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Impact of Aerosol Box on Duration of Intubation of COVID-19 Patients: Simulation Cross-over Study

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ABSTRACT

COVID-19 outbreak is highly contagious, and healthcare workers are at higher risk of infection particularly with aerosol generating procedures like intubation. Airway management guidelines of COVID-19 patients recommend swift and familiar procedures, while recent reports indicate a safety benefit of using Aerosol Box (AB) during intubation.
Aim: Explore the impact of using AB on duration of intubation, and satisfaction of physicians using AB.
Design: Crossover simulation study of intubation on a manikin with and without AB.
Results: Duration of intubation without AB and with AB was 11.2±3.6 and 18±2.7 seconds respectively ($p < 0.001$). Most physicians were unsatisfied with using AB in intubation.
Conclusion: The protective benefits of AB are not established and validated, while it prolongs time of intubation, and exposes the airway manager to unduly difficulties, which may negatively impact safety.

Key words: COVID-19 patients, Aerosol Box, Intubation

INTRODUCTION

Late 2019 an outbreak of Severe Acute Respiratory Syndrome (SARS) was recognized to result from infection by a novel corona virus usually termed COVID-19, [(1)] it is a single strand ribonucleic acid (RNA) encapsulated virus [(2)] of the Orthocoronavirinae subfamily. [(3)] It is thought to be transmitted mainly by droplet and direct contact, [(2, 4)] while controversy remains about its fecal-oral transmission. [(5)]

Owing to the high contagiousness of the virus and the probable very high viral load in patients' airway, [(6, 7)] healthcare workers (HCW) are considered to be at high risk of contracting the infection, [(8, 9)] particularly those exposed to aerosol generating procedures. [(10)] Although there is no agreed upon list of aerosol generating procedures, endo-tracheal intubation (ETI) remains highly hazardous in view of the closeness to the patient's airway and exposure to high viral load. [(2, 10)] ETI is a routine practice in an intensive care unit (ICU) that is frequently performed for COVID-19 patients, as 14-17% of patients are reported to develop COVID-19 related severe respiratory distress, and 10% require urgent intubation. [(11)] The risk HCW are exposed to is supported by the findings of a previous literature review and meta-analysis [(12)] that reported up to 15% absolute risk increase of SARS CoV-1 infection among HCW performing intubation.

In view of this information several authorities commenced to develop

guidelines with the aim of protecting HCW involved in the management of COVID-19 patients, especially those exposed to high risk aerosol generating procedures such as ETI. [2,11,12] The main focus of such guidelines was safety of HCW, through different recommendations aimed at reducing risk of infection transmission, by detailing personal protective equipment (PPE), methods of aerosol reduction, and environmental control measures during ETI (such as negative pressure rooms). Recently, a protective enclosure box commonly referred to as "Aerosol Box" (AB)was approved by United States food and drug administration (FDA) for use during intubation of COVID-19 patients, [13] and although it is yet to make it into guidelines, it is rapidly gaining popularity, with preliminary reports [14] of its protective effectiveness.

It is intriguing, however; that contrary to lack of recommendation on the use of AB by guidelines, there is a general agreement that the most experienced HCW performs ETI, preferably an anesthesiologist to minimize the duration of the procedure, [2, 6, 8, 11, 12] furthermore, there is a stress on swiftness of the procedure, by resorting to simple reliable and robust maneuvers and avoiding use of techniques HCW were not trained for or unfamiliar with, [11] to keep the duration of intubation within the recommended 15-20 seconds. [6] Hence; we designed this study to investigate whether using the AB during intubation would hinder and prolong the intubation process.

Aims:

We aimed to quantitatively compare the average duration of ETI with and without using AB, in addition to qualitatively evaluating easiness of its use and opinion of intubating physicians.

Study Design:

This was a simulation cross over study on the duration of intubation with and without AB conducted in the ICU of King Saud Medical City (KSMC) during May 2020. KSMC is the largest Ministry of Health hospital in Saudi Arabia. It harbors 1200 beds, and a closed ICU of 127 beds operated exclusively by intensivist consultants and residents round the clock. The study was approved by the department's research and ethics committee.

Inclusion:

We recruited for this study KSMC intensivists or anesthesiologists with at least three years of experience in airway management. We obtained verbal consent of the participating physicians, furthermore, a satisfaction survey included a statement that responding to the survey is assumed to indicate consent of the participant.

Simulation:

In this study we used a standard high fidelity manikin regularly used for training purposes, it resembles a 70 Kilogram adult male, with Mallampati I classification [15] which represents an easy to intubate patient. We used endotracheal tube of size 7 (internal diameter in mm), mounted on a stylet, we used a VerathonGlideScope ® Portable GVL with an adult curved blade to simulate intubation.

We used an AB made of transparent acrylic of dimensions50 x 50 x 40 cm, with two opened circles of 10 cm diameter for the operator's hands (figure 1).

Procedure and data collection:

We noted age, gender, and years of experience of each participating physician. Each participating physician attempted intubation on the same manikin using the same instruments, twice with and twice without AB, the average time of each two attempts was recorded in seconds, but only one recorded duration was accounted for if the second attempt was unsuccessful, we considered an attempt unsuccessful if it lasted more than 30 seconds, [16] if both attempts were unsuccessful no time was recorded. Then the physician was asked to respond to a small questionnaire on a five points Likert scale. The questions were about easiness of intubation, available room for maneuvering, and general satisfaction. Higher scores indicated easy, plenty of space, and high satisfaction.

The time recorded in this study starts once the physician handles the Glidescope, till inflation of the tube's cuff after removal of the stylet. Time recording was done by one of the study personnel while blinded to the procedure, he/she would start and stop the clock based on prompting instructions "start" and "stop" while not aware whether AB is used or not.

Outcomes:

The primary outcome was the mean difference of time needed to perform intubation with and without AB. Secondary outcomes included: percentage of successful attempts, and the results of satisfaction survey by participating physicians.

Statistical method:

We estimated that at least 44 physicians are required to detect a medium Cohen's D effect of 0.5 [(17)] with a type I error of 5% and power of 90%, calculated for a paired t test. We inflated the sample size to a total of 50 physicians, under the hypothesis that the effect of using AB is prolonged time to intubate.

Demographics of participating physicians were summarized as mean ± standard deviation (SD) for continuous variables, and as number (%) for discrete variables, along with corresponding 95% confidence interval (CI).

Time to intubate was compared by paired t-test, while percentage of successful intubation attempts was compared by chi square or Fisher's exact tests as appropriate. Pearson or Spearman correlation as appropriate was used to examine correlation of time to intubate in both situations of the same physician. Results of satisfaction survey were summarized and graphically presented as bar graphs.

Furthermore, we performed multiple regression analysis to correlate time of intubation with AB to physicians' experience, age, and gender. All statistical tests were two tailed and assumed statistically significant with p value < 0.05, commercially available statistical software was used for statistical analysis (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC.)

RESULTS

We enrolled 39 intensivists and 11 anesthesiologists from our institute, 42 males and 8 females, with a mean age of 35.7 ± 7 years, and a mean experience of 9.5 ± 4 years (table 1).

Table 1: Demographics of enrolled physicians, and mean duration of intubation:

	Summary	95% CI
Age (years): mean ± SD	*35.7 ± 7*	*33.7 – 37.7*
Gender: Male: number (%)	*42 (84%)*	*71 - 93*
Experience (years): mean ± SD	*9.5 ± 4*	*8.4 – 10.6*
Intubation time without AB (seconds): mean ± SD	*11.2 ± 3.6 **	*10.2 – 12.3*
Intubation time with AB (seconds): mean ± SD	*18 ± 2.7 **	*17.2 – 18.8*

SD = standard deviation, CI = confidence interval, AB = aerosol box.
*p < 0.001

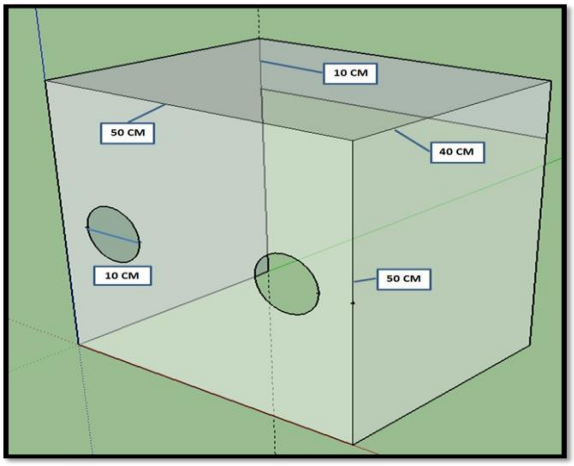

Figure 1: Dimensions of Aerosol Box:

Only one attempt of intubation with AB was not successful out of the total 200 attempts in the study, the mean duration of intubation attempts without AB was 11.2 ± 3.6 seconds (95% CI: 10.2 – 12.3), while that with AB was 18 ± 2.7 seconds (95% CI: 17.2 – 18.8), paired t-test yielded a p value <0.001 with a mean difference of 6.8 seconds (95% CI: 5.6 – 7.9). There was no correlation between time of intubation of the same physician in both situations (Pearson's r = 0.2, p = 0.1).

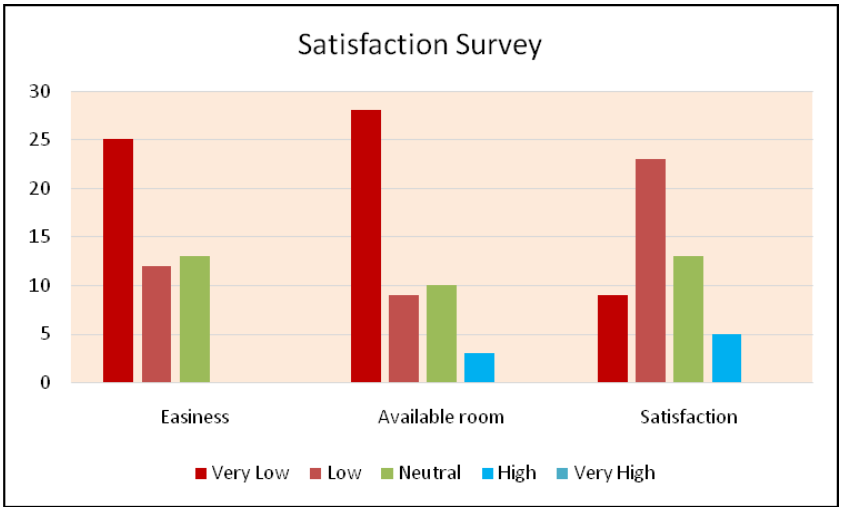

Figure 2: Satisfaction Survey Results

Results of the satisfaction survey were as follows, for the question of easiness of intubation with AB no physicians gave a score of 4 or 5, 26% gave a score of 3, 24% scored 2, and 50% scored 1. For the question of available room for manipulation score of 4 was given by 6%, score of 3 by 20%, score of 2 by 18%, score of 1 by 56%, while no physicians gave a score of 5. The satisfaction question had a score of 4 by 10%, of 3 by 26%, of 2 by 46%, of 1 by 18%, and once more no physicians gave a score of 5 (figure 2).

None of the predefined variables had any significance in the multiple regression model, specifically the Beta coefficient for age was of 0.93 (95% CI: 0.83 – 1.04; p = 0.2), for gender it was 1.1 (95% 0.9 – 1.3; p = 0.4), and for experience it was 1.2 (95% CI: 0.14 – 9.8; p = 0.9).

DISCUSSION

In this simulation study of intubation with and without AB performed by experienced intensivists or anesthesiologists the mean duration of intubation with AB was significantly longer than without. The mean time of intubation without AB was similar to that reported by other studies performed on manikins or actual patients, [18, 19] however; we are not aware of studies that measured intubation time while using AB. The lack of correlation of time to intubate in both situations by the same physician indicates that the prolonged intubation duration with AB is not operator dependent, nor related to their age or experience, but rather to the different situation, in which all variables were controlled apart from the presence of the AB. That is to say, physicians who took shorter time to intubate without AB didn't necessarily take less time to intubate with AB. Supporting the assumption that the AB itself may be responsible for the prolonged time is the lack of significance of any variable in the multiple regression analysis, as the time to intubate was prolonged regardless of age, experience, or gender.

Results of the satisfaction survey clearly demonstrate that physicians encountered difficulties during intubation, resulting from lack of maneuverability due to limited space. In general, they were mostly unsatisfied or very unsatisfied.

As previously outlined, guidelines on airway management for COVID-19 patients emphasized the importance of a swift procedure, and recommended resorting to techniques, which HCW are familiar with and trained for, [11] the correspondence by Canelli et al. [14] in fact did regard the limitation of restricted hand movement, and advised training prior to use of AB while intubating actual patients.

On the other hand, even if the AB resulted in some difficulties during intubation, if it harbors a significant

protective effect against virus transmission, it should be taken at face value, and training should be provided to physicians to overcome its limitation. Unfortunately, this protective effect is not validated yet on a large scale, furthermore; other authors [(20)] clearly expressed their concern that using AB actually decreases rather than increases safety, in view of prolonged time of intubation in an emergency situation with a fragile patient, redirection of the droplets towards the foot of the bed endangering other HCW in the room, and introduction of a new contaminated instrument that must be carefully handled after the procedure.

In this study we are not completely disregarding the idea of the AB, but rather advising to weight its advantages and disadvantages in large scale studies using robust and valid methods to justify its use, rather than following general impression that it provides protection and improves safety.

Our study definitely has many limitations, it is a single center study reflecting the expertise of a single institute, was conducted on a small scale recruiting a small number of physicians. The method might have been more robust if it was a randomized control trial with two groups rather than a across over design, which would have allowed a multiple regression model with the duration of intubation as a dependent variable, and group membership as a predictive variable, and finally, we can't be completely confident that time recording method was free of bias.

CONCLUSION

The protective benefits of AB are not established and validated, while it prolongs time of intubation, and exposes the airway manager to unduly difficulties, which may negatively impact safety.

Conflicts of interest:
All authors declare no conflicts of interest.
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