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ORIGINAL RESEARCH

The influence of a Perspex intubation box on time to intubation: a simulation-based randomised crossover study

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Background: Standard personal protective equipment guidelines are insufficient to prevent contamination of healthcare workers with droplet spread during the COVID-19 crisis. The added challenge of adequate aerosol protection has led to the development of an initial prototype intubation box. The primary objective was to determine the impact of an intubation box on the mean time to completion of intubation in a simulated airway. Secondary objectives included the best laryngoscopic view, the effect of intubator seniority and mode of laryngoscopy on intubation.

Methods: This was a randomised crossover study of the influence of an intubation box on mean time to completion of intubation of an airway management part-task trainer. Senior anaesthesiology staff were assigned to two groups and recordings of their attempts at intubation were analysed by two independent observers.

Results: The intubation box led to a significantly longer mean time to completion of intubation of 7.6 seconds (95% CI 3.1; 12.2; $p = 0.001$) with direct laryngoscopy and 9.2 seconds (95% CI 3.8; 14.7; $p = 0.001$) with videolaryngoscopy. It did not influence best glottic view.

Conclusion: We found that the use of an intubation box significantly prolonged the time to completion of intubation, but the clinical significance of the effect size is uncertain.

Keywords: COVID-19, intubation, intubation box, coronavirus, healthcare worker protection, aerosol-generating procedures

Introduction

Aerosol-generating procedures (AGPs) carry a potential risk of disease transmission to healthcare workers (HCWs) due to substantially higher concentrations of respiratory pathogen exposure. Smaller particulate sizes allow for a slower sedimentation rate out of suspension with air, which differs from normal droplets that fall to the floor shortly after generation.[1,2] The Minister of Health of the Republic of South Africa, Dr Zweli Mkhize, announced on 6 May 2020 that 511 (6.6%) of the 7 808 patients who tested positive for COVID-19 were identified as HCWs.[3] The current personal protective equipment (PPE) precautions for AGPs recommended by the World Health Organization (WHO) do not include the use of a transparent intubation box, and presently evidence is growing that intubation boxes may both hinder duration of intubation and affect the integrity of PPE.[4,5] Canelli et al.[6] demonstrated the protective capabilities of a similar box to prevent droplet contamination of HCWs, while Feldman et al.[7] also showed that the current PPE recommendations do not adequately protect HCWs from contamination on exposed skin, therefore additional layers of protection may be warranted.

At the time of performing this study, little conclusive data have been available regarding the impact that such boxes may have on the ability of the physician to perform tracheal intubation or other airway interventions. No commercial industry standard for intubation boxes has been proposed, as this is a novel medical device not yet registered for use in South Africa. Consequently, significant progress was required to study their impact on physicians' ability to perform their duties, the interaction with other PPE and patient safety standards.

We developed an initial prototype transparent intubation box in collaboration with Divine Studio, Universitas, Bloemfontein, South Africa. The aim of the study was to test the primary hypothesis that an intubation box has an impact on the duration of intubation. As secondary hypotheses, we wanted to ascertain whether the box influenced the best view at laryngoscopy using the Cormack–Lehane score, the effect of videolaryngoscopy compared to direct laryngoscopy on intubation times and views obtained, and whether intubator experience affected outcomes.

Methods

The study was designed as a randomised, crossover study. Participants were recruited from the staff of the Department of Anaesthesiology at the University of the Free State. All medical officers, registrars, and consultants with a minimum of two years' experience in administering anaesthesia were invited to participate in the study by means of a social media group. Prior to randomisation, the participants were asked to complete an anonymous online survey to determine each participant's subjective level of experience and comfort with videolaryngoscopy. This simple survey asked the participant's name (to eliminate duplicate answers) and an estimate of the number of intubations they had performed using videolaryngoscopy. The subjective levels of experience were arbitrarily set at 0 intubations (none), fewer than 50 intubations (less than adequate), between 50 and 200 intubations

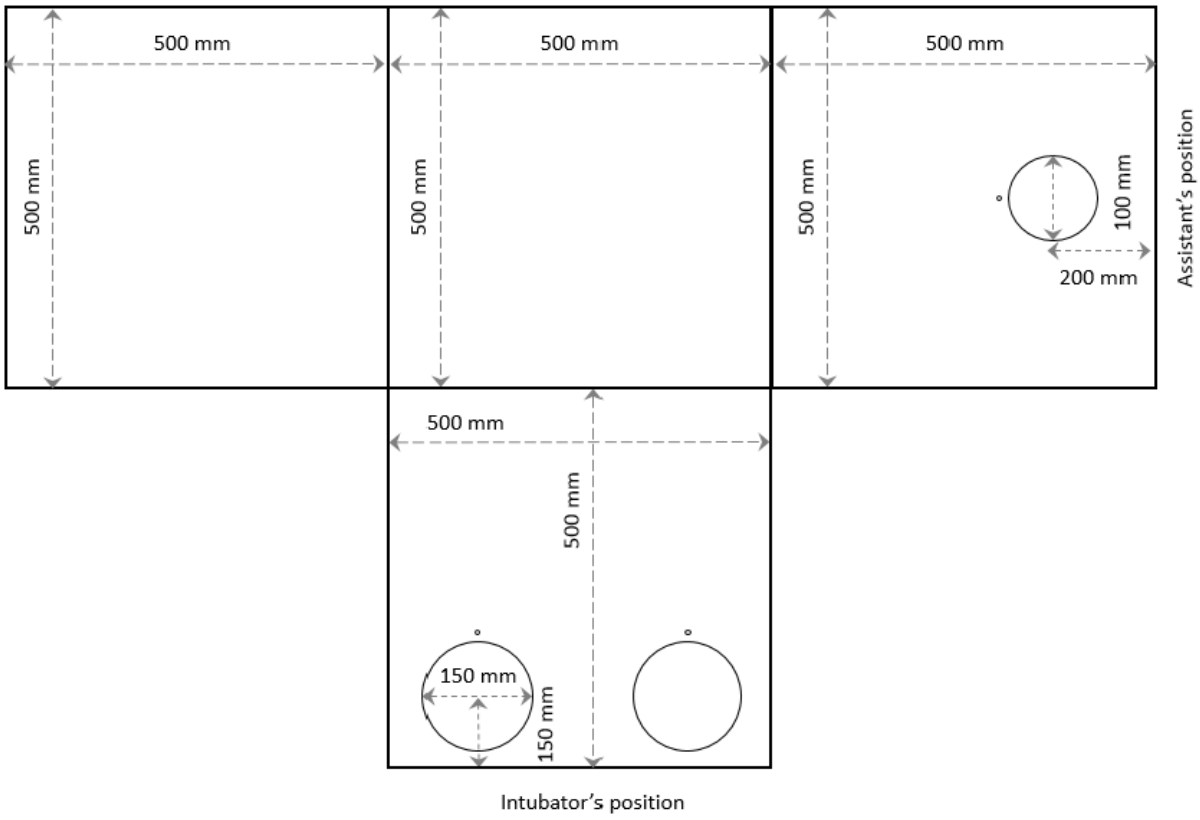

Figure 1

(adequate) and more than 200 intubations (proficient). Only the principal investigator had access to this information.

Based on the survey responses, participants were divided into two groups. The first group (participants who indicated adequate or proficient experience with videolaryngoscopy) would perform intubation attempts with both videolaryngoscopy (VL) and direct laryngoscopy (DL). The second group (participants who indicated no or a less than adequate experience) would perform the attempts with DL only. The purpose of this grouping was to eliminate bias due to unfamiliarity with VL.

The prototype of the intubation box was a simple 500 mm x 500 mm x 500 mm transparent plastic box with two arm holes for the intubator and one for the assistant (Figure 1). This prototype also had an aperture sufficient to accommodate a wide variety of patients, and a 15 mm port (located directly below the assistant's arm hole) to enable use of a standard theatre suction device to facilitate the extraction of particles.

Respondents were invited to participate in simulation testing of the intubation box in a standard operating theatre. The sequence of intubation attempts was randomised by participants drawing numbers one through four, or one and three if their survey responses indicated unfamiliarity with VL, from a box.

A Laerdal® adult airway management part-task trainer (Laerdal Airway Management Trainer product code 25000033, Laerdal; Wappingers Falls, USA) was positioned supine in the neutral position on a theatre bed. Participants could familiarise themselves with the trainer and were encouraged to perform laryngoscopy to familiarise themselves with the simulated tissue. Each participant could position the bed and part-task trainer before initiating an attempt according to their own preferences. A size 7.5 cuffed tracheal tube was used for all intubations and use of an intubating stylet was encouraged, but not mandatory. Participants were asked to wear dual eye protection consisting of a first layer of their own prescription eyewear or a standard pair of transparent splatter-proof goggles and a second layer consisting of a transparent face shield.

A video camera was placed at a right angle to the part-task trainer so that both the entire part-task trainer and the participant's hands could be videoed. Participants were informed they would be recorded and that the start of an attempt would be signalled by handling either the DL or VL (Karl Storz C-MAC, Karl Storz SE & Co., Tuttlingen, Germany). The completion of the task was defined by either inflating the cuff of the tracheal tube or removing the stylet, whichever came last. This time was divided by the number of attempts (if multiple attempts were made) to obtain the time to completion of attempt. The participants were not assisted and only the time it took to manipulate a laryngoscope and place a tracheal tube inside the simulated airway was recorded. Participants reported the laryngoscopic view at each attempt during the time of recording.

Written informed consent was obtained from the participants to analyse the video recordings. The de-identified video recordings were sent to two independent observers to record the times to successful intubation, the number of attempts required and the attempt type. The principal investigator collated these times

and took an average of those recorded by the observers as the duration of intubation. Any discrepancies in timings of more than five seconds were reviewed. This was done as a control measure to minimise the effect that improper positioning of the camera or missed prompts by the participants may have had on observers' abilities to record the attempts. Such reviews were assigned a new time and replaced the most aberrant observer's recording if found to be grossly different from the principal investigator's assessment.

Descriptive statistics were used to summarise the mean, standard deviation, minimum and maximum of numerical variables with symmetrical distributions. Where data were skewed, median, interquartile range (IQR), minimum and maximum were determined. For symmetrically distributed variables, the mean difference between methods was determined with 95% confidence interval (CI) using generalised linear models. The comparison of variables with skew distributions and categorical variables was done using Cochran–Mantel–Haenszel tests. Comparisons between doctors of different seniority (consultants versus registrars) were done using t-tests and chi-squared or Fisher's exact tests. The value for the null hypothesis was set at $p \leq 0.05$. The statistical analysis was performed by the Department of Biostatistics, University of the Free State.

Results

Thirty-seven of 38 permanent members of staff of the Department of Anaesthesiology participated in this study. The seniority profile of the participants and level of experience with VL are presented in Table I. A total of 126 intubation attempts were recorded. Ten times to intubation (8% of observer times) of one observer and none of the other observer had to be replaced by the principal investigator. Five of the ten replacements were of DL without box (14% of group), three of VL without box (12% of group) and two DL with box (5% of group). Otherwise, all observations were similar between observers across all attempts and attempt types.

Duration of intubation was significantly prolonged using an intubation box (Tables II and III), and the average time to completion of attempt was not significantly different from the total time to intubation (TTI) for participants who required more than one attempt. The use of VL did not significantly alter the duration of intubation. Most intubations were successful at the first attempt with two attempts required only once during DL and once during VL, with these events involving different intubators.

With DL, with and without the intubation box, the median (IQR) Cormack–Lehane grades of glottic view were 2 (2;2) and 2 (1;2) respectively. With VL with and without the intubation box the median (IQR) Cormack–Lehane grades were 1.5 (1;2) and 1 (1;2) respectively. In direct comparisons, significant differences in laryngeal view were found when comparing VL without an intubation box to DL with or without an intubation box. Seniority did not significantly alter either the duration of intubation nor the best glottic view obtained.

Table I: Seniority profile and level of experience of participants ($n = 37$)

Rank	Grouped according to level of experience with VL*			
	None or less than adequate† ($n = 11$)		Adequate or proficient‡ ($n = 26$)	
	n (% of group)	% of rank	*n* (% of group)	% of rank
Medical officer ($n = 1$)	1 (9)	100	0 (0)	0
Registrar ($n = 26$)	7 (63)	27	19 (73)	73
Consultant ($n = 10$)	3 (27)	30	7 (26)	70

* Videolaryngoscopy; † 0 to < 50 procedures performed; ‡ 50 to > 200 procedures performed

Table II: Mean times to completion of task and attempts, and median number of attempts to completion of task

Attempt type	Mean time task in seconds (SD)*	Median (IQR)† number of attempts	Mean time attempt in seconds (SD)
DL‡ without box	24.0 (10.0)	1 (1;1)	23.2 (8.3)
VL§ without box	23.2 (8.1)	1 (1;1)	22.4 (6.7)
DL with box	31.6 (13.5)	1 (1;1)	30.0 (10.6)
VL with box	32.5 (12.8)	1 (1;1)	30.1 (9.5)

* Standard deviation; † Interquartile range; ‡ Direct laryngoscopy; § Videolaryngoscopy

Table III: Comparison of differences between mean times to completion of task and median Cormack–Lehane score

Attempt type 1 (*n* = number of attempts)	Attempt type 2 (*n* = number of attempts)	Difference between means (seconds)	95% CI* (seconds)	*p*-value	Median (IQR)# Cormack–Lehane score Attempt type		*p*-value
					1	2	
DL† without box (37)	DL with box (37)	-7.6	-12.2; -3.1	0.001	2 (1;2)	2 (2;2)	0.189
DL with box (37)	VL‡ with box (26)	-3.0	-8.2; 2.3	0.262	2 (2;2)	1.5 (1;2)	0.177
VL without box (26)	VL with box (26)	-9.2	-14.7; -3.8	0.001	1 (1;2)	1.5 (1;2)	0.160

* 95% confidence interval for difference between groups; † Direct laryngoscopy; ‡ Videolaryngoscopy; # Interquartile range

Discussion

This study showed that an intubation box prolonged the time to completion of intubation in a part-task trainer both with direct and videolaryngoscopy. This finding is in keeping with Begley et al.[5] who showed a difference in mean time to intubation of 48.4 seconds (SD 46.4; 95% CI 18.9; 77.9). Our effect size was significantly less than that reported by Begley which could be ascribed in part to their use of the 20° head-up position (as proposed by the Safe Airway Society COVID-19 guidelines), the addition of the first breath step in completing their intubations and possibly delay caused by wearing PPE.

Although this study's results are statistically significant, the clinical importance of the time difference of < 10 seconds is uncertain. Patients with COVID-19 who are critically ill may rapidly desaturate, but adequate pre-oxygenation, head-up positioning, apnoeic oxygenation and rescue bag mask ventilation may be individualised to different patients to counterbalance the risk of desaturation.[8,9] Version 2 of the South African Society of Anaesthesiologists' (SASA) recommendations for airway management of COVID-19 patients do not contain any of these adaptations to adequate pre-oxygenation, and therefore we did not add these steps in our study.[10]

Use of VL only improved the view at laryngoscopy in the absence of an intubation box. The fact that VL increased the mouth-to-mouth distance in another study from a mean of 16.4 (SD 11.4) cm to 35.6 (SD 9.9) cm when compared to DL, reinforces the role of VL during the COVID-19 pandemic.[11,12]

This intubation box was tested in two phases. The initial phase consisted of testing the ability of the box to limit aerosol spread. Swart and Strydom[13] and Dalli et al.[14] found that an intubation box, with a transparent plastic drape, could limit but not eliminate aerosol spread, bringing into question the use of intubation boxes for this purpose.

The results of the survey showed only a 70% subjective evaluation of familiarity with VL. Owing to the recommendation to use VL in COVID-19 intubations[10,12] and recent evidence for proficiency with VL, more expansive training in the use of VL could be of benefit during this time.[15-19]

At the time of writing this article, most studies on aerosol limitation by intubation boxes have been qualitative and not quantitative, thus the extent of protection by intubation boxes has not been conclusively established. The United States Food and Drug Administration (FDA) has, subsequent to the execution of this study, released a letter to HCWs detailing their concerns about the use of barrier enclosures without negative pressure.[20] In patients not at risk of requiring complicated airway instrumentation procedures or multiple attempts at intubation, and not at risk of aspiration of gastric contents, the use of an intubation box could be individualised with a low threshold to abandon its use, as per the recent FDA recommendations.[20]

Limitations

Although there are limitations to the use of the Cormack–Lehane grading system to describe views at VL,[21] we only used this to compare views obtained during simulated intubations and thus we judged it was appropriate in this study.

The intubations performed in this study were done on a part-task trainer and this may not reflect performance in patients. The part-task trainer did not simulate difficult intubation so the results cannot be generalised to more difficult intubations. One observer noted times to intubation which differed more than five seconds from the other observer. The reason is unclear and may relate to difficulties in seeing the intubator's actions, as only one camera angle was shown and actions which may have signalled the start or end of an attempt may have been difficult to observe. Future studies could include signalling to the intubator when to start or using more than one camera angle. A pragmatic approach was followed regarding sample size given the urgency of the project. This study did not investigate the impact of airborne precaution PPE on intubation performance, which may add significant impediment to the task. Potential damage to PPE from use of the intubation box was also not investigated in this study.[5] Differences in design of intubation boxes may also affect the impact it may have on the integrity of PPE. Any future design modifications to an intubation box may also significantly affect these findings, as reported by Begley et al.[5]

Conclusion

Our findings were in keeping with previously published studies and showed that the use of an intubation box significantly affects the time to intubation of a part-task trainer, although the clinical importance of the effect size is debatable. Use of VL when using the intubation box did not improve intubation performance compared to DL but may be useful to limit intubator exposure to viral particles as part of current recommendations. Seniority also did not alter outcomes in this simulation study, despite most guidelines recommending that the most senior intubator should perform the task.

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Conflict of interest

CM Strydom designed and assisted in manufacturing of the initial prototype intubation box in association with Divine Studio, Bloemfontein, but did not receive any financial gains for this process.

Funding source

CM Strydom paid for the manufacturing of the initial prototype intubation box.

Ethical approval

Approval to conduct the study was obtained from the Health Sciences Research Ethics Committee (HSREC) (UFS-HSD2020/0560/2605).

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