ANSWERING REVIEWERS

January 15, 2015

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: 15259-review.doc).

Title: Efficacy and safety a patient-positioning device (EZ-FIX) for endoscopic retrograde cholangiopancreatography: a prospective, randomized trial.

Author: Seungho Lee, Hee Seung Lee, Ki Bae Kim, In-kwang Lee, Eun-Jong Cha, Young Duck Shin, Namgyu Park, Joung-Ho Han, Soon Man Yoon, Hee Bok Chae, Seon Mee Park, Sei Jin Youn

Name of Journal: *World Journal of Gastroenterology*

ESPS Manuscript NO: 15259

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

1 Format has been updated
Figure legends

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

This manuscript is a novelty and innovative nature of the research. Although the results were a bit simple, but them were reliably. It can be accepted to publish in WJG

1.How about the authors chose the patients? It may be more detail in the method
->
We mentioned inclusion and exclusion criteria in the manuscript. Also, the sample-size calculation was based on our preliminary study. The presence of 51 patients in each study group provided the study with a statistical power of 80%, with a significance level of 5% (propofol dose: 82.3 ± 40.4 mg, 104.4 ± 48.2 mg) So, we included 105 patients who received therapeutic ERCP between April 2013 and March 2014 at the Chungbuk National University Hospital.
However, post hoc power analysis showed a power of 0.73. Further, larger-scale studies are needed to clarify the efficacy and safety of EZ-FIX.

G*power 3.1 (Franz Faul, University Kiel, Germany) was used for sample size analysis.

2.The Discussion may describe more detail about the new methods and, the meaning of the ethod.
-> We have described the process of EZ-FIX in greater detail in Figure 1. EZ-FIX reduced the total dose of propofol because EZ-FIX can prevent prophylactic use of propofol.

In their paper the authors evaluated the efficacy and safety of a patient positioning device for ERCP. The device consists of vacuum mattress the fixes the patient during the procedure. The primary outcomes were sedation efficacy and sedation related complications, secondary endpoints were recovery time and satisfaction of the patients, physicians and nurses. The authors found that the patients in the positioning device group needed significantly less sedation and that the recovery time

was shorter. The satisfaction scores for physicians and nurses were higher in the patient device group than in the group without the device. The use of the device did not influence the success or complication rates of the ERCP. This prospective study was well planed and conducted. The results are of interest for endoscopists.
Nevertheless, the impact on clinical practice is ambiguous, since the total amount of propofol given in both groups is rather low and not likely to cause problems in either way.

-> We agree with your opinion that the total propofol dose of both groups is not sufficient to confirm the effect of the device. However, there is a significant need to reduce the demand for propofol. If more patients who needed high doses of propofol were included in the research, we think that the effect of the device would be more prominent.

The discovery time of the patients in the device group is lower than of the patients in the "conventional" group. However, it is unclear if this advantage is not more than outweighed by the time that is needed to settle the patient in the device.

-> That is a sharp observation. However, little time is required to settle the device, maybe 2–3 min. We think that is a slight advantage.
Furthermore it is unclear whether the data that is exclusively obtained in Asian patients, could be extrapolated to patients of European or American origin.

-> You are correct. We delineated the limitations, supplementally.
Minor comment: The authors should explain the satisfaction scores. How was it defined and what was the range of the score (e.g. 1-10?).

-> The endoscopists and sedation nurses answered a questionnaire, using a 10-cm visual analog scale (VAS), that inquired about patient cooperation and overall satisfaction with sedation and the procedure (ranging from 0 = poor, to 10 = excellent).
Last paragraph in the results section: "Ambu" bag is the manufactures name. It should be changed to the denomination of the device.

-> We do not think that this detail is needed. We removed "Ambu bag."

3 References and typesetting were corrected

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

Sincerely Yours,
Joung-Ho Han, M.D.
Clinical assistant professor
Division of Gastroenterology, Department of Internal Medicine
Chungbuk National University College of Medicine,
410 SungBong-Ro Heungdeok-Gu, Cheongju-Si ChungBuk,
361-771, Republic of Korea

E-mail : joungho@cbnu.ac.kr
joungho@kma.org
Blog : http://blog.hani.co.kr/medicine
Tel : +82-43-269-6802
Fax : +82-43-273-3252