Scope
Volume 14 Number 03 September 2024

A Randomised Controlled Study Comparing the Efficacy of Video - Laryngoscope Versus Direct Laryngoscope with Macintosh Blade in Patients Undergoing General Anesthesia

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Abstract:
Proficiency of use of video laryngoscopes in patients with a normal airway can help us put it use in the emergency. We compared one such Macintosh style video laryngoscope (manufactured by Anesthetics India Pvt. Ltd.) with a direct laryngoscope. After obtaining an informed written consent, the subjects were randomly allocated to one of the two groups. Patients in Group L underwent a direct laryngoscopy with Macintosh Laryngoscope whereas patients in Group K underwent video laryngoscopy, followed by stylet - assisted endotracheal intubation in both the groups.The primary outcome measures were assessment of grade of glottic view using modified Cormack Lehane and POGO Scoring and time to intubation. **Results**: Demographic variables and pre-operative airway assessment parameters were comparable between the two groups. The p- value of modified Cormack Lehane grading comparing the two groups is 0.331. The mean time to intubation was 42.39 seconds in Group L and 39.39 seconds in Group K with a p value of 0.587. There was no significant difference in of number of intubation attempts, stress response to intubation, incidence of optimization maneuvers required to intubate and complications between the two groups. **Conclusion:** There is no significant difference in time to intubation, glottic view and incidence of complications between the Macintosh type videolaryngoscopy and direct Laryngoscopy in patients with no anticipated difficult airway and when performed by trained anaesthesia personnel.

Keywords: video-laryngoscope, direct laryngoscopy, difficult airway, elective, emergency, training, general anesthesia.

Introduction

Endotracheal intubation is a lifesaving skill for securing the airway in the ICU and operation theater. With the advancement in surgical procedures and increasing life expectancy, there is an increasing incidence of patients presenting with more number of co-morbidities and difficult airway who are coming in for surgery.

Direct Laryngoscopes have been used as the gold standard for endotracheal intubation and is a well- practiced skill among anesthesiologists. It is a simple, cost- effective instrument with lesser probability of technical glitches and easier to trouble-shoot in case of a failure, when compared to the Video-laryngoscopes. The direct laryngoscope can be used in even in situations where there are excessive airway secretions or bleeding, which may not be the case in Video-laryngoscopes.

Although the direct laryngoscope may seem to be an ideal instrument, it is not without disadvantages. The alignment of the oro-pharngeal and laryngeal axis is mandatory in the direct laryngoscope. It requires several maneuvers such as head extension, neck flexion and application external laryngeal pressure sometimes. This may not be possible situations like cervical spine injury (5),(6) and is more stressful for patients. Direct laryngoscopy requires greater pressure for viewing the glottis and the tip of laryngoscope sits in the valecula. This is not the case of video laryngoscope as a good glottis view may be obtained without introducing the scope as deep as in the case of direct laryngoscopy. Thus there is less stress response with a video laryngoscope. In case of unanticipated difficult airway, video-laryngoscopes have been proven to have a higher success rate(2). Thus video-laryngoscopes have the potential to make the practice of anesthesia safer and more stress- free. Additionally, they can also be used as an educational tool(9) and serve as an electronic mode of documenting the process of intubation.

Video laryngoscopes are becoming the standard of care in several institutions, which routinely provide treatment for patients with difficult airway(3)(4). The incidence of difficult laryngoscopy and intubation in Indian population is around 9.7% and 4.5% respectively (1).Hence, proficiency of use of video laryngoscopes in patients with a normal airway can help us put it use in the emergency situations , where it can be life-saving(7) .

In spite of being a relatively new technology, video- laryngoscopes have rapidly gaining importance worldwide (8). Affordable and cost- effective video laryngoscopes like the video laryngoscope by Anesthetics India Private Ltd. are being introduced. Currently, there has been no studies on the device proposed in this study.

Materials and Methods:
Design: A randomized controlled trial.

Total number of study subjects:
The sample size is based on time to intubation, as reported in a similar study by Reena et al (10) .The sample includes patients in the age group of 18 – 50 years. The study reported an average variance estimate of 12.5² seconds, with a 90% power and an error of 1%. To detect a difference of 28% in time for intubation, an estimated sample size were 35 per group. Expecting a non - compliance, the final sample size is 35 + 5, which is equal to 40 in each group. The sample size was calculated using OpenEpi version 3.01

Mode of selection:
After approval from the central ethical committee, an informed written consent was obtained from all patients before including them in the study. The subjects for the 2 groups were chosen using block randomization technique, with a block size of 4.
Anesthetists who have a minimum experience of 100 intubations with Macintosh blade and 30 intubations with video laryngoscope performed the laryngoscopy.
Group L: Patients underwent a direct laryngoscopy with Macintosh Laryngoscope. The Cormack – Lehane Grading and POGO scoring in sniffing position were assessed. This werefollowed by stylet- assisted endotracheal intubation.
Group K: Patients underwent video laryngoscopy (by Anesthetics India Private Ltd.) with Videolaryngoscope. Endotracheal intubation assisted by a stylet was done after assessing the Cormack – Lehane Grading and POGO scoring in sniffing position.

Primary objectives :

1. Glottic view (using Modified Cormack – Lehane Grading and POGO scoring.)
2. Time for intubation in seconds

Secondary objectives :

1. Number of intubation attempts
2. Stress response to intubation
3. Optimization maneuver required to intubate
4. Complications such as mucosal trauma and bleeding

Inclusion Criteria:

1. Adults aged between 18 to 50 years,
2. ASA grade I and II planned for General Anesthesia

Exclusion Criteria:

3. Patient refusal
4. Patients with modified Mallampatti scoring of Grade 3 and 4
5. Patients with restricted neck mobility
6. Patients with decreased inter- incisor gap (18 mm-30 mm)

All patients underwent a through pre- operative evaluation. A detailed medical history was elicited and a general physical examination and airway examination was conducted. Necessary investigations were sent and reviewed.

All patients were kept nil per oral (NPO) for 8hrs prior to the surgery. They were pre-medicated with Tab Ranitidine 150mg at night on the day before surgery and also at 6:00am in the morning of the surgery and Tab Alprazolam 0.5mg in the night before surgery.

On the day of surgery, procedure was explained to the participants and a written informed consent was obtained from each participant. Intravenous access were secured and infusion of Ringer's lactate solutions were started. Patients will then be shifted to the operating room after which routine noninvasive monitors were applied and vital signs were monitored. The patients were pre-oxygenated for three minutes and Inj. Glycopyrrolate 0.2mg, Inj Fentanyl 2mcg/kg and Inj. Lignocaine 60mg i.v. were given as premedicants. The patients were simultaneously preloaded with Ringer lactate at 15ml/kg. The patients were induced with Inj. Propofol 2mg/kg. After confirmation of adequate mask ventilation, Inj. Vecuronium 0.1mg/kg were given to facilitate mask ventilation. Then patients were randomly allocated into two groups.

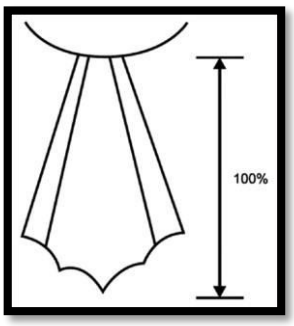
Patients then underwent laryngoscopy with either the Macintosh Blade laryngoscope or Video-laryngoscope according to the study allocation to assess the Cormack – Lehane Grading and POGO scoring in sniffing position[8]. This was followed by endotracheal intubation with a styleted tube. Correct placement of the tube was confirmed with the appearance of the capnography waveform.

Modified Cormack Lehane Grading:

Original Cormack-Lehane system	I Full view of the glottis	II Partial view of the glottis or arytenoids		III Only epiglottis visible	IV Neither glottis nor epiglottis visible
View at laryngoscopy					
Modified system Cormack-Lehane	I As for original Cormack-Lehane above	IIa Partial view of the glottis	IIb Arytenoids or posterior part of the vocal cords only just visible	III As for original Cormack-Lehane above	IV As for original Cormack-Lehane above

POGO Scoring (Percentage of Glottic opening)

A POGO score of 100 denotes visualization of the whole glottis form the anterior commissure of the vocal cords to the inter-arytenoid notch posteriorly. A POGO score of 0 indicates that no glottic structures are visible.



The heart rate, blood pressure, oxygen saturation and ECG were recorded before induction of anesthesia, before the first laryngoscopy, before the second laryngoscopy, immediately after intubation and at 1, 3 and 5 minutes post- intubation

The primary outcome measures were assessment of the grade of glottis view and time to intubation.
Secondary outcome measures included number of intubation attempts, stress response to intubation, optimization measures required to intubate and complications such as mucosal injury and bleeding.

Attempts at intubation were halted and mask ventilation were commenced if oxygen saturation dropped to 90%. A maximum of two attempts were made at intubating the patient. If the patient was not intubated within two attempts, it was declared as a “failed intubation” and was managed according to the ASA Difficult Airway Algorithm [2].

Results

Statistical methods:

Null Hypothesis: There is no significant difference in the mean value between two groups i.e. $\mu_1=\mu_2$

Alternate Hypothesis: There is a significant difference in the mean value between two groups i.e. $\mu_1\neq\mu_2$

Level of Significance: $\alpha=0.05$

Statistical test used: t- test

Decision Criterion: We compare the P-Value with the level of significance. If $P<0.05$, we reject the null hypothesis and accept the alternate hypothesis. If $P\geq0.05$, we accept the null hypothesis.

The demographic variables such as age, height , weight, and BMI were comparable between the two groups, so was the ASA grading and pre-operative airway assessment parameters.

Gender distribution:

Group	Male		Female	
	n	%	n	%
Group K	25	48%	24	65%
Group L	27	52%	13	35%
Total	**52**	**100%**	**37**	**100%**

Distribution of age group:

Group	Group K		Group L	
	n	%	n	%
≤ 30 yrs	14	29%	9	23%
31-40 yrs	11	22%	11	28%
41-50 yrs	10	20%	13	33%
>50 yrs	14	29%	7	18%
Total	**49**	**100%**	**40**	**100%**

Comparison of age, height, weight and BMI between 2 groups

Parameter	Group	n	Mean	Std Dev	SE of Mean	Mean Difference	t	P-Value
Age (yrs)	Group K	49	41.88	15.39	2.20	1.378	0.446	0.657
	Group L	40	40.50	13.30	2.10			
Weight (kgs)	Group K	49	68.43	20.04	2.86	0.404	0.112	0.911
	Group L	40	68.03	12.02	1.90			
Height (mts)	Group K	49	1.60	0.07	0.01	-0.026	-1.545	0.126
	Group L	40	1.63	0.09	0.01			
BMI	Group K	49	26.50	6.91	0.99	0.837	0.672	0.504
	Group L	40	25.66	4.18	0.66			

Association between ASA and the groups: (Chi-squared test)

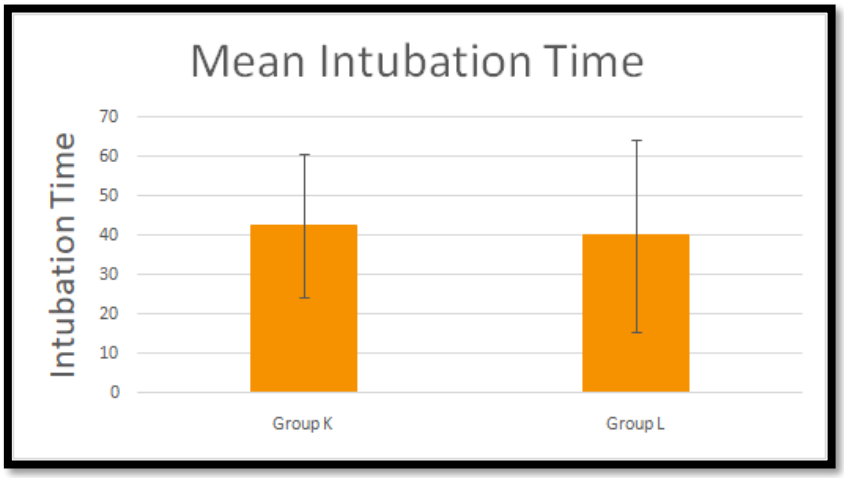
ASA	Group K		Group L		χ^2	P-Value
	n	%	n	%		
Grade 1	14	29%	9	23%	2.413	0.419
Grade 2	11	22%	11	28%		
Grade 3	10	20%	13	33%		
Grade 4	14	29%	7	18%		
Total	**49**	**100%**	**40**	**100%**		

Association between presence/absence of Difficult airway in the two groups:

Parameter		Group K		Group L		χ^2	P-Value
		n	%	n	%		
Neck Movement	Absent	49	100%	40	100%	---	---
	Present	0	0%	0	0%		
	Total	**49**	**100%**	**40**	**100%**		
Inter Incisor Gap	Absent	49	100%	40	100%	---	---
	Present	0	0%	0	0%		
	Total	**49**	**100%**	**40**	**100%**		
Dentures/Loose teeth	Absent	49	100%	40	100%	---	---
	Present	0	0%	0	0%		
	Total	**49**	**100%**	**40**	**100%**		
Thyromental Distance	Absent	49	100%	40	100%	---	---
	Present	0	0%	0	0%		
	Total	**49**	**100%**	**40**	**100%**		
Difficult Airway	Absent	49	100%	40	100%	---	---
	Present	0	0%	0	0%		
	Total	**49**	**100%**	**40**	**100%**		

Parameter	Group	n	Mean	Std Dev	SE of Mean	Mean Difference	t	P-Value
Mallampatti Score	Group K	49	1.78	0.42	0.06	0.026	0.263	0.793
	Group L	40	1.75	0.49	0.08			

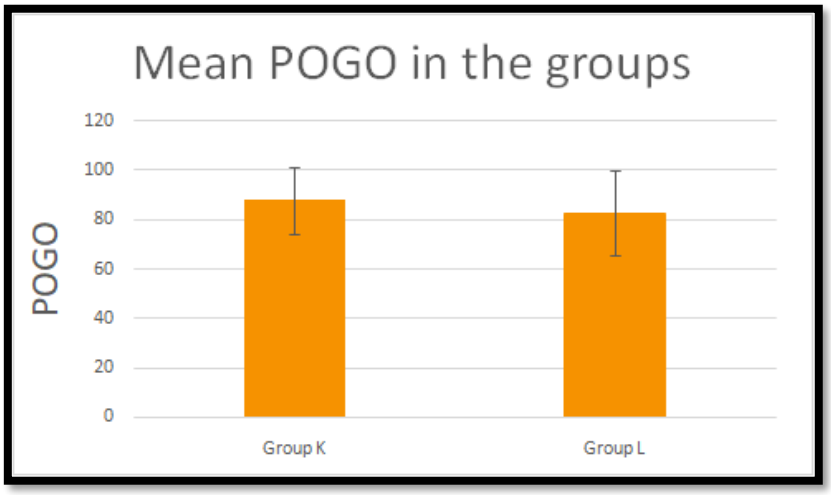
Figure1:The mean time to intubation was 42.39 seconds in Group L and 39.39 seconds in Group K with a p value of 0.587.



Modified Cormack Lehane grading was compared using the Chi- square test and p - value was 0.331.

ASA	Group K		Group L		χ^2	P-Value
	n	%	n	%		
Grade 1	14	29%	9	23%	2.413	0.419
Grade 2	11	22%	11	28%		
Grade 3	10	20%	13	33%		
Grade 4	14	29%	7	18%		
Total	**49**	**100%**	**40**	**100%**		

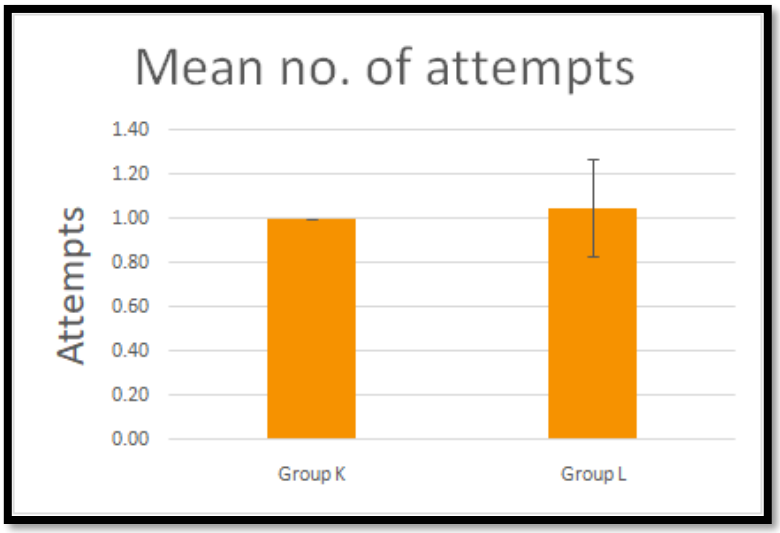
Figure 2:The POGO scoring was compared using the t - test and the p - value was 0.111.



Use of Optimization Maneuvers

Optimization	Group K		Group L		χ^2	P-Value
	n	%	n	%		
Yes	10	20%	14	35%	2.381	0.123
No	39	80%	26	65%		
Total	**49**	**100%**	**40**	**100%**		

Figure 3: There was no difference in the mean number of attempts to intubation



There was no significant difference in of time to intubation, glottic view, number of intubation attempts and incidence of optimization maneuvers required to intubate and complications between the two groups.

Discussion

Tracheal intubation is a frequently conducted procedure, traditionally facilitated by employing a Macintosh direct laryngoscope (DL). Nevertheless, the use of this method is linked to complications, leading to patient harm. In this process, maneuvers, and techniques such as adopting the "sniffing" position and applying external movement to the larynx, along with cricoid pressure, are employed to enhance the field of view. In contrast to this, video laryngoscopy enhances the success of intubation by improving the visualization of the glottis, particularly in situations where obtaining a clear view of the glottis is challenging.

The present randomized controlled study aimed to compare the efficacy of video laryngoscope (Group K) and direct laryngoscope with Macintosh blade (Group L) in patients underwenting general anesthesia. In this study a total of n=89 subjects were randomly divided to receive tracheal intubation using either Macintosh direct laryngoscope (n=40) or video laryngoscope n=49).

In this study, the POGO score and intubation time in Group K patients were observed to be higher, although not significantly different from Group L. Moreover, the proportion of modified Cormack Lehane grade I was higher in Group K compared to Group L, although this difference did not reach statistical significance. This indicates a trend towards a better glottic view with the video laryngoscope, but the clinical significance of this finding requires further exploration. Interestingly, a lower percentage of patients in

Group K required optimization maneuvers for intubation compared to Group L, although this difference was not statistically significant. Optimization measures were needed in a higher proportion of Group L patients, suggesting that video laryngoscopy might offer advantages in terms of ease of intubation. There were no complications in either group. These findings align with previous studies that have demonstrated the potential benefits of video laryngoscopy in improving glottic visualization and intubation success rates.

Several randomized, controlled trials have investigated the comparison between video laryngoscopy and direct laryngoscopy in patients anticipated to have airway difficulties. Meta-analyses synthesizing findings from these studies consistently demonstrate that, in contrast to direct laryngoscopy, video-laryngoscopy yields a more distinct view of the larynx, elevates the rate of successful intubation, and enhances the likelihood of achieving successful intubation on the initial attempt.(11-13)

Kaur G et al. This study compared the efficacy of McGrath MAC video laryngoscope, Truview video laryngoscope, and Macintosh laryngoscope for endotracheal intubation in patients underwenting general anesthesia. The time required for intubation was shorter in both video laryngoscope groups. In the video laryngoscope group, only Cormack-Lehane (CL) grades I and II views were observed, while the Macintosh laryngoscope group also exhibited CL III and IV views. Complications were less frequent in the video laryngoscope group, with two occurrences, compared to five complications in the Macintosh laryngoscope group. The video laryngoscope groups demonstrated superior glottic views and a lower incidence of complications among the patients.(14)

Abdallah et al. discovered that the Airtraq video laryngoscope facilitated intubation more easily compared to Macintosh laryngoscopy. The average time required for intubation was 14.18 seconds in the Macintosh laryngoscope group and 11.5 seconds in the video laryngoscope group. The study concluded that the use of a video laryngoscope not only aids in intubation but also results in fewer complications.(15)

Zhu et al. conducted a comparative study, assessing a KingVision video laryngoscope (non-channeled) against a McGrath MAC video laryngoscope and a Macintosh laryngoscope in patients experiencing difficult intubation necessitating nasotracheal intubation. Their findings indicated that the groups using video laryngoscopes exhibited a higher percentage of first intubation success, improved glottic views, and a reduced occurrence of complications compared to the Macintosh laryngoscope group.(16)

Bektaş H. et al. conducted a study to assess the efficacy of video laryngoscopy versus Macintosh laryngoscopy in adult patients scheduled for elective surgery under general anesthesia. Their findings indicated a significantly shorter mean intubation time in the video laryngoscope group compared to the Macintosh laryngoscope group. Despite a higher incidence of difficult intubation cases in the video laryngoscope group, the

evaluation of glottic views revealed a significantly lower Cormack–Lehane score. Furthermore, the video laryngoscope group demonstrated a lower number and percentage of complications related to intubation in comparison to the Macintosh laryngoscopy group.(17)

Hansel J. et al conducted a Cochrane systemic review and meta-analysis to assess the risk and benefit profile of video laryngoscope compared with direct laryngoscope in adults. They suggested that compared to a direct laryngoscope, a video laryngoscope was associated with fewer failed attempts and complications such as hypoxemia, whereas glottic views were improved.(18)

The present study did not demonstrate statistically significant differences in outcomes, as the study has been conducted in patients in whom 'Difficult Airway' was not anticipated, however, the observed trends suggest that videolaryngoscopy may have advantages in certain clinical scenarios. We acknowledge certain limitations as well, including the relatively small sample size. Future research with larger cohorts could provide more robust conclusions. Additionally, exploring the impact of operator experience and patient characteristics on the efficacy of these laryngoscopic techniques could offer valuable insights.

Conclusion

Thus, this device may be a useful tool in training novices in video-laryngoscopy. The blade of this video-laryngoscope is a Macintosh type blade. Hence, this may help the trainees to improve their direct laryngoscopy skills also(9). Along with this, it may help them in gaining proficiency with the hand - eye co-ordination required for video-laryngoscopy. The ASA (American Society of Anesthesiology) suggests video laryngoscopy as an initial approach in case of a predicted difficult airway and as an alternative approach during the second attempt at intubation in an unanticipated difficult airway(2). They can be used in cases with decreased mouth opening and restricted cervical spine movements. This skill were handy in case of a difficult airway scenario, where video-laryngoscopy has been proven to be useful (7).

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