Aerosol-scavenging isolation barrier mitigates exposure risk during endonasal procedures in coronavirus-2019

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The US Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) advise that severe acute respiratory syndrome–coronavirus-2 (SARS-CoV-2) may spread from asymptomatic individuals through respiratory droplets and airborne aerosols.1,2 Although masking to limit aerosol spread has been robustly demonstrated, the otolaryngology examination requires unmasking to access the nostrils and mouth. Furthermore, rigid nasal endoscopy (RNE), nasal endoscopy using a nasopharyngolaryngoscopy (NPL) scope, and RNE with sinonasal debridement (RNESD) may produce significant airborne aerosols even without sneezing.3,4 Given these substantial infection control challenges, the purpose of this study was to test the efficacy of a novel isolation barrier (IIB) (Inquis Medical, Redwood City, CA), which was specifically designed to enable endonasal procedures while capturing both respiratory droplets and airborne aerosols.

Patients and methods

Patient population and study design

This prospective, open-label study of 30 patients scheduled for RNE, NPL, or RNESD in the rhinology or laryngology clinic was approved by the institutional review board of Mass General Brigham as minimal risk.

The IIB consists of a barrier surrounding the nose and mouth with an access window and an elastic strap. The clear flexible plastic apron provides direct facial access while acting as an occlusive physical barrier during aerosolization events. The apron contains a flap valve enabling the direct passage of endoscopes and instruments under the apron, through the valve, or both. The bottom suction port connects to a standard clinic or portable suction source. The continuous suction creates a high-flow negative-pressure field within the barrier that turns over exhaled air and scavenges aerosols (Fig. 1A,B). Aerosol generation during positive (without isolation barrier [IB]) and negative (with IB donned, suction at −250 mmHg, flow rate of 50 L/min) control conditions were measured after baseline determination. Control conditions included simulated and intranasal venturi atomization.3 Clinic procedures were performed with the IB donned and suction applied. Oxygen saturation was monitored throughout the study as a routine precaution.

Aerosol sampling

Aerosol quantification was performed in a 10.3-m² room with 6 air changes per hour using a particle sizer (OPS 3330; TSI, Inc, Shoreview, MN)3 25 cm from the subject’s nares. Total particle counts were quantified and patient comfort was assessed using a satisfaction form. A sample size of 30 was determined to have a 2-sided significance of 0.001 and a power of 0.95 to detect a difference.
between the IIB and sneeze control.\textsuperscript{3} Particles were quantified as total per 10-second interval and averaged in procedures lasting up to 70 seconds. Individualized background particle concentration obtained for each patient were subtracted from each condition, as described elsewhere.\textsuperscript{5}

**Results**

**Patients’ demographics**
The mean age was 54.3 ± 19.6 years and 33% of subjects had facial hair. Mean donning and doffing times were 19.5 ± 7.1 seconds and 5.2 ± 0.9 seconds, respectively (Table 1).

**Aerosol mitigation**
The mean ambient baseline was 338.4 ± 15.1 particles/L. Mean particles over baseline during atomization and sneeze was 15,507 ± 4541.0 particles/L (fold change [FC] from background, 46.8; n = 10 subjects; \( p < 0.05 \)) and 268.6 ± 91.8 particles/L (FC from background, 1.79; \( n = 30 \) subjects; \( p < 0.05 \)), respectively. Among both negative control and procedure conditions (\( n = 30 \) subjects), aerosol production was not significantly different from ambient baseline, regardless of facial hair presence/absence (Fig. 1C). No significant correlation was observed between body mass index (BMI) and FC in particulates over baseline during any clinical procedure or sneeze control (Fig. 1D).

**Patient satisfaction**
Using a visual analog scale with 1 being “least satisfied” and 10 being “most satisfied,” patients rated their mean satisfaction with wearing the IIB at 9.5 ± 0.8 (Table 1).
TABLE 1. Patient demographics, procedural data, and satisfaction rating

| Number of subjects | 30  |
|--------------------|-----|
| Age (years)        | 54.3 ± 19.6 |
| Sex                |     |
| Male               | 13 (43%) |
| Female             | 17 (57%) |
| Body mass index    | 26.4 ± 4.6 |
| Facial hair        | 10 (33%) |
| Donning time (seconds) | 19.5 ± 7.1 |
| Doffing time (seconds) | 5.2 ± 0.9 |
| Baseline particulate (0.5-10 µm/L) | 338.4 ± 15.1 |
| Particles (0.5-10 µm/L) above baseline |       |
| Atomizer (positive control) | 15,507 ± 4541.0 |
| Sneeze (positive control) | 268.6 ± 91.8 |
| Atomizer with barrier | 31.6 ± 15.9 |
| Sneeze with barrier | −32.2 ± 20.8 |
| Procedure with barrier | 47.1 ± 13.1 |
| Mean particle size (µm) |           |
| Baseline           | 1.11 ± 0.07 |
| Atomizer positive control | 0.98 ± 0.01 |
| Sneeze positive control | 1.26 ± 0.07 |
| Procedure with barrier | 1.04 ± 0.06 |
| Barrier satisfaction (0-10 scale) | 9.5 ± 0.8 |
| Face soreness      | 1 (3%)  |
| Skin irritation    | 1 (3%)  |
| Barrier moved      | 2 (7%)  |
| Difficulty fitting barrier | 3 (10%) |
| Claustrophobia     | 0 (0%)  |
| Dry mouth          | 0 (0%)  |
| Dry nose           | 0 (0%)  |
| Dry eyes           | 0 (0%)  |
| Difficulty breathing out | 0 (0%) |
| Difficulty breathing in | 1 (3%) |
| Barrier too noisy  | 1 (3%)  |

Discussion

SARS-CoV-2 can spread by respiratory droplets and airborne aerosols and remains viable in air for 3 to 16 hours. Surgical mask efficacy is limited and may still allow significant airborne aerosol exposure. The otolaryngology exam requires direct access to the nose and mouth, thereby obviating even the partial protection afforded by surgical masks. The performance of endonasal procedures carries all of the hallmarks of a potential infectious encounter as nasal endoscopy and RNESD can produce significant aerosols, may induce cough and/or sneeze, and occur within a small clinic room in close proximity to an unmasked patient. In parallel, epidemiologic evidence of asymptomatic spread even in the absence of overt coughing or sneezing has come to light. Therefore, regardless of their generative source, unmasked patient-derived aerosols produced during the totality of the endonasal exam pose a potential infectious risk to both the provider team and the clinic air supply.

The IIB tested within this study comprises a physical barrier that provides a window enabling procedural access to nose and mouth while effectively scavenging airborne aerosols through high flow and negative pressure, as recommended by the US Food and Drug Administration. The results demonstrate that the IIB was well tolerated and no small droplet or airborne aerosol escape were detected during procedural conditions. In addition, the aerosolizing control conditions were successfully mitigated using the barrier. Finally, IIB efficacy did not appear to be dependent on BMI, presence of facial hair, or tested particle size.

The degree to which otolaryngology providers have been exposed to unmitigated patient aerosol plumes is now evident. The future of the coronavirus-2019 (COVID-19) pandemic remains uncertain in light of ongoing questions regarding vaccine efficacy, transmission blocking activity, hesitance, and durability. Even in a post–COVID-19 world, seasonal exposure to “common cold” viruses and the potential for more frequent epi/pandemics will all remain persistent threats to infectious transmission within the otolaryngology clinic. The integration of routine control strategies will help to mitigate these risks and enable us to continue to provide safe, high-level care to our patients.

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