

The potential for delivery of particulate matter through positive airway pressure devices (CPAP/BPAP)

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Abstract

Background Airborne particulate matter may induce health risk with inhalation. Special concerns exist for deployed military personnel with inhaled particulate matter in desert environments. Continuous positive airway pressure (CPAP) used in obstructive sleep apnea may facilitate inhalation of particulate matter. We evaluated the ability of commercial CPAP filter systems to eliminate inhalation of particulate matter.

Methods An ultrasonic medical nebulizer (DeVilbliss Ultraneb, DeVilbliss, Somerset, PA) atomized liquid producing “respirable” aerosol. Technetium-99m diethylene triamine pentaacetic acid dissolved in water was also aerosolized to quantify aerosol inhalation. A high efficiency particulate air (HEPA) filter placed at the patient–hose connection port in the bilevel positive airway pressure (BPAP) device captured the aerosol inbound to the patient. The HEPA filter provided a means to quantify aerosol dose delivered to a simulated patient. Commercial foam and ultrafine filters were assessed with aerosol to determine the simulated patient exposure.

Results Foam and ultrafine filters used together allowed 1.5% or less of aerosol volume to pass through the BPAP system. Foam filters alone allowed an average of 18.9% of aerosol delivered to pass through the BPAP system.

Conclusions Foam and ultrafine filters used together in BPAP systems provide excellent aerosol filtration in this laboratory simulation of BPAP use.

Keywords Filter · Particulate matter · Continuous positive airway pressure

Introduction

Patients with obstructive sleep apnea (OSA) experience periods of intermittent airway closure during sleep [1]. The possible long term consequences of untreated sleep apnea include increased risk of high blood pressure, heart attack, arrhythmia, heart failure, stroke, obesity, and diabetes, as well as an increased chance of work-related or driving accidents. This may be associated with obesity or with specific upper airway conditions. Continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BPAP) devices treat the airway occlusion by pressuring the upper airway during sleep. These devices typically incorporate an internal high-speed fan to generate air pressure and utilize sensors and control circuits to establish pressure at different levels. A nasal or oronasal mask which the patient wears during sleep is used to deliver the air pressure. CPAP devices provide a single, controlled airway pressure, while BPAP devices allow for independent pressure settings for inhalation and exhalation.

Some military personnel deploying to desert regions or regions with high airborne particulate content may be utilizing CPAP or BPAP devices to treat OSA. The fans

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within these devices draw in air from the outside environment in order to produce the required airway pressure. Particulate matter suspended in the air or present on surfaces near the air inlet of the devices could potentially be delivered through the device to the patient. This particulate matter could pose a health risk, depending on the physical and chemical properties of the material. Here we consider what is known about the hazards of inhaled particulate matter, the physical characteristics of particulate that would result in retention in the lungs, and the characteristics of the particulate found in the environments where military personnel may be deploying. We also consider the filtration available in CPAP/BPAP devices and report the results of experiments performed to determine the potential for particulate exposure through the use of these devices.

The potential health effects of inhaled particulate matter

Exposure to inhaled particulate matter has been associated with pulmonary diseases such as occupational asthma, silicosis, pneumoconiosis, hypersensitivity pneumonitis, and occupational lung cancer [2]. A variety of natural and man-made agents have been implicated, including coal dust, and silica. Typically, the mineral exposures resulting in disease occur in specific occupations where exposure to high amounts of particulate is a daily occurrence: mining, sand blasting, glass manufacturing, etc. Much lower amounts of airborne particulate matter, including the airborne particulate typical to air pollution, can affect patients with allergies or lung conditions such as asthma or chronic obstructive pulmonary disease [3, 4]. Particulate matter has also been implied as a potential factor in the development of heart disease [5].

The size of the inhaled particulate is an important factor in determining its potential toxic effects. Most inhaled particles that are larger than about 10 μm or 0.010 mm in diameter will deposit in the nose, mouth, or upper airways prior to reaching the more vulnerable surfaces of the lung. Particles smaller than 10 μm begin to deposit into the lungs after inhalation. As particle size decreases, penetration increases with the highest propensity for deep lung deposition occurring in the range of 1–5 μm with maximum alveolar deposition occurring at approximately 2.5 μm . As particles become smaller they tend to deposit more slowly and may ultimately be exhaled prior to depositing in the lungs. The deposition of particles 0.1–1 μm is substantially decreased. As particles become smaller than 0.1 μm , they begin to be influenced by the motion of gas molecules in the lung and the propensity to deposit again increases [6]. Based on these distinctions, the levels of particulate concentration in the air are often described in terms of PM10 or PM2.5. Specifically, these describe the mass of

particles in sizes smaller than 10 or 2.5 μm found in a unit volume of air. Particles smaller than 0.1 μm are typically referred to as “ultrafines”.

Measurements of PM2.5 and PM10 are often used to quantify particulate air pollution. For example, PM10 levels in Long Beach, CA were reported to be 46.8 $\mu\text{g}/\text{m}^3$ vs. 16.2 $\mu\text{g}/\text{m}^3$ in Birmingham, AL vs. 89.2 $\mu\text{g}/\text{m}^3$ measured in an urban region of China [7, 8]. Increases in hospitalizations and all causes of mortality have been associated with increased levels of PM2.5 [4, 9]. In dust prone areas, PM2.5 and PM10 provide a gauge of the natural airborne particulate. Average measurements of PM10 made at two different sites within the California desert were 46.1 and 31.0 $\mu\text{g}/\text{m}^3$, respectively. Measurements of PM2.5 at the same two sites were 23.2 and 14 $\mu\text{g}/\text{m}^3$ [10]. The PM10 levels associated with small dust events measured in Iraq, Kuwait, and Saudi Arabia were in the range of 200–1,000 $\mu\text{g}/\text{m}^3$. Larger dust storms may produce levels in excess of 1,000 $\mu\text{g}/\text{m}^3$ [11]. Measurements made in a Saharan dust storm were reported to be as high as 2,800 $\mu\text{g}/\text{m}^3$ [12]. The test aerosol used simulates the respirable component of these environmental aerosols.

Surface contamination is an important factor when considering particulate exposure during CPAP/BPAP, since the air inlet for the devices will likely be in close proximity to the floor or other surfaces during use. Contaminants recovered from surfaces inside of military vehicles used in Iraq had a high percentage of recovered particle sizes smaller than 3 μm (10–23%). Geochemistry studies demonstrated that this dust was mostly composed of silica [13].

Both airborne dust content and surface contamination are potential sources of particulate that could be inadvertently delivered to the lungs during the use of CPAP or BPAP. It is possible that increases in airway patency associated with CPAP/BPAP use might augment the delivery of particulate into the lungs. But these increases seem unlikely to represent significant changes in exposure, when compared to the amount of airborne particulate inhaled during normal breathing during the course of a day. More important to consider are the increases in particulate delivery that could be caused if the CPAP/BPAP devices were placed on a dust-covered surface where particulate levels may be substantially higher than airborne content.

Aerosol studies

Methods: general

In the following set of experiments, we aimed to determine whether an aerosol generated in proximity to the inlet port of a standard BPAP device might penetrate through the

device and be delivered to the patient. The experimental apparatus utilized is shown in Fig. 1. An ultrasonic medical nebulizer (DeVilbiss UltraNeb, DeVilbiss, Somerset, PA) was used to atomize liquid and produce a “respirable” aerosol—one that would deposit substantially in the lungs if inhaled. A radioactive liquid, Technetium-99m diethylene triamine pentaacetic acid (DTPA) dissolved in water, was added to the nebulizer reservoir so that penetration of the aerosol could be quantified. An adapter was added to the back of the BPAP device so that inlet airflows passed through the aerosol-containing reservoir of the nebulizer prior to entering the device. Large lines (22 mm) were used so that the nebulizer caused relatively little resistance to the inlet flows. A high efficiency particulate air (HEPA) filter was placed at the patient–hose connection port on the BPAP device. This filter captured the aerosol penetrating through the BPAP device and allowed us to quantify the aerosol dose that would otherwise be delivered to the patient.

A Harvard lung breathing simulator was put into the circuit in place of a patient. The simulator provided a sinusoidal breathing pattern (rate=15 breaths per min, tidal volume=700 ml, inspiration to expiration ratio=50:50). A Whisper valve was placed in line between the Harvard lung and the BPAP hose along with a port for pressure measurement. The Whisper valve, which is used adjacent to the mask during normal BPAP use, vents excess air flows allowing the BPAP to maintain the set pressure at the mask. Pressures were measured using a DPI 705 pressure meter (GE Sensing–Druck, Billerica, MA).

During testing, the BPAP device was set to deliver CPAP at 25 cm H₂O. This high setting was selected to generate inlet flows that were as high or higher than would be experienced during normal operation. During testing, the apparatus was operated until 5 ml of total liquid volume

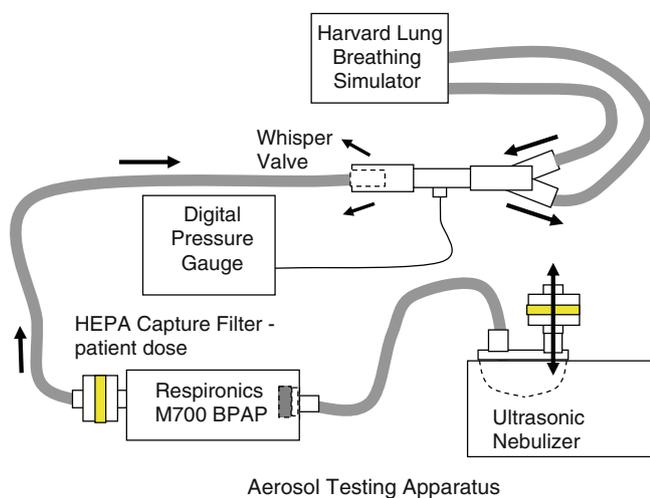


Fig. 1 Aerosol testing apparatus

was nebulized (~30 min). The humidifier was not used. The pressure generated by the BPAP device was monitored throughout testing. In general, pressure delivery was not affected by the testing equipment and the specified pressure was maintained throughout the experiments.

At the conclusion of testing, radioactivity was measured in the BPAP filters, the HEPA capture filter representing aerosol delivery to the patient, and all components of the delivery apparatus. Radioactivity not recovered from these components was assumed to have deposited within the BPAP machine itself (which was too large to be individually measured). Radioactivity was measured using a nuclear medicine dose calibrator (Capintec CRC-4, Ramsey, NJ). Measurements of radioactivity were corrected for decay time, and the total amount of radioactivity captured in the BPAP filters, the capture filter, and the BPAP device was summed. The percentage of this total is reported in each of those components. Three tests were performed with the BPAP device operated with both the ultrafine and foam filters in place. Two tests were performed with only the foam filters.

Methods: device tested

Studies were performed using a Respironics Auto-BPAP™ 700 M (Respironics, Murrysville, PA). This device came standard with two filters which fit in combination over the inlet air port of the device. This port is located on the back on the device and is approximately 1-inch wide and 3/4-inch high. Filter 1 (the foam filter) was labeled as RP-M Series/SleepEasy Pollen Filter. These filters were gray in color and composed of foam approximately 3/8-inch thick. Filter 2 (the ultrafine filter) was labeled RP-M Series/SleepEasy Ultrafine Filter. These filters were thinner and white in color. They were backed with a clear plastic mesh. The manufacturer provided specifications for filter 2 that identified its base material as Technostat 250 g/m³ with an OS100 plastic mesh. Technostat is a brand name associated with the Hollingsworth–Vose Company (Walpole, MA). This particular filter material uses a net charge built into the material itself that increases its filtering efficiency.

Test aerosol

Technetium-labeled diethylene triamine pentaacetic acid (Tc-DTPA) was added to the nebulizer prior to operation. This radioactive small molecule was used to facilitate tracking of the aerosol. Doses of 1.5–4.6 mCi were used during testing. Total volumes added to the nebulizer were approximately 5 ml.

The UltraNeb nebulizer produces a liquid aerosol using an ultrasonic method. This process does not produce any net flow of air or aerosol, so the nebulizer did not force

aerosol into the BPAP device. The aerosol size produced by this nebulizer can be controlled. We selected an aerosol size that would be associated with a high level of penetration into, and retention in the lungs since this would simulate a case with high potential toxicity. Aerosol size measurements were made using a Malvern Mastersizer S Laser Diffraction instrument (Malvern Instruments, Westborough, MA). A histogram depicting the aerosol size distribution is included as Fig. 2a. The data presented are based on the average of 20 individual measurements. This figure shows the portion of aerosol volume contained within the different aerosol size ranges listed on the horizontal axis. One-half micron wide size ranges were used from 1–10 μm . The final four bars depict the volume in large droplet populations (9.5–10, 10–12, 12–15, and 15–25 μm). The median size of the aerosol was 4.7 μm . In Fig. 2b, a standard model [14] is applied to predict what portion of the total test aerosol volume would deposit within different portions of the lung if it were inhaled.

Approximately 41% of the test aerosol would deposit in the lungs if inhaled with 28% depositing within the deep lung (alveoli).

Results

Table 1 includes the results of testing. The percentages of aerosol volume deposited in the ultrafine and foam BPAP filters, the BPAP machine itself, and the HEPA filter representing patient dose are reported.

When the ultrafine filter is in place, it captures the vast majority of the aerosol entering the inlet port of the BPAP device. For runs 1 and 3 this was more than 95% of the total aerosol volume. The percentage of activity captured by the ultrafine filter was lower in run 2. The aerosol dose penetrating to the capture filter was still not increased; however, leading us to believe that the aerosol in run 2 may have dripped onto the case of the BPAP after capture in the ultrafine filter. In all cases where the ultrafine filter was in place, 1.5% or less of the aerosol volume entering the

BPAP device was delivered through to the HEPA capture filter representing the patient.

In the cases where the ultrafine filter was removed and only the foam filter was left in place, a large dose of aerosol did penetrate through the BPAP machine and reach the capture filter representing the patient. A large portion of the dose penetrating these filters deposited within the BPAP device itself, but on average 18.9% of the aerosol volume reached the patient.

Conclusions

Some conclusions can be drawn about the importance of having a fine particle filter in place during the use of CPAP or BPAP in a potentially dusty environment. For the BPAP device tested, the use of the manufacturer supplied “ultrafine” filter increased aerosol capture substantially. With only a foam filter in place, nearly 20% of the aerosol pulled into the device along with inlet air flows was delivered to the patient. With the ultrafine filter in place this total decreased to just over 1%.

The test aerosol used for these studies had a median diameter of 4.7 μm , and based on deposition models, we estimate that 28% of the total volume delivered would reach and deposit in the deep lung. High percentage levels of particles in similar size ranges have been found in samples from vehicle interiors in Iraq [13]. Since aerosol size is the dominant characteristic affecting aerosol penetration into the lungs, the test aerosol should provide a fairly accurate characterization of the behavior of these small dust particles. Our study does not accurately characterize the potential for delivery of dust particles smaller than 1 μm , nor are we aware of any studies estimating their prevalence in a dusty or desert environment. Particles significantly larger than the test aerosol are likely to deposit in the mouth, throat, and nose and present less of a hazard.

The quality of the fine particle filters included with the CPAP/BPAP machines could vary by manufacturer. We are

Fig. 2 Test aerosol size distribution histograms. The portion of aerosol volume in different aerosol size ranges is shown in *panel A*. *Panel B* estimates the portion of the test aerosol that would deposit in various regions of the lung if inhaled

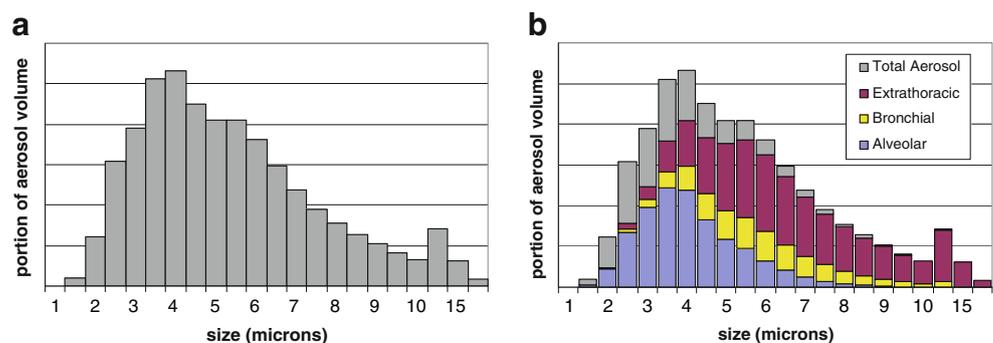


Table 1 Percentage of aerosol volume entering the BPAP that was captured within the BPAP filters, deposited within the BPAP, or delivered to the patient. The BPAP device was tested with and without the ultrafine filter in place

Percentage of aerosol	Ultrafine filter in place				Foam filter only		
	Run 1	Run 2	Run 3	Ave	Run 1	Run 2	Ave
Ultrafine filter	95.0	59.3	99.3	84.5	–	–	–
Foam	3.8	3.6	0.3	2.6	37.1	43.6	40.4
BiPAP internal	0	36.7	0	12.2	41.2	40.4	40.8
Capture HEPA (patient)	1.3	1.5	0.4	1.1	21.7	16.0	18.9

Ave average, *BiPAP* bilevel positive airway pressure, *HEPA* high efficiency particulate air

not aware of a specific FDA standard for filtration that applies to these devices. The standards for the materials used to produce the fine particle filters might be useful in evaluating their capture ability but the exact standards utilized may vary. In the case of the M700 device, the specification for ultrafine filter material reported 98.75% capture efficiency based on British Standard 4400. This standard utilizes a very fine sodium chloride test aerosol (0.65 μm) [15], and does appear to predict the favorable performance of the filters in our studies.

It is possible that some patients with specific allergies, known airway hyper-reactivity or other conditions such as immunosuppression might be vulnerable to even the small percentage of particular delivered through the ultrafine filter. An alternative for these subjects might include the use of a HEPA filter in line with the patient mask. This filter could be positioned at the outlet of the BPAP device and connected to the patient's hose, in a manner similar to the HEPA capture filter in the test apparatus (Fig. 1). The Department of Energy standard for HEPA is well defined: 99.97% capture rate for particles larger than 0.3 μm . HEPA filters designed for mechanical ventilation (such as the Gibeck HEPA Lite, Hudson-RCI, Research Triangle, NC or the Pall 6004605, Pall Corporation, East Hills, NY) would be good candidates. These filters are also likely to be usable without adapters. Further testing is required to determine if these filters might affect the performance of a CPAP or BPAP device over long periods of operation. In the short period of operation associated with our studies, delivery pressures were maintained and no problems were encountered when the filters were added in line.

A potential limitation of our studies is the use of high pressure settings that specifically require high rates of air flow through the BPAP device. This was chosen as our best estimate of the worst case scenario under the assumption that high input air flow rates would maximize the potential for aerosol to be suctioned into the BPAP device and delivered to the patient. Maximal CPAP pressures used were intended to simulate the largest possible particle deliveries at CPAP levels beyond those typically used in clinical practice. However, there is a small possibility that

the high flow rates required to sustain these pressures may have increased the capture ability of the filters on the BPAP device. Aerosols moving at high rates of speed have high inertial potential for collision and deposition, and high speed inlet flows may increase deposition on the external surface of the filter. Further testing at lower airway pressures would be useful to confirm similar filter capture rates. The effect of humidification was also not considered during testing.

Though our aerosol experiment does provide a good means of measuring filter capture efficiency, it does not provide an exact simulation of the actual quantity of surface/airborne dust content that might be found in any given environment. On site simulation would provide a final assessment of the potential for particulate delivery, and may prove more realistic than simulating dust dispersion in the lab. An apparatus similar in Fig. 1 could be designed for field use. The local surface and airborne content would take the place of the medical nebulizer, and the dose delivered and captured by the various filters could be assessed based on a change in (dry) filter mass. Increased periods of operation would increase the chances of a robust result.

In conclusion, the combined use of foam and ultrafine filters eliminated nearly all aerosol inhalation and clearly exposes the patient to far less aerosol inhalation than by normal unprotected respiration in a dusty environment. Dust particles smaller than 1 μm were not assessed in this study but overall CPAP use appears to be safe and may provide added protection from inhaled ambient aerosols.

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