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Original Article

Measurement of airborne particle exposure during simulated tracheal intubation using various proposed aerosol containment devices during the COVID-19 pandemic

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Summary

The COVID-19 pandemic has led to the production of novel devices intended to protect airway managers during the aerosol-generating procedure of tracheal intubation. Using an in-situ simulation model, we evaluated laryngoscopist exposure of airborne particles sized 0.3 - 5.0 microns using five aerosol containment devices (aerosol box; sealed box with and without suction; vertical drape; and horizontal drape) compared with no aerosol containment device. Nebulised saline was used as the aerosol-generating model for 300 s, at which point, the devices were removed to assess particle spread. Primary outcome was the quantity and size of airborne particles measured at the level of the laryngoscopist's head at 30, 60, 120 and 300 s, as well as 360 s (60 s after device removal). Airborne particles sizes of 0.3, 0.5, 1.0, 2.5 and 5.0 microns were quantified using an electronic airborne particle counter. Compared with no device use, the sealed intubation box with suction resulted in a decrease in 0.3, 0.5, 1.0 and 2.5 micron, but not 5.0 micron, particle exposure over all time-periods ($p = 0.003$ for all time periods). Compared with no device use, the aerosol box showed an increase in 1.0, 2.5 and 5.0 micron airborne particle exposure at 300 s ($p = 0.002$, 0.008, 0.002, respectively). Compared with no device use, neither horizontal nor vertical drapes showed any difference in any particle size exposure at any time. Finally, when the patient coughed, use of the aerosol box resulted in a marked increase in airborne particle exposure compared with other devices or no device use. In conclusion, novel devices intended to protect the laryngoscopist require objective testing to ensure they are fit for purpose and do not result in increased airborne particle exposure.

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Introduction

The coronavirus 2019 (COVID-19) pandemic has highlighted the urgent widespread necessity for adequate personal protective equipment (PPE) for healthcare providers. Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, is found at it's highest concentration in sputum and upper airway secretions. Although the SARS-CoV-2 coronavirus itself ranges in size from 0.075–0.160 microns, it requires a water and mucous envelope to spread [1]. Respiratory secretions, consisting of mucus and water, provide these envelopes. The size, accumulation and volume of virus-containing envelopes determine the size of respiratory droplets. Droplets can be categorised as either large (> 60 microns in diameter) or small (10–60 microns in diameter). Large droplets tend to fall on surfaces closer to the patient (< 2 m) and small droplets, with thinner mucus and water envelopes, tend to fall on surfaces further away [2]. Envelopes < 5–10 microns in diameter are not called droplets, but airborne particles or infectious droplet nuclei. Airborne particles will remain suspended in the environment for a period of time depending on a number of factors including air circulation, humidity and atmospheric pressure [2].

Aerosolisation, such as that produced during aerosol-generating procedures, produces airborne particles as well as both small and large droplets [2, 3]. Aerosol-generating procedures are thought to increase the risk of infection to healthcare providers [4]. Tracheal intubation is one of the highest risk aerosol-generating procedures performed due to direct exposure to the airway and potential patient coughing during induction [4, 5] and is of particular concern to frontline anaesthetic, emergency and intensive care teams. This has created a race to manufacture aerosol containment devices including improvised protection strategies for use during tracheal intubation. There has been significant promotion of these devices on social media, resulting in rapid proliferation and discussion globally [5–10]. Whereas these innovations aim to reduce aerosol dispersal, many have not been tested and are presented as viable options with only short reports and correspondence being cited in peer review literature. Currently, the use of aerosol containment devices is not recommended by any international PPE guideline [11–15].

The consequences of promotion of such untested devices include either a false sense of security using these devices, or paradoxical increase in healthcare workers exposure [16, 17]. Some devices claim to protect against both large and small droplets as well as airborne particles in small simulation experiments. Using a simulated cough producing fluorescent droplets, Canelli et al. [16] compared the contamination of a laryngoscopist with and without an aerosol box. They concluded that the device reduced the macroscopic contamination of both the laryngoscopist and their immediate surroundings. However, their simulation did not test for air turbulence and flow direction, nor were they able to view small droplets or airborne particles contained in aerosols. They noted that the aerosol box restricted hand movement and would require specialised training. This could result in increasing the risk of a difficult or failed intubation in what is already a difficult procedure. Chahal et al. (unpublished observations, https://doi.org/10.1101/2020.04.14.20063958) designed an aerosol containment enclosure constructed from silicone sheets with an internal negative pressure environment using standard wall suction. They demonstrated containment of vapour smoke, saccharin and nebulised fluorescein within the enclosure. However, this did not demonstrate any quantifiable reduction in either particle dispersal or subsequent risk of infection. Begley et al. [17] performed a simulated crossover study assessing the effect of two aerosol boxes on tracheal intubation performance and found the safety of the laryngoscopist and patient could be compromised by an increased time to intubation and potential damage to PPE.

To guide our institutional protocols for the airway management of patients with suspected or confirmed COVID-19, we sought to test whether different aerosol containment devices confer any protective advantage to the laryngoscopist specifically with respect to airborne particle dispersal. We also aimed to examine the pattern of airborne particle dispersal in the room upon removal of these devices.

Our primary research question was how aerosol containment devices (aerosol boxes and plastic drapes) placed over a patient during tracheal intubation compared with no intervention with respect to exposure of the laryngoscopist to airborne particles? Our secondary research question was to measure the size and distribution of the particles for each device and how effective they are, or not, at reducing airborne particle dispersion over a 5-min time period, and at 60 s post-removal of the aerosol containment device.

Methods

This was a single-centre, prospective non-blinded in-situ simulation study performed at a major metropolitan teaching hospital in Melbourne, Australia. Consent was obtained from participants for both research and publication of images.

Simulation was performed in a self-contained, intensive care unit (ICU) room measuring 5.2 × 4.2 × 2.7 m. The room was pressure-equilibrated with the rest of the ICU, with an estimated negative pressure of −10 Pa and 18 room air changes per hour of (300 $l.s^{-1}$). Seven healthy adult (> 18 years) volunteers, four men and three women, participated in this study, each volunteer acting as both patient and laryngoscopist in random order. Each patient lay supine on a pillow (10° inclination) on a standard ICU bed. Another volunteer laryngoscopist stood at the head. The room doors were closed. To conserve PPE, the laryngoscopist wore only a surgical facemask and gloves.

A Lighthouse 3016IAQ airborne particle counter (Fremont, CA) was positioned on an intravenous pole pre-set at head height (75 cm above the simulated patient's head) immediately in front of the laryngoscopist. This height of the airborne particle counter on the intravenous pole was maintained throughout the duration of the experiment. The airborne particle counter, typically used for indoor air quality testing in semiconductor cleanrooms, research laboratories and operating theatres, utilises a laser diode and photo detector to count particles by collecting scattered light from particles as they pass through a sample inlet (Fig. 1). The device counts airborne particles of 0.3, 0.5, 1.0, 2.5 and 5.0 microns. Airborne particle counter flow rate was set to 2.83 $l.min^{-1}$, with detection of the ambient air occurring in 1 s sweeps. The full specifications for the airborne particle counter used are included in online Appendix S1.

Four aerosol containment devices and no aerosol containment device were trialled once by each of seven laryngoscopists in a random order. The four aerosol containment devices tested were: a locally manufactured aerosol box with similar specifications to those reported in the literature attached to wall suction (Fig. 2a); a clear plastic drape suspended vertically above the patients' head as a barrier between the patient and the laryngoscopist, with the laryngoscopist's hands placed under the drape (Fig. 2b); a clear plastic drape forming a horizontal tent above the patients' upper torso, with the laryngoscopist's hands placed under the drape (Fig. 2c); and a sealed aerosol containment box with openings through a neoprene sheet and rubber gloves, tested using two configurations, with and without wall suction, each connected to a heat/moisture exchange viral filter (Fig. 2d). Aerosol containment devices were tested against no device use (Fig. 2e). In total, six configurations were tested with seven different laryngoscopists totalling 42 trials performed. Specifications regarding aerosol containment devices can be found in online Figures S1 and S2).

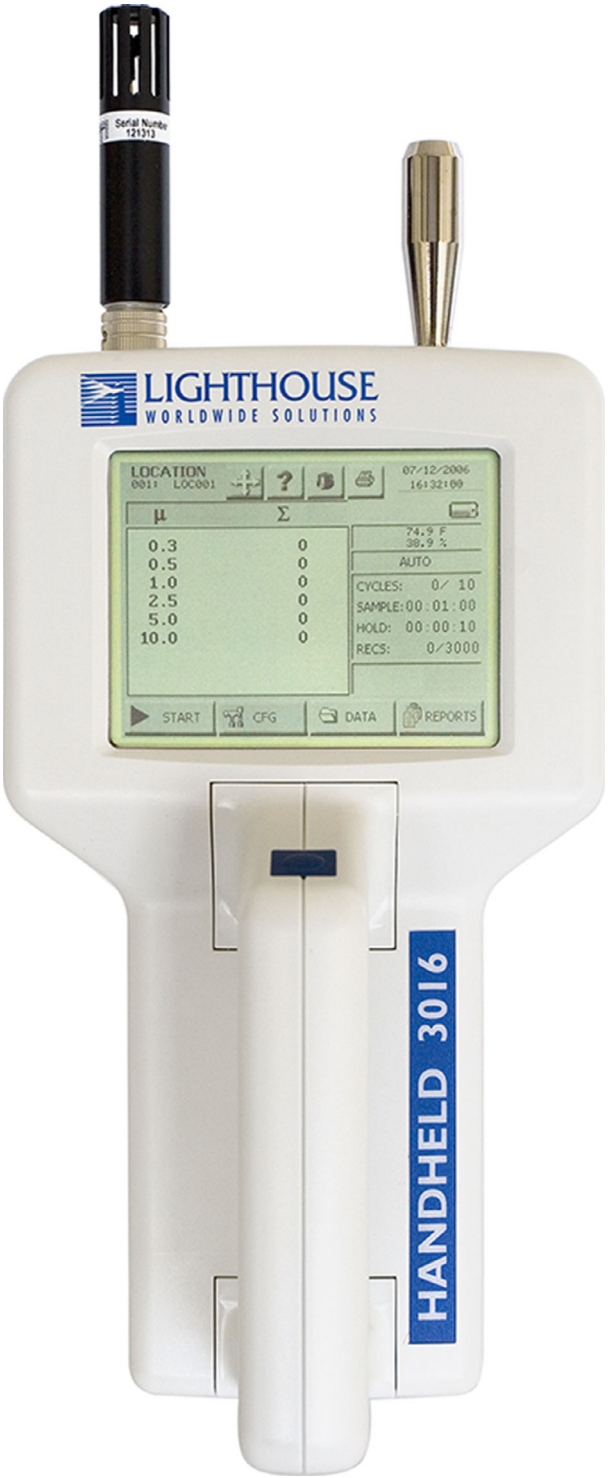

Figure 1 Lighthouse 3016 particle counter.

To simulate aerosolisation, 5 ml of saline was nebulised at 6 $l.min^{-1}$, using a standard Hudson RCI 'Micro Mist' Small Volume Nebuliser (Teleflex, Wayne, PN, USA) without the facemask, and held beneath the patient's mouth. The

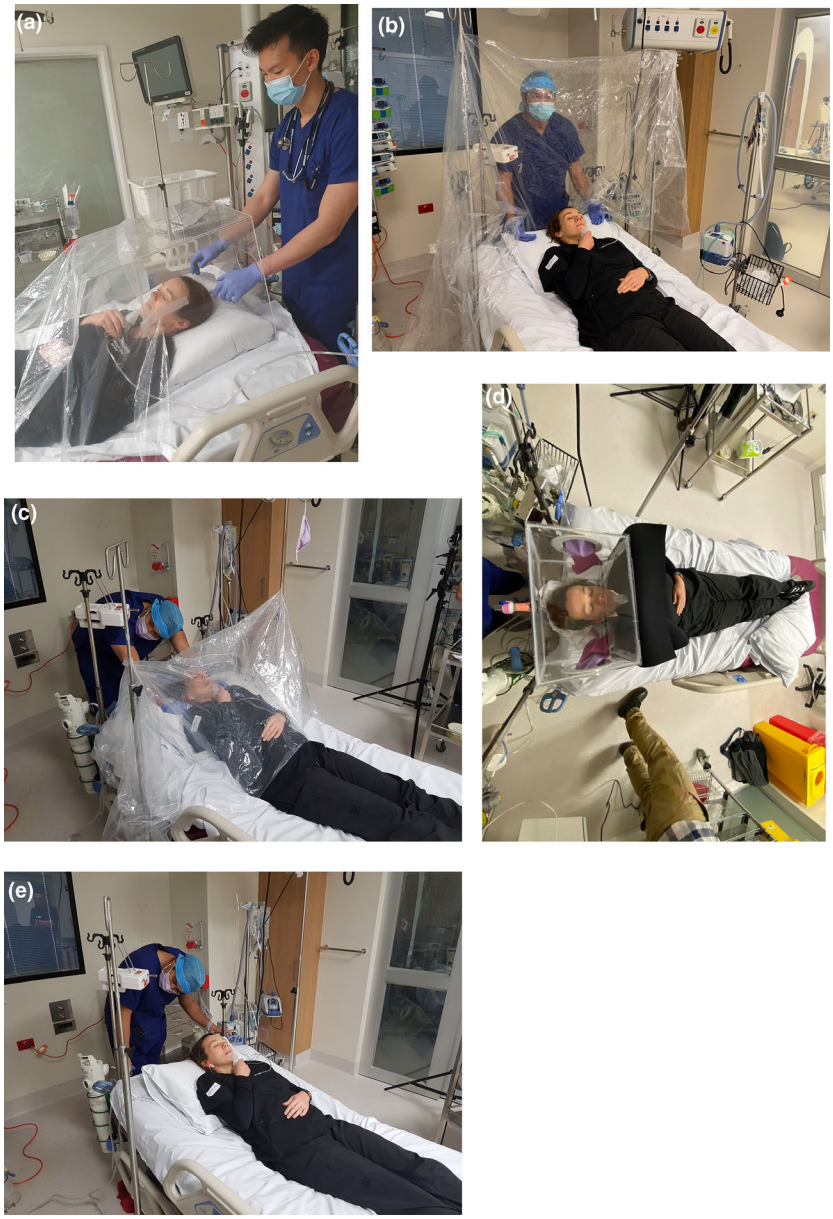

Figure 2 Sample setups for aerosol containment devices. (a) aerosol box; (b) vertical sheet; (c) horizontal tent sheet; (d) sealed aerosol box with heat and moisture exchange filter; and (e) no intervention.

patient coughed every 30 s for the duration of the 5-min trial. The aerosol containment device was then removed at the 300 s time-point and the airborne particle counts were also measured for 1 min after device removal. Following this time, the room doors were opened, and particle counts in the room were allowed to passively return to under 500 particles of 0.3 micron size between trials. Particle counts were zeroed to the baseline environmental reading at the start time of each trial.

The sample size calculation for this experiment was based on an initial pilot experiment showing a two- to three-fold increase in particle counts at 0.3 micron at 30 s. To detect a mean difference of 12,000 particles (SD 8000) from a baseline level of 8000 particles with a two-sided significance level of 1% and power of 80%, an estimated seven participants were needed per device tested.

All values were normalised against the background particle count present in the ICU room at the start of each individual trial. Time series graphs reflect median values of 5 s rolling averages of particle counts for each trial.

Differences between groups that showed heterogeneity of variance were calculated using a Kruskal-Wallis one-way

analysis of variance (ANOVA) at 30 s, and 1-min intervals. A two-sided p value of < 0.05 was used for statistical significance of the ANOVA. Post-hoc analysis between these groups was performed using a Mann–Whitney *U*-test and, as multiple testing was conducted, a Bonferroni correction was used with a p-value of 0.01 considered to be significant. All statistical analysis was performed using IBM SPSS v23 (IBM).

Results

The median 5 s rolling average of the total particle counts of all five particle sizes over the 5-min trial period for each device can be seen in Figure 3. There was no significant difference with the horizontal or vertical sheet compared with no device use. Only the sealed aerosol containment box on continuous suction demonstrated an airborne particle count similar to baseline.

A Kruskal-Wallis ANOVA testing the hypothesis that there was a difference in median airborne particle counts between the six interventions over the 5-min trial period at each time-point and at each particle size showed significance (one-way ANOVA $p < 0.001$). Median and IQR for each intervention at each particle size as well as a total count across all sizes at 0, 30, 60, 120, 180, 240, 300 and 360 s can be found in the online Supporting Information (Table S1).

Post-hoc comparisons were then performed to compare these median airborne particle counts for each

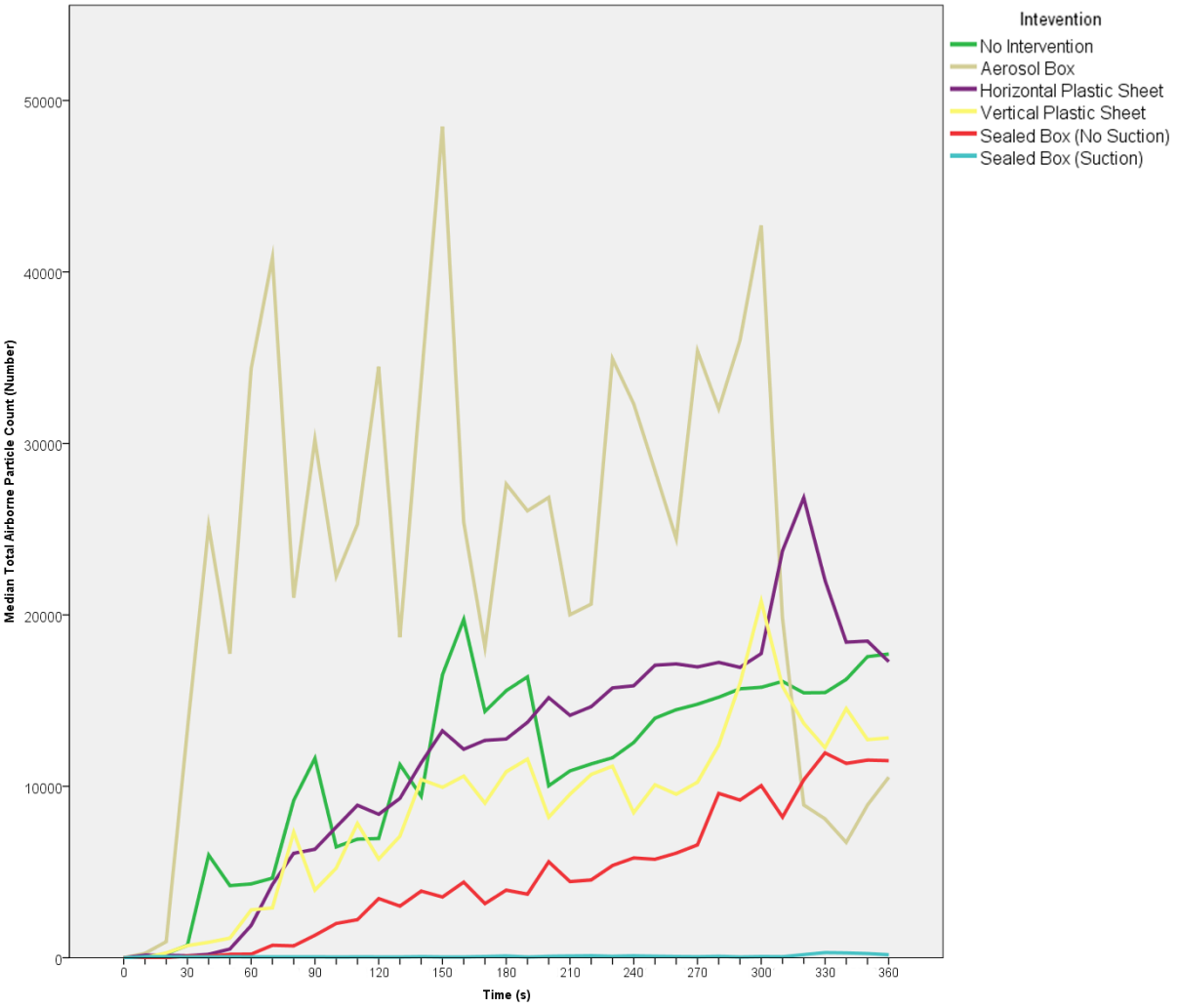

Figure 3 Time series graph of the five aerosol containment devices tested and no device use over the 360 second experimental period. Lines represent median total particle count (0.3 micron + 0.5 micron + 1 micron + 2.5 micron + 5 micron) of the seven 'patients' by aerosol containment device. All seven 'patients' coughed every 30 seconds throughout the experimental period.

Table 1 Laryngoscopist exposure of 0.3, 0.5, 1.0, 2.5 and 5.0 micron and total particles of the five aerosol containment devices tested compared with no device use at 30, 60, 120, 300 and 360 s. Values represent the p value comparing the medians at each time-point.

Time (s)	Aerosol box p value	Vertical drape p value	Horizontal drape p value	Sealed box (no suction) p value	Sealed box (suction) p value
0.3 micron compared with no device use					
30	0.046	0.045	1	0.063	0.022
60	0.199	0.063	0.317	0.015	0.003
120	0.015	0.886	1	0.317	0.003
300	0.116	0.668	0.568	0.046	0.003
360	0.391	0.775	0.253	0.046	0.003
0.5 micron compared with no device use					
30	0.032	0.046	0.886	0.116	0.032
60	0.116	0.063	0.317	0.015	0.003
120	0.015	0.886	0.886	0.317	0.003
300	0.035	0.886	0.668	0.032	0.003
360	0.568	0.568	0.153	0.046	0.003
1.0 micron compared with no device use					
30	0.015	0.063	1	0.116	0.032
60	0.046	0.046	0.199	0.015	0.003
120	0.015	0.668	1	0.153	0.003
300	0.002	0.568	0.568	0.022	0.003
360	0.391	0.568	0.116	0.086	0.003
2.5 micron compared with no device use					
30	0.02	0.099	0.83	0.474	0.018
60	0.116	0.086	0.199	0.015	0.003
120	0.015	0.775	0.943	0.174	0.003
300	0.008	0.668	1	0.004	0.003
360	0.568	0.317	0.032	0.007	0.003
5.0 micron compared with no device use					
30	0.003	0.172	0.429	0.614	0.773
60	0.044	0.942	0.313	0.471	0.168
120	0.01	0.133	1	0.667	0.719
300	0.002	0.616	0.774	0.133	0.062
360	0.568	0.567	0.72	0.282	0.192
Total count (all sizes) compared with no device use					
30	0.046	0.063	1	0.063	0.022
60	0.086	0.086	0.317	0.015	0.003
120	0.015	0.886	1	0.199	0.003
300	0.02	0.886	1	0.032	**0.006**
360	0.568	0.886	0.199	0.046	0.003

device at each time-point with no device use (Table 1). Compared with no device use, the sealed box with suction resulted in a decrease in 0.3, 0.5, 1.0 and 2.5 micron, but not 5.0 micron, particle exposure over all time periods beyond 30 s ($p = 0.003$ for all time periods) (Table 1). The sealed box without suction showed a decrease in 2.5 micron particles compared with no device use, but only at 300 and 360 s ($p = 0.004$, $p = 0.007$) (Table 1). Compared with no device use, the aerosol box showed an increase in median particle count at 300 s for 1.0, 2.5 and 5.0 micron particles ($p = 0.002$, $p = 0.008$, $p = 0.002$) (Fig. 4a–e, Table 1). Both horizontal and vertical drapes showed no difference in

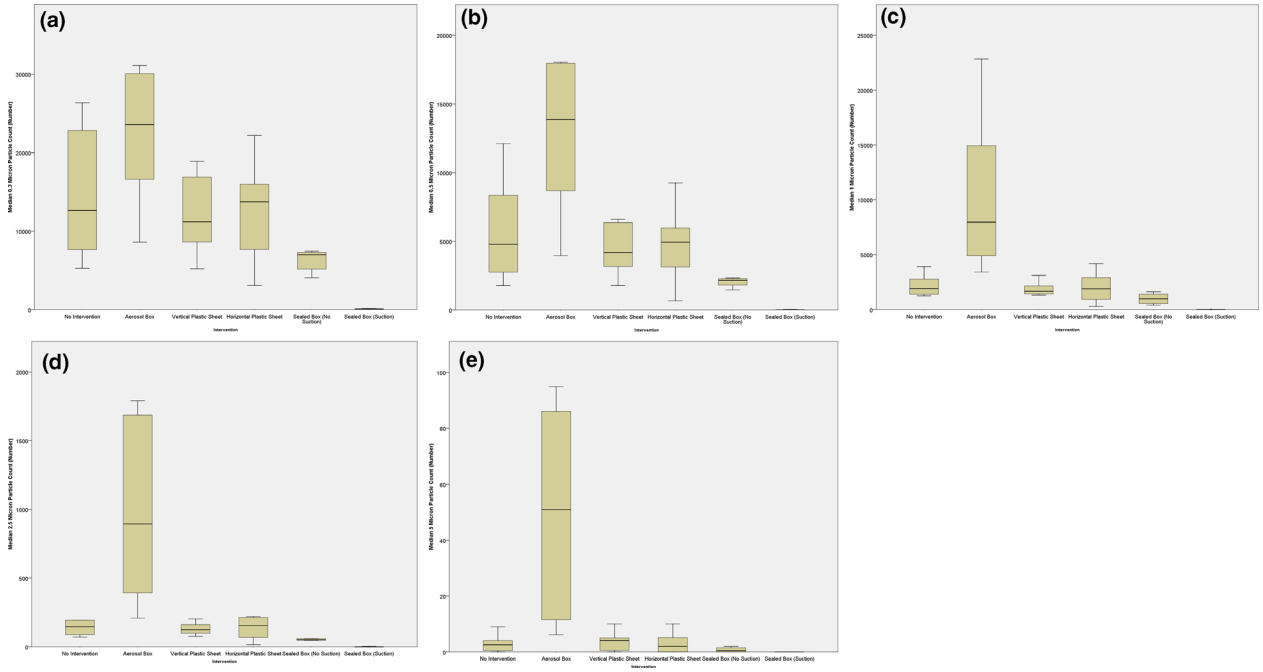

Figure 4 Box plots of median and interquartile range (IQR) of particle counts at 300 seconds for the five aerosol containment devices tested and no device use. (a) 0.3 micron. (b) 0.5 micron. (c) 1.0 micron. (d) 2.5 micron (e) 5.0 micron.

airborne particle size exposure of the laryngoscopist compared with no device use. Apart from no intervention compared with the sealed box, the difference in particle spread of 0.3 micron particles with a device when compared with no device use was not significant (Table 1, Fig. 4a).

During testing, it was also noted by investigators that clouds of aerosolised particles escaped from the arm openings of the aerosol box towards the laryngoscopist with each patient cough. For every particle size, the number of particles measured was consistently higher with the aerosol box compared with all other devices and with that of no device use (Fig. 3). There were visible spikes in particle counts when the volunteers coughed. The aerosol box was also the only intervention to record 5.0 micron particle counts above environmental baseline ($p = 0.001$). Removal of the devices did not result in a statistically significant increase in airborne particles during this study.

Discussion

The race to generate sustainable equipment to protect healthcare workers during tracheal intubation procedures in patients with suspected or proven COVID-19, particularly in settings where PPE supply is limited, has flooded the scientific community and social media with a variety of novel devices meant to contain potentially infectious aerosols produced by patients. Evidence for the safety and efficacy of these devices is lacking. Many international organisations have released consistent recommendations in the appropriate use of PPE based on the modes of viral transmission. None of these recommendations include these novel devices [11–15]. The dispersal of droplets and airborne particles from the patient depends on the aerosol (size, flow rates, turbulence, physiochemical properties) and patient (position, lung function) characteristics [18–20]. It is not clear in the manufacturing specifications of these novel devices that variables such as these have been fully considered in addition to the variability of employing these devices. The use of such devices adds to the complexity of an already complex procedure (tracheal intubation following local COVID-19 protocols including airborne PPE use) with the potential to compromise the safety of both the laryngoscopist and the patient [21].

Multiple methods of producing in situ aerosols in order to assess potential healthcare provider exposure are described in the literature. Techniques include the use of tracer particles of nebulised liquid droplets in a cloud or solid particles in smoke [1, 22–24]. These droplets are detected using optical particle detection techniques, such as particle counters and electron microscopy [22]. We selected an established and reproducible aerosol dispersion method that would maximise aerosol generation across multiple particle sizes. The number of airborne

particles produced via nebulisation of saline may far outnumber that produced during coughing and following paralysis of the patient for tracheal intubation. We selected nebulisation to generate large amounts of airborne particles to better discriminate the protective benefit, if any, of various aerosol containment devices compared with one another and to that of no device use.

Despite small numbers of volunteers, our study demonstrates a statistically significant difference in the quantity of airborne particles between the various devices described, with only a fully sealed box on suction demonstrating airborne particle quantity similar to the ICU room at baseline.

We were surprised to find airborne particle contamination of the laryngoscopist increased substantially using the aerosol box compared with all other devices and to no device use. Spikes of airborne particles were clearly seen on the time series graph, coinciding with patient coughing. We hypothesise that these represent particles escaping from the arm access holes in the aerosol box as a result of the Bernoulli principle. This was demonstrated in a recent simulation study by Dalli et al. [24] where photographic images showed that substantial amounts of air moved out of aerosol boxes into the operating theatre during coughing. These data may be extrapolated to assess the utility of aerosol containment devices for tracheal extubation, where coughing is far more likely. However, this was not the objective of this study and further trials would need to be conducted.

Equally concerning is the increased exposure of the laryngoscopist at 300 s to 1.0, 2.5 and 5.0 micron particles when using the aerosol box, compared with not using any aerosol containment device (Table 1). When compared with all other proposed aerosol containment devices and to no device use, exposure of the laryngoscopist to 5.0 micron particles was significantly greater with the aerosol box (Fig. 4e). The sealed box with suction appears to maintain airborne particle count at baseline but only with the use of ongoing suction. We hypothesise that the efficacy of suction depends on the negative pressure generated, relative to the volume of the sealed box, the potential leak of the sealed box, and the length of time it takes for the air within the sealed box to become saturated with aerosol. Whereas the sealed box was effective at maintaining environmental airborne particle counts, its design renders tracheal intubation mechanically impossible. It does, however, demonstrate the degree of enclosure necessary to eliminate particle contamination.

Wall suction has been proposed in many experimental setups [6–8] over high volume extraction as it is present in most intubating areas and is readily available. It should be noted that the flow of most wall suction is intentionally limited to reduce the risk of trauma to patients [25, 26], is not connected to any particle filter and was never intended to be used for the purposes of removal of airborne particles.

We acknowledge limitations with this small prospective in-situ simulation study. There was significant variability in the airborne particle in the aerosol box, no intervention group and vertical sheet setups compared with the other methods. This suggests that the level of laryngoscopist exposure is unpredictable and likely influenced by the aerosol containment device setup and the volume, negative pressure generated from suction and frequency of patient coughing. To better assess variability, an increased number of subjects would be required, yet such variability suggests an inability to fully predict airborne particle contamination based on device alone.

This experiment also did not assess the particle count for individuals at the side of the bed or elsewhere in the room. Given airborne particles are known to spread over distances greater than 1.5 m [1, 2, 23], this is especially pertinent for the laryngoscopist's assistant, who is often standing very close to the patient's head during tracheal intubation and extubation.

In conclusion, this study demonstrates that devices such as the aerosol box confer minimal to no benefit in containing aerosols during an aerosol-generating procedure and may increase rather than decrease airborne particle exposure. A sealed box with suction appears to decrease airborne particle exposure of the laryngoscopist, although whether it hinders assistance or execution of tracheal intubation remains a point of study. Further large-scale studies are needed to examine aerosol containment devices in this context, as well as others, such as tracheal extubation. The use of any aerosol containment device has been eliminated from our intubation protocols until their safety can be properly established.

Acknowledgements

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Supporting Information

Additional supporting information may be found online via the journal website.

Appendix S1. Lighthouse 3016-1AQ Handheld Particle Counter.

Figure S1. Aerosol box specifications.

Figure S2. Sealed box specifications.

Table S1. Median laryngoscopist exposure to particles at 30, 60, 120, 180, 240, 300 and 360 s.