

Clinical evaluation of C-MAC videolaryngoscope with or without use of stylet for endotracheal intubation in patients with cervical spine immobilization

Nidhi Gupta · Girija Prasad Rath · Hemanshu Prabhakar

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Abstract

Purpose This study was carried out to evaluate the relative efficacy of the C-MAC videolaryngoscope as compared to the conventional Macintosh laryngoscope using both stylet and non-stylet endotracheal tube (ETT) in patients undergoing elective cervical spine surgery with head and neck stabilized by manual in-line stabilization.

Methods We randomized 120 consenting adults into four groups (30 each) to undergo tracheal intubation using either the Macintosh laryngoscope or C-MAC videolaryngoscope with stylet and non-stylet ETT.

Results There was no significant difference between the C-MAC videolaryngoscope and Macintosh laryngoscope in Intubation Difficulty Scale (IDS) score using either stylet [median (IQR) 2 (1, 3) vs. 3 (2, 4); $p = 0.58$] or non-stylet ETT [median (IQR) 4 (2, 6) vs. 3 (2, 8); $p = 1.00$]. Similarly, when using a similar ETT-stylet assembly, the duration of successful intubation attempt, first attempt success rate, complications, use of airway optimization maneuvers, and adjuncts to facilitate intubation were comparable. The Cormack–Lehane view of the glottis was better with the C-MAC videolaryngoscope ($p < 0.001$). The use of stylet significantly reduced the IDS score [median (IQR) 2 (1, 3) vs. 4 (2, 6); $p = 0.02$], intubation time [median (IQR) 27 s (23, 31) vs. 52 s (28, 76); $p < 0.001$], and use of gum elastic bougie (3.3 % vs. 43.3 %, $p < 0.001$) with the C-MAC videolaryngoscope whereas no such effect was observed with the Macintosh laryngoscope.

Conclusions Use of the C-MAC videolaryngoscope and Macintosh laryngoscope resulted in similar levels of intubation difficulty during cervical immobilization when used with a similar ETT-stylet assembly. The inclusion of the stylet significantly reduced the intubation difficulty experienced with the C-MAC videolaryngoscope.

Keywords Cervical spine immobilization · Difficult intubation · Manual in-line stabilization · C-MAC videolaryngoscope · Stylet

Introduction

Neurological injury after tracheal intubation in patients with cervical spine instability is rare but disastrous [1]. Although awake fiberoptic intubation remains the safest method of securing the airway in patients with an unstable cervical spine, it is often impractical as well as technically challenging in emergency settings [2, 3]. Conventional oral intubation with manual in-line stabilization (MILS) is still the most effective approach for early control of airway in patients with an injured cervical spine [1, 3]. However, MILS may worsen the direct laryngoscopic view by preventing optimal alignment of oral, pharyngeal, and tracheal axes, thereby increasing the intubation time [4, 5].

Presently, videolaryngoscopes are being used with great interest in patients with a difficult airway [6] as they do not require the alignment of three airway axes and provide an indirect view of the glottic opening. These features provide a better laryngeal view than direct laryngoscopy even during cervical immobilization. Various studies have evaluated the efficacy of the Glidescope, Pentax Airwayscope, Airtraq, and Truview EVO2 laryngoscope in comparison with the conventional Macintosh laryngoscope in

N. Gupta · G. P. Rath (✉) · H. Prabhakar
Department of Neuroanaesthesiology, Neurosciences Centre,
All India Institute of Medical Sciences (AIIMS),
New Delhi 110029, India
e-mail: girijarath@yahoo.co.in

patients with cervical spine immobilization [7–10]. All of these devices were found to reduce the difficulty encountered during endotracheal intubation as compared to direct laryngoscopy in this difficult intubation scenario along with a higher intubation success rate.

The Macintosh blade videolaryngoscope (C-MAC; Karl Storz, Tuttlingen, Germany) is the latest addition to the pool of videolaryngoscopes that offers the unique benefit of both conventional direct laryngoscopy as well as the indirect video-assisted laryngoscopy in a single intubation attempt. It has been observed to be useful in the difficult airway scenario in both elective and emergency settings [11–16]. Until the present, few studies have evaluated the utility of the C-MAC videolaryngoscope as compared to the conventional Macintosh laryngoscope and other videolaryngoscopes during cervical immobilization, with two of them being manikin studies [12, 13, 16]. Furthermore, the use of a stylet in these studies was not standardized with the C-MAC videolaryngoscope used with a styletted endotracheal tube (ETT) and the conventional Macintosh laryngoscope used with a non-styletted ETT [12, 13]. Although various studies have proven the efficacy of stylet use with videolaryngoscopes [17, 18], the actual impact of stylet use in reducing intubation difficulty with conventional direct laryngoscopy is less clear. However, it has been observed that intubating aids such as a stylet and gum elastic bougie (GEB) improve intubation success in difficult airways when used with the Macintosh laryngoscope [19].

This study was planned to carry out a comparison between the standard Macintosh laryngoscope and C-MAC videolaryngoscope with equal ETT-stylet settings. The primary aim of this clinical trial was to evaluate the relative efficacy of the C-MAC videolaryngoscope in comparison with the Macintosh laryngoscope in reducing intubation difficulty in patients undergoing elective cervical spine surgery with head and neck immobilized by MILS, using a similar ETT-stylet assembly. The secondary aim was to determine the utility of stylet with both laryngoscopes in such difficult intubation scenarios. We hypothesized that the C-MAC videolaryngoscope would reduce intubation difficulty in comparison with the conventional Macintosh laryngoscope when using either styletted or non-styletted ETT and that stylet use would reduce the intubation difficulty experienced with both laryngoscopes compared to non-styletted ETT.

Materials and methods

The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from each participating patient. The study was carried out

over a period of 1 year (August 2011 to July 2012). The study enrolled 120 patients aged between 18 and 65 years of either gender belonging to ASA physical status I–II undergoing elective cervical spine surgery for cervical compressive myelopathy. A complete pre-anesthetic evaluation was done 1 day before surgery. Airway assessment included the modified Mallampati score [20, 21] and mouth opening as measured by the inter-incisor gap in centimeters (cm). Patients with risk factors for difficult mask ventilation, gastric aspiration (obesity, pregnancy), or difficult airway such as previous neck surgery and mouth opening less than 3 cm were excluded from the study.

On the day of surgery, the patients were premedicated with glycopyrrolate 0.2 mg intramuscularly 30 min before induction of anesthesia. In the operating theater, the patients were positioned supine with the head and neck supported on pillows so that they were as close to the neutral position as possible within their comfort range. All patients received a standard general anesthetic. Monitoring modalities included heart rate (HR), noninvasive blood pressure, electrocardiography, pulse oximetry (SpO₂), end-tidal carbon dioxide (EtCO₂), and bispectral index (BIS) monitoring. Anesthesia was induced with propofol 1–2 mg/kg and fentanyl 2 µg/kg; rocuronium 1 mg/kg was given to facilitate endotracheal intubation. Here, the patients were randomized to one of the following four groups (30 each) on the basis of a computer-generated randomization chart:

- Group I: Macintosh laryngoscope with non-styletted ETT
- Group II: Macintosh laryngoscope with styletted ETT
- Group III: C-MAC videolaryngoscope with non-styletted ETT
- Group IV: C-MAC videolaryngoscope with styletted ETT

Laryngoscopy was performed by either of the two anesthesiologists (G.P.R. or N.G.) experienced in the use of both laryngoscopes in patients requiring MILS, having done more than 50 such intubations with each device before this study. A size 3 laryngoscope blade was used in women and size 4 in men as a standard procedure. A 14 Fr. Satin-Slip Intubating Stylet (Mallinckrodt Medical, USA) was used to bend the ETT in a hockey-stick configuration. Tracheal intubation was performed at BIS score below 60, and additional boluses of propofol were administered to increase depth of anesthesia, if required. At 90 s after the administration of rocuronium, the head pillow was removed. The neck was immobilized using MILS by holding the sides of the neck and the mastoid processes, thus preventing flexion/extension or rotational movements of head and neck. The trachea was intubated with a 7.5-mm ETT in women and an 8.5-mm ETT in men. After successful tracheal intubation, the lungs were mechanically

ventilated with isoflurane in a mixture of nitrous oxide and oxygen (2:1). No other procedure was carried out for the next 5 min, during which time the hemodynamic changes were recorded. The subsequent management was left to the discretion of the attending anesthesiologist.

The primary endpoint of the study was the intubation difficulty scale (IDS) score [22]. The IDS is a seven-point scoring system based on parameters known to be associated with difficult intubation, including number of supplementary attempts (an attempt is defined as one advancement of the ETT toward the glottis), number of supplementary operators, alternative techniques used, the Cormack and Lehane (CL) grade of laryngoscopic view, lifting force required, necessity of optimal external laryngeal manipulation (OELM), and position of vocal cords (see Appendix). IDS score may vary from zero to infinity depending on degree of difficulty, with a score >5 indicating moderate to major difficulty. The secondary endpoints were duration of successful intubation, first intubation attempt success rate, number of intubation attempts, number of airway optimization maneuvers required (OELM or change of laryngoscope blade), use of GEB to assist intubation, and the CL grade of laryngoscopic view obtained during first attempt [23]. For the Macintosh laryngoscope the direct view of glottis was noted, whereas with C-MAC the indirect view of glottis obtained on the screen was documented. The assistant providing OELM was blinded to the view obtained on the C-MAC video screen.

The duration of intubation was defined as the time taken from insertion of the laryngoscope blade between the teeth until the ETT is placed through the vocal cords, as evidenced by visual confirmation. If the passage of ETT was not directly visualized, the intubation attempt was considered complete after ETT was connected to the anesthetic circuit and a capnography trace was obtained. A failed intubation attempt was defined as an attempt in which the trachea was not intubated, or which required more than 120 s to perform. A maximum of three intubation attempts were permitted ensuring adequate oxygenation ($\text{SpO}_2 > 90\%$) by intermittent mask ventilation. The GEB was used if it was not possible to pass the ETT between the vocal cords in three such attempts. If the trachea was not intubated even after all these maneuvers, flexible fiberoptic intubation was performed.

The incidence of complications during intubation such as upper lip trauma, tooth damage, soft tissue bleeding, supraglottic trauma, and hypoxia ($\text{SpO}_2 < 90\%$) were noted. SpO_2 , mean blood pressure (MBP), and HR were recorded before induction, after induction, and at every minute until 5 min after intubation. Data were collected by a single independent observer.

Sample size was calculated on the basis of the IDS score. Based on a previous study [7], we assumed a mean

IDS score of 3.0 in patients undergoing endotracheal intubation with standard Macintosh laryngoscope with non-styled ETT in the setting of cervical spine immobilization and that the clinically significant between-group change in mean IDS score would be 2.0. With an expected standard deviation of 2.25 from the previous study [7], 29 patients per study group were required for an experimental study design of four equal-sized groups with 80 % power and $\alpha = 5\%$. We therefore decided to enroll 30 patients in each group.

Statistical analysis was carried out using Stata 11.0 (College Station, TX, USA) software. Data were presented as number (percentage), mean \pm standard deviation (SD), or median [interquartile range (IQR)], as appropriate. The quantitative data were compared among the groups using one-way analysis of variance (ANOVA)/Kruskal–Wallis followed by post hoc comparison by the Bonferroni method. The categorical data were compared among the groups using the chi-square test/Fisher exact test, and the post hoc comparison was carried out by adjusting the probabilities. Hemodynamic parameters among the groups were compared using repeated-measures ANOVA. A p value less than 0.05 was considered significant.

Results

In total, 124 patients consented to participate in the study. Four patients were excluded because of alternative intubation techniques preferred by the attending anesthesiologist. The 120 patients were randomized to undergo tracheal intubation with each laryngoscope and tracheal tube assembly under study. The demographic profile was comparable among all four groups (Table 1). A significant difference in IDS score ($p = 0.01$) was observed across the four groups (Table 2; Fig. 1). On intergroup comparison, the IDS score was comparable between Macintosh laryngoscope and C-MAC videolaryngoscope groups when using either non-styled ($p = 1.00$) or styled ETT ($p = 0.58$). When comparing the effect of stylet use with the individual laryngoscope, the scores were significantly lower in C-MAC group when used with styled ETT as compared to non-styled ETT ($p = 0.02$), whereas no difference was observed with Macintosh laryngoscope ($p = 0.64$). A significant difference in intubation difficulty was observed between the Macintosh laryngoscope with non-styled ETT and C-MAC videolaryngoscope with styled ETT ($p = 0.008$).

There was no significant difference in duration of successful intubation attempt between the Macintosh laryngoscope and C-MAC videolaryngoscope when used with non-styled ($p = 0.88$) or styled ETT ($p = 0.74$) (Table 2). Similarly, no difference was observed with the

Table 1 Demographic data of the patient population [mean \pm SD or number (%)]

Parameters	Macintosh with non-styletled ETT (n = 30)	Macintosh with styletled ETT (n = 30)	C-MAC with non-styletled ETT (n = 30)	C-MAC with styletled ETT (n = 30)
Age (years)	41 \pm 16	39 \pm 16	39 \pm 16	40 \pm 12
Sex (male), n (%)	28 (93)	26 (87)	24 (80)	25 (85)
Body mass index (kg m ⁻²)	22.0 \pm 2.4	21.6 \pm 2.1	21.6 \pm 2.7	23.1 \pm 2.6
ASA physical status				
I	25 (83.3)	21 (70)	23 (76.7)	22 (73.3)
II	5 (16.7)	9 (30)	7 (23.3)	8 (26.7)
Inter-incisor distance (cm)	4.7 \pm 0.4	4.6 \pm 0.4	4.5 \pm 0.5	4.6 \pm 0.4
Mallampati classification				
I	4 (13.3)	6 (20)	6 (20)	4 (13.3)
II	15 (50)	11 (36.7)	15 (50)	14 (46.7)
III	11 (36.7)	13 (43.3)	9 (30)	12 (40)

ETT endotracheal tube, C-MAC Macintosh blade videolaryngoscope, ASA American Society of Anesthesiologists

$p < 0.05$ is statistically significant

Table 2 Data on intubation attempts [mean \pm SD, median (range) or number (%)]

Parameters	Macintosh with non-styletled ETT (n = 30)	Macintosh with styletled ETT (n = 30)	C-MAC with non-styletled ETT (n = 30)	C-MAC with styletled ETT (n = 30)	p value
IDS score, median (IQR)	3 (2, 8)*	3 (2, 4)	4 (2, 6)*	2 (1, 3)	0.01
Intubation time (s), median (IQR)	34 (22, 70)	34 (22, 53)	52 (28, 76)*	27 (23, 31)	0.006
First attempt success	27 (90)	28 (93.3)	30 (100)	30 (100)	0.17
Number of attempts					
1	27 (90)	28 (93.3)	30 (100)	30 (100)	
2	3 (10)	2 (6.7)	0 (0)	0 (0)	0.17
Cormack–Lehane grade					
1	3 (10)*	4 (13.3)*	6 (20)	11 (36.7)	<0.001
2	9 (30)	8 (26.7)	17 (56.7)	15 (50)	
3	18 (60)	18 (60)	7 (23.3)	4 (13.3)	
Facilitated by OELM	29 (96.7)*	27 (90)	25 (83.3)	19 (63.3)	0.004
Use of bougie	12 (40)*	4 (13.3)	13 (43.3)*	1 (3.3)	<0.001
Complications, n (%)					
Upper lip trauma	3 (10)	0 (0)	1 (3.3)	0 (0)	
Tooth damage	0 (0)	0 (0)	0 (0)	0 (0)	
Soft tissue bleeding	0 (0)	2 (6.7)	0 (0)	0 (0)	0.28
Supraglottic trauma	3 (10)	1 (3.3)	2 (6.7)	2 (6.7)	
Hypoxia	0 (0)	0 (0)	0 (0)	0 (0)	

ETT endotracheal tube, C-MAC Macintosh blade videolaryngoscope, OELM optimal external laryngeal manipulation

$p < 0.05$ is statistically significant

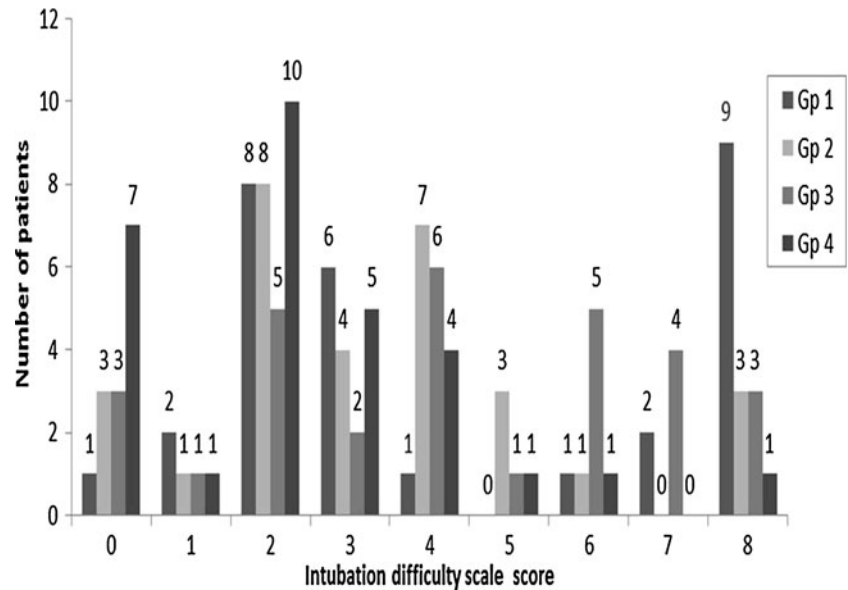
* Significantly different with C-MAC videolaryngoscope with styletled ETT

Macintosh laryngoscope when use of a styletled ETT was compared with a non-styletled ETT ($p = 1.0$). In comparison, intubation time was significantly shorter in the C-MAC group when used with a styletled ETT as compared to a non-styletled ETT ($p < 0.001$).

All patients were successfully intubated in first attempt with the C-MAC videolaryngoscope using either a

non-styletled or a styletled ETT, as compared to 90 % and 93 % with the Macintosh laryngoscope groups using non-styletled and styletled ETTs, respectively. However, there was no significant difference in the first attempt intubation success rate and number of intubation attempts between the Macintosh laryngoscope and C-MAC videolaryngoscope groups using either non-styletled or styletled ETTs (Table 2).

Fig. 1 Comparison of Intubation Difficulty Score (IDS) distributions with each laryngoscope and tracheal tube assembly. Number of patients is shown above each bar. Gp group



The CL grade on laryngoscopy was better (higher grade I/II views) with the C-MAC videolaryngoscope than with the Macintosh laryngoscope (81.7 % vs. 40 %; $p < 0.001$). Use of OELM was significantly less with the C-MAC videolaryngoscope when used with styletted ETT as compared to the Macintosh with non-styletted ETT ($p = 0.001$). None of the patients required a change in size of laryngoscope blade. Use of GEB was significantly less with C-MAC videolaryngoscope when used with styletted ETT as compared to both laryngoscopes with non-styletted ETT (Table 2).

There was no significant difference in the incidence of complications in between four groups. Similarly, there was no intergroup difference in the effects of laryngoscopy and tracheal intubation on the MBP and HR (Figs. 2, 3).

Discussion

Our study results shows that, while using similar ETT-stylet assembly, there was no significant difference between C-MAC videolaryngoscope and conventional Macintosh laryngoscope in all the outcome measures including intubation difficulty, intubation time, first attempt success rate, complications, use of airway optimization maneuvers, and adjuncts to facilitate endotracheal intubation, with the exception only of improved glottis view with the C-MAC videolaryngoscope. The addition of the stylet, however, significantly reduced the intubation difficulty, intubation time, and use of GEB with the C-MAC videolaryngoscope, although no such effect was observed with Macintosh laryngoscope.

In this study, we have used MILS as the method for cervical spine immobilization as this is the recommended and commonly applied technique. Our results showed a significant difference in intubation difficulty between two laryngoscopes while using the different ETT-stylet assembly as used in different studies [12, 13], whereas no difference was evident when use of the stylet was standardized, thus disapproving our hypothesis.

Previous studies comparing the Macintosh laryngoscope and C-MAC videolaryngoscope in manikins with cervical spine immobilized by means of hard collar and in patients with simulated difficult airway by providing MILS have demonstrated contrasting results [12, 13, 16]. McElwain and colleagues [12, 13] compared the standard Macintosh laryngoscope with a non-styletted ETT and the C-MAC videolaryngoscope with styletted ETT. C-MAC was rated as the easiest device to use in comparison to Macintosh, Glidescope, and Airtraq laryngoscopes with significantly short intubation time [12]. In patients with a simulated difficult airway, C-MAC videolaryngoscope and Macintosh performed similarly in terms of IDS scores, first attempt success rate, and overall duration of intubation attempts [13]. No explanation was offered for the difference in results. The two studies, however, differed in the number and possibly the experience of anesthesiologists performing endotracheal intubation as well as the technique of cervical immobilization used. In contrast, Wetsch et al. [16] employed a more uniform pattern for comparing various videolaryngoscopes in their manikin model. They used a semirigid stylet when the trachea was intubated using non-channeled videolaryngoscopes (Storz C-MAC), standard Macintosh laryngoscope, and McGrath videolaryngoscope.

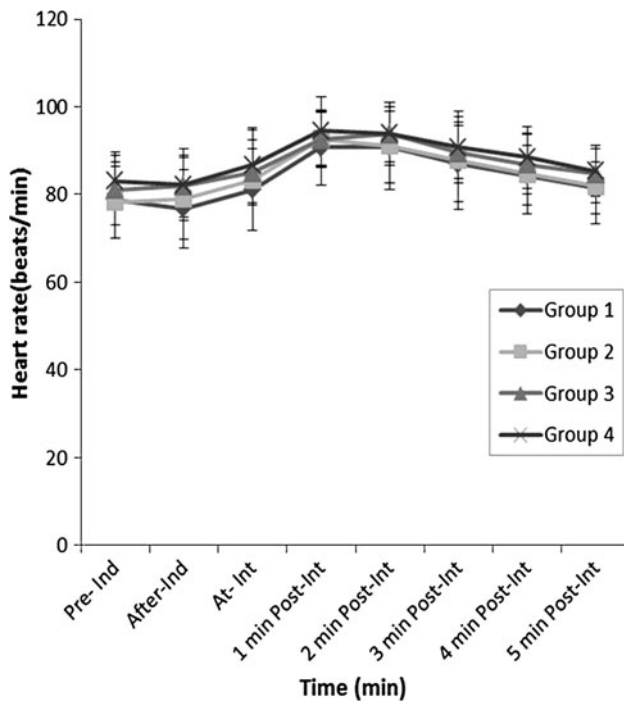


Fig. 2 Changes in heart rate after tracheal intubation with each laryngoscope and tracheal tube assembly. *Ind* induction, *Int* intubation

They observed no advantage of videolaryngoscopes over the conventional Macintosh laryngoscope, in terms of both overall success rate and intubation time. Our results seem to be in agreement more with the results of this study, while evaluating the use of two laryngoscopes with styletted ETT.

The C-MAC videolaryngoscope provided a 100 % first attempt success rate with both styletted and non-styletted ETT as compared to 90 % and 93 % with the Macintosh using non-styletted ETT and styletted ETT, respectively. Although this study is not sufficiently powered to detect a significant difference in success rates among the four intubation techniques, the finding of improved first attempt success rate with the C-MAC videolaryngoscope is consistent with other reports [12, 14, 15]. This finding holds promise for the future of videolaryngoscopes, as the greater the number of intubation attempts made, the greater is the associated morbidity, especially in patients with an injured cervical spine [24, 25].

In agreement with the results of other studies in patients with a difficult airway, we obtained a significantly better laryngoscopic view of the glottis with the C-MAC videolaryngoscope [11, 12, 14, 15]. In contrast, McElwain et al. [13] reported no difference in CL view in patients with simulated difficult airway after applying MILS.

With videolaryngoscopes, negotiating the ETT through the glottic opening may prove difficult in spite of a good laryngeal view in the absence of a direct line of sight.

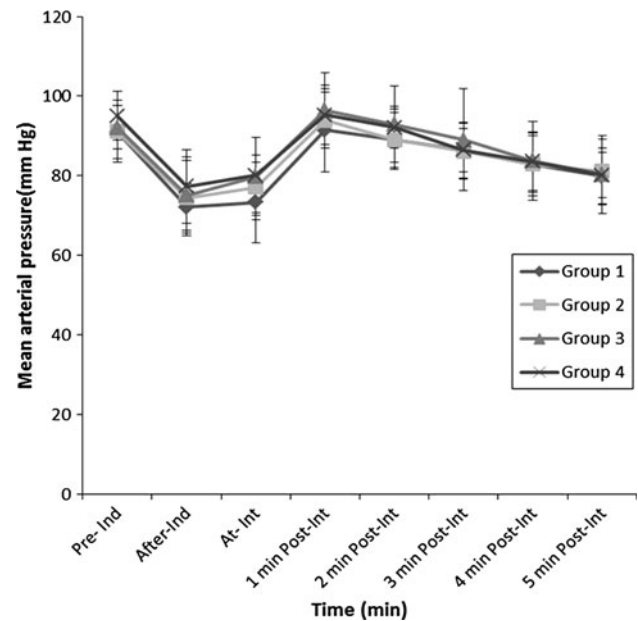


Fig. 3 Changes in mean arterial pressure after tracheal intubation with each laryngoscope and tracheal tube assembly

Hence, it is recommended to use a stylet to aid intubation while using sharp-angled, nonchanneled videolaryngoscopes such as GlideScope, McGrath, and Storz C-MAC, especially in difficult laryngoscopy scenarios [18, 26]. However, reports of oropharyngeal trauma by the use of a styletted ETT with Glidescope have led to questioning of the routine use of a stylet with other videolaryngoscopes as well [27]. The ideal shape of the stylet for the Macintosh laryngoscope is a less known entity, whereas with the C-MAC videolaryngoscope, the hockey-stick stylet configuration was found to perform best in a difficult airway scenario [28]. Levitan et al. [26] described the use of straight-to-cuff with a 35° “hockey-stick” bend-shaped stylet for both the direct Macintosh laryngoscope and C-MAC videolaryngoscope. In this study, use of a hockey-stick configuration stylet with the C-MAC videolaryngoscope significantly reduced the difficulty in intubation with no significant effect on complication rate. In contrast, no significant effect of stylet use was observed with the Macintosh laryngoscope in any of the parameters assessed. Consistent with the results of previous studies, there was no significant difference in the number of complications and the hemodynamic changes between the two laryngoscopes [13, 14].

There are certain limitations to our study. First, the study has a small sample size. Second, the use of the IDS score as a measure of intubation difficulty encountered with a videolaryngoscope is still not valid, although many recent studies evaluating the role of videolaryngoscopes in difficult airways have used the same score. There remains

a possibility of bias to the device being used, as it was not possible to blind the anesthesiologist. Moreover, laryngoscopy was performed by only two anesthesiologists and it is difficult to exclude the practitioner’s bias such as intubation skill and habit. However, most of the outcome measures were objective in nature, except the CL grading, which was a subjective measure. Furthermore, this study was carried out in elective patients with cervical myelopathy. Hence, the results of the study may not be reproduced in patients with cervical instability and in polytrauma patients with blood or secretions in oral cavity. Also, in our study we used an indirect videolaryngoscopic view, and the result might have been different if both direct and indirect views obtained by the C-MAC videolaryngoscope were used during laryngoscopy and intubation. Finally, there was lack of comparison with other videolaryngoscopes.

To conclude, the C-MAC videolaryngoscope and the conventional Macintosh laryngoscope resulted in similar levels of intubation difficulty in patients with cervical spine immobilization when used with a similar ETT-stylet assembly. The addition of the stylet, however, significantly reduced the intubation difficulty experienced with the C-MAC videolaryngoscope and hence should be routinely used in such difficult intubation scenarios.

Appendix

See Table 3.

Table 3 Intubation Difficulty Scale (IDS) Score [22]

Parameter	Score
Number of attempts >1	N_1
Number of operators >1	N_2
Number of alternative techniques	N_3
Cormack–Lehane (CL) grade 1	N_4
Lifting force required	
Normal	$N_5 = 0$
Increased	$N_5 = 1$
Laryngeal pressure	
Not applied	$N_6 = 0$
Applied	$N_6 = 1$
Vocal cord mobility	
Abduction	$N_7 = 0$
Adduction	$N_7 = 1$
Total IDS = sum of scores	N_1-N_7

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