Author's response to reviews

Title: Changes in tracheal tube cuff pressure during laparoscopic surgery in head-up or head-down position

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Author's response to reviews: see over
Dear Dr. Dawn Dillman:

Thank you for reviewing our report and giving us helpful suggestions. Here are our point-by-point replies to your comments.

Discretionary Revision

1. The question is not clearly defined. In the abstract, lines 33-35, the question is stated, "We assessed the cuff pressure changes after abdominal insufflation in both the head-up and head-down positions." This is not what they reported in the methods. In the methods it describes them doing insufflation in the supine position and then moving into the heads-up or heads-down position.

Reply:

We have rewritten the abstract. Thank you for correction.

2. There are many other related articles, including a description of positioning changes by Lizy, C http://www.medscape.com/viewarticle/818880, that provide important background.

Reply:
We did not know this article during our investigation. We have added this important literature as one of our reference in discussion. Thank you for providing this helpful information.

Major compulsory revision

3. I do think the conclusion is fundamentally flawed by not having an additional group that had neither the insufflation or change in position. Cuff pressure may tend to increase over time as the temperature of the gas in the cuff increases, so what is attributed to a change due to insufflation or positioning, may be just a change because of time. This is particularly true since there is no mention of whether nitrous oxide was used. Without including another comparison group, this should at a minimum be discussed as a limitation of the work in the discussion.

Reply:

During the surgery, nitrous oxide was not allowed in each case. We have added this description in the revised manuscript. Beside, another group of patients undergoing open abdominal surgery also have been enrolled as a comparison control. In comparison to patients undergoing laparoscopic surgery, an increase of cuff pressure
was not found in patients undergoing open abdominal surgery during the investigated period.

Minor essential revisions

4. The data analysis gives me a little pause. In Figure 1 cuff pressure and airway pressure for the insufflation state and the position state are labeled as significant but it is not clear whether the comparison for the position state is the insufflation state or the baseline state. In the text, it states that the cuff pressure and airway pressure position state is compared to the insufflation state and that the p value is <0.001, which may be true, but the 95% confidence intervals overlap quite a bit, so I find it hard to believe it is that significant, and would believe that this is really a comparison to the baseline state. At a minimum, this needs to be clearer in the figure and the text.

Reply:

The cuff pressure and airway pressure in the positioned state increased in comparison to the insufflation state as the descriptions in the text. The position effect is only statistically significant in the head-down position. However, the 95% confidence intervals really overlapped in our investigation. It may be that the positioning effects on cuff pressure and airway pressure was much less clinical relevant than the
insufflation effects. Besides, The Fig 1 and 2 were deleted due to the repetitive information in the Result section as another reviewer’s suggestion.

5. Turkey in line 96 should be Tukey.

Reply:

We have corrected this spelling error. Thank you for correction.

6. Body weight in Table 1 should be units of kg, not cm.

Reply:

We have corrected this embarrassing error.

7. English grammar is not quite correct in many places:

Line 31 should drop both the, Line 59 should drop the first the, line 60 should drop the, line 61 should have the before impact, line 85 breath should be breathing, line 125 should be that had, line 143 should drop the first the, line 151 should drop the the, the sentence beginning line 181 is very difficult to understand, line 185, influent should be influential.
Reply:

We have rewritten above contents and hope that revised text will be more comprehensive.
Dear Dr. Richard E Galgon:

We sincerely thank you for reviewing this article and giving us a lot of helpful suggestions. Here are our point-by-point replies to your comments.

Major Compulsory Revisions

1. Please clarify whether or not written informed consent was obtained from all study participants. If so, include a statement to this effect in the Methods section. If written informed consent was not obtained from all study subjects, then a valid justification for human subject research protection must be provided.

Reply:

We thank the reviewer to remind us to provide information about this important issue. Each patient including patients enrolled in the supine control group for the revision is obtained written informed consent. We have corrected this in the revised manuscript.

2. Line 75: General anesthesia was maintained with sevoflurane. Please specify the end-tidal sevoflurane concentration targeted for maintenance and adequate depth of anesthesia. Further, specify the carrier gases (air, oxygen, or air/oxygen mixture) that were used. Finally, nitrous oxide is known to diffuse into air-filled tracheal tube cuffs.
Please indicate if nitrous oxide use was allowed (or controlled for) during anesthesia maintenance, or provide a scientific rationale as to why this would not confound the study results.

Reply:

During the investigated period, 1:1 air/oxygen mixture was used in each patient and sevoflurane was maintained at 1.3 MAC. Nitrous oxide was not used in each patient. We have added these descriptions in the revised manuscript.

3. Line 80-81: It is reported that tracheal tube cuff pressures were adjusted to between 20-30 cmH2O using a VBM manometer. It is important to understand the possible measurement variation attributable to the measurement technique. First, the available on-line product literature from VBM describing and picturing their manometers illustrates pressure degradations of every 2 cmH2O. Thus, if this product literature describes the product used to set and measure the tracheal tube cuff pressures in the study, the set and measured tracheal tube cuff pressures are only accurate to within +/- 1 cmH2O (at best). The authors need to clarify the accuracy of the manometers used in the study. Second, it must be understood whether or not these gauges require periodic or routine calibration and if so, whether or not this was
undertaken during the study to control for inaccurate set and measured tracheal tube
cuff pressure results due to manometer drift. Third, it must also be understood
whether or not the same manometer or different manometers were used to set and
measure the tracheal tube cuff pressures during the study. If multiple gauges were
used during the study, the issues described above must be addressed for all gauges
used in the study. Finally, the results should be reported with appropriate precision
dictated by the resolution of the measurement technique.

Reply:

This type of manometer is only accurate as ± 1 cmH₂O as the reviewer's comment.

We have mentioned this potential limitation in our revised manuscript. The
manometer is recommended an annual calibration as the manufacturer's suggestion.

During our investigation period, we performed calibration monthly. A single
manometer was used in each patient. The result has also corrected with appropriate
precision dictated by the resolution of the measurement technique as the reviewer's
comments.

4. Line 83-85: The authors report the use of “a supplemental dose of muscle
relaxant as a fifth of induction dose” and train of four monitoring to ensure the
patient was not spontaneously breathing, presumably during the study pressure measurements. This aspect of the study is important to ensure that observed changes in tracheal tube cuff pressures were due to the study interventions of interest (i.e., abdominal insufflation and patient head-up or head-down positioning) and not due to confounding factors such as muscular tension. However, the authors do not describe where, how, or when the train-of-four measurement(s) were assessed; nor do they compare these measurements at “baseline” and at the time of subsequent study measurements to exclude this potential confounding factor. The authors should address this potential study flaw.

Reply:

During the induction and the whole investigation period, the train-of-four supramaximal twitch stimuli was set to ulnar nerve with a frequency of 2 Hz, four stimuli each separated by 0.5 s and repeated every 10 seconds. Each measurement was performed without observation of T1. These information has been added to the revised manuscript. Thank you for pointing out the potential flaw we had not addressed in the original manuscript.

5. Line 87-88: The authors report subjects were positioned in the head-up or
head-down position both at 30 degrees (presumably from horizontal). However, they
do not describe how this angle was measured to ensure tracheal tube cuff
pressure measurements were made at the appropriate positions, particularly
given the non-blinded nature of the study. The authors should address this issue.

Reply:
Positioning angle was measured using a protractor by an observer who did not
participate in other parts of this study. We have addressed this in the revised
manuscript.

6. Line 94-95: The authors do not provide an adequate study sample size
justification. They should provide the a priori estimates and assumptions used to
estimate the study sample size.

Reply:
We had calculated that a number of 10 patients in each group was required to detect a
mean cuff pressure changes by 5 cmH₂O. This information has been added to the
revised text.
7. Line 103: The authors report baseline characteristics for the study groups in Table 1. Additional possible confounding variables, such as end-tidal sevoflurane or minimal alveolar concentration (MAC) as an indicator of depth of anesthesia and train-of-four status as an indicator of muscle tension should also be described and reported for each of the study measurement points for the reasons noted above. If differences are discovered, it may be possible to statistically adjust for these differences with further data analyses.

Reply:

The maintenance of sevoflurane was at the same level of 1.3 MAC for both groups. The train-of-four status was also at the same level (disappearance of T1) in the both groups. We have added associated descriptions in the revised manuscript.

- Minor Essential Revisions

1. Line 70-71: Change “Consecutive seventy adult patients undergoing elective laparoscopic surgery between July and November 2011…” to read “Consecutive adult patients undergoing elective laparoscopic cholecystectomy or laparoscopic colorectal tumor resection between July and November 2011…”
Reply:

We have corrected this in the revised manuscript.

2. Lines 108-139: The study results should be reported with appropriate precision dictated by the resolution of the measurement technique as discussed above.

Reply:

We have corrected this issue in the revised text.

3. Line 108-113: The authors describe changes in tracheal tube cuff pressures and airway pressures due to abdominal insufflation. However, the use of “patients in the head-down position” and “patients in the head-up position” make understanding the results in this section confusing as presumably the patients remained supine for both sets of measurements. It’s suggested that the authors revise the statements on these lines to clarify that these are the study groups and not the subject positions. For example, Line 107-110 could be revised to read: “After abdominal CO2 insufflation with the study subjects in the supine position, the mean cuff pressures (SD) increased from baseline values of 27 +/- 3 and 26 +/- 3 to 33 +/- 5 and 32 +/- 6 cmH2O (both p < 0.001), respectively, for subjects undergoing
laparoscopic colorectal tumor resection surgery (head-down group) and laparoscopic cholecystectomy (head-up group).” Note, the graphical data in Figures 1 and 2 are repetitive of the information provided in the Results section. Generally, data repetition like this should be avoided. The authors should choose to present the data in either text or graphical/table format once.

Reply:

We have corrected above descriptions as the reviewer's suggestion. The Fig 1 and 2 were also deleted due to the repetitive information in the Result section as reviewer's suggestion.

4. Line 132: The authors should appropriately temper their statement regarding the correlation between changes in airway pressure and tracheal tube cuff pressure by abdominal insufflation. Although the correlation is true, the reported r value is only 0.68. The authors should simply state that the airway pressure and tracheal tube cuff pressure changes correlated with abdominal insufflation and report the correlation coefficient. The term “significant correlations” overstates the finding.

Reply:
We have tempered the statement as the reviewer's suggestion.

5. Line 142-143: It can be hypothesized that tracheal tube cuff pressure increases with laparoscopic surgery in general; however, the study results do not support this generalized extrapolation. The sentence should be revised to read “The major finding of our study is that the tracheal tube cuff pressure increases with abdominal insufflation and patient position changes, especially the head-down position, during laparoscopic colorectal tumor resection surgery and cholecystectomy.”

Reply:

We have revised as the reviewer's suggestion.

6. Line 150-151: This statement is not true and should be revised. The authors should refer to Yildirim ZB et al, Surg Endosc 2012; 26: 398-401.

Reply:

We start this study since 2011 and did not know this important article before. Further discussion between this report and our investigation is also added in the discussion section in the revised text. Briefly, the major differences between these two reports is
that our report provided additional information regarding the position effects, correlation between body mass index and intraabdominal pressure. We have also revised this statement, thank you a lot for the correction.

7. Line 157: It appears the authors are indicating that the study subjects reported a high incidence of sore throat; however, this was not described as a study endpoint in the Methods section or reported as a result in the Results section. This should be clarified.

Reply:

Postoperative sore throat is associated with multiple factors, such as numbers of attempt to intubate, use or no use of an intubating stylet, operating time, type of lubrication of endotracheal tube cuff...etc. Each factor should be considered and analyzed to clarify between the specific factor- cuff pressure and postoperative sore throat. Our current result was not able to correlate the true associations between elevated cuff pressure during laparoscopic surgery and postoperative sore throat. We have considered this as a limitation and the description has been added in our revised manuscript.
8. Lines 173-177: The authors state that their data showed no significant correlation between intra-abdominal pressure and tracheal tube cuff pressure changes, which is in contradistinction to their statement on Line 131-133. This should be clarified.

Reply:

We found that cuff pressure changes by abdominal insufflation did not correlate to the common intra-abdominal pressure usage of 10 to 15 mmHg during the laparoscopic surgery. Although we also found a correlation between airway pressure and cuff pressure changes by abdominal insufflation, the correlation coefficient was not very high (r=0.68). The intra-abdominal pressure may have more impact on the more distal airway than the tracheal compliance. However, the detailed mechanism need further investigation with more measurement of respiratory system compliance. We considered the current study was not qualified to answer this question because our finding was only to point out that the excessive endotracheal tube cuff pressure in the laparoscopic surgery may not be preventable with a CO₂ insufflation pressure at the lower limit of common intra-abdominal pressure usage. Therefore, we have rewritten this section in the revised text.
9. Lines 180-186: The study limitations should be appropriately expanded to discuss non-blinding and pressure measurement technology limitations/accuracy. The authors should caution the reader against extrapolating the study results to laparoscopic surgery in general until future data collected during multiple types of laparoscopic procedures is available.

Reply:

We have addressed above mentioned limitations in the revised manuscript.

- Discretionary Revisions

1. Please indicate if the study was registered in a clinical trials database (e.g., www.ClinicalTrials.gov). If so, please identify in which database the study was registered and include the registration number in the Methods section.

Reply:

This study was only registered in our institutional review board (Research Ethics Committee of National Taiwan University Hospital, registration number: NTUH-201107050RC). These information has been added in the revised manuscript.

2. Line 77: Change “The size of the tracheal tube was 7.5 mm for male and 7.0
mmm for female” to read “Tracheal tubes with internal diameters of 7.0 and 7.5 were used in females and males, respectively.”

Reply:

We have corrected this in the revised manuscript.