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Original Article

Anaesthesia Section

Comparison between Direct Laryngoscopy with and without Aerosol Box for Intubation in Patients undergoing General Anaesthesia during COVID-19 Pandemic- A Randomised Controlled Study

KRUPA P PATEL[1], ASHISH P JAIN[2], VAIDEHI J MEHTA[3], HETAL A PARIKH[4], CHINAR N PATEL[5]

ABSTRACT

Introduction: The airway management of patients with COVID-19 is a high risk task for anaesthesiologists. Several innovations have been born as a result of this problem, including aerosol boxes and clear plastic sheets.

Aim: To compare the timing and attempt of direct laryngoscopy with and without aerosol box for intubation in patients undergoing general anaesthesia during the COVID-19 pandemic.

Materials and Methods: This was a randomised controlled study was conducted in Parul Sevashram Hospital, Parul University, Vadodara, Gujrat, India from April 2021 to September 2021. A total of 50 patients were randomly divided into two equal groups as group A was intubated with an aerosol box and a macintosh laryngoscope, while group B was intubated with a clear plastic sheet and macintosh laryngoscope. With proper airway precautions and Personal Protective Equipments (PPE) comparative assessment of patients undergoing surgery in general anaesthesia was done. Time to intubate, number of attempts, ease of Endotracheal Tube (ETT) tube insertion, quality of Laryngoscopy view and Cormack Lehane scores were assessed in both the groups.

Results: The mean time for intubation was high at 29.72 seconds in group A, while it was 23.16 seconds in group B; the difference was significant. Overall, 20 out of 25 (80%) patients could be intubated in 1st attempt in group B as compared to 15 out of 25 (60%) in group A. Airway visualisation using Percentage of Glottic Opening (POGO) scoring and Cormack Lehane staging were suggestive of better visualisation in group B than group A. Difficulties encountered during intubation like laryngoscopy, glottic visualisation, arm movement restriction, ETT negotiation, and stylet removal were lesser in group A as compared to group B. The incidence of complications like sore throat and airway bleeding were lower in group B as compared to group A.

Conclusion: In the COVID-19 era, aerosol box and clear plastic sheets are effective barrier measures for airway management to prevent the anaesthesiologists from the aerosol transmission. But, airway management with clear plastic sheet is technically easier than aerosol box.

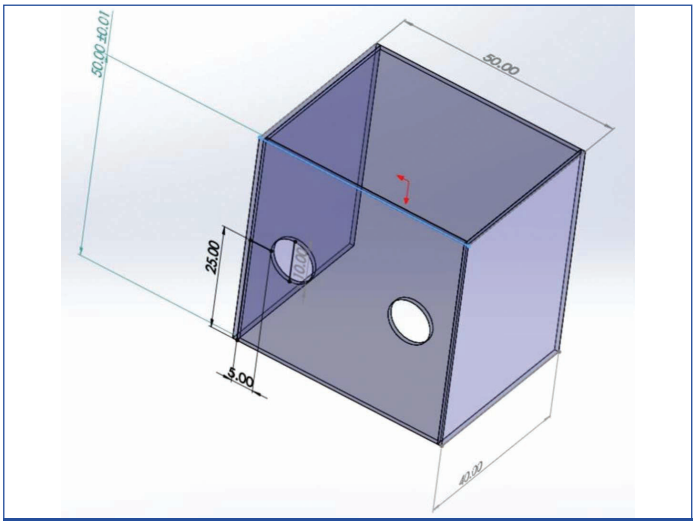
Keywords: Aerosol barrier, Coronavirus disease-2019, Endotracheal intubation, Laryngoscopes, Personal protective equipments

INTRODUCTION

In early 2020, the rapid surge of the Coronavirus pandemic 2019 (COVID-19) put anaesthesiologists at the leading edge. COVID-19 disease has a propensity to spread to the healthcare workers involved in the care of the patients, primarily during airway management [1]. The unexpected surge of patients brought about an unanticipated scarcity in protective systems needed to guard Healthcare Workers (HCWs) during intubations from a exceedingly contagious virus. Numerous innovations were born as direct requirement to tackle the problem. Among them, clear plastic sheet and the aerosol box have become quite popular within the anaesthesia community [2].

Endotracheal intubation, however, is an aerosol generating procedure and imposes a potential risk for aerosol based transmission. To reduce the aerosol exposure to the clinicians multiple protective and cost effective barriers like, plastic sheets, hoods or canopies, plastic boxes and tents have come up. These barrier devices provided another layer of protection along with Personal Protective Equipment (PPE) [3].

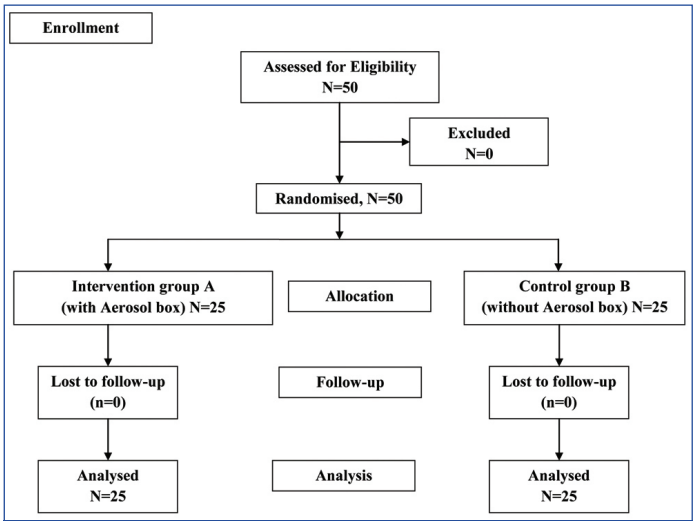
Tseng JY and Lai HY from Taiwan were first to elaborate on aerosol box [4]. The box was suggested as an additional layer of protection during endotracheal intubation, where exposure of HCWs to the virus in the form of aerosols is high. The aerosol box is a simple device and a basic version can be built with simple materials and tools [2,4] [Table/Fig-1].



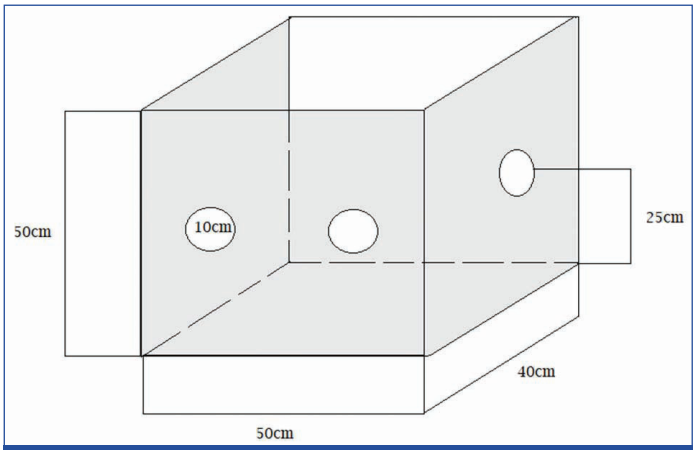
[Table/Fig-1]: Concept of Tseng JY intubation box.
Available from: https://sites.google. com/view/aerosolbox/design (opensource)

Kannaujia A et al., [1] conducted a similar study on manikin comparing two barrier enclosure methods (aerosol box and transparent sheets), whereas the current study is conducted during COVID-19 pandemic to assess the time required for successful intubation by experienced anaesthesiologists under two different

barrier enclosures namely clear plastic sheets and aerosol boxes. Additionally, the time to intubate, first pass success rate, number of attempts, quality of laryngoscopy view, ease of tube insertion and Cormack Lehane scores were assessed in both groups [Table/Fig-2,3]. At the same time, the difficulties encountered during intubation like laryngoscopy, glottic visualisation, arm movement restriction, ETT negotiation and stylet removal were studied in both the groups.



[Table/Fig-2]: CONSORT flowchart.



[Table/Fig-3]: Aerosol box- Simplified view of aerosol box used fro subjects in group A.

MATERIALS AND METHODS

This randomised controlled study was conducted in Parul Sevashram Hospital, Parul University, Vadodara, India from April 2021 to September 2021. A total of 50 patients were selected, who were admitted for elective surgery under general anaesthesia requiring endotracheal intubation. After obtaining Ethical Clearance (Ref. No: PUIECHR/PIMSR/00/081734/3104), the patients were divided randomly into two groups of 25 patients each.

Inclusion criteria: All patients requiring endotracheal intubation belonging to American Society of Anaesthesiology (ASA) grade I and II posted for elective surgeries under general anaesthesia were included in the study

Exclusion criteria: Patients with anticipated difficult airway (Malampatti class III and IV), mouth opening <2 cm, obesity with BMI >30; patient tested positive for COVID-19 (RT-PCR), history of cervical spine injury/deformity, upper respiratory tract infections, pregnant and lactating female, patient having any cardiac disease or COPD, raised intracranial and intraocular pressure.

Sample size calculation: The study records from hospital were sought for the past one year. The data related to the total number of cases requiring general anaesthesia was computed.

Data was computed as under:

$$n=\frac{z^2\times\hat{p}(1-\hat{p})}{\varepsilon^2}$$

where

z is the z score (here z=1.96)

ε is the margin of error 10%

$\hat{p}$ is the population proportion 15%

(Total 512 surgeries were conducted under GA, of which 352 qualified the inclusion criteria)

Sample size (n) was calculated at confidence level (95%), z=1.96, population proportion p=15% as 53 subjects, thus, rounding off to 50 subjects.

Study Procedure

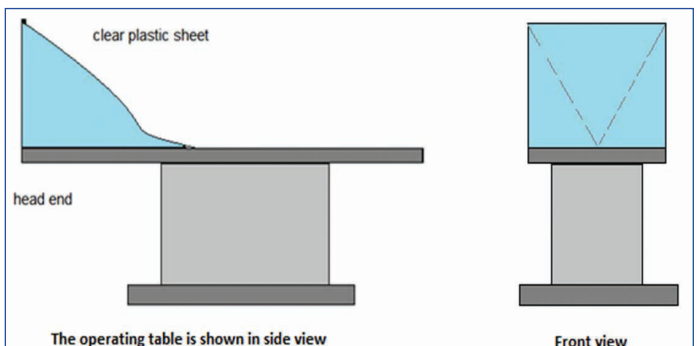
A thorough preoperative assessment and explanation of the procedure was done. Routine investigations were done and written informed consent was taken. The patient was kept nil per orally. Data was collected on predesigned proforma for the present study. In the operation theatre, an intravenous line was secured and monitors like ECG, NIBP, SpO_2 probe were applied. Baseline pulse, blood pressure, O_2 saturation and respiratory rate were recorded.

Patients were randomly divided into two equal groups by an anaesthesiologist using the sealed envelope method. Patients in group A were intubated with the aerosol box using macintosh laryngoscope patients in group B were intubated without aerosol boxes using a clear plastic sheet with macintosh laryngoscope [Table/Fig-2].

All the anaesthesiologists involved in the study wore N95 masks, PPE and face shield. After explaining to the patients the aerosol box or clear plastic sheet was kept over the patient's face. All patients were preoxygenated with 100% oxygen for five minutes. They were premedicated with i.v. Injection glycopyrrolate 4 µg/kg, Injection fentanyl 2 µg/kg, Injection ondansetron 0.1 mg/kg.

General anaesthesia was induced with intravenous injection propofol 2-3 mg/kg and injection suxamethonium 2 mg/kg. Patients in both groups were intubated in classic sniffing position with 7.5 mm (females) or 8 mm (males) cuffed endotracheal tube.

Amongst the barrier devices, in group A the aerosol box was used. The aerosol box's dimensions were 60×60×45 cm with 2 armholes in the head front and one inside panel of 10 cm in diameter. In group B, a clear plastic sheet was used, with prefabricated insulated slots for passage of the operator's hands [Table/Fig-3,4]. To increase protection, long sleeve gloves were fixed to each hole. All participants were familiarised with the devices before the commencement of the study.



[Table/Fig-4]: Clear plastic sheet- placed at the head end used for subjects in group B.

Modified rapid sequence induction technique was used to avoid mask ventilation and to reduce aerosolisation in all the patients. A consultant anaesthesiologist, with more than three years of experience, performed all intubations. After intubation, the cuff was inflated. The current placement of the endotracheal tube was

confirmed by chest rise and by the presence of $ETCO_2$. Bilateral air entry was checked and the endotracheal tube was fixed.

The following parameters were noted:

1. Time to intubate in seconds: Time to intubate was defined from the duration the laryngoscope blade is inserted till the endotracheal tube is passed through the glottis and with the confirmed trace on the capnograph.
2. Number of attempts required for successful intubation.
3. Quality of the laryngoscopy view (objectively defined as "Percentage of Glottic Opening"/POGO) and ease of intubation: The percentage of glottic opening (POGO) score for laryngeal grading [5]. The POGO score represents the distance from the anterior commissure to the inter arytenoid notch.
4. Cormack Lehane (CL) view [5].
5. Difficulty faced during intubation like during laryngoscopy, glottic visualisation, limitation of arm movement, endotracheal tube negotiation, stylet removal and fogging.

Maintenance was done with O_2, N_2O, sevoflurane inhalation and injection atracurium. After completion of the surgery, laryngoscopy and gentle suctioning was done. Neuromuscular blockade was reversed with i.v. injection glycopyrrolate 8 µg/kg and injection neostigmine 0.05 mg/kg. Patients were extubated after adequate muscle tone, the power achieved. Patients were then, shifted to the recovery room.

Failed tracheal intubation was defined as the time for intubating attempt of more than 60 seconds or oesophagal intubation. A drop in saturation to less than 92% or failure to intubate even after two attempts with direct laryngoscopy with aerosol box was considered as airway loss. Under both the circumstances, the aerosol box was removed and the patient was mask ventilated till saturation improved and intubation was attempted again without using the aerosol box [6].

STATISTICAL ANALYSIS

Statistical analysis was performed using Microsoft (MS) Excel spreadsheet. Age, weight, and gender of patients were presented as mean and Standard Deviations (mean±SD) were compared among the groups using Chi-square test. Mann-Whitney U tests were used to explore differences in non normally distributed data. Student's t-test was used to analyse the difference in mean. A p-value <0.05 was considered as statistically signifcant.

RESULTS

Demographic data (age, weight, male:female ratio) was comparable in both the groups [Table/Fig-5]. Time to intubate was significantly less in group B (23.16 sec) as compared to group A (29.72 sec). Attempting successful intubation in 1st attempt was observed in 20 patients in group B as compared to 15 patients in group A. POGO score of 0-50 was observed in five patients in group A as compared to two patients in group B . Cormack Lehane grade 1 was observed in 16 patients of group A as compared to 19 patients of group B [Table/Fig-6].

Data	Group A	Group B	p-value
Age (mean±SD)	34.4±9.3	35.44±8.9	0.23*
Weight (mean±SD)	59.28±7.98	60.68±6.10	0.18*
Gender (male/female)	10/15	13/12	0.1#

[Table/Fig-5]: Demographic data.
*Student t-test; #Chi-square test

Rate of complications like sore throat and bleeding was less in group B as compared to group A [Table/Fig-7]. Incidence of encountering technical difficulties like difficulty during laryngoscopy, poor glottic visualisation, ETT negotiation and bougie manipulation were observed to a lesser extent in group B than group A. Fogging was observed in more number of patients in group B than group A [Table/Fig-8]. Haemodynamically, patients were comparable in both the groups [Table/Fig-9].

Parameters	Group A	Group B	p-value
Time to intubate (Sec) Mean±SD	29.72±2.95	23.16±2.73	<0.05
Total number of attempts			
1st attempt	15	20	<0.05
2nd attempt	10	5	
POGO score			
0-50	5	2	<0.05
51-100	20	23	
Cormack Lehane Grading			
1	16	19	<0.05
2a	4	4	
2b	5	2	
3	0	0	
4	0	0	

[Table/Fig-6]: Observations in two groups.
*Calculated by applying Mann-Whitney's test for independent samples

Complications	Group A	Group B
Sore throat (patient interview)	3 (12%)	2 (8%)
Bleeding (observed during intubation)	2 (8%)	1 (4%)

[Table/Fig-7]: Complications in the two groups.

Variables	Group A (n=25)	Group B (n=25)
Laryngoscopy difficulty	4	2
Poor Glottic visualisation (POGO <50%)	5	2
ETT negotiation	6	1
Style/Bougie manipulation	5	2
Fogging/Glaring	1	3

[Table/Fig-8]: Technical difficulties encountered while doing Intubation in the two groups.

Vital parameters		Group A	Group B	p-value
Mean heart rate (per minute)	Baseline	83	86	>0.05
	5 min post cuff inflation	85.2	88	>0.05
Mean arterial pressure (mmHg)	Baseline	96.2	93.5	>0.05
	5 min post cuff inflation	95.7	94.6	>0.05
Mean oxygen saturation (SpO_2)%	Baseline	99	98	>0.05
	5 min post cuff inflation	99	99	>0.05

[Table/Fig-9]: Vital parameters of the patients.
Student's t-test was used to calculate p-value

DISCUSSION

Transmission of COVID-19 infection occurs through contact or droplet transmission which is increased during the aerosol-generating procedure, notable amongst which are laryngoscopy and intubation [7]. Various apparatuses have been designed to provide safety to anaesthesiologists during airway procedures. Few innovations like clean plastic sheets, aerosol box, corrugated fibreboard were reported to restrict aerosolisation and droplet spray during intubation. However, these modified barrier devices, owing to their unfamiliarity can lead to impaired manual dexterity, faulty ergonomics, limited vision during ETT intubation, thereby, adversely affecting its success and have contamination and storage issues [1].

The present study compared the time to intubate (in seconds), ease of intubation, number of attempts, POGO scoring and Cormack Lehane grading among the two groups.

Time to intubate: In the present study, time required for intubation in the aerosol box group (group A) was higher compared to the clear

sheet group (group B). In the present study, time for intubation (for aerosol box) is quite similar to the result of Kannaujia A et al., [1]. But they have found lesser intubation time with aerosol box than plastic drape while using macintosh blade, which is in contrast with the present findings. Prolonged intubation time may be due to ergonomic limitation and restriction of manual dexterity. Venketeswaran M et al., concluded that there was a non signifcant increase in time to intubate trend in patients with the use of an aerosol box. which was similar to the current study [8].

A recent study by Begley JL et al., described the significant challenges while intubating a mannequin when a barrier box was used [9]. Similarly Feldman Oren et al., also concluded in their study that , paramedics wearing PPE can successfully perform endotracheal intubation using aerosol box but the intubation time may be prolonged [10]. But Wakabayashi R et al., summarised that, the effect of an aerosol box on tracheal intubation difficulty is not clinically relevant when experienced anaesthesiologist intubated the trachea in a normal airway condition [11].

Ease of intubation: The current study concluded that intubation in a patient with a clear plastic sheet (group B) was easier than aerosol box (group A). The hand movement, tube negotiation and stylet removal was easier in group B as compared to group A. Participant's feedback in Kannaujia A et al., summarised that, the hand movement restriction was more with aerosol box but it was free with plastic drape. They also found difficulty with stylet removal in three participants with arosol box whereas five participants complained about glaring under plastic drape which is not found in the present study [1].

Brown H et al., observed that the rigid arm openings of the aerosol box restricted the insertion angle and superior caudal adjustment with the laryngoscope making the intubation environment unsuitable [12].

Many barrier devices (like plastic sheets, tents and aerosol boxes) have been used to decrease the spread of virus laden particles by containing the same within an enclosure. Such devices can be ergonomically restrictive due to the limited space available, affecting the anaesthesiologists' manual dexterity. These barrier devices also curb optimisation manoeuvres like external laryngeal manipulation, lip traction or stylet introduction. These factors along with unfamiliarity with the device and visualisation difficulties often make endotracheal intubations difficult. Although promoted for safety, the degree to which these barrier devices compromise easy and successful intubation and their limitations have not been elucidated [1].

Number of attempts: In present study, it was technically easier for the anaesthesiologists to intubate the patients without aerosol box. In the present study, the glottic visualisation was technically easier in group B than group A. In a study, the aerosol box significantly prolonged the time for successful intubation and decreased POGO score when using a direct laryngoscope [7]. Similarly Cormack Lehane grading in group B was more than in group A, suggesting better airway visualisation without aerosol box. In another study, the first attempt success was 77.8% in the DL group (direct laryngoscopy) while it was 66.7% in the Box DL group (direct laryngoscopy with aerosol box) which is similar to the present study [8]. A Canadian manikin-based simulation study reported that the meantime to intubation in a difficult airway scenario was increased with an aerosol box compared to without it (34.4 s vs 27.3 s, mean difference 7.1%) [13].

The Intubation Aerosol Containment System (IACS) with integrated sleeves and plastic drape provided an adequate protection from aerosolised particles [3]. But aerosol boxes are heavy and bulky to carry and it is also difficult to position during emergency. It makes additional manipulation and rescue mask ventilation difficult in between intubtion attempts. The aerosol box becomes contaminated after use, so it needs proper handling and sterilisation to prevent cross-infection. In contrast to this plastic sheets are cheap, disposable, provide adequate visualisation and easy to do any manoeuvre during intubation. Plastic sheets also provides multiple access points to assistant. Matava CT et al., stated that low cost clear plastic sheets significantly limit aerosolisation and it is proved by using fluroscent resin powder with UV light detection in a dark room [14].

Complications: No major side-effects were noted in either of the groups in the present study. However, the incidence of sore throat and bleeding was higher in the group A than group B.

Limitation(s)

Only intubating conditions were studied in patient with normal airway, but certain other airway procedures also need to be studied, like bag and mask ventilation, supraglottic airway device insertion, fiberoptic intubation and patients with difficult airway.

CONCLUSION(S)

In the COVID-19 era, where intubation poses a high risk of transmission to the healthcare, both clear plastic sheets and aerosol box are a definitive barrier measures for airway management to prevent the anaesthesiologists from the aerosol transmission. Though airway management with clear plastic sheet was easier than aerosol box. At the same time, difficulty arises in handling airway, ETT negotiation, stylet, bougie manipulation, glaring which may be handled better with the familiar technique of conventional intubation (without aerosol box or clear plastic sheet).

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Anaesthesiology, Parul Institute of Medical Science and Research, PIMSR, Parul University, Vadodara, Gujarat, India.
2. Assistant Professor, Department of Anaesthesiology, Parul Institute of Medical Science and Research, PIMSR, Parul University, Vadodara, Gujarat, India.
3. Associate Professor, Department of Microbiology, Parul Institute of Medical Science and Research, PIMSR, Parul University, Vadodara, Gujarat, India.
4. Professor and Head, Department of Anaesthesiology, Parul Institute of Medical Science and Research, PIMSR, Parul University, Vadodara, Gujarat, India.
5. Professor, Department of Anaesthesiology, Parul Institute of Medical Science and Research, PIMSR, Parul University, Vadodara, Gujarat, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Vaidehi J Mehta,
Flat A-501, Tower-5, Vraj-Nandan Flats, Aryakanya Road, Near Hiravanti Chamber, Karelibaug, Vadodara-390018, Gujarat, India.
E-mail : dr.aashish.jain@gmail.com

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