Author’s response to reviews

Title: Effects of lubrication on air-sealing performance of a pediatric cuffed tracheal tube

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Author’s response to reviews:

Dear Dr. Pavel Michalek
BMC Anesthesiology
Re: BANE-D-16-00319,

Thank you for your letter of Jan 12, 2017 regarding our manuscript entitled “Effects of lubrication on air-sealing performance of a pediatric cuffed tracheal tube” and valuable comments from the reviewers. According to the comments, we have conducted the additional experiments using a combination of the smaller size of tracheal tube and tracheal model, and we found that the effects of lubricants on air-sealing performance were similar to those reported in the original manuscript. We have added these results and revised the manuscript as suggested by the reviewers. I attach here both our revised manuscript and our point-by-point response to the reviewers’ comments. We believe that the revised manuscript addresses all the comments and questions raised by the reviewers and is suitable for publication in BMC Anesthesiology.

Thank you in advance for your kind consideration of our revised manuscript.
Reviewer 1

#1. These results confirm those previously reported by in vitro and clinical studies.

Response: There have been several papers studying the effects of lubrication on liquid leakage of cuffed tracheal tubes in vivo and clinical studies. However, to our knowledge, there have been no studies formally or systemically investigating the effects of lubrication on air leakage of pediatric cuffed tracheal tubes. This is the bottom line of our study, and we commented on this point in the section of introduction of the original manuscript.

In general, there are too many abbreviations in the manuscript resulting in difficult reading and understanding.

Response: We used seven abbreviations and listed them at the end of the text. I understand the inconvenience but think it is acceptable. If we avoid these abbreviations, it may render the manuscript more difficult.

#2. Abstract: actual results should be presented in this section. Additional results should also be shown here.

Response: we presented the actual results of the original and additional experiments in Abstract, as recommended. However, we could not present the comparisons of the incidence of air leakage because of the limit of word number.

#3. Background: it is unclear, at least to me, what was the rationale of this study. What is missing in the available data and what is the hypothesis?

Response: As mentioned in the response of #1, it has not been formally clarified if lubrication of pediatric cuffed tube reduces air leak. We hypothesized that lubrication of the cuff with KY jelly reduces air leak and improve air-sealing performance of pediatric CTT. We believe that these notions are clearly stated in the section of introduction of the original manuscript.

#4. Authors stated (page 3, line 20): conventional cylindrical shape. Usually, the conventional standard shape is barrel shape and not cylindrical. Please clarify.

Response: We specified the tracheal tubes by indicating the product name and the product number in the section of method. We also changed the term of “conventional cylindrical shape” to “cylindrical shaped”
#5. The authors should explain why they chose the Parker tracheal tube. Why didn't they compare different tubes, and different sizes? This might have allowed better generalization of their results.

Response: According to the comment, we have added the explanation as to why we used the Parker tracheal tube. We have also performed the additional experiments using the different type of Parker tracheal tube with ID of 4.0 along with a tracheal model with ID of 9 mm. We have added the details of methods, results and interpretation of the additional experiments. We also revised table 1-3 to include the results of additional experiments. As shown in the revised manuscript, we have observed similar improving effects of lubrication on air-sealing performance in both tracheal tubes. Of course there are many other tracheal tubes and other sizes to be studied, however, we confirmed that the improvement of air sealing performance is not specific to just one combination of tracheal tube and model trachea.

#6. They used gas-sampling tube to measure oxygen concentration, and determine the presence of air leakage. Was this method previously validated?

What was the duration of the experiments?

Response: We employed the method for detection of air leak which is modification of the method used in the earlier study by Madjdpour C et al. (reference 2 Acta Anaesthesiol Scand 2012 56: 230-235). They measured sevoflurane concentration above the cuff for detection of leakage of sevoflurane, and we measured oxygen concentration for detection of leakage of 100% oxygen. The principle of these methods is the same.

We added the sentence to present the duration of the each set of the experiment.

Discussion:

#7. This section is too long and not well focused. What is really the punch line? What this study adds to the current literature?

Response: We believe that the main findings are presented clearly in the 1st paragraph of the section of discussion of the original manuscript. These results are not new for liquid leakage, but they are novel and formally confirmed for the first time for air leakage by our study. However, we agree with the comment that the paragraphs explaining the technical issues like rational for the experimental settings are too long. Therefore, we cut the sentences and shortened these paragraphs, as suggested.
#8. As acknowledged by the authors, cuff lubrication has previously reported to be efficient for a short period of time. In addition, as shown in results section, lubrication was not totally efficient, even though it reduced leakage in part. Therefore, one could argue that this method is probably not the optimal option to reduce leakage and microaspiration in intubated patients. Other methods, such as continuous control of P_cuff were reported to be much more efficient. Please comment.

Response: We agree the comment that lubrication is not optimal for prevention of air leak. According to the comment, we added the sentences presenting this problem. As for continuous control of cuff pressure, the cuff pressure fluctuation or transient decreases in cuff pressure do not seem to be important factors contributing air leak in the short period of our experimental condition, because significant cuff pressure declines are unlikely to occur during the very short period of each measurement and high cuff pressure did not necessarily prevent air leak in the KY group. Continuous cuff pressure control is much more important in longer periods like the settings of mechanical ventilation in ICU.

#9. References are old and should be updated. There are several recent good studies and general reviews on this topic that should be discussed and cited.

Response: The reviewer probably suggests the studies and reviews dealing with the problem of cuff pressure control and prevention of aspiration pneumonia or ventilator-associated pneumonia. We intend to focus on air leakage but not liquid leakage during general anesthesia. We do not believe that there have been many recent good studies or reviews on this subject.

Reviewer 3: In general, the topic is interesting, and the primary aim of this study is to investigate the effects of lubrication on air-sealing performance of a pediatric cuffed tracheal tube. There are several comments for this study.

Major comment

1. The study based on a tracheal model. As the authors mentioned that the limitations of this study included one size tracheal tube, one size acrylic cylinder, limited duration, and difference between acrylic cylinder and real trachea. In addition, great variety of size is an important issue for a study focused on pediatric patients. Additional experiments and clinical trial are required for clinical implication.
Response: According to the comment, we performed the additional experiments using the combination of the tracheal tube and model trachea with the smaller size and found the similar effects of lubrication on air leakage. We have presented the methods, results and interpretation of the additional experiments <p2 line16-p3 line1, p4 line9-14, p6 line8-12, p7 line8-9, p8 line15, p9 line3-6, p11 line16-19, table 1-3>. Please refer to the response to #5 comment from reviewer 1.

Minor comments

1. The amount of K-Y jelly applied to the cuff might need to be described.

Response: We presented the amount of KY jelly, as recommended. <p5 line3-6>

2. A reference is needed to be cited to support that an acrylic cylinder with ID of 12 mm to simulate the trachea of an 8 years old patient.

Response: According to the recommendation, we added two references regarding the size of trachea of pediatric patients. < reference 12, 13>

3. In Table 1, the P value is not correct for peak airway pressure of 20 and 25 cm H2O. Furthermore, Fisher's exact test might be more suitable for this study.

Response: We agree the comment. We re-analyzed the results presented in table 1, 2 using Fisher's exact test and revised table 1, 2 and the sentences in the result section accordingly <p5 line21, p6 line8-12, table 1,2 >.

4. In Table 2, the result might indicated that large longitudinal fold of cuff might have significant influence. Once it leaked, increase cuff pressure did not change anything. K-Y jelly might prevent air leakage for small longitudinal fold. The author may try to investigate the factors that are related to the size of longitudinal folds.

Response: We think this may be one of possible reasons to explain the results that KY jelly is occasionally ineffective in preventing air leak. We have added the sentence describing this potential and attractive mechanism in the section of discussion < p9 line16-21>. However, clarifying the factors governing the size of longitudinal folds would need another study.