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Major article

N95 respirator use during advanced pregnancy

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Pregnancy
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Background: To determine the physiological and subjective effects of wearing an N95 filtering facepiece respirator (N95 FFR) in advanced stages of pregnancy.
Methods: Healthy pregnant women (n = 22) and nonpregnant women (n = 22) had physiological and subjective measurements taken with and without wearing an N95 FFR during exercise and postural sedentary activities over a 1-hour period.
Results: There were no differences between the pregnant and nonpregnant women with respect to heart rate, respiratory rate, oxygen saturation, transcutaneous carbon dioxide level, chest wall temperature, aural temperature, and subjective perceptions of exertion and thermal comfort. No significant effect on fetal heart rate was noted.
Conclusions: Healthy pregnant women wearing an N95 FFR for 1 hour during exercise and sedentary activities did not exhibit any significant differences in measured physiological and subjective responses compared with nonpregnant women.

Approximately 60% of US women are employed, accounting for 46% of the national workforce.[1,2] The number wearing a respiratory protective device (RPD), such as a respirator or facemask, is not precisely known, but 3.3 million industrial workers[3] have the use of RPD as a work requirement, and 4.3 million individuals employed as nurses and nursing assistants (92% women)[4] wear RPDs to varying degrees. With the US rate of pregnancy (in women age 15-44 years)[5] at 103/1,000, significant numbers of pregnant working women may be using an RPD. Furthermore, pregnant women are at increased risk for morbidity and mortality from some viral respiratory infectious diseases (eg, SARS, pandemic influenza) that may necessitate the use of an RPD.[6-9]

The respiratory system undergoes pregnancy-associated changes[6,10,11] that might be negatively impacted by an RPD. The N95 class of filtering facepiece respirator (N95 FFR) is the most commonly used RPD in both industrial and health care settings in the United States,[3,12] but little scientific data exist on the physiological and subjective burdens imposed by RPDs on pregnant women,[13-15] and none directly addresses N95 FFRs. The present study was undertaken by the US National Institute for Occupational Safety and Health to evaluate the physiological and subjective effects of wearing an N95 FFR during advanced pregnancy.

MATERIALS AND METHODS

Subject demographics

Twenty-two healthy, nonsmoking women in the second to mid-third trimester of pregnancy (ie, 13-35 weeks gestation) and 22 healthy, nonsmoking, nonpregnant women controls were enrolled in the study. All subjects were experienced RPD users. Mean (SD) demographic values of the pregnant subjects were as follows: gestation, 20.6 (4.5) weeks; age, 28.0 (2.9) years; height, 166.7 (5.7) cm; weight, 73.8 (18.5) kg; and body mass index (BMI), 26.8 (6.0) kg/m^2. Mean (SD) demographic values for the controls were age 26.1 (4.0) years, height 167.5 (5.9) cm, weight 67.5 (9.5) kg, and BMI 24.1 (3.2) kg/m^2. The study was approved by the National Institute for Occupational Safety and Health's Human Subjects Review Board. All subjects provided oral and written informed consent.

Assessment of respirator fit: N95 respirator fit testing

Subjects underwent an Occupational Safety and Health Administration respirator quantitative fit test[16] with either a flat-fold N95 FFR or a premolded, cup-shaped N95 FFR. A subject who

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did not pass fit testing with the randomized N95 FFR was subsequently fit-tested with the other style, and all subjects ultimately passed fit testing on 1 of the 2 respirator models.

Subject instrumentation

Respiratory rate (RR) and chest wall skin temperature (T_{chest}) were monitored continuously with the Zephyr Bioharness (Zephyr Technology Corp, Annapolis, MD). Heart rate (HR), transcutaneous partial pressure of carbon dioxide ($PtcCO_2$), and pulse-derived oxygen saturation (SpO_2) were monitored continuously with the Tosca 500, a heated (42°C) combination pulse oximeter and CO_2 sensor (Radiometer, Copenhagen, Denmark) attached to the right earlobe. Aural temperature (T_{aural}) was obtained from the left ear with a WelchAllyn Pro 400 tympanic thermometer (Braun, Kronberg, Germany). Fetal heart rate (FHR) was measured with a Bidop ES-100V3 ultrasound fetal Doppler (Koven Technology, St Louis, MO).

Study protocol

Subjects were instrumented, and the order of the trials (N95 FFR) and controls (no N95 FFR) was randomized. For trials, at baseline $PtcCO_2$, subjects donned the N95 FFR (following the manufacturer's instructions) and performed a user seal check.[17] The subjects then performed 3 contiguous 20-minute activity phases consisting of (1) standing upright, (2) exercising by pedaling a Kettler RX7 reclining bicycle ergometer (Ense-Parsit, North Rhine-Westphalia, Germany) at 60 pedal cycles/minute and 50 W resistance, and (3) sitting upright in a chair. T_{aural} was obtained at the beginning of each activity phase and every 5 minutes until phase completion. Subjective impressions of thermal comfort and exertion were obtained simultaneously using the Frank Scale of Perceived (Thermal) Comfort (FSPC),[18] which ranges from a rating of 0 ("the coldest you have ever been") to 10 ("the hottest you have ever been"), and the Borg Rating of Perceived Exertion (BRPE),[19] which ranges from a rating of 6 ("very, very light") to 20 ("very, very hard").

In 17 pregnant subjects, FHR was measured at the beginning and end of each seated and standing session (FHR was not assessed during exercise bicycle ergometer testing owing to motion artifactm[20] and could not be evaluated in 5 subjects during standing and sitting.) There was a minimum 30-minute respite between controls and trials.

Statistical analysis

Physiological and subjective data were summarized at the first (1 minute) and last (20 minutes) time points of each activity phase for statistical analysis. Repeated-measures ANOVA in a mixed design (2 within-subjects factors [condition × time] and 1 between-subjects factor [pregnancy]) was used to determine the main effect of wearing an N95 FFR (condition) on the study variables (except FHR) over different phases (time), along with the effect of pregnancy on each main effect. A Greenhouse-Geisser correction was adopted for assumption of sphericity, and a post-hoc pairwise comparison with Bonferroni adjustment was carried out for a significant F value. A P value $< .05$ was considered to indicate statistical significance. All analyses were performed using a SPSS version 18 (IBM, Armonk, NY).

RESULTS

Age was the sole demographic that was significantly greater for pregnant subjects ($P = .03$). Wearing an N95 FFR did not significantly affect any of the physiological or subjective responses in pregnant and nonpregnant subjects: HR ($F = 0.582$; $P = .45$), RR ($F = 0.042$; $P = .83$), SpO_2 ($F = 1.767$; $P = .19$), $PtcCO_2$ ($F = 0.971$; $P = .33$), T_{chest} ($F = 0.006$; $P = .93$), T_{aural} ($F = 1.444$; $P = .23$), BRPE ($F = 0.019$; $P = .89$), or FSPC ($F = 2.389$; $P = .13$). Wearing an N95 FFR did not significantly affect FHR ($F = 0.009$; $P = .92$).

For all subjects, wearing an N95 FFR was associated with a significant effect on RR ($F = 12.548$; $P = .001$), and FSPC ($F = 34.276$; $P < .001$). Time had a significant effect ($P < .05$) on all measured variables except $PtcCO_2$ and T_{aural} (Tables 1-3). N95 FFR use was associated with increased $PtcCO_2$ over time during exercise ($P = .04$).

DISCUSSION

Our study data indicate that the physiological and subjective effects of wearing an N95 FFR during 1 hour of combined sedentary activities and exercise do not differ significantly between healthy pregnant and nonpregnant women.

HR

The effects of N95 FFR use on the normally higher HR of pregnancy (owing to metabolic demands[10]) was not significantly different from those in the nonpregnant subjects in the present series and in other investigations with similar workloads.[21,22]

RR

RR is relatively stable during pregnancy,[10] and no significant differences were noted between pregnant and nonpregnant subjects. The significant ($P = .001$) overall decreased RR noted with N95 FFR use (Table 1), reflects minor RR decrements (mean, 0.94 breaths/minute; range, 0.1-2.2 breaths/minute, median, 0.9 breaths/minute) reported previously[23] and related to a mild concomitant compensatory increase in the tidal volume.

SpO_2

No significant differences in SpO_2 were noted between pregnant and nonpregnant subjects (Table 1), and no subject had a SpO_2 <97%. A previous study found that in pregnant women in the third trimester, SpO_2 levels did not decrease over normal baseline values after 30 minutes of wearing a gas mask with significantly greater resistance (20 cm H_2O pressure) than an N95 FFR.[15] Wearing an N95 FFR at low work levels for 1 hour results in mixed inhalation/exhalation N95 FFR dead space O_2 levels below (16.6%) ambient levels,[23,24] but these have not resulted in SpO_2 values <95%, because the sigmoidal shape of the oxygen-hemoglobin dissociation curve allows healthy individuals to maintain an SpO_2 value of 92%-98% breathing fractions of inspired air (FiO_2) below normal ambient level (0.21).[25] Furthermore, the rightward shift of the oxygen-hemoglobin curve during pregnancy favors unloading of O_2 in the periphery and O_2 transfer across the placenta.

$PtcCO_2$

$PtcCO_2$ declines with pregnancy to 32-34 mm Hg owing to increased minute ventilation necessitated by the added metabolic demands, ventilatory stimulant effects of elevated progesterone, and need to develop a fetal/maternal CO_2 gradient.[10] No significant differences in $PtcCO_2$ were found between the pregnant and nonpregnant subjects (Table 1). No subject was hypercapneic, and none had an increase in baseline $PtcCO_2$ >3 mm Hg (Table 2). At low work levels over 1 hour, mixed inhalation/exhalation N95 FFR