Prophylactic temporary 3F pancreatic duct stent to prevent post-ERCP pancreatitis in patients with a difficult biliary cannulation: a multicenter, prospective, randomized study

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Background: Post-ERCP pancreatitis (PEP) is the most common and serious complication of ERCP. Difficult biliary cannulation can be a procedure-related risk factor for PEP. Recent studies reported that a prophylactic pancreatic stent (PS) can reduce the frequency and severity of PEP.

Objective: To evaluate the efficacy and usefulness of a temporary 3F PS to prevent PEP in patients with difficult biliary cannulations.

Design: A multicenter, prospective, randomized study.

Setting: Two tertiary-care academic medical centers.

Patients: In total, 101 patients with a difficult biliary cannulation were randomly divided into the 3F PS placement group (PS group, n = 50) or the nonstent (NS) group (NS group, n = 51).

Interventions: Endoscopic placement of a 3F unflanged PS.

Main Outcome Measurements: The incidence and severity of PEP in the 2 groups, spontaneous dislodgment of stents, and procedure-related complications.

Results: The technical success rate of 3F PS placement was 96% (48/50). The lengths of the stents were 4 cm (n = 21), 6 cm (n = 15), and 8 cm (n = 12). Spontaneous stent dislodgment within 7 days occurred in 94% of patients (45/48). The mean duration until spontaneous dislodgment was 3.5 days. The incidence rate of PEP was 12% (6/50: mild, 5; moderate, 1) in the PS group and 29.4% (15/51: mild, 12; moderate, 2; severe, 1) in the NS group. Severe pancreatitis occurred in only 1 patient in the NS group. In a multivariate analysis, prophylactic placement of PS was the only prophylactic factor for PEP (odds ratio, 0.126; 95% CI, 0.025-0.632, $P = .012$).

Limitations: No comparative results for stent size and diameter and a low-risk cohort group.

Conclusions: Prophylactic temporary 3F PS placement in patients with a difficult biliary cannulation during ERCP seems to be a safe and effective method for reducing PEP and results in a high rate of spontaneous passage of stents without complications. (Gastrointest Endosc 2012;76:578-85.)

Abbreviations: NS, nonstent; PD, pancreatic duct; PEP, post-ERCP pancreatitis; PS, pancreatic stent; SD, standard deviation; SOD, sphincter of Oddi dysfunction.

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Post-ERCP pancreatitis (PEP) is the most common and serious complication of ERCP and occurs after 1% to 40% of procedures. Its prevalence depends on several factors, including case mix, thoroughness of the follow-up evaluation, definition used, factors related to patient susceptibility, types of instrumentations used, and the skill of the endoscopist.[1-6] Recent studies reported that prophylactic placement of a pancreatic stent (PS) reduces the frequency and severity of PEP in various risk groups, including those with known or suspected sphincter of Oddi dysfunction (SOD), papillectomy, precut sphincterotomy, pancreatic sphincterotomy, history of PEP, or a difficult cannulation.[5-23]

The overall success rate for selective cannulation during ERCP ranges from 90% to 95%, even when performed by experts.[7] During biliary cannulation, the rate of PEP increases when cannulation is difficult and prolonged.[3] However, few data are available concerning the effect of a prophylactic pancreatic duct (PD) stent on this technical difficulty with respect to cannulation time or frequency of papillary contacts. In addition, the sizes and lengths of stents are variable, and no guideline or consensus yet exists regarding which type or length of PS is optimal.[16-18]

This prospective, randomized, controlled study was designed to evaluate the efficacy and usefulness of a 3F PS to prevent PEP in patients with difficult selective biliary cannulations.

Take-home Message

- Difficult biliary cannulation can be a risk factor for post-ERCP pancreatitis. Prophylactic temporary placement of a 3F pancreatic duct stent was technically feasible and effectively reduced the rate of post-ERCP pancreatitis with a high rate of spontaneous dislodgment in patients with a difficult biliary cannulation.

PATIENTS AND METHODS

Study population and design

Consecutive consenting patients referred for therapeutic ERCP between January 2008 and July 2011 were included from 2 academic tertiary referral centers. All patients underwent abdominal US, CT scans, and/or magnetic resonance cholangiopancreatography before ERCP. Patients who satisfied the following inclusion criteria were enrolled: difficult biliary cannulation, age 18 years and older, and agreement to participate in this study. Difficult biliary cannulation was defined as failure to achieve selective biliary access despite 10 minutes of attempted cannulation, more than 5 attempted unintentional pancreatic cannulations, or frequent papillary contact of more than 10 times, whichever occurred first. Papillary contact was defined as sustained contact between the catheter and the ampulla of Vater for at least 3 to 5 seconds.[4,24] Exclusion criteria were the following: age younger than 18 years, successful deep biliary cannulation without difficulty, surgically altered anatomy (Billroth II gastrectomy or Roux-en-Y anastomosis), previous biliary or pancreatic sphincterotomy, uncontrolled coagulopathy, radiological and clinical evidence of acute pancreatitis at the time of the procedure, a tumorous condition invading the ampulla of Vater, pancreatic head cancer with main PD obstruction, intraductal papillary mucinous neoplasm, pancreatic divisum, and refusal to participate in the study. In total, 101 patients with difficult biliary cannulations were enrolled, and patients who met the eligibility criteria were randomly assigned by computer-generated randomization to 2 groups (PS group [3F plastic stent inserted] vs nonstent [NS] group; block randomization with the medical centers as blocks) (Fig. 1). The allocation sequence was concealed from all patients and endoscopists. A second assisting nurse was assigned at the point of difficulty with the cannulation. The procedure time, including cannulation time, papillary contacts, and unintentional PD cannulation, was recorded by same assisting nurse during the procedures. All institutional review boards involved approved this study. Written informed consent was obtained from all enrolled patients.

Endoscopic procedure

All patients underwent ERCP with a standard duodenoscope (JF 260 or 260V; Olympus Optical Co, Ltd, Tokyo, Japan). The procedure was performed after the patient fasted overnight, was placed in the prone position, and was sedated with intravenous midazolam (0.05 mg/kg) and/or propofol (0.5 mg/kg).

Prophylactic antibiotics and analgesics were permitted. All procedures started with a standard double-lumen sphincterotome or conventional catheter. A wire-guided cannulation technique was not attempted initially, but was used as a rescue method for difficult biliary cannulations or selected PD cannulations for stenting. In the PS group, a guidewire in the PD for pancreatic stenting was used, and then selective biliary cannulation was attempted with the guidewire in the PD (double wire-guided cannulation technique). After successful biliary cannulation and/or sphincterotomy, patients underwent pancreatic stenting. The endoscopic approach to PS placement involved passing a 0.018- or 0.021-inch/480-cm guidewire (Cook Endoscopy, Winston-Salem, NC) deep into the PD, at least past the genu. Before pancreatic stenting, pancreatography was performed to visualize the correct direction of the PD. Then, an unflanged single pigtail-type PS (Zimmon; Cook Endoscopy) with a small-caliber (3F) and 4, 6, or 8 cm in length was placed over the guidewire. Successful PS placement was achieved when the stent was appropriately positioned within the PD and its distal end was positioned in the duodenal lumen. Prophylactic PS placement was performed before biliary therapeutic procedures such as