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Brief Communication

# Particle generation during positive airway pressure therapy

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## 1. Introduction

Coronavirus disease 2019 (COVID-19) has emerged as a pandemic viral disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) with more than 100 million confirmed cases worldwide [1]. Because of the airborne transmission of SARS-CoV-2, COVID-19 has restricted in-laboratory positive airway pressure (PAP) titration sleep studies due to concerns regarding their aerosol generation potential and thus the possibility to increase transmission risk to staff [2,3]. PAP therapy is a type of non-invasive ventilation that is widely used to treat sleep disordered breathing and in some cases of respiratory failure, but the positive pressure in the airways of patients has the potential to increase potentially infectious particles. In addition, this concern for exposure is also present for household members of patients on PAP therapy especially if individuals with OSA are infected with COVID-19 [4]. To better understand the exposure risk associated with PAP use, we sought to quantify and characterize the amount of detectable particulate generation during PAP use at pre-specified distances with different pressure and device settings.

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## 2. Methods

### 2.1. Design

This was a single-center prospective study conducted at the Mayo Clinic Florida This study was approved by the Mayo Clinic Institutional Review Board (20−005544). Healthy adult participants were recruited and consented for this study.

Testing was conducted in an in-laboratory sleep study room (86.9 $m^3$ in size with a room exchange rate of 7.8/hr with a minimum efficiency reporting value (MERV) of 11, which means the air filters were capable of filtering down to 1 micron sized particles. To control for ambient variables, such as humidity and temperature, testing room occupancy was limited to three persons during each experimental session (the participant and two investigators). Ambient room humidity was measured at 48%, and temperature was 21 °C on the day of the testing.

Each participant wore a F&P Vitera full face mask (Fisher and Paykal Healthcare SAS; Auckland, New Zealand) for each predefined setting, which were CPAP of 5 and 10 cmH2O and BiPAP of 15/10 and 20/15 cmH2O. Two additional measurements were made with a simulated air leak, which was created with settings CPAP 10 cmH2O and BiPAP 20/15 cmH2O by lifting the mask off the participant's face by 2 cm and had the participant engaged in a conversation. These settings were achieved by using a Philips Respironics OmniLab Advanced and Titration system (Andover, MA, USA) with the reusable filter. Each of these settings were maintained for 1 min before each measurement was performed.

### 2.2. Measurements

A light-scattering particle counter (FLUKE® 985; Everett, Washington, USA) was used to simultaneously measure six channels of particle size distribution (0.3, 0.5, 1, 2, 5 and 10 μm). These measurements are recorded as particles per liter of sampled air. This device was calibrated according to manufacturer and zeroed before each participant. A background count was measured before each participant entered the room and used as background for every PAP setting. Once the PAP device was started, measurements were obtained to the side at predefined distances of 0 m (particle

counter in contact with mask), 0.3 m, 0.9 m, and 1.8 m away from the exhalation port of the mask with each PAP device setting. Each setting and distance was measured once for each participant.

The particle data obtained was separated by size into two categories: 1) small micron sized particles (all particles <5.0 μm); and 2) large micron sized particles (all particles ≥ 5.0 μm). To account for a nonsignificant variation in the background counts, all particle counts were corrected by subtracting the background count from the measured counts.

### 2.3. Statistical analysis

A non-normal distribution was assumed with continuous data displayed as median with interquartile ranges and categorical data displayed as frequency with percentage. Each device setting and pressure level was considered a group and a Wilcoxon/Kruskal–Wallis test was used to compare each group amongst itself. If a group comparative result was significant, a Steel test was performed to compare each measured distance to the control (background measurement). All analyses were performed using JMP® version 14.1.0 (SAS Institute Inc.; Cary, NC). Statistical significance was determined to be a p value less than 0.05.

## 3. Results

There were five subjects recruited for this study. Three were females (60.0%) with a median age of 43 (IQR, 32–47) years old and a median BMI of 25.0 (IQR, 24.5–30.5). All participants were healthy without cardiac or pulmonary disease.

The measured background small micron sized particles per liter of sampled air were 25144.0 (IQR, 22514.0–28493.0) and large micron sized particles per liter of sampled air were 100.0 (IQR, 90.0–104.0). These values were used to correct the participant measurements as described in the “Methods”.

Table 1 shows the corrected particle counts for a settings and distances. For all CPAP and BIPAP pressure settings, including the simulated leak, there was no difference between the small micron sized particle counts and background at any distance measured (Fig. 1). The large micron sized particle counts had multiple significant decreased counts when compared to the background (Table 1) (Fig. 1). These significant values mainly occurred with the closer measurements and higher pressure settings.

## 4. Discussion

In this study, we examined the particle generation potential in relation to vicinity during PAP therapy use in healthy individuals using several CPAP and BIPAP settings. The main finding was that there were no significant increases in particle generation, 0.3 μm–10 μm in size, over background measurements with PAP therapy.

Concerns have been raised that PAP use is an aerosol generating procedure at this time, per CDC [5]. It is reported that noninvasive ventilation is considered an aerosol generating procedure which could increase risk of pathogen exposure and infection and has been recommended for non-vented masks to be used if available [6]. Recently, PAP machine performance was tested and completely sealed systems resulted in worse maximal inspiratory pressures, inspiratory effort to trigger the machine, tidal volume, and work of breathing [7]. This present study showed that particulate generation was found to be very low and did not significantly differ from background readings in any PAP setting or distance measured. These results add to the recent paper that showed a trend to decreased particles with BiPAP settings, but only at 5 cm [8]. Both of these studies show that having vented mask is potentially safe for surrounding people as well better for the patient in regards to the PAP machine.

Air leakage from a PAP mask is common among PAP users due to poor fitting or during adjustments of the mask on the face. We performed a simulated leak by having the mask lifted off the face by 2 cm while participants were talking and then measured the particle counts. This is where the significant decrease in particle counts was seen. Recent studies have shown that normal speaking does not generate significant particles [8,9].

In this study, we observed that in some cases, there was a decrease in particle counts when at the nearest measurement, especially when there was a large leak. This was also seen in a previous study that looked at particles counts with different oxygen delivery devices [8]. We previously have shown that using pure oxygen causing a simulated air leak in a chest tube collection system that at higher flow rates, there was decreased particles measured at all size ranges when a filter was used [10]. This finding could be explained by an increased proportion of filtered air elements (nitrogen, oxygen, and carbon dioxide) versus the non-filtered elements in the sampled air coming out of the PAP device, which is seen more with increased flows and larger particle sizes. These elements are not able to be detected by any particle counter and do not carry any SARS-CoV-2 viral particles, as the reported particle size for transmission is 2 μm–20 μm in size [11]. These larger particles would be more likely to deposit along the inner surface of the masks and tubing versus the smaller particles through the process of inertial impaction, which could explain the lower particle counts.

This study provides valuable information for guiding infection control measures for health-care workers and individuals who use PAP therapies at home or in the clinical setting in that PAP therapy is a low particulate generating procedure. It is important to note that this study was not performed on individuals with COVID-19 infection nor was this study designed to assess the composition or infectivity of the measured particles. Because the participants were healthy, the amount and size of particles generated could be considered less than a symptomatic patient with a productive cough or nasal secretions which may theoretically generate more particles. Therefore, the possibility of COVID-19 transmission is unknown and cannot be concluded by this study. Patients in respiratory failure who require PAP therapy in the hospital have altered breathing mechanics such as tachypnea, paradoxical breathing patterns, accessory muscle usage and physiologic obstructed airways. These breathing alterations may lead to changes in inspiratory peak flows, tidal volumes, dead space, V/Q mismatches, and inspiratory/expiratory times resulting in increased work of breathing that were not able to be evaluated in this study and could all effect particulate generation. Another limitation would be the limited number of participants, but the results were consistent with all participants so it is unlikely that a larger sample size would provide differing results. Further work in examining aerosol generation and potential viral transmission with PAP use in active COVID-19 cases will be needed.

As such, we recommend that individuals on PAP therapies who have COVID-19 infection to follow CDC guideline to mitigate the transmission of SARS-CoV-2. The CDC recommends that affected individuals to stay in a specific room at home away from other people as much as possible. This study also does not change mitigation strategies in the clinical setting for healthcare workers as proper personal protective equipment including a N95 mask should be used in caring for patients with COVID-19 on PAP.

In conclusion, findings from this study show that there is no significant increase in small or large micron sized particles within six feet to PAP use at various pressure settings in healthy individuals when compared to ambient room environment and suggest that PAP usage is a low-risk aerosol generating procedure.

**Table 1**
Corrected particle quantity per liter of sampled air by size when compared to the background particle counts.

| PAP Setting | Corrected particle quantity per liter of sampled air by size | | PAP Setting | Corrected particle quantity per liter of sampled air by size | |
|---|---|---|---|---|---|
| | Small micron sized particles | Large micron sized particles | | Small micron sized particles | Large micron sized particles |
| | 0.3 μm–4.9 μm | 5.0 μm–10 μm | | 0.3 μm–4.9 μm | 5.0 μm–10 μm |
| **CPAP 5** | | | **BiPAP 15/10** | | |
| **0 m** | 1393.0 (−46.0–3981.5) (p = 0.38) | −58.0 (−62.5–−46.0) (p = 0.03) | **0 m** | 179.0 (−1192.0–2364.5) (p = 0.99) | −59.0 (−82.5–−34.5) (p = 0.03) |
| **0.3 m** | −200.0 (−421.0–197.0) (p = 0.38) | 6.0 (−14.0–27.5) (p = 0.99) | **0.3 m** | −341.0 (−583.5–985.5) (p = 0.99) | −23.0 (−26.0–−7.5) (p = 0.03) |
| **0.9 m** | −7.0 (−115.5–531.5) (p = 0.99) | −5.0 (−14.5–−3.0) (p = 0.03) | **0.9 m** | 343.0 (−275.0–1131.5) (p = 0.99) | −8.0 (−27.5–−3.5) (p = 0.03) |
| **1.8 m** | 73.0 (−171.0–608.5) (p = 0.99) | 1.0 (−4.5–15) (p = 0.73) | **1.8 m** | −203.0 (−791.0–1413.5) (p = 0.99) | −18.0 (−29.5–−16.0) (p = 0.03) |
| **CPAP 10** | | | **BiPAP 20/15** | | |
| **0 m** | 967.0 (−269.0–2153.0) (p = 0.38) | −62.0 (−71.5–−33.5) (p = 0.03) | **0 m** | 431.0 (−1764.0–1159.0) (p = 0.99) | −69.0 (−83.5–−37.5) (p = 0.03) |
| **0.3 m** | −150.0 (−239.0–654.0) (p = 0.99) | 1.0 (−29.0–9.0) (p = 0.99) | **0.3 m** | −329.0 (−637.0–1387.0) (p = 0.99) | −27.0 (−45.5–2.0) (p = 0.38) |
| **0.9 m** | −67.0 (−156.5–870.0) (p = 0.99) | −2.0 (−15.0–2.5) (p = 0.38) | **0.9 m** | −153.0 (−925.0–1769.5) (p = 0.99) | −29.0 (−41.0–−19.5) (p = 0.03) |
| **1.8 m** | −374.0 (−532.5–800.0) (p = 0.99) | −3.0 (−28.0–18.5) (p = 0.99) | **1.8 m** | −431.0 (−626.5–2118.5) (p = 0.99) | −25.0 (−29.0–15.5) (p = 0.99) |
| **CPAP 10 with leak** | | | **BiPAP 20/15 with leak** | | |
| **0 m** | −2826.0 (−3682.5–−633.0) (p = 0.99) | −52.0 (−69.0–−18.5) (p = 0.03) | **0 m** | −1628.0 (−4503.5–518.0) (p = 0.99) | −41.0 (−61.5–0.5) (p = 0.38) |
| **0.3 m** | −429.0 (−1634.5–2033.5) (p = 0.99) | −31.0 (−49.0–−21.5) (p = 0.03) | **0.3 m** | −662.0 (−895.0–1777.0) (p = 0.99) | −46.0 (−58.5–−31.5) (p = 0.03) |
| **0.9 m** | −319.0 (−1299.0–2226.5) (p = 0.99) | −42.0 (−53.5–−9.5) (p = 0.03) | **0.9 m** | −50.0 (−811.5–1969.0) (p = 0.99) | −46.0 (−62.0–−25.5) (p = 0.03) |
| **1.8 m** | −56.0 (−859.0–2874.5) (p = 0.99) | −32.0 (−35.0–33.5) (p = 0.99) | **1.8 m** | 564.0 (−752.5–2349.0) (p = 0.99) | 4.0 (−43.0–20.0) (p = 0.99) |

Table showing the measured small and large micron sized particles per liter of sampled air. An air sample was obtained before each setting used and at set distances of 0 m, 0.3 m, 0.9 m, and 1.8 m. The background was considered 0 and these counts were corrected for the measured background before sampling. Data is displayed as median (interquartile range). Analysis was performed by using a nonparametric Wilcoxson/Kruskal–Wallis Rank Sums test for each setting as a whole system along with the background and then a Steel's test with the background as the control. PAP = positive airway pressure. CPAP = continuous positive airway pressure. BiPAP = bilevel positive airway pressure. m = meters.

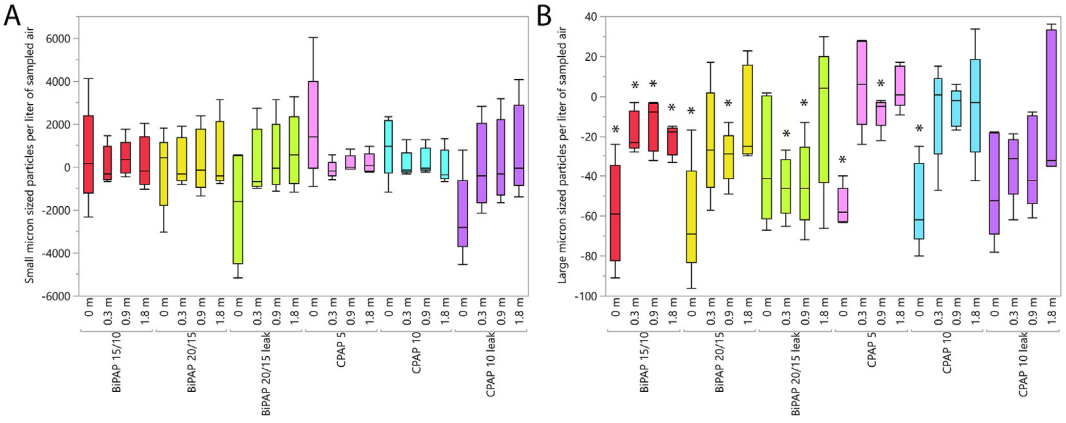


**Fig. 1.** Figure shows the A) small micron and B) large micron particle counts per liter of sampled air separated by device settings and distance from the participant. Data is displayed as median with interquartile range. An asterisk (*) signifies a p value < 0.05 when compared to the background. Analysis was performed by using a nonparametric Wilcoxson/Kruskal–Wallis Rank Sums test for each setting as a whole system along with the background and then a Steel's test with the background as the control. CPAP = continuous positive airway pressure. BiPAP = bilevel positive airway pressure. m = meters.

## Credit author statement

Scott Helgeson and Joseph Cheung, Conceptualization, Methodology, Writing – original draft, Data curation, Formal analysis, Project administration, Supervision. Kaiser Lim, Methodology, Writing – review & editing, Visualization, Resources, Supervision. Neal Patel, Conceptualization, Writing – review & editing, Visualization, Resources, Supervision. Alexander Niven, Methodology, Writing – review & editing, Visualization, Resources, Supervision. Augustine Lee, Methodology, Writing – review & editing, Visualization, Resources, Supervision.

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## Disclosures

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## Conflict of interest

None declared.

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: https://doi.org/10.1016/j.sleep.2021.05.008.

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