Author’s response to reviews

Title: Laryngeal mask airway reduces incidence of post-operative sore throat after thyroid surgery compared with endotracheal tube: a single-blinded randomized controlled trial

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Author’s response to reviews:

Dear reviewers and editors,

We would like to thank you for carefully reviewing our manuscript and providing constructive comments. We have revised the manuscript to address your comments. All the alteration was marked in red in the re-submitted manuscript. Here are our point-to-point responses.

Susanne Sujatta, M.D. (Reviewer 1):

1. General Comments:

Thank you for submitting your manuscript to the BMC Anesthesiology and giving me the opportunity to read and critique your article - Laryngeal mask airway reduces incidence of post-operative sore throat after thyroid surgery compared with endotracheal tube - I hope you will find these comments useful in revising your manuscript.

This is a well written article, however I feel you should provide readers with a greater reasoning of the equipoise of why this should be done.

Temporary sore throat and hoarseness up to 72 hours appear to be a low risk in the context of serious vocal cord injury, which could be avoided by using an endotracheal tube with electrode
and following monitoring of the recurrent laryngeal nerve to identify and save this nerve during thyroid surgery.

Reply: Thanks a lot for your constructive suggestion. We have added this into the discussion in page 11 line 8-12.

Specific comments:

2. P5L6 Please specify "definitive identification of recurrent laryngeal nerve" and detection of injury during surgical intervention e.g. by naming the method

Reply: Thank you very much. Actually, all the patients scheduled for thyroid surgery received laryngofiberscope preoperatively to evaluate the function of vocal cord. We added it to page 5 line 3-5.

3. P5L48 Please specify "standard digital technique"

Reply: "Standard digital technique" means to insert LMA with digital intraoral manipulation (page 5 line 25-26), which is suggested in the instruction of flexible LMA.

4. P6L1 How much experience in this specific field had the anesthesiologist performing ETT intubation?

Reply: Thanks a lot for your reminding. The two anesthesiologists both inserted FLMA successfully for over 200 times. We added this to page 6 line 5.

5. P6L16 Train of Four, number of ETT attempts and C/L status would have been interesting at time of ETT insertion to exclude vocal cord injury during intubation via technical failures.

Reply: Since the FLMA and ETT was inserted by experienced anesthesiologists, all the insertion was successful at the first attempt. We totally agree that we’d better detect vocal cord injury during intubation. Although we didn't evaluate Train of Four or C/L status, we think patients enrolled in this trial did not have vocal cord injury, since no one had postoperative prolonged hoarseness or buckling.

6. P6L47 Which method or scale for measurement of "postoperative numbness and hoarseness" was used? Why was no ENT specialist involved?

Reply: Thank you very much. Numbness was reported by patients themselves. Hoarseness was evaluated by anesthesiologists based on whether there were changes in quality of voice. This method was also used by other researchers [1,2]. We have clarified this in page 7 line 4-6. We
totally agree that ENT specialists should be involved. Unfortunately, it usually took more than 2 days to get feedback from an ENT specialist after we schedule a consultation, thus it could be difficult to evaluate the symptoms at 1, 24, and 48 h after surgery. We have added this to limitations (page 11 line 5-7).


7. P7L9-37 First of all thank you for including a power analysis in your paper, but there are a few questions:

8. Reference 5 shows no incidence of sore throat at the level of 84% after thyroid surgery, therein is no incidence given at all as it is a correspondence letter. Citing reference 8 there would be an incidence about 48% for the use of ETT size 7.0 in female patients and an incidence of 68% overall male and female with any given size of ETT. Citing reference 6 the use of small tubes downsizes the incidence of sore throat from 48% to 22%.

Please check your power analysis in the view of this background. There may be to few patients included if the approximated incidence is below 84%.

Your power analysis states the necessity of 38 patients per group, why including 48?

Reply: Thank you for your reminding. Because the reported incidence of sore throat varied in a large range in previous literatures, we further estimated the statistical power given 38 patients in each group. The actual incidence of sore throat was 68.9%, hence, the statistical power with a risk decrease by 30% was 76.8%, which was acceptable. Moreover, the statistical test of the primary outcome was significant, so there should be only the risk of type I error rather than type II error.

9. P9L38 Wrong citation: compare head line of reference 23; reference 8 suggested that the lignocaine may be irritating or damaging to the tracheal mucosa and therefor increases the incidence of sore throat.

Reply: We are sorry for the mistake. We have double-checked and clarified it in page 10, line 1-2.
Katherine Saied (Reviewer 2):

1. Although methodology is properly described, reproducibility seeming difficult to achieve, it is stated that only experimented surgeons were involved in this study (which could affect technique and thus tissue manipulation and inflammation) it raises the question whereas this study could be applied in smaller centers with junior surgeons or staff, with similar results.

Reply: We totally agreed with you. Therefore, we clarified this in limitations in discussion (page 11, line 1-3).

2. Supplementary material should have been added, such as methods of managing postoperative pain or soreness in PACU which is not mentioned in this study or described, and as one of the primary outcome was to measure sore throat in the POST OPERATIVE period It is essential to describe methods and medications used for pain management, as it could also bias the results and interpretations, especially when comparing to similar studies.

Reply: Thank you for your comments. Actually, no patient received additional analgesics in PACU or wards during postoperative 48 hours. We have clarified it in page 6 line 21-23.

3. Visually the article is lacking visual aids. A flow diagram summarizing patient selection criteria could be a good tool and aid in this aspect. Only one graphic is presented, and it's not related to the primary outcome. A graphic could be supplied related to severity of hoarseness data obtained.

Reply: Thanks a lot. We have a figure indicating selection criteria (Fig 1). We are so sorry that we only assessed the incidence, rather than severity of hoarseness. Since the primary outcome was sore throat, the severity of sore throat was presented in Table 3.

4. Also of note, HD profiles during and after intubation should be included as secondary outcomes as they were recorded and present in the results subsection.

Reply: Thank you. We have added in page 7 line 1.

5. Regarding to incidence percentages, it is stated that 65-80% is the observed incidence and that 30% reduction is considered significant. In addition, it is mentioned that a previous study registered a higher incidence, but it is not stated in the discussion the possible reasons for this variability in incidence between studies, for example using remifentanil infusions instead of fentanyl or difference in postop pain management between studies.

Reply: Thanks a lot. Actually, the intra- and post-operative pain management strategy was not clearly stated in those studies, and the main reason for the variability in incidence is the tube size, just as we discussed in page 9 line 27. Furthermore, there is a recent study showed that
high-dose intraoperative remifentanil infusion is associated with increased incidence of postoperative sore throat. We also added the possible effects of pain management in discussed in page 10 line 11-16.

6. Evaluation of hoarseness is assessed only by changing of voice and not by vocal chords evaluation or LN stimulation which could be a limitation validity of this data and should be added to limitations section.

Reply: Your recommendation is highly appreciated. We have added it to the discussion (page 11 line 6-7).

7. Finally, conclusions are clear and short, it is mentioned as a hypothesis for the results, that the benefit for FLMA vs ETT could be due to a more careful manipulation and less tissue injury from surgical team to avoid displace FLMA, given its likelihood to do, which seems difficult to prove in order to use as an explanation for results or to justify the selection of a 1st generation supraglottic device over an ETT in this particular surgery.

Reply: We agreed that the surgical team might affects the results, thus we added it to the limitation (page 11 line 3-5). We also believe that 1st generation supraglottic device may not be the best choice for all the patients receiving thyroid surgery, especially the ones require LN monitoring. This was also added to the limitations (page 11 line 8-12). The performance of other types of supraglottic device should also be investigated in the future (page 11 line 13-15). Therefore, we modified the conclusion according to your recommendations (page 11 line 19-22).

8. It could also be added if further studies are needed and why, which seems reasonable, as previous recent evidence is limited. Moreover, there are no studies that evaluated these symptoms after 48h, which is still a period of time when they can occur.

Reply: Thanks a lot. We have added it to page 11 line 13-17.