Author’s response to reviews

Title: Determination of the optimal inspiratory pressure providing adequate ventilation while minimizing gastric insufflation using real-time ultrasonography in Chinese children: a prospective, randomized, double-blind study

Authors:

Xiaowei Qian (qxwzhejiangedu@163.com)
Qiong Hu (huqiong_1221@qq.com)
Hang Zhao (zhaohang17777@163.com)
Bo Meng (mengbo1206@163.com)
Yang Nan (nay0000@163.com)
Hong Cao (Caohongwz@163.com)
Qingquan Lian (lianqingquanmz@163.com)
Jun Li (lijunwzmu@126.com)

Version: 1 Date: 05 May 2017

Author’s response to reviews:

Dear Prof. Spadaro

We thank you very much for giving us an opportunity to revise our manuscript, we appreciate editor and reviewers very much for their constructive comments and suggestions on our manuscript entitled “The optimal inspiratory pressure during pressure-controlled facemask ventilation in Chinese children that provides adequate ventilation while minimizing gastric insufflation”. (ID: BANE-D-17-00041).

We have studied reviewer’s comments carefully and have made revision which marked in red in the paper. We have tried our best to revise our manuscript according to the comments. Attached please find the revised version, which we would like to submit for your kind consideration.

We would like to express our great appreciation to you and reviewers for comments on our paper. Looking forward to hearing from you.
Thank you and best regards.

Yours sincerely,

Jun Li

List of Responses

Dear Editors and Reviewers:

Thank you for your letter and for the reviewers’ comments concerning our manuscript entitled “The optimal inspiratory pressure during pressure-controlled facemask ventilation in Chinese children that provides adequate ventilation while minimizing gastric insufflation”. (ID: BANE-D-17-00041). Those comments are all valuable and very helpful for revising and improving our paper, as well as the important guiding significance to our researches. We have studied comments carefully and have made correction which we hope meet with approval. Revised portion are marked in red in the paper. The main corrections in the paper and the responds to the reviewer’s comments are as flowing:

Editor Comments:

Dear authors,

Please pay attention to clarify any aspects required by referee. First of all, I have a several concern about the "replicated paper" in different setting. The section method required an important revision. Please explain in details the aspects regarding the process of approval of ethics committee.

Best regards.

Answer: We have added some details regarding the process of approval of ethic committee, we do not know whether it is good or not. The method section has been revised according to the reviewers. Please do not hesitate to contact us if there is any problem. Thanks!

Reviewer reports:

(Reviewer 1):
Title
Since a major studied intervention is the realtime detection of stomach insufflation by the ultrasound aid, this should be specified in the title. Moreover, authors should also specify the study design.

Answer: Thanks, we have changed our title. “Determination of the optimal inspiratory pressure providing adequate ventilation while minimizing gastric insufflation using real-time ultrasonography in Chinese children: a prospective, randomized, double-blind study”.

Introduction
In the background section, authors define gastric insufflation as the appearance of a comet-tail or an acoustic shadow on ultrasonography. These findings describe the entry of air into the stomach. Further, authors assessed the cross-sectional antral area before and after face mask ventilation. For a better understanding also by non-expert readers, authors may better describe the meaning of these two ultrasound measures.

Answer: Thanks for your kind suggestion. In ultrasonography, air entry into stomach can be detected with acoustic shadows or comet-tail appearance that appears in the gastric antrum, which provides a qualitative examination of gastric insufflation. Ultrasonographic measurement of antral cross-section area (CSA) was a quantitative approach to determine gastric insufflation during facemask ventilation. In order to describe this clear, we modified this part in the introduction.

Methods
Authors should specify the study period.

Please specify the type of surgery children were scheduled for.

Answer: Thank you very much. We are very sorry for our negligence of these. We have added the study period and the type of surgery in the methods.

It is not clear, from the methods section, if real time assessment of gastric insufflation occurred during facemask ventilation. I realized that this occurred from interpretation of results, since authors classified patients as GI+ or GI - according to gastric insufflation which was detected, I suppose, as comet tails.

Answer: We have described this in our methods. “In brief, using the aorta and the superior mesenteric vein as internal landmarks, longitudinal (D1) and anteroposterior (D2) diameters of
the gastric antrum in cross-section on a sagittal plane were measured (Figure 1 and Figure 2) as described previously [8,12]”. “After the trachea was intubated, real-time ultrasonographic measurement of antral CSA was performed again”. We detected the gastric insufflation (antral CSA) before facemask ventilation and after facemask ventilation.

Since this description is missing, it is also not reported whether the anesthesiologist performing the ultrasound assessment during facemask ventilation was the same as the one assessing the antral area during the preoperative period. Moreover, since authors define the study as randomized and blinded, they should specify whether the anesthesiologist performing ultrasound was blinded to patient group allocation.

Answer: Thanks for your suggestion. We described in our text that “The preoperative measurement of antral area was performed by a physician blinded to the history and status of the children [10]”. We have re-written this part according to the Reviewer’s suggestion. We have deleted this sentence added your advice in our method. “The anesthesiologist performing ultrasound assessment was blinded to group allocation and was the same as the one assessing the antral CSA during facemask ventilation”.

Results

Author should provide a flow chart of the study describing the total number of eligible patients, the number of enrolled patients, the number of excluded patients and reasons for exclusions.

Answer: We have uploaded a flow chart of the study describing the total number of eligible patients when we submitted this text.

Author should define what GI+ and GI - mean. (See comment above).

Answer: We have added this definition in our results.

Vt increased in group P12 (10.0 ± 3.0 ml/kg) in comparison with group P10 (6.8 ± 2.5 ml/kg) (P = 0.000). What is the p value for this comparison? The same comment applies to figure 4.

Answer: We are very sorry for our negligence of this. We have made correction according to the Reviewer’s comments and have changed it to P =0.001.
Figure 5: It is rather difficult to read this figure in relation to the significant p-values reported for the various comparisons.

Answer: It is really true as reviewer suggested. Because there are many time points and groups in this figure, we also think it is really rather difficult to clarify it clearly. We have deleted some p-values and tried our best to describe these in our figure legends, so it may be cost some time to read and understand.

Discussion

After summarizing major findings, the discussion starts describing the advantages of pressure controlled ventilation compared to manual ventilation in terms of peak airway pressures. However, this is not the main focus of the study and this section may be postponed in the discussion.

Answer: Considering the Reviewer’s suggestion, we have postponed this section.

Authors should clearly describe which are the study limitations (i.e. difference in antral area not necessarily means gas insufflation and increased risk of aspiration, impossibility to assess cross-sectional antral area in four patients due to marked gastric insufflation with subsequent patient exclusion from the analysis)

Answer: Thanks. We have added the study limitations in the discussion.

Reviewer 2: Well designed study highlighting a new technique in use of ultrasound for examining gastric distension/contents. One major concern is that I think there needs to be discussion of actual adverse events that occurred (e.g. aspiration, desaturation events, difficult airway management, cardiovascular hemodynamic instability). And whether the findings are clinically relevant. While the data and findings are interesting there is no discussion as to whether the increase in antral CSA post facemask ventilation in subgroups P14 and P16 increases risk of aspiration events. Clinically is it relevant whether antral CSA is increased - does this actually increase aspiration events? This needs to be addressed as to the clinical importance of this finding. Similarly did the inadequate lung ventilation in the P8 (EtCO2 of 40.8) and P10 groups result in any clinical complications. Again need to address whether having a higher end tidal CO2 after facemask ventilation results in adverse clinical outcome. If not this is more an interesting finding without clinical relevance.

Answer: Thanks very much for your excellent suggestions. We have added this part in the discussion. “Adverse events such as aspiration and desaturation events were not found in the
present study. Although antral CSA after facemask ventilation statistically increased in subgroups P14GI+ and P16GI+, aspiration events were not occurred in both groups. However, increased inspiratory pressure results in a higher occurrence of gastric insufflation which might increase the risk of aspiration”.

SpO2 was greater than 98% in all children during FMV. “Inadequate lung ventilation in the P8 and P10 groups did not result in desaturation events may due to application of 100% oxygen and nearly common minute ventilation. In order to prevent the adverse events, we chose the inspiratory pressures from 8 to 16 cmH2O which are commonly used in clinic. We think that adverse events might occur when larger or smaller inspiratory pressures were applied. In addition, small sample size may result in these meaningless”. We did not record cardiovascular hemodynamic data during FMV and further investigation may be needed.

And how is it determined that an end tidal CO2 of 40.8 correlates to inadequate ventilation?

Answer: We do not determine that an end tidal CO2 of 40.8 correlates to inadequate ventilation. As we showed in the methods, “Adequate ventilation was defined as Vt greater than 7 ml/kg according to Lagarde et al [7]”.

Also think a limitation needs to be addressed that "Three patients from group P16 and one patient from Group P14 were excluded from the study, because the antral CSA could not be measured due to a large air insufflation in the stomach after FMV." Again why would those with large amounts of air insufflation be excluded? Isn't this what the investigation is examining? Please clarify and discuss in limitations (e.g. patients with significant air insufflation that couldn't be quantified were excluded.)

Answer: As Reviewer suggested that a limitation needs to be addressed that "Three patients from group P16 and one patient from Group P14 were excluded from the study, because the antral CSA could not be measured due to a large air insufflation in the stomach after FMV." We have added this in the discussion. Please see the red part in the text in discussion.

It is really difficult to assess the antral CSA when marked air insufflation in the stomach after FMV. In order to observe the relationship between the inspiratory pressure and gastric insufflation objectively, we excluded those with large amounts of air insufflation. We have added this aspect in the discussion.