Original Article

Comparison of aerosol box intubation with C-MAC video laryngoscope and direct laryngoscopy–A randomised controlled trial

Address for correspondence:
Dr. Sundeep Vijayaraghavan, Department of Plastic Surgery, Amrita Institute of Medical Sciences, Amrita Vishwa Vidyapeetham, Kochi, Kerala – 682041, India.
E-mail: veesundeep@gmail.com

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Nitu Puthenveettil, Sajan Rahman, Sundeep Vijayaraghavan, Sneha Suresh, Dilesh Kadapamannil, Jerry Paul

Department of Anaesthesia and Critical Care, Department of Plastic Surgery, Amrita Institute of Medical Sciences, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India

ABSTRACT

Background and Aims: Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) is a highly infectious disease and healthcare workers are at constant risk for contracting it. Nowadays, aerosol box is used in conjunction with WHO-recommended safety kits, to avoid health workers from getting SARS-CoV-2 infection during aerosol-generating procedures. In our study, we compared the ease of oral intubation with C-MAC video laryngoscope and direct laryngoscopy, when the aerosol box was used. The secondary objectives were to compare the incidence of airway loss, haemodynamic changes, number of attempts, and time required for intubation between these two techniques. **Methods:** This prospective randomised controlled study was conducted on 60 non-coronavirus disease (COVID) patients presenting for elective surgery under general anaesthesia. Patients were randomly assigned into two groups:C and D using a computer-generated random sequence of numbers by closed envelope technique. In group D, laryngoscopy was performed with Macintosh blade and in group C, with Storz® C-MAC video laryngoscope. **Results:** The ease of intubation was better (grade 1) in group C than D (68.6% vs. 31.4% respectively) with a *P* value of < 0.001. 10% of patients required more than one intubation attempt in group D compared to none in group C, but this difference was not statistically significant. The intubation time was comparable between the two groups. There were no incidences of loss of airway or failure to intubate in both groups. **Conclusion:** The use of C-MAC video-laryngoscopy resulted in easier orotracheal intubation as compared to intubation with direct laryngoscopy when the aerosol box was used.

Key words: Aerosol, infection, intubation, laryngoscopy, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

INTRODUCTION

Severe acute respiratory syndrome-related coronavirus (SARS-CoV-2) is a disease with high infectivity and healthcare workers (HCWs) are at a constant risk of contracting it.[1] The disease is transmitted by droplet, contact and through fomites.[2] The aerosol box is nowadays used in conjunction with WHO-recommended safety kits to avoid health workers from getting SARS-CoV-2 infection during aerosol-generating procedures.[3,4] The use of videolaryngoscopes for intubation results in improved glottic visualisation.[5] We conducted a study with the hypothesis that video laryngoscopic intubation would be easier than direct laryngoscopy when aerosol box was used.The primary objective of this study was to compare the ease of oral intubation with C-MAC video laryngoscope and direct laryngoscopy, when

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the aerosol box was used. The secondary objectives were to compare the incidence of airway loss, damage to personal protection equipment (PPE) orodental damage, injury to HCW, haemodynamic changes, number of attempts and time required for intubation between the two techniques.

METHODS

After approval from the hospital ethical committee (IEC-AIMS-2020-ANES-094), Clinical Trials Registry-India clearance (CTRI/2020/07/026663) and written informed consent from patients, this prospective single-blinded randomised controlled trial was conducted in a tertiary care teaching hospital from July to September 2020 on 60 non-coronavirus disease (COVID) patients [Figure 1]. American Society of Anesthesiologists (ASA) physical status I and II patients of age group 18–60 years presenting for elective surgery under general anaesthesia with orotracheal intubation were included in this study. The study followed the principles of the 2013 Declaration of Helsinki. Patients with anticipated difficult airway (Mallampati class3 and 4, <2cm inter-incisor gap, restricted head extension, prognathism and obesity with body mass index >30) hypertension, coronary heart disease, valvular heart disease, pregnancy, raised intracranial and intraocular pressures were excluded from the study.

All patients were kept fasting, 6h for solids and 2h for clear fluids. They were premedicated with alprazolam 0.25mg and pantoprazole 40mg orally on the night before surgery. In the operating room, intravenous access was secured and baseline monitors like 5 lead electrocardiogram, non-invasive blood pressure and saturation probe were attached and haemodynamic parameters were recorded. After explaining to the patient, the aerosol box was kept at the head end of the patient.The aerosol box was a transparent box 50 × 45 × 45cm^3 in size with three elliptical openings, two for passing the anaesthesiologist's arms and one on the right side for the assistant to hand over the laryngoscope and tube. The size of the elliptical opening was 10 × 12 cm^2. The anaesthesiologist draped in PPE (disposable fluid resistant long sleeved gown, fluid resistant hood, disposable boot covers, face shield and N95 mask) passed his/her arms through the holes in the aerosol box and preoxygenated the patient for 5 min.This was a single-blinded study; only participants were

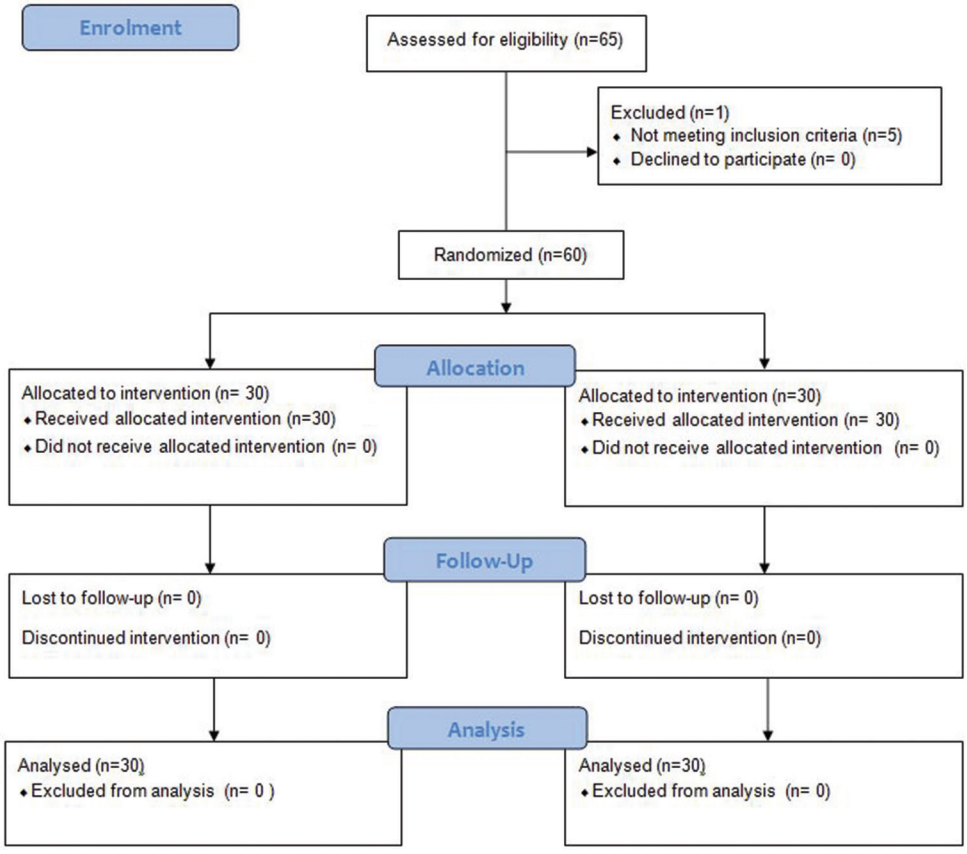

Figure 1: Consort flow diagram

blinded to the technique used. The patients were randomly allotted to either Group C or D based on a computer-generated random sequence of numbers by sequentially numbered sealed opaque envelope technique.In group C, laryngoscopy was performed with Storz® C-MAC video laryngoscope and in group D, it was performed with Macintosh blade. All intubations were performed using aerosol box. All patients underwent modified rapid sequence induction to avoid mask ventilation and to reduce aerosolisation.Cricoid pressure was not applied in both the groups.Patients were induced with intravenous fentanyl 2 μg/kg, propofol 2 mg/kg followed by suxamethonium 2 mg/kg. In group D patients, laryngoscopy was performed with Macintosh blade and in group C, it was performed with Storz® C-MAC video laryngoscope (Karl Storz-Endoscope 8403 ZX, Germany). Endotracheal tube with stylet (Rusch® Flexi-slip stylet) was used in both groups to aid in intubation. Patients in both groups were intubated in classic sniffing position with 7.5mm (females) or 8mm (males) cuffed endotracheal tube. A consultant anaesthesiologist with more than 5 years of experience performed all intubations. After intubation, the cuff was inflated. Correct placement of the endotracheal tube was confirmed by chest rise and by the presence of end-tidal capnography. Patients were then mechanically ventilated. The heart rate (HR) and mean arterial pressures (MAPs) were noted at induction (baseline), 1, 3, 5 and 15 min after intubation.

Any loss of airway, orodental injury to patient, cough response during intubation, damage to PPE or injury to HCW with the use of aerosol box was noted. In case of airway loss during procedure, patient was dropped from the study. Airway loss was defined as a drop in saturation to less than 92% or failure to intubate even after two attempts with direct laryngoscopy or C-MAC videolaryngoscopy with aerosol box. If there was desaturation during the intubation process, aerosol box was removed and patient was mask ventilated till saturation improved and intubation was attempted again without using aerosol box.In case of failure to intubate even after two attempts with direct laryngoscopy or C-MAC videolaryngoscopy with aerosol box, intubation was attempted after removing the aerosol box.

The ease of intubation was assessed as grade 1–3[6] [grade1(good): Glottis visualised adequately and intubation accomplished easily, grade2 (satisfactory): Glottis visualised adequately but required external manipulation over the larynx, grade3(poor): Glottis visualised adequately but failed to intubate in the first attempt irrespective of external manipulation]. The proportions of patients in both groups having grade 1 ease of intubation were compared. The number of attempts required, failure to intubate and time for intubation was noted. Intubation time was considered as the time from the introduction of the laryngoscope into the oral cavity to the appearance of end-tidal carbon dioxide waveform.

Based on the proportion of ease of intubation of grade 1 in group D (25%) and group C (75%) observed in a pilot study conducted with 10 patients in each group with 90% power and 95% confidence interval, the minimum sample size came to 38 (19 in each group) using the formula: $n = \{ z_{1-a/2}\sqrt{[2\bar{P}(1-\bar{P})] + z_{1-\beta}\sqrt{[P_1(1-P_1) + P_2(1-P_2)]}\}/(P_1-P_2)^2$. However, we enroled 30 patients in each group to take care of any dropouts and to decrease type 2 errors. This study was single blinded and the participant was blinded to the technique used. The recruited patients were divided into two equal groups by sequentially numbered sealed opaque envelopes. 65 patients were checked for eligibility. Five patients were excluded as they did not meet the inclusion criteria. Remaining 60 patients were randomised into two equal groups and the results were later analysed.For all the continuous variables, the results are given in mean ± standard deviation (SD) and categorical variables as a percentage. To compare the mean difference of numerical variables between groups, Student's *t*-test was applied. To obtain the association of categorical variables, the Chi-Square test was applied after testing the normality of data. A P value <0.05 was considered statistically significant. Statistical analysis was done using Statistical Package for the Social Sciences International Business Machines-(IBM SPSS) version 20.0 (SPSS Inc, Chicago, USA).

RESULTS

The study included 60 non-COVIDpatients who were randomly allocated into two equal groups [Figure 1]. Mean age, weight, sex, height, ASA physical status and Mallampati scores between the two groups were comparable [Table 1]. The ease of intubation was better (grade1) in group C than D (68.6% vs. 31.4%, respectively) and this difference was statistically significant with a P value of < 0.001 [Table 2]. Ease of endotracheal intubation was grade 1 (80% vs. 36.7%), grade2 (20% vs. 30%) and grade3 (0% vs. 33.3%) in

Table 1: Demographic Data, ASA grade and Mallampati class

Variable		Group D *n*=30	Group C *n*=30	*P*
Age in years (Mean±SD)		46.53±11.96	46.43±13.17	0.976
Weight in kg (Mean±SD)		63.70±10.01	60.67±5.75	0.156
Sex *n* (%)	Male	13 (46.42%)	15 (53.57%)	0.605
	Female	17 (53.12%)	15 (46.87%)	
ASA	1	18 (54.5%)	15 (45.5%)	0.436
Grade *n* (%)	2	12 (44.4%)	15 (55.6%)	
MP Class	1	19 (52.8%)	17 (47.2%)	0.598
n (%)	2	11 (45.8%)	13 (54.2%)	

ASA - American Society of Anesthesiologists, MP-Mallampati, SD-Standard deviation.Student's t test and Chi-square test applied. *P*<0.05 is significant

Table 2: Ease of intubation, number of attempts and intubation time

Variable and grading		Group D *n*=30	Group C *n*=30	*P*
Ease of Intubation Grade *n* (%)	1	11 (31.4%)	24 (68.6%)	0.001*
	2 and 3	19 (76%)	6 (24%)	
Number of attempts *n* (%)	1	27 (90%)	30 (0%)	0.236
	2	3 (10%)	0 (0%)	
Intubation time in sec (Mean±SD)		23.40±5.23	22.37±3.81	0.386

SD - Standard deviation. Student's *t* test and Chi-square test applied. *P** value<0.05 is significant

groups C and D, respectively [Figure 2]. The number of patients requiring more than one attempt at intubation was 10% in group D compared to none in group C. This was not statistically significant with a *P* value of 0.236. The intubation time in seconds was comparable between the two groups C and D (22.37 ± 3.81 vs. 23.40 ± 5.23 respectively, *P* of 0.386) [Table 2]. There were no cases of loss of airway or failure to intubate in both groups. Haemodynamic variables like mean arterial pressure and heart rate did not show any significant change between the two groups at any time points [Tables 3 and 4]. There was no damage to PPE, any injury to HCW or orodental injury to patient in both the groups. None of the patients coughed during the intubation process.

DISCUSSION

This study is probably the first study comparing the ease of intubation when aerosol box is used.It demonstrated that intubation was easier with C-MAC laryngoscope than with conventional laryngoscope when aerosol box was used in patients undergoing elective surgery under general anaesthesia with endotracheal intubation. There was no difference

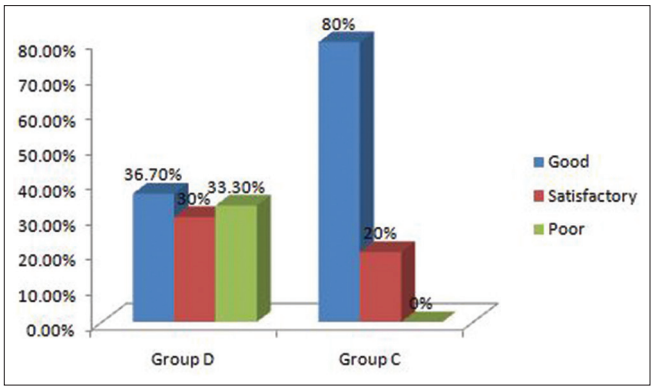

Figure 2: Comparison of ease of intubation

in the number of attempts, intubation time and haemodynamics between the two groups. None of the patients in both study groups had any airway loss or any other adverse effects associated with the use of the aerosol box. Aerosol box use was not associated with any damage to PPE, patient or HCW.

High infectivity of the virus has forced HCWs to produce novel devices such aerosol boxes to protect themselves from getting infected with coronavirus.[3,7] Anaesthesiologists involved in aerosol-generating procedures like intubation have six times increased risk of acquiring coronavirus infection than other HCWs.[8] The aerosol box was first described by Dr Lai Hsien-yung.[9] It consists of a transparent acrylic box to cover the patient's head and shoulders. It has two circular ports for the intubating arms.Several modifications of the original device have been incorporated later.[9,10] We had designed our box with a base of 50 cm so that it just fits on our operation theatre (OT) table cushion. The ports for the arm were elliptical and ergonomically placed with the left side opening larger and higher than the right.[3] But there are reports addressing concerns that the intubation box may restrict the movement of the anaesthesiologist's arms making it difficult to manoeuvre the laryngoscope.[11,12] Some authors have also raised concerns regarding damage to PPE with use of the aerosol box.[4] But we did not encounter any such incidence. Use of long surgical gloves helps to minimise the risk of arm exposure during intubation with aerosol box.

Endotracheal intubation using Macintosh laryngoscope is the most commonly performed technique in anaesthetic practice. With Macintosh laryngoscope, head extension and neck flexion are necessary to align pharyngeal and laryngeal axis.[13] This requires skill and training. Video laryngoscopes

Table 3: Comparison of mean arterial pressures between the groups

MAP (mm of Hg)	Group D *n*=30 (Mean±SD)	Group C *n*=30 (Mean±SD)	*P*
Baseline	85.30±11.63	81.27±10.84	0.170
1 min	84.93±10.62	81.50±10.39	0.211
3 min	84.87±10.28	81.33±10.00	0.183
5 min	86.27±11.70	81.03±10.65	0.075
15 min	84.33±11.36	79.57±10.47	0.096

MAP - Mean arterial pressure, SD - Standard deviation. Student's t test applied., *P* value of<0.05 is significant

Table 4: Comparison of mean heart rate between the groups

Mean HR (beats per min)	Group D *n*=30 (Mean±SD)	Group C *n*=30 (Mean±SD)	*P*
Baseline	78.23±12.57	78.33±12.01	0.975
1 min	77.70±11.19	78.63±11.19	0.748
3 min	77.13±11.36	79.47±12.55	0.454
5 min	78.45±10.45	77.70±12.75	0.807
15 min	78.63±11.52	77.80±11.75	0.782

HR - heart rate, SD - Standard deviation
Student's *t* test applied, *P* value <0.05 is significant

are known to facilitate endotracheal intubation by providing direct visualisation of the glottis.[14,15] With video laryngoscopes, lesser upward lifting force is required to view the glottis and there is no need to align the laryngopharyngeal axis. Failure to intubate, loss of airway and desaturation would force the anaesthesiologist to give positive pressure ventilation with a mask. This increases the aerosol production and risk to HCWs involved in the operating room.[16] C-MAC video laryngoscopes are reported to make intubations easier for junior anaesthesiologists, in difficult airways and in intensive care unit (ICU) intubations where intubating conditions may be compromised.[17]

The Storz® C-MAC video laryngoscope (Karl Storz-Endoscope 8403 ZX, Germany) available in our institute was selected for the study as it has a separate screen and the anaesthesiologist could remain away from the airway. Use of videolaryngoscopes with a Macintosh blade and a bougie could reduce aerosolisation further. Some centres even use disposable videolaryngoscopes for confirmed COVID cases. We did not use these disposable devices as our study group included healthy patients who were tested negative for COVID preoperatively.

Guidelines recommend the use of rapid sequence induction for intubating a coronavirus positive or suspected case.[18] All patients in this study underwent modified rapid sequence induction to avoid mask ventilation and to reduce aerosolisation. Meticulous preoxygenation with 100% oxygen for 5 min is necessary to prevent early desaturation.[16,19] Cricoid pressure was not applied as all the patients were fasting and there was no risk of aspiration. Patients were induced with fentanyl, propofol followed by high dose of suxamethonium (2 mg/kg) to avoid coughing during induction. Endotracheal tubes with stylets are used in rapid sequence intubations to aid and reduce the intubation time.[20] Stylet is also used to aid intubation with C-MAC videolaryngoscopes.[21] Hence we used endotracheal tube with stylet in both our groups. But there are concerns reported regarding the use of stylet as its removal after intubation could increase the risk of contamination.

During direct laryngoscopy, upward and forward force is applied to align the oro-pharyngeal and laryngeal axis. This requires a force of around 30–40 newton which may be associated with the haemodynamic stress response. With the use of C-MAC laryngoscopy, less force is required during intubation. In this study, we could not demonstrate any significant difference in the haemodynamic response between the two groups. This may be explained by the fact that intubation was performed by an experienced anaesthesiologist and intubation response was not very significant in both the groups.

Our study has limitations. All intubations were performed by consultant anaesthesiologists with a minimum of 5 years of experience. Hence, the obtained data may differ if less experienced anaesthesiologists were performing the procedure. Ease of intubation in the ICU settings and difficult airways was also not assessed.

CONCLUSION

The use of C-MAC video-laryngoscopy resulted in easier orotracheal intubation as compared to intubation with direct laryngoscopy when the aerosol box was used.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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