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# The modified pancreatic stent system for prevention of post-ERCP pancreatitis: a case-control study

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## Abstract

**Background:** Prophylactic pancreatic stents after endoscopic retrograde cholangiopancreatography (ERCP) can help prevent post-ERCP pancreatitis. However most of the pancreatic stents need to be removed by another ERCP. The aim of this observational study was to investigate the feasibility and effectiveness of the modified pancreatic stent system for prevention of post-ERCP pancreatitis.

**Methods:** From November 2013 to November 2015, a total of 230 patients who had prophylactic pancreatic stent placed for prevention of post-ERCP pancreatitis at a single institution were identified and stratified. In this case-control design, 150 patients received an ordinary pancreatic stent, and 80 patients received the modified pancreatic stent. The main outcome measures were the difficulty level and complications of pancreatic stent placement and extraction between the two groups.

**Results:** In ordinary group, the average time of pancreatic stent and nasal biliary drainage placement was  $3.5 \pm 0.6$  min. There were 13 cases of stent proximal migration (8.7%), 20 cases of stent spontaneous abscission (13.3%), 5 cases of acute pancreatitis (3.3%) (2 cases for stent abscission) and 7 cases of hyperamylasemia (4.7%) after ERCP. One hundred thirty patients received extra duodenoscope (86.7%) to remove the stent, and 4 cases had acute pancreatitis and 5 patients had hyperamylasemia after removing the proximal migratory stents. In modified group, the average time of pancreatic stent system placement was  $4.9 \pm 0.7$  min, but there was only one case of stent abscission (1.3%), 2 cases of acute pancreatitis (2.5%) and 3 cases of hyperamylasemia (3.8%). The new pancreatic stents were removed directly under x-ray without complication.

**Conclusions:** The modified pancreatic stent system has the same effect of preventing post-ERCP pancreatitis, lower rate of stents proximal migration and spontaneous abscission, and the advantage of easier removed compared with ordinary pancreatic stent.

**Keywords:** Acute pancreatitis, Endoscopic retrograde cholangio pancreatography, Pancreatic stent, Endoscopic nasal biliary drainage

## Background

Endoscopic retrograde cholangiopancreatography (ERCP) is the primary method used to manage pancreatobiliary disease, but it is also an invasive procedure that carries significant risks for the patients. The most common complication from the endoscopic sphincterotomy (EST) is acute pancreatitis, and other complications from the

procedure include perforations, sepsis and bleeding [1]. Post-ERCP pancreatitis (PEP) is defined as acute abdominal pain within 48 h following ERCP with levels of serum lipase elevated at least 3-fold and a requirement for analgesic drugs for at least 24 h. A systematic survey of 21 prospective studies with 16,855 patients conducted between 1987 and 2003 found a 3.5% occurrence of PEP, 0.4% instances of severe pancreatitis and 0.11% deaths [2].

There are a number of risk factors associated with PEP and they can be divided into either patient-related risk

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factors or endoscopist-related risk factors. Patient-related risk factors include female gender, previous pancreatitis and Sphincter of Oddi Dysfunction (SOD) [3]. Endoscopist-related risk factors include difficult instrumentation of papilla and pancreatic duct, precut sphincterotomy, endoscopic sphincterotomy, endoscopic pancreatic sphincterotomy (EPT), injection of contrast medium into the pancreatic duct and intraductal ultrasonography [4, 5]. The consequences of these risk factors are various injuries including, mechanical injury, thermal injury, hydrostatic injury, chemical injury, allergic injury, enzymatic injury with intraluminal activation of proteolytic enzymes and infection from contaminated endoscope and accessories.

Despite the introduction of various techniques over several decades to prevent PEP or limit its severity only a few strategies have been proven effective and have been integrated into clinical practice. Several systematic reviews and meta-analyses of randomized, double-blind, clinical trials have examined pancreatic stent placement and the efficacy of drugs, such as diclofenac, somatostatin, and nonsteroidal anti-inflammatory drugs to reduce the incidence of PEP [6–9]. In a meta-analysis of controlled clinical trials involving 481 patients the group that did not have stents implanted had 3-fold higher odds of developing pancreatitis compared with the group of patients that were treated with stents (15.5% vs. 5.8%; Odds Ratio (OR) 3.2; 95% Confidence Interval. Number needed to treat analysis showed that one in every 10 patients could be expected to benefit from pancreatic-duct stent placement [10]. A more recent meta-analysis of 1541 patients found that prophylactic pancreatic stent (PS) placement prevented PEP after ERCP compared with no PS placement thus supporting the importance of PS placement after ERCP for the prevention of PEP [11].

Plastic stents can be divided into three categories including straight PS, single pigtail PS and double pigtail PS. The straight PS and single pigtail PS are commonly used for pancreatic duct drainage. Compared to straight PS single pigtail PS has been demonstrated to minimize stent proximal migration, but there is a higher incidence of spontaneous abscission with single pigtail PS.

The observations made in the previous studies prompted us to design a modified of pancreatic stent system for prevention of PEP. In our system, the PS can be removed along with the nasobiliary catheter. The aim of this observational study was to investigate the feasibility and effectiveness of the modified pancreatic stent system for prevention of post-ERCP pancreatitis.

## Methods

### Design

This study was an analysis of clinical outcomes data associated with different types of pancreatic stent

placement. It is a retrospective review of patient medical records documented in the Department of Biliary Minimally Invasive Surgery affiliated to Zhongshan Hospital of Dalian University in China. The study was approved by the Conduct of Human Ethics Committee of the Affiliated Zhongshan Hospital of Dalian University.

### Patients

A single endoscopist performed ERCP in 735 consecutive patients with pancreatobiliary disease from November 2013 to November 2015. Exclusion criteria were, malignant tumor with biliary metal stent insertion, pancreatic duct stone, and cases that did not place nasobiliary drainage tubes at the same time. Two hundred thirty patients who had prophylactic pancreatic stent placed were eligible for inclusion. One hundred fifty received an ordinary pancreatic stent and nasobiliary drainage tubes (ordinary group) from November 2013 to October 2014 and 80 received the modified pancreatic stent (Modified group) from November 2014 to November 2015. The main outcome measures were the difficulty level and complications of pancreatic stent placement and extraction between the two groups.

### Endoscopic equipment and accessories

The following equipment and accessories were utilized during endoscopy: JF-260v/TJF-240 electronic duodenoscope (Olympus, Japan), VIO-200 s high frequency generator (mixed currents, cut current of 40-W, coagulation current of 40-W) (ERBE, German), papillary sphincter knife (Endo-Flex, German), balloon dilatation catheter (balloon diameter: 6 to 12 mm, length: 4 cm, pressure: 8 to 18 ATM) (OptiMed, German), inflation device (Boston Scientific, USA), yellow zebra guide wire, pancreatic stent, nasal biliary drainage tube (Boston Scientific, USA), sutures (Wego, China).

### Standard and method of pancreatic stent placement

Prophylactic PS should be placed if the patient has more than two factors as following: younger age, female gender, previous pancreatitis, SOD, normal serum bilirubin, difficult cannulation, precut sphincterotomy, EST, EPT, pancreatic duct injection, intraductal ultrasonography, sphincter of Oddi manometry, minor papilla sphincterotomy and trainee involvement in procedure [12]. PS was required be placed if the patient was diagnosed with acute or chronic pancreatitis or in patients in which contrast medium in the pancreatic duct drained slowly.

### Therapeutic endoscopy

ERCP was performed using digital subtraction angiography (DSA). EST was performed using a high frequency generator with the following settings: blend 1, cutting of 55, and coagulation of 30. The bile or pancreatic duct

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