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Brief Report

Comparison of the Efficiency and Usability of Aerosol Box and Intubation Tent on Intubation of a Manikin Using Personal Protective Equipment: A Randomized Crossover Study

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□ **Abstract—Background: The aerosol box and intubation tent are improvised barrier-enclosure devices developed during the novel coronavirus pandemic to protect health care workers from aerosol transmission. Objective: Using time to intubation as a crude proxy, we aimed to compare the efficiency and usability of the aerosol box and intubation tent in a simulated manikin. Methods: This was a single-center, randomized, crossover manikin study involving 28 participants (9 anesthetists, 16 emergency physicians, and 3 intensivists). Each participant performed rapid sequence intubations in a random sequence of three different scenarios: 1) no device use; 2) aerosol box; 3) intubation tent. We compared the time to intubation between different scenarios. Results: The median total intubation time with no device use, aerosol box, and intubation tent were 23.7 s (interquartile range [IQR] 19.4–28.4 s), 30.9 s (IQR 24.1–52.5 s), and 26.0 s (IQR 22.1–30.8 s), respectively. Post hoc analysis showed a significantly longer intubation time using the aerosol box compared with no device use ($p < 0.001$) and compared with the intubation tent ($p < 0.001$). The difference between the intubation tent and no device use was not significant. The first-pass intubation success rate did not differ between the groups. Only aerosol box use had resulted in breaches of personal protective equipment. Participants considered intubation with the intubation tent more favorable than the aerosol box. Conclusions: The intubation tent seems to have a better barrier-enclosure design than the aerosol box, with a reasonable balance between efficiency and usability. Further evaluation of its efficacy in preventing aerosol dispersal and in human studies are warranted prior to recommendation of widespread adoption. © 2021 Elsevier Inc. All rights reserved.**

□ **Keywords—aerosol box; aerosol; infection; COVID-19; manikin, intubation tent; rapid sequence intubation**

1. Introduction

The novel coronavirus disease 2019 (COVID-19) pandemic has infected more than 116 million people worldwide and poses a significant risk to health care workers (1–6). It is generally believed that the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was mainly transmitted by droplets or contact from contagious respiratory secretions, but airborne transmission also occurred after exposure to virus-laden aerosols (7–9). Airway management with endotracheal intubation is recognized as a high-risk aerosol-generating procedure in various guidelines (10,11). Around 1 in 10 health care workers involved in endotracheal intubation of COVID-19 patients subse-

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quently developed suspected or confirmed infection despite the use of personal protective equipment (PPE) (12).

To protect health care workers, practical recommendations and consensus guidelines on endotracheal intubation in patients with COVID-19 have been published (13–18). In general, these guidelines recommend appropriate donning and doffing of PPE, an experienced provider performing the rapid sequence intubation (RSI), the use of video-assisted laryngoscopy, and a negative-airflow airborne isolation room. The worldwide shortages of PPE have triggered the improvisation of various novel barrier-enclosure devices to augment PPE. Among them, the aerosol box and intubation tent are popular designs (19–22).

Most of these novel barrier-enclosure devices, however, have not been subjected to stringent scientific evaluation prior to implementation due to the urgent need for better protection (23). In particular, the impact of these devices on the technical ability to perform intubation has not been well studied. The aerosol box increases intubation time even when used by experienced airway specialists and therefore, might expose patients to a higher risk of hypoxia (24). Restriction of movement and vision, and increased cognitive load can reduce the ability to manipulate devices within the rigid box. Theoretically, maneuverability is better inside an intubation tent because it is made of elastic transparent plastic sheets supported by a frame. However, studies comparing intubation tent and aerosol box are lacking.

We hypothesized, firstly, that the time to intubation with the intubation tent would be significantly shorter than with the aerosol box; and secondly, that the time to intubation for both the intubation tent and the aerosol box would be significantly longer than with no device. Therefore, in this study, we compared the impact of the aerosol box and intubation tent on the time to tracheal intubation in a manikin, with no device use as control.

2. Method

This was a single-center, randomized, crossover manikin study conducted between October 28 and November 16, 2020. The study was approved by the Institutional Review board (IRB 2020-05) on September 8, 2020. We followed the Consolidated Standards of Reporting Trials statement in reporting this study (25).

Anesthetists, intensivists, and emergency physicians with clinical experience in emergency airway management were invited through departmental e-mail and personal communication to participate in the study. Participation was voluntary and all participants signed a written informed consent at enrollment. Prior to randomization, all participants were asked to fill in a questionnaire, which collected demographic data, including clinical specialty, years of experience, and experience with video laryngoscopy.

Figure 1A. Illustration of the aerosol box, which is a plastic container with dimensions: 50 cm wide, 50 cm tall, 40 cm deep; with four holes, each 10 cm in diameter, with just enough room to admit hands and forearms.

To simulate the conduct of an emergency RSI in a COVID-19 patient, all endotracheal intubations were performed in an isolation room on a full-body adult manikin (MegaCode Kelly, Laerdal Medical, Stavanger, Norway) with the tongue inflated to simulate a Cormack–Lehane Grade 2A airway. The manikin was placed on a standard hospital stretcher in a neutral position. The participant could adjust the height of the bed and position of the manikin. All participants donned PPE that consisted of a disposable cap, face shield, fit-tested N95 respirator, fluid-resistant gown, and double nitrile gloves (26). All intubations were performed using a video laryngoscope (C-MAC®, Karl Storz SE and Co, Tuttlingen, Germany) with a disposable blade (MAC®-4), an endotracheal tube (internal diameter 7.5 mm, as recommended by the manufacturer of the manikin), a bougie, and a malleable stylet. An experienced emergency nurse provided assistance from the right side of the manikin as instructed by the intubation provider. The airway assistant had no role in the study design or data collection.

The aerosol box in this study was fabricated as previously described, with modifications made to improve access to the patient during intubation: access holes on the right side of the box for the assistant's hands and a hole on top for insertion of bougie (Figure 1A, 1B, 2A, 2B, 2C, 3 and 4 - please send to author for figure citationsA & B) (19,24). The box was placed to cover the manikin's head and shoulders prior to each intubation attempt. The intubation tent was designed and manufactured by a local company, with modifications made based on clinicians' comments (Figures 2A & B). It was made of transparent polyvinyl chloride (PVC) sheets hung from a customized aluminum frame with wheels. The PVC sheets formed a tent that would be placed to cover the manikin's head

Figure 2(A). Illustration of the plastic intubation tent.

and shoulders prior to each intubation attempt. One-way access ports covered by four flaps on the inner surface (Figure 2C) were present on all four sides of the tent to allow access to the manikin during intubation. The flaps were designed to achieve the effect of a one-way valve such that, when the ports were not in use, they would not be opened to the rest of the room directly. The PVC sheet is disposable, thus obviating the need for cleansing, to minimize contact of health care workers with potentially contaminated surfaces. The study team purchased the devices without any funding support.

Each participant was given 15 min to practice and familiarize themselves with each barrier device with at least two intubation attempts using a C-MAC®. Each participant was then asked to perform RSI in three different scenarios: 1) RSI with no device use; 2) RSI with an aerosol box; 3) RSI with an intubation tent. To minimize the learning effect, the sequence of the three intubation scenarios was randomized in a 1:1:1 ratio by a research assistant not involved in data analysis. For allocation concealment, we used sequentially numbered opaque, sealed envelopes that contained the sequence of intubations, which was revealed to the participants only after enrollment and the practice session. It was, however, not feasible to blind the participants.

The primary outcome was the time to intubation in seconds from when the facemask was removed to the first breath delivered via a correctly positioned endotracheal tube with an inflated cuff, as evident by visible chest rise upon ventilation. The time to intubation is an important indicator of the efficiency of a novel barrier device. An intubation attempt was defined as the insertion of the video laryngoscope blade into the manikin's mouth and its removal, irrespective of whether an endotracheal tube was inserted. The lead researcher timed the whole intubation process. The participants were blinded to the time that they used for each intubation. However, an intubation attempt was aborted by the investigator if it lasted longer than 60 s. In each scenario, the total time needed to intubate was the sum of the time of all individual attempts. If the trachea could not be intubated after three attempts, the intubation was considered as failed, and total intubation time was censored at 180 s. Each intubation attempt was video recorded. Another investigator reviewed all video recordings to verify the time measurement.

Secondary outcomes included the first-pass intubation success rate (defined as correct placement of the endotracheal tube in the trachea at the first attempt), number of intubation attempts required, the best laryngoscopic view on the video-screen as assessed by the lead investigator, the need for optimization maneuvers (use of bougie and cricoid pressure), breach or damage to PPE, and complications of intubation, such as dental compression. The breach or damage to PPE was assessed and recorded by a research assistant. At the end of each scenario, participants were asked immediately for qualitative comments on their experience on the barrier device. Their perceived difficulty of intubation was assessed with a numerical score from 0 (very easy) to 10 (very difficult).

We also assessed the usability of the devices by asking participants to choose between aerosol box, intubation tent, or no barrier device for future RSI of COVID-19 patients. All data were collected using a standardized data collection form.

Based on the study conducted by Begley et al., the use of the latest-generation aerosol box delayed the mean time to intubation by 28.2 s (SD for difference = 44.1 s) (24). The required sample size was 28 at alpha = 0.025 and power of 80% for a two-tailed Wilcoxon signed rank test. Descriptive statistics were used to analyze the data, with categorical variables reported as proportions and continuous variables as mean ± standard deviation or median with interquartile range (IQR), as appropriate. For continuous variables, normality was assessed using the Kolmogorov–Smirnov test. We used chi-squared test or Fisher's exact test for comparison of categorical variables between groups. We compared the time to intubation between groups using the Friedman test, with post hoc analysis using the Wilcoxon signed rank test because the data were not normally distributed. The Statistical Package for the Social Sciences for Windows version 26.0 (IBM Corp., Armonk, NY) was used for data analysis. To

Table 1. Demographic Characteristics and Clinical Experience of the Participants

	n (%)
Clinical specialties	
Anesthesiology	9 (32.1)
Emergency Medicine	16 (57.1)
Intensive Care	3 (10.7)
Position	
Consultant/specialist	23 (82.1)
Trainee	5 (17.9)
Clinical experience	
0–10 years	8 (28.6)
> 10–20 years	16 (57.1)
> 20 years	4 (14.3)
Reported average number of emergency intubation with video laryngoscope per year	
0–10	18 (64.3)
> 10–50	7 (25.0)
> 50	3 (10.7)

Abbreviations: IQR = interquartile range.

account for multiple comparisons, we conducted Bonferroni correction of the p value by dividing $\alpha = 0.05$ by 3 (the number of comparisons between group), that is, 0.017 in post hoc analysis.

3. Results

In total, 28 participants, including 9 anesthetists, 16 emergency physicians, and 3 intensivists performed 84 tracheal intubations. The majority of participants (82.1%) were specialists in their respective disciplines, and most (71.4%) reported at least 10 years of clinical experience. To be qualified as specialists, the participants must be actively practicing in their corresponding specialty for at least 6 years, have passed their specialty fellowship examination, and have acquired specialist registration in local Medical Council. A total of five trainees (17.9%) participated in our study. Among them, one was from Intensive Care and four were from Emergency Medicine. The demographic characteristics and clinical experience of the participants are summarized in Table 1. Figure 3 shows the number of participants randomly assigned to different sequences of device use.

The median total intubation time with no device use, aerosol box, and intubation tent were 23.7 s (IQR 19.4–28.4 s), 30.9 s (IQR 24.1–52.5 s), and 26.0 s (IQR 22.1–30.8 s), respectively (Figure 4). The total intubation times were significantly different between the three scenarios; $\chi^2(2) = 25.071$, $p < 0.001$ (Table 2). Post hoc analysis showed that the total intubation time with the aerosol box was significantly longer than that with no device use ($Z = -4.419$, $p < 0.001$) and that with the intubation tent ($Z = -3.598$, $p < 0.001$). The difference in the total time required for intubation with no device use and with the intubation tent was not statistically significant ($Z = -1.310$, $p = 0.19$). No intubations with the tent took more than 1 min, whereas one participant (3.5%) failed three attempts in the aerosol box scenario. Subgroup analysis of the intubations with the aids of bougie showed a much more prolonged total intubation time. The median bougie-aided intubation times with no device use, aerosol box, and intubation tent were 38.5 s (IQR 27.3–57.2 s), 79.7 s (IQR 55.8–121.8 s), and 37.8 s (IQR 30.7–48.2 s), respectively.

The first-pass success rate, best assessor Cormack–Lehane glottic view, the need for airway optimization maneuvers, and the proportion of dental compression did not differ significantly between the groups (Table 2). Of note, breaching of PPE was observed only in the aerosol box scenario. All three breaches involved exposure of the wrists with retraction of sleeves and glove slippage when the operators inserted their hands through the arm access holes. None of the PPE gowns were torn or damaged.

The perceived difficulty of intubation was slightly higher when intubating with the tent (median difficulty score: 3.0 [IQR 2.0–4.0]) compared with no device use (median difficulty score: 2.0 [IQR 1.0–3.0]) ($Z = -3.743$, $p < 0.001$). Intubation with the aerosol box (median difficulty score: 4.5 [IQR 3.0–6.0]) was more difficult than with the intubation tent ($Z = -3.639$, $p < 0.001$) (Table 2). As for future RSI of COVID-19 patients, most participants (n = 25/28) preferred the intubation tent.

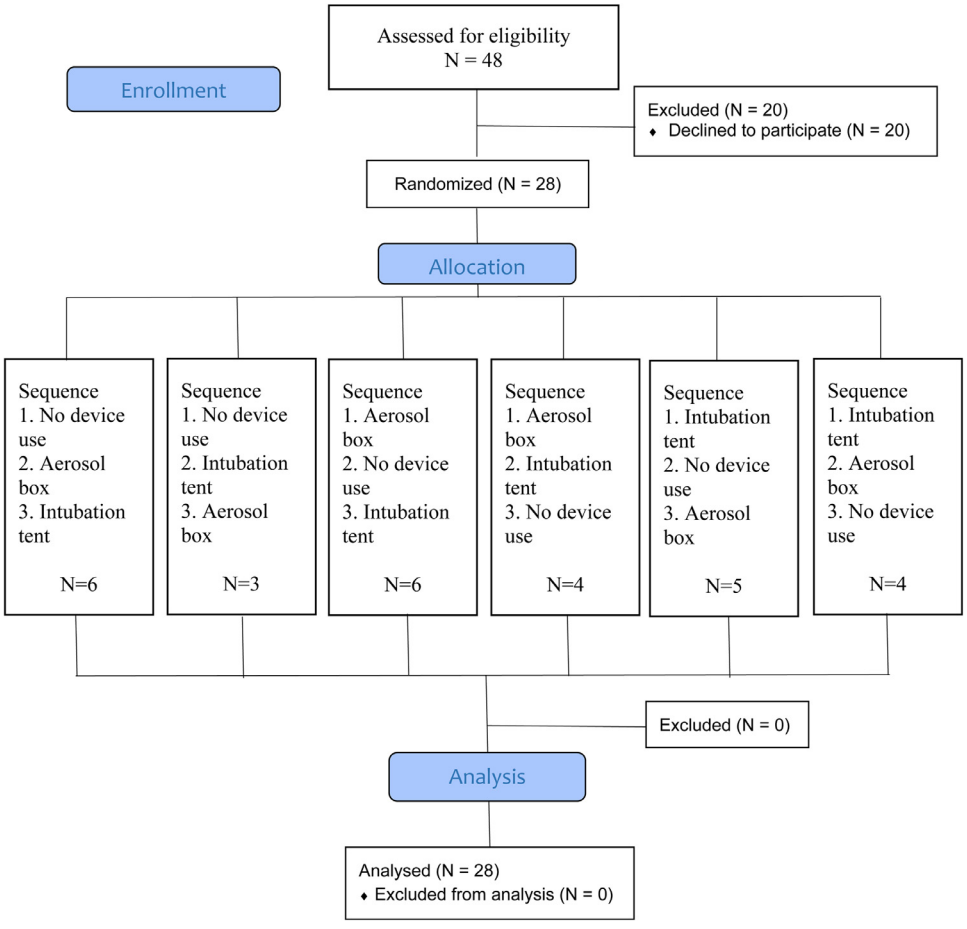

Figure 3. Consolidated Standards of Reporting Trials flow diagram of six groups of participants randomly assigned to different sequences of scenarios.

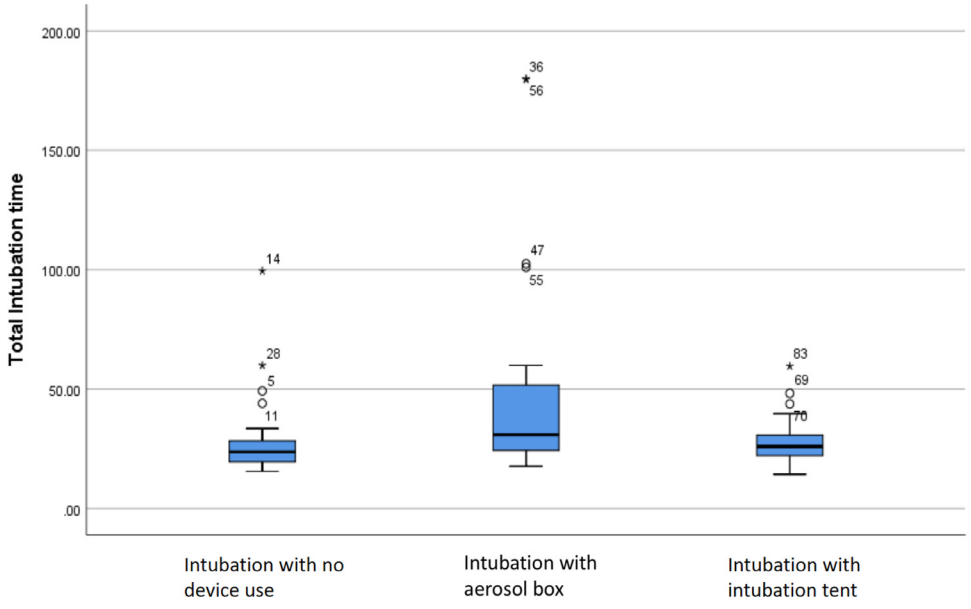

Figure 4. Box and whisker plot of total intubation time in each scenario.

Table 2. Comparison of the Primary and Secondary Outcomes Between Three Scenarios

	Intubation with No Device Use(n = 28)	Intubation with Aerosol Box(n = 28)	Intubation with Intubation Tent(n = 28)	*p* Value*
Time to intubation, seconds, median (IQR)	23.7 (19.4–28.4)	30.9 (24.1–52.5)	26.0 (22.1–30.8)	< 0.001
First-pass success	27 (96.4%)	24 (85.7%)	28 (100.0%)	0.063
Total number of attempts				
1 attempt	27 (96.4%)	24 (85.7%)	28 (100.0%)	
2 attempts	1 (3.6%)	2 (7.1%)	0 (0)	
3 attempts	0 (0)	2 (7.1%)	0 (0)	
Best C-L glottis view				
2A	13 (46.4%)	6 (21.4%)	12 (42.9%)	0.111
2B	15 (53.6%)	22 (78.6%)	16 (57.1%)	
Optimization maneuvers required				
Bougie	8 (28.63%)	8 (28.6%)	7 (25.0%)	0.942
Cricoid pressure	5 (17.9%)	7 (25.0%)	4 (14.3%)	0.582
Complications				
Dental compression	7 (25.0%)	11 (39.3%)	9 (32.1%)	0.519
Esophageal intubation	0 (0)	0 (0)	0 (0)	NA
Breach of PPE	0 (0)	3 (10.7%)	0 (0)	0.045
Perceived difficulty (0–10)	2.0 (1.0–3.0)	4.5 (3.0–6.0)	3.0 (2.0–4.0)	< 0.001
Preference over the devices	2 (7.1%)	1 (3.6%)	25 (89.2%)	

* Friedman test was carried out for time to intubation and perceived difficulty; chi-squared test was carried out for other variables.IQR = interquartile range; C-L = Cormack-Lehane; NA = not applicable; PPE = personal protective equipment.

Figure 1B. Illustration of rapid sequence intubation with the aerosol box.

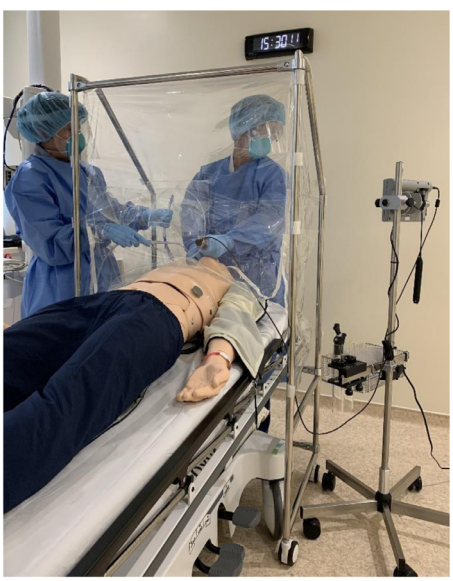

Figure 2(B). Illustration of rapid sequence intubation with the intubation tent.

Figure 2(C). Illustration of the one-way access port of plastic intubation tent.

4. Discussion

Our study aimed at testing the effects of novel barrier devices on intubation. These devices should be instituted once a patient with respiratory distress is identified. During the COVID-19 pandemic, every patient with respiratory distress, for example, requiring high-flow oxygen, would be considered a novel coronavirus-infected patient until proven otherwise, and the application of a device, together with other standard infection control measures, will be implemented over the patient to prevent the spread of aerosol. In fact, not only intubation is considered an aerosol-generating procedure; the use of high-flow oxygen and bag-valve masking in the pre-oxygenation process would also generate a lot of contagious aerosol. Thus, we proposed early application of the barrier device once a patient with respiratory distress is identified.

Efficacy, efficiency, and usability are important considerations when evaluating a novel barrier-enclosure device. In the context of RSI in patients with suspected or confirmed COVID-19 infection, efficacy refers to the ability of the device to contain airborne particles; efficiency refers to the time to complete an aerosol-generating procedure; and usability refers to user experience (23). Efficacy of these devices in reducing aerosol dissemination was outside the scope of our study and was not tested. We found that intubation with an aerosol box resulted in a longer intubation time, a higher risk of PPE breach, and a higher rating of procedure difficulty compared with use of an intubation tent or no device.

This corroborates the findings of other manikin studies (24,27,28). The median total intubation time in the aerosol box scenario was 30.9 s in our study, which is similar to that reported by Fong et al., but shorter than the time reported by Begley et al. (52.4 s, [IQR 43.1–70.3 s]) (24,28). The difference may be partly explained by the use of a bougie. In Begley's study, all participants elected to use a bougie on the first attempt, whereas in our study only 8 participants (28.6%) used a bougie in the aerosol box scenario. If we only look at these eight intubations, the total time of intubation was much more prolonged (median 79.7 s, IQR 55.8–121.8 s). This finding reinforces concerns regarding the limitation of the aerosol box on the use of airway adjuncts, as the space inside is limited (29). Even with a hole on the top to allow passage of a bougie, restrictions on hand movements and limited headroom impair manipulation of any device inside the box. In particular, railroading an endotracheal tube over the bougie inside the box was difficult. Based on our observations, we recommend preloading the bougie with an endotracheal tube when it is used inside the box.

Even though the first-pass success rate did not differ significantly across three settings, the aerosol box had the lowest first-pass success rate, and one emergency medicine trainee failed all three intubation attempts. The participants also commented that the aerosol box hindered the access of the airway assistant, potentially encumbering aid in case of an airway crisis. In emergency airway management of patients with COVID-19, it is important to maximize first-pass success rate and secure the airway rapidly because prolonged intubation and multiple attempts increase the risk to sick patients and staff (15,16). Increasing the height of the aerosol box might solve part of the problem by providing more space for manipulation. However, this will further increase the weight, causing problems in transport, placement, and removal of the device during emergencies.

The plastic intubation tent did not delay intubation compared with no device use. Compared with the aerosol box, the time to intubation with the intubation tent was significantly shorter, although the absolute difference (26.0 s vs. 30.9 s, $p < 0.001$) was not clinically significant. A study by Madabhushi et al. set the non-inferiority margin to be 15 s, as a perceived safe period of apnea tolerated by most patients (30). Unlike the aerosol box, our findings suggest that the use of the plastic intubation tent is associated with a similar time to intubation and first-pass success rate compared with no device use. The larger headroom and flexible plastic sheet walls that improve ergonomics and dexterity can explain this. Participants considered intubation with the plastic tent easier than the aerosol box. Most participants favored the plas-

tic tent for future use in patients with possible COVID-19 infection.

There were no significant differences between the three settings with respect to best glottic view, the need for optimization maneuvers, or the occurrence of complications. However, the study was not powered to detect such differences. Even with a small sample size, we showed that the use of an aerosol box was associated with a higher occurrence of PPE breach compared with no device use or the intubation tent. The sleeves of the PPE gown were easily caught by the rigid edge of the arm access holes and the overlying occlusive film. Similar PPE breaches were observed by Begley et al. and Fong et al. (24,28). To avoid glove slippage over the sleeves, longer-sleeved gloves or securing gloves with tape strips should be considered when using an aerosol box (14).

Taken together, assuming similar efficacy of both devices in limiting aerosol spread, which is yet to be evaluated, the intubation tent seemed to be a better barrier-enclosure design in terms of balancing efficiency and usability. In addition, the plastic tent design has several advantages over the aerosol box. First, the tent design can accommodate intubation in different positions, such as the ramped position in obese patients, whereas the aerosol box requires modifications to secure it to the bed. Second, the plastic tent can be wrapped from the bottom to trap any aerosol inside after intubation. Removal of the aerosol box after intubation may create 'secondary aerosolization' by releasing trapped aerosol particles. Third, SARS-CoV-2 can survive on plastic surfaces for days (31). The low-cost plastic sheet in the tent is disposable, thus obviating the need for decontamination. Disinfection of the metal frame carries a much lower risk, as it stays outside the tent. In contrast, used aerosol boxes might become reservoirs for transmission in the absence of proven protocols for disinfection.

4.1. Limitations

This study has several limitations. First, this was a manikin-based simulation study, which is a necessary step prior to clinical studies for novel devices (16,32). A manikin cannot totally reproduce the laryngoscope conditions of real patients. In general, the times to intubation are shorter in manikins than in patients, especially with repeated intubation on the same manikin. A recent study on human subjects with normal airways undergoing tracheal intubation for elective surgery showed that the time to intubation was 10 s longer with an aerosol box compared with no device use, but the difference did not reach the non-inferiority margin of 15 s set by the authors (30).

Second, around 64.3% of our participants performed fewer than 10 video laryngoscopy intubations annually. This could be a confounder of our results. The delay in intubation could be due to insufficient experience with video laryngoscopy intubation or due to the novel barrier device. But because all the participants would perform the three scenarios eventually, if the delay was due to the inexperience issue, the delay should be evenly affecting the intubation time in all of the scenarios instead of predominately prolonging the intubation time in the aerosol box scenario. Nevertheless, we proposed further study in the future with exclusively experienced airway managers to eliminate the effect of experience on video laryngoscopy intubation.

Third, it was not possible to include all the modifications of the aerosol box and intubation tent proposed by various researchers. Therefore, we cannot extrapolate our results to devices with other modifications and design features.

Finally, we did not compare the efficacy of these devices in reducing aerosol dissemination. Apart from the risk of PPE damage, recent studies have shown that the aerosol box without the use of suction increased operator exposure to airborne particles escaping through the arm access holes (33,34). We cannot extrapolate efficacy data from previous studies on plastic wrap or tent to the intubation tent used in this study due to the vast difference in design (22). The efficacy of the current intubation tent design as compared with the aerosol box remains uncertain.

5. Conclusions

Compared with the aerosol box, the intubation tent seems to have a better barrier-enclosure design that balances efficiency and usability. It does not delay trachea intubation or increase the risk of breaching PPE. Users also favor it over the aerosol box. However, prior to clinical adoption as an adjunct to PPE during emergency airway management, further simulation and human studies are warranted to evaluate its efficacy, efficiency, and usability in different clinical scenarios.

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ARTICLE SUMMARY

1. Why is this topic important?

Various novel barrier-enclosure devices were designed to enhance protection for health care workers, though most of them have not been subjected to stringent scientific evaluation prior to implementation and the impact of these devices on the technical ability to perform intubation was not well studied. Particularly, studies comparing intubation tent and aerosol box are lacking.

2. What does this study attempt to show?

Our study aimed to compare the impact of the aerosol box and intubation tent on the efficiency of tracheal intubation. Theoretically, maneuverability is better inside an intubation tent because it is made of elastic transparent plastic sheets supported by a frame.

3. What are the key findings?

a) The aerosol box resulted in a longer intubation time than intubation tent.
b) The aerosol box also was associated with a higher risk of personal protective equipment (PPE) breach, and a higher rating of procedure difficulty compared with use of an intubation tent or no device.
c) Participants considered intubation with the intubation tent more favorable than the aerosol box.

4. How is patient care impacted?

When intubating a contagious patient, the intubation tent is preferred over the aerosol box, as the tent allows better maneuverability and has lower risk of delaying intubation and breaching PPE.