

## Risk factors for post-ERCP pancreatitis in wire-guided cannulation for therapeutic biliary ERCP

Yousuke Nakai, MD, PhD, Hiroyuki Isayama, MD, PhD, Naoki Sasahira, MD, PhD, Hirofumi Kogure, MD, PhD, Takashi Sasaki, MD, PhD, Natsuyo Yamamoto, MD, PhD, Kei Saito, MD, Gyotane Umefune, MD, Dai Akiyama, MD, Shuhei Kawahata, MD, Miho Matsukawa, MD, Tomotaka Saito, MD, Tsuyoshi Hamada, MD, PhD, Naminatsu Takahara, MD, PhD, Suguru Mizuno, MD, PhD, Koji Miyabayashi, MD, PhD, Dai Mohri, MD, PhD, Kenji Hirano, MD, PhD, Minoru Tada, MD, PhD, Kazuhiko Koike, MD, PhD

Tokyo, Japan

**Background:** Wire-guided cannulation (WGC) was reported to decrease post-ERCP pancreatitis (PEP), but risk factors for PEP in WGC are not fully elucidated.

**Objective:** To evaluate the incidence and risk factors of PEP in WGC.

**Design:** Single-center retrospective study.

**Setting:** Academic center.

**Patients:** A total of 800 consecutive patients with a native papilla.

**Interventions:** Biliary therapeutic ERCP by using WGC.

**Main Outcome Measurements:** The rate of PEP and its risk factors.

**Results:** Biliary cannulation was successful by using WGC alone in 70.5%, and the final cannulation rate was 96.1%. Unintentional guidewire insertion and contrast material injection into the pancreatic duct (PD) during cannulation occurred in 55.3% and 21.8%, respectively. The incidence of PEP was 9.5% (mild 5.6%, moderate 2.9%, severe 1.0%). Multivariate analysis revealed a common bile duct (CBD) diameter of <9 mm (odds ratio [OR] 2.03;  $P = .006$ ) and unintentional guidewire insertion into the PD (OR 2.25;  $P = .014$ ) as risk factors for PEP. PD opacification was not a risk factor for PEP (OR 1.15;  $P = .642$ ), but the incremental increase of the PEP rate was seen in patients with CBDs <9 mm: 4.6% without any PD manipulation, 8.3% with contrast material alone, 16.9% with guidewire alone, and 22.1% with both contrast material and guidewire.

**Limitations:** Retrospective design in a single center.

**Conclusion:** Unintentional PD manipulation was not uncommon in WGC. Guidewire insertion into the PD and a small CBD were risk factors for PEP in biliary therapeutic ERCP with the use of WGC. (Gastrointest Endosc 2015;81:119-26.)

About 4 decades have passed since ERCP was used as a diagnostic and therapeutic tool for biliary tract diseases, but post-ERCP pancreatitis (PEP) still remains a dreadful

adverse event. Wire-guided cannulation (WGC), which can avoid pancreatic duct (PD) opacification, has been reported to reduce PEP compared with conventional

*Abbreviations:* CBD, common bile duct; DGW, double guidewire; NSAID, nonsteroidal anti-inflammatory drug; PD, pancreatic duct; PEP, post-ERCP pancreatitis; PGW, pancreatic duct guidewire; WGC, wire-guided cannulation.

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Current affiliations: Department of Gastroenterology, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan.

Reprint requests: Hiroyuki Isayama Department of Gastroenterology, Graduate School of Medicine, the University of Tokyo 7-3-1 Hongo Bunkyo-ku, Tokyo, Japan 113-8655.

contrast material–assisted cannulation. Although some conflicting data were reported,<sup>1,2</sup> most randomized controlled trials<sup>3–6</sup> and meta-analyses<sup>7–9</sup> showed that WGC can reduce the rate of PEP as well as increase the cannulation rate. We reported that the introduction of WGC decreased the PEP rate with a short learning curve.<sup>10</sup>

Given these accumulating evidences, WGC is increasingly used as a primary cannulation technique. However, little is known about risk factors for PEP in WGC, and, thus, we conducted this analysis of risk factors for PEP in WGC for therapeutic biliary ERCP.

## METHODS

### Patients

Consecutive patients with a native papilla undergoing therapeutic ERCP by using WGC were retrospectively studied. Patients undergoing ERCP with a planned PD intervention or patients with altered GI anatomy undergoing enteroscopy-assisted ERCP were excluded. Patients with histories of ERCP or with concomitant acute pancreatitis also were excluded from the analysis.

### Biliary cannulation

WGC was performed as follows. A sphincterotome (CleverCut3; Olympus Co, Tokyo, Japan or Autotome; Boston Scientific, Natick, Mass) or a cannula (ERCP catheter; MTW Endoskopie, Wesel, Germany or Tandem XL; Boston Scientific) preloaded with a 0.035-inch standard (Revowave; Piolax, Yokohama, Japan or Jagwire; Boston Scientific) or hydrophilic (Radifocus; Terumo, Tokyo, Japan) guidewire was slightly inserted into the papilla at the direction of the bile duct axis. Then, the guidewire was gently advanced into the bile duct. Entry into the bile duct was confirmed by fluoroscopy. If the guidewire was inserted into the PD or did not advance without resistance, the guidewire was withdrawn, and the sphincterotome was redirected to the bile duct axis until the guidewire was inserted into the bile duct. The bile duct was opacified after biliary cannulation was achieved. The guidewire was controlled by assistants who were endoscopists with ERCP experience. In cases of difficult cannulation, the method and timing of rescue techniques were determined at the discretion of the endoscopists. Rescue techniques applied in this study were contrast material–assisted cannulation, a double-guidewire (DGW) technique,<sup>11</sup> a pancreatic duct guidewire (PGW) technique,<sup>12,13</sup> or a percutaneous transhepatic biliary drainage–assisted rendezvous technique. Prophylactic PD stent placement was performed at the discretion of the endoscopists. Some patients received ulinastatin and/or risperidone<sup>14,15</sup> as a study protocol, but no patients received nonsteroidal anti-inflammatory drugs (NSAIDs) as a prophylaxis for PEP during this period. In the presence of cholangitis due to choledocholithiasis, biliary drainage alone was performed at the initial ERCP session.

All patients were hospitalized for at least 24 hours after the procedure. Serum amylase levels were measured before and at 18 to 24 hours after ERCP. Abdominal radiograph, US, or CT was performed if needed.

### ERCP data

ERCP data were prospectively collected into our ERCP database at the University of Tokyo Hospital. The database included patient characteristics (eg, age, sex, diagnosis, history of upper GI tract surgery, and presence of periamпуляр diverticulum), procedure data (eg, cannulation method, cannulation success, the number of cannulation attempts, time to cannulation, the number of PD injections or guidewire insertions, interventions performed after cannulation, and total procedure time), and procedure outcome data (eg, clinical symptoms and serum amylase levels before and after ERCP, and ERCP adverse events and their severity). If biliary cannulation was difficult in cases performed by trainees, experienced endoscopists took over. This study was approved by the ethics committee at the University of Tokyo Hospital.

### Definition

Time to biliary cannulation was defined as time from initiation of biliary cannulation to successful selective insertion of a sphincterotome or catheter into the bile duct. Total procedure time was defined as time from endoscope insertion to endoscope removal.

ERCP-related adverse events were defined according to a lexicon for endoscopic adverse events.<sup>16,17</sup> PEP was defined as abdominal pain persisting for at least 24 hours after the procedure associated with a high serum amylase level equivalent to  $\geq 3$  times the upper limit of normal at 18 to 24 hours after the procedure. PEP was graded according to a modification of the same lexicon: mild—requiring fasting and treatment for  $\leq 3$  days; moderate—requiring fasting and treatment for 4 to 10 days; severe—requiring fasting and treatment for  $> 10$  days, intensive care, or surgical intervention. Asymptomatic hyperamylasemia was defined as amylase levels  $> 3$  times the upper limit of normal at 18 to 24 hours after ERCP in the absence of PEP.

### Statistical analysis

Univariate and multivariate analyses to identify risk factors for PEP were performed by using logistic regression analysis. The model included age ( $< 60$  vs  $\geq 60$  years), sex, body mass index ( $< 22.2$  vs  $\geq 22.2$  kg/m<sup>2</sup>), reasons for ERCP, ERCP by trainees, pancreatic cancer, periamпуляр diverticulum, jaundice at ERCP, common bile duct (CBD) diameter ( $< 9$  vs  $\geq 9$  mm), procedure time, catheter type, guidewire type, number and time of cannulation attempts, final cannulation failure, biliary sphincterotomy, papillary balloon dilation, stone extraction, transpapillary biliary stricture brushing and biopsy, intraductal US, nasobiliary drainage, plastic stent, metal stent, PD guidewire insertion, PD opacification, and prophylactic PD stent.

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