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# Aerosol particle concentrations with different oxygen devices and interfaces 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 oxygen and aerosol devices among COVID-19 patients.[2-5] Spontaneous breathing patients with tracheostomy represent a more direct conduit for dispersing aerosol particles with risk of virus transmission.[6] Tracheostomy procedure is considered a high-risk aerosol generating procedure and high-level personal protection equipment (PPE) is recommended when the tracheostomy is being performed for COVID-19 patients.[7] However aerosol dispersion transmission risk of bioaerosols via tracheostomy during spontaneous breathing has not been evaluated and the impact of different humidification devices and interfaces are unknown.

A heat-moisture exchange filter (HMEF) provides heat and humidification while filtering the exhaled gas from patients (Table 1),[6,8] but is not suitable for patients with copious or thick secretions, and can be occluded by secretions, resulting in an increased work of breathing or complete obstruction of the inner cannula. Large volume nebulizers (LVNs) are commonly used with tracheostomy mask for patients with a tracheostomy, despite concerns that cool gas may cause airway irritation or dry secretions. A venturi adapter with tracheostomy mask is commonly utilized during transport or patient mobilization. Lastly, heated high-flow high humidity has been shown to improve comfort and secretion management in tracheostomy patients.[9-11] The aerosol particle concentrations generated by patients via tracheostomy stoma with these devices is unknown. This study aimed to investigate the ambient aerosol particle concentrations among different oxygen and humidification devices for spontaneous breathing patients with a tracheostomy, in order to reflect the transmission risk.

## Methods

This prospective, randomized cross-over trial was approved by the Rush university ethics committee (approval No. 20112506-IRB01) and registered in clinicaltrials.gov (NCT04654754). Adult tracheostomy patients who were able to breathe without ventilator support were enrolled. Patients were excluded if meeting any of the criteria: had positive test of COVID-19 within the last two weeks; were non-English speaking or unable to communicate or make any decision; refused to participate in the study; were receiving palliative care or extracorporeal membrane oxygenation.

After signing the consent form, patients received oxygen therapy with four devices in a random order: 1) HHFHH device with tracheostomy adapter (Airvo2, Fisher & Paykel healthcare, Auckland, New Zealand) operated at 30 L/min (Table 1); 2) LVN (AirLife Prefilled Nebulizer Kit, Vyaire Medical, Mettawa, IL) with tracheostomy mask (AirLife, Vyaire Medical); 3) LVN with T-piece and a bacteria/viral filter (AirLife, Vyaire Medical);[8] 4) Venturi-adapter with tracheostomy mask. Both LVN and Venturi-adapter were operated at 6 L/min and fraction of inspired oxygen ($F_IO_2$) at 0.28. Each device was used for 5 mins. An HMEF placed at the tracheostomy tube was used prior to study and between devices, with the interval of 10 mins. A particle counter (Model 3889, Kanomax, Andover, NJ) was placed at 1 foot from patient face to continuously measure aerosol particle concentrations in the room. During the study, the investigator wore N95 mask and stayed in the room with patients, and activities (talking or moving around) were discouraged. The door of the patient room remained closed and none of the rooms had negative pressure. If suctioning was required, aerosol particle concentration measurement was paused and restarted 10 mins after suctioning. Patient's comfort was self-

evaluated using a visual numerical scale (VNS) ranging between 1 (very uncomfortable) and 5 (very comfortable).[12]

HMEF was expected to reduce the aerosol particle concentrations, with treatment effect set at medium to large as 0.1. Using G-power software to calculate the sample size in repeated ANOVA measures, with confidence level (α) of 95%, power (1-ß) of 80%, the number of patients was 12. Friedman test was used to compare the aerosol particle concentrations and comfort scores among five devices (including baseline with HMEF) and Wilcoxon sign rank test was used to analyze the differences between devices. $P<0.05$ was statistically significant for all tests. Data analysis was conducted with SPSS software (SPSS 26.0; SPSS; Chicago, IL).

## Results

Twelve patients were enrolled, with Age of 50.5±16.6 years, height of 166.5±10.4 cm, weight of 83.1±27.6 kg, and BMI of 29.5±7.6 kg/m$^2$. Tracheostomy had been in placed for 18.5 (5.3, 250.5) days, 10 patients had tracheostomy tube size of 6, of whom 4 had cuffed tubes and two patients had tracheostomy tube size of 4. All cuffs were deflated during study. Patients required suctioning frequency of 3 (2, 5) times in the past 24 hours. Only 2 patients required suctioning during the duration of the study, which lasted ~90 minutes per patient.

No significant differences of aerosol particle concentrations at each size were found among different devices (Table 1). Patients' comfort was similar among devices as well.

## Discussion

Aerosol particle concentrations were similar among different humidification devices used with tracheostomy patients with a deflated cuff. These findings differ from our previous study of high-flow nasal cannula for COVID-19 patients, in which aerosol particle concentrations at 1 foot from patients were reduced when placing a surgical mask over nasal cannula at particle sizes of 0.3-5.0 μm.[5] In contrast, the effect of placing a bacteria/viral filter or HMEF on tracheostomy tube was negligible. Hypothetically a bacteria/viral filter or HMEF should have higher efficiency to filter aerosol particles than a surgical mask, however all of the tracheostomy patients could breathe via their mouth and nose, and none wore a surgical mask. In contrast to COVID-19 patients in the acute phase, the stable tracheostomy patients enrolled in our study required minimal suctioning and barely coughed during the study, while cough in patients without tracheostomy was found to generate higher fugitive aerosol particle concentrations than nebulization.[13] Future studies should explore whether placing a surgical mask to cover the mouth and nose for tracheostomy with deflated cuff could reduce the aerosol particle concentrations, and to investigate the effects of a bacteria/viral filter or HMEF with a surgical mask during cough or suctioning.

Interestingly, LVN with tracheostomy mask did not generate higher aerosol particle than other devices, in contrast to small volume nebulizer, which was found to significantly increase the aerosol particle concentrations.[14] This difference might be explained by the long tubing (3m) used to connect LVN and tracheostomy mask, and the aerosol output produced with more particles deposited in the tubing, allowing mostly small particles of 0.3-0.5 μm to reach the patients.

There are several limitations. Due to the unknown transmission risk of tracheostomy, we did not enroll COVID-19 patients, however COVID-19 patients recovered from the acute phase and weaned off ventilator would be expected to have low virus load[15] and less frequent cough, thus our results might provide a reference for the future studies with tracheostomy patients with airborne disease. We did not investigate the virus load, while the aerosol concentrations only directly reflected the transmission risk, future studies are needed to measure the virus load with different devices. Regardless, appropriate PPEs are still recommended when taking care of tracheostomy patients, especially during suctioning.

For stable tracheostomy patients with uncuffed airways, different humidification devices and interfaces did not generate clinically significant differences of aerosol particle concentrations. Future studies are still needed to assess the effects of humidification devices during coughing or suctioning and the effects of wearing a surgical mask.

**Author Contributions:** JL and JBF conceived of the idea. CS and JL implemented the study, JL performed data analysis and drafted the manuscript. JL, CS and JBF interpreted the data. All authors reviewed and approved the final version.

**Ethical approval:** This study was approved by the institutional review board in Rush University Medical Center (approval No. 20112506-IRB01).

**Clinicaltrial registration:** NCT04654754

**Conflict of Interest Disclosures:** Dr. Li received research funding from Fisher & Paykel Healthcare Ltd, Aerogen Ltd, and Rice Foundation, lecture honorarium from American Association for Respiratory Care, Aerogen Ltd, and Fisher & Paykel Healthcare Ltd. Dr. Fink is Chief Science Officer for Aerogen Pharma Corp. Other authors have no conflicts to disclose.

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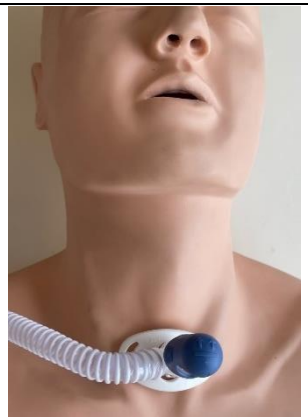
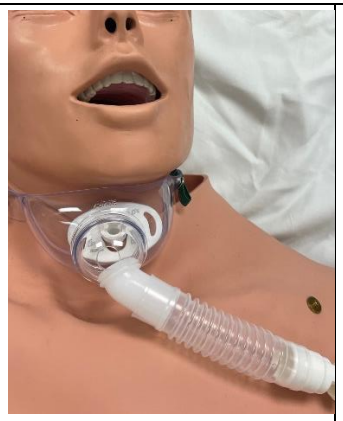
**Data share agreement:** De-identified data will be available upon reasonable request after publication.

## References


1. Liu Y, Ning Z, Chen Y, et al. Aerodynamic characteristics and RNA concentration of SARS-CoV-2 aerosol in Wuhan hospitals during COVID-19 outbreak. Nature 2020; 582, 557–560.
2. Dhand R, Li J. Coughs and sneezes: Their role in transmission of respiratory viral infections, including SARS-CoV-2. Am J Respir Crit Care Med 2020; 202(5):651-659.
3. Li J, Fink JB, Ehrmann S. High-flow nasal cannula for COVID-19 patients: low risk of bio-aerosol dispersion. Eur Respir J 2020; 55(5):2000892.
4. Li J, Ehrmann S. High flow aerosol dispersing- versus aerosol generating procedures. Am J Respir Crit Care Med 2020; 202(8):1069-1071.
5. Li J, Fink JB, Elshafei AA, et al. Placing a mask on COVID-19 patients during high-flow nasal cannula therapy reduces aerosol particle dispersion. ERJ Open Research 2021; 7(1):00519-2020
6. Rovira A, Dawson D, Walker A, et al. Tracheostomy care and decannulation during the COVID-19 pandemic. A multidisciplinary clinical practice guideline. Eur Arch Otorhinolaryngol. 2020; 278(2):313-321.
7. McGrath BA, Brenner MJ, Warrillow SJ, et al. Tracheostomy in the COVID-19 era: global and multidisciplinary guidance. Lancet Respir Med. 2020;8(7):717-725.
8. Kaur R, Weiss T, Perez A, et al. Practical strategies to reduce nosocomial transmission to healthcare professionals providing respiratory care to patients with COVID-19. Crit Care. 2020; 24: 571.
9. Hernández Martínez G, Rodriguez ML, Vaquero MC, et al. High-flow oxygen with capping or suctioning for tracheostomy decannulation. N Engl J Med. 2020;383(11):1009-1017.

10. Lersritwimanmaen P, Rittayamai N, Tscheikuna J, et al. High-flow oxygen therapy in tracheostomized subjects with prolonged mechanical ventilation: A randomized crossover physiologic study. Respir Care. 2021;66(5):806-813.
11. Birk R, Händel A, Wenzel A, Kramer B, Aderhold C, Hörmann K, Stuck BA, Sommer JU. Heated air humidification versus cold air nebulization in newly tracheostomized patients. Head Neck. 2017;39(12):2481-2487.
12. Mauri T, Galazzi A, Binda F, et al. Impact of flow and temperature on patient comfort during respiratory support by high-flow nasal cannula. Crit Care. 2018;22(1):120.
13. Bem RA, van Mourik N, Klein-Blommert R, et al. Risk of aerosol formation during high-flow nasal cannula treatment in critically ill subjects. Respir Care. 2021;66(6):891-896.
14. O'Neil CA, Li J, Leavey A, et al. Characterization of aerosols generated during patient care activities. Clin Infect Dis. 2017;65(8):1335-1341.
15. Lescure FX, Bouadma L, Nguyen D, et al. Clinical and virological data of the first cases of COVID-19 in Europe: a case series. Lancet Infect Dis. 2020;20(6):697-706.

Table 1. Aerosol particle concentrations at baseline and during the use of different devices for patients with tracheostomy

| Particle size, μm | Particle concentrations, particles/$m^3$ | | | | | p* |
|---|---|---|---|---|---|---|
| |  |  |  |  |  | |
| | **Baseline with HMEF** | **Airvo2 with tracheostomy adapter** | **LVN with a tracheostomy mask** | **Venturi adapter with a tracheostomy mask** | **LVN with T-piece and a filter** | |
| **<0.3, ×$10^6$** | 13.0 (7.9, 25.4) | 10.5 (7.7, 23.0) | 15.2 (7.2, 26.0) | 12.1 (6.9, 26.6) | 11.9 (7.3, 25.5) | 0.569 |
| **0.3-0.5, ×$10^5$** | 6.8 (4.1, 19.6) | 6.1 (4.6, 17.9) | 7.3 (3.8, 31.5) | 6.1 (3.6, 22.1) | 5.9 (3.9, 17.6) | 0.061 |
| **0.5-1.0, ×$10^4$** | 5.0 (4.2, 13.9) | 5.3 (3.5, 13.7) | 5.5 (3.6, 14.0) | 4.6 (3.6, 13.2) | 5.2 (3.6, 10.1) | 0.663 |
| **1.0-3.0, ×$10^4$** | 1.3 (0.9, 2.5) | 1.3 (1.0, 3.1) | 1.1 (0.6, 2.9) | 1.0 (0.8, 2.3) | 1.2 (0.7, 2.6) | 0.644 |
| **3.0-5.0, ×$10^3$** | 6.7 (4.9, 12.7) | 6.7 (5.3, 15.2) | 6.0 (2.5, 15.5) | 5.7 (4.6, 12.0) | 6.0 (3.5, 14.1) | 0.994 |
| **5.0-10.0, ×$10^3$** | 3.2 (2.5, 5.3) | 3.5 (2.1, 7.1) | 3.2 (1.4, 7.4) | 3.9 (1.8, 4.6) | 3.5 (2.5, 6.4) | 0.872 |
| **Comfort score** | 3.5 ± 1.2 | 3.5 ± 1.5 | 3.8 ± 1.3 | 3.5 ± 1.2 | 3.3 ± 1.3 | 0.593 |

The concentrations for aerosol particles at each size were presented as median (interquartile), comfort score was presented as mean ± standard deviation.

* compared among five devices (Friedman test). HMEF, heat-moisture exchange filter; LVN, large volume nebulizer.