Author’s response to reviews

Title: Semiprone position is superior to supine position for paediatric endotracheal intubation during massive regurgitation: a randomized crossover simulation trial

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Version: 1 Date: 05 Jan 2018

Author’s response to reviews:

Dear editor and reviewers,

Thank you very much for your insightful comments. We have tried to incorporate all addressed concerns, and we believe the manuscript has improved considerably by these changes.

We hope you will consider this reviewed manuscript, a point-by-point response to your comments follows:

Reviewer #1:

It is important to perform ETI in semiprone position and this method is probably useful for the patients with regurgitation. However, it is difficult to prove that semiprone position is superior to supine position during massive regurgitation in real situations. Regarding their simulated regurgitation, it could have been an excessively unfavorable situation for the supine position. Thus, their model might not have represented the real situation. Please make a comment about the validity of their simulated regurgitation. In addition, this study was not blinded. Therefore, each evaluation might have been strongly biased by participants. It is probable that participants
thought that semiprone position provided better conditions than expected, which might have affected subjective assessment. Please make a comment about this concern.

We thank the reviewer for pointing out this crucial aspect. Limitations concerning non-blinded simulation experiments was indeed also our major concern before conducting the study. However, due to the lack of other publications exploring the semiprone position method, and with high-quality evidence in the form of a blinded randomized controlled trial being near impossible to obtain in this type of clinical setting, we believe that a simulation study like the one presented in our paper is a necessary starting point for further research into the performance of the method. We also believe that the practicality of the experiment is somewhat strengthened by the fact that this experiment was conducted after a real-life situation where intubation in the supine position was impossible due to on-going regurgitation, and intubation in the semiprone position was uncomplicated. We also emphasize that the method is meant to be used as a rescue method when intubation in the supine position is hindered, and not as a primary technique.

Following the reviewer’s important comment, we have extended the limitations chapter to elaborate on this matter, and the risk of bias connected to the participants’ expectation has been included. We believe this has improved the robustness of the manuscript, and hopefully the chance of readers potentially misinterpreting what we believe is the core message of our findings has been reduced.

Reviewer #2:

Introduction please describe what has been shown, and why the authors chose to do a new study on this topic.

Given the simplicity of the intervention, we were surprised not to find any previous studies investigating the described method. Hence, this is not a new study on this technique, but rather a first study on a new technique. We do however understand the reviewer’s wish for some more contextualization, and some studies regarding related subjects, as well as a wider explanation behind our rationale for the study have now been added to the introduction.
It is unclear why the authors chose clinicians with different experiences with direct laryngoscopy in the study. There seems to be clinicians that are relatively inexperienced and clinicians that are very experienced with direct laryngoscopy. This would have influenced the results. Why didn't the authors choose clinicians that were relatively inexperienced or had similar levels of experience in order to have similar baseline clinician skill sets?

The groups studied are not homogeneous and this should represent a limitation in the current study. For further studies (even simulated), the groups should be more homogeneous.

The concern raised by the reviewer is an essential one. How to handle this issue is a question of viewpoint. In our service personnel with all levels of experience may be exposed to difficult intubations. In our study, we wanted to examine the performance of a typical sample of personnel within our medical service. We also hypothesized the method to be a viable rescue method regardless of level of experience. Information about experience was included as this, like the reviewer points out, could nonetheless turn out to be of vital importance. The results are however largely homogeneous across groups, regardless of the heterogeneity of the personnel, which is in line with our hypothesis. Following the reviewer’s concern a more thorough explanation regarding this matter is now included in the methods chapter.

It is difficult to visualize how a clinician intubating and stabilizing the head in the semi prone position (as shown in the picture), also would successfully place the tracheal tube in the trachea.

This point raised by the reviewer is an interesting one, and is indeed something we considered might be a potential problem during the simulation study. However, both in the motivating incident, as described in the introduction, and for all simulation experiments, this turned out to be surprisingly uncomplicated. We instructed the participants to do whatever they felt was the most intuitive, and no participants hesitated at this point. The assistant supported the manikin head upon participant request during the intubation in most cases. For some, like in the picture, the person performing the intubation supported the head with the inside of the hand, while using digits one and two to insert the tube. We realize that this point has been somewhat understated in the manuscript, and a more thorough explanation of this point is now included in the methods chapter of the revised version of the manuscript.
Why was a rigid suction not used for suctioning the simulated regurgitation? It is uncommon that a flexible suction be sufficient for the purposes of massive regurgitation? Is use of flexible suction by an assistant the standard practice in the author's country?

We agree with the reviewer that a rigid suction unit would be a better alternative than a flexible one in this particular situation. However, these are normally not readily available in emergency situations outside hospitals in our services, where we hypothesize that massive regurgitation during airway management is most likely to occur. The aim of our study was to investigate the performance of this new method in a situation where there is limited equipment available, as our proposed method is primarily intended to be used when normal procedures fail. This is now explained in greater detail in the methods chapter.

The power calculation used in the study is unclear. How was a difference of 5 seconds chosen? Can the authors provide also SD used for sample size calculation?

Performing a power calculation for this study was a challenge, as the intervention is new, and the numbers needed for a power calculation thus not readily available in the literature. However, as we believe this intervention is particularly valid regarding patients in cardiac arrest receiving chest compressions, we used this as a basis for our power calculation. In 2015 ERC guidelines on advanced life support, 5 seconds is considered the maximum hands-off time during endotracheal intubations during CPR [Soar, J., et al. (2015). "European Resuscitation Council Guidelines for Resuscitation 2015: Section 3. Adult advanced life support." Resuscitation 95: 100-147]. In Wang’s 2009 article on interruptions in CPR during intubation [Wang HE1, Simeone SJ, Weaver MD, Callaway CW. Interruptions in cardiopulmonary resuscitation from paramedic endotracheal intubation. Ann Emerg Med. 2009 Nov;54(5):645-652.e1], 5 seconds was also used as a definition for what should be considered an interruption. We agree that the minimal clinically important time difference between airway management methods is yet to be addressed, but with the little evidence and consensus available, we found 5 seconds to be a valid starting point. We could not find any SD on this type of data in the literature. In our small pilot study the estimated SD in the difference was measured to be 6.2, and this number was used in the power calculation for the larger study. This information is included in the power calculation, and we have extended the power calculation chapter to elaborate on these aspects.

What was the definition of successful intubation? How were the time points measured for this study? How was the correct placement of the ETT verified?
Following the reviewer’s comment, we can see how this was not clearly stated in the submitted manuscript. Accordingly, we have now tried to be more detailed in the methods chapter. The definition of successful intubation was a correctly placed tube in the manikin’s trachea, controlled with bag ventilations and with visual confirmation by one of the observers after the attempt was discontinued. The time was noted when the tube was considered to be correctly placed by the participant. In the case of an incorrectly placed tube on examination, the total time before successful intubation was noted. All participants managed a successful intubation after a maximum of two attempts, so all cases ended with a correctly placed tube.

The authors’ should acknowledge that the main limitation in this study is there is the manikin that they chose (a lack of dynamic components in the simulator) they chose, including oxygen desaturation, reflex activation of the airway including coughing, bearing down (leading to more regurgitation), bronchospasm, laryngospasm all of these would have influenced the results in real life including the time for successful tracheal intubation.

We fully agree with the reviewer on all the mentioned limitations. These are also in line with the other reviewer. The limitations chapter has been extended accordingly.

Turning an unconscious patient with an injured cervical spine may be problematic. I am unclear of whether pre-hospital providers would turn a patient in the emergency setting to intubate the trachea in the semi-prone position. Do the authors currently do this in their practice?

The presence or suspicion of neck injury is of course problematic. The explained technique is also novel to us, to our knowledge, intubation in the semiprone position is not common practice in any services. In our setting, it has only been improvised and used in situations where all other airway management attempts failed, as a last resort before performing an emergency tracheostomy. Hence, this article is an attempt to perform an evaluation of semiprone position as an alternative rescue method when complications occur. We acknowledge that this was not clearly stated in the previous manuscript, and it is now described in greater detail.

I doubt that the presence of a neck collar or even manual stabilization in case of suspected neck fracture can allow to perform this kind of positioning and ETI. The authors should address this issue and create a kind of list of pro and cons for placing the patients in this position.
In the suggested semiprone position the presence of a neck collar or suspected neck injury can indeed affect the way the airway is managed, and might interfere with intubation. In an earlier draft of the manuscript we had a section on the difficulties concerning patients with neck injury, but removed it to make the article more compact before submission. Following the reviewer’s comment, we see that this removal took away a central part of the discussion, and we have re-added this information in the revised version of the manuscript.

We tried intubation with a neck collar on the manikin in both positions, and in our experience, this does not complicate the intubation as much as one perhaps would expect. Manual stabilization during a log roll is difficult, but not impossible, but this implies the need for more personnel. When actually placed in the position, however, there is some protection from aspiration due to the possible drainage of regurgitation, and one aspect that actually might reduce the need for neck movement during the actual intubation is the fact that the tongue tends to fall away from the uvula and somewhat improving the laryngeal view with less pressure on the laryngoscope. However, as this method is still only sparsely described, we believe that a more thorough examination of all these important aspects will have to come at a later stage. We strongly agree that a pro and con list for intubation in the semiprone position could be both useful and informative, but with the limited amount of available evidence, we feel we are not in the position to make sufficiently valid considerations yet. However, if this article can lead to more interest and research into the technique, this would certainly be a central aspect for future studies.

The discussion should focus on the main results and not repeat results and methodology.

Following the reviewer’s comment, the discussion has been shortened and some parts re-written, to make the discussion more concise and less repetitive.

Kind regards on behalf of all authors,

Espen Fevang, M.D., PhD-student

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