A multicentric prospective study on clear plastic drape versus acrylic box during airway management of COVID-19 patients

INTRODUCTION

Health-care workers (HCWs), especially anaesthe siologists, are at a high risk of contracting coronavirus disease (COVID)-19 as they are involved in aerosol-generating procedures (AGPs). Hence, innovations in new protective barrier enclosures are laudable.^[1]

The advisory and position statement of the Indian Society of Anaesthesiologists has mentioned important points including the use of protective barrier enclosures for airway management in COVID-19-positive/ suspected patients.^[2] The HCWs are at a higher risk risk because of the exposure to AGPs.^[3]

AGPs include intubation, extubation, cardiopulmonary resuscitation, and ventilation through supraglottic airway devices, and transmission of virus-loaded droplets can occur through a facemask, contaminated surfaces, and personnel.^[4]

Two types of barrier devices, that is, acrylic boxes and clear plastic drapes are used for protection during intubation. We decided to conduct a study to find the appropriate barrier device. This study aimed to find which technique (acrylic box or plastic drape) is better and safer for HCWs while intubating a COVID-19 patient to reduce the incidence and risk among the HCWs. The objectives were to compare the participants' opinion parameters on the protection of HCWs using the two barrier devices.

METHODS

This multicentric randomised trial was carried out at three tertiary care hospitals from July 2020 to August 2021. The trial was registered at the Clinical Trial Registry of India (CTRI/2020/08/027081) after obtaining institutional ethics committee approval (GCSMC/EC/PROJ/APPROVE/2020/155).

Inclusion criteria were patients with COVID-19 positivity confirmed by reverse transcription-

polymerase chain reaction (RT-PCR) report, approval of informed consent, age >15 years and<90 years, tachypnoea, altered sensorium/shock/convulsion, no improvement in respiratory distress, poor oxygenation (partial pressure of oxygen in arterial blood : fraction of inspired oxygen concentration $[PaO_2:FiO_2]$ ratio <150 mmHg) after 2 h of high-flow oxygen therapy or non-invasive mode ventilation, hypoxia (PaO₂ <60 mm Hg) or hypercarbia (partial pressure of carbondioxide[PaCO₂]>60 mm Hg) on arterial blood gas sampling. Exclusion criteria were limited mouth opening and airway pathology (oral, pharyngeal, laryngeal carcinoma).

Patients fulfilling these criteria were intubated and given invasive ventilation. Randomisation was done based on odd/even distribution into group A (acrylic box) and group P (plastic drape) [Figure 1]. All patients were intubated by senior skilled anaesthesiologists with more than 10 years of experience, across three centres pan India. Rapid sequence intubation was done using video laryngoscopy after giving intravenous propofol 2 mg/kg and succinvlcholine 1.5 mg/kg. All the patients were intubated.A sterile green gown over a personal protective equipment (PPE) kit was worn for every patient before intubation. During the procedure, the acrylic box was kept at the head-end to cover the torso of the patient. Similarly, the plastic drape was used in such a way that it covered the entire body from the head to the

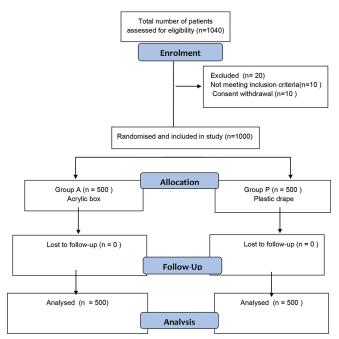


Figure 1: Consolidated standards of reporting trials (CONSORT) diagram

toe [Figure 2]. All equipment required for intubation, such as videolaryngoscope, bougie, and endotracheal tube (ET), were kept ready inside the aerosol box as per the hospital protocol. After successful intubation, the ET was clamped with artery forceps. A circuit with two heat and moisture exchange filters, one at the patient end and the other at the expiratory hose of the ventilator circuit, was attached and the patient was ventilated with controlled mandatory ventilation mode on the ventilator.

The green gown was thrown in a bucket of sodium hypochlorite. Acrylic box cleaning was done by sterillium (each 100 gm containing propan-2-ol 45.0 gm, propan-1-ol 30.0 gm, and mecetronium ethyl sulphate 0.2 gm), and a disposable plastic drape was used in each patient. An online survey in the form of a questionnaire regarding the use of barrier devices was sent to the anaesthesiologists performing the

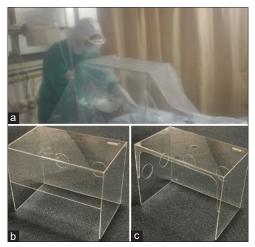


Figure 2: Acrylic box and clear plastic drape. (a): Plastic drape with a stand. (b): Plastic acrylic box front view.(c): Plastic acrylic box top view

intubation, and the responses were filled by them once they finished their first rotation of COVID-19 duty to avoid experience bias.

The questionnaire that was filled by the doctors was entitled 'acrylic box versus plastic drape technique' and included questions related to discomfort, airway device restriction, issues with the laryngoscope, difficulty in migration, circuit component disconnection, time, laryngoscope grade, attempts required for intubation, PPE breaches, assistance required, etc.

All data were collected from the Google response sheet, and statistical calculations were carried out using Microsoft Office Excel. The primary objective was to compare the barrier device technique between an acrylic box and a clear plastic drape. The secondary objective was to assess the safety parameters of HCWs as per the participant questionnaire. We used the Graph Pad Prism 6.05 (QuickCalcs) software. Variables were tested using the Z proportion test among Group A and Group P.

A *P* value of less than 0.05 was considered statistically significant and a value less than 0.0001 was highly significant. Various variables with regard to the use of different barrier devices in both groups were compared [Table 1].

RESULTS

A total of 1,000 patients were included in the study and were divided into two groups [Figure 1]. Each group consisted of 500 patients. The questionnaire was sent to 78 senior anaesthesiologists, out of whom, all responded and thus 78 anaesthesiologists were

Table 1: Comparison of acrylic box and plastic drape in terms of various variables				
Variable	Response	Acrylic box Number of respondents Number (percentage)	Plastic drape Number of respondents Number (percentage)	Z proportion value (<i>P</i>)
Discomfort felt by participant	Yes	58/78 (74.3%)	20/78 (25.64%)	6.356 (<0.0001)
	No	20/78 (25.64%)	58/78 (74.3%)	
Difficulty in migration	Yes	65/78 (83.3%)	13/78 (16.6%)	8.327 (<0.0001)
	No	13/78 (16.6%)	65/78 (83.3%)	
Circuit disconnection	Yes	68/78 (87.18%)	10/78 (12.82%)	9.287 (<0.0001)
	No	10/78 (12.82%)	68/78 (87.18%)	
Less time required for intubation	Yes	30/78 (38.46%)	48/78 (61.53%)	2.882 (0.004)
	No	48/78 (61.53%)	30/78 (38.46%)	
Laryngoscopy grade	Yes	43/78 (61.53%)	48/78 (61.53%)	0.812 (0.417)
	No	35/78 (44.87%)	30/78 (38.46%)	
Less attempts for intubation	Yes	17/78 (21.79%)	32/78 (41.02%)	0.812 (0.417)
	No	61/78 (78.20%)	46/78 (58.97%)	2.587 (0.01)

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involved in the intubation procedure. Also, 83.3% of participants faced difficulty in migration of the acrylic box versus 16.6% in the plastic drape group. 87.18 % of participants reported circuit disconnection in the acrylic box and 12.82% in the plastic drape group. 74.3% of participants faced discomfort in using the acrylic box and 25.64% of participants faced discomfort in using the plastic drape. Also, 41.02% of participants recorded less time for intubation using the plastic drape, and 21.79% of participants observed less time for intubation using the acrylic box[Table 1]. There was no statistically significant difference in the laryngoscopic view between the two groups.

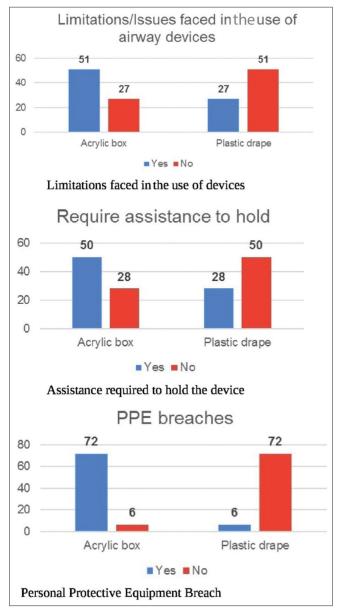


Figure 3: Limitations faced in the use of airway devices, assistance required to hold and personal protective equipment breaches

Finally, 92.30% of participants mentioned PPE breaches in an acrylic box and 7.69% in plastic drapes [Figure 3].

DISCUSSION

Coronavirus can be transmitted as droplets or through direct contact causing mild illness in 80% of patients. Fifteen percent of patients need oxygen therapy and 5% need intensive care unit management. The overall mortality is 0.5 to 3%(0.67%). Mortality is higher (13%) in patients with age >80 years^[3] As it is a new disease, airway management guidelines are being updated regularly and so are subject to change.^[2,5]

The most common and severe complication in patients with COVID-19 is an acute hypoxaemic respiratory failure or acute respiratory distress syndrome (ARDS), requiring oxygen and invasive ventilation therapy. However, in COVID-19 patients, endotracheal intubation is cumbersome due to PPE, non-availability of the latest difficult airway equipment, newer environment, anxiety, phobia and airway oedema due to disease pathology.^[6]

During the selection of a barrier device, one should consider various aspects of barrier devices such as user-friendliness, cost-effectiveness, the time required to set up the device for patient use, patient's tolerance, containment of aerosolisation^[7] and ease of access to the airway. The safety of the HCWs is of utmost importance during an AGP. Apart from negative pressure rooms, proper use of PPE, barrier enclosure devices and strict adherence to airborne precautions, the equipment used should also satisfy patient-related concerns and should be user-friendly. In the current study, a significant number of participants faced discomfort and faced limitations such as restriction of hand movements while using acrylic boxes compared to plastic drapes (*P*-value < 0.0001) [Figure 3]. Additionally, users required assistance to hold the acrylic box due to cumbersome weight and stability problems and faced difficulty in migration (P-value < 0.0001) [Figure 3, Table 1].

There are some suggestions from around the world proposing the placement of large transparent plastic sheets over patients' faces.^[8]Matava *et al*.^[8] had reported the advantages of a plastic sheet such as disposability, lower cost, and less restriction to hand movement. However, improper discarding of the plastic cover sheet can lead to cross-contamination of HCWs. In an *in-situ* simulation cross-over study, early- and late-generation aerosol boxes were used for intubation of COVID-19 patients. The study put forward several concerns and concluded that the cleaning methods are still inconclusive, leading to cross-contamination. Secondly, the hand slots limit hand movement for complicated airway procedures. Thirdly, if the patient is agitated or not cooperative, there is a risk of minor trauma to the staff.^[9] Similarly, in the present study, 78 skilled anaesthesiologists with more than 10 years of experience performed intubation on 1,000 patients. On an average, one anaesthesiologist had done 12 intubations and filled out the Google questionnaire form.

Aletreby *et al.*^[10] had done a simulation cross-over study on the impact of the aerosol box on the duration of intubation of COVID-19 patients. The authors concluded that intubation is prolonged due to the aerosol box and causes difficulty for the airway manager, which can have a negative impact on safety. Nevertheless, 30/78 (38.46%) participants recorded less time in an acrylic box for intubation and 48/78 (61.53%) participants observed less time in a plastic drape for intubation (*P*-value = 0.004) in the current study.

In a study, 50% of anaesthesiologists had discomfort and 33% had increased cognitive load using an acrylic box in a simulated intubation model.^[9] That means, a suspected difficult airway should be evaluated cautiously, and personnel should be adequately trained before the use of an acrylic box as a barrier.^[6]

In another study of 132 intubations using an aerosol box, it was reported that 109 patients were intubated at the first attempt, 19 at the second attempt and two in the third attempt. The authors concluded that there was no significant difference with respect to time to intubation among patients with Mallampati grade I to IV.^[4]

The limitations of this study are that the aerosol behaviour with barrier devices could not be studied. Due to logistic issues, the survey was conducted online and only qualitative assessment with subjective parameters could be performed.

CONCLUSION

A plastic sheet is more user-friendly compared to an acrylic box in terms of difficulty in migration, circuit disconnection and safety for HCWs. The plastic drape is superior, as fewer intubation attempts are required compared to the acrylic box. Both barrier devices have their individual pros and cons.However, future studies are required to strengthen the evidence for the concrete utility of the plastic drape and acrylic box for intubation.

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Conflicts of interest

There are no conflicts of interest.

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