

Study to compare the efficacy of C-MAC video laryngoscope with conventional direct laryngoscope using miller's blade 0 for neonatal intubation at tertiary care hospital

Yogita Karemore¹, Saurabh Rokde², Shubham Shende³, Vaibhav Solanke⁴,
Vrishali Ankalwar⁵

¹SR, Department of Anesthesia, GMC Nagpur, India.

²Assistant Professor, Department of Medicine, Sukhsagar Medical College Jabalpur, India.

³Senior Resident, Department of Paediatrics, AIIMS Nagpur, India.

⁴Senior Resident, Department of Anaesthesiology, Government Medical college and Hospital, Jalgaon, India.

⁵Associate Professor, Department of Anesthesia, GMC Nagpur, India.

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Abstract

Airway management in neonates is a major challenge for pediatric anesthesiologists. Neonates allow a very short apnea time during induction of anesthesia; therefore, intubation should be quickly achieved within this narrow safety period. Present study was aimed to compare the efficacy of C-MAC video laryngoscope with conventional direct laryngoscope using miller's blade 0 for neonatal intubation at tertiary care hospital. **Material and Methods:** Present study was single-center, prospective, comparative study, conducted in term/ Late preterm neonates, weighing more than 1500 gms, undergoing elective and emergency surgeries. Neonates were randomized into two groups (45 in each group) as Group C-MAC & Group DL. **Results:** In present study, mean postnatal age, Gender-wise distribution, mean gestational age & mean birth weight in both groups was comparable. Mean duration of successful laryngoscopy with C-MAC was (16.6 ± 4.85 sec) less than direct laryngoscope (28.11 ± 6.82 sec), difference was statistically significant (P-value: <0.0001). Majority neonates in group C-MAC showed CL grade I, and grade II (35.56% each), whereas in group DL, majority neonates showed CL grade I (75.56%), difference was statistically significant (P-value: <0.0001). Laryngoscopy in the first attempt was successful in 93.33% of neonates using C-MAC VL whereas using DL, the laryngoscopy was successful in the first attempt in 66.67% of neonates. difference was statistically significant (P-value: 0.016). Majority neonates were intubated in the first attempt in group C-MAC (90.11%) as compared to group DL (64.4%), difference was statistically significant (P-value: 0.009). The adverse events like bradycardia episodes, oesophageal intubations, gastric distention were more with group DL as compared to group C-MAC, though it is not statistically significant (p-value: >0.05). **Conclusion:** C-MAC video laryngoscope is found to be superior to Conventional Direct Laryngoscope for neonatal intubation in terms of lesser intubation time, the higher first-attempt success rate.

Keywords: C-MAC video laryngoscope, Direct Laryngoscope, neonatal intubation, neonatal anaesthesia

Corresponding Author: Dr. Vaibhav Solanke, Senior Resident, Department of Anaesthesiology, Government Medical college and Hospital, Jalgaon, India.

Address: flat no 502 vedant Height Ranchos Nagar , Pande Square, old BJ Market , Jalgaon, India.

Email: vsolanke7@gmail.com

Introduction

Airway management in neonates is a major challenge for pediatric anesthesiologists. Respiratory-related complications are the major causes of perioperative mortality and morbidity.^{1,2} In contrast to adults, airway management in children can be more difficult, particularly in neonates and infants. The overall incidence of difficult laryngoscopy (Cormack and Lehane Class $\geq$ III) is significantly higher in infants (4.7% vs. 0.7%) as compared to older children.³

Neonates allow a very short apnea time during induction of anesthesia; therefore, intubation should be quickly achieved within this narrow safety period. Low functional reserve, high oxygen consumption, difficulty in mask ventilation, and intubation are the factors affecting this safety margin.⁴ Moreover, compared with adults, the airway anatomy in neonates is unique. A more cephalad larynx, a relatively larger tongue, more limited mouth opening, and prominent occiput in a neonate present difficulty for laryngoscopy and intubation.^{4,5}

Advent of pulse oximetry and capnography greatly reduced adverse events during induction of anesthesia. Conventional Direct laryngoscope (DL) is one of the most preferable devices for airway management because of its simplicity and easy accessibility. However, DL needs a direct line of sight to a glottis view, which is not always available in neonates. Video laryngoscopes (VLs) are the further addition to the armamentarium in an effort to reduce complications during intubation.^{3,4} Using video laryngoscopes enables the intubator to see the vocal cords and glottis indirectly, without the need for aligning the oral, pharyngeal, and tracheal axes.⁶ Present study was aimed to compare the efficacy of C-MAC video laryngoscope with conventional direct laryngoscope using miller's blade 0 for neonatal intubation at tertiary care hospital.

Material And Methods

Present study was single-center, prospective, comparative study, conducted in department of Anesthesiology, at XXX medical college & hospital, XXX, India. Study duration was of 2 years (December 2019 – November 2021). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Term/ Late preterm (35 completed weeks of gestation) neonates, weighing more than 1500 gms, undergoing elective and emergency surgeries, parents willing to participate in present study

Exclusion criteria

- Parents not willing to give consent
- Preterm neonates (<35 completed weeks of gestation)
- Birth weight less than 1500 grams
- Neonates with a facial abnormality or upper airway malformations
- Extremely moribund neonates with cardiorespiratory compromise

For sample size determination, we referred study conducted by Parmekar *et al.*⁷ A total of 90 neonates were randomized into two groups (45 in each group) using a computer-generated randomization chart:

- Group C-MAC (non-channelled miller's blade 0 of C-MAC video laryngoscope)
- Group DL (conventional direct laryngoscope with Miller's blade 0).

All the parents were informed regarding details of the anaesthetic procedure and complications. All the intubations were done by trainee anaesthesiologists. A senior anaesthesiologist trained in neonatal anaesthesia was present for each endotracheal intubation done by a trainee anaesthesiologist. Devices included Conventional Direct Laryngoscope (Rusch, Teleflex Medical, Markham, Canada) with miller's blade size 0 and C-MAC Video Laryngoscope (KarlStorz,Tuttlingen, Germany) with miller's blade size 0. Video laryngoscope was used to perform endotracheal intubation under indirect vision with the use of the video monitor.

Pre-anaesthetic evaluation done on day prior to surgery for elective procedure and two hours before surgery for emergency procedures. All cases underwent necessary investigations such as per Hemoglobin, complete blood count, Blood grouping, Blood urea, Serum creatinine, uric acid, Serum Bilirubin (total & direct), X ray-chest & 2D-Echocardiography.

In operation theatre neonates were positioned supine on a warming mattress and the body rapped using folded blankets. ASA standard Monitoring devices, including automatic non-invasive blood pressure, five-lead electrocardiogram, capnography, and pulse oximeter, were opted for all patients. Intravenous access was secured half an hour before induction outside the operation room. All the patients were premedicated with inj. Atropine 0.01mg/kg. To calm the neonate inj. Ketamine 0.5-1 mg/kg was used. All patients were pre-oxygenated with 100% oxygen for 3 min before induction of anaesthesia using a face mask with a JRM circuit to achieve baseline oxygen saturation greater than 98%. This will increase the physiological stores of oxygen in order to prolong the time for desaturation during a period of apnea.

A standardized intravenous induction technique consisting of propofol 1.5 mg/kg IV was utilized. Inj. atracurium 0.5 mg/kg IV was used for muscle relaxation. All patients were manually ventilated with 100% oxygen following the onset of neuromuscular blockade. After three minutes of mask ventilation, the neonate was intubated with an allocated device either conventional direct laryngoscope miller's blade 0 or C-MAC VL Miller's blade size-0. The laryngoscope blade was inserted from the right angle of the mouth and the tongue was displaced towards the left side. The epiglottis was included with the tip of the blade to visualize the glottis. Airway maneuvers like OELM or stylet were used only if required after assessing the glottic view by the intubator. And intubation was carried out with the uncuffed endotracheal tube of appropriate size. Air entry confirmed with stethoscope and tube secured. Intubation in both groups was performed in a neutral position of the head. The shoulder roll was used for optimal positioning in all infants.

The attending anaesthesiologist rated the glottic visualization using the Cormack-Lehane grade. The Cormack-Lehane grading systems evaluate the glottis view during tracheal intubation using a classification of C-L grading I, II, III, IV. Variables studied were number of laryngoscopy attempts required for successful intubation, number of intubation attempts required for successful intubation, time required for successful intubation, maneuver required for obtaining best glottic view and to perform tracheal intubation, hemodynamic variables & complications if any. The difficulty of intubation was assessed using the modified Intubation Difficulty Scale(IDS) using seven parameters.^[53] Alternative techniques such as the need for optimal external laryngeal manipulation (OELM maneuver) or the need for another specialist were employed. After each endotracheal intubation, a survey consisting of '5-point Likert scale questions' was carried out amongst the trainee anestesiologist and senior anestesiologists.

Data was collected, compiled, and analysed using EPIinfo (version7.2). Qualitative

variables are expressed in the terms of percentages. Quantitative variables were categorized and expressed in terms of percentage or mean and standard deviations. The difference between the two proportions was analysed using Chi-square or Fisher exact test. The difference between the two means was tested using student t-test. All analysis was two-tailed and the significance level was set at 0.05. A P-value of <0.05 was considered statistically significant.

Results

In present study, 90 cases were equally distributed in Group C- MAC (n=45) & Group DL (n=45). Maximum number of neonates belonged postnatal age of 3-4 days in group C-MAC (40%), whereas, in group DL belonged to birth- 2 days postnatal age (48.89%). The mean postnatal age, Gender-wise distribution, mean gestational age & mean birth weight in both groups was comparable. The maximum number of neonates were between 38-40 weeks of gestational age in group C-MAC (51.12 %), while in group DL majority were between 35-37 weeks of gestation. Majority of the patients in both groups were weighing in the range of 2-2.5 kg (55.56 % in group C-MAC and 48.89 % in group DL).

In the present study, we noted no statistically significant variations in hemodynamic parameters (heart rate, SBP, SpO₂) at different time points (baseline, after induction, during intubation, after intubation at 1,5,10,15 min) to assess stress response to laryngoscopy and intubation.

Table 1: General characteristics

	C-MAC		DL		p-value
	N	%	N	%	
Age in days					
Since birth-2	15	33.33	22	48.89	
3 –4	18	40.00	12	26.67	
5 –6	5	11.11	4	8.89	
>6	7	15.56	7	15.56	
Mean Age	4.44 ± 4.10		3.78 ± 3.36		0.4020
Gender					
Male	23	51.11	18	40.00	0.397
Female	22	48.89	27	60.00	
Gestational age (weeks)					
35–37	22	48.88	24	53.33	
38–40	23	51.12	21	46.67	
Mean Gestational age (weeks)	37.11±1.27		37.24±1.43		0.8162
Birth Weight (kg)					
1.5-2.0	3	6.67	8	17.78	
2.0-2.5	25	55.56	22	48.89	
>2.5	17	37.78	15	33.33	
Mean weight	2.45±0.42		2.38±0.47		0.4383

We included neonates posted in elective as well as emergency surgeries. In the C-MAC group, majority neonates were posted for elective procedures (57.78 %), and difference was statistically not significant. Mean duration of successful laryngoscopy with C-MAC was (16.6 ± 4.85 sec) less than direct laryngoscope (28.11 ± 6.82 sec), difference was statistically significant (P-value: <0.0001). Majority neonates in group C-MAC showed CL grade I, and grade II (35.56% each), whereas in group DL, majority neonates showed CL grade I

(75.56%), difference was statistically significant (P-value: <0.0001).

Table 2: Procedures

Variables	C-MAC		DL		p-value
	N	%	N	%	
Procedures					
Elective	23	51.11	19	42.22	0.398, NS
Emergency	22	48.89	26	57.78	
Other					
Mean duration for successful laryngoscopy	16.6	4.85	28.11	6.82	<0.0001, HS
CL Grade					
I	16	35.56	34	75.56	p<0.0001
II	16	35.56	9	20.00	
III	13	28.89	2	4.44	

Laryngoscopy in the first attempt was successful in 93.33% of neonates using C-MAC VL whereas using DL, the laryngoscopy was successful in the first attempt in 66.67% of neonates. difference was statistically significant (P-value: 0.016).

Table 3: Number of attempts required for Successful Laryngoscopy

No. of Attempts	C-MAC		DL		P-value
	N	%	N	%	
1	42	93.33	30	66.67	Chi2=10.11 P=0.016, S
2	3	6.67	14	31.11	
3	0	0	1	2.22	

In the present study, we used airway maneuvers to facilitate quick successful laryngoscopy and intubation. Optimal external laryngeal manipulation (OELM) used more in C-MAC (53.33%) as compared to conventional direct laryngoscopy (33.33 %), similarly styleted ETT used more in C-MAC (20 %) as compared to conventional direct laryngoscopy (4.44 %), difference was statistically significant (P-value: 0.003).

Table 4: Airway Maneuvers required for successful laryngoscopy and intubation.

Airway Maneuver	C-MAC		DL		p-value
	N	%	N	%	
OELM	24	53.33	15	33.33	Chi2=13.07 P=0.003, HS
STYLET	9	20	2	4.44	
None	12	26.67	28	62.22	

Majority neonates were intubated in the first attempt in group C-MAC (90.11%) as compared to group DL (64.4%), difference was statistically significant (P-value: 0.009).

Table 5: Number of attempts for successful Intubation.

Number of attempts	C-MAC		DL		P-value
	N	%	N	%	
1	41	90.11	29	64.44	Chi2=9.51 P=0.009, HS
2	3	6.67	14	31.11	
3	1	2.22	2	4.44	

In majority neonates, duration required for successful Intubation was 21-30 seconds in group C-MAC (46.67%) whereas using DL, duration required for successful Intubation was 31-40 (35.36 %). difference was statistically significant (P-value < 0.001). The group C-MAC required a significantly lesser mean time for successful intubation (22.93 ± 6 sec) as

compared to group DL (36.86 ± 10.23 sec) with a p-value: <0.0001 .

Table 6: Duration for successful Intubation

Duration (in sec)	CMAC		DL		p-value
	N	%	N	%	
10–20	19	42.22	1	2.22	Chi2=40.41 P<0.001, HS
21–30	21	46.67	12	26.67	
31–40	5	11.11	16	35.56	
41–50	0	0	12	26.67	
50–60	0	0	4	8.89	
Mean duration (in sec)	22.93 ± 6		36.86 ± 10.23		<0.0001, HS

In 84 % of neonates, IDS score was zero when C-MAC is used whereas, using DL, IDS score was zero in 53% of neonates. So, using DL, intubation is more difficult than C-MAC VL (p-value:0.024)

Table 7: Intubation Difficulty Scale (IDS) score.

IDS	CMAC		DL		p-value
	N	%	N	%	
0	38	84.44	24	53.33	Chi2=12.95 P=0.024, S
1	0	0	4	8.89	
2	2	4.44	3	6.67	
3	3	6.67	4	8.89	
5	2	4.44	9	20.00	
6	0	0	1	2.22	

In the present study, we found that there were significantly more events of desaturation with the group DL (28.89%) as compared to group C-MAC (4.44%) with a p-value of 0.003. In 3 neonates, mucosal injury during laryngoscopy & 5 neonates had bronchospasm in group DL whereas in group C-MAC no airway injury/bronchospasm noted.

Table 8: Incidence of Injuries of the airway, Bronchospasm/ Laryngospasm, and desaturation

Parameters	C-MAC		DL		p-value
	N	%	N	%	
Injuries of airway	0	0	3	6.67	0.242, NS
Bronchospasm/ Laryngospasm	0	0	5	11.11	0.021, S
Episodes of Desaturation	2	4.44	13	28.89	0.003, HS

The adverse events like bradycardia episodes, oesophageal intubations, gastric distention were more with group DL as compared to group C-MAC, though it is not statistically significant (p-value: >0.05)

Table 9: Comparison of adverse events between two groups.

Parameters	CMAC		DL		p-value
	N	%	N	%	
Bradycardia	0	0	4	8.89	0.117, NS
Oesophageal intubation	0	0	1	2.22	0.117, NS
Gastric distension	0	0	2	4.44	0.494, NS
Cardiac arrest	0	0	0		--
Extubation after procedure	44	97.78	42	93.33	0.616, NS

Discussion

After induction of general anaesthesia, securing a definitive airway is a crucial period in the perioperative management and outcome of the neonate. Due to anatomical and physiological differences, they allow minimum apnea time.⁴ Despite the use of conventional direct laryngoscopes for decades in neonates, respiratory-related complications are the most common intraoperative adverse events.^{1,2} Consequently, a number of other devices that facilitate endotracheal intubation with a low failure rate have been added to the armamentarium of pediatric anesthesiologists.^{4,5}

C-MAC is a novel optical laryngoscope with a series of lenses, mirrors with a specialized blade that provides glottis display without any deviation of oral, pharyngeal, or tracheal axes. It allows intubation with minimal manipulation of the neck.⁶ C-MAC was found to be better in several aspects like lesser duration for intubation, better success rate, and lesser injury to the airway.^{7,8,9}

Neonates posted for elective or emergency surgeries in our hospital were included in the study. The neonates were equally distributed based on procedure, whether elective or emergency, in both the groups similar to Sackle *et al.*,¹⁰ Hackle *et al.*,¹¹

We also found that number of attempts for successful laryngoscopy using C-MAC was lesser than with Direct Laryngoscope. Also, the number of laryngoscopies attempts which resulted in successful intubations were more with C-MAC. Our study results were comparable with the study done by Renu Sinha *et al.*,⁸ & Sun *et al.*,¹²

Cormack Lehane grading was one of the important parameters used to assess the laryngoscopy view. In the present study the CL grade obtained with C-MAC was higher initially which improved after airway maneuver (OLEM). This finding is similar to a study conducted by Anju Gupta *et al.*,⁹ in which they compared C-MAC video laryngoscope with TruView picture capture device for endotracheal intubation and Kim *et al.*,¹³ when they compared the use of Glide Scope with direct laryngoscopy for the laryngoscope view and intubation time in children. Another study conducted by Divya Jain *et al.*,¹⁴ where they compared intubation conditions with C-MAC miller's video laryngoscope and conventional miller's laryngoscope in lateral position in infants, also observed that to improve glottis visualization with C-MAC VL, OELM is needed.

In present study, duration required for successful laryngoscopy was lesser when a C-MAC video laryngoscope is used as compared to a direct laryngoscope. These results are similar to a study conducted by John E. Fiadjoe *et al.*,¹⁵ in which they studied Glide-Scope Cobalt video laryngoscope (GCV) with direct laryngoscope with Miller's blade in anatomically normal neonates and infants.

In our study, we used two airway maneuvers to facilitate laryngoscopy and intubation quickly. OELM was used to improve glottic visualization and styletting ETT was used to facilitate quick intubation. Group C-MAC required more styletting ETT for quick intubation than group DL. This finding is similar to a study conducted by Renu Sinha *et al.*,¹⁶ in which they concluded that styletting ETT significantly reduces the time for intubation in comparison to non-styletting ETT in children with C-MAC VL. Also, in another study by Renu Sinha *et al.*,⁹ they compared C-MAC VL with direct laryngoscope for efficacy in intubation in preterm and ex-preterm infants, they used styletting ETT.

In present study, maximum number of neonates (46.67%) were intubated within 21-30 seconds when C-MAC is used whereas, in group DL, only 26.67% of neonates were intubated within the same time range (21-30 sec), difference was statistically significant (p-value: <0.001). Our study results were comparable with the results of studies done by Renu Sinha *et al.*,⁸ Manirajan *et al.*,¹⁷ who observed less mean intubation time with C-MAC as

compared to direct laryngoscope. Also, Divya Jain *et al.*,¹⁴ and Gupta *et al.*,¹⁶ found lesser time for intubation with C-MAC VL.

In this study, the mean Intubation difficulty scale (IDS) score was significantly less with C-MAC VL compared to the direct laryngoscope ($P = 0.024$). These findings are comparable with Divya Jain *et al.*,¹⁴. They found that C-MAC VL reduces intubation difficulty when compared to direct laryngoscope.

Hackell *et al.*,¹¹ reported successful intubation in seven infants with C - MAC VL after the failure of direct laryngoscopy. Similarly, Sinha *et al.*,⁹ conducted a retrospective analysis of the performance of video laryngoscope for endotracheal intubation in preterm and ex-preterm, they concluded that C- MAC video laryngoscope blade 0 is suitable for endotracheal intubation in preterm and ex preterm infants. A meta-analysis done by Abdelgadir *et al.*,¹⁸ compared video laryngoscopes with a conventional direct laryngoscope in pediatric intubation which excluded neonates. Among the available video laryngoscopes, C-MAC video laryngoscope (C-MAC CL) with Miller blade size 0 is appropriately designed for newborns.^{8,19}

Limitations of present study were impossible to blind the anesthesiologist to the device used, the potential for bias exists. Study was conducted on patients with normal airways and hence cannot be extrapolated to difficult airway situations. We tested only C-MAC video laryngoscope; therefore, results may not apply to other video laryngoscopes.

Conclusion

C-MAC video laryngoscope is found to be superior to Conventional Direct Laryngoscope for neonatal intubation in terms of lesser intubation time, the higher first-attempt success rate with fewer events of desaturation.

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