#### **Clinical Science**

# The role of endoscopic biliary sphincterotomy for the treatment of type 1 biliary dysfunction (papillary stenosis) with or without biliary stones

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#### **KEYWORDS:**

Papillary stenosis; Biliary stones; Endoscopic sphincterotomy; Postcholecystectomy syndrome; Biliary pain; Sphincter of Oddi dysfunction

#### Abstract

**BACKGROUND:** This study assesses the safety and effectiveness of endoscopic biliary sphincterotomy (ES) in the treatment of papillary stenosis (PS) with and without biliary stones.

**METHODS:** The records of all patients who had endoscopic retrograde cholangiopancreatography (2,689 patients) from January 1, 1991, to August 1, 2010, were reviewed. There were 117 patients with PS who had ES.

**RESULTS:** All patients had biliary pain, a dilated common bile duct (CBD) with a maximum diameter of 10 to 25 mm, and elevated liver function tests. There were 46 patients who had prior cholecystectomy of whom 20 patients had CBD stones. The remaining 71 patients had no prior biliary surgery; there were no biliary stones in 14 patients. All patients were symptom free after ES with or without CBD stone retrieval.

**CONCLUSIONS:** ES is the optimal treatment for PS in patients with or without biliary stones. ES eliminates pain, corrects CBD dilation, and restores LFTs to normal. © 2014 Elsevier Inc. All rights reserved.

Sphincter of Oddi dysfunction (SOD) is a benign, obstructive disorder of the ampullary sphincter. SOD causes pain by impeding the flow of bile and/or pancreatic

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juice, resulting in ductal hypertension. SOD is a possible cause of 3 clinical conditions: (1) persistent or recurrent biliary-type pain after cholecystectomy; (2) recurrent idiopathic pancreatitis; and (3) biliary-type pain in patients with an intact gallbladder but without cholelithiasis. The pathogenesis of SOD can be divided into 2 subtypes: stenosis, which results from passive obstruction at the sphincter of Oddi caused by fibrosis, inflammation, or both; and dyskinesia, which results from intermittent obstruction caused by sphincter muscle spasm.

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The Modified Milwaukee Classification (MMC) categorizes SOD into 3 types. <sup>1,2</sup> Type 1 SOD causes biliary pain, elevated liver function tests, and dilation of the common bile duct (CBD) beyond 9 mm; this is also known as stenosis or fibrosis of the sphincter of Oddi<sup>3–6</sup> or ampullary or papillary stenosis (PS). <sup>1,7,8</sup> Type 2 SOD causes pain plus either elevated liver function tests or CBD dilation; type 3 SOD causes only pain without elevated liver function tests or CBD dilation. <sup>1,2</sup>

A significant body of literature has shown that endoscopic sphincterotomy (ES) is an effective and safe modality for PS.<sup>4,9,10</sup> However, the literature is less informative about the role of ES in the treatment of PS in patients with coexistent biliary stones. Cholecystectomy alone or with CBD exploration and stone removal may not be effective at resolving biliary pain when PS and ductal hypertension are not corrected. The purpose of this study was to investigate the role of ES in the management of PS in patients with or without biliary stones and with or without prior cholecystectomy.

#### **Materials and Methods**

After Wayne State University/Detroit Medical Center Human Investigational Committee approval, the records of patients with PS who subsequently underwent ES by a single endoscopist (CS) from 1991 through 2010 were reviewed. During this interval, 2,689 patients underwent endoscopic retrograde cholangiopancreatography (ERCP) including patients with endoscopic biliary sphincterotomy; 127 patients (4.7%) were diagnosed with PS.

Ten patients were excluded. ES was not performed in 5 patients without CBD stones but with severe comorbidities including liver cirrhosis in 2, severe cardiopulmonary disease in 2, and refractory coagulopathy in 1. ES was successfully performed in 4 patients with concomitant sickle cell disease but not included because of confusion in determining the cause of subsequent pain. ES was not technically possible in 1 patient although PS was diagnosed by successful ERCP. The remaining 117 patients had successful ES. These 117 patients were followed for an average of  $72 \pm 38.3$  months and a median of 48.7 months; this includes 2 patients who have been followed over 20 years.

Preoperative workup always included liver function tests (LFTs), including aspartate aminotransferase, alanine aminotransferase, alkaline phosphate, total bilirubin, and an abdominal ultrasound. An upper endoscopy was performed to rule out disease in the esophagus, stomach, and duodenum. Ninety-eight percent of the study population underwent a computed tomographic scan of the abdomen to examine the distal bile duct and pancreas followed by ERCP to look for retained stones or strictures of the bile duct. All patients included in this study had the classic MMC triad for PS with the triad of biliary pain, dilated CBD, and elevated LFTs.

ES was performed using a Valley Laboratory (Force FX, Boulder, CO) cautery unit with a setting of blend 1, cutting of 55, and coagulation of 30. Sphincter pressure was not measured. The length of the sphincterotomy cut varied depending on the size of the intraduodenal portion of the bile duct. The papilla was cut as large as possible without perforation usually a papillary bulge in the duodenal wall; the papillotomy length was measured by using a bowing sphincterotomy knife and/or pulling out an inflated balloon catheter in the CBD through the papillotomy site in some patients. Endpoints of treatment efficacy were symptomatic resolution of pain and the return of LFTs to normal.

#### **Results**

The 117 patients included 84 women and 33 men with a mean age of 48 years. All patients presented with biliarytype pain; 29% had nausea with vomiting, and 19% had pancreatitis. All patients had bile duct dilatation that averaged  $12.8 \pm 0.33$  mm and ranged from 10 to 25 mm. All patients had abnormal LFTs; the mean values were aspartate aminotransferase (U/L) of mean 220.2, SD 80.5, alanine aminotransferase (U/L) of mean 203.8, SD 70.5, alkaline phosphatase (U/L) of mean 280, SD 95.3, and total bilirubin (mg/dL) of 3.2, SD 1.2. Endoscopic cannulation of the duct was difficult, which was defined as more than 4 attempts at cannulation, in 67 patients; a guide wire papillotome was used in 35 patients, and precutting before cannulation was required in 2 patients. There were no acute complications such as pancreatitis, perforations, bleeding, or cholangitis after ES. However, 1 patient who had CBD stones after a prior cholecystectomy and 3 patients with no prior cholecystectomy and no CBD stones developed a moderate restenosis of the papilla months or years after ES requiring repeat ES. They subsequently did

## Endoscopic biliary sphincterotomy after prior cholecystectomy

There were 46 PS patients who had prior cholecystectomy; 20 had CBD stones present at the time of ES (Fig. 1). The retrieval of CBD stones was successful in all 20 patients. The ES with stone removal was performed less than 1 month after cholecystectomy in 9 of these 20 patients. The 26 patients who had prior cholecystectomy with no evidence of CBD stones were further divided into 5 who had CBD exploration performed at the time of prior cholecystectomy and 21 who had no prior CBD exploration. The ES was performed less than 1 month after cholecystectomy in 7 of the 21 patients who had no prior CBD exploration; 4 of these 7 patients had ES within 1 week after cholecystectomy because of persistent right upper quadrant pain, jaundice, and CBD dilatation. One of the 5 patients who had prior CBD exploration had ES performed within 3 weeks of surgery because of a persistent high

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