Author’s response to reviews

Title: A novel technique for repositioning a nasobiliary catheter from the mouth to nostril in Endoscopic Retrograde Cholangiopancreatography

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Author’s response to reviews:

Dear editor and reviewers,

I would like to express my appreciation on behalf of all the authors for the effort you all put to help us improve the quality of our article, and we are more than willing to listen to the comments from the reviewers and revise our article to be more suitable and well organized to be published to BMC gastroenterology.

Followings are the point-by-point response from the authors to the comments that reviewers sincerely made for us.

Response to the Reviewer reports 1.
1) Though I understand this study is retrospective fashion, it is necessary to explain how the patient was allocated. Thank you for your comment. Before September 2016, which was before the introduction of J-loop, we used conventional method to reposition the ENBD catheter, but from September 2016, we only used the J-loop method instead of conventional method. We included this explanation in our manuscript. (Page 11, line 3)

The conventional catheter repositioning technique was used from January 2015 to August 2016, and the new technique was used since September 2016 in our center. The patients who underwent ERCP from January 2015 to August 2016 were allocated to the conventional technique group, and those who underwent ERCP from September 2016 to December 2017 were allocated to the J-Loop technique group.

2) Page 8, line 10: "Patients without sufficient~", how many patients were excluded? The authors should clarify the number of patients who were excluded in this study in each group. Thank you for helping us to be more specific about our data. It is important to clarify the data, and we revised our statement regarding the exclusion as follows:

- Patients without sufficient medical data, such as procedure time record or Mallampati score, were excluded.

◊ Total of 160 patients were enrolled, 80 patients for each group, and 9 patients from conventional technique group and 6 patients from J-loop technique group, who were without sufficient medical data such as procedure time record or Mallampati score, were excluded. (Page 11, line 7)

3) Page 9, line 42; "mean ± SDs", Were all continuous variables normally distributed? If not, continuous variables should be presented "median (range)". If continuous variables were normally distributed, t-test should be used.

Thank you for pointing out the huge flaw in our study. Because of the inadequate statement, we revised the statistical analysis part. Since ENBD reposition time was not normally distributed, we presented data as median (range), and other continuous variables, which were normally distributed, were compared with t-test. Followings are the revised edition from the previous manuscript.

All continuous variables were presented as mean ± standard deviations (SDs) and categorical variables as numbers and proportions. Statistical analysis was conducted using the Pearson’s Chi-square test or Fisher’s exact test for comparison of accuracy and the Mann-Whitney U-test for continuous variables.

-&gt; Normally distributed data were expressed as mean ± standard deviation (SD), and student t-test was used to compare the parameters. Not normally distributed data were expressed as median (range), and Mann-Whitney U test was used to compare the parameters. Chi-square test
or Fisher’s exact test was used for compare the distribution of a categorical variable. (Page 13, line 3)

We also revised some of the data from table 2 and table 3 after recalculating the values.

4) Page 10, line 35; I cannot understand the reason why difficult to use the new technique in two patients, anatomical reason? Please make it clear. How about Mallampati score of this two patients? How to tube reposition in this two patients?

Thank you for the comment. We also think it is appropriate to clarify the failure cases. We experienced two failure cases, both unable to insert the J-loop device into the pharynx, and both were managed with conventional method barely. It is unclear why we failed it, but these are the lists of facts we discussed that might have induced the failure: high Mallampati score (each 3 and 4), low range of head and neck movement (both below 80°), low thyromental distance (both less than 6.5 cm), and high BMI (each 38.5 and 39.1 kg/m2). However, we think this idea must be further investigated to be included in the publication, so we added the following sentence to the paper. (Page 13, line 17) However, if you feel it is appropriate to include this in the paper, we are more than willing to, so please let us know.

Two patients who underwent the new technique experienced difficulty due to deep insertion of the J-loop into the throat, and were barely successful with conventional method.

5) Page 11, line 53; "Appropriate depth", how to decide the "appropriate depth"?

We measured the distance from the nostril through the nasal cavity into the pharynx, and marked on the plastic tube. Since the line is curvilinear, there are variations among the patients. Therefore, we marked the minimal appropriate depth on the plastic tube, and the plastic tube was inserted a little bit further depending on the patients.

6) Page 13, line 21; Was this study approved by Ethics Committee of each institutes? (e.g. Methods section, line 12, page 5).

Our study was performed in a single tertiary center, and we acquired the approval of the Ethics Committee of Korea University Anam Hospital as we stated in Declarations section in Ethics approval and consent of participate paragraph. Since we misput the IRB number here, we revised the number from K2019-1340-001 to 2019AN0313, and also added the following comment on Methods section.

The study was reviewed and approved by the Ethics Committee of Korea University Anam Hospital(2019AN0313).

(Page 11, line 12)

Response to the Reviewer report 2:

Hirofumi Kogure (Reviewer 2): The authors evaluated the usefulness of the new loop-device for facilitating the repositioning of an ENBD catheter from the mouth to nostril. However, this paper
has little clinical significance. I think that the wire loop technique reported by Hamano et al. is enough for the repositioning of an ENBD catheter. In addition, the wire loop technique has the advantage of not incurring extra costs. The authors have to clarify whether this new device is reusable and how to sterilize.

As the reviewer mentioned, the wire loop technique reported by Hamano et al. is one of good methods to reposition the ENBD catheter from the mouth to the nostril. It has many advantages over the conventional method, that it is single-operator performed and there is no need to remove the mouthpiece before the procedure. However, we experienced some difficulties with this method as we commented in Introduction section, (Page 10, line 1), especially when the patients had lots of salivary excretion or when endoscopists’ hands were wet from the procedure or washing, and sometimes the guidewire-made loop was twisted or slipped. Also, it was sometimes hard to recognize whether the guidewire from the nose had passed through or passed next to the guide-wire-made loop, and it was also hard to know with eye measure how big the loop should be or how big was appropriate for the procedure. These difficulties became one of good motives for us to develop our device.

Our new method has those advantages that Hamano’s method has, that it is performed by a single operator, there’s no need to remove the mouth piece, and the operator does not need to look into patient’s mouth in order to pull back the guidewire/tube. Moreover, our method does not use x-ray fluoroscope guidance compared to the Hamano’s method, also shortens the time took for ENBD reposition greatly, and have a not-slipping handle and ready-made loop for the convenience of the operator, preventing slipping or twitching of the loop. We also made our loop to be not straight forward but little bit bent and bendable since there is a curve in oral cavity because of the tongue, and it prevents the loop to slide into pharynx easily instead of poking the hard palate. Because our study does not compare our methods directly with the wire loop technique by Hamano et al, it is hard for us to comment on superiority or non-inferiority of two methods. However, study to compare these methods would be valuable, and we are willing to compare two methods in near future.

For the cost issue, we do not recommend reuse or sterilization of new loop-device because we made it for a single-use because of hygiene, and the cost that took us made the loop was about 1-2 US dollar, similar cost to the nelaton used in conventional method, which comprises less than 0.1% of total ERCP procedure cost in our hospital. We are further planning to include the J-loop device as an appendage to the ENBD set without raising any cost. We did not include the comment regarding cost or single-use in our paper, but we are willing to include the comment if the editor or reviewer recommends it is appropriate.

Thank you for the valuable comments, and we hope our responses could answer the questions well and are satisfactory. We are always willing to listen to your comments about our manuscript, and we look forward to hear a good news.

Sincerely,
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