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Reusable elastomeric air-purifying respirators: Physiologic impact on health care workers

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Background: Elastomeric air-purifying respirators offer the benefit of reusability, but their physiological impact on health care workers is unknown.

Methods: Ten health care workers exercised at 2 health care-associated work rates wearing an elastomeric air-purifying respirator. Mixed inhalation/exhalation respirator dead space gases (oxygen, carbon dioxide) were sampled, and physiological parameters were monitored (heart rate, breathing rate, tidal volume, minute volume, oxygen saturation, transcutaneous carbon dioxide). Numerical rating scales were used to evaluate comfort and exertion.

Results: Compared with controls (no respirator), significant decreases in the breathing rate at both work rates ($P < .05$) and increases in tidal volume at the lower work rate ($P < .01$) were noted with respirator use. Approximately half the subjects had transcutaneous carbon dioxide levels above the upper limit of normal after 1 hour of use. Although well tolerated, comfort was negatively impacted by elastomeric air-purifying respirators wear.

Conclusion: Reusable elastomeric air-purifying respirators impose little additional physiological burden over the course of 1 hour at usual health care work rates. However, the potential for carbon dioxide retention in a significant proportion of users exists and requires further investigation.

Key Words: Elastomeric respirators; reusable; physiological impact.

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The current pandemic influenza and previous experience with other respiratory infectious outbreaks (eg, avian influenza, severe acute respiratory syndrome) have raised concerns about the availability of disposable N95 filtering face piece respirators (N95 FFRs). Given the very real possibility of N95 FFR shortages, elastomeric air-purifying respirators (EAPRs) for health care workers (HCWs) have been suggested as one alternative.¹ These are reusable, air-purifying respirators with face pieces made of pliable materials (eg, silicone, rubber, plastic) that employ 1 or 2 particulate filters and come in full face piece or half-mask

models, of which the latter is the more commonly used in health care.² Compared with disposable N95 FFRs, EAPRs offer advantages that include improved face seal (for some wearers), easier donning and doffing, enhanced user seal check capability, ability of the face piece to be decontaminated multiple times, capacity for use by single or multiple HCWs, and potential cost savings during a pandemic.²⁻⁵ Widespread use of EAPRs in the health care industry has not occurred,⁵ and little is known about their physiological impact on HCWs. This study, part of a larger investigation of multiple types of respiratory protection equipment that was carried out over 6 months,⁶ was undertaken to determine the physiological burden imposed on HCWs when wearing an EAPR.

MATERIALS AND METHODS

Ten HCWs (7 women, 3 men), none of whom had previously used an EAPR, were recruited. Demographic variable means included the following: age, 25.1 years; body weight, 76.0 kg; height, 169.1 cm; and body mass index, 26.4. Nine subjects had never smoked, and 1 subject had not smoked in >1 year (20 pack year smoking history). The study was approved by the National Institute for Occupational Safety and Health's Human Subject Review Board, and all subjects provided oral and written informed consent.

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Physiological parameters (heart rate, breathing rate, tidal volume) were monitored with the LifeShirt[®] System (VivoMetrics, Ventura, CA), a lightweight spandex vest incorporating physiological sensors and circumferential respiratory inductive plethysmography (RIP) bands. Minute ventilation was calculated as the product of breathing rate \times tidal volume. The LifeShirt[®] was calibrated against a fixed volume immediately prior to each trial. Oxygen and carbon dioxide concentrations (percentage) in the EAPR dead space were sampled at 18 samples/second (total sampling volume of 500 mL/min) via a 2-mm internal diameter sampling line attached to a port in the EAPR face piece (positioned equidistant between nares and mouth) that directed samples to gas analyzers (AEI Technologies, Naperville, IL). The gas analyzers were calibrated before each trial with gas mixtures weighed into the cylinder using a balance that has been calibrated with weights that are certified to the National Institute of Standards and Technology standards.⁷ Continuous oxygen saturation and transcutaneous carbon dioxide values were obtained with the Tosca 500 Monitor (Radiometer, Copenhagen, DK), a heated (42°C) combination pulse oximeter and Severinghaus-type PCO₂ sensor that is earlobe mounted. The unit was calibrated over a 10-minute period immediately prior to use.

A single model EAPR (North 5500; North Safety, Providence, RI) that incorporates 2 P-100 filters was selected for the study because it had previously been shown to be well tolerated by HCWs⁸ (Fig 1). To ensure proper fit, quantitative respirator fit testing was carried out with the PortaCount[®] Plus (TSI, Shoreview, MN). All subjects attained fit factors ≥ 100 (ie, ratio of ambient particles to within-face piece particles), indicating $\leq 1\%$ leakage, the level required by the Occupational Health and Safety Administration for half mask respirators.⁹

Subjects donned the LifeShirt[®] and were tested in athletic shorts, tee shirts, and athletic shoes (no headgear of any type [eg, caps, head nets, or others] was worn). The EAPR was donned according to the manufacturer's instructions, negative and positive user seal checks¹⁰ were carried out with the sample line pinched off, and the Tosca 500 sensor was attached to the left earlobe. Subjects were exercised for 1 hour (cumulative length of respiratory protective equipment use per shift by nursing staff¹¹) in a randomized fashion at each of 2 treadmill rates representative of HCW activities¹² that have been used in other studies^{13,14}: (1) 1.7 mph (2.74 km/h) treadmill speed (0% grade) that equates to stationary work (eg, writing nursing notes, using a telephone, and others) and (2) 2.5 mph (4.03 km/h) treadmill speed (0% grade) that equates to some bedside nursing patient care activities. Data were compared to 15-minute control values (no EAPR use) for the same subjects, at the same randomized work rates,



Fig 1. Elastomeric respirator used by a health care worker.

and obtained no more than 3 weeks prior (15-minute values were considered valid for control purposes because, at relatively low intensity steady state exercise, steady state respiratory parameters are achieved in 3-6 minutes in healthy subjects^{15,16}). Numerical rating scales (ie, modified Borg Rating of Perceived Exertion [numerical range, 0-5; least to most exertion¹⁷]; modified Perceived Comfort Scale [numerical range, 1-5; most comfortable to least comfortable¹⁸]) were utilized for subjective evaluations of exertion and comfort. Speaking was allowed ad lib by subjects throughout the trials to mimic HCW communicating with staff, patients, and visitors. At the end of each trial, subjects filled out questionnaires related to any subjective sensations experienced (eg, facial heat, sweating, and others) or design features (pinching, odor, and others) causing discomfort. EAPRs were weighed pretrial and post-trial to determine moisture retention. A new EAPR was utilized for each of the 2 sessions, and there was a minimum 30-minute respite between sessions. The study laboratory average temperature was 21.76°C (range, 20.1°C - 22.4°C) and the relative humidity averaged 58.3% (range, 47.4% - 71.5%).

Statistical analysis

All physiological data and respirator dead space CO₂ and O₂ data are reported as means (standard deviation). The time of the sessions is 1 hour, and all variables are reported as mean 1-minute values at 5 time increments (1, 15, 30, 45, 60 minutes [Tables 1 and 2]). One-hour averages were used for the statistical analysis because no significant changes over time were observed at the individual time increments. To assess differences between the EAPR and controls at the 2 intensity levels during

Table 1. Study variables during use of an elastomeric air-purifying respirator at 1.7-mph and 2.5-mph work rates over a 1-hour period

| Variables | 1 min | 15 min | 30 min | 45 min | 60 min |
|---|---------------|----------------|----------------|----------------|----------------|
| 1.7 mph | | | | | |
| Respirator dead space O ₂ [%] | 17.74 (±0.55) | 17.99 (±0.51) | 17.67 (±0.54) | 17.84 (±0.26) | 17.90 (±0.37) |
| Respirator dead space CO ₂ [%] | 2.47 (±0.50) | 2.47 (±0.42) | 2.65 (±0.52) | 2.49 (±0.33) | 2.49 (±0.35) |
| SaO ₂ [%] | 98.56 (±0.71) | 98.59 (±0.77) | 98.49 (±0.66) | 98.47 (±0.67) | 98.47 (±0.57) |
| tcPCO ₂ [mm Hg] | 40.83 (±3.87) | 44.56 (±5.24) | 44.71 (±5.15) | 44.84 (±5.78) | 44.95 (±5.96) |
| f _B | 21.71 (±5.36) | 22.83 (±5.09) | 22.33 (±4.43) | 23.61 (±4.12) | 23.42 (±3.13) |
| V _T [mL] | 904 (±227) | 927 (±217) | 920 (±275) | 882 (±264) | 901 (±198) |
| V _E [L] | 18.75 (±5.34) | 20.67 (±4.70) | 19.95 (±5.34) | 20.32 (±5.32) | 21.08 (±5.52) |
| HR | 92.60 (±6.27) | 95.58 (±8.04) | 96.47 (±8.82) | 95.55 (±9.15) | 96.82 (±8.67) |
| 2.5 mph | | | | | |
| Respirator dead space O ₂ [%] | 17.46 (±0.68) | 17.87 (±0.46) | 17.95 (±0.82) | 17.85 (±0.79) | 17.89 (±0.60) |
| Respirator dead space CO ₂ [%] | 2.47 (±0.45) | 2.47 (±0.44) | 2.47 (±0.34) | 2.49 (±0.40) | 2.43 (±0.36) |
| SaO ₂ [%] | 98.43 (±0.96) | 98.53 (±0.87) | 98.53 (±0.80) | 98.38 (±0.91) | 98.33 (±0.49) |
| tcPCO ₂ [mm Hg] | 40.31 (±4.17) | 43.98 (±7.01) | 43.40 (±6.80) | 43.41 (±7.70) | 43.89 (±8.20) |
| f _B | 23.35 (±5.48) | 23.46 (±5.88) | 23.84 (±5.26) | 23.14 (±4.68) | 23.90 (±4.14) |
| V _T [mL] | 925 (±231) | 988 (±244) | 958 (±244) | 921 (±223) | 941 (±218) |
| V _E [L] | 21.08 (±6.16) | 21.09 (±6.88) | 22.72 (±7.54) | 22.69 (±6.21) | 21.10 (±5.21) |
| HR | 96.82 (±8.67) | 95.07 (±10.35) | 100.02 (±8.77) | 101.07 (±9.01) | 101.06 (±9.14) |

NOTE. Values are mean (±standard deviation). 1.7 mph = 2.74 km/h and 2.5 mph = 4.03 km/h.

f_B, breathing rate in breaths per minute; HR, heart rate; min, minute; SaO₂, percentage oxygen saturation; tcPCO₂, transcutaneous partial pressure of carbon dioxide in millimeters of mercury; V_E [L], minute ventilation in liters; V_T [mL], tidal volume in milliliters.

Table 2. Comparison of elastomeric respirator use and controls, no respirator, at 1 hour

| Conditions | Work rate mph-km/h | Heart rate (beats per minute) | Breathing rate (breaths per minute) | Tidal volume [mL] | Minute ventilation [L] | % O ₂ saturation | Transcutaneous CO ₂ [mm Hg] |
|------------------------|--------------------|-------------------------------|-------------------------------------|-------------------------|------------------------|-----------------------------|--|
| Elastomeric vs control | 1.7-2.74 | 95.5 (±7.8) | 22.7 (±4.0)* | 904 (±231) [†] | 20.1 (±4.8) | 98.5 (±0.63) | 43.9 (±4.9) |
| | | 92.3 (±8.1) | 27.7 (±7.1) | 793 (±215) | 20.9 (±3.7) | 98.5 (±0.84) | 40.7 (±3.4) |
| Elastomeric vs control | 2.5-4.03 | 100.1 (±9.2) | 23.5 (±4.9)* | 947 (±228) | 21.9 (±6.2) | 98.4 (±0.75) | 42.9 (±6.6) |
| | | 101.3 (±11.8) | 27.7 (±8.6) | 864 (±205) | 23.0 (±6.4) | 98.5 (±0.84) | 40.8 (±3.1) |

NOTE. Values in columns 3-8 are means (±standard deviation).

*P < .05.

[†]P < .01.

1 hour of exercise, a 1-way (4 conditions) repeated measures analysis of variance (ANOVA) was performed. To determine differences for physiological variables, repeated-measures ANOVAs for oxygen saturation, partial pressure of transcutaneous carbon dioxide, breathing rate, tidal volume, minute volume, and heart rate were performed. Significant differences were further analyzed utilizing pair-wise comparisons tests with least significant differences adjustments with the α level set at $P = .05$. Paired t tests were performed to examine respirator dead space oxygen and carbon dioxide responses to EAPR at the 2 exercise intensities. Exertion scores, comfort scores, and EAPR weights were analyzed by paired t tests. SPSS version 16.0 (SPSS, Inc., Chicago, IL) was used for statistical analyses.

RESULTS

All subjects were able to complete all trials. Compared with controls, the EAPR resulted in significant

decreases in breathing rate at both work rates and significantly increased tidal volume at the 1.7-mph work rate; otherwise, there were no statistically significant differences in measured physiological variables (Tables 1 and 2). There were no significant differences in mean mixed inhalation/exhalation respirator dead space carbon dioxide concentrations at 1.7 mph and 2.5 mph ($P = .61$) or respirator dead space oxygen concentrations at 1.7 mph or 2.5 mph ($P = .80$) (Table 2). There were no significant differences between controls and EAPR in mean exertion scores at 1.7 mph ($P = .67$) and 2.5 mph ($P = .96$), mean comfort scores ($P = .67$ for both comparisons), or EAPR moisture retention ($P = .72$) (Table 3). Subjective complaints and EAPR features associated with discomfort are listed in Table 3.

DISCUSSION

The study data indicate that the use of an EAPR by healthy HCWs, over 1 hour at work rates associated

Table 3. Exertion scores,* comfort scores,[†] moisture retention, and number of subjects with subjective complaints and design feature concerns associated with the use of elastomeric air-purifying respirators by health care workers

| Study parameters | Elastomeric air-purifying respirator at 1.7 mph (2.73 km/h) | Elastomeric air-purifying respirator at 2.5 mph (4.03 km/h) |
|--------------------------------------|---|---|
| Exertion scores, mean (\pm SD) | | |
| Controls | 0.60 (\pm 0.84) | 0.83 (\pm 1.32) |
| Elastomeric air-purifying respirator | 1.05 (\pm 1.16) | 1.07 (\pm 1.34) |
| Comfort scores, mean (\pm SD) | | |
| Controls | 1.10 (\pm 0.31) | 1.17 (\pm 0.35) |
| Elastomeric air-purifying respirator | 1.40 (\pm 0.51) | 1.31 (\pm 0.44) |
| Moisture retention | 1.32 g (range, 0.3-2.6 g) | 1.62 g (range, 0.4-3.2 g) |
| Complaints/design features | | |
| Facial heat | 5 | 7 |
| Pinching | 2 | 2 |
| Skin irritation | 3 | 3 |
| Facial sweating | 2 | 2 |
| Speech difficulty | 1 | 0 |
| Tightness of elastomeric | 2 | 2 |
| Slippage of elastomeric | 2 | 2 |
| Odor of elastomeric | 2 | 0 |
| Weight of elastomeric | 2 | 3 |

SD, standard deviation.

*The modified Borg Scale of Perceived Exertion used in the study is: 0, extremely easy; 1, easy; 2, somewhat easy; 3, somewhat hard; 4, hard; 5, extremely hard.

[†]The Perceived Comfort Scale used in the study is: 1, very slightly or not at all uncomfortable; 2, a little uncomfortable; 3, moderately uncomfortable; 4, quite a bit uncomfortable; 5, extremely uncomfortable.

with the health care environment, was associated with statistically significant decreases in the breathing rate at 1.7 mph ($P = .02$) and 2.5 mph ($P = .03$) that was compensated by a significant increase in the tidal volume at 1.7 mph ($P = .009$) and nonsignificant increase at 2.5 mph ($P = .14$) compared with controls (Table 3). This is not unexpected because all respirators alter breathing patterns, and the increased ventilation associated with the (generally) greater dead space of the EAPR compared with FFRs (eg, N95 FFR, and others) usually employed by HCWs, favors an increase in tidal volume over breathing rate because it is more efficient from an energy standpoint.¹⁹ A recent review concluded that respirator use has little impact on minute volume during resting or low-intensity work conditions like those normally encountered in health care environments.²⁰

Mean absolute increases in transcutaneous carbon dioxide with the EAPR at 1.7 mph (+3.2 mm Hg) and 2.5 mph (+2.1 mm Hg) were not significantly different from controls ($P = .09$, $P = .27$, respectively). Of

concern is the finding that mean transcutaneous carbon dioxide levels, averaged over the course of the last 15 minutes of the EAPR use, were elevated (ie, >45 mm Hg) in 4 of 10 subjects at the 1.7-mph work rate (range, 46-56 mm Hg) and 5 of 10 subjects at the 2.5-mph work rate (range, 45.4-62.8 mm Hg), despite the EAPR being equipped with an exhalation valve that presumably allows for a smaller proportion of the exhaled breath (and associated carbon dioxide) to be retained in the respirator dead space (all subjects were asymptomatic of hypercapnia).²¹ Furthermore, at the 2 work rates, the mean mixed inhalation/exhalation respirator dead space oxygen concentrations (17.85%, 17.81%, respectively) and respirator dead space carbon dioxide concentrations (2.50%, 2.47%, respectively) did not meet Occupational Health and Safety Administration ambient workplace standards (ie, $<19.5\%$ is considered oxygen deficient; maximum 0.5% carbon dioxide as an 8-hour time weighted average),²² although these standards apply to the workplace, not to respirators. Oxygen saturation was not adversely affected. Nonetheless, this raises concerns that extended continuous EAPR wear (>1 hour) might lead to further increases in transcutaneous carbon dioxide that could be deleterious to the wearer. Also, the impact of mild-to-moderate EAPR-associated increased retention of carbon dioxide upon specific subgroups of HCWs who might be more susceptible to hypercapnia (eg, pregnant, asthmatics, and others) needs to be considered. Although the use of other air-purifying respirators (ie, gas masks) for upwards of 2 hours by pregnant women in active labor without adverse effects on mother or fetus has been reported,²³ as has tolerance to EAPR use by controlled asthmatics over short periods of mild-to-moderate work activities,²⁴ data are scarce overall.

Comfort is an important determinant of compliance with the use of respiratory protective equipment.⁸ In the current study, mean comfort scores with the EAPR were low (indicating less discomfort) and were not significantly different from controls at either work rate, suggesting that EAPRs are reasonably comfortable. Part of this comfort may be related to the low exertion work rates employed in this study, as supported by the fact that no significant differences were noted in the (low) mean exertion scores reported when comparing controls and EAPR use at either work rate. Furthermore, recent findings on HCWs respirator tolerance (a measure of comfort) reported that the same model of an EAPR as used in the current study was tolerated, on average, for 6.8 hours of use.⁸ Nonetheless, numerous complaints were offered by the current study subjects regarding subjective symptoms and design features (Table 3) that lend some credence to other recent findings that an EAPR, although tolerable, has a greater adverse subjective impact on wearers than N95 FFRs.²⁴

Moisture retention in respiratory protective equipment has been anecdotally suggested as a possible mechanism for increased respirator breathing resistance with prolonged use because of trapping of moisture in filter pores^{4,25,26} but has not been subjected to scientific scrutiny of any significant degree. Although no significant differences in moisture retention were noted at the 2 work rates ($P = .72$), we did not perform airway pressure measurements and cannot comment on any physiological effect of the moisture retention. We observed that there was significant moisture on the inner surface of the EAPR, including the exhalation valve, no doubt related to the relatively nonporous nature of the materials.

Limitations of the current study include the relatively small sample size ($n = 10$). There are many differences between this model and the many EAPRs available on the market with respect to materials (eg, silicone, rubber, plastic), price, size, weight, tethering device configuration, filters and performance so that we are unable to generalize our findings to other EAPRs. The study subjects had no prior experience with an EAPR, and that could have negatively impacted performance, but this may be a more plausible study group given that most HCWs have not had experience with EAPRs.⁶ The use of RIP for ventilation data is subject to intra- and interpersonal variability¹⁹ and is not as reliable as standard laboratory monitoring equipment (eg, spirometer, pneumotachygraph), but refinements in RIP have led to improved accuracy in recent exercise studies.^{27,28} Similarly, transcutaneous carbon dioxide levels are not as precise as arterial measurements, but improvements in sensors have led to greater precision,^{29,30} and this technique is not discomforting to the subject and avoids needle puncture-associated complications. Last, the current study was not carried out in a health care facility; however, laboratory studies have been suggested as actually representing the upper boundary of study parameter measurements.²⁴

CONCLUSION

Compared with controls over the course of 1 hour at 2 work rates associated with the health care environment, EAPR use by HCWs results in a lower breathing rate and compensatory higher tidal volume. Absolute increases in transcutaneous carbon dioxide levels over control values were not statistically significant over the course of 1 hour and not associated with symptomatology of hypercapnia, but variable retention of carbon dioxide occurred in a significant proportion of subjects and is a cause for concern. This will have to be evaluated further in a larger study and over more prolonged periods of continuous use. Subjective ratings

indicated that, although an EAPR was tolerable over 1 hour and not associated with significant perceptions of exertion, comfort was negatively impacted.

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