

Comparative evaluation of intubation performances using two different barrier devices used in the COVID-19 era: A manikin based pilot study

ABSTRACT


Background and Aims: Protection of anaesthesiologists from contaminated aerosols of COVID 19 patients during endotracheal intubation has spurred the development of barrier devices like aerosol boxes and clear transparent plastic sheets and usage of videolaryngoscopes in COVID 19 patients. However, the efficiency, feasibility and difficulties faced by anaesthesiologist while performing endotracheal intubations under barrier devices require scientific validation. This manikin-based pilot study aims to assess the laryngoscopic performances of experienced anaesthesiologists under two different barrier enclosures.

Methods and Materials: 53 anaesthesiologists (14 Consultants and 39 Senior Residents) who were undergoing an airway training module as a part of preparedness for handling the COVID 19 pandemic were recruited. Using an aerosol box over a manikin, the participants attempted intubation using a Glidescope Videolaryngoscope and Macintosh laryngoscopes (GA and MA Groups). Subsequently, intubation was attempted under a transparent plastic sheet using both laryngoscopes (GP and MP groups). Time required for intubation, first pass success rates, subjective ease of intubation and the feedback obtained from the participants were recorded and analysed.

Results: Time required for accomplishing successful intubation was 38.55 ± 12.16 seconds, 26.58 ± 5.73 seconds, 46.89 ± 15.23 seconds and 37.26 ± 8.71 seconds for GA, MA, GP and MP groups respectively. Time for intubation and difficulty (VAS) was least for Macintosh group with aerosol box (MA) and maximum time was taken in Glidescope group with transparent polythene drape (GP). First attempt success rate for Glidescope groups (GP and GA) were 100% and in MA and MP group was 98% and 96% respectively. Restriction in hand movement and stylet removal were the major difficulties reported

Conclusion: Longer intubation times were observed while using Glidescope Videolaryngoscopes with either of the two barrier devices in place compared to Macintosh laryngoscopes.

Key words: COVID -19; laryngoscopes; manikin; personal protective equipment; pilot study; videolaryngoscope

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Introduction

COVID 19 disease has the propensity to infect health care workers involved in care of the patients especially during airway management. Amongst aerosol-generating procedures [Table 1], endotracheal intubations are high-risk procedures and have a propensity to generate enormous viral loads.^[1,2] Guidelines by various societies and experts have recommended the use of videolaryngoscopes to minimize contamination, as the operator's face and the patient's oral cavity are distanced.^[3,4] The GlideScope Videolaryngoscope (GVL) (Avante Health Solutions) is a common video laryngoscope which includes a video monitor, reusable laryngoscopes, video cable, and a rigid stylet. However, as videolaryngoscopes may not being universally available, direct laryngoscopy with Macintosh laryngoscope, remains the universal technique of airway management.

Various barrier devices (like plastic sheets, tents and aerosol boxes) have been advocated to prevent the spread of virus laden particles by containing the same within an enclosure^[5,6] These devices can be ergonomically restrictive due to the limited space available, affecting the anaesthesiologists' manual dexterity. These barrier devices also curb optimization manoeuvres like external laryngeal manipulation, lip traction or stylet introduction. These factors along with unfamiliarity with the device and visualization difficulties often make endotracheal intubations difficult.^[7] Although promoted for safety, the degree to which these barrier devices compromise easy and successful intubation and their limitations have not been elucidated. We conducted this unblinded, manikin-based pilot study to assess the time required for successful intubation by experienced anaesthesiologists under two different barrier enclosures namely clear plastic sheets and aerosol box. Additionally, the first pass success rates, subjective ease of performance and feedback on the impediments faced were recorded.

Table 1: Commonly Performed Airway Generating Procedures

Procedure
Endotracheal Intubation
Tracheostomy
Nebulisation
Bag and Mask Ventilation
Bronchoscopy
Non invasive ventilation
High Flow Nasal Cannula and oxygen mask
Nasal swab collection
Sputum collection
Endoscopy
Transoesophageal echocardiography
Cardiopulmonary resuscitation

Methods and Materials

The data for this study was obtained from an airway training module at our institute for enhancing preparedness during the COVID outbreak. The study protocol was approved by the Institute Ethics Committee (2020-129-IP-EXP-18 dated 30th April 2020) and was registered with the Clinical Trial Registry of India (CTRI/2020/05/024985). Inclusion criteria consisted of anaesthesiologists (both Consultants and Senior Residents) of either gender possessing greater than three-year experience who consented to participate in the study and were familiar with the usage of both GVL and Macintosh laryngoscopes. Anaesthesiologists who had previous training using these barrier devices or those who refused to participate were excluded. To estimate the sample size, intubation times between these two methods were compared and assuming detected effect size of 0.40 (for paired mean differences, medium effect size range 0.3 to 0.49), at minimum two-sided 95% confidence interval and 80% power of the study, minimum sample size of the paired groups came to be 44. (G Power version - 3.1.9.2, Düsseldorf University, Germany). Finally, by the end of this study, we recruited 53 participants.

A total of 53 trainees who underwent the training from 6th May 2020 to 30th May 2020 and who consented to have their performances evaluated and recorded anonymously for the study, were included and their data recorded.

Two anaesthesiologists conducted the training in batches of 3-4 participants per session. The manikin used was an AmbuMan W which allows the passage of 6.5 mm cuffed endotracheal tubes. The manikin's airway was lubricated with silicon spray before and cleaned after each insertion. A standard Macintosh laryngoscope and GVL were used for performing all the intubations. Amongst the barrier devices, plastic drape was a transparent sheet with prefabricated insulated slots for passage of the operator's hands (Microscope Cover, Surgiware, India). The aerosol box used was a modification of the one described by Dr Lai Hsien-yung, an anaesthesiologist from Taiwan.^[8] Our aerosol box's dimensions were 60 × 60 × 45 cm with 2 armholes in head front and one in side panel of 10 cm in diameter. To increase the protection long sleeve gloves were fixed to each hole. All participant was familiarised with the devices prior to commencement of the study.

Before testing, all participants were instructed on the correct techniques for using the video laryngoscope. The participants were not allowed to undertake any practise attempts prior to their actual attempts on the manikin.

In the scenario, the manikin was placed on a table stimulating a hospital bed with the Macintosh and the videolaryngoscope preassembled and easily accessible. In the first part of the process, the manikin was draped using a transparent plastic drape. Each participant performed endotracheal intubation using a styleted endotracheal tube, including cuff inflation, using both the laryngoscopes one after the another (two different attempts) [Figures 2 and 4]. The time required for successful intubation (calculated from the time of grasping of the laryngoscope till the first visible chest rise following ventilation with Ambu Bag) and first attempt success rates were recorded by an independent observer who was not part of the study on a predesigned proforma. The parameters obtained were recorded under the headings of Glidescope with plastic drape (GP) and Macintosh with plastic drape (MP). In a cross over manner, the same participant attempted to intubate the manikin under an aerosol box using both the laryngoscopes in two separate attempts [Figures 1 and 3]. The parameters were then recorded under the headings of Glidescope with aerosol box (GA) and Macintosh with aerosol box (MA).

The sequence of clear plastic and aerosol box was changed every second participant to avoid any learning bias of the subsequent participant. Additionally, the independent observer also recorded the answers to the following questions:

1. Cormack and Lehane (CL) grade observed (grade 1-4)
2. Level of difficulty during intubation (VAS 1-10).
3. Difficulty faced during intubation which included difficulty in visualisation, insertion of laryngoscope, endotracheal tube negotiation, stylet removal, confirmation of tube, glaring, restricted arm movement, confirmation)
4. Any specific comments.

Intubation times (which were continuous and normally distributed) were presented as mean \pm SD and were compared amongst four study methods (GA, GP, MA, MP) by repeated measure ANOVA. VAS scores (ordinal scale) were presented in median (with mean \pm standard deviation) and compared amongst four groups by Friedman test. Proportions amongst the repeated observations (in four groups) were compared using Cochran Q test. When results obtained from the above method were statistically significant pairwise multiple comparisons were used (using Bonferroni corrections in repeated measures ANOVA as well as Friedman test). One sample Chi-square test was used to compare the proportions. Statistical analysis was conducted using Statistical Package for Social Sciences Version-23 (SPSS-23, IBM, Chicago, USA)

Results

A total of fifty-three participants were enrolled out of which 14 were consultant anaesthesiologists (CA) and 39 were senior residents (S.R). Mean age (years) (40.28 ± 5.67 vs. 31.15 ± 2.81 , $P < 0.001$) and experience (years) (11.93 ± 2.16 vs. 4.62 ± 0.67 , $P < 0.001$) were significantly higher of the consultant as compared to senior residents [Table 2].

Time required for accomplishing successful intubation in different groups were 38.55 ± 12.16 secs, 26.58 ± 5.73 secs, 46.89 ± 15.23 secs and 37.26 ± 8.71 secs for GA, MA, GP and MP groups respectively. Repeated measures ANOVA indicated highly significant difference in the Glidescope groups (GA, GP). First attempt success rates were similar for Glidescope groups (GP and GA = 100%) and Macintosh groups (MA-98% and MP-96%). Although, CL grades of either 1 or II was universally observed, Cochran Q test revealed highly significant difference in CL grades amongst senior residents ($P = 0.009$) as well as when the total participants were compared (consultant and senior residents) ($P = 0.029$). Multiple comparisons showed that proportion of grade 1 was significantly different in GA and MA (amongst senior residents) and in between MA and MP (total participants) [Table 3].

Friedman test was used to compare the VAS score amongst consultants ($P = 0.01$), senior residents ($P = 0.029$) as well as total ($P < 0.001$) between the four groups (GA, GP, MA, MP). Consultants reported significantly less difficulty (on VAS scale) in the Glidescope groups (GA and GP) [Table 3].

Participants reporting restriction of hand movement under the aerosol box were 13 in the MA group and 9 in the GA group. Under plastic drapes, participants reporting difficulty in hand movements were 6 and 7 in the GP and MP groups respectively. Problems in stylet removal was reported by 18 and 15 participants in the MP and GP groups respectively. Glaring, as an issue under plastic drapes was complained by 5 participants in MP group and 4 participants in the GP group respectively [Table 4].

Discussion

Transmission of COVID-19 infection occurs through contact or droplet transmission^[9] which is accentuated during aerosol generating procedures, notable amongst which are laryngoscopy and intubation.^[1,2] Various apparatuses have been designed to provide safety to the anaesthesiologists during airway procedures, however their safety as well as efficacy have to be considered in unison. Few innovations like clear plastic drapes,^[10] transparent plastic cube

Table 2: Demographic Characteristics of the Study Participants (n=53)

Variable's	Consultant Anaesthesiologists (CA) (n=14)	Senior Residents (SR) (n=39)	P
Age (in years)	40.28±5.67	31.15±2.81	<0.001
Gender (Male/ Females)	10/4 (71.4%/28.6%)	22/17 (56.4%/43.6%)	0.324
Experience (in years)	11.93±2.16	4.62±0.67	<0.001

Presented as mean±standard deviation and compared using Independent Samples t-test or Frequency (%) by Chi-square test. $P<0.05$ significant

Table 3: Comparison of Intubation Performances (n=53)

Groups	Designation	Intubation Time in Secs (Mean±SD)	First attempt success rate	CL Grade (I/II)	Difficulty VAS [Mean±SD (Median)]
GA	CA	28.36±5.34	14 (100%)	13/1	2.79±0.69 ^[3]
	SR	42.21±11.85	39 (100%)	28/11	4.26±0.94 ^[4]
	TOTAL	38.55±12.16*	53 (100%)	41/12	3.87±1.09* ^[4]
GP	CA	32.36±8.11	14 (100%)	12/2	3.2±1.06 ^[3]
	SR	52.1±13.76	39 (100%)	25/14	4.92±1.17 ^[5]
	TOTAL	46.89±15.23*	53 (100%)	37/16	4.49±1.35* ^[5]
MA	CA	26.21±4.67	14 (100%)	12/2	2.71±0.46 ^[3]
	SR	26.72±6.11	38 (97%)	20/19	3.31±1.03 ^[3]
	TOTAL	26.58±5.73	52 (98%)	32/21	3.15±0.95 ^[3]
MP	CA	35.07±9.16	14 (100%)	10/4	4.14±1.09 ^[4]
	SR	38.05±8.52	37 (95%)	1=18,2=21	3.74±1.06 ^[4]
	TOTAL	37.26±8.71	51 (96%)	1=28,2=25	3.85±1.08 ^[4]
CA		$P=0.162$	$P=0.999$	$P=0.087$	$P=0.01$ (Except 4-1, 3)
SR		$P<0.001$ (Except 1-4)	$P=0.882$	$P=0.029$ (1-3)	$P<0.001$ (Except 1-3 and 2-3,4)
TOTAL		$P<0.001$ (Except 1-4)	$P=0.514$	$P=0.009$ (3-4)	$P<0.001$ (Except 1-4)
Pairwise comparisons followed by Statistical test i.e.		Repeated Measures ANOVA	Chochran Q Test	Chochran Q Test	Friedman test

GA=Glidescope With Aerosol Box, GP=Glidescope With Polythene Drape. MA=Macintosh With Aerosol Box, MP=Macintosh With Polythene Drape. SR=Senior Resident, CA=Consultant Anaesthesiologist, CL Grade=Cormack Lehane Grade, VAS=Visual Analogue Score. $P<0.05$ significant.

Table 4: Difficulty Faced During Intubation Using Two Different Barrier Devices (n=53)

Difficulty Faced	GA (n=53)	GP (n=53)	MA (n=53)	MP (n=53)
Inserting Laryngoscope	3 (5.7) ($P<0.001$)	5 (9.5) ($P<0.001$)	6 (11.3) ($P<0.001$)	7 (13.2) ($P<0.001$)
Visualisation	2 (3.8) ($P<0.001$)	3 (5.7) ($P<0.001$)	7 (13.2) ($P<0.001$)	9 (16.9) ($P<0.001$)
Tube Negotiation	8 (15.1) ($P<0.001$)	7 (13.2) ($P<0.001$)	4 (7.6) ($P<0.001$)	6 (11.3) ($P<0.001$)
Confirmation	2 (3.8) ($P<0.001$)	1 (1.9) ($P<0.001$)	6 (11.3) ($P<0.001$)	5 (9.4) ($P<0.001$)
Stylet Removal	3 (5.7) ($P<0.001$)	15 (28.3) ($P=0.002$)	2 (3.8) ($P<0.001$)	18 (33.9) ($P=0.020$)
Restriction of arm	9 (16.9) ($P<0.001$)	6 (11.3) ($P<0.001$)	13 (24.5) ($P<0.001$)	7 (13.2) ($P<0.001$)
Glaring	1 (1.9) ($P<0.001$)	4 (7.6) ($P<0.001$)	2 (3.8) ($P<0.001$)	5 (9.4) ($P<0.001$)

Data presented as frequency (%) and compared using One sample Chi-square test. P values are given within parenthesis. GA=Glidescope With Aerosol Box, GP=Glidescope With Polythene Drape MA=Macintosh With Aerosol Box, MP=Macintosh With Polythene Drape. $P<0.05$ significant

(aerosol box),^[5] corrugated fibreboard^[11] were reported in medical literature to limit aerosolization and droplet spray during intubation. However, these modified barrier devices, owing to their unfamiliarity can result in impaired manual dexterity, faulty ergonomics, limited vision during endotracheal intubation thereby adversely affecting its success and have contamination and storage issues [Table 5].

Videolaryngoscopes, provide better glottic visualization, high first pass success rate, postural advantages, enhanced supervision and assistance, easier management of unanticipated difficult airways,^[12,13] and are recommended

to avoid placing the face of the anaesthesiologist close to the patient.^[3,4]

In our study, time required for intubation in aerosol box groups (both Glidescope or Macintosh laryngoscope) was lower compared to the transparent sheet groups. [38.55 ± 12.16 sec (GA) and 26.58 ± 5.73 sec (MA) versus 46.89 ± 15.23 sec (GP) and 37.26 ± 8.71 sec (MP)]. A previous study comparing intubation times between Macintosh and Glidescope laryngoscopes in manikins with normal airways showed a median intubation time of 23 seconds and 31 seconds respectively.^[14] Extended duration could be attributed to the ergonomic limitations,

Table 5: Relative advantages and disadvantages of barrier devices used in the study

Advantages of barrier devices	Disadvantages of barrier devices
Additional safety for the clinician while performing endotracheal intubation if used along with PPE	Restriction during inserting the laryngoscope and glottic visualisation
Provides certain amount of safety in case of breach of PPE or inadequate PPE of the clinician performing endotracheal intubation	Difficulty in negotiating the endotracheal tube, stylet removal
Prevents exposure to other health care workers in the operation theatres/ICU's during the performance of endotracheal intubation	Glaring can impede vision
Can prevent aerosol generation during the process of extubation too	Claustrophobia for susceptible individuals
	Decontamination issues and source of infection in case of inadequate decontamination
	Additional procedures like central venous catheterisation becomes complicated
	Storage and transportation



Figure 1: Simulated intubation under aerosol box using videolaryngoscope



Figure 2: Simulated intubation under transparent plastic sheet using videolaryngoscope



Figure 3: Simulated intubation under aerosol box using Macintosh laryngoscope



Figure 4: Simulated intubation under transparent plastic sheet using Macintosh laryngoscope

unfamiliar equipment visualization difficulties and limitation of manual dexterity under the barrier devices, observed more under transparent sheets.

Time required for intubation was less for Consultants as compared to Senior Residents while using Glidescope in both groups (GA, GP). Reason could be due to difference in the experience levels in use of videolaryngoscopes as they are not ubiquitously available during residency training. Notably, the

time required for intubation using Macintosh laryngoscope was similar between the two groups which can be attributed to greater familiarity of using it.

Barriers place the patients at an increased risk and are known to be kinaesthetic challenges and increase intubation times.^[15] Previous study by Scroeder *et al.* had revealed that while wearing personal protective equipment (PPE), the time to tracheal intubation using Macintosh was 31.7 ± 16.3 seconds

and 35.4 ± 21.6 seconds while using Glidescope.^[16] It was seen that anaesthetists with lesser experience performed intubation more slowly with the Glidescope than with the Macintosh laryngoscopes. The unfamiliarity with the technique overshadowed the excellent monitor view increasing the technical difficulty during intubation.^[16]

First attempt success rate for Glidescope groups (GA and GP) were 100% and 98% in MA and 96% in MP groups respectively. Video laryngoscopy resulted in higher first attempt and overall intubation success rates and improved the grades of laryngoscopic views. In a previous study to evaluate the resident's learning curves for direct laryngoscopy (DL) and GVL, the authors reported that although there was no improvement in the first pass success with the use of DL, substantial improvement was observed with GVL.^[17] Similarly, videolaryngoscopy improves the first pass success rates during ICU intubations compared to DL by improving laryngoscopic views and reducing oesophageal intubations.^[18]

Highest level of difficulty (VAS) to achieve successful intubation was observed in the GP group as manipulating the laryngoscope and styleted tube under the drape was problematic. Stylet removal was problematic under plastic drape and 18 participants encountered difficulty in MP group and 15 in GP group. Although Brown *et al.*^[6] proposed the removal of clear drapes during mid laryngoscopy to ameliorate difficulties with intubation, elimination of the barrier sheet defeats its purpose, and may further aerosolize viral particles when removed emergently. Glaring was also an issue under plastic drapes for 5 participants in MP and 4 in GP groups.

Feedback of the participants revealed that arm movement restriction was the commonest difficulty. 13 participants in MA group and 9 in the GA group reported it. Movement restriction was less under plastic drapes (7 in MP group and 6 in GP group). This supports the observations of Brown *et al.* where they postulated that the rigid arm openings of the aerosol box, restricted the insertion angle and superior-caudal adjustments with the laryngoscope making the intubation environment unsuitable. However, the mobility of the plastic containment setup allowed greater arm movement while allowing the assistant to perform tasks through the drape's exterior.^[19] Stylet removal was another problem encountered by 3 participants in the MA group.

Aerosol boxes are heavy and bulky and are difficult to carry, position or reposition during emergencies.^[20] Emergency situations may require quick, additional manipulations and rescue mask ventilation between intubation attempts. Despite

dimensional modifications, they increase intubation times when used by experienced airway specialists.^[21] Modified technique, unfamiliar equipment, fear of contamination and infection can all add up and affect the airway manager's performance.^[7] The aerosol box also introduces a contaminated device that must be properly handled during use and disinfected to prevent cross-contamination. The box probably redirects droplets and aerosols toward the foot of the bed, and all staff in the room become exposed to them.^[22] Plastic drape has the advantage of being inexpensive, flexible, and disposable. It allows increased manoeuvrability, adequate visualization, has multiple access points for assistance and simultaneously protects the health care providers staff.^[22] However, the weight of the plastic drape on anaesthesiologists hands might be an issue when performing airway procedures. The proximity of the plastic drape to the patient's face might not be tolerated by some patients.^[6]

The study has certain limitations. Primarily it was an unblinded study. Our study was concerned with just the process of intubation, however other airway procedures like bag and mask ventilation, supraglottic airway device insertion, tracheostomy and fibreoptic intubation were not considered. Complicated clinical scenarios with secretions, blood or vomitus could not be assessed. Similarly, the feasibility of using these barrier devices in difficult airway cases and the agitated patient also needs to be studied. Since variations may exist in the designs and dimensions of the barrier devices, as well as the patient characteristics the universal generalizability of the findings is questionable. If needed to be removed urgently, then the time required for the same, associated exposures and any damage to PPE were not studied. The intubation parameters could well be influenced when the operator is wearing a PPE (which increases complexities of airway management as well as obscures vision) as well as while using different videolaryngoscopes (channelled versus non channelled). Lastly, our study included qualified anaesthesiologists well versed with airway management. Possibly non anaesthesiologists with limited airway management skills might experience greater difficulties. These can be the topic of future research.

Conclusion

In our manikin-based pilot study, the intubation times were higher using videolaryngoscopes with either of the two barrier devices in place compared to Macintosh laryngoscopes. Ergonomic challenges were faced during movement of hands and stylet removal during intubation under barrier devices. Longer time for intubation, restricted hand mobility and difficulty in manoeuvrability are the

compromises which are needed to be made for the safety afforded by these devices.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient (s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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