

External nasal dilator decreases N95 respirator-related respiratory effort and symptoms in gastrointestinal endoscopy unit staff



Authors

Asif Khalid¹, Christopher Thomas^{1,2}, Michael Kingsley^{1,2}, Kishore Vipperla², Jeffrey Dueker^{1,2}, Christianna Kreiss², Anna Evans Phillips², Rohit Das², Kenneth Fasanella², James Ibinson^{1,2}

Institutions

- 1 VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania, United States
- 2 University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, United States

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Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Corresponding author

Asif Khalid MD, VA Pittsburgh Healthcare System, University Drive C, Pittsburgh, PA 15213
Fax: +1-412-360-6959
khalida@upmc.edu

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ABSTRACT

Background and study aims N95-filtering facepiece respirators (FFR) use is associated with physiological changes and symptoms due to impaired nasal airflow and increased breathing resistance. We prospectively studied the effect of using an external nasal dilator (END) in gastroenterology laboratory (gastrointestinal lab) staff using N95FFR.

Patients and methods N95FFR qualitative saccharine fit testing was performed on study participants with and without an END. Prospective data collection and comparisons included: 1) survey of perceived symptoms and difficulty of performing one day of gastrointestinal procedures with N95FFR and 1 day of gastrointestinal procedures with END plus N95FFR in random sequence; and 2) vitals and respiratory belt plethysmography in ten gastroenterologists performing simulated colonoscopy while wearing a surgical mask (SM), N95FFR plus SM, END plus N95FFR plus SM for 20 minutes each in random sequence and rapid succession.

Results Twenty-nine of 31 participants passed the N95FFR and the END plus N95FFR fit test. Twenty-two participants (12 physicians; 11 males; mean age 44.1 years, range 31–61) performed 1 day of gastrointestinal procedures with an N95FFR and 1 day of gastrointestinal procedures with an END plus N95FFR. Significantly less difficulty with nasal breathing and severity of symptoms including breathing difficulty, headache, fatigue and frustration, occurred while using an END plus N95FFR. Respiratory plethysmography peak-to-trough measurement showed an increase during the N95FFR stage compared to the END plus N95FFR stage and the SM stage.

Conclusions N95FFR related respiratory changes and symptom development may be mitigated by END use.

Introduction

N95 filtering facepiece respirators (FFRs) decrease risk of beta-coronavirus infection in health care workers (HCWs) compared to surgical masks (SMs) [1] and are being used in clinical areas like gastrointestinal endoscopy laboratories (gastrointestinal

lab) considered high risk for respiratory aerosol generation during the SARS-CoV-2 pandemic. N95FFR users including gastroenterologists suffer a variety of physical and psychological symptoms due to the associated impaired nasal airflow and increased breathing resistance [2–5].

Data regarding measures aimed at mitigating the N95FFR-related physiological changes and development of symptoms is absent.

External nasal dilators (ENDs) are adhesive bands containing a central elastic strip that reduce nasal resistance and inspiratory pressure by preventing collapse of the lateral nasal vestibule [6–10]. We undertook an exploratory prospective study to test the effect of an inexpensive, over-the-counter END (Breathe Right, GlaxoSmithKline, North Carolina, United States) on N95FFR (dome-shaped, 3M, St. Paul, Minnesota, United States)-related physiological changes and symptom development in gastroenterology lab staff including gastroenterologists, nurse anesthetists, nurses and technicians.

Patients and methods

Ethics

VA Pittsburgh Healthcare System (VAPHS) Gastrointestinal Endoscopy Lab (gastrointestinal lab) staff, including physicians, nurse anesthetists, nurses and technicians, were invited to voluntarily participate in this study. Gastroenterologists performing endoscopic procedures at VAPHS and the University of Pittsburgh Medical Center (UPMC) were invited to voluntarily participate in the physiological experiments. The study was conducted as a VAPHS institutionally approved quality improvement project. No personal health information was collected, and all data was de-identified.

Survey-based data collection

All study participants underwent N95-filtering facepiece respirator (N95FFR) qualitative saccharine fit testing with and without an END. Those that passed with and without the END were allowed to continue to participate in the study and performed 1 day of gastrointestinal procedures with an N95FFR, and 1 day of gastrointestinal procedures with an END and N95FFR in random order over a 3-month time frame. A surgical mask (SM) (American Society for Testing and Materials level 1 SM, Precept, Arden, North Carolina, United States), was worn over the N95FFR on both days to protect the N95FFR for reuse.

At the end of each workday, study participants completed a survey (Supplementary Form A) focusing on a number of symptoms with severity assessed on a Likert scale.

Physiological experiments

Gastroenterologists performed simulated colonoscopy while vitals and respiratory belt plethysmography data was collected. Data was collected in 3 stages while the gastroenterologists wore a SM; American Society for Testing and Materials level 3. Precept, Arden, North Carolina, United States), N95FFR plus SM, END plus N95FFR plus SM for 20 minutes each in random sequence and rapid succession. We were able to include a SM stage in the physiological experiments to serve as a negative control due to simulated exams being performed as opposed to endoscopy on patients during the survey-based data collection. A gastrointestinal endoscopy unit registered nurse assisted the physicians and collected data on physiological parameters.

Electrocardiogram chest leads were attached, a blood pressure (BP) cuff was attached to the right arm, and a pulse oximeter detector was applied on the left fifth digit. The physician was instructed to relax and drop the right arm during BP check. The physician and vital signs including heart rate (HR), peripheral pulse oximetry (SpO₂), systolic BP (SBP), and diastolic BP (DBP) were continuously monitored and recorded at 5-minute intervals. An anesthesiologist (JI) with expertise in cardiopulmonary physiology supervised the collection of continuous respiratory waveform recordings. The physicians were also connected to a BIOPAC Respiratory Belt (BIOPAC Systems, Goleta, California, United States) around their abdomen or chest. The belt was adjusted to maximize movement during respiration. Data were digitized using a BIOPAC MP160 (BIOPAC Systems, Goleta, California, United States) data acquisition unit with BIOPAC ECG100C, TSD221, DA100C transducers and amplifiers, and Acknowledge version 5.0 (BIOPAC Systems, Goleta, California, United States) software, running on a Macintosh PC (Apple Inc., Cupertino, California, United States).

Respiratory effort was calculated by measuring the time duration (in seconds; reflecting respiratory rate) and peak-to-trough height (in volts; reflecting depth of each breath) of the respiratory waveform for five consecutive breaths every 5 minutes, and classified by the experiment stage during which it occurred: SM only, N95FFR plus SM, END plus N95FFR plus SM. Since each experiment stage was 20 minutes in length, there were 5 measurements of respiratory variables in these phases (time 0, 5 min, 10 min, 15 min, and 20 minutes). The 5 recorded sets of vitals were averaged together for each experiment stage to produce one measure for each stage. During each stage, the physician performed self-selected simulated colonoscopy exams (gastrointestinal Mentor, 3 D Systems, formerly Symbionix, Rock Hill, South Carolina, United States) from a collection of 10 modules of varying skill level. The session was terminated at 20 minutes regardless of extent of simulated exam. The experiment room (VAPHS simulation lab) was kept dimly lit, temperature controlled between 68 to 70°F, and occupancy limited to the one assisting nurse and investigator (JI). All 3 phases of the physiological experiments were completed in random order and in rapid sequence, with pauses only to change personal protective equipment.

Statistical analysis

We compared the paired survey responses of the 22 study participants during each day of survey data collection (N95FFR vs. N95FFR+END). The frequency distribution of gastrointestinal procedures performed on each day was compared with the Stuart-Maxwell chi-square test. The median responses to survey questions on each day were compared with the Wilcoxon Signed Rank Test. As an overall *P* value of 0.05 was sought, a Bonferroni-corrected *P* value of 0.006 was used for each of the nine survey questions.

We compared the physiologic measures between the 3 testing stages (SM vs. SM+N95FFR vs. SM+N95FFR+END) with the Friedman test using the average of five measures taken in 5-minute intervals during each 20-minute testing stage. We

used IBM SPSS Statistics, Version 26.0 (Armonk, New York, United States: IBM Corp.) for analyses.

For the physiologic data (HR, oxygen saturation, and blood pressures) and the respiratory waveform data, analysis was performed using a general linear model with mixed effects fitting experiment Stage as fixed and Subject as a random effect assuming a compound symmetry covariance type, as testing showed this structure to have the smallest Akaike's Information Criterion. Results are expressed as the estimated overall marginal means, with 95% confidence intervals (CIs).

Results

Thirty-one gastroenterologists, nurse anesthetists, nurses and technicians participated in the N95FFR and the END plus N95FFR fit test. Twenty-nine (93%) passed the N95FFR and the END plus N95FFR fit test. Two gastrointestinal staff members failed both the N95FFR and the N95FFR plus END fit test.

Between November 2020 and January 2021, 22 of these 29 gastrointestinal lab staff (12 physicians; 11 males; mean age 44.1, range 31–61 years) performed 1 day of gastrointestinal procedures with an N95FFR under a SM and 1 day of gastrointestinal procedures with an END plus N95FFR under a SM in random order. Seven of 29 staff did not participate. The number and type of gastrointestinal procedures in the N95FFR and END plus N95FFR groups were not significantly different (► **Table 1**).

Study participants reported significantly less difficulty with nasal breathing (17 of 22 participants) and decreased severity of symptoms (breathing difficulty, headache, fatigue and frustration among others) while working in the gastrointestinal lab and using an END plus N95FFR compared to the N95FFR alone (► **Table 2** and **Supplementary Table 1**). A majority of study participants indicated END use improved tolerability of N95FFR (20 of 22) and would personally purchase ENDS (18 of 22) or use ENDS if provided (20 of 22) by the hospital for use with an N95FFR. Two physicians noted they would not use an END with N95FFR due to lack of a noticeable improvement in N95FFR tolerability (1) and discomfort during END removal (1).

There was no significant difference in gastroenterologists' vitals while performing simulated colonoscopy with a SM, N95FFR plus SM, and END plus N95FFR plus SM (► **Table 3** and **Supplementary Table 2**). There was no significant difference in time duration for 5 breaths in seconds (SM: 18.8 [17.9–19.6] vs. N95FFR plus SM: 19.1 [18.2–19.9] vs. END plus N95FFR plus SM: 18.9 [18.1–19.7]). Respiratory peak-to-trough measurement (volts) showed an increase during the N95FFR plus SM stage (0.019 [0.016–0.022]) compared to the END plus N95FFR plus SM stage (0.017 [0.014–0.020]) and the SM stage (0.016 [0.013–0.020]) (► **Fig. 1**), signifying a larger respiratory effort was needed when wearing the N95FFR without the END in place.

► **Table 1** Number and type of gastrointestinal procedures performed by gastrointestinal lab staff while wearing an N95FFR for 1 day and an END plus N95FFR for 1 day.

Median number and type of gastrointestinal exams performed per participant per day [interquartile range]	N95FFR	END + N95FFR	P value
Total	5.5 [2.25]	6 [3]	0.9
Colonoscopies	2.5 [2.25]	3 [2.25]	0.5
Esophagogastroduodenoscopy	2 [2]	2 [2]	0.5
Endoscopic ultrasound	0 [1]	0 [2]	0.3
Endoscopic retrograde cholangiopancreatography	0 [0.5]	0 [0.25]	1

The table summarizes the type of gastrointestinal procedures performed by the gastrointestinal lab staff while wearing an N95 filtering facepiece respirators (N95FFR) for 1 day and an external nasal dilator (END) plus N95FFR for 1 day in random order.

► **Table 2** Gastrointestinal lab staff reported symptoms while performing gastrointestinal procedures and wearing an N95FFR with and without an END.

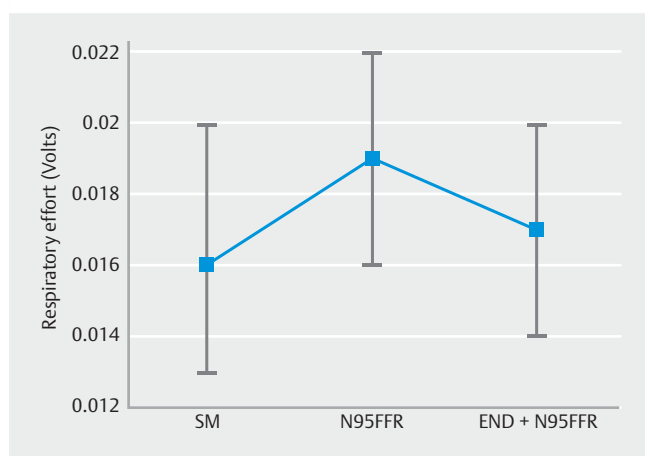
Survey question/symptom	Median symptom severity score (scale 1–5) [25th percentile, 75th percentile]		
	END + N95FFR	N95FFR	P value
Nasal (1) vs. oral (5) breathing	2 [1,2]	3 [2,4.25]	0.001
Overall difficulty of PPE use	2 [1,3]	3 [2.75,3]	0.003
Breathing difficulty	1 [1,2]	3 [1.75,4]	0.002
Dizziness, confusion, sweating	1 [1,1.25]	2 [1,3.25]	0.008
Headache	1 [1,1]	1.5 [1,3.25]	0.005
Fatigue	1 [1,2]	2 [1,4]	0.002
Frustration, irritability, impatience	1.5 [1,2]	2 [1,4]	0.005
Claustrophobia	1 [1,1.25]	1 [1,2]	0.01
Palpitations	1 [1,1]	1 [1,1]	0.3

Tabular summary of gastrointestinal lab staff survey of symptoms while working in a gastrointestinal endoscopy unit for 1 day and wearing an external nasal dilator (END) under an N95 filtering facepiece respirator (FFR), and 1 day and wearing an N95FFR in random order. Symptom severity is scored from 1 (least severe) to 5 (most severe) on a Likert scale. See Form A in appendix for survey questionnaire details. PPE, personal protective equipment.

► **Table 3** Gastrointestinal physician vitals while performing simulated colonoscopy and wearing a SM, an N95FFR plus SM, and an END plus N95FFR plus surgical mask.

Physician vitals Mean [95% CI]	Surgical mask	N95FFR + surgical mask	External nasal dilator + N95FFR + surgical mask	P value
Heart rate/minute	82.5 [64–101]	83.7 [66–101]	82.9 [65–101]	0.16
Peripheral oxygen saturation (%)	97.7 [94–100]	97.9 [95–100]	97.8 [94–100]	0.78
Systolic blood pressure (mm/Hg)	122.2 [105–140]	122.9 [105–149]	123.4 [101–146]	0.72
Diastolic blood pressure (mm/Hg)	83.2 [66–100]	83.4 [67–99]	83.6 [66–101]	0.74

The table summarizes gastrointestinal physician vitals while performing simulated colonoscopy and wearing a surgical mask for 20 minutes, an N95 filtering face-piece respirators (N95FFR) plus surgical mask for 20 minutes, and an external nasal dilator plus N95FFR plus surgical mask for 20 minutes.



► **Fig. 1** Gastroenterologist respiratory effort while performing simulated colonoscopy and wearing a SM, N95FFR, or END + N95FFR. Gastroenterologist respiratory belt plethysmography breath peak-to-trough measurements reflecting respiratory effort while performing simulated colonoscopy and wearing a surgical mask (SM), N95 filtering facepiece respirator (N95FFR) and SM, or external nasal dilator + N95 filtering facepiece respirator (END + N95FFR) and SM in random order. The values reflect the estimated marginal means for each stage from mixed general linear modeling with 95% CI error bars.

Discussion

N95FFR are superior to SMs in preventing betacoronavirus infection in HCWs and are recommended while performing gastrointestinal endoscopy during the SARS-CoV-2 pandemic [1, 11]. Unfortunately, N95FFR use is associated with impaired nasal airflow, increased breathing resistance and possibly increased levels of inhaled CO₂, and a shift to anaerobic metabolism resulting in a number of symptoms including respiratory difficulty, headaches, increased irritability, and impaired physical work capacity [2–5].

Interventions aimed at increasing nasal airflow may prevent some of the N95FFR-related physiological changes and decrease the associated symptoms. An END applies on the nose across the nasal valve, increases the cross-sectional area of the nasal valve and reduces nasal resistance and inspiratory pressure by preventing collapse of the lateral nasal vestibule during

inspiration [6]. Small studies have shown their benefit in patients with nasal obstruction (e.g. deviated nasal septum), and during labor and delivery by delaying the switch of breathing from nasal to oral [7–9]. A placebo-controlled study showed END associated decreased perception of exertion, and lower HR, ventilation, and oxygen consumption in athletes performing submaximal exercise [10]. Current data also suggests that END use is considered low-risk and inexpensive [6]. The cost of purchasing ENDs for this study was approximately 38 cents each from an on-line vendor.

For concurrent use of an END and an N95FFR, the END has to be applied on the nose under the N95FFR. Data regarding how an END may affect the N95FFR seal around the nose and thus N95FFR effectiveness is absent. Our results indicate that all study participants that passed the N95FFR saccharine fit test also passed the N95FFR plus END fit test. This allowed the safe use of an END under an N95FFR in clinical areas in our study in accordance with institutional regulations.

Our staff reported a significant decrease in multiple symptoms while working in the gastrointestinal lab and using an END with an N95FFR (► **Table 2**). We believe this resulted from easier nasal breathing due to the END preventing the lateral nasal vestibule from collapse while inspiring against resistance due to the N95FFR. To test this hypothesis, we undertook physiological experiments involving respiratory belt strain plethysmography in gastroenterologists as they performed simulated colonoscopies and wearing a SM (negative control), an N95FFR and an N95FFR plus an END. The results obtained from respiratory belt plethysmography have been shown to highly correlate with continuous spirometers [12] and have been reported by us in these experimental conditions previously [4]. Our results indicate an increased respiratory effort with N95FFR use compared to when an END is used with an N95FFR or a SM alone, suggesting a change in nasal airflow dynamics due to an END leading to at least partial reversal of N95FFR-related increased nasal air flow resistance. This physiological data supports the survey data of staff working in the gastrointestinal lab reporting easier nasal breathing and less severe symptoms while using an N95FFR with an END.

We note that while there was an increase in respiratory effort in gastroenterologists when using an N95FFR compared to an N95FFR plus an END, this did not translate into a change in

other physiological parameters e. g. HR. We have previously reported that N95FFR use is associated with statistically significant HR elevation compared to a SM, especially in gastroenterologists reporting multiple symptoms due to N95FFR use [4]. We believe the difference in experiment duration is the cause for these results. In our previous study [4], the duration of simulated exams for each stage (e. g. SM, N95FFR) was 60 minutes, while in the current study it is 20 minutes. We selected 20 minutes as the experiment stage duration for this study based on the observation from our prior study [4] that the N95FFR-related increase in depth of breathing occurred immediately. We anticipate that this alteration in respiratory physiology leads to change in N95FFR user vitals with increasing duration of N95FFR use, i. e. over 20 minutes. We also selected a shorter experiment stage duration for the current study so as to complete all stages of the experiment under uniform conditions at the same time of the day and to minimize the effect of other variables e. g. external stress and meals.

Our study limitations include this being an exploratory study involving a small sample size and a single-center design. Because our sample size includes staff in our center willing to participate in the study, the possibility of selection bias must also be entertained. Also, some staff members that were able to participate in the N95 fit testing with and without an END subsequently could not participate in the study due to not being assigned to the gastrointestinal endoscopy lab. While the lack of participant blinding to the intervention (END) as they worked in the gastrointestinal lab is also a study weakness, we believe our respiratory belt plethysmography data are less sensitive to placebo effect. Finally, our results may not be generalizable to all types of N95FFRs and ENDs. We believe that further multicenter studies involving multiple clinical areas where N95FFR are in use are required to validate our results.

Conclusions

In conclusion, we show that N95FFR use is associated with increased respiratory effort and development of multiple symptoms in gastrointestinal lab staff performing their clinical duties. These results are consistent with prior studies. This is the first report of a measure to mitigate N95FFR-related symptoms. We show that an END does not affect N95FFR fit thus allowing its use in our gastrointestinal lab. We also show that an END decreases N95FFR-related symptom development and provide physiological data to support this conclusion. Furthermore, we believe that our findings are also applicable to other clinical areas where healthcare workers are required to use N95FFR.

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Competing interests

The authors declare that they have no conflict of interest.

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