

December 02, 2014

Dear Lian-Sheng Ma,
President and Company Editor-in-Chief

Title: Visual distraction alone for the improvement of colonoscopy-related pain

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Thank you for your decision about the above-mentioned manuscript. I received e-mail on 19th November and have revised the manuscript. I am pleased to note the favorable comments of the reviewers and have made the necessary corrections, as described in detail in the following pages. I appreciate the reviewers' comments and hope that the revised manuscript will meet with their approval.

1 Format has been updated.

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

Response to Reviewer #1

Thank you very much for your useful suggestions. That have been addressed in the revised manuscript, which we feel is now greatly improved as a result.

The manuscript revealed that visual distraction alone improves satisfaction in patients undergoing colonoscopy and decreases anxiety and pain during the procedure among patients with a high pre-procedural anxiety score. The work has good study design, well-performance, and constructive findings, but some points need further clarification Major 1.In statistical method, why do the authors use median rather than mean and standard deviation in Table 1-4, including age. 2.In Table 1, What is IQR ? what is number

of times ? in Table 2, why the group 2 did not show range in each parameter? 3.The insertion depth (length) when the scopy reached cecum is also an important factor for pain sensation, you should have the data of the insertion depth (length) in your study and showed them in Table 2 4.The parameters of Table 2, such as cecal insertion rate, time to reach, time needed for total procedure should be demonstrated in Table 4-patients with higher anxiety score. Minor 1.In the Discussion, page 15, the descriptions “Among the responses to the questionnaire conducted after the procedure, the patients reported that animations, sports videos, landscape films, or images of their own endoscopy would be useful for relaxing.” was suggested to be removed. They do not have tested yet. 2.How much is the equipment of head-mounted display (MOVERIO EPSON?; SEIKO EPSON CORPORATION, Nagano Japan) ? Is it available in most country in the world ?

Major.

- 1) As you mentioned, mean and standard deviation are used in many studies. However, the data of current study were out of normal-distribution and we considered it is appropriate to use median and IQR (interquartile range) rather than mean and standard deviation.
- 2) IQR means interquartile range, which is an index of variability. Number of times means number of previous colonoscopy experience. We corrected table2 with range of each parameter and revised from “Number of times” to “Number of colonoscopies”. We are sorry to mistake range description in table2.
- 3) We admit that you have a point and the insertion depth (length) when the scope reached cecum is actually also an important factor for pain sensation. However, we do not have the complete data of insertion depth. We considered that it is better not to describe rather than to show incomplete data. We have added this point to limitation.
- 4) We add the parameters you pointed to the table4.

Minor

- 1) We removed the description as absolutely you suggested.
- 2) The head-mount display costs ¥ (Japanese Yen) 23130 and is available most country in the world by the internet.

Response to Reviewer #2

Thank you very much for your useful suggestions. Accordingly that have been addressed in the revised manuscript which we feel is now greatly improved thanks to your comment.

This randomized control trial demonstrated that visual distraction alone improved

satisfaction in patients who were undergoing screening colonoscopy. The authors concluded that visual distraction alone improves satisfaction and decreases anxiety and pain during the colonoscopy especially in patients with great anxiety. This is well written study and novel information, but with some limitations in the following areas. Major 1. The results in the high pre-procedure anxiety group are based on few patients and a p value of 0.04-0.05 is of questionable statistical significance in this setting. The authors should add this point to the limitation of this study. Minor 1. Table1-4. What is IQR? Add explanation. 2. Table2. Authors should show the range data of patients in group2.

Thank you for your useful suggestion.

Major.

- 1) As you mentioned, the number of patients with the high pre-procedural anxiety score was small and the result may be considered to be of borderline significance. We have added it limitations.

Minor

- 1) IQR means interquartile range, which is an index of variability. We added the explanation of IQR.
- 2) We corrected table2 with range of each parameter. I am sorry to mistake description in table2.

Response to Reviewer #3

Thank you very much for your useful suggestions. That have been addressed in the revised manuscript which we feel is now greatly improved as a result.

Dear authors, Congratulations on your work. I really enjoyed this article and I think it will be interesting for many professionals of the field. Overall it is an interesting well performed and written study. Here s my comments: 1) Based on what assumptions, sample size was 60 patients? 2) Is VAS a sound method for assessing patient satisfaction or anxiety after procedures? Is there relevant literature? In the case of satisfaction what is the meaning of 100% (the best satisfaction after procedures? what if that was their first procedure?) 3) Primary endpoints were used to calculate sample size of the study? Otherwise what is the meaning of define them as primary endpoints? 4) How did the ensure that wearing the bulky device w/o the silent movie did not have the oposite effects (i.e. increasing anxiety) and thus bias significantly the results?

5) Having noticed that the device is black, i wonder if the patients w/o movie could see clearly through it or if it was dark. Having a colonoscopy in dark may also increase your anxiety particularly if you nobody talks to you and knowing that you missed the potential benefit of a funny movie. 6) Two thirds of the patients have had previous colonoscopy. This is very high. How do the authors define "elective colonoscopy for screening". Obviously patients with previous experiences have less anxiety. 7) Regarding the inclusion criteria: "attending a non-sedated screening colonoscopy" means that patients had agreed to do the endoscopy w/o sedation and if they required sedation finally they were excluded? If this is the case, then this could have introduced bias. 8) Regarding the exclusion criteria. Personal history of anxiety or psychiatric disorders is essential, as well as chronic pain disorders (i.e. polymyalgia) 9) For the procedural time minutes are more meaningful than seconds. 10) "Lembo et al. [24] investigated whether audio and visual distractions reduced discomfort during a flexible sigmoidoscopy. Pls correct sigmoidoscopy 11) In the limitations section of the discussion more sources of bias should be included, some of them already mentioned above. 12) Please explain in Table 1: "Number of times" 13) Explain IQR 14) Table 2. Pls use minutes rather than seconds and explain IQR. 15) Table 2. Third column. Some ranges are missing. 16) Table 3,4. Pls define IQR Sincerely.

Thank you for your useful suggestion.

- 1) We estimated sample size based on the previous study which Ovayolu carried out. In this study, the effect of music on pain during colonoscopy was evaluated with 60 patients. Accordingly, we have added this estimation to "patients & methods."
- 2) We appreciate your concerns on this point. VAS was found to be valid and reliable for the assessment of subjective conditions, including anxiety. There is a literature of McCormack (McCormack, Heather M., David J. de L Horne, and Simon Sheather. "Clinical applications of visual analogue scales: a critical review." *Psychological medicine* 18.04 (1988): 1007-1019.). Although VAS is useful for measuring anxiety, we could not find out a study for VAS reliability in measuring just satisfaction. We used VAS for satisfaction, because VAS is a very convenient means for evaluating. 100% satisfaction means the best satisfaction level after procedure which patients had expected as best before procedure.
- 3) We used primary endpoint, pain during colonoscopy, to calculate the sample size.
- 4) I appreciate your comment. To ensure that wearing the device did not have opposite effects, we asked patients if they feel fear or anxiety just after they wore the display. As a result, none of the patients answered increasing anxiety or fear. We thought it is due to that the device is clearly see-through.

- 5) As you mentioned, having a colonoscopy in dark may increase anxiety. However the device was see-through and patients could see clearly through it.
- 6) We defined elective colonoscopy as procedure for fecal occult blood, post-polypectomy follow-up, or cancer screening, which did not need an emergent procedure. Surely, patients with previous colonoscopy are considered to have less anxiety. However no significant difference in proportion of previous experience. Although we thought that the result of comparison between two groups could not be biased, we added this point to limitation.
- 7) The inclusion criteria “attending a non sedated colonoscopy” means that patients agreed to received the colonoscopy without sedation. However we were ready to provide conscious sedation as a rescue measure for patients that could not tolerate pain and we did not intend to exclude patients even if they finally needed sedation. As a result none of the patients turned out not to need sedation for any reason.
- 8) Your comment is correct. Of course, we excluded personal history of anxiety, psychiatric disorder or chronic pain disorders. In accordance with your indication, we have added this point.
- 9) As you pointed, for the procedural time minutes are more meaningful than seconds. However we used seconds in order to evaluate with more accuracy
- 10) Your comment is correct and we have corrected the spelling.
- 11) In limitations section, we added more sources of bias, including the points of your suggestion,
- 12) Number of times means “number of colonoscopies”. I have revised in an appropriate term.
- 13) IQR means interquartile range, which is an index of variability. Accordingly we added the explanation.
- 14) As you pointed also in No9, for the procedural time minutes are more meaningful than seconds. We prefer to evaluate more accurately using seconds.
- 15) We regret the oversight in table2. We have revised correctly.
- 16) We added the explanation of IQR also in Table 3 and 4.

3 References and typesetting were corrected.

I would like to thank the reviewers for their helpful comments, and hope that the revised manuscript is found to be acceptable for publication in *World Journal of Gastroenterology*.

Sincerely,

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