Subjective Response to Respirator Type: Effect of Disease Status and Gender

Philip Harber, MD, MPH, Silverio Santiago, MD, Samantha Wu, BS, Siddharth Bansal, MD, Yihang Liu, MD, MS, and David Yun, BS

Objective: To assess the effect of respirator type and user characteristics (eg, health status) on the subjective response to respirator use. **Methods:** The subjective responses for multiple domains were evaluated in 104 volunteers performing work tasks in a simulated work environment. Each used a dual cartridge half face mask and a filtering facepiece (N95) respirator. The study population was recruited to include four groups (normal respiratory status, mild asthma, chronic obstructive pulmonary disease, or chronic rhinitis). Mixed model regression analyses determined the effects of respirator type, disease, gender, and age. **Results:** Half face mask produced more adverse subjective response than the N95 for most scales. There were significant interactions such that disease status modified the effect of respirator type. In general, women reported greater adverse ratings than did men. **Conclusions:** The effect of respirator type depends on disease status. Respirator design evaluation panels should include persons with mild respiratory disease.

Respirators provide effective protection only if they are worn properly and used regularly when needed. Studies have shown that several types of respirators reduce the maximal level of exercise that can be achieved or the duration of exercise at high exertion levels.[1] Under such heavy exertion circumstances, limitation of ventilation and exertion is likely to determine proper use. Nevertheless, other factors may be more important for the lower exertion levels that characterize most jobs[2] and during use by the general community,[3,4] in epidemics,[5] and in community mass use situations.[6–8] and other factors may be more important. This study is part of a project to characterize the overall response to respirator use; other aspects include physiologic responses,[9] productivity effect, mask dislodgement, and anxiety. The development and characterization of the subjective response scales were described in an earlier study.[10] Despite extensive studies, the precise factors determining whether respirators will be properly used remain undefined.[11–13] Therefore, this study considers the subjective effects of using respirators.

Respirator users are increasingly heterogeneous. Therefore, the study intentionally included a diverse group; in addition to healthy subjects, the group includes individuals with several types of mild respiratory disorders (chronic obstructive pulmonary disease [COPD], asthma, and chronic rhinitis). In addition to comparing the effect of two respirator types, the study also considered the effect of personal characteristics, such as age, gender, and disease status. This study may facilitate selecting the optimal respirator type for each user and help guide designing respirators.

From the Occupational and Environmental Medicine Division (Dr Harber, Ms Wu, Dr Bansal, Dr Liu, Mr Yun), Department of Family Medicine, David Geffen School of Medicine at University of California at Los Angeles; and Division of Pulmonary Medicine (Dr Santiago), Department of Medicine, VA Greater Los Angeles Healthcare System, Los Angeles, Calif.

Address correspondence to: Philip Harber, MD, MPH, Occupational and Environmental Medicine, UCLA, 10880 Wilshire, #1800, Los Angeles, CA 90024; E-mail: pharber@mednet.ucla.edu.

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METHODS

This study was approved by the institutional review boards of the 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 contacts with practicing physicians. All study participants came from the Los Angeles area. Four groups of subjects were recruited—mild COPD, asthma, chronic rhinitis, and those known to be free of these disorders. Criteria for selection are described in detail elsewhere.[9,10]; see the accompanying article in this issue for selection criteria.[14]

Each subject participated on three separate days. On two of the days, the subject performed a series of simulated work tasks in a laboratory setting. On one day, the subject used a half face mask (HFM) dual cartridge respirator (Comfo-Elite with P100 filters; Mine Safety Appliance Co, Pittsburgh PA), and he/she used an N95 filtering facepiece single use type respirator (8210; 3M, St. Paul, MN) on the other day. On a third day, the subject was studied in a pulmonary exercise laboratory; these data are not included in the current report because they were collected under different conditions for the purpose of ascertaining mechanisms.

Tasks used for the work simulation included both sedentary and more active tasks; the tasks are summarized in Table 1 and described elsewhere,[9,10] including an article in this issue.[14] The tasks were as follows: i) Sedentary: familiarize subject with rating procedures (lern); sort bolts into bins (bolt); simulate driving (driv); produce towers with plastic blocks after 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); walk across the room and place magnets on boards at proper coordinates based on oral instruction (magw). iii) Moderate exertion: carry and stock store shelves with cereal boxes and juice jugs (stor); 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.

Subjective responses were measured for multiple subjective domains, including 12 specific symptoms and assessment of respirator-related duration decrement (how much the respirator would reduce and how long the task could be continued). The methodology has been described in detail previously.[9,10] Subjects rated each of the scales after 4 and 8 minutes of task performance. Subjects performed rating using paper or touch screen methods using a modified Borg scale (range 6 to 20) for each variable. To facilitate subjects' understanding of the scales and rapid rating, each underwent a brief training before the study began. In addition, visual clues concerning the scale being rated were used using cartoon pictures (see Fig. 1).

Statistical Methods

Mixed model regression analyses were performed using SAS version 9.1 (SAS Institute Inc, Cary, NC). Each of the subjective

TABLE 1. Subjects

	Asthma	COPD	Rhinitis	Normal
n	44	15	18	27
Age (yr)*	44 (12)	53.8 (4.5)	48.8 (9.5)	38.1 (11.7)
Gender (% male)	64	86	77	50
Race (% black)	50	67	44	48
FEV1% predicted*	87% (14%)	72% (12%)	92% (16%)	99% (12%)
FEV1/FVC*	74% (9%)	67% (8%)	76% (6%)	83% (5%)

Subject characteristics are summarized as the mean and (standard deviation). Subjects are classified by the hierarchical method (single category by subject).

P values refer to significance of differences among the groups: $^*P < 0.05$.

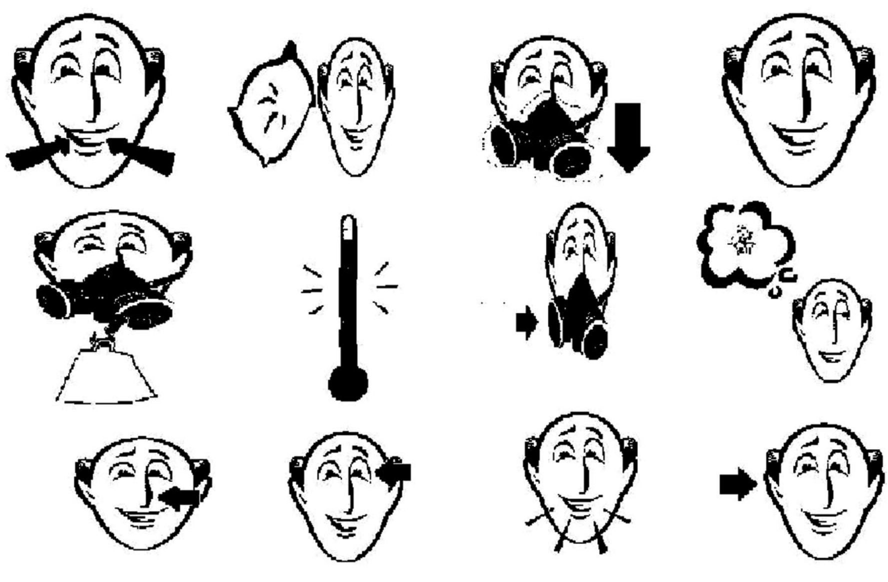

FIGURE 1. Rating cartoons. The figure illustrates cartoon figures used to prompt subjects for rating subjective responses for multiple domains: Breathing, Comfort, Slippery, Face, Heavy, Hot, Wet, Concentration, Nose, Vision, Speech, and Hearing.

outcomes was tested independently. The subjective response was the dependent variable, and the predictor variables included respirator type, disease status, task type, gender, and age. In addition, two interaction terms (disease status × respirator type and gender × respirator type) were independently incorporated into models for evaluation.

Two distinct regression models were used to reflect disease status. In model A (multiple disease), the physiologic variable was regressed on respirator type (either HFM or N95), three dichotomous dummy variables (COPD, asthma, and rhinitis), and task (eight categories). In addition, three interaction terms were included for respirator type × asthma, respirator type × COPD, and respirator type × rhinitis. In model B (hierarchical disease class), a single disease class was assigned based on the hierarchy: COPD > asthma > rhinitis > healthy. The predictor variables were respirator type, task, disease status (a single variable with the four hierarchical categories as described earlier), and respirator type × disease status interactions. Age and gender were included as covariates in both models. A third model, C, extended model A by adding a gender respirator type interaction term. A $P < 0.05$ was considered statistically significant, and $P < 0.10$ was considered borderline. The covariance structure was specified as compound symmetry, and a repeated measures design was incorporated.

The figure suggests that the gender effect was similar in magnitude to the respirator effect. It also shows that the effects of respirator type itself were of greater magnitude than the disease-respirator interactions. Finally, the direction of many of the disease-respirator interactions tended to be opposition in direction for asthma in comparison with the two other disease groups.

RESULTS

Table 1 summarizes the characteristics of the subjects. The results of the regression analyses are shown in Table 2. There were statistically significant differences between respirator types for all scales except vision. Ratings for HFM were more adverse than for N95 except for the "Hot" scale, for which N95 was more adverse. Figure 2 presents the coefficient estimates graphically to demonstrate their relative magnitudes of the regression coefficients for respirator type, age, gender, and the interaction between disease status and respirator type.

Disease itself was not associated with statistically significant differences on any of the individual scales when adjusted for the other factors. Furthermore, there were no significant effects of disease on the overall composite score based on the sum of adverse ratings for all of the scales.

Female gender was associated with reporting of greater subjective effect on multiple scales—Comfort, Breathing, Nose, Hot, Wet, Face, Heavy, and Work reduction. Conversely, there were no gender differences in scales such as hearing or concentra-

TABLE 2. Subjective Response Regression Analyses

				Disease Status			Respirator × Disease Status					
	Model	Respirator	Task	Asthma	COPD	Rhinitis	Asthma	COPD	Rhinitis	Age	Gender	Respirator × Gender
Breathing	A	1.07**	−0.62**	0.36	−0.07	0.76	0.29	−0.07*	−0.48**	−0.01	1.61**	
	B	1.14**	−0.62**	0.59	−0.04	0.39	0.09	−0.60*	−1.16**	0.00	1.57**	
	C	1.25**	−0.62**	0.51	−0.32	0.38	—	—	—	−0.01	2.12**	−0.99**
Comfort	A	2.11**	−0.54**	0.78	−0.34	0.26	0.38*	−0.34**	−0.78**	−0.01	1.50*	
	B	2.05**	−0.54**	1.07	0.06	0.45	0.18	−0.78**	−0.76**	−0.02	1.50*	
	C	1.96**	−0.54**	0.97	−0.74	−0.17	—	—	—	−0.01	1.59*	−0.17
Nose	A	2.49**	−0.54**	0.35	−0.63	0.18	0.14	−0.63	−0.01**	−0.03	1.67**	
	B	2.05**	−0.54**	0.73	−0.21	0.33	0.14	0.25	−0.28	−0.04	1.72**	
	C	1.86**	−0.54**	0.44	−0.61	−0.50	—	—	—	−0.03	1.34*	0.68**
Heavy	A	2.87**	−0.48**	0.35	0.34	0.20	0.65**	0.34**	−0.88	−0.01	2.15**	
	B	2.69**	−0.48**	0.42	0.43	0.03	0.85**	−0.63*	0.08	−0.01	2.14**	
	C	2.91**	−0.48**	0.67	−0.11	0.10	—	—	—	−0.01	2.05**	0.21
Hot	A	−0.74**	−0.44**	0.30	−0.46	0.51	−0.1	−0.46**	0.74**	0.01	1.58**	
	B	−0.67**	−0.44**	0.55	−0.24	0.74	−0.36	0.55*	−1.23**	0.01	1.59**	
	C	−0.27**	−0.44**	0.27	−0.08	0.07	—	—	—	0.01	2.57**	−1.96**
Face	A	1.81**	−0.37**	0.73	−1.08	0.67	0.23	−1.08	−0.12**	−0.03	1.73**	
	B	1.73**	−0.37**	1.09	−0.77	0.66	0.06	−0.13	−0.82**	−0.03	1.73**	
	C	1.77**	−0.37*	0.85	−1.14	0.21	—	—	—	−0.03	1.97**	−0.48**
Wet	A	0.19	−0.51**	0.07	−0.19	−0.09	−0.36**	−0.19	0.13*	0.01	0.79	
	B	−0.06	−0.51**	0.15	−0.17	−0.34	−0.23	0.29	0.35	0.00	0.79	
	C	0.44**	−0.51**	−0.11	−0.14	−0.26	—	—	—	0.01	1.51**	−1.42**
Slippery	A	0.69**	−0.33*	0.19	0.05	−0.56	−0.23	0.05	−0.08*	0.02	0.73	
	B	0.68**	−0.33*	0.12	0.09	−0.62	−0.3	−0.15	−0.37	0.01	0.67	
	C	0.82**	−0.33**	0.07	0.00	−0.73	—	—	—	0.02	1.24*	−1.00**
Concentration	A	1.28**	−0.24**	0.6	−0.72	0.26	0.26*	−0.72**	−1.03**	−0.02	0.77	
	B	1.43**	−0.24**	0.68	−0.66	−0.08	−0.23	−1.28**	−1.39**	−0.02	0.68	
	C	1.08**	−0.24*	0.72	−1.25	−0.26	—	—	—	−0.02	1.01	−0.45**
Speech	A	1.04**	0.03	0.04	−0.41	0.86	0.01	−0.41**	−0.89**	−0.04	0.12	
	B	1.14**	0.03	0.42	−0.25	0.95	−0.25	−1.06**	−0.71**	−0.04	0.16	
	C	0.95**	0.03	0.04	−0.88	0.63	—	—	—	−0.04	0.37	−0.51**
Hearing	A	0.53	−0.05	−0.16	−0.36	−0.07	0.05	−0.36**	−0.58**	0.00	0.08	
	B	0.56**	−0.05	−0.31	−0.58	−0.48	−0.13	−0.66**	−0.48**	0.00	0.01	
	C	0.45**	−0.05	−0.14	−0.67	−0.28	—	—	—	0.00	0.24	−0.31**
Vision	A	0.62	−0.02	−0.52	−0.4	0.16	0.38**	−0.40*	−0.39**	0.00	0.51	
	B	0.58**	−0.02	−0.43	−0.45	0.03	0.11	−0.43*	−0.84**	−0.01	0.48	
	C	0.49**	−0.02	−0.32	−0.59	−0.32	—	—	—	0.00	0.59	−0.16
Work reduction	A	0.49**	−0.30**	0.04	0.05	0.28	0.15*	0.05*	−0.22**	−0.02	0.38*	
	B	0.66**	−0.30**	0.09	−0.01	0.02	−0.27**	−0.44**	−0.69**	−0.01	0.34	
	C	0.39**	−0.30**	0.12	−0.06	0.04	—	—	—	−0.02	0.42*	−0.07
Work within-mask	A	−0.65**	0.32**	−0.44	0.45	0.17	−0.02	0.45	0.07**	−0.01	−0.72**	
	B	−0.87**	0.32**	−0.49	0.33	0.14	0.39**	0.34**	0.71**	−0.01	−0.67**	
	C	−0.39**	0.32**	−0.46*	0.48	0.33	—	—	—	−0.01	−0.51*	−0.42**
Composite score	C	13.69**	−4.10**	3.97	−6.53	−1.13	—	—	—	−0.12	16.61**	−6.58**

The table summarizes the regression model coefficients for respirator type (HFM-N95), disease, interactions of factors, age (per year), and gender (female-male).
Both models A and C use dichotomous dummy disease variables, such that an individual may have more than one disorder, whereas model B uses a hierarchical disease classification method.
P values refer to significance of differences among the groups: $*P < 0.05$; $**P < 0.01$.

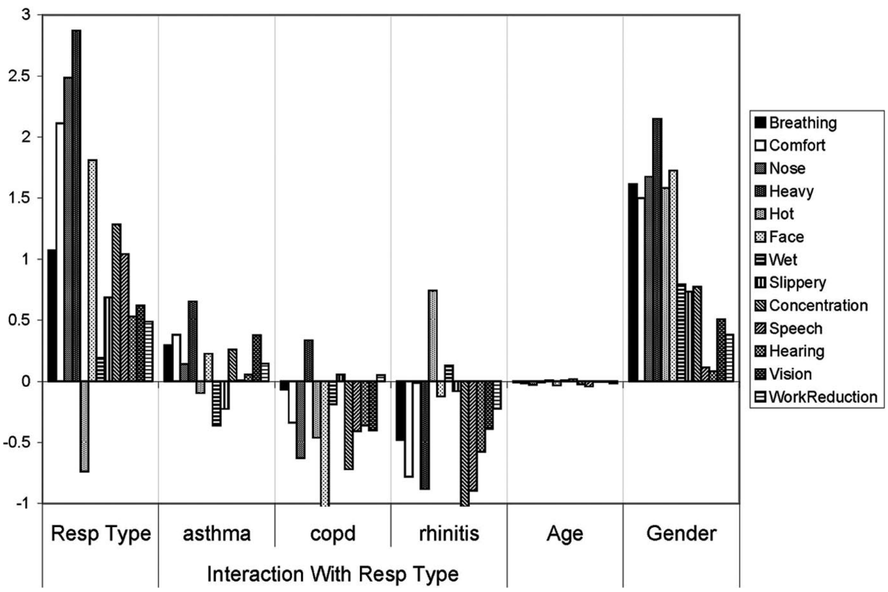

FIGURE 2. Summary of regression coefficients. The figure graphically summarizes the regression coefficients from Table 2. The coefficients for disease category are not shown, and statistical significance is summarized in Table 2. Results are based on model A.

tion. Nevertheless, the results showed that women who use respirators had a lower increment in subjective responses due to respirator type than men. As seen in Table 2 (model C), there was a statistically significant interaction between gender and respirator type, such that the difference between HFM and N95 was lower in women than men. Age did not significantly affect any of the rating scales.

There were notable differences in the interactions among factors (Table 2, model A). Asthma significantly increased the adverse effect of the HFM for six of the scales and showed a borderline significant effect for another. Conversely, the presence of COPD or rhinitis tended to decrease the differences between using an HFM versus an N95 device for many of the subjective rating variables. That is, asthma tended to further augment the adverse effect of HFM use, whereas COPD and rhinitis tended to decrease the magnitude of the adverse effect of the HFM. Similar results were observed with the second statistical model (Table 2, model B).

As anticipated, task affected the subjective ratings. Vision and Wet were not affected significantly, although some tasks (eg, driving) were more visually demanding than others. In general, the magnitude of the effect of task effect was greatest for the higher exertion tasks. Subjective ratings for the heavier exertion tasks were generally greater than for the low exertion tasks, and the magnitude of the effect of respirator type was greater in the higher exertion tasks.

DISCUSSION

Respirators (respiratory personal protective equipment) have significant subjective effects on users. Although physiologic limitation may constrain use in high exertion settings, subjective tolerance may be particularly important during the more common low-moderate exertion applications.[15,16] This study reports the subjective effects of respirator type (comparing an HFM with an N95 filtering facepiece), respiratory health status, age, and gender during a variety of simulated work tasks. The study also assessed interactions among several of these factors, noting that the effects of respirator type differed according to disease.

Multiple scales were used to measure the subjective effects. Several investigators have characterized subjective responses. Most used a small number of scales (often, a single "comfort" scale).[17–22] This study supports the findings of previous analyses that there are several distinct categories of effects.[10] For example, gender differences were observed for the variables reflecting physiologic and facial comfort effects, but gender did not affect the scales more closely related to functional effects (eg, concentration). In addition, respiratory comfort, temperature,[15,23,24] mask comfort,[25] nasal airflow,[26] effect on communication, or dyspnea may be significant.

In general, subjects tolerated the N95 better than the HFM. Validity of the symptom reporting system is suggested by finding consistent effects for those scales with a priori likelihood of being respirator related (ie, face validity).

The N95 received more adverse ratings only for the Hot scale; this is consistent with its design (smaller mask size and nondirected airflow without valves). Other studies have also shown increased within-mask temperature for filtering facepiece designs.[27] This may be particularly bothersome to workers, if the respirator is used in a warm humid environment.[25]

On the average, women reported higher symptom scores than did men. As seen in Fig. 2, the magnitude of the gender differences for most of the scales was nearly as great as the effect of respirator type. The higher ratings provided by women are unlikely to represent a nonspecific tendency to complain. The differences were seen predominantly in those scales with a priori likelihood of being affected by respirator use, whereas the more nonspecific scales such as vision or hearing were not affected. Although women may report greater symptoms than men, female gender decreased the difference between the two respirator types. Most women may still adequately tolerate the HFM.

In contrast to the gender effect, age did not have a significant effect on ratings.

Interaction Between Health Status and Respirator Type

The results also indicate that there are significant effects of respiratory health status (ie, disease category) on the subjective effects of respirator use. Persons with asthma tended to have further augmented adverse subjective responses to use of the HFM respirator. This is particularly notable because the study protocol excluded subjects having acute asthma symptoms during the study time. Hence, particular caution is necessary when considering respirator use by persons with asthma. In addition to the synergistic adverse effect of respirator type and asthma per se, asthma is characterized by enhanced reactivity to environmental irritants. The degree of perception of added loads, which affects respirator tolerance,[28] may also differ. Asthmatics may be more prone to detecting inspiratory loads and to panic type response[29,30] than are healthy persons or patients with COPD, who have chronically increased airflow resistance. Therefore, they are at increase risk of developing worsening clinical status when exposed to many inhaled irritants that may otherwise warrant respirator use.

In contrast to asthmatics, persons with rhinitis or COPD generally showed a reduced effect of using an HFM rather than an N95 respirator. Because these disorders are characterized by long-term increases in airway resistance, persons with these disorders become accustomed to breathing with added resistance, decreasing the reaction to the added resistance of the respirator itself. Steven's psychophysical law[31] relating sensation to stimuli indicates that the increment in a sensation induced by an added load is related to the proportional increase of the load, thereby decreasing the effect of the respirator load in persons with preexisting loads. The asthmatics, however, are likely to have greater reactivity because they often have normal airflow resistance in the times between attacks.

Implications

New respirator designs require certification; this is typically done by measuring the airflow resistance of the device using inanimate flow generating test equipment. In addition, limited physiologic testing in human panels is sometimes performed. The present results suggest that respirators should be evaluated for subjective effects on users and should focus on the direct or imputed physiologic limitations. This is particularly true when the device will be worn while performing activities at low or moderate exertion levels. Panels for evaluating respirator designs should have sufficient diversity to reflect the different disease categories.

In addition, the different patterns of interaction between health status and respirator type (see Fig. 2 and Table 2) indicate that a single respirator type may not be optimal for all individuals. For example, some users may be particularly bothered by the facial temperature sensation induced by the N95; other researchers showed that a different disposable respirator raised facial temperature by 7.5°C.[24] The evaluation process should be standardized because acceptability to users may depend on the magnitude of the perceived health threat.[32]

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