Author’s response to reviews

Title: A prospective, randomized comparison of the LMA-ProtectorTM and i-gelTM in paralyzed, anesthetized patients

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A prospective, randomized comparison of the LMA-ProtectorTM and i-gelTM in paralyzed, anesthetized patients

Dear Dr. Guangde Tu,

We deeply appreciate your comments on our article, and we are very glad to hear from you. In addition, we would like to thank the reviewers for their constructive comments and efforts in improving our manuscript.

According to the reviewers’ advice, we revised the manuscript.

The changes in the contents are indicated by highlighting and underlining. Our point-by-point responses to their comments are as follows.

We thank you again for your interest and consideration.

Sincerely,
Dr. Hwang

Reviewer reports:

Jong-Yeop Kim (Reviewer 1): The authors conducted the prospective, randomized study to compare the clinical performance of the LMA-Protector and the i-gel in regard to airway sealing pressure, insertion time, ease and accuracy of insertion, and the incidence of postoperative sore throat. The study protocol was prospectively registered and generally well written.

I need authors to do a few corrections for the well-structured paper.

: We deeply appreciate your comments to improve our manuscript. Our point-to-point answers to your comments are as below

Consider the following:

Introduction

- Clarify the primary hypothesis
- The reason why authors compare the LMA protector and i-gel, among the numerous supraglottic airway devices.

=> The primary hypothesis of the present study was that the LMA-ProtectorTM would provide an improved airway seal than the i-gelTM, and we compared the recently developed supraglottic airway device, LMA-ProtectorTM, with the i-gelTM because the i-gelTM has been widely used in the clinical practice and has been reported to show a comparable performances including airway sealing effect compared to previous other LMA devices. According to your advice, we clarified them as follows

“A preliminary assessment of the LMA-ProtectorTM showed that it is easy to insert and provides a reliable and adequate seal [7], and a recent primary evaluation of the LMA-ProtectorTM reported that the LMA-ProtectorTM provides a high pharyngeal seal [8]. However, its performance, particularly airway sealing effect, has not been compared with other well-identified supraglottic airway devices such as the i-gelTM. The i-gelTM has been widely used in the clinical practice and has been reported to show a comparable performances including airway sealing effect compared to previous LMA devices [5, 9, 10]. We hypothesized that the LMA-ProtectorTM would provide an improved airway seal than the i-gelTM, and compared the clinical performance of the LMA-ProtectorTM and the i-gelTM in terms of the adequacy of airway seal, insertion time, ease and accuracy of insertion, and the incidence of postoperative sore throat in paralyzed and anesthetized patients.”

Newly added reference

Methods

The description of blinding should be clearer, regarding to primary and secondary outcome, although authors mentioned it as limitations.

=> We agree with you that the description of blinding should be clearer.

The primary outcome (the airway leak pressure) and most of the secondary outcomes (the success rate at the first attempt, insertion time, ease and accuracy of supraglottic airway device insertion, ease of gastric tube placement, the presence of blood on the device) were assessed by unblinded investigators. The incidence and severity of postoperative sore throat at 1 and 24 hours after surgery was assessed by blinded investigators.

In the original manuscript, we miswrote that the blood staining on the device was blinded in the limitation section, which couldn’t be blinded. In this revision, we corrected it, and described the blinding clearly in the method section as follows.

“Investigators who inserted the supraglottic airway device, assessed the airway leak pressure and the anatomic position of the device, and inserted the gastric tube and the observers who recorded data were not blinded to the group assignment.”

“............ the presence of blood on the device was recorded by anesthesiologists unblinded to the group assignment.”

“The sore throat was evaluated at 1 and 24 hours after surgery. A 0- to 100-mm numerical rating scale was used to evaluate the severity of sore throat (0, no pain; 100, worst pain imaginable) by investigators unaware of the group allocation.”

“This study had several limitations. First, the investigators who inserted the supraglottic airway device were not blinded to the group assignment due to the nature of the study. They followed the standardized and detailed study protocol. The investigators that evaluated postoperative sore throat, and all patients were blinded to the group allocation. Yet, there is still the potential for bias.”

- P4 line 13

Did authors use neuromuscular monitoring?

=> In the present study, we did not use a neuromuscular monitoring device during the induction of anesthesia. After injecting rocuronium 0.6 mg/kg, we performed mask ventilation with sevoflurane in 100% oxygen for 100 seconds to achieve maximum neuromuscular
blockade, taking into consideration the pharmacodynamic effects of rocuronium (rocuronium 0.6 mg/kg with isoflurane: time to maximum block: 1.5 min, the variation in the potentiation of nondepolarizing relaxants by different inhalational agents may be much less) (Miller’s Anesthesia 8th edition, 2015. 971-2).

In this revision, we described it directly as follows.

"After 100 seconds of mask ventilation with sevoflurane in 100% oxygen, the i-gelTM or LMA-ProtectorTM was inserted by two board-certified staff anesthesiologists according to the manufacturer’s instruction."

- P4 line 17 and 25

How do you differentiate between 'head extension and flexion position' and additional maneuver?

=> In this study, the airway devices were inserted in the sniffing position described as ‘head extension and flexion position’ (With the head extended and the neck flexed). Then, if required, additional head extension and flexion beyond the sniffing position were performed during the device insertion.

In this revision, we revised it as follows.

“In the sniffing position, it was introduced pressing against the hard and soft palate with a circular motion until resistance was felt in the hypopharynx.”

“During insertion of the device, the following manipulations were allowed: jaw thrust, adjusting insertion depth, or head extension and flexion beyond the sniffing position.”

- P5 line 3

Describe order and number of Required 3 maneuvers.

=> In the present study, the following manipulations were allowed: jaw thrust, adjusting insertion depth, or head extension and flexion during insertion of the device, and any maneuvers of the three could be chosen at the discretion of anesthesiologists depending on the clinical situation, without a fixed order. The number of required maneuvers was counted by the type of applied maneuver.

In this revision, we described it in detail as follows.

"During insertion of the device, the following manipulations were allowed: jaw thrust, adjusting insertion depth, or head extension and flexion. If required, any maneuvers among the three were chosen at the discretion of anesthesiologists."
"Ease of insertion was evaluated according to the required maneuvers (jaw thrust, adjusting insertion depth, or head extension and flexion) during insertion as follows: easy for no maneuver, fair for one type of maneuver, difficult for more than one type of maneuver."

- P5 line 16

Clarify the confirmation of full recovery of the spontaneous ventilation. Describe the antagonism of neuromuscular block.

=> The full recovery of the spontaneous ventilation was confirmed by regular and adequate trace of end-tidal CO2 waveform and chest rise without assistance. At the end of the operation, residual neuromuscular block was reversed by pyridostigmine and glycopyrrolate.

According to your advice, we added them to the revised manuscript as follows.

“At the end of surgery, residual neuromuscular block was reversed by pyridostigmine and glycopyrrolate. After confirming full recovery of the spontaneous ventilation by the presence of regular and adequate trace of end-tidal CO2 waveform and proper chest rise without assistance, the supraglottic airway devices were removed, and the presence of blood on the device was recorded…..”

- P5 line 24

Describe the pilot study. Enrolled number, mean SD in leak pressure.

=> We performed a preliminary study in 30 patients (15 per each group). The airway leak pressure was 27.0 (6.4) cmH2O with the i-gelTM and 30.8 (6.6) cmH2O the LMA-ProtectorTM. According to your advice, we described a pilot study in detail as follows.

“A preliminary study was performed in 30 patients (15 per each group), and the airway leak pressure was 27.0 (6.4) cmH2O with the i-gelTM and 30.8 (6.6) cmH2O the LMA-ProtectorTM. Based on the results of a preliminary study, a sample size calculation was performed assuming as a clinically significant difference in the airway leak pressure of 3.8 cmH2O between the two devices, and 50 patients per group were required at a significance level of 95% and with a power of 80%.”

Discussion

- P8 line 6~

Whilst the primary outcome, oropharyngeal leak pressure shows a statistically significant difference, the question of clinical significance is questionable. Any firm clinical benefit?

=> In the present study, the mean airway leak pressure was slightly higher with the LMA-ProtectorTM (31 cmH2O) than with the i-gelTM (27 cmH2O), which might be clinically
insignificant. However, this result should not be ignored because it may also suggest that the LMA-ProtectorTM can be a choice in some clinical situations where a higher oropharyngeal leak pressure is required such as laparoscopic surgery, although it was not evaluated in this study. We described it in the revised manuscript as follows.

“In the present study, the mean airway leak pressure was slightly higher with the LMA-ProtectorTM than with the i-gelTM, which might be clinically insignificant. However, this result should not be ignored because it may also suggest that the LMA-ProtectorTM can be a choice in some clinical situations where a higher airway leak pressure is required such as laparoscopic surgery, although it was not evaluated in this study.”

- P8 line 12


=> Thank you for your suggestion. According to your advice, we added it to the revised manuscript as follows.

[Introduction]

A recent preliminary assessment of the LMA-ProtectorTM showed that it is easy to insert and provides a reliable and adequate seal [7], and a recent primary evaluation of the LMA-ProtectorTM reported that the LMA-ProtectorTM provides a high pharyngeal seal [8].

[Discussion]

“The oropharyngeal airway seal, quantified by the airway leak pressure, is essential for the …………………. may provide a more individualized fit in the pharynx and hypopharynx. According to a preliminary evaluation, the median pharyngeal seal pressure of the LMA-ProtectorTM was 34 cmH2O [8]. In another preliminary assessment in non-paralyzed female patients with the LMA-ProtectorTM size three….”


- P8 line 18-20

Is there any other factor influence on insertion time except cuff inflation?

=> Except the cuff inflation time, the longer and larger cuff of the LMA-ProtectorTM may influence insertion time because it took more time to introduce the larger cuff into the
oropharyngeal space. Moreover, as we described in the limitation section, anesthesiologists’ more familiarity with the i-gelTM may affect the insertion time. In this revision, we described them as follows.

“The success rate of the device insertion at the first attempt (91% vs. 93%, LMA-Protector™ vs. i-gelTM, respectively), and ease of insertion were not different between the two devices, but the insertion time was longer with the LMA-ProtectorTM than with the i-gelTM. The i-gelTM has a non-inflatable cuff, whereas the LMA-ProtectorTM has a longer and larger inflatable cuff, therefore, it might take more time to introduce the larger cuff into the oropharyngeal space and inflate it. Moreover, anesthesiologists had more familiarity with the i-gelTM than the LMA-ProtectorTM, which may influence insertion time.”

- P8 line 28

It would be helpful if the reference is added.

=> According to your advice, we added the references as follows.

The i-gel™ has an epiglottic rest preventing the epiglottis from down-folding or obstructing the distal opening the airway [1], whereas the LMA-ProtectorTM has no component to prevent epiglottic down-folding, such as the epiglottic elevating bar in the LMA-FastrachTM [13, 14].


- P10 line 4

Clarify whether the two physicians had similar distribution of the use of the two devices in the method

Section

=> Two anesthesiologists who performed the insertion of two airway devices had a similar distribution for both devices. We clarified it in the method section.
“...the i-gelTM or LMA-ProtectorTM was inserted by two board-certified staff anesthesiologists according to the manufacturer’s instruction. They inserted them alternately in each group to achieve a similar distribution for using them.”

- P10 line 9

Add obesity considering BMI

=> According to your advice, we added it as follows.

“Fourth, this study was conducted in patients with a mean body mass index of 24 kg/m^2, not in obese patients, and our results may not be applicable to obese patients.”

Table 3

- Severity of sore throat

You mean not VAS? I wonder if there is small number of results despite authors used 100 mm scale. Pain is not severe?

=> In this study, we used a 0- to 100-mm numerical rating scale (NRS: 0, no pain; 100, worst pain imaginable), and the incidence of postoperative sore throat was 20% at 1 hr and 15% at 24 hr after surgery in the i-gelTM group, and 29% at 1 hr, and 16% at 24 hr after surgery in the LMA-ProtectorTM group.

When we calculated the average of severity of postoperative sore throat, we included all data including NRS 0 (no pain). Therefore, although we used 100-mm scale, mean NRS was four at 1 hr and three at 24 hr after surgery in the i-gelTM group, and nine at 1 hr and three at 24 hr after surgery in the LMA-ProtectorTM group.

If we calculate the average of severity of postoperative sore throat only in patients who had postoperative sore throat, the severity of sore throat is 20 at 1 and 24 hr after surgery, respectively, in the i-gelTM group, and 31 at 1 hr and 20 at 24 hr after surgery in the LMA-ProtectorTM group.

Reviewer 2 (Reviewer 2): PEER REVIEWER ASSESSMENTS:

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: The study has been performed rigorously and the manuscript is well written. The methods used and statistical analysis are appropriate, the interpretation of the results is reasonable, as are the conclusions drawn. The figures and tables are clear.
ADDITIONAL REQUESTS/SUGGESTIONS:

: We deeply appreciate your comment. Our point-to-point answers to your comments are as below

The only real change that the authors may wish to consider is an expansion of the discussion of potential bias. This is acknowledged in the limitations section of the Discussion, but it might be worthwhile mentioning that anesthesiologists are often considered to be inherently conservative individuals. Is there a possibility that they had a conscious (or unconscious) bias against the newer device, especially as they were less experienced in its use?

=> We completely agree with you that a conscious (or unconscious) bias against the newer device, the LMA-ProtectorTM, could affect the results in this study. Furthermore, less experience with the newer device may be a potential bias. In this revision, we added it to the limitation section as follows.

“Second, the investigators who inserted the supraglottic airway device had more experience with the i-gelTM (more than 100 insertions) than with the LMA-ProtectorTM (more than 30 insertions). They did have experience with more than 50 insertions of the LMA-SupremeTM which has a similar insertion method to the LMA-ProtectorTM. However, a conscious (or unconscious) bias against the newer device, LMA-ProtectorTM, might affect the results. Furthermore, the difference in experience with the two devices, especially less experience with the newer device, may be a possible source of bias.”

The study also requires a few small revisions - please write out numbers less than 10 as words.

=> In this revision, we wrote out numbers under 10 as words throughout the manuscript.

Thank you.