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**Newly designed J-shaped-tip guidewire: A preliminary feasibility study in wireguide cannulation**

Omuta S *et al*. J-shaped-tip guidewire for cannulation

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**Abstract**

**AIM:** To perform Wire-guided cannulation using a newly designed J-shaped-tip guidewire, and verified feasibility and safety for use.

**METHODS:** The study was conducted on endoscopic retrograde cholangiopancreatography (ERCP) patients with naïve papilla undergoing diagnosis and treatment of biliary diseases between September 2011 and July 2012. We performed a succession of 50 cases with J-shaped tip guidewire. The first insertion attempt began with a trainee who had 5 min to complete cannulation, followed if necessary trainer for another 5 min. We assessed the primary success rate of selective biliary cannulation within 10 min and adverse events such as post-ERCP pancreatitis (PEP), bleeding, perforation.

**RESULTS:** The primary success rate was 90% (45/50) within 10 min, the initial success rate within 5 min by trainee staffs was 76% (38/50). The rate of PEP was 6% (3/50), but all 3cases were mild pancreatitis. All patients were managed successfully with conservative treatment. There was no bleeding and perforation.

**CONCLUSION:** A newly designed J-shaped tip guide-wire has possibility may facilitate selective biliary cannulation for ERCP. It may be safety.

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**Key words:** J-shaped-tip guidewire; Wire-guided cannulation; Endoscopic retrograde cholangiopancreatography; Biliary tract; Cannulation technique perforation

**Core tip:** We conducted the feasibility study that performed Endoscopic retrograde cholangiopancreatography (ERCP) with a newly designed J-shaped tip guidewire. This new guidewire has a strongly-flexed atraumatic tip with hydrophilic coating, Therefore, it may contribute to the improvement of the passage through intra-duodenal biliary segment and the decrease of adverse events such as post-ERCP-pancreatitis. We assessed the primary success rate of selective biliary cannulation within 10 min and post-ERCP-pancreatitis. The primary success rate was 90% (45/50), the rate of post-ERCP-pancreatitis was 6% (3/50), but all 3 cases were mild. J-shaped-tip guiderire may facilitate selective biliary cannulation in ERCP.

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**INTRODUCTION**

Endoscopic retrograde cholangiopancreatography (ERCP) is used to diagnose and treat biliary disease. Deep cannulation of the common bile duct is required for this procedure, and the current success rate for the relatively difficult conventional contrast-guided cannulation (CGC) technique ranges from 50%-90%[1-5]. Wire-guided cannulation (WGC) is a recently developed alternative to CGC that has been shown to increase primary biliary cannulation rate[6-11], chiefly by reducing incidence of post-ERCP pancreatitis (PEP)[12-20]. However, despite efficiency improvements, the sharp tips of guide-wires are sometimes associated with perforation[21-23]. Even without perforation, complications can occur when the guidewire tip hits the fold and flexion of the intra-duodenal biliary segment. While a looped tip guidewire has been developed, its utility in avoiding perforation has not sufficiently been evaluated[24,25].

Here, we assessed the efficiency of ERCP using a newly J-shaped-tip guidewire with a strongly flexed atraumatic tip and hydrophilic coating designed to improve passage through intra-duodenal biliary segments and decrease the adverse events, such as PEP, bleeding, perforation.

**MATERIALS AND METHODS**

***Patient***

Fifty patients with naïve papilla undergoing diagnosis and treatment for biliary diseases between September 2011 and July 2012 received ERCP using J-shaped-tip guidewires. Patients were excluded if only their pancreatic ducts were diagnosed or treated, if they had previously undergone endoscopic sphincteroplasty, or if they had duodenal stenosis or Billroth II or Roux-en-Y anastomosis, or refusal to provide informed consent.

Patients were sedated via intravenous administration of midazolam (5-10 mg) and buprenorphine (0.2 mg). Scopolamine butylbromide (20 mg) or glucagon (1 mg) was injected intravenously to inhibit gastrointestinal peristalsis, and each patient received nafamostatmesilate (20 mg/d) prior to ERCP. Blood samples collected 2 h after ERCP were used to determine complete blood counts and serum amylase levels, and those collected after 18-24 h also measured hepatobiliary enzymes and C-reactive protein. We did not place a pancreatic duct stent for the prevention of pancreatitis in either procedure.

***J-shaped-tip guidewire***

The guidewire (RWHJ-2545A, 0.025-inch; Paiolax Medical Devices, Inc., Kanagawa, Japan) tip was bent to attain a 1-mm radius, and a hydrophilic coating was applied starting 50 mm from the tip. The shaft was covered by a sheath and jacket coated with water-repellent material (Figure 1).

***Endoscopic procedure***

Endoscopy was performed with JF-260V (Olympus, Tokyo, Japan) or ED-530XT8 (Fujinon, Tokyo, Japan) endoscopes. After catheters were preloaded with guidewires. In the present study, in general, a regular catheter was chosen except for the case undergoing sphincterotomy. “First, catheters (CleverCut3 V, Olympus, Tokyo, Japan; Tamdem XL, Boston Scientific, Natick, MA, United States) were preloaded with guidewires”, the guidewire tip was extended 5 mm from the catheter, bent into a “J” shape, and then the guidewire was pulled back into a stand-by position (Figure 2A). Endoscopists controlled the direction parallel to the axis of bile duct of the catheter by inches. Assisting endoscopists participated in the guidewire manipuration in all cases. An assisting endoscopist moved the guidewire back and forth in small motions by using a tactile feedback (in-and-out movement method). No fluoroscope was used during attempts of insertion, but once the guidewire was inserted without resistance and fluoroscopy was used only after insertion to confirm success (Figure 2B). The catheter was then inserted into the biliary system along the guidewire, and contrast medium was injected (Figure 2C). No test injection was performed before successful cannulation.

The first insertion attempt began with a trainee who had 5 min to complete cannulation, followed if necessary trainer with career experience of over 500 ERCPs (Maetani I or Shigoka H or Omuta S) for another 5 min. If both attempts failed, efforts continued with a standard biliary guidewire (Jagwire 0.035 angle type, Boston Scientific) for another 10 min (second attempt) and were repeated as necessary according to the trainers’ recommendations (exchange of endoscopist or guidewire, pancreatic duct guidewire placement method, or pre-cutting sphincterotomy).

***Definitions***

Success was defined as completing cannulation with the J-shaped-tip guidewire and obtaining a cholangiogram within 10 min. Cannulation time was defined as from a tip of the guidewire first touched the orifice of the papilla to the obtainment of cholangiogram. PEP was defined as continued abdominal pain ≥ 24 h after ERCP, with more than 3 times the normal (upper limit) serum-amylase level[26]. Pancreatitis severity was classified using the Atlanta International Symposium criteria[27]. Suspected sphincter of Oddi dysfunction was defined according to the revised Milwaukee classification[28]. Sphincter of Oddi manometory was not performed. Hyperamylasemia was defined as 3 times the normal (upper limit) amylase level 18-24 h after ERCP.

***Ethics***

The protocol adhered to the Helsinki Declaration and was approved in advance by the Institutional Ethical Review Board. The trial was registered with the University hospital Medical Information Network Clinical Trials Registry (UMIN000007526). All participants gave written informed consent beforehand.

***Outcome measurement***

The primary study endpoint was the success rate of cannulation with J-shaped -tip guidewire performed within 10 min. The secondary endpoints were as follows: (1) the rate of the occurrence of PEP; (2) time to selective biliary cannulation; (3) number of attempts for selective biliary cannulation; and (4) number of accidental pancreatic duct insertion. Data are presented as median and interquartile ranges (IQR).

**RESULTS**

Baseline characteristics and indications are summarized in Table 1, and details of the endoscopic procedure are given in Table 2.

The overall success rate of endoscopy was 90% (45/50, Table 3), with cannulation achieved within the first 5 min in 38 patients (76%). Cannulation was achieved on the second attempt in 3 patients. The median time to cannulation for these 48 patients was 42.5 s (IQR: 5-262 s). Of the remaining two patients, one required pancreatic duct guidewire placement and the other a pre-cutting sphincterotomy. The median number of attempts was 2.0 (IQR: 1-6), and the median number of accidental pancreatic duct insertions was 1.0 (IQR: 0-3). The median serum-amylase level was 148 IU/L (IQR 94-331 IU/L), and hyperamylasemia occurred in 4 patients.

Mild PEP occurred in 3 patients (6%); in 2 of these, success was achieved within 5 min after endoscopic papillary large balloon dilation, while the third patient received the pre-cutting sphincterotomy mentioned above. All patients were managed successfully with conservative treatment. There were no other adverse events including bleeding or perforation.

**DISCUSSION**

The success rate for selective biliary cannulation using J-shaped-tip guide-wire was comparable to that found in previous studies[6-16,29,30], and no guidewire-related adverse events such as bleeding or perforation occurred. Although ours was a preliminary study, the atraumatic and blunt tip of new guide-wire may facilitate selective biliary cannulation (Figure 3A) and reduce instances of perforation and bleeding.

Although straight and angled tips are the most common types used in WGC[1-20,29,30], these sharp tips often stick in the intra-duodenal biliary segment (Figure 3B). While the superiority of the J-shaped-tip cannot be definitively shown without controls, the success rate, speed of cannulation, and facility of use appear improved compared to other studies. While similar procedures using standard guide-wires resulted in a 77.9% overall success-rate (trainees and trainer combined)[29], here we achieved a 76% success rate with trainees, and an overall success rate of 90%. Additionally, the 6% PEP rate is similar to that of other studies[14,18,19,20].

WGC was first introduced by Siegel *et al*[31]in 1987. Meta-analysis has shown that the reduction of pancreatic duct opacification is another possible advantage over CGC[14,18,19]. Further, WGC has been suggested to decrease the risk of PEP[14,18,19], facilitating its spread across the globe as a potential first-line method.

Usually, when guidewires are extended from the tip of a catheter without enough space for advancement, the wire may act like a needle and pierce the epithelium. The J-shaped of the guidewire protrudes from the catheter before approaching the biliary orifice, and reduces this likelihood. We therefore believe our J-shaped-design to be the aspect that improved insertion into the biliary system. Limitations to this study include small sample size, no controls, a single institution, and involvement of multiple endoscopists. A randomized comparison is warranted for objective evaluation of its performance. One drawback of the J-shaped-tip guidewire is the 1-mm radius, which is wider than a standard guidewire and may hamper selective cannulation through a narrow orifice.

In conclusion, a newly designed guidewire with a J-shaped-tip may facilitate selective biliary cannulation in ERCP. However, a large prospective randomized control trial is necessary to verify the performance of this guidewire in comparison with standard guidewires.

**COMMENTS**

***Background***

Selective biliary cannulation is essential for diagnosis and therapeutic endo scopic retrograde retrograde cholangiopancreatography (ERCP) in biliary diseases. Wire-guided cannulation (WGC) increases the primary biliary cannulation rate and decreases the risk of post-ERCP pancreatitis (PEP). Therefore, WGC is now widely performed. However, even experts meet with the difficulty and possible risk of bleeding and perforation due to the guidewire.

***Research frontiers***

The authors performed ERCP using a newly designed J-shaped-tip guidewire. A newly J-shaped-tip guidewire with a strongly flexed atraumatic tip and hydrophilic coating designed to improve passage through intra-duodenal biliary segments and decrease the adverse events, such as PEP and bleeding, perforation. The authors conducted the feasible study.

***Innovations and breakthroughs***

This is a single center pilot study. The primary success rate was 90% (45/50) within 10 min. The rate of PEP was 6% (3/50), but all 3 cases were mild pancreatitis. All patients were managed successfully with conservative treatment. There was no bleeding and perforation.

***Applications***

A newly designed J-shaped-tip guidewire may facilitate selective biliary cannulation and the structure of the tip may contribute to decrease PEP and bleeding, perforation. However, it must be necessary to conduct a large prospective randomized control trial to verify the performance.

***Peer review***

This is a single center pilot study of a newly designed J-shaped-tip guidewire for wire-guided cannulation. The authors hypothesized J-shaped tip prevented perforation or PEPduring cannulation. The limitation of this study is a small sample size without a control group as the authors discussed.

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**Figure 1 Newly designed J-shaped-tip guidewire.** A shape of the tip is a radius of 1 mm and 50 mm from the tip is coated with hydrophilic.

**Figure 2** **Endoscopic and fluoroscopic images showing the technique with J-shaped-tip guidewire.** A: Assistant endoscopist extended approximately 5 mm of the guidewire tip and restored it to the original ‘J’ configuration (stand-by position); B: Selective biliary cannulation was attempted under endoscopic control without fluoroscopy; C: The guidewire was moved in-and-out motion by an assisting endoscopist. Once the guidewire was advanced without resistance, fluoroscopy was used to confirm successful cannulation; D: Contrast medium was injected after confirmation of successful biliary cannulation.

**Figure 3** **An image *via* intra-duodenal biliary segments of J-shaped-tip guidewire (A) and standard guidewire (B).** A:Blunted J-shaped-tip may facilitate passage through intra-duodenal segment;B: Normal guidewire tips may be become stuck in epithelial folds or flexion of intra-duodenal biliary segments.

**Table 1 Baseline patient characteristics and indications**

|  |  |
| --- | --- |
| Item  (*n* = 50) | Value |
| Age, yr [median (IQR)] | 75.3 (68-83) |
| Sex (Male) | 24 |
| Periampullary diverticulum, *n* (%) | 22 (44) |
| Indications |  |
| Choledocolithiasis (including suspicion) | 27 |
| Cholangiocarcinoma | 7 |
| Pancreatic cancer | 6 |
| Gallbladder cancer | 4 |
| Other malignant disease | 2 |
| Cholangiocellular carcinoma | 1 |
| Suspected biliary SOD | 1 |
| Mirrizi syndorome | 1 |
| Biliary leak after cholecystectomy | 1 |

IQR: interquartile rage; SOD: sphincter of Oddi dysfunction.

**Table 2 Number of patients receiving different procedures**

|  |  |
| --- | --- |
| Item | ***n*** |
| Endoscopic papillary (large) balloon dilation | 24 |
| Endoscopic sphincterotomy | 19 |
| Endoscopic nasobiliary drainage | 20 |
| Endoscopic nasobiliary gallbladder drainage | 2 |
| Placement of biliary stent (plastic or metal) | 18 |
| Intraductal ultrasonography | 7 |
| Aspiration, Biopsy | 12 |
| Only cholangiogram | 0 |

**Table 3 Cannulation outcomes**

|  |  |  |
| --- | --- | --- |
| Item  (*n* = 50) | | Value |
| Success, *n* (%) | 45 (90) | |
| < 5 min | 38 | |
| 5-10 min | 7 | |
| Median time to selective biliary cannulation, s (IQR) | 42.5 (5-262) | |
| Median number of attempts (IQR) | 2.0 (1-6) | |
| Median number of accidental pancreatic duct insertion (IQR) | 1.0 (0-3) | |
| Median amylase level, IU/L (IQR) | 148 (94-331) | |
| Post-ERCP pancreatitis, *n* (%) | 3 (6) | |
| Mild | 3 | |
| Severe | 0 | |
| Hyperamylasemia, *n* (%) | 4 (8) | |

IQR: interquartile range; ERCP: Endoscopic retrograde cholangiopancreatography.