

Letters

RESEARCH LETTER

Peripheral Oxygen Saturation in Older Persons Wearing Nonmedical Face Masks in Community Settings

Based on the evidence that nonmedical face masks prevent the spread of severe acute respiratory syndrome coronavirus 2,^{1,2} many governments are mandating the wearing of masks in the community. However, fueled partly by claims on social media that masks can cause hypoxia and are therefore dangerous,³ concerns have emerged about the safety of wearing face masks. We examined whether wearing nonmedical face masks was associated with a change in oxygen saturation.

Methods | This was a crossover study in which participants self-measured peripheral oxygen saturation (SpO₂) before, while, and after wearing a mask. The study protocol was approved by the Hamilton Integrated Research Ethics Board. We included individuals aged 65 years or older and excluded those who had comorbid cardiac or respiratory conditions that could lead to dyspnea or hypoxia at rest or who were unable to remove the mask without assistance.⁴ Participants were prospectively recruited from a retirement condominium in Ontario between July 27 and August 10, 2020, following approval from the condominium's board of directors. Residents were contacted by email, and those who were interested were approached to obtain (verbal or written) informed consent.

To minimize variability, we provided participants with a 3-layer plane-shaped disposable nonmedical face mask with ear loops (Boomcare DY95 model, Deyce Leather Co Ltd) and a portable pulse oximeter (Homiee). Instructions on how to correctly wear the mask (to ensure adequate nose and mouth coverage) and how to measure SpO₂ were provided. Participants were instructed to self-monitor and record SpO₂ 3 times 20 minutes apart for 1 hour before, 1 hour while, and 1 hour after wearing the mask while they were at rest or performing usual activities of daily living at home. Participants were offered opportunities to clarify these instructions.

We determined whether wearing a face mask would be associated with a decrease of 2% or more in SpO₂. A decrease in SpO₂ of 3% or more has been previously considered clinically important,⁵ and for this study, a value of 2% was chosen because older people have lower baseline SpO₂.⁶ For a 2% decrease in SpO₂, a standard deviation of 3, an α level of .05, and a power of 90%, a sample size of 27 participants was required (see the eAppendix in the Supplement for the sample size calculation). For each participant, we calculated the mean of the 3 SpO₂ readings for each period (before, while, and after wearing the mask). Pairwise comparisons of these values (while vs before and while vs after) for each participant were per-

Table 1. Baseline Characteristics of Participants

Characteristics	No. (%) of participants (N = 25)
Age, mean (SD), y	76.5 (6.1)
Sex	
Men	13 (52)
Women	12 (48)
Medical conditions	
Hypertension	6 (24.0)
Respiratory	3 (12)
Bronchitis	1 (4)
Interstitial lung disease	1 (4)
Asthma	1 (4)
Cardiac surgery	2 (8)
Diabetes	2 (8)
Smoking	1 (4)
Medications	
Statins	12 (48)
ACEIs or ARBs	10 (40)
Diuretics	8 (24)
Calcium channel blockers	4 (16)
Anticoagulants	4 (16)
β -Blockers	4 (16)
Acetylsalicylic acid	2 (8)
Oral hypoglycemic agents	2 (8)
Prednisone	1 (4)

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

formed, and the paired mean differences (95% CIs) in SpO₂ were calculated using GraphPad Prism for Windows (GraphPad Software). The pooled mean SpO₂ (95% CI) for all participants was also calculated for each period.

Results | Twenty-eight people were approached, 3 declined participation, and 25 participants (mean age, 76.5 years [SD, 6.1 years]; 12 women [48%]) were enrolled. Nine participants (36%) had at least 1 medical comorbidity (Table 1). The pooled mean SpO₂ was 96.1% before, 96.5% while, and 96.3% after wearing the mask (Table 2). None of the participants' SpO₂ fell below 92% while wearing masks. The paired mean differences in SpO₂ while wearing the mask were minimal when compared with the value before they wore the mask (0.46%; 95% CI, 0.06%-0.87%) and the value after wearing the mask (0.21%; 95% CI, -0.07% to 0.50%), with both 95% CIs excluding a 2% or greater decline in SpO₂.

Discussion | In this small crossover study, wearing a 3-layer non-medical face mask was not associated with a decline in oxygen saturation in older participants. Limitations included the

Table 2. Oxygen Saturation Before, While, and After Wearing Nonmedical Face Masks

	SpO ₂ , mean (SD), %
No. of participants	25
Before mask wearing, SpO ₂ reading	
1	96.1 (1.3)
2	95.8 (2.1)
3	96.3 (1.6)
Pooled mean SpO ₂ , % (95% CI) ^a	96.1 (95.5-96.7)
While mask wearing, SpO ₂ reading	
1	96.4 (1.2)
2	96.5 (1.3)
3	96.7 (1.1)
Pooled mean SpO ₂ , % (95% CI) ^a	96.5 (96.1-97.0)
After mask wearing, SpO ₂ reading	
1	96.4 (1.3)
2	96.4 (1.4)
3	96.2 (1.4)
Pooled mean SpO ₂ , % (95% CI) ^a	96.3 (95.8-96.8)

Abbreviation: SpO₂, oxygen saturation measured using a portable oximeter.

^a 95% CIs are 2-sided.

exclusion of patients who were unable to wear a mask for medical reasons, investigation of 1 type of mask only, SpO₂ measurements during minimal physical activity, and a small sample size. These results do not support claims that wearing non-medical face masks in community settings is unsafe.

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Neurodevelopmental Outcomes at Age 5 Years After Prophylactic Early High-Dose Recombinant Human Erythropoietin for Neuroprotection in Very Preterm Infants

Although recombinant human erythropoietin (rhEpo) has been shown to be neuroprotective in experimental and clinical studies,^{1,2} prophylactic early high-dose rhEpo did not improve neurodevelopment among 2-year-olds who had been born very preterm in a randomized clinical trial.³ We report the prespecified secondary neurodevelopmental outcomes of the trial cohort at early school age.



Supplemental content

Methods | This was a randomized, double-blind, placebo-controlled, multicenter phase 3 trial with a primary objective of investigating the effect of early high-dose rhEpo (3000 IU/kg intravenously vs saline within 3, at 12-18, and at 36-42 post-natal hours) on the neurodevelopment of 2-year-olds who had been born very preterm (ie, <32 weeks' gestation). Enrollment occurred at 5 Swiss perinatal centers in 2005-2012, with the date of last neurodevelopmental evaluation in January 2018. Details of the trial, the study protocol (Supplement 1), and short-term safety data have been published.^{3,4}

At age 5 years, the following were assessed: (1) a measure of general intelligence, the Mental Processing Composite (norm, 100 [SD, 15]; higher values indicating better function) of the Kaufman Assessment Battery for Children, first edition (the prespecified second edition was not available at the start of the study)^{3,4}; (2) cerebral palsy (graded according the Gross Motor Function Classification System³) and severe hearing and visual problems³; and (3) somatic growth. Fine motor function was a prespecified outcome but was not reliably assessed in all centers. Behavior will be reported separately.

We used generalized estimating equations to account for the cluster structure of outcomes with same-birth siblings. Because we used an exchangeable working correlation structure for continuous outcomes, the estimated mean differences differ slightly from the mean group's differences. For binary outcomes, we used an independence working correlation structure. Comparisons between groups of children at age 5 years were performed including participants as originally randomized and including only children who completed the allocated treatment (R software, version 3.1.028),