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

Authors:

Erol Cavus (cavus@anaesthesie.uni-kiel.de)
Carsten Thee (thee@anaesthesie.uni-kiel.de)
Thora Moeller (thora.moeller@kliniksued-rostock.de)
Joerg Kieckhaefer (joerg.kieckhaefer@kliniksued-rostock.de)
Volker Doerges (doerges@anaesthesie.uni-kiel.de)
Klaus Wagner (klaus.wagner@kliniksued-rostock.de)

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

16th November 2010

Dear Dr. Norton,

we would like to 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’ thoughtful 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.

Please direct all correspondence to: Dr. Erol Cavus, University Hospital Schleswig-Holstein Campus Kiel, Department of Anaesthesiology and Intensive Care Medicine, Schwanenweg 21, D-24105 Kiel, Germany, phone +49 431 597-2991, Fax +49 431 597-3002, E-mail: e.cavus@t-online.de.

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:
I thank the authors for their clarification of several points that had been unclear to this reviewer. I believe the revised manuscript is substantially improved, however I still have some concerns that have not been addressed.

Major compulsory revisions:
Page 9, line 21: in most countries—with possible exceptions of Germany and The Netherlands—the use of a stylet is not considered a disadvantage and may in fact be routine as it potentially reduces the number of laryngoscopic attempts. This presupposes that the stylet is used properly. I am unaware of any evidence of a properly used stylet inducing injury with DL or VL. From this reviewer’s perspective, the use of a stylet reduces the known complications resulting from multiple laryngoscopies, compared with the unproven complications associated with a stylet. Please clarify which patients with a suboptimal view, required the use of a tube guide.

Thank you for your comment. The restrictive use of a tube stylet is not specific for Germany or the Netherlands, which is also supported by, even if rare, published complications and injuries, when using a stylet (e.g. Sato H, Int J Legal Med 2009; Moschini V, Minerva Anestesiol 2006; Fan CM, Am J Emerg Med 2004; Besmer I, Anaesthesist 2001). We agree with the reviewer that a properly used stylet should not result in oro-pharyngeal and laryngo-tracheal injuries. However, this presupposes that the stylet is always used by highly experienced staff. In fact, the hospital reality, intubation attempts by non-anaesthesiologists with a lower routine of (difficult) intubations, and published injuries from all over the world, tell another story. Therefore, from our point of view, the use of a tube stylet should not be routine and be omitted, if the tip of the tube has not to be guided to the glottic entrance due to difficulties of endotracheal intubation.

Table 2 does still use the term “C-MAC4 Miller” which elsewhere has been referred to as C-MAC4/SBT. Please use this term consistently.

We want to apologize for this correction error, which we have changed in the revised manuscript.

Page 9/10: 6 of 8 patients with highly limited direct laryngoscopic views—does this mean that with the C-MAC, a tube guide (stylet) was used whenever the video view was relied upon or was an attempt first made without a tube guide?
In those cases with highly limited direct laryngoscopic view, where videolaryngoscopy resulted in a glottic visualization better than C/L 2b, intubation was tried without a stylet, in the other cases a stylet was used a priori.

Table 2 does not appear to differentiate between C-MAC3 and C-MAC4SBT. It appears from Table 2 that there were actually more patients with incomplete glottic exposure (C/L IIa and IIb than C/L I) compared with studies using more angulated blades (see Cooper RM, Pacey J et al. CJA 529(2) 191, 2005) where the proportions were C/L I and II were 92% and 7% respectively. If incomplete glottic exposure is not clinically important, the authors should say this. Furthermore, if sub-optimal views are common, and this may necessitate a tube-guide, the authors should state whether the evidence supports that such a guide entails greater risk than a subsequent laryngoscopy. This reviewer does not believe that the literature supports such a position. The primary and secondary endpoints were stated in the Background and statistical methods but these terms were not specifically referred to thereafter. These have an important bearing on the authors’ conclusions since they have not demonstrated consistent superiority over DL and improved laryngeal

Thank you for your statement. Indeed, table 2 does not differentiate between C-MAC3 and C-MAC4/SBT, because this table focuses on patients with “impeded” glottic view that were managed with a C-MAC4/SBT technique. Therefore, it should not be compared with glottic visualisations seen in a whole patient collective. Additionally, it is in the nature of higher angulated blades that they will allow better visualisation of the glottis, often at the expense of a more difficult tube advancement and subsequent intubation success. This important subject has been addressed by the reviewer in an interesting article published ahead of print (Levitan RM, Heitz JW, Sweeney M, Cooper RM; Ann Emerg Med. 2010 Jul 29. [Epub ahead of print]). As suggested by the reviewer, we added this information to the discussion of the revised manuscript.

Unfortunately, the last sentence is incomplete, and could therefore not be addressed.

Page 10, line 10: I have reviewed 10 of my own video recordings of VL with both the GlideScope and the C-MAC and cannot see a difference between the pharyngeal exposure provided when the larynx is seen. I am unconvinced that viewing the monitor during the introduction of the ETT is any safer with the C-MAC compared to the GlideScope. I believe that palatopharyngeal injuries are just as likely to occur with both devices if the use is watching the monitor rather than looking into the oropharynx during endotracheal tube insertion. It is neither the stylet nor the blade that has resulted in palatopharyngeal injuries but
rather blind advancement of the endotracheal tube (which can be equally observed with both devices).

We appreciate your interesting advices. From our data, we are unable to show whether the use of the C-MAC may result in a lower incidence of palatopharyngeal injuries when compared to the GlideScope, because this was not the aim of the study. In fact, both videolaryngoscopes display the pharyngeal space in a comparable manner; however, we believe that due to the Macintosh shape of the C-MAC you have kind of a “you get what you see” effect, which eases the advancement of the tube to the glottis. With the higher angulated blades, such as GlideScope, McGrath, and D-Blade, you have straight visualisation of the glottis but an angled pathway to the glottis.

We disagree with you that the stylet was not the cause for any observed injuries. In our opinion, the stiffness of the tube, achieved by the use of a rigid stylet, predisposes for palatopharyngeal injuries during the pharyngeal passage. Injuries during advancement of an unstyleted, flexible tube are less common.

Page 10, line 21: suggest elevation of the epiglottis rather than performing “an upload of the visualized epiglottis (glottic side).”

Thank you for your suggestion which we have incorporated in the revised manuscript.

Page 11, line 2: please clarify whether the modifications to reduce fogging and dazzling were made during or following the study of 150 patients. If during, please indicate the number of patients studied before and after so the reader might have a better sense if confidence whether this problem has truly been rectified. It would appear from the authors’ response to the reviewers that the modifications to the C-MAC occurred during the study.

Thank you for this very important advice. In fact, most of the patients were managed with the previous version of the C-MAC. Therefore, the sentence in the limitations’ section should read: “Second, fogging of the optical lens was transiently observed in 11 of 112 patients. As a result, the manufacturer has optimised the pre-heating system of the lens; thereafter, we did not observe any case of fogging in the remaining 38 patients.”

Table 1: please rename reclination as cervical extension as has been done elsewhere.

We renamed reclination as suggested by the reviewer.

Table 3: this table would have been more useful had the authors provided data relating the subjective assessment of handling in the setting of good vs. sub-optimal laryngeal exposure. If the laryngeal view is good with DL, it is not surprising that the users would prefer DL. If the
view is poor, it is more likely that they would prefer VL. As the authors stated in their Background, since poor laryngeal exposure may be found in up to 9% of patients, this is probably the group of greater concern interest for VL. As it stands, the study indicates that poor handling was experienced in only 11 patients when DL was used compared with 19 for C-MAC3 and 19 for C-MAC4. Please comment.

Thank you for your suggestion, which we used to revise table 3. Even if the proportion of patients with poor glottic view (C/L >2b) is small, there is a trend to favourable handling with videolaryngoscopy. However, from our point of view, the most important thing affecting handling data is that the user is more familiar with a conventional laryngoscope (including handle, grip etc.) compared to any VL. Subsequently we added the following wording to the discussion section: “As expected, subjective handling in patients with good or acceptable glottic view was best with the conventional Macintosh laryngoscope, which may result from the greater familiarity with this device (handle, grip, etc.); however, there were no differences between devices, or even a slight advantage for C-MAC3 and C-MAC4, if glottic visualisation was poor.”

Data from Table 2 indicates that “suboptimal views” were seen in 24 patients by DL, of which 16 were still C/L II (a or b). They are generally not a challenge to intubate. In contrast, 15 patients were C/L II using the C-MAC, which is not an inspiring improvement. If the primary endpoint is improved glottic view, have the authors will need to present their case more convincingly that C-MAC offers significantly superior laryngeal viewing compared with DL? The conclusions should be modified to indicate that there is a greater likelihood of reducing the number of C/L III or IV views and but a study with more challenging airways would be required to confirm this suspicion.

In dependence on the reviewers’ suggestion we have reworded the conclusion to: “In patients with impeded glottic view, the C-MAC size 4 with straight blade technique may reduce the number of C/L 3 or C/L 4 views, and therefore facilitate intubation. Further studies on patients with difficult airway should be performed to confirm these findings.”

Minor Revisions

Methods: line 3—I suggest that stainless steel Macintosh-shaped blade might be further simplified as “This stainless steel blade retains the original Macintosh shape. It has a closed blade design…”

We reworded the sentence according to the reviewers’ suggestion.
Page 4, line 18—I suggest “computer-based open randomization to determine the sequence of the three laryngoscopies: conventional direct laryngoscopy, C-MAC3 and C-MAC4.”

We reworded the sentence according to this reviewers’ suggestion combined with the suggestions made by reviewer 2: “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 randomization. The blade was introduced to the right of the tongue and advanced toward the vallecula by one of three anaesthesiologists with at least eight years experience (after being trained on manikins with the C-MAC).”

Page 5, line 14—I suggest “…in the sequence determined by randomization. The blade was introduced to the right of the tongue and advanced toward the vallecula.”

We reworded the sentence according to the reviewers’ suggestion.

Page 8, line 3: please provide the name of the semi-flexible tube guide used and its manufacturer. Is this in fact the same as a gum elastic bougie or Eschmann Introducer?

The semi-flexible tube guide used (Flexislip, Rüsch, Teleflex Medical Europe, Ireland) was only for guidance of the tube, if necessary, but not for introduction of the tube into the trachea (as known from the Eschmann Introducer or the Cook tube exchanger).

Page 8, line 5: please make it clear in the text, whether fogging interfered with intubation.

We added the following wording to the limitations’ section of the revised manuscript: “However, since fogging occurred transiently, it had no impact on intubation success.”

Page 8, line 6: the meaning of the term “dazzling” was provided to the reviewers but not the readers.

We added the meaning of dazzling to the limitations’ section of the revised manuscript.

Page 9, line 15: suggest changing “short time to laryngoscopy” to “times comparable to direct laryngoscopy”

We incorporated this reviewers’ suggestion in the revised manuscript.

Reviewer 2:

The authors have addressed most of my previous questions satisfactorily and the manuscript is now clearer. However I still have some concerns as detailed below:

Major compulsory revisions
1. I am very concerned about the inconsistent use of BURP and the effect this may have had on the results. The primary outcome measure was change of glottic visualisation - BURP may have improved the view obtained and since not all patients had BURP performed the authors have not compared solely the difference in view between laryngoscope blades but the potential combination of BURP (in some patients) and blade design. Thus the inconsistent use of BURP is a major confounder (and significant methodological flaw) and requires the findings and their interpretation to be considered with great caution. Unless the authors can satisfactorily address this point the manuscript will be limited and the findings open to considerable question.

In response to the concerns raised by this reviewer we added figure 4 to the revised manuscript that displays (video-)glottic view without any extralaryngeal manipulations in all studied groups. As expected, this view was worse compared to the best achievable view after extralaryngeal manipulations. However, overall, initial glottic views according to C/L were comparable between DL, C-MAC3, C-MAC4 and C-MAC4/SBT groups both with and without extralaryngeal manoeuvres; therefore, further results and conclusion have not changed. We added the following wording to the methods section of the revised manuscript: “A comparable initial glottic view according to C/L score in DL, C-MAC3 Macintosh, C-MAC4 Macintosh, and C-MAC/SBT groups is shown in figure 4. C/L view after extralaryngeal manipulation, such as BURP manoeuvre, could be improved and resulted in a glottic view as shown in (figure 5a)”.

2. It is mentioned that all patients underwent 3 separate laryngoscopies using each blade / technique but this is not explicit enough. I would suggest that the authors include a sentence in the methods section such as "All patients underwent three separate laryngoscopies using conventional direct laryngoscopy, videolaryngoscopy with a C-MAC size 3 blade, and a C-MAC size 4 blade, the order of which was determined by computer randomisation." This should also be made explicit in the abstract.

Thank you for this advice. Combined with the suggestions from reviewer 1 we changed the wording in the methods to: “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 randomization. The blade was introduced to the right of the tongue and advanced toward the vallecula by one of three anaesthesiologists with at least eight years experience (after being trained on manikins with the C-MAC).”

3. The authors responded to my suggestion that the data for each of the three groups should be shown separately by saying that this would give no additional information. I disagree. The
secondary outcomes were time taken for intubation and success rate of tracheal intubation. Although all patients underwent laryngoscopy with each blade, only one third of patients underwent intubation with any blade and the composition of each of these three groups may have been different which may have influenced the findings - for example it is entirely possible that all 7 patients with morbid obesity may have undergone intubation using the same blade with no morbidly obese patients in either of the other 2 groups. According to this reviewers’ suggestion we have changed table 1, displaying demographic and patients’ characteristics data for each device used for intubation. However, as we have stated in the first revision, there were no major differences between groups.

4. Although a secondary endpoint was success rate of intubation using each device it is not clear in the results that only 50/56 (89%) patients were successfully intubated using conventional direct laryngoscopy, compared with 100% success for either C-MAC sizes 3 or 4. This should be made explicit.

We greatly appreciate this important advice. We added the following wording to the methods:

“Taking this into account, intubation success rates with DL, C-MAC3, C-MAC4, and C-MAC4/SBT were 50/56 (89%), 37/37 (100%), 18/18 (100%), and 45/45 (100%), respectively.” and hope that this will clarify intubation success rates.

5. I thank the authors for adding information about calculation of sample size. However they have not stated what sample size their calculations suggested - this should be added.

Calculated sample size was 97 patients. We added this information to the statistics section.

Discretionary revisions

1. The authors show in table 2 a comparison of laryngoscopic views obtained at direct laryngoscopy and C-MAC Miller SBT technique. What were the differences in laryngoscopic view if direct laryngoscopy was compared with size 3 C-MAC blade in these patients?

In most cases, videolaryngoscopy with the C-MAC3 also improved glottic visualisation by at least one C/L class. However, the greatest changes of glottic view could be observed in the C-MAC4/SBT group; in order not to confuse the reader by different tables and comparisons we decided to display only the greatest changes of view (i.e. DL versus C-MAC4/SBT), including the cases that could not be intubated with DL.