Aerosol particle concentrations among different oxygen devices for spontaneous breathing patients with tracheostomy: a randomized cross-over trial

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Introduction

The transmission route of the SARS-CoV-2 virus remains controversial,[1,2] and concerns persist of potentially increased virus transmission and aerosol dispersion when utilizing high-flow devices and aerosol devices among COVID-19 patients.[2-5] For spontaneous breathing patients with tracheostomy, whose lower airway more directly communicates to the room air, the aerosol particles generated by these patients would be directly dispersed into the room air, which might be an direct resource of virus transmission.[6] Thus tracheostomy procedure is considered as a high-risk aerosol generating procedure and high-level personal protection equipment is recommended when the procedure is performed for COVID-19 patients. [7] However, the transmission risk of tracheostomy during spontaneous breathing has not been evaluated and the impact of appropriate humidification therapy is unknown.

Heat-moisture exchange filter (HMEF) should be an ideal humidification modality for those patients, as it can provide heat and humidification for patients and more importantly, it can filter the exhaled gas from patients.[6,8] However, this device should be used for long periods of time and could not be used for patients who had copious or thick secretions, due to the low efficiency of humidification. More importantly, it can be easily occluded by patients' secretion, resulting in dyspnea. Large volume nebulization, also named as cool aerosol, is commonly used for spontaneous breathing patients with tracheostomy. However, it can be easily contaminated by patients' secretions, resulting in generation of bio-aerosol that carries virus into the room air. Thus, nebulization should be avoided for COVID-19 patients.[5] Lastly, high-flow high humidity device that provides heated and humidified gas has been shown to improve comfort and secretion management in tracheostomy patients,[9,10] it has also been shown to have similar aerosol particle concentrations as conventional oxygen devices,[11,12] which might be used for spontaneous

breathing patients with tracheostomy. However, since it still keeps airway open, the aerosol particle concentrations generated by patients via tracheostomy stoma as well as the virus load in the room air is still unknown. Thus this study is aimed to investigate the aerosol particle concentrations among different oxygen and humidification devices for spontaneous breathing patients with tracheostomy, in order to reflect the transmission risk.

Furthermore, our previous study found that wearing a surgical mask over high-flow nasal cannula can significantly reduce aerosol particle concentrations for COVID-19 patients,[13] thus we also aim to explore the effects of wearing a surgical mask or using a scavenger tent over the high-flow device for tracheostomy patients can reduce the aerosol particle concentrations.

Methods

1. Study design: a randomized cross-over trial
    1) Inclusion criteria: (1) adults; (2) tracheostomy; (3) able to spontaneous breathing without ventilator support.
    2) Exclusion criteria: (1) confirmed diagnosis of COVID-19 within recent two weeks; (2) non-English speaking; (3) refuse to participate in the study; (4) palliative care; (5) receiving ECMO; (6) unable to connect with tracheostomy adapter, such as laryngectomy tube.
    3) Reason for excluding COVID-19 patients in this trial is: the transmission risk of using different devices especially large volume nebulizer is still unknown, to protect the study investigators and other clinicians who might enter into the room with patients' airway open, we would not keep anyone inside the room with patient's airway open.

2. Comparisons: 1) high-flow high humidity device with tracheostomy adapter; 2) large-volume nebulizer (cool aerosol) with trach collar; 3) Venturi-adapter with trach collar; 4) large-volume nebulizer (cool aerosol) with T-piece and a filter; 5) high-flow high humidity device with tracheostomy adapter and a scavenger or a surgical mask over the adapter.
3. Sample size: This study is a superiority study. From our previous clinical study, wearing a surgical mask significantly reduced aerosol particle concentrations,[13] particularly in proximity, the use of HMEF would reduce the aerosol particle concentrations even more, thus we expect the treatment effect would be medium to large as 0.1.[14] Using G-power software[15] to calculate the sample size in repeated ANOVA measures, with confidence level (α) of 95%, power (1-ß) of 80%, the number of patients that need to be enrolled is 12.
4. Study process: after consent, respiratory therapist assesses patient to see if patient needs suctioning. If needed, suction patient. Place HMEF on patient for 10 mins in order to measure the baseline data. Then use different devices in a pre-determined random order (prepared in an opaque envelope) for 5 mins, followed by 10 mins HMEF for the baseline data (figure 1). Aerosol particle sizes (Model 3889, Kanomax, Andover, NJ) will be placed at 1 and 3 feet from the patient airway measure aerosol particle concentrations. Patient's comfort will be self-evaluated using an visual numerical scale (VNS) ranging between 1 (very uncomfortable) and 5 (very comfortable) (Figure 2).[16]
5. Data collection: age, gender, ethnicity, diagnosis, tracheostomy placement duration, tracheostomy tube size, cuff inflation, secretion amount and color, aerosol particle concentrations and patient comfort at baseline and during the use of different humidification devices

6. Outcome: 1) aerosol particle concentrations at baseline and during the use of different humidification devices; 2) patient comfort with different devices
7. Statistical analysis: Kolmogorov-Smirnov will be used to test normality of distribution for considered variables. Continuous variables will be expressed as mean (standard deviation [SD]) or median (Inter-Quartile Range [IQR]), depending on the normality of distribution. Friedman test will be used to compare the aerosol particle concentrations among five devices. A p-value of < 0.05 was considered statistically significant for all tests. Data analysis was conducted with SPSS statistical software (SPSS 26.0; SPSS; Chicago, IL).

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Figure 1. Study process (total duration: 90 mins for one patient)

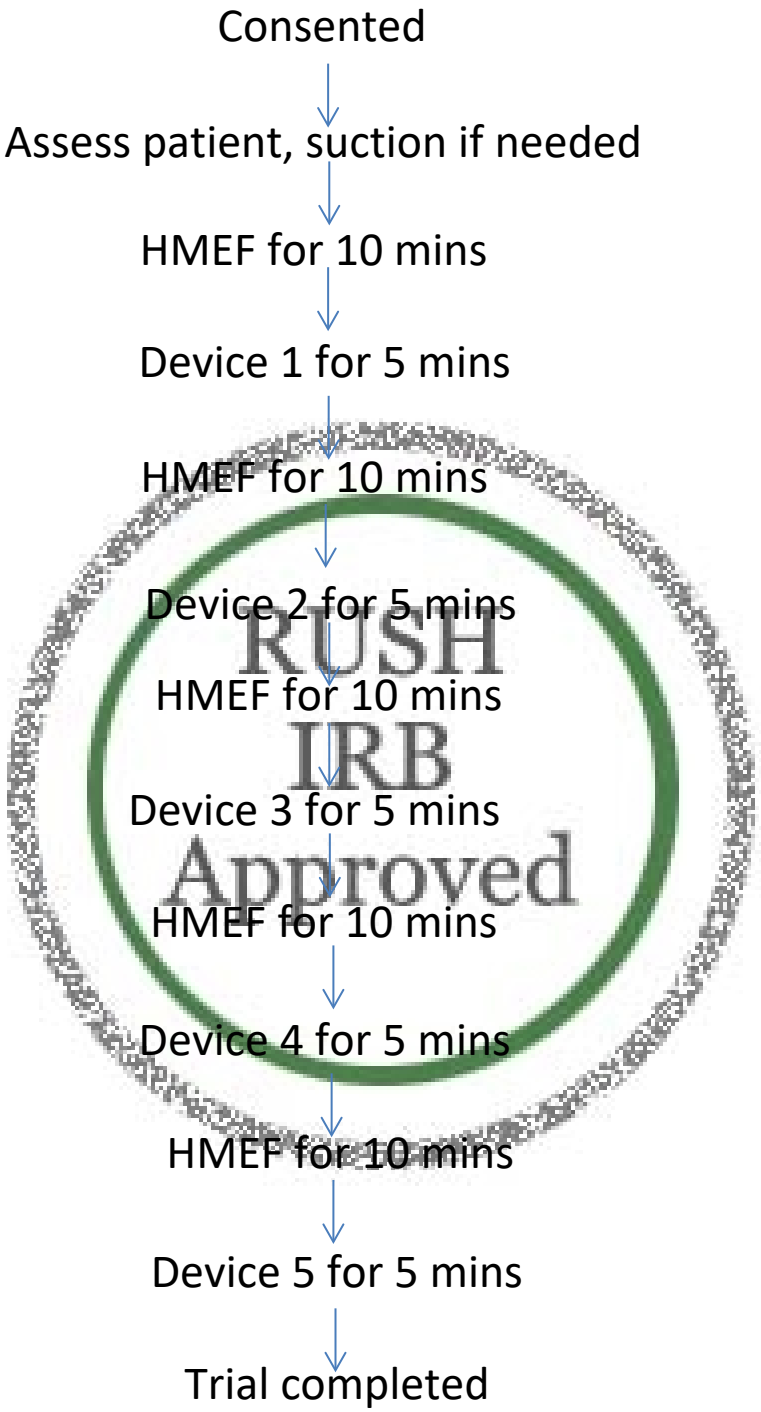

Figure 2. Patient's comfort visual numerical scale (VNS)

Scale	Explanation
1	Very uncomfortable
2	Uncomfortable
3	Neutral
4	Comfortable
5	Very comfortable