Author’s response to reviews

Title: Prevalence and key radiographic spinal malalignment parameters that influence the risk for gastroesophageal reflux disease in patients treated surgically for adult spinal deformity

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Author’s response to reviews:

Thank you for considering our manuscript, titled “Prevalence and key radiographic spinal malalignment parameters that influence the risk for gastroesophageal reflux disease in patients treated surgically for adult spinal deformity”. We are grateful for the editorial input and reviewers’ suggestions that have enabled revision and improvement of our manuscript.

We submit herewith a document with point-by-point responses to all of the reviewers’ comments and an updated version of our manuscript, which has been revised in accordance with the comments from the reviewers. We hope that our responses are well received and that the revised manuscript is now acceptable for publication in the BMC Gastroenterology. Thank you for your time and thoughtful consideration of our work.

Sincerely yours,

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Reviewer reports:

Shiro Imagama, MD, PhD (Reviewer 1): This is a great research. I recommend that it will be suitable for publication as is.

→ All authors appreciated your thorough review and favorable evaluation. We will continue the current study in the future.

Mitsushige Sugimoto (Reviewer 2): Major comments:

1. In general, the epidemiology and pathology of GERD in patients with adult spinal deformity is known.

→ We agree with the reviewer’s comment that there are recent studies focusing on the epidemiology and pathology of GERD in patients with spinal deformity. In contrast, there are few studies concerning the epidemiology and pathology of GERD in patients with severe spinal deformity who need to undergo treatment with thoracolumbar corrective surgery. Additionally, the efficacy of surgical spinal correction for GERD is still largely unknown. These are our primary motivations for this study, and now these points are presented in the manuscript (Background, line 16-19).

2. Sensitivity of the FSSG for diagnosis of GERD is about 70%. In addition, GERD included reflux esophagitis and non-erosive reflux esophagitis. In this study, because most of patients grouped as GERD-positive were dosed PPI, those may be patients with NERD or functional heart burn.

→ With respect to this suggestion, we have discussed this issue more specifically in the limitations section of this study (Discussion Page 3, line 2-9).
3. Serious problem of this is luck of endoscopic evaluation, as authors suggested.

→ We completely agree with the reviewer about the direction of the next step in this research. Further study using endoscopic evaluation is needed to elucidate the epidemiology and pathology of GERD in ASD more precisely. Now, we have discussed this point in the limitations section of this manuscript as a topic requiring further study (Discussion Page3, line2-9).

4. Most of readers of this study is Gastroenterologist. Therefore, authors should add detail explanation about spinal deformity-related words.

→ With respect to this suggestion, we have added a detailed explanation about spinal deformity-related words in the manuscript (Methods Page1, line8-10; Page2, line3-12).

5. Did authors enroll all of patients with spinal deformity who were treated with thoracolumbar corrective surgery between April 2010 and March 2014?

→ Seventy-three patients were treated with thoracolumbar corrective surgery between April 2010 and March 2014, but two patients missed follow-up visits. Therefore, seventy-one consecutive patients with ASD who were treated with thoracolumbar corrective surgery and followed up for a minimum of 1 year were enrolled in this study. Now, this information is presented in the manuscript (Methods Page1, line16-20)

6. Ethical committee approved in 2014. However, this study was performed between April 2010 and March 2014. Did authors receive informed consent from all eligible patients to enroll this study, not operation?

→ We had initiated a clinical study regarding spinal surgery in ASD patients in 2010 and obtained written approval to enroll these patients before surgery. Later, we developed the plan to investigate the mechanism between spinal alignment and GERD symptoms in these patients in a retrospective manner; we received approval for this study from the ethical committee. The information about this study was posted at the outpatient clinic in our hospital to inform the eligible patients that they may opt out of the study.
7. Intake of NSAIDs is a risk factor for the development of GERD. This situation may influence occurrence of GERD-related symptoms.

→ We agree with this point; therefore, we evaluated the frequency of NSAID intake. Unexpectedly, there were no significant differences in the frequency of intake of NSAIDs between the GERD+ and GERD− groups in the current study.

8. Patients improved GERD-related symptom after operation might stop intake of PPI. Because PPI is first-line drug for GERD treatment, discontinuous of PPI may affect FSSG score.

→ We completely agree with the reviewer regarding the direction of the next step in this research. Unfortunately, the current study allowed the patient’s physician to determine when PPIs should be discontinued based on their experience. Therefore, it is very difficult to evaluate the influence of the oral administration of PPIs and their discontinuation on the FSSG score. Now, this limitation has been discussed in the manuscript (Discussion Page3, line2-9).

9. What did difference between standing and FBB position mean?

→ We apologize for the lack of explanation. The preoperative evaluation for flexibility of the thoracolumbar spine is essential to conduct the optimum surgery, and it assists in determining the necessity for osteotomy and/or the range of fusion. Obtaining radiographs with the patient supine and in a fulcrum backward-bending (FBB) position is one of the effective techniques for evaluating the flexibility of the thoracolumbar kyphotic curvature preoperatively. A decreased TLK or increased LL curvature in the FBB position indicates flexibility of the thoracolumbar kyphotic curvature.

10. Please show parameters used at the multivariate analysis.

→ Based on this suggestion, we showed the parameters used in the multivariate analysis in the manuscript (Results Page2, line5-6).
11. Fig2; Please divided FSSG score into acid-related score and dysmotility score.

→With respect to this suggestion, we divided the FSSG score into an acid-related score and a dysmotility score (Figure 2A.B.C). We appreciate this suggestion that improved this paper.

12. Fig3; Please show association with FSSG score and TLK (FBB) at post-operation.

→We apologize for our lack of explanation. Usually, radiographs are not obtained in supine patients in the FBB position after thoracolumbar corrective surgery.

13. If possible, authors should compare with adult spinal deformity patients operated and not for GERD-related symptoms.

→We completely agree with the reviewer about the direction of the next step in this research.

However, as mentioned above and in the introduction section (Background Page1, line16-19), our motivation for the current study was based on the fact that there are few studies about the epidemiology and pathology of GERD in patients with severe spinal deformity who need to be treated with thoracolumbar corrective surgery. Additionally, the efficacy of surgical spinal correction for GERD is still largely unknown. Therefore, we have only data for adult spinal deformity patients who underwent surgery so far.