Format for ANSWERING REVIEWERS

August 8, 2015

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: 20843- Revised manuscript.docx).

Title: Unsedation colonoscopy can be not that painful--Evaluation of the effect of 'Lamaze method of colonoscopy'

Author: Shao-Ping Yu, Xiao-Dong Lin, Guang-Yao Wu, Song-Hu Li, Zong-Quan Wen, Xiao-HongCen, Xian-Guang Huang, Mei-Ting Huang

Name of Journal: *World Journal of Gastrointestinal Endoscopy*

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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

(1) This a nice article. However some methodological aspects need to be made clearer. 1. The authors informed that patients were randomly in three groups. However there is a large difference in the number assigned to each one of the groups. Why there is such a difference? Why the Lamaze group has 224 patients as compared with 178 and 183 in the other two study groups? 2. How many patients had ileocolic anastomosis? Is there a diffrence among groups? 3. Table 5 is not clear. There should be na explanation about its results. Was there a median score of pain for each study group? 4. Discussion: which is the current method of choice for colonoscopy at their institution? NO sedation or anesthestic control?

Answer: The study included consecutive patients underwent colonoscopy at endoscope center in our hospital from November 2012 to October 2014. The first 3 patients whom underwent sedation colonoscopy were enrolled in anesthetic group every Monday(Monday is our sedation colonoscopy day) except for holidays and those whom needed endoscopic treatment such as polypectomy. The first 3 patients whom underwent unsedation colonoscopy were enrolled in Lamaze group every Tuesday. Those whom needed endoscopic treatment were also ruled out. The

first 3 patients whom underwent unsedation colonoscopy were enrolled in control group every Thursday. Those whom needed endoscopic treatment were exclude too. Patients with severe cardiopulmonary dysfunction, stroke, moderate to severe ascites, renal insufficiency, severe malnutrition and patients who were bed ridden were excluded from the study. All patients enrolled in the experiment had signed a consent form of colonoscopy examination. Patients in anesthetic group all signed a consent form of sedation. A total of 585 patients aged from 25-82 years old were enrolled. There were 224 patients in Lamaze group, 178 patients in anesthetic group and 185 patients in control group finally. Because Monday is our sedation colonoscopy day, we selected the first 3 patients to be enrolled into anesthetic group, we selected the first 3 patients on Tuesday and Thursday to be enrolled into Lamaze group and control group. If some in these selected needed endoscopic treatment were ruled out. So the numbers of patients of the 3 groups is not the same. There are 2 patients had ileocolic anastomosis, one is in the anesthetic group and the other is in the Lamaze group. There is no difference among the three groups. We had added some expiations for Table 5(which was Table 6 in the revised manuscript) . There is no best choice for colonoscopy by now in my opinion. Sedation colonoscopy will relieve patients' pain effectively than unsedation colonoscopy. This is for sure. But there is risk for it and will raise medical fee. Method of best choice still need to be explored. Our goal in this manuscript is to explored one and test it.

(2) In my opinion, the study is interesting and can be very useful in the pain-relief area of study. However, in my view, the manuscript does not have the quality needed for publication in a journal like the World Journal of Gastroenterology, unless authors undertake major revision. - Incorporate in the title how participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”) - Avoid repeatedly use the expression ‘Lamaze method of colonoscopy’ and Lamaze method of childbirth. Maybe using acronyms. - In the Introduction, expanding the scientific background and explanation of the rationale of the Lamaze method of childbirth, and why authors thought it was plausible to adapt it to colonoscopy. - Add the bibliographic reference that supports the eligibility criteria for participants. - Specifies the settings and locations where the data were collected. - It is repeated in two separate paragraphs that patients signed informed consent. - How many endoscopists actually were involved? Were they experienced? - Precise details of the interventions intended for each group, especially in the Lamaze method group. It is stated that “patients in Lamaze group were trained by the assigned nurse in endoscope center, 5-8 minutes before examination” How authors made sure that this time was enough? Is this method so simple to learn? For all patients, for all ages, for all intellectual levels? - Specify objective and hypotheses. - Clearly define primary and secondary outcome measures - How sample size was determined? - Which method was used to generate and implement the random allocation sequence? - Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups? - Were the patients blind to group assignment? - Were the endoscopists blind to group assignment? - Who were those assessing the outcomes? Were they blinded to group assignment? - I recommend incorporating a diagram of the flow of participants through each stage. - Was the analysis made by

"intention-to-treat"? - In the Discussion, authors claim "The Lamaze method of colonoscopy could maintain a relatively constant position of intestinal tract by deepening abdominal respiration, made colonoscope passed easily" How do they know that? Did they measure this in some way? - In the Discussion, authors used acronyms (ARDS, SPO2) not previously defined.

Answer: Thank you for your comment. As I mentioned above, The study included consecutive patients underwent colonoscopy at endoscope center in our hospital from November 2012 to October 2014. The first 3 patients whom underwent sedation colonoscopy were enrolled in anesthetic group every Monday(Monday is our sedation colonoscopy day) except for holidays and those whom needed endoscopic treatment such as polypectomy. The first 3 patients whom underwent unsedation colonoscopy were enrolled in Lamaze group every Tuesday. Those whom needed endoscopic treatment were also ruled out. The first 3 patients whom underwent unsedation colonoscopy were enrolled in control group every Thursday. Those whom needed endoscopic treatment were exclude too. Patients with severe cardiopulmonary dysfunction, stroke, moderate to severe ascites, renal insufficiency, severe malnutrition and patients who were bed ridden were excluded from the study. All patients enrolled in the experiment had signed a consent form of colonoscopy examination. Patients in anesthetic group all signed a consent form of sedation. A total of 585 patients aged from 25-82 years old were enrolled. There were 224 patients in Lamaze group, 178 patients in anesthetic group and 185 patients in control group finally. Because Monday is our sedation colonoscopy day, we selected the first 3 patients to be enrolled into anesthetic group, we selected the first 3 patients on Tuesday and Thursday to be enrolled into Lamaze group and control group. If some in these selected needed endoscopic treatment were ruled out. So the numbers of patients of the 3 groups is not the same. The patients were blind to group assignment, but not for the endoscopists. Patients preparation is rewritten and they are not duplicated any more. Five doctors with at least 5 years experience of performing colonoscopy performed the procedure. This is added to the revision. Patients in Lamaze group were trained 'the Lamaze method of colonoscopy' 5-8 minutes before examination, this will help patient grasp the basic breathing technique. As I mentioned in the manuscript, the education would be continuously practiced during the whole process of colonoscopy. This will help patients to manage it. The data were recorded mainly by nurses in endoscopy centre and was analyzed by one of the author. Intention-to-treat analysis was not used because patients needed endoscopic treatment will take much longer the time, and they were all ruled out. In Lamaze group, we observed patients' splenic flexure moved near the camera while patient use deepening abdominal respiration when reach it and hold the scope still. But there is no direct evidence of colon stationary. So the sentence was revised as "Lamaze colonoscopy may could maintain a relatively constant position of intestinal tract by deepening abdominal respiration". Acronyms like ARDS,SPO_2 were defined in the revised manuscript. Bibliographic were added. Thank you again for your carefully review.

3 References and typesetting were corrected

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

Sincerely yours,

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