Reviewer’s report

Title: The influence of different patient positions during rapid induction with severe regurgitation on the volume of aspirate and time to intubation. A prospective randomised manikin simulation study

Version: 0 Date: 16 Nov 2018

Reviewer: Jochen Hinkelbein

Reviewer's report:

Dear Dr. Guangde Tu,

we would like to submit the revised manuscript of our empirical investigation

"The influence of different patient positions during rapid induction with severe regurgitation on the volume of aspirate and time to intubation. A prospective randomised manikin simulation study"

for publication in BMC Anesthesiology.
Yours sincerely,

Michael St.Pierre, M.D.

Reviewer reports:

Jochen Hinkelbein (Reviewer 1):


Page 9: Patient positioning was analyzed in several recent studies, e.g. the above mentioned. Please add.

The suggested publications have been included in the discussion (p9, LL 260 – 273).

The Limitation of manikin studies should be elaborated, especially the stiffness, Respiration efforts or suction by muscular tone in the airways in human.
We interpreted the reviewers concern as a request to take a broader perspective on different aspiration scenarios not limited by the static properties of our simulation model (e.g. regurgitation and aspiration in an unconscious but spontaneously breathing patient). We added this aspect to the limitations; the passage reads as follows (p.14, lines 416 - 420):

“Third, our model can only simulate the clinical condition of passive aspiration following gravity. However, the clinical consequences of regurgitation may be more severe in a spontaneously breathing patient where respiration efforts may actively suction regurgitated fluid into the airways, hereby increasing the volume of aspirate.”

Depth of anaesthesia should be discussed as a relevant factor for Aspiration.

The aspect of depth of anaesthesia as a factor influencing the likelihood of regurgitation and aspiration has been included. The passage reads as follows (p12, line 367 - p13, line 380): “In the setting of aspiration, regurgitation occurs more commonly than active vomiting. General anaesthetic techniques attenuate the protective upper airway reflexes and physiological mechanisms that prevent regurgitation and aspiration. Excessively light depths of anaesthesia in combination with insufficient neuromuscular blockade may evoke gastrointestinal motor responses during laryngoscopy and intubation such as gagging or retching that may increase gastric pressure over and above lower oesophageal sphincter pressure facilitating regurgitation. Allthough study protocol left the choice of drugs at the discretion of the anaesthetist, all participants followed local clinical guidelines for rapid sequence induction which included fentanyl, an induction agent (e.g. etomidate, propofol, or thiopental), and rocuronium as non-depolarizing neuromuscular blocking agent which would have provided an adequate depth of anaesthesia in a real patient.”

Anthony Kovac (Reviewer 2): The authors are to be congratulated on a well thought out study on a controversial topic.

I have only a few minor comments.

I would add the word manikin to the title, such as a randomized manikin simulation study.

The title has been changed as suggested.

Page 6, lines 155 to 167. I would omit the scenario.

The section heading “scenario” as well as details on patient history and clinical workup have been deleted. However, we chose to retain the information concerning acute mesenterical infarction to provide the reader with a plausible explanation for the volume of regurgitated fluid (small bowel ileus vs. non-fasted patient). The text has been added to the previous section “Study protocol” and now reads as follows (p.6, lines 157 - 162): “Participants were asked to perform a rapid sequence induction in a patient with a suspected acute mesenteric infarction. Once anaesthesia had been induced, the patient was positioned according to the randomisation protocol. Every participant expected to receive a verbal cue when to start with laryngoscopy and was surprised when the mannekin regurgitated fluid instead.”
Morgan Le Guen (Reviewer 3):

Review BMC Anesthesiology BANE-D18-000469 The article entitled "The influence of different patient positions during rapid induction with severe regurgitation on the volume of aspirate and time to intubation. A prospective randomised simulation study » submitted by St Pierre et al. compared aspiration after anaesthesia induction according to the head position on a manikin. This is an original study with a dedicated simulator which aims was to reproduce and assess the volume of aspirate in the three followed groups: regurgitation during induction in proclive position with laryngoscopy in Trendelenburg, regurgitation after anesthesia but before intubation in Trendelenburg position and regurgitation after anesthesia but before intubation in Trendelenburg with sellick position. The other primary outcome was the time to intubate. The author demonstrated the third position as the more protective against regurgitation with a prolonged delay of intubation (15s [8-30] in comparison to 10s [8-15], with p<0.05. The method was clearly described and the sample is interesting. The manuscript is well-written and it could be accepted pending minor revisions.

Major comments:

There are two methodological limits which could be discussed or revised in the manuscript. The first one is the fact that authors have not optimized their human resources with a cross-over study. The best method may be the repetition of the three situations for every participant with a randomized order in the groups. This would have decreased a possible bias in each group about experience and technical skills.

Second, the power would be significantly increased.

We chose to discuss the limitations in the “limitations”-section of the manuscript. The passage now reads as follows (P14, lines 426-433): “A major limitation of our study is the fact that it was not conducted as a separate clinical study but instead part of our annual institutional simulation training programme. Time and resources available only permitted one rapid sequence induction per participant which possibly introduced a bias in each group about experience and technical skills. A cross-over study with the repetition of the three situations for every participant with a randomized order in the groups might have avoided this possibility and would have increased the power of our study.”

Second, I am sometimes disturbed by the choice to analyze separately Trendelenburg (before and after regurgitation) and Sellick position. In fact, the behavior and the delay to manage the airway may be influenced by the group especially with a situation awareness more acute in the first group. As a consequence statistics may vary with a different conclusion. I think this is important to explain your choice in the statistic section.
Thank you for pointing us to an aspect of our methodology that apparently can easily be misunderstood. All participants were briefed that they were about to manage a case in which the patient would aspirate and that they were asked to laryngoscope and intubate the patient in the position defined by randomization. Thus, every participant expected to receive a signal when to start with laryngoscopy. What they expected was a verbal cue; what they did not reckon with was that the mannequin actually vomited fluid. As a result, we are confident that the behavior of all three groups as a response to the surprise regurgitation is comparable.

We inserted a short explanation in the methods (p.6, lines 157-162): “Participants were asked to perform a rapid sequence induction in a patient with a suspected acute mesenteric infarction. Once anaesthesia had been induced, the patient was positioned according to the randomisation protocol. Every participant expected to receive a verbal cue when to start with laryngoscopy and was surprised when the mannekin regurgitated fluid instead.”

You have built a 3-group trial and finally you have described only two samples regarding the primary outcome. In a similar manner, the Figure 2 represents only 2 groups: why do you do this?

While we wanted to compare the volume of aspirate associated with the three different positions for the reasons explained in the manuscript, our point of interest with respect to laryngoscopy was how participants experienced two unfamiliar intubation situations (Trendelenburg) with a familiar head positioning (sniffing position) as well as an unfamiliar head positioning (Sellick extension).

All participants started with laryngoscopy as soon as regurgitation had ceased which by then was always in the Trendelenburg position. As the amount of aspirated fluid (research question 1) does not correlate with or affect the laryngoscopic view (research question 2), we chose to combine the results of both Trendelenburg groups without Sellick extension to increase group size. As we understand that our description might not have been sufficiently explicit we clarified the primary objectives (p.4, LL 100-105): “The two primary objectives of this study were to a) determine the influence of three different positions during induction of general anaesthesia on the volume of aspirate in the manikin’s trachea and bronchi when severe regurgitation occurred and b) the mean time to intubate in the two final head positionings (Trendelenburg position with sniffing position and Trendelenburg with Sellick extension).”

Minor comments:
Abstract: please starting with results about regurgitation. It is your main hypothesis: last sentence of the background section.

The results about regurgitation have been placed at the beginning of the section.
In the method section: In my opinion, I was a little confused in reading your manuscript about the timing of regurgitation in the 2d and 3rd group. Then I have understood the followed:

- regurgitation during induction in proclive position and laryngoscopy in the Trendelenburg position
- regurgitation after induction but before intubation in the Trendelenburg position
- regurgitation after induction but before intubation in the Trendelenburg + sellick position.

Yes, this understanding is correct. To enhance clarity we rephrased the relevant passage as follows (p.5; lines 131-145): Group 1: Induction of anaesthesia in reverse Trendelenburg position (+15°). As soon as regurgitation occurred the mannekin was placed in Trendelenburg position (−15°) and intubated in Trendelenburg position with the head supported by a pillow (‘sniffing position’).

Group 2: Induction of anaesthesia in reverse Trendelenburg position (+15°). As soon as the ‘patient’ had been anaesthetised the mannekin was placed in Trendelenburg position (−15°). Thereupon regurgitation occurred and the simulator was intubated in Trendelenburg position with the head supported by a pillow (‘sniffing position’).

Group 3: Induction of anaesthesia in reverse Trendelenburg position (+15°). As soon as the ‘patient’ had been anaesthetised the mannekin was placed in Trendelenburg position (−15°) and full cervical spine extension (Sellick). Thereupon regurgitation occurred and the simulator was intubated in Trendelenburg position without the pillow supporting the head and with full cervical spine extension.

In the result section; Keep a similar order in the method, the results and the discussion.

The result section has been restructured and now addresses primary endpoints first, and then secondary endpoints.

In the discussion: it could be interesting to discuss the intubation during or after regurgitation. This is a challenge: should I wait for the end of regurgitation? Or should I protect the upper airway as quick as possible.

You are absolutely right, and there was a lively debate amongst us authors which clinical conclusions to draw from our findings. We concluded that this decision cannot be resolved by recommending a single strategy to be preferred, but most certainly will depend upon the anaesthetist’s situational assessment. We added the following argument to the manuscript (p. 12, lines 356 - 366): “Our finding that a head-down tilt (-15°) with full cervical spine extension can prevent pulmonary aspiration raises the clinical question whether intubation should be delayed until the end of regurgitation with the patient placed in Trendelenburg position or whether the upper airway should be protected as quickly as possible with the aid of a large bore suction. Our
preliminary findings in a simulated setting offer the clinician another strategy to consider in case of regurgitation but do not warrant any final conclusion. Rather, this decision will continue to depend upon the anaesthetist’s situational assessment of the volume of regurgitating fluid, the dynamic of the regurgitation (continuous oesophageal rise or one short surge) and the effectiveness of the suctioning efforts.”

Figure 2: Only two groups are represented.

Our reasons for combining group 2 and 3 have been explained above.

References: some of them are old! You must limit this kind of reference. Please reduce the number of references.

The number of old references has been reduced to one historic reference to each position.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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