Combating COVID-19 during Airway Management: Validation of a Protection Tent for Containing Aerosols and Droplets

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Abstract: The COVID-19 pandemic has made it necessary for medical personnel to protect themselves from aerosol-producing procedures, especially during airway management. The tracheal intubation process has a significant risk based on the spreading of aerosol, especially when the medical service provider is very close to the airway of the patient. We have developed a novel conservation tent that provides a barrier for healthcare professionals and patients. Through a simulation study, the relationship between the use of the protection tent during intubation and the contamination of medical personnel before and after the movement of the protection tent was explored. A series of experiments in this article provide a theoretical basis for the verification of spray morphology during gas curing and droplet intubation. This inexpensive and simple method for using transparent cloth in the intubation of patients with unknown COVID-19 status can be applied by frontline medical personnel as an additional precautionary measure.

Keywords: aerosol; protection tent; intubation; COVID-19; airway

1. Introduction

SARS-CoV-2 continues to pose a significant risk of infection and mortality among medical personnel [1–3]. The World Health Organization (WHO) and the International Council of Nurses have reported that thousands of medical personnel have had COVID-19 and hundreds have died because of that [4,5]. Risks of infection could occur during the medical treatment of COVID-19 patients. Medical personnel who perform aerosol-generating procedures are at particular risk [6–8].

Aerosol-generating procedures may expose healthcare professionals to pathogens causing respiratory infections [6–8]. Procedures that generate aerosols and droplets include endotracheal intubation, airway suction, positive pressure ventilation, tracheostomy, chest physiotherapy, nebulizer treatment, sputum induction and bronchoscopy [7–9]. Current guidance for the management of patients with COVID-19 infection suggests that a negative airflow room is preferable during aerosol nebulization treatment [9,10].

For the most serious patients and those receiving long-term mechanical ventilation, medical personnel use personal protective equipment (PPE) to protect themselves from aerosols from patients with suspected COVID-19 and contaminated surfaces [11–13]. PPE can include goggles, masks, aprons, gowns, clothing, gloves and respirators. PPE is uncomfortable to wear. PPE must be installed properly, and medical personnel may contaminate themselves when they dismantle it [14].

Innovative devices, such as the “Aerosol Box”, have been introduced for tracheal intubation [15–18]. While we appreciate these recommendations for protecting medical personnel, these barriers still have limitations when handling patients with COVID-19. Droplets of various sizes can be generated due to a patient coughing during an airway
intervention. Although PPE may prevent the large droplets resting on the physician’s face or body surface, the smaller droplets (<5 µm, i.e., “aerosols”) will be delayed, floating inside the barrier device.

The risk of infection from recovered COVID-19 patients should also be considered. With the continual recovery of confirmed COVID-19 patients, a new task arises in determining the timing of emergency treatment for this kind of patient. Studies have shown that the duration of viral shedding is 20 days and can extend to 37 days [19]. Four recovered COVID-19 patients (with absence of clinical symptoms) who conformed to the criteria for hospital discharge or discontinuation of quarantine had positive test results 5 to 13 days later, indicating that a proportion of recovered COVID-19 patients may still be shedding virus [20]. For emergent events where intubation should advance regardless, patients should be supposed to still be infectious; hence, the protection tent could also play a role in risk stratification [21].

We recently developed a protection tent that could potentially reduce the infection risk during airway management [18]. The aim of this study was to validate the protection tent in containing aerosols and droplets.

2. Materials and Methods

2.1. The Protection Tent

In this work, we have developed a tent that medical staff can use to provide protection, especially when performing intubation on patients with COVID-19. This tent-like device was inspired by an umbrella and a raincoat. The device was made of two L-shaped frames and a transparent polyvinyl chloride membrane. These thin film materials were relatively inexpensive. The schematic design of the protection tent is shown in Figure 1.

![Figure 1. The schematic design of the protection tent.](image)

2.2. Laboratory Setting

In order to ensure high-quality performance, the laboratory must meet certain requirements, such as performing validation studies on authorized available tests, the use of internal quality controls, and involvement in external quality assessment plans (EQA). Since the WHO and the Innovative New Diagnostic Foundation started organizing to deal with the pandemic, only reference materials and EQA recommendations for SARS-CoV-2-based molecular detection have become available to date [22]. To obtain fast, sensitive, highly specific and reliable results about the presence of specific viruses, the quantitative real time polymerase chain reaction (RT-qPCR) is the method of choice.

The AccuPlex™ SARS-CoV-2 Reference Materials Kit (SeraCare, Milford, MA, USA) was used as the test kit for viral aerosols [23]. This positive reference material contains recombinant virus particles composed of the SARS-CoV-2 genome sequence, including the E gene, RdRp (RNA polymerase dependent on RNA), ORF1a gene and N gene. In addition, the positive references have high similarity with the SARS-CoV-2 virus, which results in the advantages of more realistic virus detection and lower measurement uncertainty.
The Reference Materials Kit has been approved by the US FDA (U.S. Food and Drug Administration) and is compliant with federal regulations and laboratory standard quality control procedures.

The external control used the AccuPlex™ SARS-CoV-2 Reference Material Kit and the Reliance One-Step Multiplex Supermix (Bio-Rad Laboratories, Hercules, CA, USA). External positive controls were handled like patient samples to check the RNA extraction, reverse transcription, and RT-qPCR amplification and detection. The supposed outcome was obtained with the external positive control, along with performing positive (template) and negative (non-template) RT-qPCR controls, to clarify the results obtained from patient samples. Primers and probes were synthesized by Tri-I Biotech, New Taipei City, Taiwan. Viral extraction was performed using a Quick-RNA Viral Kit (Zymo Research, Irvine, CA, USA). Two hundred microliters of the sample of the AccuPlex™ SARS-CoV-2 Reference Material Kit was added to the column and eluted in 15 µL of DNase/RNase-Free water, provided in the kit.

The SuperScript™ III Platinum™ Taq Mix (Thermo Fisher Scientific, Waltham, MA, USA) was applied for the RT-qPCR with specific primers and probes tagged with FAM. The final concentration of the primers in the reaction was 200 nM in a 50 µL reaction. The final concentration of the probe was 100 nM. The primers and probes described by the WHO for the diagnostic detection of the SARS-CoV-2 virus by RT-qPCR are shown in Table 1. Thermal cycling was performed at 50 °C for 15 min for reverse transcription, followed by 95 °C for 2 min and then 40 cycles of 95 °C for 15 s and 60 °C for 30 s. Table 2 shows the setup for the RT-qPCR for the 2019 novel coronavirus.

Table 1. Primer and probe sequences.

| Primers         | Sequence (5′–3′)                  | Annealing Temperature |
|-----------------|-----------------------------------|-----------------------|
| E_Sarbeco_F1    | 5′-ACAGGTACGGTTAATAGTTAATACGT-3′ | 60 °C                 |
| E_Sarbeco_R2    | 5′-ATATTCGCGACGTACGCACACA-3′      |                       |
| E_Sarbeco_P1    | 5′-ACACTAGCCATCTTAAGTCCCTGCGGTCG-3′ |                      |

Table 2. RT-qPCR setup.

| Process           | Temperature | Time | Cycles |
|-------------------|-------------|------|--------|
| RT                | 50 °C       | 15 min | 1      |
|                   | 95 °C       | 2 min  |        |
| Polymerase activation |           |       |        |
| PCR               | 95 °C       | 15 s  | 40     |
|                   | 60 °C       | 30 s  |        |

2.3. Experimental Setup

A schematic figure of the experimental setup is shown in Figure 2. A commercial aerosol generator (model ATM228, Topas GmbH, Dresden, Germany) was used to generate positive reference material at 800 hPa and sodium chloride (NaCl) aerosol particles from a 5 wt% solution prepared in deionized water. The NaCl droplets were dried by using a silica dryer. Infectious aerosols are suspensions of small organisms in the form of particles in the air. The size of the particle is the most important decisive factor for aerosol behavior. Particles that are 2 µm or smaller in size can remain airborne in most indoor environments unless there is removal by air filtration.

Two groups of 10 collectors (MF-Millipore™ Membrane Filter VSWP02500, Merck, Darmstadt, Germany) were set up with/without protection tents. Each collector performed three intubation simulations with no protection tent and three with a protection tent. In all the tests, the L-shaped frames that were originally placed were not moved. An easy, highly efficient, and sensitive method for the monitoring of airborne pathogenic microorganisms and viruses is the mixed cellulose ester membrane filter method [24]. The suitability of water-soluble filters, especially for virus sampling, has already been tested and proven. These filters are particularly suitable because they show excellent virus collection efficiency.
with high retention rates. As soon as the filter has been dissolved in deionized water, or any other appropriate buffer or medium, all the viral particles retained on the filter can be further processed and detected using RT-qPCR.

![Diagram of experimental setup](image)

**Figure 2.** The experimental setup. Numbers 0~10 are the collection locations.

Even sensitive RNA material can be detected by a combination of gelatin filtration and RT-qPCR. However, it should be considered that RNA extraction is a crucial step within sample preparation. Therefore, to reduce the loss of genetic material, attention should be given to this step. Several studies have shown that RT-qPCR analysis after air sampling using filters provides recovery results superior to those obtained with other detection methods and hence can be considered a precise and practicable method for the detection of airborne viruses [25,26].

With the recognition that the procedures for generated aerosol are of particular importance to practice in situations with a high risk of infection, an additional tool for intubation training that helped in focusing knowledge and motivating changes to practice in hospitals to use the protective tent was tested. The Glo Germ™ (Marlatek Inc., Brockville, ON, Canada) was used as the UV fluorescent solution in these simulations, which is 5~10 microns in size. A simulated study was conducted to explore the relationship between protective tent usage during intubation and contamination by medical personnel pre-doffing and post-doffing PPE. This study tested video laryngoscope-assisted intubation on an intubation mannequin with and without a protection tent in a random order.

### 2.4. Image Processing

ImageJ (U. S. National Institutes of Health, Bethesda, MD, USA) was used for particle analysis. The images were cropped to include only the segment to be analyzed [27]. A rolling ball radius of 5 pixels was used to subtract the background algorithmically, with separated colors, and the sliding paraboloid method was used to modify background reflected light and surface reflection. Following this, the function of color adjustment was presented to eliminate red and blue hues. The image was modified for consistency issues and nonparticulate edges, which were then removed manually. The image was converted to an 8-bit image and a binary black and white pixel threshold was applied to the analysis.
3. Results

The overall contamination results of the two L-shaped frames and the medical personnel were the main outcomes, shown in Table 3. There were considerably more areas of contamination noticed on the two L-shaped frames and the PPE of the medical personnel without the aerosol box. The RT-qPCR results show the contamination of 10 locations: Nos. 0 and 9 were the outlets of commercial aerosol generators, and Nos. 1 and 2 were the locations of the medical personnel. Nos. 2–8 were on the two L-shaped frames. These locations are shown in Figure 2. The cleaning effect of the L-shaped frames were tested by using rubbing alcohol, which is often used to clean wounds and surgical instruments. The study results showed that the cleaning effect with disinfection was sufficient for reuse.

| Location No. | With Tent | Without Tent | With Disinfection (after Testing) | Without Disinfection (after Testing) |
|--------------|-----------|--------------|-----------------------------------|--------------------------------------|
| 0            | 3/3       | 3/3          | Not calculated                    | Not calculated                       |
| 1            | 0/3       | 3/3          | 0/3                               | 2/3                                  |
| 2            | 0/3       | 3/3          | 0/3                               | 1/3                                  |
| 3            | 0/3       | 3/3          | 0/3                               | 3/3                                  |
| 4            | 0/3       | 3/3          | 0/3                               | 1/3                                  |
| 5            | 0/3       | 3/3          | 0/3                               | 2/3                                  |
| 6            | 0/3       | 3/3          | 0/3                               | 2/3                                  |
| 7            | 0/3       | 3/3          | 0/3                               | 0/3                                  |
| 8            | 0/3       | 3/3          | 0/3                               | 1/3                                  |
| 9            | 3/3       | 3/3          | Not calculated                    | Not calculated                       |

Studies concerning speech-generated and breathing aerosols from patients with various respiratory infections have shown significant similarities in the size distributions of aerosols, with a majority of the organism in small particles (<5 µm). These are immediately adapted for respiration, suggesting the need for intubation protection for medical personnel in proximity to potentially infected patients. Positive reference material was generated in the tent for 6 min. The particle numbers in the tent were measured, and particles of different sizes were detected, as shown in Figure 3. The smaller particles were found to be still in the air until the 15th minute and then gradually disappeared. However, when the tent was removed at the 16th minute, the number of smaller particles gradually increased.

The contamination process was simulated with an aerosol generator. The study results showed that using the protection tent could decrease contaminations over the front and back body regions of medical personnel pre-doffing and post-doffing PPE. The protection tent is useful for containing the droplets, as shown in Figure 4a,b, showing that without the protection tent, fluorescent powder could be found in the neck regions when the medical personnel only wore a medical mask. The floor still had fluorescent powder after putting away the tent, as demonstrated in Figure 4c. The observed region was 1.5 m away from the tent. Before putting away the tent, the observed region did not show the fluorescent powder (image not shown). Finally, the measurement was repeated five times to calculate the fluorescent percent area using ImageJ.

Particle analysis was used with a particle size of 0-infinity and a circularity of 0.0–1.0, with particle counting and percent area calculation, as shown in Figure 4d. The calculated percent area was 0.58% ± 0.06%. The protection tent may prevent the secretions splashing and decreased the dispersion of aerosolized particles during the intubation procedure. However, medical personnel may still be exposed during the post-intubation period, especially when the protection tent is removed.
Although mechanisms of COVID-19 infection and treatment have been proposed and investigated [28,29], the concept of using physical barriers to reduce infection risks still plays an important role in clinical practices [30,31]. PPE with various types and levels are available to provide certain protection for medical personnel from infectious diseases [31–33]. However, wearing PPE is generally cumbersome and may interfere with technical performance, especially during life-saving procedures. Performing endotracheal intubation for patients with COVID-19 carries a high risk for medical personnel. The
current SARS-CoV-2 pandemic poses significant challenges for front-line medical personnel, especially those working in the emergency department. They often engage in treatment with insufficient information about the patients.

Filter half-masks for respiratory protection are subject to various regulatory standards worldwide [1,7,8]. These standards specify certain required physical properties and performance characteristics for respirators to comply with a particular standard or norm [34]. However, the medical masks mainly serve to prevent the spread of small particles from their users to the environment. The medical masks prevent the penetration of microorganisms from the inside out and thus primarily protect the surroundings (infected or potentially infected) of the user, although the N95 respiratory mask filters particles and microorganisms more efficiently. The data of the maximum permissible resistance for inhalation, the minimum filtering protection efficiency and the respirator filtering capacity must be qualified using a standard. However, unknown patients should be supposed to still be infectious; hence, the protection tent could also play a role in risk stratification, and healthcare professionals must wear a medical mask or N95 respiratory mask.

In order to manage the current COVID-19 outbreak, extensive measures need to be taken to lower the person-to-person transmission of the virus. In addition to this, special efforts and attention are required to reduce or protect susceptible populations, such as elderly people, health care providers and children. More studies are also essential to understand the mechanisms related to COVID-19 pathogenesis. This better understanding will help the development of specific and effective therapies against SARS-CoV-2. Since the respiratory tract is mainly affected by SARS-CoV-2, special consideration is required to deliver drugs into the respiratory tract.

To reduce the exposure of medical personnel to SARS-CoV-2 via airborne aerosols, a potential solution is portable tents that not only create barriers between medical persons and patients during airway management, but also utilize negative pressure with HEPA filtration. The bench tests in simulated hospital environments could provide significant support for the function of several recently developed devices and localized negative pressure systems. Prior to and during clinical use of the tent, the patient’s body temperature and CO₂ and oxygen levels should be monitored. Infection control measures might not only reduce the probability of infection but might also reduce the size of the droplets/aerosols. However, the aerosol eventually evaporates, and the final particle may have a relatively high charge. Humidity creates a bridge between a particle and a surface. The effect of evaporation decreases in the case of high air humidity, so smaller aerosols will still be present in the form of fine droplets for a certain period. Moving the tent might also result in an increase in droplet diameter and spread efficiency.

A major limitation of our protection tent is that before removing the tent from the patient, medical personnel should wait at least 20 min after performing airway management or aerosol-generating procedures. This 20-min waiting period helps to ensure that aerosols have been cleared prior to opening the tent. We hope the 20-min waiting period can be reduced to 5 min by improving our design.

5. Conclusions

Our series of experiments were a proof of concept of the patterns of aerosolization and droplet sprays during intubation. The use of the protection tent was able to create a barrier and limit aerosolization and droplet spray. The inexpensive and simple method of using clear drapes during the intubation of patients with an unknown COVID-19 status may be considered by front-line medical personnel as an additional precaution. Modifications of the plastic tent can be adapted for surgical procedures or during ambulance transfer.

6. Patents

The tent used in this study was granted a patent by the Intellectual Property Office, Ministry of Economic Affairs, Taiwan (A Protection Tent for Airway Management in Patients, M598615).
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