Reviewer's report

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

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Reviewer: Richard E Galgon

Reviewer's report:

- 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.

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.

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.

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 due 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.

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.

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.

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.

- 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…”

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

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.

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.

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.”

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.

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.

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.

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.

- 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.

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.”

Level of interest: An article whose findings are important to those with closely
related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests (financial or otherwise) related to the work described in the manuscript.