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

28th July 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.

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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:

The authors describe the use of a new videolaryngoscope (the C-MAC) and compare its performance with direct laryngoscopy in 150 patients. The article is original, interesting, and adds to the current information available about alternative laryngoscopy techniques. The paper suggests that the C-MAC may be a useful addition to the range of airway devices but there are a number of limitations which the authors should address:

Major compulsory revisions:

1. The author’s conclusion that the C-MAC may serve as a standard intubation device is not supported by their data. The laryngoscopic view obtained using the C-MAC is usually as good as, or better than using direct laryngoscopy. However tracheal intubation is not as good as using direct laryngoscopy - from the authors own data 26% of patients required more than 1 attempt to successfully intubate the trachea using the C-MAC compared with only 4% using the standard Macintosh laryngoscope (Fishers exact test P=0.0007). In addition a gum elastic bougie was used in 12% of patients intubated using the C-MAC compared to 2% using direct laryngoscopy. Although the median times taken to intubate were similar for all devices, these data suggest that the laryngoscopic view may be improved but tracheal intubation may be more difficult (this is consistent with the performance of many other videolaryngoscopes). This may reflect the subjective assessment of the handling of the C-MAC (38% very good, 13% poor) compared to 57% very good and 7% poor for the standard Macintosh laryngoscope.

We appreciate your important advices. Our conclusion generates exactly from the points you have raised, namely that videolaryngoscopy is known to result in more intubation attempts than conventional direct laryngoscopy. Therefore, from our point of view, it is important to have the option of both direct- and videolaryngoscopic view with the same device. Taking a C-MAC 3 as a standard, one will be able to perform direct laryngoscopy as known from a conventional Macintosh laryngoscope, or videolaryngoscopy. In all cases with easy intubation conditions there will be no need for videolaryngoscopy-guided intubation; moreover, use of the videolaryngoscopic view instead of the direct view for intubation should be avoided, since it has the risk of increasing the number of intubation attempts, and the use of a tube-guide, respectively, as shown in the present study. We have accounted for this by adding the following wording to the revised manuscript: “However, in all cases with easy intubation conditions the anaesthesiologist should prefer the direct laryngoscopic view of the C-MAC 3 over the videolaryngoscopic view, since generally videolaryngoscopy-guided
intubation has the potential risk of increasing the number of intubation attempts, and the use of a tube-guide, respectively, as shown in the present study.”

Technical difficulties (dazzling and fogging of the lens) were experienced in 13 of 150 (9%) uses of the C-MAC, suggesting an important limitation with the current C-MAC technology. The authors should temper their conclusions and enthusiasm for the C-MAC accordingly. Thank you for your advice. In fact, part of the study was conducted with an earlier version of the C-MAC. As a result of the present observations, the pre-heating system of the optical lens has been optimised. In a very recent study we did with the C-MAC device, we did not observe fogging in any patient; however, in the present study we reported in fairness the observed problems. To show the reader that this problem has been solved, we added to the limitations section the following sentence: “Fogging of the optical lens was transiently observed in 11 of 150 patients. As a result, the manufacturer has optimised the pre-heating system of the lens; thereafter, we did not observe any case of fogging.”

2. It is not clear from the manuscript what the primary outcome measure was - was it laryngoscopy view or time taken to intubate the trachea? Similarly there is no information on how the authors decided on the number of patients they required to study. Based on data from a preliminary investigation (Cavus et al., Anesth Analg 2010), we calculated the sample size to detect at least a difference of one class between devices in the primary end-point glottic visualisation (C/L) with a type I -error of 0.05 and a power of 0.9. We added this information to the statistics section.

3. It is not clear whether the "optimal" views obtained at laryngoscopy were with or without external laryngeal manipulation. Thank you for your advice. According to your and the second reviewers comments we amended the sentence to: “The attending anaesthesiologist was requested to identify the best achievable Cormack-Lehane (C/L) view [13], modified by Yentis-Lee [14], with direct Macintosh and C-MAC videolaryngoscopy; depending on necessity, the use of external manipulation (BURP manoeuvre [15]) at the discretion of the anaesthesiologist was allowed, but not prescribed.”

Minor essential revisions:

1. It is not entirely clear from the text that each patient underwent laryngoscopies using each of the 3 devices - this should be made explicit.
Thank you for this advice. To clarify this issue we changed the wording of the sentence: “Next, one of three anaesthesiologists with at least eight years experience (after being trained on manikins with the C-MAC) **consecutively** inserted 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 order of randomisation,...”.

2. **What was the size of the blade used for direct laryngoscopy with the standard Macintosh?**
   For direct laryngoscopy we used the appropriate size 3 or 4, dependent on patients’ physiognomy. However, this was not done for the C-MAC videolaryngoscopes sizes 3 and 4; in our opinion, during the videolaryngoscopic use, the blade size is not as important as with the direct view use, since the relocation of the optical axis towards the glottic entrance compensates for a smaller blade in most cases (e.g. DL 4 vs. C-MAC 3). This is underlined by the results of the present study, since we could not observe a difference between the use of C-MAC sizes 3 and 4, unless we changed the use of the C-MAC 4 to the straight-blade-technique. We added the information that appropriate Macintosh blades were used to the revised manuscript.

3. **How did the authors confirm successful endotracheal placement - was it seeing the tube pass through the vocal cords, or confirmation using capnography?**
   Endotracheal tube placement for the recording of time intervals was determined by seeing the tube passing through the vocal cords. However, standard institutional guidelines require confirmation of correct tube position, and subsequently successful ventilation by capnography and bilateral chest auscultation.

4. **The term "optimal laryngoscopy" is inaccurate and should be replaced with "best laryngoscopic view" if that is what the authors mean.**
   Thank you for this advice. We have changed the wording according to your suggestion.

5. **The term "complicated airway" suggests that the authors consider a Cormack & Lehane grading of more than 1 as a complicated airway - 16 of these 24 patients were C&L grade 2a or b which I would not consider complicated.**
   We agree with the reviewer that the term "complicated airway" may be unsuitable for a C&L grade 2; therefore, we changed "complicated airway" to ‘**suboptimal glottis visualisation**’.

6. **Table 1 may be more useful if body mass index was shown rather than weight and height. It would be more informative to show the data separately for the groups of patients intubated with each device.**
Thank you for this interesting advice; accordingly, we added the BMI in table 1. Since the study design is based on a cross-over randomisation, the groups of patients intubated with each device consisted of the same patients; therefore, in our opinion, further subdivision gives no additional information.

7. Figures 2, 3 and 4 are labelled incorrectly. Figure 3b is not particularly helpful - a graph showing the individual changes for each of the 8 laryngoscopies would be more instructive.

We want to apologise for this confusing mislabelling. Unfortunately, unlike other editorial managing programs, the BMC submission program does not allow for self labelling the figures. In the revised manuscript, we have adapted the figure numbers to the numbers given by the program.
Reviewer 2:

Abstract
The term C-MAC Miller is confusing. I had read this over several times thinking that Storz had in fact produced a C-Miller blade. Perhaps the authors would consider abbreviating this as C-MAC/MT (for Miller technique) so that the Miller blade design is not so strongly suggested.

We greatly appreciate this reviewers’ comment, since we were not aware of the current description being a basis for misinterpretation. Accordingly, we changed the abbreviation as suggested by the reviewer to C-MAC/SBT (SBT for “straight blade technique”).

“no optimal glottic view with DL” is awkward phrasing.
Thank you for this advice. We chanced the wording to “suboptimal”.

“impeded glottic view”-consider “suboptimal” or Cormack-Lehane>1
Thank you for this advice. We chanced the wording to “suboptimal”.

Methods include Results (eg age, gender, weight)
According to the reviewers’ advice we have moved patient data to the results section.

Background
The purpose of the study should be more precisely stated. What specifically do the investigators wish to compare--the laryngeal view, time to intubation, success or complication rate? It is reasonable to state this explicitly in the Methods section.

We added the following wording to the background: “Primary endpoint was change of glottic visualisation; secondary endpoints were time to tracheal intubation and success rate.”

Methods and methodology
page 4, line 2: change “details” to “detail”
page 4, line 3: change “steel blade shape” to “stainless steel Macintosh-shaped blade”
Thank you for these suggestions, which we have incorporated into the revised manuscript.

what is meant by “edges are slant”
This means that all blade transitions are free of square-cuts to avoid damage of parts of the mouth or the teeth.
Methods and results have been combined: eg. details regarding the gender, age, weight. Details regarding the demographics should be moved to Results.

Thank you very much for this advice. Accordingly, we deleted patients’ data from the methods section that were already implemented in table 1.

What was the rationale for using the MAC 3 and 4 blades interchangeably? Generally, the larger blade would be reserved for larger patients. Please confirm whether randomization was to DL, C-MAC3 or C-MAC4/Miller4 rather than DL or C-MAC.

We appreciate this reviewer’s comment. For direct laryngoscopy we used the appropriate size 3 or 4 blade, dependent on patients’ physiognomy. However, this was not done for the C-MAC videolaryngoscopes sizes 3 and 4; in our opinion, during the videolaryngoscopic use of the C-MAC, the blade size is not as important as with the direct view use of the C-MAC, or with a conventional Macintosh direct view, respectively, since the relocation of the optical axis towards the glottic entrance compensates for a smaller blade in most cases (e.g. DL 4 vs. C-MAC 3). This is underlined by the results of the present study, since we could not observe a difference between the use of C-MAC sizes 3 and 4, unless we changed the use of the C-MAC 4 to the straight-blade-technique. Furthermore, the C-MAC 4 blade corresponds to the original shape described by Macintosh (Macintosh, Lancet 1943); the original blade had higher angulations compared to actually available Macintosh blades. We added the information that appropriate Macintosh blade sizes were used, to the revised manuscript.

“Since it became obvious after 50 patients...” belongs in the Results section. In the Methods section, it should state that after the initial 50 patients, randomization for the initial laryngoscopy was to either C-MAC 3 or C-MAC 4 Miller.”

Did each patient undergo three laryngoscopies in a randomized sequence?

We greatly appreciated this suggestion, and moved the explanation for the change of technique into the results section.

As described in the methods, “...patients.... were computer-based open randomised in a crossover design to conventional direct laryngoscopy (HEINE Macintosh classic, Herrsching, Germany; blade sizes 3 and 4; DL group), videolaryngoscopy with a C-MAC size 3 blade (C-MAC3 group), and a C-MAC size 4 blade (C-MAC4 group), respectively.” Therefore, each patient underwent three randomised laryngoscopies.

“Patients were excluded if...” should be “if pathology of the upper respiratory or alimentary tract were known or suspected or if a rapid sequence induction was indicated. In addition,
patients were excluded if an awake intubation was appropriate due to a suspected or known difficult airway.” Please confirm that “pathology of the upper airway” does not include features suggestive of a difficult direct laryngoscopy.

We appreciate your re-phrasing and incorporated the text into the revised manuscript. Existence of predictors for difficult direct laryngoscopy was no exclusion criteria.

“reclination” should be changed to “cervical extension”
We reworded according to your suggestion.

how was randomization achieved?
We respectfully point out that randomisation method was described in the methods section: “...patients... were computer-based open randomised in a crossover design to conventional direct laryngoscopy (HEINE Macintosh classic, Herrsching, Germany; blade sizes 3 and 4; DL group), videolaryngoscopy with a C-MAC size 3 blade (C-MAC3 group), and a C-MAC size 4 blade (C-MAC4 group), respectively.” Therefore, each patient underwent three randomised laryngoscopies.

how was the sample size determined?
Based on data from a preliminary investigation (Cavus et al., Anesth Analg 2010), we calculated the sample size to detect at least a difference of one class between devices in the primary end-point glottic visualisation (C/L) with a type I-error of 0.05 and a power of 0.9. We added this information to the statistics section.

please provide details concerning the technique used (e.g. midline vs. right-sided insertion, use or avoidance of stylet, prior application of an anti-fogging spray to the blade)
As usual for the use of Macintosh-shaped blades, tube insertion was performed from the right side, and stylets were not used a priori. Further, no anti-fogging substances were used at all. We added this information to the methods section of the revised manuscript.

when BURP was used, was this at the discretion of the anesthesiologist or was its use prescribed by the experimental protocol. This must be clearly stated in the Methods section.
Please clarify whether that we are not comparing views obtained in one case with and the other without BURP.
The attending anaesthesiologist was requested to identify the best achievable Cormack-Lehane (C/L) view [13], modified by Yentis-Lee [14], with direct Macintosh and C-MAC videolaryngoscopy: depending on necessity, the use of external manipulation (BURP manoeuvre [15]) at the
discretion of the anaesthesiologist was allowed, but not prescribed. In favour of clarity, we omitted the illustration of eight subgroups with either BURP or not; further, this would have not influenced the results, since in all groups the best achievable view was reported.

It is confusing to refer to the modification by “Lee-Yentis” (reference 14), suggesting that this may differ from the paper they actually referred to in reference 14 (wherein Yentis is the first author).

We want to apologise for this confusion and have subsequently changed the reference to Yentis-Lee.

how was the ease/difficulty of intubation scored?
how was “handling” defined and rated? Were any guidelines provided?

As stated in the methods and limitations sections of the manuscript (“Finally, all data of handling the airway devices are subjective.”), handling data were a subjective assessment of the attending anaesthesiologist; this included data about ease/difficulty of intubation, since to our knowledge, there is no common scale that quantifies this issue. Accordingly, we amended the wording in the limitations section to: “Finally, both data of ease or difficulty of intubation and handling the airway devices were subjective.”

Results

Table 1 (gender (female/mail; n (%))--omit % since not provided.

Thank you for this advice. We omitted %.

Please provide the mean (SD) time to successful intubation; it appears that several patients required multiple laryngoscopic attempts using the C-MAC yet the median times are not very much different from DL which required a single attempt in 48/50 patients. It is unclear what p=0.21 pertains to. Which values are being compared? In the subsequent paragraph, it is unclear was p=0.32 refers to. Again, please express the times to intubation as mean (SD)

Thank you for this interesting consideration. Accordingly, we first have explained the definition of intubation attempt in the revised manuscript: “Further, the number of intubation attempts was recorded; every time the tube was newly advanced to the glottic entrance was recorded as a new attempt.” Since the tube had not to be removed from the mouth to result in a new attempt, the time delay of an intubation attempt was not so high. Second, there is broad agreement with reviewers from highly ranked journals that time intervals are better represented by the median with additional range than with the mean, since the mean is highly influenced by a few outliers of values, as in the
present study. Additionally, different group sizes as a result of the open randomisation procedure, also more frequently affect the mean, compared to the median. However, according to your suggestion, we have displayed the mean ± SD additionally in the text.

Finally, both p-values represent the overall significance between groups and did not reach significance level. We have amended this information in the revised manuscript.

The use of a gum elastic bougie was required relatively often in all the C-MAC patients. What were the indications for using the gum elastic bougie? Was this used in lieu of a stylet? It is unclear how many patients required BURP to achieve the C/L views detailed in Table 2. If a view other than C/L 1 was obtained, was BURP routinely deployed? Was BURP used more or less commonly with DL or C-MAC/Miller?

Thank you for this important advice. Obviously, there is some confusion about the difference between a gum-elastic bougie and a stylet. In Germany, we use, if necessary, a semi-flexible stab that may allow directing the tube into a specific direction; but this stab is not as rigid as a stylet. The term gum-elastic bougie, however, may also be irritating; therefore, we changed “gum-elastic bougie” to “semi-flexible tube-guide” throughout the whole manuscript.

As described above, in favour of clarity, we omitted the illustration of eight subgroups with either BURP or not; further, this would have not influenced the results, since in all groups the best achievable view was reported. As an example, use of BURP in DL (24/50; 48%) and C-MAC4/SBT (21/45; 47%) groups was almost identical. Again, in favour of clarity, we would suggest to omit details of BURP use in all the groups.

Fogging was seen in 11/150 (7.3%) cases despite the claims by Storz that this product is fog-resistant.

Thank you for your advice. In fact, part of the study was conducted with an earlier version of the C-MAC. As a result of the present observations, the pre-heating system of the optical lens has been optimised. In a very recent study we did with the C-MAC device, we did not observe fogging in any patient; however, in the present study we reported in fairness the observed problems. To show the reader that this problem has been solved, we added to the limitations section the following sentence: “Fogging of the optical lens was transiently observed in 11 of 150 patients. As a result, the manufacturer has optimised the pre-heating system of the lens; thereafter, we did not observe any case of fogging.”
please explain what is meant by “dazzling” of the monitor screen. Did either the fogging or “dazzling” image interfere with the operator’s ability to perform intubation? Were these relatively minor impediments?

“Dazzling” meant reflexions or inadequate luminance in comparison to bright surrounding light. This is a problem we encountered in the past with all used monitor screens, regardless of the manufacturer. However, both fogging and dazzling were only transiently or could be improved by light shielding and therefore were only minor impediments.

The legends are incorrect. There are three legends but 4 figures. Figure 2 is not described at all.

It should be better labelled. I cannot see anything resembling a Miller style blade.

Figure 4 (described in Legend as Figure 3a and 3b) is poorly described.

We want to apologise for this confusing mislabelling. Unfortunately, unlike other editorial managing programs, the BMC submission program does not allow for self labelling the figures. In the revised manuscript, we have adapted the figure numbers to the numbers given by the program.

Although 20 patients had better C/L scores with VL, the observation that better laryngeal views were obtained in 6 patients with DL, is almost without precedent for indirect laryngoscopy.

Thank you for your commentary. In our opinion it is not very astonishing that the observation of better view with direct- compared to videolaryngoscopy has not been published yet; this observation will be unique in video-blades that also allow for direct laryngoscopy (e.g. Macintosh-shape), such as the C-MAC, which is relatively new on the market. The incidence of this observation with highly angulated blades with no possibility for direct laryngoscopic view will be negligible; if the video-view would be bad, there would be no possibility for direct-view, and subsequently a different airway management adjunct has to be used. However, this observation underlines the importance of the possibility for direct laryngoscopic view with the same device, as long as the video-laryngoscopic technique will not be used exclusively for the management of the difficult airway.

Discussion

the statement that “if the video view is worse than the direct view, as observed in six patients in the present study, or the intubation itself is difficult due to high blade angulations [16]” is confusing since the latter refers to a different device, not the C-MAC.

To avoid any confusion, we have re-worded the sentence to: “On the other hand, this may have important ramifications, if the video view is worse than the direct view, as observed with the C-MAC.
in six patients of the present study, or the intubation itself is difficult due to a high blade angulation, as shown with the GlideScope [16]."

It is unclear from this study whether the user can actually achieve the best of direct or indirect viewing using a single device, since they were not comparing intubation by direct laryngoscopy using the same device. It would be reasonable to refer the reader to a previous publication by the same group (reference 4) that addresses this issue.

Thank you for this suggestion, which we have incorporated into the revised manuscript.

a full 8% (12/150) patients required GEB. Are these patients who might have been successfully managed using a stylet?

As described above, there is obviously some confusion about the difference between a gum-elastic bougie and a stylet. In Germany, we use, if necessary, a semi-flexible stab that may allow directing the tube into a specific direction; but this stab is not as rigid as a stylet. The term gum-elastic bougie, however, may also be irritating; therefore, we changed “gum-elastic bougie” to “semi-flexible tube-guide” throughout the whole manuscript. Since the semi-flexible tube-guide can be adapted to the anatomic airway conditions, a rigid stylet most probably would have had no benefit.

Complications reporting with the GlideScope (references 19-23) were not likely to have resulted from the stylet, which in all cases were recessed within the ETT, but rather from the failure to directly observe the insertion of the ETT into the mouth and passed the palato-pharyngeal folds. This complication is entirely avoidable with good technique and is misrepresented in this report.

Thank you for this important amendment. Accordingly, we added to the revised manuscript the following wording: “For avoidance of such complications, training on the device combined with a good technique is mandatory.” Further, we reworded the sentence to: “...; 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 styleted tube.”

It may be accurate to suggest that a more highly-angulated blade prolongs the time required to complete endotracheal intubation. In the subsequent paragraph, however, the authors make the statement that “Videolaryngoscopy is not a technique to make endotracheal intubation faster...[but] to make intubation safer.” Interestingly there are almost no reports of better views being obtained by DL compared with VL using the more highly-angled devices. In fact,
Storz is about to release a “D-blade” that is quite similar in shape to the angled GlideScope (Verathon) and McGrath (Aircraft Medical).

As discussed above, this observation will be unique in video-blades that also allow for direct laryngoscopy (e.g. Macintosh-shape), such as the C-MAC, which is relatively new on the market. The incidence of this observation with highly angulated blades with no possibility for direct laryngoscopic view will be negligible, regardless of the used highly-angled blade (GlideScope, McGrath, D-Blade, ...); however, if the video-view would be bad with fixed highly-angled blades, such as GlideScope and McGrath, there would be no possibility for direct-view, and subsequently a different airway management adjunct has to be used. In contrast, using the D-Blade that is part of the C-MAC system, allows interchanging with the C-MAC Macintosh blades. In our opinion, this underlines the importance of the possibility for direct laryngoscopic view with the same device/system, as long as the videolaryngoscopic technique will not be used exclusively for the management of the difficult airway.