Effect of two barrier devices on the time taken and ease of intubation of a paediatric intubation manikin - A randomised cross-over simulation study

Sailaja Kamabathula, Gita Nath

Department of Anaesthesia and Intensive Care, Axon Anaesthesia Associates, Hyderabad, Telangana, India

Abstract

Background and Aims: During the present COVID-19 pandemic, several inventions have been employed to protect personnel involved in intubation from inhalational exposure to the virus. In this study, we compared the effect of two barrier devices, Intubation Box versus Plastic Drape, on the time taken and difficulty in intubating a pediatric manikin.
Material and Methods: Nineteen experienced anesthesiologists performed six different intubations: without barrier, with intubation box, with plastic drape; with and without a bougie, using the Latin Square Design for randomizing order of intubations. The time taken for intubation (TTI) was compared using Student's *t* test, and nonparametric values were analyzed using Chi-square test with Yates correction.
Results: Both barrier devices increased the TTI from 14.8 (3.5) s to 19.8 (6.8) s with intubation box ($P = 0.068$) and 19.3 (8.9) s with plastic drape ($P = 0.099$). Use of bougie significantly prolonged TTI to 25.8 (6.7) s without barrier ($P = 0.000$), 32.5 (13.3) with intubation box ($P = 0.000$), and 29.8 (7.3) s with plastic drape ($P = 0.000$). The number of attempts was not different ($P = 0.411$), and the visibility was slightly impaired with both barriers ($P = 0.047$). The ease of intubation, even without the bougie, was significantly different compared to default, with *P* values of 0.009 and 0.042 for intubation box and plastic drape, respectively. The highest significance was with intubation box with bougie with a *P* value of 0.00017.
Conclusion: Both the intubation box and plastic drape increased the time taken as well as difficulty in intubation. The extra protection afforded should be balanced against risks of hypoxia in the patient.

Keywords: Barrier device, COVID-19, intubation, intubation box, plastic drape

Introduction

SARS COVID-19 has infected a large number of health care workers (HCW), especially those involved in airway management. Experience from the previous SARS CoV-1 outbreak in 2003 showed that aerosol-generating procedures (AGP) played a role in viral transmission, and intubation, especially carried an increased risk with an odds ratio (OR) of 6.6.[1] This data was from a review of retrospective cohort and case-controlled studies, and the quality of evidence was categorized as "very low quality based on GRADE"; however, it has formed the basis of airway management protocols since the beginning of the coronavirus pandemic.[2]

In the present pandemic scenario, considerable attention is being directed towards the protection of HCW during airway management; and specifically, during intubation. In recent

Address for correspondence: Dr. Sailaja Kamabathula, Department of Anaesthesiology, 4th Floor, Rainbow Children's Hospital, Road No 2, Banjara Hills, Hyderabad - 500 032, Telangana, India.
E-mail: sailu_k_78@yahoo.co.in

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months, several inventions and innovations have been described in order to provide extra protection to the intubating personnel, in addition to standard personal protective equipment. Examples of these barriers are transparent plastic boxes and transparent plastic drapes used in different configurations.

In April 2020, a Taiwanese doctor invented an aerosol box – a transparent plastic box with an opening on one side enclosing the head and shoulders of the patient; with two holes on the opposite side to insert the hands.[3] Canelli and colleagues[4] demonstrated that the use of the aerosol box prevented droplets of fluorescent dye expelled from a simulated cough from falling on the face and chest of the laryngoscopist. However, hand movements of the operator were restricted during intubation. Two papers described the use of transparent plastic drapes to contain droplets expelled during airway procedures, either as a single sheet or in combination with a bag or additional sheets.[5,6]

Several authors have commented on the difficulty in maneuvering airway equipment under the aerosol box, because of restriction of hand movement by the box.[7] Others have reported prolongation of intubation time, more intubation attempts, and breaches in PPE and optimization maneuvers when the aerosol box was used.[8]

In this study, we compared the effect of two barrier devices, Intubation Box versus Plastic Drape, on the time taken as well as difficulty in intubating a pediatric manikin. We hypothesized that intubation box might make intubation more difficult. We chose to intubate with a Macintosh laryngoscope (size 2) rather than a video laryngoscope, as video laryngoscopy is available only in major tertiary level centers, not in the majority of hospitals in India.

Material and Methods

The study received approval from the Institutional Ethics Committee and was registered with the Clinical Trials Registry – India (CTRI/2020/07/026779). Calculation of sample size was based on our pilot study with 8 anesthesiologists, in which the mean time to intubation by direct laryngoscopy without a bougie or barrier was 14.0 (2.7) seconds. Considering a 10 second delay to be clinically significant, with type I error set at 5% and type II error set at 20%, at least 14 participants were required. We included all the 19 anesthesiologists in our department with anesthesia experience of more than 5 years and well versed in pediatric intubations. A written consent was obtained from all the participants. We evaluated the impact of the two barrier devices on tracheal intubation of a Laerdal Pediatric Intubation Trainer (Laerdal Medical, Stavenger, Norway). The primary outcome was the time taken for intubation (TTI), and secondary outcomes were the number of attempts, visibility, and ease of intubation.

The Intubation box was locally made (Mahavir Plastics and Electronic Industries) with acrylic of 4 mm thickness. The dimensions of the box were 59 × 59 × 45 cm, and it had two holes at the head end for the intubator's hands (15 cm diameter) and a side hole (12 cm diameter) on the right for the assistant. The side of the box facing caudad was incomplete with a curved edge to accommodate the manikin's torso [Figure 1].

The second barrier device was a transparent plastic drape of 100 × 80 cm dimensions, which was draped over an L-shaped metal rod [Figure 2].

The participants wore an N95 mask and a visor along with their prescription glasses if any. They were allowed a practice time of 5 min to get familiar with intubating the manikin by direct laryngoscopy, with and without a bougie.

For the study, each participant performed the following intubations:

1. Intubation without bougie, without barrier device
2. Intubation with bougie, without barrier device
3. Intubation without bougie, with Intubation Box
4. Intubation with bougie, with Intubation Box
5. Intubation without bougie, with Plastic Drape
6. Intubation with bougie, with Plastic Drape

A maximum of 3 attempts were allowed for each intubation. The order of intubations was specified with the help of a Latin Square design, and each anesthesiologist was randomly assigned a sequence amongst A to F [Figure 3]:

The demographic data recorded included participant's age and years of experience. For each intubation, the following data were noted:

a. Time taken for successful intubation
b. Number of attempts
c. Ease of intubation (Grade I to IV)
d. Visibility (Grade I to IV)

The participants were blinded to each other's performances. All the data were collected in a Case proforma (Annexure 1) and tabulated for statistical analysis in an Excel master chart.

Time taken for intubation was compared using Student's *t*-test. The remaining nonparametric values were analyzed using Chi-square test with Yates correction where appropriate.

Figure 1: Intubation box

Figure 2: Plastic drape on a metal rod

A	B	C	D	E	F
4	1	6	3	5	2
3	6	5	2	4	1
1	4	3	6	2	5
5	2	1	4	6	3
2	5	4	1	3	6
6	3	2	5	1	4

Figure 3: Latin square design

Results

Nineteen participants (6 men and 13 women) performed 6 intubations each, making a total of 114 intubations. They had a median (IQR [range]) of 8 (6–16 [5–42]) years of anesthesia experience including pediatric intubations.

Both barrier devices increased the time taken for intubation (TTI); however, this increase was not significant when the bougie was not used. The use of the bougie significantly increased the TTI compared to the default technique of no barrier-no bougie [Table 1]. Only 4 of the 114 intubations required more than one attempt, and there was no significant difference among the various techniques (*P* value 0.991). Similarly, the visibility of laryngeal structures was not significantly different with either of the barriers when compared to without barrier (*P* value 0.785) [Table 2].

On comparing the ease of intubation, the difference between the various techniques was highly significant (*P* value 0.000). Even without the use of the bougie, both barrier devices showed a significant difference compared to the default technique, but the level of significance was more with the intubation box (*P* value 0.009 vs. 0.042 for plastic drape). The highest significance was when the intubation box was combined with the use of the bougie (*P* value 0.00017). A head-to-head comparison of the two barrier devices with bougie yielded a *P* value of 0.07, almost reaching significance, with easier intubation with the plastic drape [Table 3].

Discussion

The main findings from our observations are that the use of either the intubation box or plastic drape increased the subjective difficulty in intubation, but intubation was assessed as even more difficult when the intubation box was combined with the use of a bougie. The time taken for intubation was longer with both devices, but did not reach statistical significance when the bougie was not used. Intubation using a bougie increased TTI significantly with both barrier devices.

The TTI in the present study of 14.8 s without barrier was comparable to 19.8 s with intubation box and 19.2 s with plastic drape; and consistent with the findings of Wakabayashi and colleagues who reported TTI of 14 and 17 s on intubation with direct laryngoscopy without and with an aerosol box, respectively.[9] Saito and colleagues found intubation with direct laryngoscopy to take 27 s when the aerosol box was used.[10]

In our practice, whenever the laryngoscopic view is suboptimal, one of the first intubation aids used is the bougie. Hence, we studied intubation time and difficulty with and without the use of a bougie. As expected, additional use of the bougie combined with a barrier device did increase intubation time as well as difficulty.

Table 1: Comparison of time taken for intubation with the different techniques

Technique	No Barrier, No Bougie (Default technique)	No Barrier, With Bougie	Intubation Box, No Bougie	Intubation Box, With Bougie	Plastic Drape, No Bougie	Plastic Drape, With Bougie
Time taken for intubation in seconds Mean (SD)	14.8 (3.5)	25.8 (6.7)	19.8 (6.8)	32.5 (13.3)	19.3 (8.9)	29.8 (7.3)
*P**	NA	0.000 (HS)	0.068 (NS)	0.000 (HS)	0.099 (NS)	0.000 (HS)

**Paired t-test, compared to default technique. NA: Not applicable, HS: Highly significant, NS: Not significant*

Table 2: Comparison of Number of Attempts and Visibility with the different techniques

Technique	No Barrier, No Bougie (Default technique)	No Barrier, With Bougie	Intubation Box, No Bougie	Intubation Box, With Bougie	Plastic Drape, No Bougie	Plastic Drape, With Bougie
More than 1 attempt for intubation (%)	0 (0)	1 (5.3)	1 (5.3)	0 (0)	0 (0)	2 (11.1)
Chi-Square Value=5.044, P=0.411. Not significant						
Visibility						
Clearly Visible (%)	18 (94.7)	18 (94.7)	13 (68.4)	13 (68.4)	13 (68.4)	13 (68.4)
Moderate Clarity (%)	1 (5.3)	1 (5.3)	6 (31.6)	6 (31.6)	5 (26.3)	5 (26.3)
Visible with Difficulty (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5.3)	1 (5.3)

Chi Square Value (Yates correction) = 13.273, df 10, P=0.785, Not Significant

Table 3: Comparison of ease of intubation with the various techniques

Technique	No Barrier, No Bougie (Default technique)	No Barrier, With Bougie	Intubation Box, No Bougie	Intubation Box, With Bougie	Plastic Drape, No Bougie	Plastic Drape, With Bougie	Total
Intubation Easy	19	19	10	5	12	11	76
Slight Difficulty	0	0	9	9	7	7	32
Moderate Difficulty	0	0	0	5	0	1	6
Chi Square Value=48.539, P=0.000, Highly significant							
Comparison with default							
**P*	NA	1	0.009 (HS)	0.00017 (HS)	0.042 (S)	0.033 (S)	

**Chi square test, Yates correction where appropriate. NA: Not applicable, S: Significant, HS: Highly significant, NS: Not significant*

Our findings agree with previous studies, which described the problems with barrier devices. Restriction of movement with rigid barrier devices has been mentioned repeatedly.[4,7] A study comparing early and new generation (extra holes on the right side and provision for insertion of bougie) aerosol boxes found that both boxes significantly increased the intubation time (to more than 1 min in 58% cases). Incidences of failure at the first attempt (25% and 17%) and breaches of PPE (8% and 58%) occurred with both early and new generation boxes, respectively.[8] Fong and colleagues found that the aerosol box increased intubation time in difficult airways during intubation with a Glidescope.[11] Also, there were more intubation attempts, breaches in PPE, and optimization maneuvers when the aerosol box was used.

All the above studies compared the intubation time and difficulty with and without the aerosol box. We have not found any studies in the literature comparing the effects of aerosol boxes with plastic drapes on technical aspects of intubation, as we have done in the present study.

There are several studies looking at the effectiveness of barrier devices in protecting HCW. Comparisons between aerosol boxes and plastic drapes have reported that both devices reduce exposure of HCW to droplets generated by simulated coughs.[7,12] However, aerosol particles were found to accumulate under them and may even be directed towards HCW when the barrier was removed. Simpson and colleagues[13] studied the number and size of airborne particles with an electronic particle counter at the level of the laryngoscopist's head. Nebulized saline was dispersed by the volunteer coughing every 30 s for 300 s, and the ability of four barrier devices to prevent exposure of the laryngoscopist to particles 0.3–5.0 microns size was compared. The sealed aerosol box with suction reduced particle count, the vertical and horizontal drapes showed no difference, whereas the unsealed aerosol box actually increased the particle count when compared to no device. Turer and coworkers assessed commercially available intubation boxes during simulated intubation using tests used to certify Class I biosafety cabinets. They found that aerosol escaped from all openings in the enclosure, but the addition of vacuum and active air filtration fully contained the generated aerosol.[14] Thus, barrier devices do reduce exposure of HCW to droplets but do not protect from airborne particles. It should be noted that all these studies examined the spread of artificially generated droplets and airborne particles and, therefore, do not represent real-life conditions.

A recent study monitored aerosol generation during intubation (n = 19) and extubation (n = 14) in ultraclean ventilation operating theaters with an optical particle sizer that could measure the number and size of airborne particles. The baseline particle count was 0.4 particles per liter, intubation including bag-mask ventilation produced a concentration of 1.4 ± 1.4 particles per liter; whereas extubation, especially when the patient coughed, produced 21 ± 18 particles per liter. A volitional cough produced 732 ± 418 particles per liter, a value 35-fold greater than an extubation cough and over 500-fold greater than at intubation. Thus, according to this data, extubation carries a higher risk than intubation and forceful coughing carries an even higher risk of aerosol and droplet generation.[15] As studies done in real-life conditions have shown that intubation and mask ventilation produce only a minute increase in airborne particles, the additional protection afforded by barrier devices should be balanced against the greater likelihood of hypoxia in the patient and increased risk to the HCW due to breaches of PPE, as reported in the literature. These devices are probably more useful during extubation, which is often associated with coughing and the generation of droplets and airborne particles.

The main limitation of this study was that it was only a simulation; hence, the effect of time taken for intubation on the saturation and other vital parameters could not be assessed. Also, we did not use the full PPE kit in order to conserve resources and not waste vital protective equipment.

Conclusion

Both the intubation box and plastic drape increased the time taken for as well as difficulty in intubation by direct laryngoscopy with a MacIntosh laryngoscope, especially when the bougie was used. These findings were more pronounced with the intubation box than with the plastic drape.

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Conflicts of interest
There are no conflicts of interest.

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