Original Article

Comparative performance of two protective barriers during tracheal intubation of COVID-19 patients: A simulation cross-over study

SUMMARY

COVID-19 was declared a pandemic by the WHO in 2020. In light of the global shortage of PPE and concerns regarding the safety of healthcare providers, clinicians have resorted to the use of novel protective barriers, such as aerosol boxes and plastic sheets, during aerosol generating procedures, especially tracheal intubation. We compared the effect of these barriers on the tracheal intubation of simulated patients with severe COVID-19 in a crossover study. The study was approved by the Ethics Committee of King Faisal Specialist Hospital, and the procedures were compliant with the COVID-19 airway management guidelines of the Saudi Anesthesia Society. The time to intubation was our primary outcome. Secondary outcomes included number of optimization maneuvers, number of intubation attempts, time to glottic view and ventilation of the lungs, and damage to PPE. Thirteen consultant anesthetists performed 39 tracheal intubations on a manikin using each of three approaches (aerosol box, plastic sheet, and no-barrier). Data were collected via direct and video observation. The plastic sheet approach demonstrated the highest time to intubation (mean ± StE [95% CI]: 33.3s ± 3.5 [25.8– 40.9]) compared to the aerosol box (22.0s ± 2.5 [16.5 – 27.5], $P < 0.01$) and no-barrier approaches (16.1s ± 1.1 [13.7 – 18.4], $P < 0.0001$). Similarly, the plastic sheet approach had the highest time to glottic view, and ventilation intervals compared to the other two approaches, while the no-barrier approach had the shortest time intervals. There were no failed intubations or damage to the PPE sustained during the use of any of the three approaches. The aerosol box does not impose a significant delay in tracheal intubation using video laryngoscopy, unlike the plastic sheet barrier. Further research on the aerosolization risk is warranted before these protective barriers can be considered as mainstay approaches during aerosol generating procedures.

Key words: Aerosol box, aerosol generating procedures, coronavirus, manikin, tracheal intubation, video-laryngoscope.

Introduction

The emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-COV2) in Wuhan, China in 2019 resulted in a global health emergency, which was declared a pandemic on March 11, 2020 by the World Health Organization (WHO).[1] Safely managing an increasing number of patients with a highly transmissible infection quickly surfaced as a challenge for healthcare providers (HCPs),

Access this article online	
Website: www.saudija.org	Quick Response Code
DOI: 10.4103/sja.sja_274_21	

How to cite this article: Abolkhair AB, El-Kabbani A, Al Raffa A, AlFattani A, Norris A. Comparative performance of two protective barriers during tracheal intubation of COVID-19 patients: A simulation cross-over study. Saudi J Anaesth 2021;15;396-402.

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Submitted: 15-Apr-2021, **Revised:** 10-May-2021, **Accepted:** 01-Jun-2021, **Published:** 02-Sep-2021

especially anesthesiologists and intensivists, whose work mandates close patient-contact and performance of aerosol generating procedures (AGPs). Data suggests that these AGPs, particularly tracheal intubation and extubation, pose an increased risk of viral transmission to the HCPs, owing to their potential of generating droplets and aerosolized respiratory secretions harboring viral material, from coughing or gagging.[2]

Following strict infection control measures such as staff personnel protection, rigorous disinfection procedures, and minimizing staff during airway management, has been shown to significantly reduce the risk of transmission.[3,4] However, addressing the risk of aerosolization and spread of respiratory droplets during airway manipulation remain a concern.[5] In light of the global shortage of personal protective equipment (PPE), and concerns regarding the safety of HCPs attending to COVID-19 patients, clinicians have developed and used innovative protective barriers, such as aerosol boxes, plastic sheets, and tents, acting as adjunctive measures to PPE.[6] These techniques have been adopted with no evidence of their effectiveness as a barrier to infection or of the potential impact of their use on the process of tracheal intubation itself.[6]

Reports of experiments modelling the dispersal of material following simulated coughs indicated that these measures could reduce gross contamination of personnel and the environment by mitigating the spread of large droplets. However the validity of such models is uncertain and, evidence regarding protection of HCPs against aerosolized viral particles remains to be established.[7,8] Concerns regarding the implications of these novel protective barriers on intubation times, airway manipulation, airway emergencies, and PPE integrity, have also been raised.[6]

Two novel protective barriers have been commonly reported in the literature. The first being an "aerosol box" consisting of a solid transparent cube made out of plexiglass, designed to cover the patient's head, shoulders, and upper chest, and containing two ports intended to give way to the operator's hands for performing the airway procedure.[9] The second protective barrier consisted of a flexible and transparent plastic sheet or tent that is draped over the patient's head and chest, and taped down at the sides to minimize leak.[5,8]

In this study, we sought to compare the impact of two commonly reported protective barriers, the "aerosol box" and the "plastic sheet", on the ability to perform tracheal intubation with minimal manipulation and delay compared to standard practice. We also compared these devices in terms of their effects on PPE integrity.

Methods

Following approval from the research ethics committee of King Faisal Specialist Hospital and Research Center (KFSH and RC) (REF: C380/1114/41), we assessed the effects of three approaches (aerosol box, plastic sheet, and no-barrier) [Figures 1-3] on the tracheal intubation of simulated COVID-19 using a cross over design. The study was conducted at the simulation center of KFSH and RC. All simulated procedures complied with the COVID-19 airway management guidelines of the Saudi Anesthesia Society (SAS),[10] which were developed to ensure safe practice in dealing with affected patients.

Three simulation rooms were utilized in parallel, one for each of three approaches (aerosol box, plastic sheet, no-barrier). The procedures were performed on a standardized adult Hi-Fidelity manikin (SimMan® 3G; Laerdal Medical®, Stavanger, Norway). Mannikins were placed on a gurney raised to a consistent height from the floor. The mannikins were programmed to simulate a critically-ill patient with oxygen desaturation reaching below 90% SpO_2 in two minutes from the start of simulated induction. The neck of the manikin was stiffened, and the tongue was inflated to simulate a difficult airway with Cormack-Lehane grade 2 on the video-laryngoscope (VL) monitor.[9] Conforming to the guidelines recommending the use of a VL during the tracheal intubation of patients with COVID-19, we used a Glidescope® VL with a size 3 blade in all cases. A 7.0 mm tracheal tube (TT) with a malleable stylet and a self-inflating bag-valve-mask for pre-oxygenation were provided for all the intubations.

Vital signs including pulse oximetry and capnography, simulating time to desaturation in a critically ill patient, were displayed on an external monitor. We used a modified version of Begley *et al.*, "latest-generation aerosol box"[9] [Figure 1], that included additional two side ports for the assistant's hands and the attached plastic drape covering the patient's chest, but without the additional ports for the bougie and suction. For the "plastic sheet" barrier, we used a clear plastic drape covering the patient's head to chest and taped down at the sides of the bed to minimize leak [Figure 2].

Thirteen consultants, who were familiar with use of the video-laryngoscopy technique and performed it regularly, were recruited via an electronic message to participate in the study. Each participant performed tracheal intubation using the three approaches (aerosol box, plastic sheet, no-barrier).

Figure 1: Modified aerosol-box barrier placed on manikin

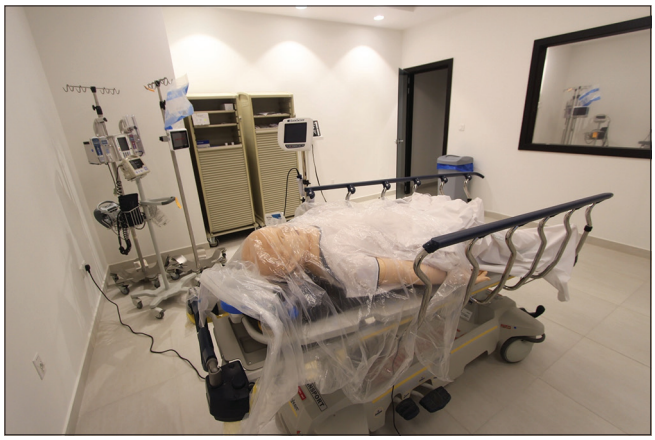

Figure 2: Plastic sheet barrier placed on manikin

Figure 3: No-barrier approach

The participants complied with the local guidelines for high-risk generating procedures of COVID-19 patients, requiring full PPE attire (surgical mask, face shields, and gowns were used in place of Power Air Purifying Respirators (PAPRs) in view of the increased demand on PPE supplies). Ten minutes of orientation to the simulation setting, instructions for the protective barriers, and a demonstration of the intubation method using video-laryngoscopy, were given for the participants. Each subject had the opportunity to test the different approaches until they achieved successful intubation of the manikin. The participants started by pre-oxygenation of the manikin with a bag-valve-mask, during which, administration of the induction and neuromuscular blocking agents were simulated. Laryngoscopy was performed one minute after the induction.

The time to intubation was our main endpoint and was defined as the elapsed time from removal of the bag-valve mask till the visualization of the tracheal tube passing the vocal cords on the video-laryngoscopy VL monitor. Additional endpoints included: number of optimization maneuvers during tracheal intubation, number of tracheal intubation attempts, time to glottic view, incidence of successful tracheal intubation, time to ventilation of the lungs, and disruption or damage to the PPE. Any readjustments to the head position or application of external laryngeal pressure were recorded as optimization maneuvers. The time to glottic view was defined as the time from the removal of the face mask until the visualization of the glottis on the VL monitor. The time to ventilation of the lungs was the time from the removal of the face mask until the tracheal tube was connected to the self-inflating bag. An assistant was present to help with handing out equipment to the participants while performing the procedure. The time intervals and other end-points were recorded on site by a study investigator equipped with an electronic stopwatch, and another observer recording the same data by video observation.

The timer was started upon removal of the face mask, and intervening times were recorded at the view of the glottis and the passing of the TT through the vocal cords. Finally, the timer was stopped at the first ventilation of the lungs. Each participant was given a total of two intubation attempts per approach. A successful-intubation attempt was recorded once tracheal intubation was achieved, whereas, a failed-intubation attempt was designated to an unsuccessful intubation (*e.g.* esophageal intubation), an intubation attempt lasting for more than 120 seconds, or removal of the VL from the oral cavity.

The required sample size that would provide a power of 80% to detect a meaningful reduction in the intubation time (15 seconds), at a significance level of 0.05 and confidence level of 95%, and a within subject design was 12 subjects. Subjects were randomly allocated using a computer generated list created by the randomization software "Random.Org"[11] to alternating three-intervention

cross-over groups with the sequences ABC, BCA, and CAB, within a period of a single day, where A would stand for the aerosol box approach, B for the sheet/tent approach, and C for the no-barrier approach.

Data of scale variables were summarized as means with standard deviations (SD) or medians with interquartile rage where appropriate. Frequencies and proportions were used to summarize categorical data. The differences of the performance between the protective barriers of intubation were assessed using analysis of variance (ANOVA). Pairwise comparison was estimated with Tukey's HSD correction. The inter-rater reliability with Kappa statistic was used to test the agreement between the two observers. The level of significance was $\alpha = 0.05$ with 95% confidence interval. Data was analyzed by the statistical software JMP®, version 15, SAS Institute Inc.

Results

Thirteen participants with a median age of 35 years performed one laryngoscopy and tracheal intubation using each of the three protective barriers (aerosol box (B), plastic sheet (S), no-barrier (N)). In total, 39 tracheal intubations were performed. The participants were consultants (11 of anesthesiology and 2 of adult emergency medicine) with a median experience of 10 years as a consultant.

We collected our data both by direct observation and remotely via video observation. There was high agreement between both observations, as demonstrated by an inter-rater reliability (IRR) of 0.95 for the "time to intubation" and "time to grade", and an IRR of 0.97 for the "time to lung ventilation", with a P value of < 0.001 for all.

Using the plastic sheet as a protective barrier during the intubation of simulated patients revealed the highest time to intubation, to glottic view, and to ventilation intervals compared to the other two approaches, while the no-barrier approach demonstrated the shortest time intervals. There were no failed intubations or damage to the PPE sustained during the use of any of the three approaches. The number of optimization maneuvers (such as application of external laryngeal pressure, or head-position readjustment) was highest during the use of the plastic sheet barrier, followed by the aerosol box, and then the no-barrier approach. The average of the two observations (direct and video visualization) of the primary and secondary outcomes for tracheal intubation of simulated patients using the three barrier approaches are presented in Table 1.

Looking at our primary endpoint, the time to intubation, there was an overall significant difference across the different barriers with a P value of < 0.001. The time to intubation with the sheet was higher compared to the no-barrier (33.3s vs 16.1s, $P < 0.001$) and the aerosol box (33.2s vs 22s, $P = 0.031$), with a significant mean difference of 17.2s (95% CI 8.5 – 26.1, $P < 0.0001$) and 11.3s (95% CI 2.5 – 20.1, $P < 0.01$), respectively. No significant difference between aerosol box and the no-barrier approach was observed in regard to the time to intubation.

Compared to using no-barrier, there was a significant increase in the time to glottic view with the sheet barrier of 10.2s (95% CI 3.0 – 17.5, P value < 0.01). No significant difference of the time to glottic view was observed between the aerosol box and the sheet barrier, or the no-barrier approach.

Lastly, the time to lung ventilation showed a significant difference of 24.2s (95% CI 14.4 – 34.0, $P < 0.0001$) between the plastic sheet and the no-barrier, as well as a significant time difference between the plastic sheet and the aerosol box, in favor of the box by 15.4s (95% CI 5.6 – 25.2, $P = 0.0014$). No significant time-to-lung-ventilation difference was observed between the aerosol box and the no barrier approach. The pairwise difference of time-intervals of primary and secondary outcomes between the three barrier approaches are presented in Table 2, and a comparison of the primary outcome between different approaches is illustrated in Figure 4.

Discussion

The COVID-19 pandemic has led many institutions to develop new protective barrier modalities for tracheal intubation of infected patients.[6] We compared the latest version aerosol box to the plastic screen design versus no barrier at all.[9,12] We believe this is the first study comparing these three modalities in a randomized crossover fashion with a simulated difficult airway.

Several modifications to the "aerosol box" have been proposed following the original concept design by the Taiwanese anesthesiologist, Dr. Lai Hsien-Yung,[12] including the incorporation of additional circular ports for an assistant as well as other equipment, and adopting a pentagon or "Igloo" configuration rather than a cube.[6,13] A recently published simulation study demonstrated higher intubation failure rates and prolonged intubation times associated with the use of two generations of "aerosol boxes", in addition to higher rates of PPE disruption.[9]

We found that using the plastic sheet as a barrier device significantly delayed times to intubation, time to epiglottic

Table 1: The Average of Primary and Secondary Outcomes of Two Observations (Direct and Video Visualization) of the Tracheal Intubation of Simulated Patients Using Three Barrier Approaches

	No-barrier (n=13)	Aerosol box (n=13)	Plastic sheet (n=13)
Time to intubation (s), mean±StE (95% CI)	16.1±1.1 (13.7 - 18.4)	22.0±2.5 (16.5 - 27.5)	33.3±3.5 (25.8- 40.9)
Time to glottic view (s), mean±StE (95% CI)	10.2±0.8 (8.5 - 11.8)	13.6±2.3 (8.7 - 18.6)	20.4±2.7 (14.4 - 26.3)
Time to ventilation (s), mean±StE (95% CI)	28.7±2.4 (23.6 - 33.9)	37.5±2.7 (31.7 - 43.3)	52.9±3.4 (45.5 - 60.3)
First-pass success, *n* (%)	13 (100%)	13 (100%)	13 (100%)
No. of optimization maneuvers, *n* (%)			
0	9 (69.2%)	5 (38.5%)	1 (7.7%)
1	4 (30.8%)	5 (38.5%)	9 (69.2%)
2	0	2 (15.4%)	1 (7.7%)
3	0	1 (7.7%)	2 (15.4%)
PPE damage, *n* (%)	0	0	0

Table 2: Pairwise Difference of Outcome Time-Intervals Between the Barrier Approaches

Pairwise Comparison	Time to intubation (s), Mean diff±StE (95% CI)	Time to glottic view (s), Mean diff±StE (95% CI)	Time to ventilation (s), Mean diff±StE (95% CI)
Sheet vs No-barrier	17.2±3.6 (8.5 - 26.1 P<0.0001	10.2±3.0 (3.0 - 17.5) P<0.01	24.2±4.0 (14.4 - 34.0) P<0.0001
Sheet vs Box	11.3±3.6 (2.5 - 20.1) P<0.01	6.8±3.0 (-0.5 - 14.0) P=0.07	15.4±4.0 (5.6 - 25.2) P<0.01
Box vs No-barrier	5.9±3.6 (-2.9 - 14.8) P=0.24	3.4±3.0 (-3.8 - 10.7) P=0.48	8.8±4.0 (-1.0 - 18.6) P=0.09

view, time to lung ventilation and time to end tidal CO2 tracing. This was most likely due to difficulty with visualizing the patients head and laryngoscope under the plastic barrier and difficulty in handling the airway equipment as well. This result differs from previous findings.[9] The number of optimization maneuvers for the plastic sheet were also significantly increased compared to the aerosol box and no barrier. This is probably due to the limited space available under the plastic barrier. We found it to be more difficult to manage the airway in this fashion compared to previous reports.[14]

There was no significant difference between the aerosol box and the no barrier station in times to intubation, time to glottic view, time to ventilation and end tidal CO2 tracing. We found no difference between the three barriers in first pass success, number of intubation attempts, and number of PPE breaches.

Recently in a letter to healthcare providers the emergency Federal Drug Administration approval for the aerosol box being used as a protective barrier was revoked.[15] This was following studies showing that protective barrier enclosures without negative pressure used during the COVID-19 pandemic may increase risk to patients and health care providers.[9,16] Their main points were: barrier enclosures may not decrease HCP exposure to airborne particles, and may make it more difficult; if using a protective barrier enclosure then addition of negative pressure is recommended; protective barrier enclosures (with or without negative pressure) should never be a replacement for using PPE.

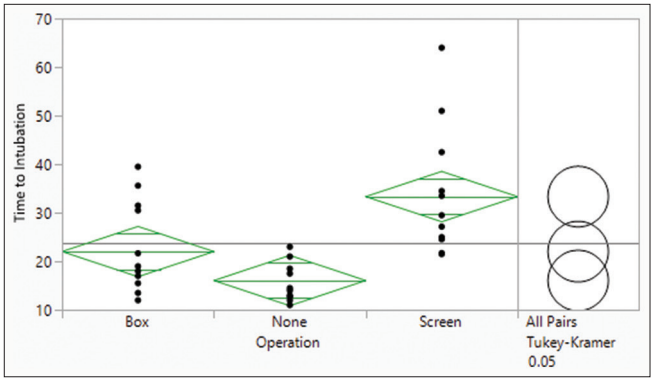

Figure 4: Comparison of the time to intubation interval across the different barrier approaches

The main limitation of this study was the small sample size and it being a manikin study. Although statistically significant, the sample size limits inferences that can be drawn on secondary outcomes. The validity of manikin-based studies in terms of applicability to critically ill humans can be questioned but may be the best design available to address some questions. We chose to simulate a difficult airway, but many of our patients may have other contributing factors to such as large body habitus, limited functional residual capacity, high alveolar-arterial (A-a) gradients, cardiovascular fragility or other chronic diseases. Neither the participants nor researchers were blinded. Although used to performing VL, participants had little training on each barrier method. The

study tested two different barriers including a new generation aerosol box and a plastic sheet barrier, and obtained different results for both. All participants used a Glidescope® VL for intubation. It is possible that the Glidescope® VL made the intubations easier in this particular scenario. It may not be available in all settings, or different VL options may be used and the performance of VL is context dependent.[14]

This study examined laryngoscopy and tracheal intubation only; however, airway management is a process that involves much more than this one procedure. Procedures may include: oropharyngeal suctioning; supraglottic airway insertion; patient repositioning; front-of-neck access (cricothyrotomy); and fiberoptic intubation, none of which were examined in our study, and many of which might be expected to be challenging with barriers in place. These procedures remain untested and should be studied before aerosol boxes can be used safely.

This study did not examine the efficacy of aerosol box in reducing the viral exposure risk to clinicians. This cannot be assumed, and research is required.[15] The barrier device should be removed if difficulty is encountered. We did not allow this in our study, but it is likely that some of the barrier devices would have been removed. Concerns with an emergency removal of the box during airway management include patient or healthcare worker injury, dispersal of aerosols and droplets from within the box, and the contamination of healthcare workers from the box surfaces. Finally, we examined the use of these devices by the most experienced airway specialists, being consultant anesthetists and emergency room doctors. It is possible that physicians that are not experienced with airway management would experience more difficulty with intubating using these devices.

Conclusion

The use of an aerosol box of our design does not seem to increase time to a successful tracheal intubation in simulated COVID-19 patients when compared to no barrier. These data may provide some reassurance to teams who wish to use these devices to reduce contamination. However, many other important questions exist regarding use of these approaches, including their effectiveness in reducing dispersal of true airborne particles. Incorporation of "negative" pressure function has been recommended even just addition of simple suction inside the box as this may improve efficacy.[15,17]

We find that the aerosol box as a protective barrier does not impose a significant delay in tracheal intubation using VL. Various other maneuvers which may be required were not evaluated. We also recommend that although there have been many innovations in the form of protective barrier devices in managing the airway for COVID-19 infected patients, these devices have not been thoroughly studied for aerosolization and are not a substitute for full PPE during airway management.

Acknowledgments

The authors would like to thank Mayyan Mubarak, Mohamad Nagy, Dr. Hani Alghamdi, Dr. Riaz Ahmed, Dr. Sultan Babar, Dr. Abdulaziz Alali, Dr. Khalid Sultan, Dr. Husam Anbar, Dr. Michael Ayeko, Dr. Narendran Ilango, Dr. Gyanendra Mohan, and Dr. Yasser Tolba for their help in carrying out this project.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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