Respirator Physiologic Impact in Persons With Mild Respiratory Disease

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Objective: To assess whether mild respiratory disease affects physiologic adaptation to respirator use. **Methods:** The study compared the respiratory effects of dual cartridge half face mask and filtering facepeice (N95) respirators while performing simulated-work tasks. Subjects with mild chronic obstructive pulmonary disease (n = 14), asthma ($n = 42$), chronic rhinitis ($n = 17$), and normal respiratory status ($n = 24$) were studied. Mixed model regression analyses determined the effects of respirator type, disease status, and the respirator-disease interactions. **Results:** Respirator type significantly affected several physiologic measures. Respirator type effects differed among disease categories as shown by statistically significant interaction terms. Respiratory timing parameters were more affected than ventilatory volumes. In general, persons with asthma showed greater respirator-disease interactions than chronic obstructive pulmonary disease, rhinitis, or healthy subjects. **Conclusions:** The effects of respirator type differ according to the category of respiratory disease.

Respirator users are increasingly diverse. Although respirators have traditionally been used predominately in industrial and mining settings by healthy workers, they are now used in many service sectors. In the future, use may become very widespread in both occupational and community settings.[1] Much of the research evaluating the physiologic impacts of respirator use has, however, focused on healthy individuals. We have, therefore, conducted a series of studies evaluating responses to respirator use among individuals with mild respiratory impairments.

The study was conducted in volunteer subjects with mild asthma, chronic rhinitis, early chronic obstructive pulmonary disease (COPD), or normal respiratory status. Previous research has demonstrated that persons with either asthma or COPD adjust their respiratory patterns in response to their respiratory disorders.[2] In addition, detailed studies have shown that respirators also affect ventilatory physiologic parameters; these studies have been performed in controlled research laboratory conditions and less frequently, under conditions comparable with actual work. Studies have shown that half-mask respirators and N95 filtering facepiece devices differ in their physiologic and subjective consequences.[3,4]

This report describes the impact of combining respirator use and mild respiratory disease. Is the impact of combining respirator use and mild respiratory disease additive, greater than additive, or less than additive? That is, is the adverse physiologic impact of respirator use particularly enhanced in individuals with mild respiratory impairment? In addition, the study evaluates whether the effect of respirator use differed according to the type of respiratory disease. These data may help inform policy about which type of respirator should be recommended for widespread occupational or community use in the event of an epidemic or terrorist threat.[5] In addition, the information may help determine whether a single approach can be used for persons with respiratory disorders or if respirator selection should differ according to the type of respiratory disease.

METHODS

The study was approved by the Institutional Review Boards of University of California at Los Angeles and of the Greater Los Angeles Veterans Administration Medical Center. Subjects were recruited from the ambulatory clinical services of the Veterans Administration, posted brochures, newspaper recruitment, and contact with practicing physicians. Study participants came from the Los Angeles area. Subjects with three categories of mild respiratory disorders were recruited. In addition, a control group known to be free of these disorders participated. Criteria for selection for the three disease groups were as follows: COPD: presence of a diagnosis of COPD as well as documentation of airflow obstruction with a ratio of the forced expiratory volume in 1 second (FEV_1) to the forced vital capacity that was <0.70. Asthma: documented diagnosis of asthma by a physician. In addition, the selection criteria required the use of asthma medications for at least 6 months and reversibility of FEV_1 reduction on spirometry. Chronic rhinitis: participants with chronic rhinitis were eligible if they had a documented medical diagnosis of rhinitis that had been present for at least 3 mo/yr and symptoms at least 3 d/wk for prior month.

Subjects were excluded if they were not in stable condition (eg, if they had a hospitalization or an unscheduled physician visit for respiratory disease within 6 months). In addition, persons with active cardiac disease, regular use of psychiatric medications, musculoskeletal conditions that would interfere with the ability to safely conduct the work tasks, or inability to communicate effectively in English were excluded. Spirometry criteria excluded persons with advanced COPD if they had a $FEV_1 < 50\%$ predicted. Each potential participant underwent screening interview, review of selected medical records, and physician examination.

The study was conducted over three separate days. On two of the days, the subject performed a series of simulated-work tasks while using either a half-face mask (HFM) dual cartridge respirator (Comfo-Elite; Mine Safety Appliance Co, Pittsburgh, PA) or a N95 single-use type respirator (8210 3M; St. Paul, MN). On the third day, the subject was studied in a pulmonary exercise laboratory; these data are not included in current report because they were collected under different conditions for the purpose of ascertaining mechanisms.

Tasks used for the work simulation included sedentary and more active tasks. The tasks were i) sedentary: familiarize subject with rating procedures (lern), sort bolts into bins (bolt), simulate driving (driv), and produce towers with plastic blocks following

prescribed instructions (lego); ii) mild exertion: walk across room, obtain paper, and place into proper bins (case), place magnets on boards at proper coordinates based on oral instructions (mags), and walk across the room and place magnets on boards at proper coordinates based on oral instruction (magw); and iii) moderate exertion: stock store shelves with cereal boxes and juice jugs (stor) and walk and stock store shelves with rice buckets (carr). Each task was ~8 to 10 minutes in length. Subjects were permitted breaks between the tasks as required. The order of days and the order of tasks within days were randomized.

Measurement methods have been described in more detail elsewhere.[3] A respiratory inductive plethysmograph (Vivometrics Life Shirt® models 200 and 100, Ventura, CA) was used to measure ventilatory and respiratory control parameters unobtrusively. Continuous measurement of the circumference of the chest and of the abdomen allows calculation of the volume of air exchanged. In addition, respiratory timing parameters are automatically calculated. Calibration of the system was performed for each individual by the "fixed volume" calibration procedure—having the subject repetitively inhale a fixed volume using different chest and abdomen configurations.

In addition, an electrocardiogram was continuously recorded. The data were recorded on a small solid-state recorder worn by the subject and also transmitted for monitoring purposes by a WiFi system. Sections free of notable artifact were included for analysis. A combination of manufacturer provided software and programs developed in our laboratory was used.

Measurements included tidal volume (volume per breath), minute ventilation (total air moved per minute), and flow rates throughout inspiration and expiration. In addition, several measures of respiratory control were determined. These included inspiratory time (T_i), expiratory time (T_e), respiratory rate, and average total respiratory cycle time (T_t). The duty cycle (T_i:T_t) represents the proportion of the total respiratory cycle during which inspiratory effort is made. Other derived physiologic parameters included the average inspiratory flow rate (tidal volume divided by inspiratory time), which is an indirect measure of the ventilatory drive. Additional measures included the average expiratory flow rate, the peak inspiratory flow/inspiratory time ratio, the peak expiratory flow/expiratory time ratio, peak inspiratory flow/tidal volume ratio, and peak expiratory flow/tidal volume ratio. Several of these parameters are well-accepted indicators of respiratory control. Several of the variables were also adjusted for the body size by dividing the observed value by the square of height.

Statistical analysis was based on application of mixed regression model. Data were managed in a relational database (Access, Microsoft) and statistical analysis with SAS for PC (Version 9.1; SAS Institute, Cavy, NC). The regression models assessed several factors:

- Respirator type: comparing HFM dual cartridge with filtering facepiece N95
- Task activity performed: 8 distinct stimulated work tasks, including low exertion and moderate exertion activities
- Health status
- Interaction between health status and respirator type

The analytic models were specified a priori and included the interaction terms described earlier. Because a person may have more than one disorder (eg, both chronic rhinitis and asthma), health status was characterized in two different ways. Model A: in this method, each subject was characterized by separate dichotomous coding for each of three separate variables: asthma, COPD, and rhinitis. Model B (hierarchical): a single health status variable disease group was assigned to each individual by the following hierarchical scheme: COPD > asthma > rhinitis > normal. For example, a person with both rhinitis and asthma would be classified in the disease group "asthma."

The results of spirometry testing were used as an indicator of severity of illness in Model A. The degree of airflow obstruction was summarized by the FEV_1 expressed as percentage of predicted. The prediction equations of Hankinson et al[6] were used, derived from National Health and Nutrition Examination Survey (NHANES); these equations directly incorporate adjustment of predicted values for blacks. Gender (dichotomous) and age (a continuous variable) were also used in this model.

In the first regression model, the physiologic variable was regressed on respirator type (either HFM or N95), three dichotomous dummy variables (COPD, asthma, and rhinitis), task (eight categories), gender, age, and FEV_1 percentage of predicted as a continuous variable; in addition, three interaction terms were included respirator type and asthma; respirator type and COPD; and respirator type and rhinitis. In the second regression model, the predictor variables were respirator type, task, disease status (a single variable with the four hierarchical categories described earlier), and respirator type and disease category interaction. A $P < 0.05$ was considered statistically significant. In addition, unadjusted mean values for each combination of respirator, disease type, and task were calculated. Furthermore, the mixed regression model was used to calculate the adjusted least squares mean values for each disease category and respirator type. The covariance structure was specified as compound symmetry, and a repeated-measures design was incorporated.

RESULTS

Characteristics of the research study participants are summarized in Table 1. As intended, the respiratory disease subjects had relatively mild disease.

The statistical analyses are summarized in Tables 2 and 3. Table 2 shows the unadjusted mean for selected variables according to respirator type, task type, and disease status (using the hierarchical disease categorization method). Table 3 shows the results of formal hypothesis testing and coefficient estimation using mixed regression models.

The statistical models estimated the effect of three main factors (respirator type, task performed, and disease status) as well as the interaction between respirator type and disease status. The coefficient for respirator type reflects the effect of use of the HFM in comparison with the N95. Two distinct statistical models, Model A and Model B, were used. Model A included age, gender, and FEV_1 percentage of predicted as covariates; in this model, disease is expressed by a series of three dummy variables, so that an individual may have more than one disorder. Model B uses the hierarchical disease status classification and does not include the covariates.

Several of the key variables are also summarized graphically in Table 4. The direction of the main effects and of the interaction is shown; statistically significant values are shown by solid arrowheads, and borderline effects are shown by thin arrows.

Comparison of the two respirator types studied (HFM versus N95) showed several statistically significant effects. Ventilatory volumes showed minor, inconsistent effects. For example, tidal volume and minute ventilation were slightly lower with the HFM, but this reached statistical significance only for Model A with borderline significance in Model B. Respiratory rate was lower with the HFM (statistically but perhaps not clinically significant).

The pattern of respiratory timing was significantly affected by respirator type. With the HFM, the inspiratory time and the duty cycle (T_i:T_t) were prolonged, and the expiratory time was concomitantly reduced (all with $P < 0.001$). Both the

TABLE 1. Subject Characteristics

	n	Age* (yr)	Gender (% Male)	Race (% Black)	FEV$_1$ % Predicted*	FEV$_1$/FVC*
Hierarchical classification						
Asthma	42	44.0 (12.0)	64	52	88% (14%)	75% (10%)
COPD	14	53.8 (4.7)	86	71	72% (13%)	70% (8%)
Chronic rhinitis	17	48.7 (9.7)	77	41	90% (15%)	76% (7%)
Normal	24	39.7 (11.3)	50	54	100% (12%)	83% (5%)
Total	97	47.3 (10.2)	66	54	88% (16%)	76% (9%)
Multiple disease classification						
Asthma	45	44.6 (11.8)	67	51	86% (15%)	74% (10%)
Chronic rhinitis	34	52 (9.7)	68	44	89% (14%)	75% (7%)

The table summarizes the characteristics of the participating subjects. Means and standard deviations are shown. Subjects were each classified into a single disease class in a hierarchical manner as described under Methods section. In addition, subject characteristics are shown when a subject can be included in multiple groups if he or she has concomitant medical conditions; because of the hierarchical scheme, only asthma and chronic rhinitis are affected. Statistical significance for differences among groups is shown for the hierarchical classification scheme.

*$P < 0.05$.

FVC, forced vital capacity.

TABLE 2. Average Values for Selected Physiologic Variables by Task, Respirator, and Disease (Unadjusted)

	Disease	Respirator	Task							
			Bolt	Carr	Case	Driv	Lego	Mags	Magw	Stor
Minute ventilation	Asthma	HFM	18.9	26.5	28.9	14.9	20.1	18.8	25.5	29.4
		N95	18.1	27.0	31.0	15.2	17.9	15.8	22.5	28.8
	COPD	HFM	22.0	33.3	27.9	19.0	21.5	20.1	27.9	33.9
		N95	20.6	31.8	32.8	20.1	20.4	18.4	28.5	35.6
	Rhinitis	HFM	18.1	29.3	32.5	14.8	20.5	16.4	24.3	30.9
		N95	18.3	28.1	35.9	14.6	19.8	17.0	24.1	31.9
	Normal	HFM	15.9	25.3	25.1	12.7	16.8	15.6	23.0	27.5
		N95	17.0	26.2	27.4	15.1	18.6	17.0	23.6	28.9
Inspiratory time (T_i)	Asthma	HFM	1.19	1.06	1.12	1.29	1.20	1.26	1.12	1.06
		N95	1.19	1.02	1.11	1.25	1.20	1.25	1.09	1.04
	COPD	HFM	1.09	1.01	1.09	1.17	1.12	1.15	1.02	1.01
		N95	1.07	0.98	1.00	1.18	1.11	1.13	0.98	0.95
	Rhinitis	HFM	1.27	1.11	1.18	1.34	1.24	1.32	1.17	1.14
		N95	1.20	1.04	1.15	1.30	1.23	1.31	1.10	1.04
	Normal	HFM	1.20	1.05	1.13	1.24	1.20	1.22	1.09	1.05
		N95	1.15	0.96	1.09	1.14	1.13	1.19	1.02	0.97
Duty cycle (T_i:T_t)	Asthma	HFM	0.88	1.04	1.11	0.77	0.90	0.91	0.97	1.07
		N95	0.83	0.98	1.08	0.74	0.86	0.89	0.94	1.02
	COPD	HFM	0.93	1.01	1.08	0.86	0.95	0.95	1.01	1.09
		N95	0.87	0.98	1.05	0.81	0.84	0.84	0.95	1.05
	Rhinitis	HFM	0.93	1.05	1.15	0.85	0.95	0.94	1.01	1.11
		N95	0.89	0.99	1.14	0.79	0.94	0.88	0.96	1.08
	Normal	HFM	0.87	1.01	1.11	0.79	0.90	0.90	1.00	1.07
		N95	0.83	0.99	1.11	0.75	0.86	0.87	0.96	1.05

Unadjusted average values for selected physiologic parameters are shown for of the tasks according to respirator type (HFM = half-face mask dual cartridge) and disease status (using the single disease hierarchical approach).

peak and mean inspiratory flow rates were reduced, and the peak flow was reached earlier in inspiration (ie, the flow profile was "squared"). Differences within the expiratory phase were less consistently noted.

The effect of disease status per se is also shown in Tables 2–4. No consistent significant effects were noted for volumes for the COPD and asthma groups. Subjects with COPD showed evidence of expiratory flow limitation as suggested by reduced time to reach peak expiratory flow rate. Subjects with rhinitis were noted to have larger volumes and flow rates in model A; because age, gender, and FEV$_1$ percentage of predicted were included as covariates, this is unlikely to be due to confounding per se.

TABLE 3. Regression Analysis Results

	Units	Model	Respirator Type	Task	Disease Asthma	Disease COPD	Disease Rhinitis	Interactions of Respirator Type With Asthma	Interactions of Respirator Type With COPD	Interactions of Respirator Type With Rhinitis	Age	Gender	FEV$_1$ % Predicted
Heart rate	Beats/min	A	2.11**	−15.72**	4.70*	10.21	2.55	−0.82*	−3.72**	1.49	0.19	8.66**	10.11*
		B	0.58	−15.61**	0.59*	5.09	−4.53	1.77**	−2.14*	2.55**			
Ventilation													
Tidal volume	mL	A	−67.58**	−345.13**	40.83*	140.92**	226.36**	117.89**	62.18*	93.13**	2.16	−163.59*	521.66*
		B	−19.06	−343.12**	90.22*	117.52	154.47	98.47**	51.73*	0.30			
Tidal volume/ht²	mL/cm²	A	−20.96**	−115.39**	5.83*	39.04*	68.26**	36.51**	18.65*	31.90**	1.07	−0.92*	165.13*
		B	−4.44	−114.67**	6.31*	9.17	15.94	29.97**	14.36*	0.57			
Minute ventilation	L/min	A	−1.79**	−12.63**	0.73*	5.29*	5.77**	2.93**	1.31*	1.86**	0.08	−4.84*	14.54*
		B	−0.96	−12.58**	1.32*	4.12	2.28	2.67**	1.37*	0.35			
Minute ventilation/ht²	L/min/cm²	A	−0.57**	−4.25**	0.04*	1.49*	1.74	0.92**	0.41*	0.63**	0.04	−0.29*	4.59*
		B	−0.30*	−4.22**	−0.16*	0.57*	−0.12	0.84**	0.42*	0.13			
Respiratory pattern													
Respiratory rate	Breaths/min	A	−0.84**	−7.26**	−0.35*	1.42*	1.01*	1.25**	1.14**	0.41	0.07	−2.22*	5.73*
		B	−1.01**	−7.29**	−1.29*	0.48*	−1.21	1.62**	1.63**	0.60			
Inspiratory time	s	A	0.06**	0.14**	0.02*	−0.08	0.00*	−0.04**	−0.02*	−0.01	0.00	0.03*	−0.05*
		B	0.06**	0.14**	0.05*	−0.04	0.08	−0.05**	−0.03*	−0.02			
Expiratory time	s	A	−0.04**	0.40**	0.08*	−0.15*	−0.10	−0.06**	0.00*	0.03	0.00	0.05*	−0.13*
		B	−0.02	0.40**	0.11*	−0.08	0.05	−0.07**	−0.02*	0.00			
Total cycle time	s	A	0.01*	0.54**	0.10*	−0.22*	−0.10	−0.09**	−0.01*	0.02	0.00	0.08	−0.18*
		B	0.04	0.54**	0.16*	−0.12	0.14	−0.12**	−0.06*	−0.02			
Ti/Tt (duty cycle)	Ratio of time	A	0.015**	−0.035**	−0.005*	0.004*	0.014**	0.000*	−0.001*	−0.005**	0.000	−0.003*	0.019*
		B	0.013**	−0.036**	−0.004*	0.002*	0.007	0.001*	0.001*	−0.001			
Ti/Te ratio	Ratio of time	A	0.041**	−0.190**	−0.004*	0.005*	0.049*	0.004*	0.021*	0.003	0.003**	−0.040*	0.171*
		B	0.036**	−0.190**	−0.009*	−0.004*	0.029	0.010*	0.027*	0.007			
Flow rates													
Time to reach peak inspiratory flow	% of time	A	−0.15*	1.05**	0.05*	1.59*	−0.53	−0.45*	−0.99**	0.53	−0.01	0.31	0.99*
		B	−0.19*	1.06**	−0.16*	1.15*	−0.51	−0.28*	−0.96**	0.66			
Time to reach peak expiratory flow	% of time	A	−0.07*	−3.52**	−0.22*	−1.85	−0.19	0.10*	1.59**	0.74	0.05	0.02	4.52**
		B	0.12*	−3.47**	−0.99*	−2.75**	−0.40	0.19*	1.54**	0.10			
Mean Inspiratory Flow	L/s	A	−104.11**	−443.58**	123.51*	255.57*	249.50*	155.02**	67.81*	111.46**	4.20	−249.36*	1034.78**
		B	−76.36**	−440.26**	92.79*	115.35	34.78	168.87**	88.52*	48.14			
Peak inspiratory flow	L/s	A	−177.44**	−817.04**	208.34*	418.05*	432.62*	264.69**	118.48*	204.53**	7.39	−449.52*	1780.57**
		B	−127.87**	−810.63**	161.30*	189.15	82.72	290.36**	153.71*	90.60			
Peak expiratory flow	L/s	A	−116.45**	−840.11**	181.07*	378.57*	457.09	265.46**	136.00*	185.01**	8.50	−431.77*	1771.10**
		B	−71.97	−834.67**	144.61*	160.23	128.84	289.58**	173.60**	80.06			
Peak:midflow ratio—inspiratory	Ratio of flow	A	0.002*	0.003**	−0.001*	−0.003*	−0.001	−0.001*	−0.003*	−0.002	0.000	0.001*	−0.008*
		B	0.002*	0.003**	−0.000*	0.000*	0.004	−0.001*	−0.004*	−0.002			
Peak:midflow ratio—expiratory	Ratio of flow	A	0.001*	0.028**	−0.001*	0.001*	−0.002	0.000*	−0.004*	−0.003	0.000	0.008	−0.028*
		B	0.002*	0.027**	0.002*	0.004*	0.001	−0.001*	−0.005*	−0.003			

Regression coefficients are shown for the primary effect of respirator type (RT, as HFM–N95), task, disease status, and interaction between disease status and respirator type. For simplicity, only the coefficient for the task of bolt sorting is shown in the table. Models A and B differ in the disease classification method: in model B, a single disease category is assigned to each individual, whereas model A used dummy variables to express multiple diagnoses per subject. In addition, model A include several additional predictor variables of forced expiratory volume in 1 s (FEV$_1$) % predicted, age, and gender (female–male). *$P < 0.05$; **$P < 0.01$.

TABLE 4. Summary of Interactions Between Respirator Type and Disease

	RT	Task	Disease Asthma	COPD	Rhinitis	Interaction RT and Asthma	RT and COPD	RT and Rhinitis	Age	Gender	FEV$_1$ % Predicted
Heart rate	▲	▼	↑	▲	—	—	▼	▲	↑	▲	—
Tidal volume	▼	▼	—	—	▲	▲	▲	▲	—	▼	▲
Tidal volume/height^2	▼	▼	—	—	▲	▲	▲	▲	—	—	▲
Minute ventilation	▼	▼	—	↑	▲	▲	↑	▲	—	▼	▲
Minute ventilation/height^2	▼	▼	—	—	▲	▲	↑	▲	—	—	▲
Respiratory rate	▼	▼	—	—	—	▲	▲	—	—	↓	—
Inspiratory time	▲	▲	—	—	—	▼	—	—	—	—	—
Expiratory time	▼	▲	—	—	—	▼	—	↑	—	—	—
Total time		▲	—	—	—	▼	—	—	—	—	—
Ti:Tt (duty cycle)	▲	▼	—	—	▲	—	—	▼	▲	—	—
Ti:Te	▲	▼	—	—	▲	—	▲	—	▲	↓	▲
Time to reach peak inspiratory flow	—	▲	—	▲	—	↓	▼	▲	—	—	—
Time to reach peak expiratory flow	—	▼	—	▼	—	—	▲	▲	▲	—	▲
Mean inspiratory flow	▼	▼	—	—	▲	▲	▲	▲	—	▼	▲
Peak inspiratory flow	▼	▼	—	—	▲	▲	▲	▲	—	▼	▲
Peak expiratory flow	▼	▼	—	—	▲	▲	▲	▲	—	▼	▲
Peak:midflow ratio—inspiratory	▲	▲	—	—	—	—	▼	↓	—	—	—
Peak:midflow ratio—expiratory	—	▲	—	—	—	—	▼	▼	▼	▲	▼

The effects of disease, respirator type, and their interaction are summarized. The results are based on model A. Arrows show the direction of the effects. Statistically significant effects are in solid bold arrowheads, and effects of borderline significance by thin arrows. Interaction refers to the statistical interaction term between the disease and the respirator type. "Respirator" refers to the difference HFM − N95.

RT, respirator type.

Model A examines the effects of several covariates. Female gender was associated with lower volumes and flow rates. However, this probably reflects smaller body size because the gender effect was not present when the tidal and minute volumes were scaled for body size (dividing by height squared). Age did not have significant effects.

The FEV$_1$ percentage of predicted was associated with several of the volume and flow variables (eg, tidal and minute volumes) as well as with respiratory timing control. For example, the inspiratory:expiratory time ratio was positively associated with the FEV$_1$ percentage of predicted.

Interactions in the statistical regression analyses were examined to determine whether the impact of the different respirator types was consistent across all the disease categories or if some groups were affected disproportionately.

Table 4 shows that there are numerous statistically significant respirator-disease interactions. For several, the combined effect of the disease and HFM respirator use was greater than the sum of the individual effects (described as "synergistic"), whereas the combined effect was significantly less than the sum of the individual disease plus respirator effects (termed "antagonistic") for others. In general, model A is more informative for this analysis because the disease classifications are partially confounded in the single disease category-based model B.

The presence of any of the three disease groups opposed the effect of HFM on reducing volumes. Indeed, the overall effect of mild disease plus HFM use is to slightly increase the volumes. Similar results were seen for the peak inspiratory flow rate, peak expiratory flow rate, and average inspiratory flow rate.

The two disorders associated with lower airway obstruction (asthma and COPD) had synergistic interactions with respiratory rate. The interactions with respiratory timing were most notable for asthma. Asthma reduced the ability to compensate for HFM use by increasing Ti. The effect of the HFM on reducing expiratory time was accentuated in persons with asthma.

DISCUSSION

The current study addresses the four factors that are likely to influence whether a person will safely and effectively continue work activities using respiratory protection: a) type of respirator; b) type of work activity performed; c) health status and other personal characteristics; d) interactions among health status, respirator type, and work characteristics. Most studies have emphasized the first factor, seeking to delineate the effects of using a respirator in comparison with work without respirator,[7,8] and several studies had considered disease status.[9–11]

Comparisons of respirators may depend on the personal characteristics of the groups in which the testing is conducted. Therefore, the current study measured the interactions between disease factors in addition to independently evaluating the main effects of the respirator type and health status. The interplay among these factors may fall into three categories: a) no interaction: the net effect in individuals with the disease and the respirator is simply the sum of the average effect of the respirator and of the disease; b) synergistic: the effect is greater than the sum of the average effects of the respirator and of the disease; c) antagonistic: the combined effect of the respirator and of the disease is less than the sum of the average effects of each of these factors.

We compared two common types of respirators—HFM dual cartridge and filtering facepiece N95—under different work conditions among volunteers with four different respiratory conditions. The studies were conducted during simulated-work conditions rather than exercise laboratory conditions.

The determination of which respirator type to use and which potential users represent the greatest risk may be based on several

considerations. The optimal outcome measure, effective protection of the population against health risks, usually cannot be directly measured even for traditional industrial uses. With high-resistance respirators and very high exertion levels, one might simply measure the ability to continue working.[12–14] Nevertheless, the more common scenario is one of low-moderate exertion with a low-resistance device.[15,16] Therefore, the study assessed several physiologic variables. Adequate tolerance of respirator use, rather than the ability to overcome its resistance, is likely to be a major determinant of effective public health protection. There may be a trade-off between a high protection factor and better tolerance.[17] Related studies are looking at subjective responses and adequacy of work performance.[4]

Effect of Respirators

Physiologic patterns differed between the respirator types. Most notably, the HFM prolonged inspiration and compressed the expiratory phase. Volumes were reduced slightly by the HFM in comparison with the N95. These findings are consistent with those of several previous studies.[2,3,18] Although the physical mask volume of an HFM is larger than an N95, dynamic streaming of airflow within the mask may reduce the effective dead space.[19]

The inspiratory prolongation and the reduction of peak flows ("squaring" of the flow profile) is likely a consequence of the greater inspiratory resistance; these adjustments reduce the peak inspiratory respiratory muscle work rates and may influence the sensation of breathing.[2] Others have suggested using peak mouth pressure as the criterion for allowable exertion during respirator use[20]; "squaring" the flow pattern avoids high peak mouth pressure. Controlled physiology laboratory studies of added low resistances demonstrated that humans adjust the breathing pattern to reduce the subjective impact of peak work rates and pressures[21] and adjust the $T_i:T_t$ ratio to reduce adverse sensation.[22] A study of firefighters using an SCBA suggests that they adapt their respiratory pattern to limit dyspnea.[23] Speech while using a respirator increases the $T_i:T_t$,[24] producing an effect that may be additive to that of the respirator per se.

Laboratory studies have shown that ventilation is reduced with high levels of inspiratory or expiratory resistance or both; in addition, peak flow rates at maximal exercise are reduced.[12,14] Nevertheless, the resistances studied were higher than seen with most respirators, and the results may not be directly applicable to the devices in this study. The actual mechanisms by which respirator loads affect ventilation are complex. Inspiratory resistive loading seems to be more significant than expiratory loading.[12,25] The effects may be linearly related to the resistance or external work of breathing and therefore may be anticipated to occur across the full range of resistances[12,26]; conversely, effects might depend on resistance levels sufficient to produce respiratory muscle fatigue,[27] so that findings with high resistances may not be applicable to respirators of considerably lower level resistance. The effects are also likely to depend on the exertion level.[28]

The study compared two types of air-purifying respirators. Other device types impose different physiologic burdens.[24] For example, pressure demand[29,30] and powered air purifying[7] respirators add in-mask positive pressure. For a self-contained breathing apparatus (SCBA), device weight per se seems significant.[31,32]

Disease Effects

Asthma or COPD diagnosis per se was not associated with ventilatory physiologic effect, respiratory pattern adaptation, or subjective responses to the two respirator types. Ventilatory volumes and flow rates were positively associated with FEV_1 percentage of predicted. Most of the respiratory timing parameters were not associated with FEV_1. Rhinitis was associated with larger flows and volumes. This set of results probably indicates that the level of airway function, even in the near normal range of our subjects, does have discernible ventilatory effects. Both reduced FEV_1 and HFM use adversely affect ventilation. Unlike ventilation, respiratory timing control was affected by neither disease diagnosis nor FEV_1 percentage of predicted. Nevertheless, studies of individuals with considerably more advanced asthma and COPD have demonstrated that these disorders have significant effects.[33]

Our finding that age did not have an effect is consistent with other studies of respirator type loads.[34]

Interaction of Disease and Respirator Type

The effect of respirator type differed according to the respiratory disease status. For both the physiological and respiratory timing adaptations, there were numerous statistically significant interactions between respirator type and disease status. The results suggest that individuals with either of the two disorders of intrathoracic airflow obstruction, particularly asthma, might have difficulty adapting to HFM. The total adaptation effects were less than the sum of the individual effects for the disease and the respirator type. For example, both asthma and HFM use prolong the total respiratory cycle time, but the interaction is negative (implying less complete adaptation when both are present).

Several studies in exercise laboratory settings have shown minor differences in response to respirator use in persons with COPD; one study with respirator surrogate resistance loads showed that subjects with moderate COPD had less response than those with milder COPD.[10] In another study, differences between pulmonary impaired and healthy subjects were seen only at high exertion levels.[11]

Limitations

The physiologic and respiratory patterns were measured unobtrusively using a respiratory inductive plethysmograph.[35–38] Although less precise than direct measurements of airflow or volume with a mouthpiece and hose, this method avoids the artifact introduced with methods requiring connection to the airway. Adding resistive loads does not degrade accuracy except at very high loads.[39] It also allows spontaneous adjustment of airflow between the oral and nasal routes.[5,40–43]

The study included individuals with three forms of respiratory disease. Nevertheless, the study did not address subjects with two less common categories of respiratory disease: the restrictive diseases (such as usual interstitial pneumonitis or asbestosis)[44] and primary respiratory control disorders.

The study used two distinct statistical models for analysis. Overall, the results were generally consistent, suggesting that the results are robust to the differing statistical and disease classification assumptions.

Although measurement of physiologic response as a means for evaluating respirator-disease interactions has both precedent in the published literature and face validity, other outcomes may also be appropriate. In related studies, we are looking at subjective tolerance across multiple domains,[4] impact on work performance, and stability of mask position. Because the studies measure response on a short-term basis, it is hypothetically possible that long-term users would develop a different pattern of adaptation.

Implications

First, physiologic responses to respirator use differ according to the health status of the user. For several important respiratory measures, the interaction between respirator type and health status is greater than the effect of the disease per se. In addition, health conditions may constrain the normal physiologic adaptation to respirator use (eg, airway obstruction opposes the normal inspiratory prolongation response to HFM use).

Second, routine evaluation of respirator users with physical examination or spirometry or both may be insensitive for detecting individuals who will tolerate poorly use. Because the respiratory variables with greatest respirator-health interactions (pattern adaptation) are difficult to evaluate in the routine clinical setting, clinicians should be sensitive to subjective reports of users. Furthermore, because the responses differed according to respiratory disease category, "generic" criteria for medical clearance should be used cautiously.

Third, testing of new respirator designs should include sufficient subjects in each health status category to determine whether the respirator will be particularly poorly tolerated in the subgroup. In addition, multiple outcomes should be measured. Ability to maintain high exertion levels may not be the optimal outcome measure for respirators that are used widely in community in general workplace settings. Extrapolation from mechanical simulators ("breathing machines") should be verified by human testing. Pulmonary physiology research studies have shown that breathlessness may be dissociated from the actual increased work of breathing.[45]

Fourth, there are significant differences between the protection afforded by different classes of respirators, such as elastomeric dual cartridge half mask versus filtering facepiece disposable respirators. Furthermore, there are differences in the degree of protection within any class depending on the respirator design. For example, the study used a highly protective dual cartridge respirator with P100 cartridges and a somewhat less protective filtering facepiece N95 type, whereas the other half-mask devices may use less efficient cartridges such as those rated as N95 and other disposable filtering facepiece respirators may be more designed for greater protection such as N99 ratings. Therefore, design of a respiratory protection program or making public health recommendations should consider the trade-off between higher levels of protection versus greater cost, complexity of equipment, and discomfort. There is likely to be a trade-off between higher protection factors and better user tolerance.

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