Title: Comparison of C-MAC D-Blade videolaryngoscope and McCoy laryngoscope efficacy for nasotracheal intubation in simulated cervical spinal injury: a prospective randomized comparative study

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Author’s response to reviews:

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Dear D John Doyle, MD PhD

We would like to thank you and the reviewers of BMC anesthesiology for taking the time to review our article. We have made some corrections and clarification in the manuscript after going over the reviewers’ comments. The responses to the reviewers’ comments have been prepared and attached herewith.

&lt;Responses to the reviewers’ comments&gt;

Reviewer #1
Reviewer reports:
Boris Mraovic, MD (Reviewer 1): The manuscript is well written.
Only minor cements:

1. It should be put generic name what is in Bosmin solution and/or explain what it is
⇒ We have added the generic name in response to the reviewer’s recommendation.
; Bosmin solution is 0.1% epinephrine solution which was used for nasal vasoconstriction (page 7, lines 15 – 16).

2. Table 2 does not need p values. It is not needed in randomized studies.
⇒ We have deleted the p values in Table 2 as reviewer’s comments.
3. Figure 3 is not necessary.
⇒ We agree with the reviewer about that. We have deleted Figure 3 as reviewer’s comments.

Reviewer #2
ikas O'Reilly-Shah (Reviewer 2): BANE-D-20-00124

Summary:
This is a well-written report of a prospective trial comparing McCoy laryngoscope vs CMAC for nasotracheal intubation (NTI) and found CMAC yielded faster intubation times, better visualization, and improved chances to encounter no difficulty in NTI. Complications were not different.

General Comments:

1. Why was the trial retrospectively registered? This raises some question about the ethics of the trial given the detailed data collection that was performed. It is reassuring that local IRB approval was sought and obtained, and that written informed consent was obtained.
⇒ We have agreed the reviewer’s comment that this trial retrospectively registered with clinical trial registry, which raises some question about the ethics of the trial given the detailed data collection. Although this trial has retrospectively registered with the Clinical Research Information Service of the Korea National Institute of Health (CRIS, http://cris.nih.go.kr, identification number: KCT 0004535), the present study’s protocol was approved by the Sacred Heart Hospital, Hallym University, Institutional Review Board (approval No. 2018-04-024-004). Also, written informed consent was obtained from all patients prior to any study-related procedures.

2. Given that this is a prospective randomized trial, likely not appropriate to report statistics on demographic characteristics.
⇒ We have deleted the p values in Table 2 as the reviewer’s comments.

3. Should consider performing Kaplan Meier analyses on times to event rather than using t-test/Mann-Whitney.
⇒ We have added the result of Kaplan Meier analysis in Fig.3.

4. Unclear why 10 additional seconds of time would be considered clinically significant. More broadly, the Methods indicate that the most important parameters I would want to evaluate for differences (SpO2, failed intubations) were recorded but are unreported in Results.
⇒ 1) We considered it is clinically significant that 10-second difference in the time taken for NTI between the two devices referred to a previous study (Saudi J Anaesthe. 2018; 12(1): 35-1), which compared the C Mac D Blade videolaryngoscope™ with the conventional Macintosh laryngoscope for nasal intubation in patients with difficult airway. And we added the reference literature in statistical analysis section in response to reviewer’s comments (page 10, line 5).
2) We have added the results about the differences of SpO2 and failed intubations between the two groups as reviewer’s comment (page 12, the last paragraph).

→ There was no significant difference between groups in incidence of failed intubation due to an inability to intubate the patient’s trachea within 120 seconds (4.0 % (2/50) in group M vs. 6.0 % (3/50) in group C, P = 1.0). There was no patient who was showed SpO2 < 95\% during and after intubation. We compared SpO2 of two groups in just after intubation, there was no significant difference in SpO2 just after NTI (99% (99-100%) in group M vs. 100% (99-100%) in group C, P = 0.392)

5. In the abstract and as a limitation of the study, it should be added that this was a study of experienced airway operators. The findings will not apply to those more novitiate in direct laryngoscopy or the CMAC.

⇒ We have added about that concern in the abstract and limitation of the discussion section as reviewer’s recommend (page 2, line 11-12 and page 15, the last sentence).

→ Single experienced anesthesiologist performed NTI.

→ Thirdly, an experienced anesthesiologist conducted intubation in, applying the results of the present study to beginners may be different in time taken intubation and complications.

Specific Comments:

1. Abstract - Methods should specify this was a prospective trial.

⇒ We have additionally described about that concern as reviewer’s comments in the abstract-methods section (page 2, line 8 and page 6, line 9).

→ This was a prospective, randomized, controlled, study done in a tertiary hospital.

⇒ One hundred patients scheduled for elective surgery under general anesthesia with NTI were enrolled in this prospective, randomized, controlled, study done in a tertiary hospital.

2. P4ln15-16 "... simulated difficult airway with cervical spine immobilization." -- Should be clear that these are real patients and that they were simulated to require cervical spine precautions.

⇒ We have revised the sentence as the reviewer suggested (page 5, the last sentence).

→ Thus, in the present study we explored the clinical performance of airway management with the McCoy laryngoscope and the C-MAC D-Blade videolaryngoscope for NTI in a simulated difficult airway with cervical spine immobilization in patients undergoing elective surgery.

3. P9ln17-19 BMI may have been statistically larger but probably not practically/clinically significant. See also #2 above. This is discussed in the limitations section.

⇒ We agreed the reviewer’s comments that the difference of BMI was not clinically significant, as we have discussed. And we revised about that concern in the results section (Page 11, lines 10 – 13)

→ The BMI for group M was significantly larger than that for group C (22.8 ± 3.5 kg/m2 vs. 24.4 ± 3.8 kg/m2, P = 0.033), but it was probably not practically/clinically significant.

4. P11ln7 - Unclear if this is of practically significant benefit, but agree it is statistically significant using the tests used by the authors.

⇒ There may be some reason in what the reviewer pointed out. However, we thought that we can apply the result to the clinical situation. Because we proved the effectiveness of CMAC videolaryngoscopy in patients with simulated cervical injury, the result of the present study
would be applied to patients with head and neck trauma, cervical spine disorders and difficult intubation anticipated. We have added this in the discussion section (page 13, the last sentence).

→ The result of the present study would be applied to patients with head and neck trauma, cervical spine disorders and difficult intubation anticipated.

5. Table 4 - Report percentages as well as raw numbers.
⇒ We have added the percentages with raw numbers as reviewer’s comment in Table 4

6. I don’t know that I agree with reporting mean/SD for parameters that may not be normally distributed. Would assess and report median/interquartile range (25th-75th) for those nonparametric parameters.
⇒ We have revised about that concern in the methods, results section and tables. The nonparametric parameters were presented as median (interquartile range).

7. P10ln13 - Check that the difference is actually 19% (as compared to P12ln17). Think it is 29%
⇒ We have revised about that concern in results section as reviewer’s comment (Page 12, lines 11–12).
→ Also, Magill forceps were used approximately 29% more in group M than in group C (Table 4).

Reviewer #3

Sheila Nainan Myatra, MD,FCCM (Reviewer 3): Thank you for the opportunity to review your work. The authors have conducted a prospective randomised study comparing C-MAC D-Blade videolaryngoscope and McCoy laryngoscope efficacy for nasotracheal intubation in simulated cervical spine injury. This is an interesting study where two devices have been compared for nasotracheal intubation, which has not been much studied in patients receiving a neck collar.

I have the following comments and queries

Major

1. Comparing a videolaryngoscope (VL) with a direct laryngoscope and that too a device with a hyperangulated blade (D Blade) is like comparing apples with oranges. What was the rationale for doing this?
⇒ We tried to reveal the better intubation devices in patients requiring nasotracheal tube with cervical spine injury. We choose McCoy blade and CMAC D-blade as intubation devices. Because one is a direct laryngoscopy with a hinged tip at the end of the laryngoscope blade to facilitate easy lifting the epiglottis and the other is a videolaryngoscope with pronounced elliptical curvature with the distal end facing distinctly upward. Both devices have been found as one of useful beneficial in patients requiring neck immobility. Also, there are several studies regarding intubation device for orotracheal intubation in difficult cases, but literature provides scant evidence for validating the use of McCoy blade and/or C-Mac D-Blade for nasotracheal intubation in cases with cervical injury. We thought it could be applied to clinical practice if the present study proved a better device. And we revised
Inappropriate airway management in patients with cervical spine injuries can lead to deleterious effects on neurologic injury. For this reason, international guidelines recommend keeping the cervical spine in a neutral position and avoid movement of the cervical spine during endotracheal intubation with a rigid neck collar or manual in-line stabilization [1, 2]. It is well documented that immobilization of the cervical spine in patients with known or suspected cervical spine injuries is associated with increased rates of failed intubation of the trachea, secondary to adverse impact on the laryngeal view during direct laryngoscopy [3, 4]. NTI using fiber-optic bronchoscopy is a useful technique in patients in whom direct laryngoscopy and orotracheal intubation are impeded, for example, those with cervical spine injury [7]. However, its use is restricted by availability, lack of expertise and additional time required to perform bronchoscopy. Recognition of these limitation had led to introduction of the variety of endotracheal intubation devices including various videolaryngoscopes to secure the airway for NTI in patients with cervical spine instability [9-11].

These two devices have been used successfully for orotracheal intubation in various anticipated difficult airway scenarios [10,16,17], but literature provides scant evidence for validating the use of McCoy blade and/or C-Mac D-Blade during NTI in cases with cervical injury or in a simulated difficult airway in humans.

2. Using a single operator for all the cases is a serious limitation of this study. This is not only due to a potential for bias, but the influence of familiarity with a device. This could significantly affect the results

⇒ We have agreed the reviewer’s comments about that concern. Therefore, we additionally have described about that in the limitation section. (page 15, the last two sentences)

⇒ Thirdly, an experienced anesthesiologist conducted NTI, the effect of familiarity with the intubation device on the results cannot be excluded. Also, applying the results of the present study to beginners may be different in terms of time taken intubation and complications.

Other comments

3. What matters is the first pass success and time to intubation without complications when comparing two devices for tracheal intubation. What was the rationale to split this into 3 timelines, especially the first one with the tracheal tube passage from the nostril in to the oropharynx. Were you expecting this to be different between the two groups?

⇒ No, we thought that the first step should be comparable. Because the first step was not affected by the type of intubation devices, we have checked it separately. We wanted to exclude the step which was same regardless of devices. After that, we tried to compare the two devices in the second and third steps closely related to the type of intubation devices.

4. Having a better CL grade with VL use means nothing clinically, as this will not necessarily facilitate passage of the tracheal tube, especially in case of a D blade.

⇒ There may be some reason in what the reviewer pointed out. However, D blade CMAC videolaryngoscopy could achieve not only excellent glottis exposure but also patency of the native upper airway in the present study. Therefore, D blade CMAC less needed a lifting force or/and external pressure to expose the vocal cords and align the ETT into glottic inlet in the second step and it was less required slight ETT manipulation or/and Magill forceps in the third step.
5. Why was the SpO2 dropping below 95% considered as your criteria for failure to intubate? Desaturation should have been noted as a complication

⇒ In the present study, cervical neck collar was intentionally applied to perform the simulated cervical spine injury model in patients scheduled for elective surgery. Therefore, to make patients’ safety the most important priority, the SpO2 dropping below 95% considered as failure to intubate and stop conducting the study. In that case, the cervical neck collar was removed and nasotracheal intubation was performed in the traditional position using the desired device by a skilled anesthesiologist.

6. The D blade is a hyperangulated VL blade, which is known to give you an excellent view especially in difficult airway cases. However, negotiating the tracheal tube is usually difficult. I am surprised you have less use of Magill’s forceps in this group.

⇒ As we have mentioned in the discussion section and showed in Fig. 2, D blade of CMAC videolaryngoscopy could facilitate both excellent glottis exposure and patency of the native upper airway. Therefore, CMAC blade could negotiate tracheal tube better and it was required less additional maneuver than McCoy laryngoscope.

7. The introduction is too long and not focused. Please give your rationale for comparing these two devices.

⇒ We have revised the introduction section as reviewer’s comment and added rationale for comparing the two device (page 4 – 5, the last paragraph).

8. The discussion is rambling. The results need to be discussed more systematically.

⇒ We have revised the discussion section as reviewer’s comment.

We hope that the revised manuscript will better meet the requirements of your journal for publication. We thank the editor and the reviewers of BMC anesthesiology once again for the constructive review of our paper. It is difficult time for everyone due to COVID-19. We hope you are staying safe and healthy through these unusual times!

Sincerely yours,

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