through an anastomosis. Even with the use of DBE, however, therapeutic ERCP for the removal of common bile duct stones remains difficult, because devices for endoscopic mechanical lithotripsy and stone removal specific to forward-viewing endoscopes have not been developed.

In 2003, Ersoz et al. [2] introduced the procedure of endoscopic papillary large-balloon dilatation (EPLBD), which has been shown to be useful for the extraction of stones without crushing. Subsequently, Itoi et al. [3] successfully introduced the EPLBD procedure for the removal of common bile duct stones in patients with a prior Billroth-II gastro-jejunal anastomosis through balloon-assisted endoscopy (BAE). However, there have been few reports of DBE-assisted EPLBD (DBE-EPLBD) for common bile duct stone removal in patients with a Roux-en-Y reconstruction [4].

In the present study, we evaluated the efficacy and safety of DBE-EPLBD for the removal of common bile duct stones in patients with gastrointestinal reconstruction. Also, we compared the therapeutic efficacy of the procedure with that of DBE without EPLBD in a historical control population.

2. Materials and methods

2.1. Study design

This is a retrospective case series with a comparison to historical controls.

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http://dx.doi.org/10.1016/j.dld.2015.02.006
1590-8658/

2.2. Subjects

From June 2009 to October 2013, at our institution we treated 11 postoperative patients with common bile duct stones with DBE-EPLBD (Group A). From November 2004 to October 2011, we treated 32 postoperative patients with common bile duct stones with DBE and without EPLBD (Group B); these patients served as controls for comparison of the therapeutic efficacy and safety of EPLBD. Common bile duct stones were confirmed by computed tomography or magnetic resonance cholangiopancreatography. All patients in both groups had an intact papilla.

2.3. Measurements

The results were evaluated based on the following parameters: utilization rate of mechanical lithotripsy, procedure time, single-procedure stone clearance rate, complication rate, and recurrence.

2.4. Devices and procedures

We used short-type DBE (EC-450BI5; Fuji, Tokyo, Japan) under carbon dioxide insufflation to approach the ampulla. For a tip hood, Elastictouch (Top Co., Tokyo, Japan) was used for all cases when performing the enteroscopy part of the procedure. For EPLBD, one of two types of through-the-scope balloon was applied, either a CRE balloon (Boston Scientific, CA, USA) or a Giga balloon (Kaneka Co., Tokyo, Japan). The former balloon ranged from 12 to 15 mm in its largest diameter with a length of 5.5 cm, and the latter ranged from 12 to 14 mm in diameter with a length of 4 cm. For sphincterotomy, Clevercut (Olympus Tokyo) or a double-lumen guided B-II sphincterotome (Cook Medical, CA) was used. The stones were removed from the bile duct with a basket or a balloon catheter (Extracter XL, Boston Scientific, CA). When an impaction of the stone in the duodenal ampulla was suspected, a mechanical lithotriptor (Xemex Crusher Catheter, Zeon Medical, Tokyo) was added for removal.

The procedure for EPLBD was the following (Figs. 1 and 2): (a) to confirm the presence of a common bile duct stone, we first cannulated the duodenal papilla and performed ERCP in a standard manner; (b) after the existence of a stone was confirmed, the condition was rated from minor to moderate, and endoscopic sphincterotomy was carried out before EPLBD in all patients; (c) a large balloon catheter was positioned across the main duodenal papilla; (d) the balloon was dilated with a pressure great enough to obtain the largest inflation for 1 min. The size of the balloon was chosen on the basis of the diameter of the stone and the transverse diameter of the dilated bile duct to avoid bile duct perforation.

2.5. Assessment

All the following parameters were then reviewed: the size and the number of extracted stones, the advisability of the balloon-expanded diameter up to the bile duct transverse diameter, the utilization of mechanical lithotripsy, the success of stone clearance in a single procedure, as well as the procedure time, complications, and subsequent clinical course. Adverse events were classified as pancreatitis, bleeding, perforation, and others. Post-ERCP pancreatitis (PEP) was defined according to the Cotton classification.

2.6. Statistical analyses

Statistical analyses were carried out with SPSS version 11.0J software (SPSS Inc., Chicago, IL, USA). The significance of differences in categorical variables was determined either with a chi-square test or Fisher's exact test. Quantitative data were analyzed either by the unpaired Student's *t* test or Mann–Whitney test, and are presented as mean ± SD. A p value below 0.05 was regarded as statistically significant.

3. Results

Group A consisted of 11 patients (63.6% males, mean age 78 ± 10 years), and Group B consisted of 32 patients (78.1% males, mean age 75 ± 7 years). In Group A, 10 patients had a Roux-en-Y reconstruction and one had a Billroth-II reconstruction; in Group B, 27 patients had a Roux-en-Y reconstruction and 5 had a Billroth-II reconstruction. All patients had an intact papilla; subjects with hepaticojejunostomy were not enrolled. Eight patients had not undergone cholecystectomy, and one had gallbladder stones. Table 1 shows the demographical data and the results of the procedures for patients who underwent DBE-EPLBD (Group A) and those who underwent DBE without EPLBD (Group B). Patients' age and gender, as well as type of intestinal reconstruction did not differ between the two Groups.

In Group A, we could reach the papilla to apply the balloon dilatation in all patients. The size of the balloon was 15 mm for 5 patients, 13 mm for 3 patients, and 12 mm, 13.5 mm, and 14 mm for 1 patient each. While we were able to dilate the balloon to the diameter of the bile duct in 10 patients, such a dilatation could not be achieved in the remaining patient, who had a tightly bent bile duct.

The mean number of stones extracted was not significantly different between groups (Group A: $n = 2$, range, 1–3 vs. Group B: $n = 1.6$, range 1–6). Both groups had similar mean stone diameters (Group A: 12 ± 4.9 mm vs. Group B: 11.3 ± 4.5 mm, $p = 0.061$). The utilization rate of mechanical lithotripsy was significantly lower in Group A than in Group B (18% vs. 53%, respectively; $p = 0.046$). The stone clearance rate was significantly higher in Group A than in Group B (100% vs. 65.6%, respectively; $p < 0.05$). Furthermore, the median procedure time was significantly shorter in Group A than in Group B (52 ± 27 min vs. 101.6 ± 45.6 min, respectively; $p < 0.05$).

The complication rate was not significantly different between Group A and Group B (18% vs. 15.6%, respectively; $p = 0.586$). No serious complications occurred in Group A, despite two patients experienced post-ERCP pancreatitis of moderate severity. Complications occurred in five patients in Group B: three patients developed post-ERCP pancreatitis of mild to moderate severity, one of the remaining patients had perforation, and the other had retroperitoneal emphysema. The incidence of stone recurrence was not significantly different between Group A and Group B (1 vs. 0, respectively; $p = 0.256$). After a mean follow-up period of 528 days, only in 1 patient the dilation of the balloon to the diameter of the common bile duct could not be achieved during the initial DBE-EPLBD.

4. Discussion

Management of CBD stones remains a challenging issue for patients with intestinal reconstruction. Since the introduction of DBE, ERCP-related intervention therapy has become possible for patients with GI tract reconstruction who have an intact papilla, such as patients who have undergone B-II and RY anastomosis [5–9]. Nevertheless, extraction of CBD stones remains problematic because of the technical difficulties in cannulation and sphincterotomy for an intact papilla with a forward-viewing endoscope [10]. In addition, the small diameter of the working channel of DBE (2.8 mm or 3.2 mm) does not easily allow for the application of commercially available devices, such as wire-guided mechanical lithotripsy and the basket catheter.

At present, the Crusher Catheter is the only mechanical lithotripter applicable to DBE. However, the catheter should be