

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Intubation performance using different laryngoscopes while wearing chemical protective equipment – a manikin study
AUTHORS	Schröder, Hanna; Zorembo, Norbert; Rossaint, Rolf; Deusser, Karla; Stoppe, Christian; Coburn, Mark; Rieg, Anette; Schälte, Gereon

VERSION 1 - REVIEW

REVIEWER	David Healy MD Department of Anesthesiology, University of Michigan, Ann Arbor, USA Scientific Adviser to Brio Device LLC, no direct competing interests with this project or review
REVIEW RETURNED	30-Oct-2015

GENERAL COMMENTS	<p>Thank you for the opportunity to review this interesting article. The authors should be congratulated for attempting to investigate device performance in these unusual (yet topical) circumstances of difficult airway management due to equipment constraints.</p> <p>Summary: This study investigate the manikin endotracheal intubation performance characteristics of a variety of laryngoscopes when wearing chemical / biological protection equipment</p> <p>Major concerns:</p> <ul style="list-style-type: none"> - I can find no description of randomization, or statistical compensation for the "try effect" - ie. the improvement encountered when performing the same repeated task. For instance the findings would be unsurprising if the same device order was used for each participant. - I can find no attempt at observer blinding to the device under test. I understand this is very difficult in this type of study, but this should be addressed or mentioned as a limitation. - the authors clearly state the limitations of a manikin study and extrapolation of performance advantage to a clinical population, this is inevitable as a prospective clinical study would be very difficult to perform - but greatly reduces the relevance of any and all findings - the study is described as a comparative pilot study but it remains unclear how the finding are intended to be used - I see no evidence of a power study to guide group sizes <p>Minor concerns:</p> <ul style="list-style-type: none"> - the outcome of C&L1 as the sole view outcome used in their analysis is extreme, as a C&L1 or 2 is generally considered easy
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	<p>- the version of a "time to successful intubation" is an unreliable outcome prone to (mis) interpretation</p> <p>Style:</p> <p>- the manuscript would benefit from some stylistic proofreading to improve the sentence structure</p> <p>References:</p> <p>- please update reference 25 to the current version of the ASA practice guidelines for management of the difficult airway</p>
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REVIEWER	<p>Dr Nick Castle Frimley Park Hospital. UK Durban University of Technology, RSC</p> <p>I published a number of the papers referenced in this paper. i do not see this as a conflict of interest</p>
REVIEW RETURNED	01-Nov-2015

GENERAL COMMENTS	<p>I thank and congratulate the authors for this interesting study. it would benefit from pictures off all the devices used.</p> <p>My main concern is that the written English is not at an acceptable standard due, I'm sure, to the fact that the authors first language is not English. it requires a full review of language and grammar as currently it is difficult to read. in addition in places incorrect words are used e.g. preclinical instead of prehospital</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1, Professor Healy

Major concerns:

"I can find no description of randomization, or statistical compensation for the "try effect" - ie. the improvement encountered when performing the same repeated task. For instance the findings would be unsurprising if the same device order was used for each participant."

We completely agree with this major concern. To eliminate bias caused by a potential learning curve, the order of the 4 devices tested was rotated from the sequence 1,2,3,4 to 2,3,4,1 to 3,4,1,2 and finally, to 4,1,2,3. We have added this information to the "Study protocol" section.

"I can find no attempt at observer blinding to the device under test. I understand this is very difficult in this type of study, but this should be addressed or mentioned as a limitation."

Again, we agree with your comment. For observers who are well trained and familiar with all of the devices tested, we hypothesized that it would be impossible to create a kind of a "neutral image quality" that prevent the experienced observer from identifying the device used. We have added this statement to the "Limitations" section.

"The authors clearly state the limitations of a manikin study and extrapolation of performance advantage to a clinical population, this is inevitable as a prospective clinical study would be very difficult to perform - but greatly reduces the relevance of any and all findings."

We agree again. On the other hand, this trial was initialized to improve our knowledge about different laryngoscopes, their handling and operation being stuffed with CBRN equipment and, moreover, individuals judgment on visualization and manual feedback under this circumstance. Nevertheless, our findings may basically emphasize that direct and indirect laryngoscopes are feasible for endotracheal intubation wearing CBRN equipment and may be the fundament of approving a clinical trial. We added this information to the „Conclusion“.

"The study is described as a comparative pilot study but it remains unclear how the findings are intended to be used"

We would like to refer to our statement given above.

"I see no evidence of a power study to guide group sizes"

This is absolutely right. We waived to calculate power and sample size for our intention was to gather more qualitative than quantitative information.

Minor concerns:

"The outcome of C&L1 as the sole view outcome used in their analysis is extreme, as a C&L1 or 2 is generally considered easy"

Thank you again for this valuable comment. You are right in principle but according ASA Task Force on Management of the Difficult Airway (reference 25) tracheal intubation on the floor can be classified as difficult and already mentioned in the „Limitations“

"The version of a "time to successful intubation" is an unreliable outcome prone to (mis) interpretation"

We agree and added an explanation how "time to successful intubation" should be understood in the „Limitations

Style:

"The manuscript would benefit from some stylistic proofreading to improve the sentence structure"

In order to improve language, style and structure proofreading by American Journal Experts was initialized. You will find the certification attached.

References:

"Please update reference 25 to the current version of the ASA practice guidelines for management of the difficult airway"

Done.

Reviewer: 2, Dr. Castle

"My main concern is that the written English is not at an acceptable standard due, I'm sure, to the fact that the authors first language is not English. It requires a full review of language and grammar as currently it is difficult to read. In addition in places incorrect words are used e.g. preclinical instead of prehospital"

Thank you very much for your main concern. The manuscript was reedited and corrected by American Journal Experts. You will find the certification attached.

VERSION 2 – REVIEW

REVIEWER	David Healy Associate Professor Department of Anesthesiology University of Michigan Medical School Ann Arbor USA Paid scientific advisor to Brio Device LLC (Airway Device design startup company)
REVIEW RETURNED	01-Dec-2015

GENERAL COMMENTS	<p>I appreciate the authors response and revisions. The manuscript has benefited from extensive revision and improved sentence structure, and Specifying the randomization order of device performance is helpful.</p> <p>Major concerns; The introductory paragraph describing the benefit of videolaryngoscopy and should be deleted in it's entirety.</p> <p>In the past years, video laryngoscopy has become increasingly popular in clinical and prehospital settings. The use of a video laryngoscope reduces the duration of endotracheal intubation and significantly improves the intubation success rates in manikins and humans, as well as in patients with expectedly and unexpectedly difficult airways.[10,11] This is not true, the evidence is mixed. In fact the consensus is that endotracheal intubation with videolaryngoscopes (in general) takes longer than direct techniques. The reference of 2 studies examining device performance in manikins does not support this assertion.</p> <p>"While indirect laryngoscopy with an optical laryngoscope such as the Airtraq has been assessed and has been mainly demonstrated to be inferior to the use of conventional intubation devices,[9] until now, the use of a video laryngoscope while wearing CBRN-PPE has not been sufficiently evaluated." - unclear, I don't believe the reference study support this assertion concerning Airtraq use (DL and LMA study on manikins in different positions)</p> <p>"Only a brief instructional period is required to learn to operate video laryngoscopes; thus, they are attractive for use in hazardous situations because they not only allow for adequate visualization of the glottis but are also relatively easy to use.[13]" - this is not completely true, and certainly not supported by the evidence of the small paramedic manikin study used as it's reference. The learning curve, competency levels of videolaryngoscopic skill remain imprecise and a matter of opinion.</p> <p>Consider replacement of this paragraph with: "videolaryngoscopy may be beneficial performance of successful endotracheal intubation under difficult conditions due to their improved ability to provide adequate glottic visualization. However, there is little current evidence for or against the use of videolaryngoscopy when wearing chemical protective equipment. The aim of the current small, unblinded, pilot study is to describe the performance characteristics of various laryngoscopic techniques</p>
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	In summary, the authors have gone a long way to address the clear limitations of their pilot study. I think their findings are useful in a limited field of research which necessarily examines the technical limitations of cumbersome equipment impacting procedures performed on manikins. As such, their findings should remain extremely limited and placed firmly within that context without extrapolating to patient care. The brief review of the general benefit of videolaryngoscopy should be removed and replaced with accurate text.
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REVIEWER	Dr. N Castle UK I published a number of the papers referenced in this paper. i do not see this as a conflict of interest
REVIEW RETURNED	18-Dec-2015

GENERAL COMMENTS	I apologise for the minor review but 1) the term preclinical is used throughout the article where the correct term is prehospital. preclinical means something different and is an inappropriate term. 2) i recommended pictures pictures so we could better understand the devices used. i have found no pictures
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VERSION 2 – AUTHOR RESPONSE

Review 1:

"The manuscript has benefited from extensive revision and improved sentence structure, and Specifying the randomization order of device performance is helpful.

Major concerns:

The introductory paragraph describing the benefit of videolaryngoscopy and should be deleted in it's entirety.

In the past years, video laryngoscopy has become increasingly popular in clinical and prehospital settings. The use of a video laryngoscope reduces the duration of endotracheal intubation and significantly improves the intubation success rates in manikins and humans, as well as in patients with expectedly and unexpectedly difficult airways.[10,11]

This is not true, the evidence is mixed. In fact the consensus is that endotracheal intubation with videolaryngoscopes (in general) takes longer than direct techniques. The reference of 2 studies examining device performance in manikins does not support this assertion.

"While indirect laryngoscopy with an optical laryngoscope such as the Airtraq has been assessed and has been mainly demonstrated to be inferior to the use of conventional intubation devices,[9] until now, the use of a video laryngoscope while wearing CBRN-PPE has not been sufficiently evaluated."

- unclear, I don't believe the reference study support this assertion concerning Airtraq use (DL and LMA study on manikins in different positions)

"Only a brief instructional period is required to learn to operate video laryngoscopes; thus, they are attractive for use in hazardous situations because they not only allow for adequate visualization of the glottis but are also relatively easy to use.[13]"

- this is not completely true, and certainly not supported by the evidence of the small paramedic manikin study used as it's reference. The learning curve, competency levels of videolaryngoscopic skill remain imprecise and a matter of opinion.

Consider replacement of this paragraph with:

"videolaryngoscopy may be beneficial performance of successful endotracheal intubation under

difficult conditions due to their improved ability to provide adequate glottic visualization. However, there is little current evidence for or against the use of videolaryngoscopy when wearing chemical protective equipment. The aim of the current small, unblinded, pilot study is to describe the performance characteristics of various laryngoscopic techniques

In summary, the authors have gone a long way to address the clear limitations of their pilot study. I think their findings are useful in a limited field of research which necessarily examines the technical limitations of cumbersome equipment impacting procedures performed on manikins. As such, their findings should remain extremely limited and placed firmly within that context without extrapolating to patient care. The brief review of the general benefit of videolaryngoscopy should be removed and replaced with accurate text. "

Thank you for your comment Prof. Healy and your constructive support. We agree on your interpretation of the cited literature and thank you for your suggestion for modification. We deleted the section entirely and adopted the proposed text.

Reviewer: 2

"I apologise for the minor review but

1)the term preclinical is used throughout the article where the correct term is prehospital. preclinical means something different and is an inappropriate term."

Thank you again for you constructive comment. We completely agree that the term has do be used correctly and changed it to prehospital throughout the manuscript.

"2) i recommended pictures pictures so we could better understand the devices used. i have found no pictures"

Thank you again! We agree that pictures facilitate understanding of the devices and uploaded them.

Correction

Schröder H, Zoremba N, Rossaint R, *et al.* Intubation performance using different laryngoscopes while wearing chemical protective equipment: a manikin study. *BMJ Open* 2016;**6**:e010250. doi:10.1136/bmjopen-2015-010250

There is a mistake in the Contributors section. It should say:

“**Contributors** HS and NZ developed the conception and design of the study and performed data interpretation. HS performed statistical analysis, wrote and finalized the manuscript. NZ revised the manuscript. GS and KD participated in the data collection and interpretation. CS, MC, RR critically revised the manuscript and supervised statistical analysis. RR and GS critically revised the manuscript, and GS initiated coordinated and supervised the trial. All of the authors read and approved the final manuscript”.

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