

Newly designed J-shaped tip guidewire: A preliminary feasibility study in wire-guided cannulation

Shigefumi Omuta, Iruru Maetani, Hiroaki Shigoka, Katsushige Gon, Michihiro Saito, Junya Tokuhisa, Mieko Naruki

Shigefumi Omuta, Iruru Maetani, Hiroaki Shigoka, Katsushige Gon, Michihiro Saito, Junya Tokuhisa, Mieko Naruki, Division of Gastroenterology, Department of Internal Medicine, Toho University Ohashi Medical Center, Tokyo 153-8515, Japan
Author contributions: Omuta S contributed to analysis and interpretation of the data, drafting of the article and revising for reviewers comments; Maetani I contributed to conception and design, critical revision of the article and data collection; Shigoka H contributed to data collection; Omuta S, Gon K, Saito M, Tokuhisa J and Naruki M contributed to treatment of patients and data collection; all authors approved the final version of the paper.

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Correspondence to: Iruru Maetani, MD, Division of Gastroenterology, Department of Internal Medicine, Toho University Ohashi Medical Center, 2-17-6 Ohashi, Meguro-ku, Tokyo 153-8515, Japan. mtmr50637@med.toho-u.ac.jp

Telephone: +81-3-34681251 Fax: +81-3-54650210
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Abstract

AIM: To perform wire-guided cannulation using a newly designed J-shaped tip guidewire, and to verify 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 ERCP in a succession of 50 cases with a J-shaped tip guidewire. The first insertion attempt began with a trainee who had 5 min to complete cannulation, followed if necessary by the 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 or perforation.

RESULTS: The primary success rate was 90% (45/50) within 10 min, the initial success rate within 5 min by trainee staff was 76% (38/50). 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 or perforation.

CONCLUSION: A newly designed J-shaped tip guidewire has the possibility to facilitate selective biliary cannulation for ERCP and appears to be safe.

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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 a 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 the intra-duodenal biliary segment and to the decrease of adverse events such as post-ERCP pancreatitis. We assessed the primary success rate of selective biliary cannulation within 10 min and rate of 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. The J-shaped tip guidewire 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 guidewires 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].

Here, we assessed the efficiency of ERCP using a newly designed 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 or perforation.

MATERIALS AND METHODS

Patients

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 refused 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 nafamostat mesilate (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 the jacket coated with water-repellent material (Figure 1).

Endoscopic procedure

Endoscopy was performed with JF-260V (Olympus, To-

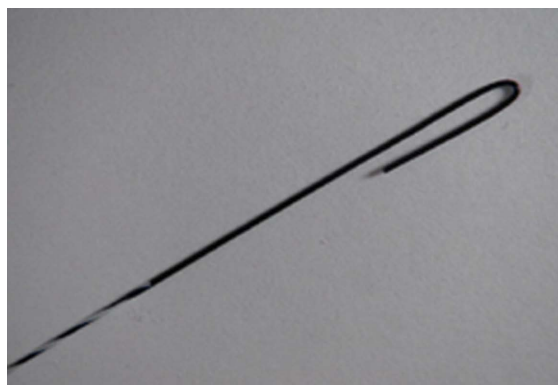


Figure 1 Newly designed J-shaped tip guidewire. The shape of the tip is a radius of 1 mm; 50 mm from the tip is the start of a hydrophilic coating.

kyo, 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 manipulation 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 then 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 by a 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 when a tip of the guidewire first touched the orifice of the papilla to the obtainment of cholangiogram. PEP was defined as continued abdominal pain \geq 24 h after ERCP, with more than 3 times the normal (upper limit) serum-

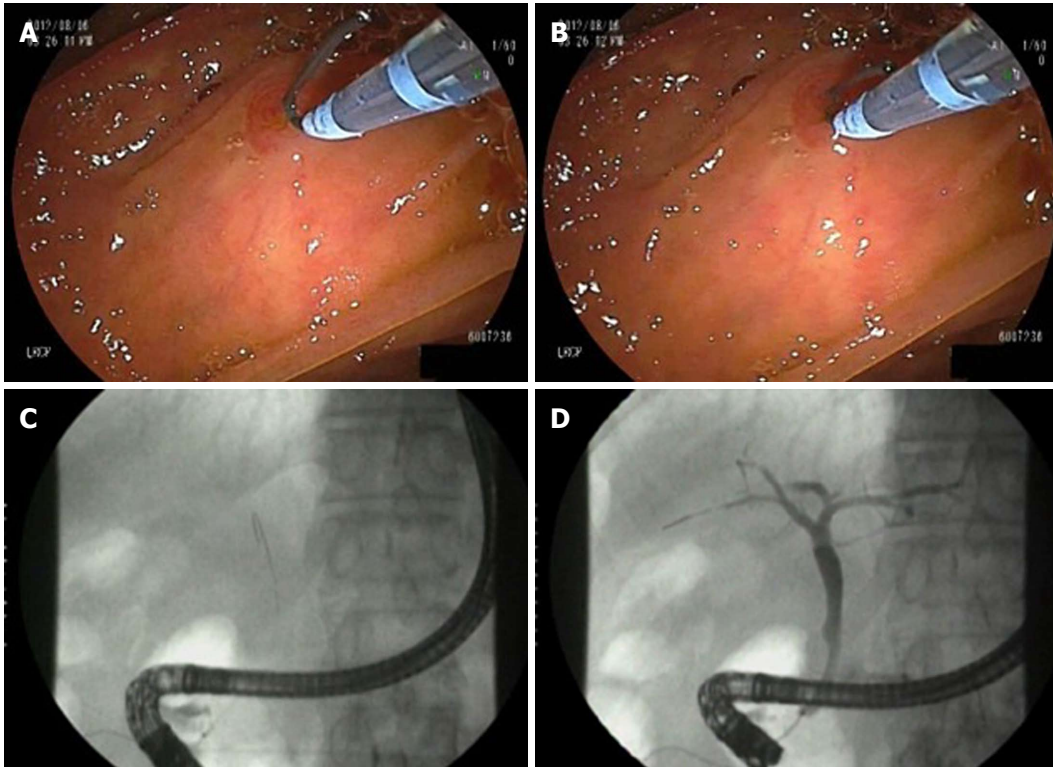


Figure 2 Endoscopic and fluoroscopic images showing the technique with J-shaped tip guidewire. A: Assistant endoscopist extended approximately 5 mm of the guidewire tip and restored it to the original "J" configuration (stand-by position); B: Selective biliary cannulation was attempted under endoscopic control without fluoroscopy; C: The guidewire was moved in an 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.

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 syndrome	1
Biliary leak after cholecystectomy	1

IQR: Interquartile range; SOD: Sphincter of Oddi dysfunction.

amylase level^[25]. Pancreatitis severity was classified using the Atlanta International Symposium criteria^[26]. Suspected sphincter of Oddi dysfunction was defined according to the revised Milwaukee classification^[27]. Sphincter of Oddi manometry 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 Re-

view 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 the 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 insertions. 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:

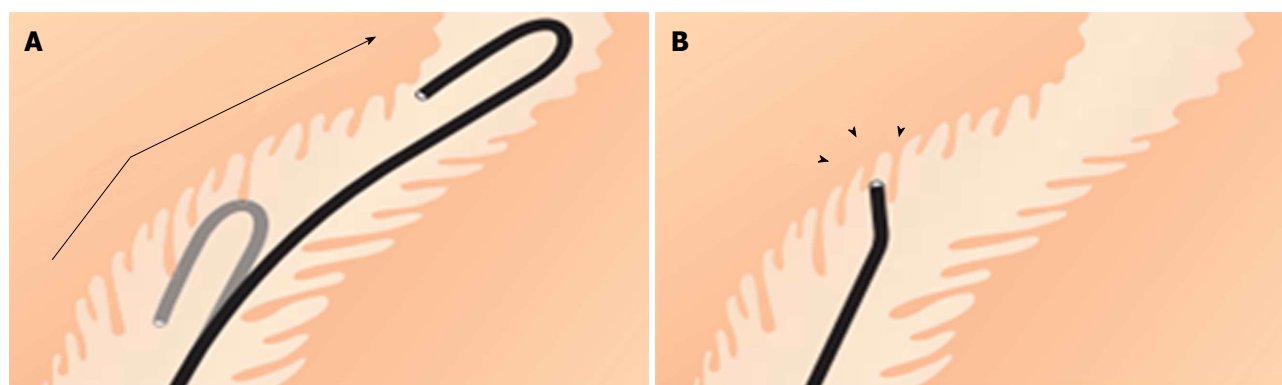


Figure 3 An image via intra-duodenal biliary segments of J-shaped tip guidewire (A) and standard guidewire (B). A: Blunted J-shaped tip may facilitate passage through intra-duodenal segment (arrow); B: Normal guidewire tips may become stuck in epithelial folds or flexion of intra-duodenal biliary segments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

Table 2 Number of patients receiving different procedures

Procedure	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

1.0-6.0), and the median number of accidental pancreatic duct insertions was 1.0 (IQR: 0.0-3.0). 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 a J-shaped tip guidewire was comparable to that found in previous studies^[6-16,28,29], and no guidewire-related adverse events such as bleeding or perforation occurred. Although ours was a preliminary study, the atraumatic and blunt tip of the new guidewire 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^[1-20,28,29], 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 guidewires resulted in a 77.9% overall success

Table 3 Cannulation outcomes

Item (n = 50)	Value
Success, n (%)	45 (90)
< 5 min	38 (76)
5-10 min	7 (14)
Time to selective biliary cannulation ¹ , s	42.5 (5.0-262.0)
No. of attempts ¹	2.0 (1.0-6.0)
No. of accidental pancreatic duct insertion ¹	1.0 (0.0-3.0)
Amylase level ¹ , IU/L	148 (94-331)
Post-ERCP pancreatitis, n (%)	3 (6)
Mild	3
Severe	0
Hyperamylasemia, n (%)	4 (8)

¹Data is shown as median (IQR). IQR: Interquartile range; ERCP: Endoscopic retrograde cholangiopancreatography.

rate (trainees and trainer combined)^[28], 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.*^[30]. 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-shape 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 endoscopic 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 difficulty and the 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 J-shaped tip guidewire with a strongly flexed atraumatic tip and hydrophilic coating was designed to improve passage through intra-duodenal biliary segments and decrease the adverse events, such as PEP, bleeding and perforation. The authors conducted a 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 or 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, or perforation. However, it is 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 that the J-shaped tip prevented perforation or PEP during cannulation. The limitation of this study is a small sample size without a control group as the authors discussed.

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