Digestive and Liver Disease xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Digestive and Liver Disease

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

Digestive Endoscopy

Endoscopic papillary large balloon dilation in patients with large biliary stones and periampullary diverticula: Results of a multicentric series

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ARTICLE INFO

Article history:
Received 6 March 2017
Received in revised form 18 March 2018
Accepted 27 March 2018
Available online xxx

Keywords:
DASE
Dilation assisted stone extraction
Difficult choledocholithiasis
Endoscopic papillary large balloon dilation
EPLBD
Large bile duct stone
Therapeutic ERCP

ABSTRACT

Introduction: Stone extraction represents the most frequent indication for endoscopic retrograde cholangiopancreatography (ERCP). Endoscopic papillary large balloon dilation (EPLBD) is a recent introduced approach consisting of an endoscopic papillary large balloon dilation following limited endoscopic sphyncterotomy (ES), which has been proven to be safe and effective for extraction of large common bile duct (CBD) stones. Peri-ampullary diverticula (PAD) are described in 10–20% of patients undergoing ERCP. Aim of our study is to evaluate efficacy and safety of EPLBD for the extraction of large biliary stones in patients with PAD.
Methods: The prospectively collected endoscopy databases of 4 Italian ERCP high-volume centers were reviewed retrospectively, and all consecutive patients with an instrumental diagnosis of large biliary stones and PAD, between September 2014 and October 2016, were included in this study.
Results: Eighty-one patients (36 males, median age 75 years) were treated between September 2014 and October 2016. Deep biliary cannulation was reached in 78/80 patients. Successful extraction was achieved in 74/78 patients at the first attempt. AEs occurred in 8 patients (1 severe). Younger age, stone size and incomplete stone extraction were significantly associated with AEs.
Conclusions: EPLBD is an effective and safe technique in patients with PAD and large biliary stones, which avoids the need of other techniques, thereby reducing the risks of adverse events.
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1. Introduction

Stone extraction represents the most frequent indication for endoscopic retrograde cholangio-pancreatography (ERCP). Endoscopic sphincterotomy (ES) followed by balloon extractor catheter or wire basket passage is widely considered as the gold standard technique, being successful in more than 90% of cases, with an overall rate of adverse events of approximately 5% [1]. Nonetheless, the Vater's ampulla dysfunction resulting from the ablation of the Oddi's sphincter implies an increased risk of subsequent retained choledocholithiasis and biliary tree inflammation [2–4,5]. In addition, several stone features including size (>10 mm), number (≥3), shape and location, together with the presence of anatomical biliary peculiarities or peri-ampullary diverticula (PAD) may hamper stones extraction, resulting in multiple attempts and ERCP-related complications [1,2,6,7]. Consistently, large biliary stones and PAD are recognized to be the two main causes of difficult extraction, described in approximately 10–20% of ERCP [1,7–10,15] (Fig. 1). Removal of large stones from the common bile duct (CBD) often requires advanced techniques, such as mechanical lithotripsy, extracorporeal or intracorporeal lithotripsy [8–10,36]. PAD represents a technical obstacle to the CBD cannulation and a risk factor

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https://doi.org/10.1016/j.dld.2018.03.034
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Please cite this article in press as: Zulli C, et al. Endoscopic papillary large balloon dilation in patients with large biliary stones and periampullary diverticula: Results of a multicentric series. Dig Liver Dis (2018), https://doi.org/10.1016/j.dld.2018.03.034

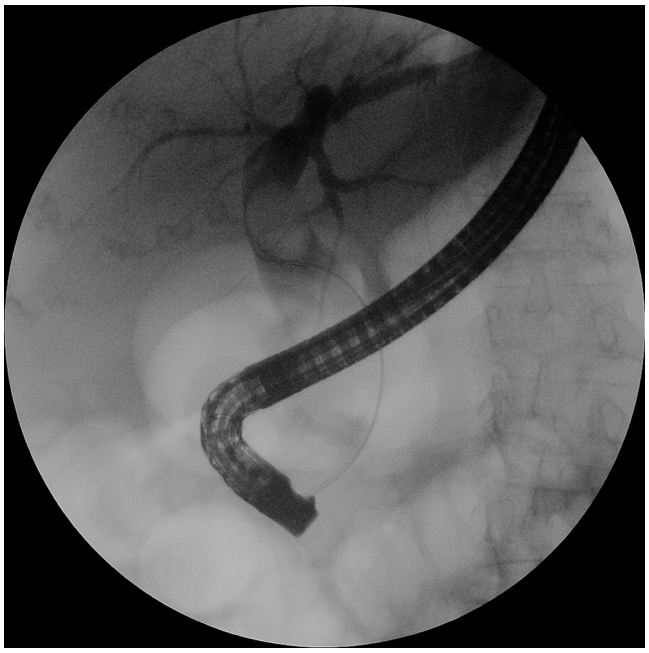

Fig. 1. Contrast cholangiography revealing macrolithiasis of CBD in patient with PAD.

for ERCP-related complications (e.g., bleeding and perforation) due to the absence of the muscle layer [2,6,15–19].

To overcome these limitations, in 2003 Ersoz et al. have introduced the innovative technique of Endoscopic papillary large balloon dilation (EPLBD), consisting of pneumatic papillary dilation with large ballon following a sub-maximal ES [11]. This approach has been proven to be safe and effective for extraction of large CBD stones [12], reducing the rates of post-ERCP complications and the need for mechanical lithotripsy as compared to ES alone [13,14,37–40].

To date, there is no prospective evidence on the use of EPLBD for large CBD stone extraction in patients with PAD. Aim of our study is to evaluate both efficacy and safety of EPLBD for the extraction of large biliary stones in a consecutive series of patients with PAD.

2. Methods

The prospectively collected endoscopy databases of 4 Italian ERCP high-volume centers were reviewed retrospectively, and all consecutive patients with an instrumental diagnosis (i.e., CT scan, endoscopic ultrasound, or magnetic resonance imaging) of large biliary stones and PAD, between September 2014 and October 2016, were included in this study.

After an exhaustive explanation of the procedure, a written informed consent was obtained from all patients. This study was carried out in accordance with the Declaration of Helsinki adopted in 1964 incorporating all later amendments. Patients with previous sphincterotomy and/or previous papillary sphincteroplasty were excluded. All ERCPs were performed in high-volume centers (ranging from 250 to 550 ERCPs/year) by the same experienced endoscopist (>1000 ERCP/life by each endoscopist) using side-viewing duodenoscopes. Each patient received a deep sedation (propofol-based) with anestesiological support.

Based on the location of major papilla with respect to diverticulum, PAD were classified into three subtypes: type 1, if the papilla is inside the diverticulum; type 2, when the papilla is on the edge of

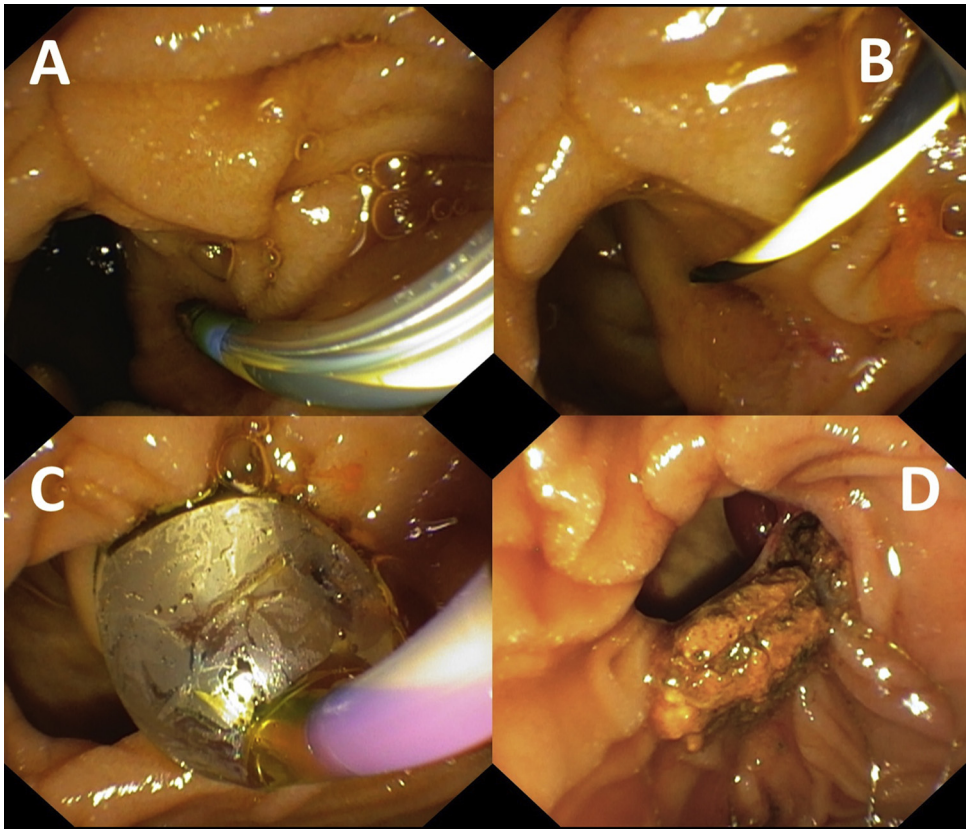

Fig. 2. Endoscopic view: *a,b* cannulation of CBD in patient with type-1 PAD; *c* large balloon dilation after limited sphincterotomy of papilla of Vater; *d* spontaneous stone extraction from CBD.

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