

Format for ANSWERING REVIEWERS



March 19, 2013

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: 1869-review.doc).

Title: A newly designed J-shaped-tip guidewire: a preliminary feasibility study in wire-guided cannulation.

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

Name of Journal: *World Journal of Gastroenterology*

ESPS Manuscript NO: 1869

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the reviewer

We wish to express our strong appreciation to the reviewers for their insightful comments on our paper. We feel the comments have helped us significantly improve the paper. We answer your comments.

From *Reviewed by 01430761*

Major points

1.

The feature of J-shaped-tip guidewire is a strongly flexed atraumatic tip and hydrophilic coating. Because this configuration is not stuck in the intra-duodenal biliary segments, it may be contributed to facilitate passage through intra-duodenal biliary segments.

Thus, in this study, we think the primary endpoint was the success rate of cannulation with J-shaped tip guidewire performed within 10 min.

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, (4) number of inadvertent pancreatic duct insertion.

We will revise the text. P 7, it is 28 lines from 24 lines

2.

As you mention, the concept of J-shaped tip guidewire is partly similar to that of the loop-tipped guidewire. But specifications of these two guidewires are significantly different.

First, the tip of the loop-tipped guidewire is spring structure without coating whereas the J-shaped-tip guidewire has a very soft tip with hydrophilic coating. Therefore, the feature of J-shaped-tip guidewire might be beneficial for facilitating passage through narrow distal bile duct.

Second, the distal part of the J-shaped-tip guidewire is very flexible in comparison with loop-tipped guidewire. This feature might allow a guidewire to pass a tortuous intra-duodenal biliary segment.

Minor points

1.

The first attempt began with a trainee who had 5 min to complete cannulation, if failed trainer made an attempt with the same technique for another 5 min. The attempts within 10 minutes represent the first attempt.

If the first attempt failed, efforts continued with a standard biliary guidewire for another 10 min. This represents the second attempt. So, seven cases with success in 5-10 min are included in success of the first attempt.

2.

J-shaped-tip guidewire used in the present study is 0.025 inch in diameter. But, the present study is a preliminary study without control, so we cannot tell whether or not thinner guidewire may facilitate selective biliary cannulation.

3.

Kawakami et al stated there was no significant difference in the success rate of the biliary cannulation between a regular catheter and sphincterotome with guidewire. In this study, we assumed

the evaluation only for guidewire and do not evaluate the catheter.

in the present study, in general, a regular catheter was chosen except for the case undergoing sphincterotomy. Although our study design does not allow us to evaluate success rate of two different catheter, the success rate with a standard catheter and sphincterotome was similar (73.5% and 69.1%, respectively).

4.

After starting this study, we found the possible drawback that passing a narrow orifice might be difficult. So, we did not have precise data of the shape of ampullary orifice.

We do have an experience of any other disadvantage. Although it looks like hook, it was easily removed from the ducts.

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From *Reviewed by 00009417*

Until now, there is no article that J-shaped-tip guidewire was similar to the conception. We suppose from a previous report that results in J-shaped-tip guidewire and standard guidewire do not have the difference. No longer, we cannot mention about other providers. Sorry, we are lacking in explanation.

We will describe that conflict of interest is disclosed in the end of conclusion.

Disclosures

Dr. Shigefumi Omuta, Iruru Maetani, Hiroaki Shigoka, Katsushige Gon, Michihiro Saito, Junya

Tokuhisa, Mieko Naruki have no conflicts of interest or financial ties to disclose.

P 9 , It is lines 21 lines from 18 lines.

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From *Reviewed by 02444953*

Major points

1. I am sorry not to be able to list it definitely. The feature of J-shaped-tip guidewire is a strongly flexed atraumatic tip and hydrophilic coating. We consider that it may be contributed to facilitate passage through intra-duodenal biliary segments. As a result, the occurrence of post-ERCP-pancreatitis may decrease. These images show Figure 3, 4 in text.
2. This study is the research that can be feasible with this shape and material, therefore, we can not answer your question, sorry and think this has to be proved in randomized controlled trial so, too.

Minor points

1. I am sorry, Explanation was insufficient. **In the present study, in general, a regular catheter was chosen except for the case undergoing sphincterotomy.**

We will revise the text. P 6 , It is lines 22 lines from 20 lines.

2. Because it is a teaching hospital, less experienced endoscope trainees also attempted cannulations. Therefore, the first insertion attempt began with a trainee who had 5 min to complete cannulation. There are the reasons mentioned above.

Thank you again for your comments on our paper. I trust that the revised manuscript is stable for publication.

3 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Gastroenterology*.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Shigefumi Omuta'. The signature is written in a cursive, fluid style with some overlapping letters.

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