Author's response to reviews

Title: A randomised, controlled crossover comparison of the C-MAC videolaryngoscope with direct laryngoscopy in 150 patients during routine induction of anaesthesia

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Author's response to reviews: see over
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**A randomised, controlled crossover comparison of the C-MAC videolaryngoscope with direct laryngoscopy in 150 patients during routine induction of anaesthesia**

27th December 2010

Dear Dr. Norton,

we would like to re-re-submit the enclosed manuscript „**A randomised, controlled crossover comparison of the C-MAC videolaryngoscope with direct laryngoscopy in 150 patients during routine induction of anaesthesia**“ as a research article for publication in *BMC Anesthesiology*. I have discussed your and the reviewers' comments with all co-authors, and have subsequently incorporated the comments, as appropriate, into the manuscript. We hope that this paper now merits publication in *BMC Anesthesiology*, and look forward to your response.

This material, in whole or in part, has not been published previously, and is not being considered for publication elsewhere.

All authors have made significant contributions to the study, and have read and approved submission of this revised manuscript to *BMC Anesthesiology*. Funding was restricted to institutional and departmental sources. No author receives any compensation for this work. However, Volker Doerges is a member of the Karl Storz advisory board, and receives grant support from Karl Storz, Tuttlingen, Germany, for studies related to airway management.

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We would like to thank you in advance for consideration of this work.

Respectfully,

Erol Cavus, M.D.
Corresponding author
Answers to Reviewers:

Reviewer 1 (Ray):
The revised manuscript is now much improved with the changes made by the authors - thank you. Despite this I believe that there are still some areas which need addressed.

Major compulsory revisions
1. Page 6. The authors state in their response to previous comments that they have modified the text to clarify that each patient underwent 3 separate laryngoscopies. Unfortunately the text they suggest in their response (which is acceptable) does not appear in the text of the manuscript (which is not acceptable). Please change the text in the manuscript to that shown in the response - ie: "Next, all patients underwent three separate laryngoscopies using the standard Macintosh laryngoscope with an appropriate size 3 or 4, the C-MAC size 3, and the C-Mac size 4, respectively, in the sequence determined by randomisation."
We apologise for this translational error and have subsequently added the sentence to the revised manuscript.

2. Thank you for providing the data in figures 4 and 5a. This clearly shows that only around 40% of patients had a Cormack & Lehan grade 1 view with any device without application of optimising manoeuvres such as BURP – this percentage is much lower than I would expect. Even after the application of BURP this percentage rose to only around 75% for all devices, again much lower than I would expect and certainly much lower than the >90% grade 1 views obtained with other videolaryngoscopes. I am also concerned that 6 of the patients scheduled to be intubated using the Macintosh were unsuccessful – this equates to a failed intubation rate for unselected patients of around 11% - again much higher than would be expected. I would be very grateful if the authors could comment on these concerns. Similarly since the percentage of grade 1 views obtained with the C-MAC is much lower than those obtained with other videolaryngoscopes perhaps the authors should temper their conclusion that "...the C-MAC may serve as a standard intubation device for both routine airway management and educational purposes."
Thank you for this comment. We are happy that this reviewer is excited by the data we have delivered; however, the data are as they are, even if this reviewer was expecting different results. In fact, the percentage for real C/L I views is relatively low; however, in the present study we used a modified C/L classification with a divided C/L class II. There is a very smooth transition between C/L I and C/L IIa classes, therefore a user-dependent effect on this classification cannot be ruled out. Taking for instance classes I and IIa together, after the application of BURP the percentage of C/L I views rose to >90% for all devices, which is in the range of reported views for Macintosh laryngoscopy.
Further, it is not surprising that “other videolaryngoscopes”, presumably videolaryngoscopes with a higher angulation of the blade, which do not allow direct visualisation of the glottis, provide more C/L I views; however, this improved view may result at the expense of tube advancement, i.e. intubation difficulties. Therefore, we adhere to our statement that "...the C-MAC may serve as a standard intubation device for both routine airway management and educational purposes."
3. Page 10. "The C-MAC videolaryngoscope is a relatively new device with the unique advantage that it provides the possibility to obtain both a direct laryngoscopic view and a camera view that is displayed on the video screen, in contrast to many previous videolaryngoscopes." This is not a unique feature as other modified videolaryngoscopes now offer this dual possible view.
We respectfully would like to point out that it is not unlikely that in a more than 7 months lasting review process new devices will come into the market; nevertheless, the GlideScope direct™ is designed as an intubation trainer, and both GlideScope direct™ and the McGrath Mac™ have been presented at the ASA in October this year, but to our knowledge both have not yet been introduced into the market.

4. Page 9. "Taking this into account, intubation success rates with DL, C-MAC3, C-MAC4 and C-MAXC/STB were 50/56 (89%), 37/37 (100%), 18/18 (100%), and 45/45 (100%) respectively." Presumably since the 6 patients who had failed intubation using DL were intubated using the C-MAC4/STB the success rate should be 51/51 for this technique.
We greatly appreciate this reviewer’s important comment and need to apologise for this confusion in data presentation. We have subsequently revised the intubation success rates: "Taking this into account, intubation success rates with DL, C-MAC3, C-MAC4 and C-MAXC/STB were 44/50 (88%), 37/37 (100%), 18/18 (100%), and 51/51 (100%) respectively."

5. Table 1. The authors state in their response that they have changed the term "reclination of the head" to "cervical extension" but this has not been changed in the manuscript.
Thank you for this advice, we have changed the wording in the revised table.

Minor essential revision
1. Page 7. "Peripheral oxygen saturation, mean arterial blood pressure, and heart rate were recorded continuously." Unless the patients had an arterial line in place I suspect that mean arterial pressure was not recorded continuously, but rather intermittently.
Indeed mean arterial pressure was recorded intermittently every 5 minutes, which we have changed in the revised manuscript.
Reviewer 2 (Cooper):

Discretionary revisions:
Page 8, line 14/legend for Figure 5a): suggest changing “extralaryngeal manipulation” to the more commonly used phrase, “external laryngeal manipulation” or BURP. If the two terms are being used interchangeably, I would recommend one or the other. The terms “highly limited” and “impeded” views are vague and should be replaced with a specific CL grade (eg CL> 2B), in the text, not just in the comments to the reviewers.
We have changed the wording according to the reviewers’ suggestion. Further, if not already present, we added the specific C/L grade (C/L≥2a) to the term impeded.

Table 1: again—reclination is not a word in my dictionary. The term appears again in the new Table 1. Is this the same as atlanto-occipital extension?
Thank you for your advice, we changed the wording to cervical extension.

Table 2: suggest changing “impeded” view to sub-optimal or CL>2
We changed the wording according to the reviewers’ suggestion.

Table 3: were the anesthesiologists offered choices of specific concerns (eg comfort, guidance, glottic exposure)?
We added the categories, from which the anaesthesiologists had to choose, to the methods section of the revised manuscript.

Minor essential revisions:
Please confirm (and explicitly state) whether the views referred to with the C-MAC all pertain to those on the monitor, not direct viewing while all references to DL pertain to the Heine laryngoscope. Use of the C-MAC as a direct laryngoscope is mentioned in the Background making statements about the C-MAC view ambiguous. Please clarify the meaning of the statement, page 6, 5 lines from the bottom, “…anesthesiologist was requested to identify the best achievable Cormack-Lehane view…with direct Macintosh and C-MAC videolaryngoscopy.”
As desired by the reviewer, we explicitly stated that all C-MAC views applied to the video view on the monitor screen.

It remains unclear which patients received BURP. From figure 5a, it would appear that when BURP is permitted, there was almost no difference between the CL views with the exception of a small percentage of CL. From Table 2, it appears that there were 3/150 CL IV views. If BURP alone was performed on those patients, did they all remain CL IV views?
Unfortunately, the first sentence is truncated, which makes it hard to understand. I assume that the reviewer meant a small percentage of C/L IV views. As it can be seen from figures 4 and 5a, the application of BURP had no improving influence on the 3 patients with a C/L IV view.

The statement that the C-MAC is unique in that it can provide a direct and indirect view was correct at the time the manuscript was originally submitted. However, in October 2010, both Aircraft Medical (McGrath Mac™) and Verathon Medical (GlideScope Direct™) introduced Macintosh- style VL blades. Neither device has been investigated, to the best of this reviewer’s knowledge. These recent products might be acknowledged in a footnote.
We respectfully would like to point out that it is not unlikely that in a more than seven months lasting review process new devices will come into the market; nevertheless, the GlideScope direct™ is designed as an intubation trainer, and both GlideScope direct™ and the McGrath Mac™ have been presented at the ASA in October this year, but to our knowledge both have not yet been introduced into the market.

**Major Compulsory Revisions:**
I do not wish to debate the safety of the stylet or tube-guide, which is widely regarded as standard practice; in much of the world, a styletted ETT is part of the “rapid sequence induction”; the technique is taught to medical students and respiratory therapists who are definitely not regarded as “highly experienced staff.” I do not think that the majority of the journal’s readers will regard avoidance of a stylet as a safety advantage, particularly if it reduces the number of required intubation attempts. I would request a statement in the Discussion that “avoidance of a stylet” may be regarded as a safety issue but this matter is debatable. It would be helpful if the authors indicated clearly whether the tube guide was used as a recessed stylet (not protruding beyond the tip of the ETT) or like an Eschmann Tracheal Tube Introducer, wherein the introducer protrudes several cm beyond the tip of the ETT. Perhaps, this is the crux of our disagreement but the manuscript is unclear.

We agree with this reviewer that a styletted ETT is part of the “rapid sequence induction (RSI)” technique; however, neither medical students nor non-physician personnel perform RSI, at least at our institution. Nevertheless, we added a statement about the debatable safety issue to the discussion section. Additionally, we refined the explanation of the semi-flexible tube guide that is not an introducer but a guide. We agree that there may be some confusion with the definition of a tube-guide: The tube-guide we used in the study is a semi-flexible stab made out of rubber-coated metal whose tip remained in the tube, and that allowed to give the tube a specific shape. It differs completely from rigid stylets or fully flexible introducers or tube exchangers.

I am also inclined to disagree with the authors’ contention that intubation should be performed with the direct view if possible. Although for the moment this issue has not been fully explored, I suspect that more force may have to be applied to the laryngoscope when a direct view, rather than the monitored view is used. Again, I would not take major issue with this point since for the moment, it remains speculative, but the Discussion would be enhanced if this matter is briefly stated.

As the reviewer has stated the issue of forces during laryngoscopy has not been fully explored. We agree that this issue may be debatable; on the one hand, increased forces on the maxillary incisors with conventional laryngoscopy compared to videolaryngoscopy have been observed during difficult intubation (van Zundert, Anesth Analg 2009), on the other hand, indirect laryngoscopy results in longer intubation time and more intubation attempts (Maassen, Anesth Analg 2009), in particular with highly angulated blades. We added this information to the discussion section of the revised manuscript, but keep our opinion that the direct view should be used at first: “In our opinion, in all cases with easy intubation conditions the anaesthesiologist should prefer the direct laryngoscopic view of the C-MAC 3 over the videolaryngoscopic view. However, this issue may be debatable, since increased forces on the maxillary incisors with conventional laryngoscopy compared to videolaryngoscopy have been observed during difficult intubation, but more importantly, videolaryngoscopy-guided intubation has the potential risk of increasing the number of intubation attempts and time, and the use of a tube-guide, respectively, as shown in the present study.”
My opinion regarding the cause of the palatopharyngeal injuries has been conveyed as clearly as I know how and there seems to be a fundamental disagreement, which is fine. I would however, encourage the author to bring to the attention of the reader the possibility that these injuries may be a consequence of blindly inserting the ETT into the pharynx and might very well occur with our without a stylet or with or without a modified Macintosh blade. (In teaching intubation with the C-MAC, I still insist on direct observation of the insertion of the ETT insertion into the oropharynx.)

We appreciate this reviewer’s comment and fully agree with the statement that insertion of the ETT into the oropharynx should be directly observed; unfortunately, the strictly indirect videolaryngoscopes have a “blind spot” during direct visualisation and therefore do not allow observing ETT passage in the deeper oropharyngeal spaces. This underlines our opinion that direct laryngoscopy should be performed at first in cases without difficult intubation. We respectfully point out that we already have addressed this issue in the manuscript: “in that device, a highly angulated blade caused difficulty in advancing the tracheal tube to the glottic entrance, because both pharynx and the glottis were not under direct view, resulting in a partly blind oropharyngeal passage of the styletted tube.” In order to highlight the importance of direct visualisation of ETT advancement we reworded the following sentence: “For avoidance of such complications, insertion and oropharyngeal passage of the endotracheal tube should be directly visualised as long as possible, and training on the device combined with a good technique is mandatory.“

However, as we stated before, we disagree with this reviewer that the probability of injury is independent of a stylet use.”