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Original Article

Role of endoscopic papillary balloon dilation in patients with recurrent bile duct stones after endoscopic sphincterotomy

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Abstract

Background: Endoscopic sphincterotomy (ES) is an established treatment for patients with choledocholithiasis or common bile duct stones (CBDS), but further management of patients after ES with recurrent CBDS remains controversial. Endoscopic papillary large balloon dilation (EPLBD) has been used safely and effectively for stone removal in patients after ES with recurrent CBDS. The aim of this study was to evaluate the clinical efficacy of EPLBD in patients after complete ES with recurrent CBDS.

Methods: Records of 891 patients with CBDS after complete ES from January 1991 to December 2008 were reviewed. Of 133 patients with recurrent CBDS, 122 had complete endoscopic bile duct clearance. Twenty-three patients (Group 1) underwent EPLBD and 99 (Group 2) underwent stone extraction without dilatation. Basic demographics and endoscopic findings at the first recurrence were recorded and analyzed. The primary end point was the second CBDS recurrence.

Results: No statistical differences were observed between the two groups, except for larger CBDS size in Group 1. The bile duct clearance rate was 96% in Group 1 and 91% in Group 2. No complications such as pancreatitis, perforation, and bleeding were noted in Group 1, and one patient in Group 2 suffered from bleeding after stone extraction. The rate of second recurrent CBDS after endoscopic clearance for the first recurrent CBDS was 17% in Group 1 and 60% in Group 2 ($p < 0.001$). There were two independent factors for the second recurrence, including cirrhosis (odds ratio 4.734, $p = 0.023$) and stone extraction directly without major papilla expansion (odds ratio 6.050, $p = 0.003$).

Conclusion: EPLBD is a safe and effective endoscopic treatment for recurrent CBDS in patients after ES. It can also facilitate complete clearance of CBDS and prevent further CBDS recurrence.

Keywords: endoscopic papillary large balloon dilation; endoscopic retrograde cholangiopancreatography; endoscopic sphincterotomy; recurrent common bile duct stone

1. Introduction

Endoscopic sphincterotomy (ES) is a widely used method of treatment for patients with choledocholithiasis or common bile duct stones (CBDS).[1] The actual ES procedure is technically demanding and associated with about 9.8% complications.[2] Most complications are primarily related to the indications for the procedure and the endoscopic technique.[2] Endoscopic papillary balloon dilatation (EPBD), which was

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introduced by Staritz et al[3] in 1982, is an alternative method for removing bile duct stones. It is more easily accessed and less technically demanding than ES. It also causes less hemorrhage and less perforation, and can preserve the sphincter of Oddi function.[4,5] However, EPBD is not widely used due to its associated higher risk of pancreatitis and a higher rate of using mechanical lithotripsy, as reported in some studies.[6] Endoscopic papillary large balloon dilation (EPLBD) after limited ES, which was introduced by Ersoz et al,[7] is effective in removing bile duct stones and has an acceptable complication rate.[8] Recent studies have shown that EPLBD alone is a safe and effective method for removing bile duct stones, and the procedure is also technically easy to navigate.[9,10]

Patients after ES still have the risk of recurrent CBDS, with the rate ranging from 4% to 24% over the duration of long-term follow-up.[11−14] There has been no consensus for the management of patients with recurrent CBDS after prior ES. Although most of the recurrent stones in Chinese patients are loose bilirubinate stones,[15] stone extraction is sometimes difficult, especially in patients with multiple large stones and/or papillary stenosis, even using a mechanical lithotripter. Data on the repeated use of ES for extending the previous sphincterotomy in these patients are limited and controversial. Some studies suggested that EPLBD could be used safely in these patients, with effective results.[16−18]

The aim of our study was to retrospectively evaluate the long-term clinical efficacy of EPLBD compared with direct stone extraction without balloon dilation in patients with recurrent CBDS after prior ES.

2. Methods

2.1. Patients

This study has been approved by the Institutional Review Board of Kaohsiung Veterans General Hospital (VGHKS12-CT7-02).

Consecutive patients with recurrent CBDS after complete ES in Kaohsiung General Veterans Hospital, Taiwan, from January 1991 to December 2008 were reviewed. Patients with previous biliary surgery, those with pancreatic or biliary malignant disorders, and pregnant women were excluded. We recorded the basic demographics and endoscopic findings at the first recurrence. Next, we divided the patients into two groups (Groups 1 and 2) according to the endoscopic management approach for the recurrent CBDS.

2.2. Procedures

The preparation included local anesthesia of the pharynx using 10% xylocaine, and intramuscular injection with 40 mg hyoscine-*N*-butylbromide and 25−50 mg meperidine. Endoscopic retrograde cholangiopancreatography (ERCP) was performed in the standard manner using a side-view endoscope (JF-240; Olympus Optical Corporation, Tokyo, Japan). After selective cannulation of the common bile duct using the catheter, cholangiography was performed to confirm the diagnosis of recurrent CBDS. For Group 1 patients, a 0.035-inch guidewire (Boston Scientific Corp., Marlborough, MA, USA) was then inserted into the bile duct through the catheter. EPLBD was performed by passing a dilating balloon (CRE balloon 5.5 cm in length and 1.0−1.2 cm/1.2−1.5 cm/1.5−2.0 cm in diameter; Boston Scientific Corp., MA, USA) via the prepositioned guidewire into the bile duct using fluoroscopic and endoscopic guidance. The balloon was inflated up to the optimal size ($\geq$10 mm in diameter) for 1−5 minutes according to the patients' condition and tolerance. In order to minimize the risk of perforation, the size of the balloon should not exceed the largest diameter of the CBD, and further expansion of balloon was avoided once the patient felt intolerable pain. After removal of the balloon and guidewire, the CBDS were removed using a Dormia basket or balloon-tipped catheter, with or without the aid of mechanical lithotripsy. A mechanical lithotripter (BML-4Q; Olympus Optical, Tokyo, Japan) was used to fragment the stones if the maximal stone diameter was larger than the diameter of the distal bile duct or the stones could not be removed using the Dormia basket or balloon-tipped catheter. The decision to use balloon dilation was made depending on the endoscopists' personal experiences. For Group 2 patients, direct stone extraction was performed after cholangiogram without balloon dilatation. A second attempt at stone extraction was performed within 7 days for incomplete removal of stones in the first treatment session. All patients were observed in the hospital for at least 24 hours after endoscopic treatment. Procedure-related adverse events and incidents were recorded according to the definitions and grading systems of the recent workshop held by the American Society of Gastrointestinal Endoscopy.[19] During the ERCP procedure, dimensions of the juxtapapillary diverticulum and CBD as well as size and number of stones were recorded. Stone removal was declared complete if the final cholangiogram showed no residual stones. Clinical evaluation of symptoms and serum amylase was performed the following day.

2.3. Follow up

Patients with complete clearance of the bile duct were assigned to regular follow-up after discharge at a special clinic. We followed up the patients every 2 weeks until normalization of liver function tests, and every 3 months thereafter. During each visit, a blood sample was taken routinely for liver function tests, including total serum bilirubin, albumin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase. Abdominal ultrasound was suggested every 6−12 months, or when abnormal liver function test results or clinical symptoms suggested CBDS recurrence. Endoscopic retrograde cholangiography was performed if recurrent biliary symptoms, abnormal liver function tests, or sonography suggested recurrent CBDS. When repeated endoscopic retrograde cholangiography confirmed the diagnosis of recurrent CBDS, endoscopic removal of stones (with or without further balloon dilation) was performed simultaneously in the same session, or the patient was referred to a surgeon. Telephone contact was made with patients who were unable to return to the hospital.