

A randomized comparative evaluation of C-MAC video-laryngoscope with Miller laryngoscope for neonatal endotracheal intubation

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Abstract

Background and Aims: An efficient neonatal airway management is peculiarly challenging even in the most experienced hands. Considering the recent interest in assessing the performance of various video-laryngoscopes (VL) in pediatric cohort, the prospective randomized study was contemplated to stage a comparative evaluation of C-MAC with Miller laryngoscope for neonatal endotracheal intubation.

Material and Methods: 150 neonates were randomized to undergo intubation with either the C-MAC VL ($n = 75$) or the Miller laryngoscope ($n = 75$) performed by an experienced anesthesiologist in a tertiary care perioperative setting. The percentage of glottic opening (POGO), time to best glottic view (TTBGV), time to intubation (TTI), number of attempts, optimal external laryngeal manipulation (OELM) employed, and the complications were assessed and compared between the two groups.

Results: C-MAC group demonstrated a significantly higher POGO, compared to the Miller group ($88 \pm 26.7\%$; $76.8 \pm 32.1\%$, respectively, $P = 0.022$). TTBGV was significantly lower in the C-MAC ($7.7 \pm 0.1s$) group as opposed to the Miller group ($11.3 \pm 1.1s$). The C-MAC group displayed higher TTI values compared to the Miller group ($25.4 \pm 1.6s$; $19.7 \pm 1.2s$, respectively, $P < 0.01$). The first-attempt intubation success rate and the number of attempts were comparable in both the groups. OELM was required in 24% of the patients in the Miller group as opposed to 10.7% in the C-MAC group ($P = 0.031$). Higher patient percentage in the C-MAC group required the need of stylet for assisting a successful intubation, although the difference between the two groups was not statistically significant.

Conclusion: Despite an improved view of the glottis, the TTI was higher for C-MAC compared to direct laryngoscopy with a comparable first-attempt success rate in the two techniques.

Keywords: C-MAC, endotracheal intubation, miller laryngoscope, neonates, POGO, video-laryngoscope

Introduction

Efficient airway management is certainly an anesthesiologist's 'holygrail' with certain patient subsets such as the neonates

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presenting unique challenges owing to their anatomical and physiological peculiarities.^[1-3] Considering the fact that multiple intubation attempts, associated cardio-respiratory consequences, and failed intubation are major and avoidable predecessors of perioperative critical events during neonatal anesthetic induction, refinement in the airway management in this vulnerable cohort continues to be emphasized.^[2] Video-laryngoscopes (VL) have been actively investigated for pediatric airway management over the last decade.^[2,4,5] In this context, the introduction of the Miller blade in the C-MAC VL system (Karl Storz GmbH and Co. KG, Tuttlingen, Germany) presents a promising pediatric airway tool.^[4]

Albeit a considerable literature suggesting an improved glottic visualization with VL in infants, the data regarding the intubation success rate and time to intubation (TTI) is inconclusive.^[2,4,6,7] Therefore, we conducted a prospective randomized controlled study to evaluate the Miller blade in C-MAC VL and the Miller laryngoscope for their respective percentage of glottic opening (POGO), time to best glottic view (TTBGV), TTI, number of attempts, optimal external laryngeal manipulation (OELM) employed, and complications exclusively in the neonatal age group.

Material and Methods

After the institutional ethics committee approval (ethics committee of VMMC and Safdarjung hospital, serial number IEC/VMMC/SJH/October 30th/2017-051) and written informed consent from the parents or the legal guardian, this prospective randomized study was conducted on 150 neonates admitted requiring endotracheal intubation for surgical intervention under general anesthesia. Inclusion criteria were all neonates of either gender of age 0-28 days, American Society of Anaesthesiologists physical status (ASA-PS) I and II and birth weight more than 1.5 kg. All neonates with anticipated difficult airway or with any congenital defects of the upper airway, head, and neck surgery, coagulation defects, birth asphyxia, prematurity, and risk of pulmonary aspiration were excluded from the study.

A pre-anesthetic check-up was performed for all the neonates. Prior to the planned surgery, the neonates were kept nil per oral as per the ASA guidelines. Routine monitors were attached including pulse oximetry, non-invasive arterial blood pressure, electrocardiography, temperature probe, and capnography for standard intraoperative monitoring.

In the operating room, neonates were randomized into two groups using computer-generated randomization labels with one group undergoing intubation with either Miller blade, C-MAC VL size 0 or 1 ($n = 75$) and the intubation in

the other group with the conventional Miller blade size 0 or 1 ($n = 75$). All tracheal intubations were performed by an anaesthesiologist with more than 20 years of experience in pediatric anesthesia.

Neonates were made to lie with the head in neutral position and a small cotton roll under the neck to recoup for the large occiputs. All neonates were preoxygenated with 100% O₂ for 3 minutes. General anesthesia was induced with sevoflurane 5–8% with 100% oxygen with bag and mask using pediatric breathing system. After ensuring adequate depth of anesthesia, intravenous cannulation was performed with appropriately sized IV cannula. Intravenous fluids were administered as required and injection fentanyl 2/μg/kg, followed by atracurium 0.5 mg/kg, was given for muscle relaxation after confirming mask ventilation. Thereafter, the following peri-intubation parameters were assessed:

The POGO score was used to grade the laryngeal view and was considered 100% if the entire glottis structure was visible, 33% when only the lower third of the vocal cord and arytenoid was visible, and 0% when no glottic structure was visible. The TTBGV was measured as the time taken from the touching of the tip of the laryngoscope to the lip of the neonate till the TTBGV was achieved. The TTI was assessed from the time the laryngoscope entered the neonate's mouth until the first capnograph trace was seen on the monitor. The number of attempts: Every time the device was withdrawn and re-introduced again in the oral cavity, the attempt was counted and the total number of required attempts was recorded. OELMs employed to provide the best glottic view were noted. While the first intubation attempt was performed without the aid of a stylet, the need for stylet assistance (at the discretion of the intubator) in the subsequent intubation attempts was also recorded. The complications, including any major or minor complications, were assessed and compared between the two groups. These included any abrasion or bleeding on the lips, gums, angle of mouth and any blood/clot observed in the laryngoscope after intubation, bradycardia (less than 100beats/min), or a decrease in the heart rate by 30bpm from baseline, bronchospasm or desaturation (a fall in SpO₂ equal or less than 90% was noted and managed with 100% oxygen to restore SpO₂ to 98–100% before any further attempt).

Statistical analysis

The sample size was estimated based on the finding of the previous study demonstrating a higher POGO with the VL compared to the direct laryngoscope.⁶ The analysis of the data was contemplated using the statistical package for social sciences (SPSS) for Windows version 17.0, released 2008 (SPSS Inc., Chicago, IL). The data was expressed in percentages, mean ± standard deviation. Chi-square test

was applied to assess the associations between the dependent variable and the categorical variables, while independent sample *t*-test was used to compare the means of the continuous variables. The *P* value of <0.05 was considered statistically significant.

Results

A total of 180 neonates were assessed for eligibility wherein 150 neonates were randomized following the exclusion of 30 neonates as per the study protocol [Figure 1]. The C-MAC group ($n = 75$) and the Miller group ($n = 75$) were comparable with regards to the demographic characteristics [Table 1].

All the neonates were successfully intubated in both the groups with either 3 or 3.5 ID ETT as appropriate. The C-MAC group demonstrated a significantly higher POGO compared to the Miller group ($88.0 \pm 26.7\%$; $76.8 \pm 32.1\%$, respectively $P = 0.022$). As an extension of the aforementioned, the TTBGV was considerably shortened for the neonates undergoing intubation with the aid of C-MAC (7.7 ± 0.1 s) VL in contrast to the Miller group (11.3 ± 1.1 s) ($P < 0.001$) [Figure 2]. In addition, OELM was required in 24% patients in the Miller group as opposed to only 10.7% in the C-MAC group ($P = 0.031$). However, TTI was significantly higher for the neonates in the C-MAC (25.4 ± 1.6 s) group in contrast to the Miller group (19.7 ± 1.2 s) ($P < 0.001$) [Table 2, Figure 3].

The number of attempts at intubation and the first-attempt intubation success rates were comparable in the two groups. A higher overall patient percentage (although not statistically significant) in the C-MAC group required the need of a stylet for assisting a successful intubation [Table 2]. The peri-intubation complication rates were comparable between the two groups [Table 3]. All the neonates were successfully extubated with no incidence of post-operative desaturation or stridor in either of the groups.

Discussion

The major findings of our study were constituted by an improved glottic visualization, reduced TTBGV, and prolonged TTI with the Miller blade of C-MAC VL as opposed to the conventional Miller blade while performing neonatal intubation.

The demonstration of a better glottic view with the aid of a VL as compared to direct laryngoscopy in the present study is in harmony with the existing literature.^[7] The overall TTI value (25.4 ± 1.2 s) obtained in the present study is comparable to the majority of the pediatric airway research

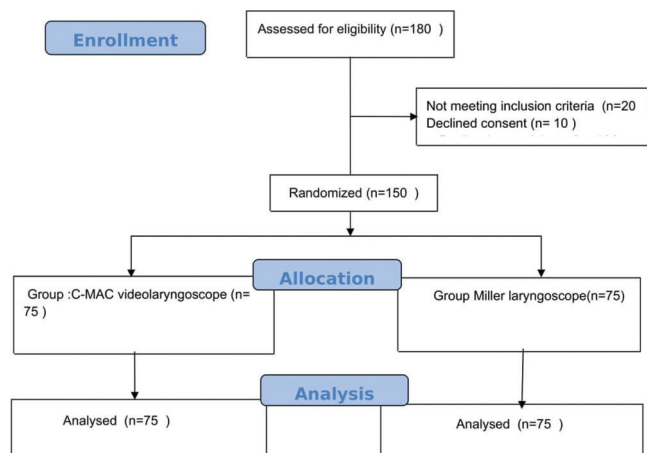


Figure 1: CONSORT Flow chart

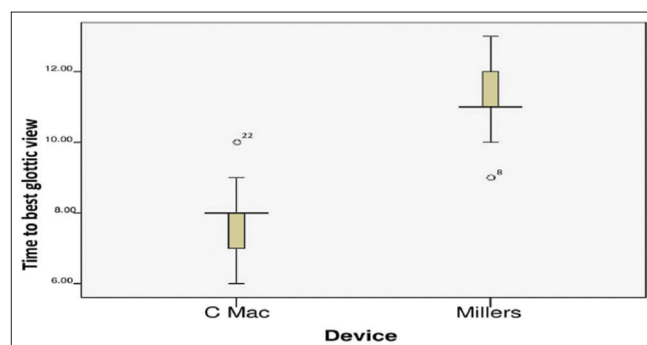


Figure 2: Box-and-whisker demonstrating time to glottic view (in seconds) with C-MAC and Miller videolaryngoscope. The inner horizontal line within the box represents the median time for glottic view and the outer horizontal lines represents the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals

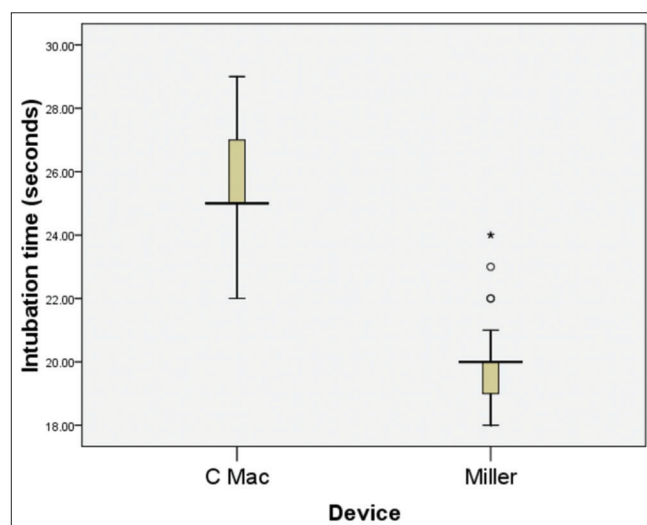


Figure 3: Box and Whisker plots illustrating time to tracheal intubation (in seconds) with C-MAC videolaryngoscoes and Miller laryngoscope. The inner horizontal line within the box represents the median time for tracheal intubation and the outer horizontal lines of the box represents the 25th and 75th quartiles. The horizontal lines of the whiskers represent the 95% confidence intervals

groups.^[5-7] However, the C-MAC-Miller TTI comparison yields interesting observations. On one hand, a group of

Table 1: Demographic data of the neonates

Variables	C-MAC	Miller	P
Age (days)	5.2±3.2	4.7±2.9	0.36
Weight (kg)	2.4±0.2	2.3±0.3	0.61
ASA			
(I/II)	71 (94.7%)/4 (5.4%)	69 (93.2%)/6(8%)	0.51
Gender			
Male/female	45:30	49: 26	0.4

Data of gender expressed in absolute number; ASA: American society of Anesthesiologists

Table 2: Data of laryngoscopy and tracheal intubation

Variables	C-MAC	Miller	P
POGO (%)	88±26.7	76.8±32.1	0.02*
TTBGV (s)	7.7±0.1	11.3±1.1	<0.001*
TTI (s)	25.4±1.6	19.7±1.2	<0.001*
OELM	8 (10.7)	18 (24.0)	0.031*
No.of attempts			
(I/II)	59 (78.7%)/16 (21.3%)	61 (81.3%)/14 (18.3%)	0.68
Stylet	15 (20.0%)	7 (9.3%)	0.06

*P<0.05 statistically significant

Table 3: Complications

Complication	C-MAC	Miller	P
Minor complication	3 (4%)	2 (2.6%)	0.64
Desaturation	1 (1.3%)	2 (2.6%)	0.56
Bradycardia	4 (5.3%)	3 (4%)	0.69
Bronchospasm	1 (1.3%)	3 (4%)	0.31

independent researchers outline a reduced TTI with C-MAC when compared to the Miller as exemplified by Jain *et al.*^[4] in their randomized controlled trial (RCT) involving experienced anesthesiologist while intubating infant in a lateral position^[2,8,9] and Saran *et al.*^[2] evaluating VL-guided verbal feedback to assist neonatal and infant intubation by novices. On the other hand, a recent comprehensive meta-analysis by Sun *et al.*^[7] (comprising of 14RCTs) staging a comparison between the VL and direct laryngoscope elucidates a prolonged TTI in background of video-laryngoscopic or indirect video-laryngoscopic-airway management. The index study and a Cochrane database systematic review also highlight the finding of the aforementioned meta-analysis in the neonatal age group.^[10]

Certain caveats of video-laryngoscopic intubation such as the requirement of a dynamic interplay of hand-eye coordination and innate visuospatial orientation of the intubator are pivotal for the successful manipulation and passage of endotracheal tube through the vocal-cords.^[11] The above-mentioned procedural intricacies in conjunction with the experience level of the intubator with the pediatric VL can prove to be an important determinant of the eventual TTI while contemplating video-laryngoscopy. In this study, a higher TTI was obtained

in the C-MAC group despite the performance of all the intubations by an experienced anesthesiologist. In addition, our study depicted a first-pass intubation rate of 78.7% for C-MAC which was comparable to 81.3% of the Miller blade. This finding is supported by the meta-analysis by Arulkumaran and colleagues.^[12] It is noteworthy that following a failed first intubation attempt, 93.8% (15 out of 16 neonates) in the C-MAC group required a stylet for assisting endotracheal intubation in the second attempt. This was in sharp contrast to the 50% (7 out of 14 neonates) second intubation attempt stylet requirement in the Miller group. Sinha *et al.*^[13] also revealed that a styletted endotracheal tube significantly improved the intubation success while using C-MAC video-laryngoscopy.

To the best of our knowledge, this is the first study comparing the intubation parameters between C-MAC and Miller laryngoscope exclusively in the neonatal age group, whereas a majority of the existing literature till date is characterized by study population in infancy with the varying degree of neonatal age representation.^[4] This study adds to the literature base on the application of VL in pediatric patients and is in congruence with the findings of the majority.^[6,7,14-17] A large sample size constitutes the major strength of the index study. Moreover, the involvement of a single experienced anesthesiologist limits the performance bias. In addition, the objectivity of the defined intubation parameters and the continuous nature of the study variables (such as POGO scoring unlike the discrete Cormack–Lehane scoring) adds incremental comparative value to the study observations.^[6,18,19]

The study had a few limitations. First, this study was conducted on neonates with apparently normal airway precluding the extrapolation of observations to difficult airway situation. Second, the likelihood of observer bias considering the inability to blind to the assigned laryngoscope group presents an inherent limitation.^[20] Last, the inclusion of the scoring system, such as intubation difficulty score, could have rendered the assessment of complex intubation process more holistic.^[21]

Conclusion

To conclude, a higher TTI was observed while employing C-MAC VL as compared to the Miller laryngoscope, despite an improved glottic view and faster TTBGV with the C-MAC. The study bears testimony to the fact that the quality of the glottic view cannot be simplistically equated with the ease of intubation. Requisite training and research efforts should be devoted to improve endotracheal tube insertion with specific VL devices in order to reach our ultimate airway pinnacle.

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Conflicts of interest

There are no conflicts of interest.

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