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ORIGINAL ARTICLE

Nasal endoscopy, room filtration, and aerosol concentrations during live outpatient encounters: a prospective, case-control study

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Abstract

Background: The coronavirus disease 2019 (COVID-19) pandemic has highlighted safety concerns surrounding possible aerosol-generating procedures, but comparative data on the smallest particles capable of transmitting this virus remain limited. We evaluated the effect of nasal endoscopy on aerosol concentration and the role of a high-efficiency particulate air (HEPA) filter in reducing aerosol concentration.

Methods: Otolaryngology patients were prospectively enrolled in an outpatient, cross-sectional study. Demographic information and clinic room characteristics were recorded. A scanning mobility particle sizer and GRIMM aerosol monitor measured aerosols 14.3 nm to 34 μm in diameter (i.e., particles smaller than those currently examined in the literature) during (1) nasal endoscopy (± debridement) and (2) no nasal endoscopy encounters. One-way analysis of variance (ANOVA) and Student's *t* test were performed to compare aerosol concentrations and impact of HEPA filtration.

Results: Sixty-two patients met inclusion criteria (25 nasal endoscopy without debridement; 18 nasal endoscopy with debridement; 19 no nasal endoscopy). There was no significant difference in age or gender across cohorts. Aerosol concentration in the nasal endoscopy cohort (± debridement) was not greater than the no nasal endoscopy cohort ($p = 0.36$; confidence interval [95% CI], −1.76 to 0.17 $\mu g/m^3$; and $p = 0.12$; 95% CI, −0.11 to 2.14 $\mu g/m^3$, respectively). Aerosol concentrations returned to baseline after 8.76 min without a HEPA filter versus 4.75 min with a HEPA filter ($p = 0.001$; 95% CI, 1.73–6.3 min).

Conclusion: Using advanced instrumentation and a comparative study design, aerosol concentration was shown to be no greater during nasal endoscopy versus no endoscopy encounters. HEPA filter utilization reduced aerosol concentrations significantly faster than no HEPA filter.

KEYWORDS
aerosol, COVID-19, filter, nasal endoscopy, otolaryngology

1 | INTRODUCTION

The severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) coronavirus disease 2019 (COVID-19) pandemic has raised questions among healthcare providers regarding the safety of performing exams and procedures in the nasal cavity, given the predilection of this virus to reside within the nares.[1] As a response to these concerns, there has been increasing awareness about the role of varying rates of air exchange to ensure appropriate clearance of aerosols in the setting of potentially aerosol-generating procedures (AGPs). High-efficiency particulate air (HEPA) filters have also been incorporated into clinic practice to mitigate these risks and augmenting air exchange.[2]

The Centers for Disease Control and Prevention (CDC) defines an AGP as a procedure "more likely to generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking, or breathing."[3] The World Health Organization (WHO) has a slightly different interpretation of an AGP, labeling it as "any procedure on a patient that can induce the production of aerosols of various sizes, including droplet nuclei."[4] The CDC has acknowledged the limitations of designating various procedures as potentially aerosol-generating, because there is "neither expert consensus, nor sufficient supporting data" to confirm true aerosol generation and associated risk of infectivity in this setting.[3] Nevertheless, the CDC has recommended six air changes per hour (ACHs) in the setting of an AGP[5]; treating nasal endoscopy and other similar procedures as APGs has had a significant impact on clinic productivity, increasing room turnover time among specialties performing these procedures.[6]

Given that nasal endoscopy demonstrates a potential for aerosol generation in the setting of patients with unknown COVID-19 statuses, several investigations have been performed to better characterize these risks. The vast majority of these studies have focused on surgical procedures in the cadaveric or laboratory setting.[7–10] More recently, Sharma et al.[11] examined aerosol concentrations associated with nasal endoscopy in the clinic setting, but findings were limited by a focus on fine particles (i.e., droplets, size 0.30–10.0 μm). Although the size of the virus-laden particles is governed by the particle with which the virus is associated, the human coronavirus is much smaller, ranging from 80 to 160 nm in diameter.[12] Consequently, the ability to measure particles as small as 80 nm would be beneficial in understanding potential aerosol transmission. Furthermore, no study has compared aerosol generation during nasal endoscopy to a routine non-procedural control group to understand how these two groups differ.

Here, we seek to fill the knowledge gap highlighted by the CDC and WHO regarding the aerosol-generating potential of nasal endoscopy in the outpatient clinic setting using a novel comparative study design. This study measures a broad range of particle sizes (14.3 nm to 34 μm) to characterize potentially virus-laden aerosols. Simultaneously, we seek, for the first time, to quantify the amount of time required to reduce aerosol concentration to baseline levels after the end of the patient visit both with and without a HEPA filter.

We hypothesize that: (1) aerosol generation is not significantly greater in nasal endoscopy visits compared to non-nasal endoscopy clinic visits independent of debridement status; and (2) HEPA filters can significantly reduce the time for aerosol levels to reach baseline levels. We hope to translate the knowledge gained from this study to improve safe operating procedures, while also optimizing clinic productivity.

2 | PATIENTS AND METHODS

2.1 | Study design and sample population

This study was approved by the University of Utah Institutional Review board (IRB #00137104). Informed consent was obtained for all research participants. Aerosol concentrations were measured during Otolaryngology clinic visits among patients who underwent nasal endoscopy (± debridement) ($n = 43$) and those who did ($n = 19$). Pregnant women, as well as patients who had any procedure other than a nasal endoscopy during their clinic visit, were excluded.

During routine outpatient clinical encounters, one of four providers obtained a clinical history, performed a head and neck physical exam (and nasal endoscopy ± debridement when indicated), and developed and discussed a care plan. All patients donned a facemask except during exam of the oral cavity and nasal cavity, or when endoscopy was performed, per standard of care at our institution. All patients were examined in the same room to standardize air exchange, which is dependent on room size, temperature, and clean air delivery rate (CADR), and to standardize aerosol measurements. The room volume was 1049 ft^3,

and the room temperature was standardized at 70.5°F during the airflow measurements.[6]

2.2 | Classification of clinical events

A dedicated research assistant (RA), who was present during each encounter, noted the following events: (1) patient enters room with medical assistant (MA) and research assistant (RA); (2) MA leaves; (3) provider enters room with MA and obtains clinical history; (4) provider performs physical exam; (5) if applicable, provider starts nasal endoscopy (± debridement); (6) if applicable, provider concludes nasal endoscopy (± debridement); (7) provider discusses results of endoscopy (if applicable), and provides an assessment and plan; (8) provider exits room; (9) MA, RA, and patient exit room; (10) if applicable, MA turns on the HEPA filter (in the case of nasal endoscopy, per standard of care) and closes the door; (11) after 12 min, MA enters room to wipe down/clean equipment and turn over the room for the next patient.

2.3 | Room turnover

Turnover of a patient room after nasal endoscopy was only performed after allowing a fan filter unit (FFU) with a HEPA filter (Clean Rooms International, Grand Rapids, MI, USA) to run for 12 min on a high setting with the clinic room door closed. This time interval was selected as it is the minimal amount of time required to achieve the CDC recommended six air changes for this room, based on its CADR, which was measured at 500 cubic feet per minute (cfm) using The Alnor Balometerä (TSI Incorporated, Shoreview, MN, USA) flow hood.[6] For clinic visits that did not involve a nasal endoscopy, no HEPA filter was used during room turnover.

2.4 | Aerosol measurements

The study used three different aerosol instruments to measure the particle size distribution and concentration. These included: (1) scanning mobility particle sizer (SMPS) (TSI 3081; TSI Incorporated) with a long-differential mobility analyzer (TSI 3081) and ultrafine condensation particle counter (TSI 3025A), which measured particles in the range of 14.3 to 673.17 nm in 107 size bins, and required 2 min 15 s for a full scan; (2) aerodynamic particle sizer (APS) (TSI 3022; TSI Incorporated) measured particles in the range of 0.523 to 19.81 μm in 52 size bins, which required 20 s for a full scan; (3) GRIMM 1.109 (GRIMM Aerosol Technik, Ainring, Germany) provided estimates of particulate matter less than 10 μm in diameter, the inhalable fraction (PM10) mass concentration and size distribution in the range of 0.225 to 34 μm in 31 size bins, which operated with 1 min average scans. All the aerosol instruments operated continuously during the days when patient visits occurred. The measurements were collected within 30 cm of the patient's breathing zone. Aerosol samples flowed through conductive tubing (copper or stainless steel) into the instruments. The SMPS and APS data were recorded using the manufacturer-provided software AIM 8.1.0.0 (TSI Incorporated). The GRIMM data was stored in the instruments' memory card and retrieved using the GRIMM spectrometer's software. The instruments were placed on a cart, stationed at the back of the clinic chair (Figure 1). The patient was positioned in the exam chair, below the vent that provides air into the room; the sampling ports were located slightly to the side and below the patient, which allowed the ventilation air to push aerosols toward the ports. The clinic room did not contain an exhaust vent.

2.5 | Data analysis

The analysis focused on two key indicators of aerosol concentration: particle number concentration from the SMPS and estimated PM10 mass concentration from the GRIMM. These measurements differed in their scan time and target particle size ranges. The SMPS particle number concentration is a good measurement for events with large numbers of small particles (<300 nm in diameter) because particles in this size range contribute little to particle mass. The GRIMM estimated PM10 mass, which is a good measurement for events associated with larger particles (>300 nm). The particle number concentrations from the APS were <1/cm^3, which are too low to provide meaningful differences in particle number or estimated mass concentration. Consequently, APS measurements were not analyzed further in this study.

2.6 | Particle number concentration and correlations with clinical events

The SMPS measurements were plotted for each patient visit versus time on the x-axis and total particle concentration on the y-axis. Aerosol peaks were identified as increases in aerosol concentration over baseline that corresponded to recorded clinical events (as described above in Classification of Clinical Events). For each patient visit, the baseline was determined by fitting a line between the time between event stamp "MA set-up the room" and the minute before time stamp for "MA, RA, and patient

FIGURE 1 Setup of the aerosol measurement equipment in the clinic. Copper tubing was used to transfer the aerosols from near the patient to the SMPS and APS. Abbreviations: APS, aerodynamic particle sizer; SMPS, scanning mobility particle sizer

exit the room" (Figure 2). Particle concentration typically increased when everyone exited the room at the end of the visit, and this increased particle concentration was not included in the baseline fit.

During a patient visit, if an event class corresponded to an increase in aerosol concentration, it was counted as one event. If multiple peaks in aerosol concentration corresponded to an event during a patient visit, this was considered as a single event. For each event class, the total number of patient visits with corresponding aerosol events were divided by the total number of patients in the cohort to obtain the percentage of visits for which an event was observed:

$$Percentage\ of\ patients\ for\ which\ each\ event\ was\ observed = \frac{\#\ of\ patient\ visits\ when\ event\ observed}{\#\ of\ patients\ in\ cohort} * 100 \quad (1)$$

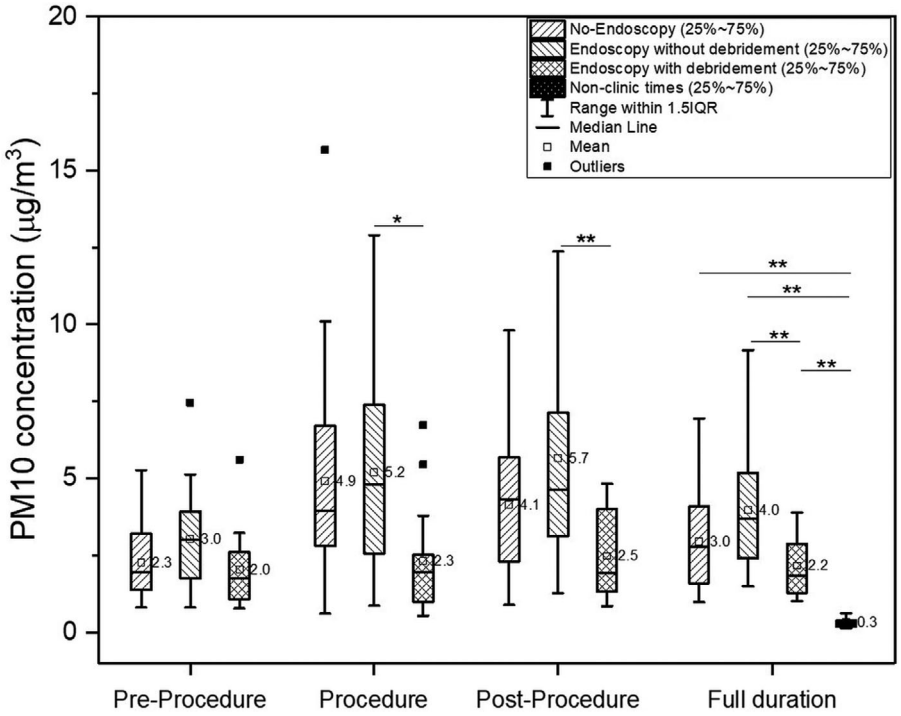

FIGURE 2 Total particle number concentrations, as measured by the SMPS, for (A) example non-clinic times (4:00 a.m. to 6 a.m.; March 23, 2021), (B) no endoscopy during the visit and no HEPA use at the end of the visit, (C) endoscopy during the visit and HEPA use at end of the visit. The dotted line represents the baseline fit, the dash-dot line represents the drop fit, the red square represents exit time, and the blue circle represent turnover time. The intersection point (denoted with a star) was used to estimate time to reach baseline concentrations. The aerosol peaks were labeled (time, # concentration) with corresponding events, from the datasheet. The estimated baseline concentration (circle with dot) at turnover time was also identified. Of note, a few encounters (outlined in Figure S1A–C) were excluded from this analysis for one of the following reasons: (1) room was turned over immediately after everyone exited and the next patient entered within next 5 to 7 min; (2) the extrapolated baseline did not intersect with the drop fit; (3) the intersection point occurred after the "room turned over." Abbreviations: HEPA, high-efficiency particulate air; SMPS, scanning mobility particle sizer

2.7 | Particle number concentrations during non-clinic hours

The aerosol concentration in the clinic from the air supply system was measured during period 4:00 a.m. to 6:00 a.m., when no activities occurred in the clinic, and the effect of other disturbances was minimal. These measurements were done for baseline concentration levels and are referred as non-clinic times (Figure 2).

2.8 | Determining the time required for particle number concentrations to return to baseline levels

The time for aerosol concentrations to reach baseline was evaluated using two methods. The first method applied a linear model to data points between the time stamp "MA, RA, and patient exit the room" and the "room turned over" to estimate the rate of decrease in particle concentration (drop fit, Figure 2). The intersection points of drop fit and the extrapolated baseline fit were used to estimate the time required to reach background levels after everyone exited the room (Figure 2). The second method to estimate time needed to reach baseline aerosol concentrations used the expected baseline concentration at the room turnover and compared this to the measured particle concentration at the turnover time. The comparison classified the turnover time concentration as higher, lower, or within the expected baseline range (±10%). Finally, a comparison was made between time to reach baseline for HEPA and no-HEPA conditions.

The time to reach baseline was only evaluated for particle number concentration and not for estimated PM10 mass concentration because small particles can remain suspended for hours, and small particles dominate particle number concentration. Estimated PM10 mass is dominated by particles with larger diameters, which tend to settle quickly.

2.9 | Particle mass concentration, PM10

Similar to number concentrations, a time series of estimated PM10 mass concentration ($\mu g/m^3$) was plotted for each patient visit. The baseline PM10 concentration for all patient visits was 0.3 ± 0.3 $\mu g/m^3$. Aerosol peaks (defined as increases in aerosols compared to the baseline concentration) were correlated with specific, time-stamped clinic events. The percentage of patient visits when an event-specific aerosol peak was observed within a cohort was calculated, and the mass concentrations associated with peaks of different events were compared.

The average PM10 mass concentration generated during the full duration of each patient visit was calculated between "room setup" and "turnover time." If the baseline mass concentration was achieved before turnover, the average PM10 concentration was calculated between "room setup" and when the PM10 concentrations reached baseline. The estimated average PM10 mass concentration during patient visits with and without endoscopy was compared to concentrations during non-clinic times. Then, a comparison was made between average PM10 concentration measured before, during, and after either endoscopy (endoscopy cohort) or a physical exam (non-endoscopy cohort). For endoscopy events, the PM10 concentrations were averaged between time stamp "Endoscopy start" and "Endoscopy ends." For physical examinations, the PM10 concentrations were averaged between time stamp "Mask removed for physical exam" and "Mask put back." The PM10 concentration during non-clinic times was estimated by averaging the measurements between 6:00 p.m. and 8:00 p.m. (just after the clinic ended) or 4:00 a.m. to 6:00 a.m. (just before clinic begins).

2.10 | Statistical analysis

Patients were assigned unique study identification numbers (AE01–AE62); all protected health information was removed. A two-tailed, Student's *t* test was used to compare the mean time to reach baseline for HEPA and no-HEPA scenarios. Statistical significance was set at $p < 0.05$. One-way analysis of variance (ANOVA) and Tukey's honest significant difference (HSD) post hoc test was performed using Astatsa online software (https://astatsa.com/) to compare aerosol concentration across various clinic cohorts (non-clinic, no-endoscopy, endoscopy, and endoscopy with debridement), and clinic events in the three cohorts. A post hoc power analysis was run using R (R Core Team; 2020; R Foundation for Statistical Computing, Vienna, Austria; https://www.r-project.org/) for the comparison of estimated total PM10 mass concentration across the entire duration of the following clinical encounters and demonstrated an estimated achieved power of 0.926: no endoscopy versus endoscopy with debridement versus endoscopy without debridement.

3 | RESULTS

3.1 | Demographics and clinical characteristics

A total of 62 patients ($n = 25$ nasal endoscopy without debridement, $n = 18$ nasal endoscopy with debridement, and $n = 19$ without endoscopy (control)) were included in the final analysis. There was no significant difference in age or gender between these cohorts (Table 1).

3.2 | Particle number and mass concentration measurements

Figure 3 illustrates that the estimated PM10 mass concentrations were higher during clinic visits compared to non-clinic times (Figures 3 and 4). The estimated PM10 mass concentrations for the full duration of endoscopy, endoscopy with debridement, and no endoscopy patient cohort visits were significantly higher than baseline ($p = 0.001$; 95% CI, 2.89–4.41 $\mu g/m^3$ for endoscopy; $p = 0.01$; 95% CI, 1.35–2.33 $\mu g/m^3$ for endoscopy with debridement; and $p = 0.001$; 95% CI 1.79–3.48 $\mu g/m^3$ for no endoscopy) (Figure 3). The estimated PM10 mass concentrations for the full duration of endoscopy and endoscopy with debridement were not significantly higher than no nasal endoscopy ($p = 0.12$; 95% CI, −0.11 to 2.14 $\mu g/m^3$; and $p = 0.36$; 95% CI, −1.76 to 0.17 $\mu g/m^3$, respectively). The PM10 concentrations for endoscopy without debridement were significantly higher than the PM10 concentration for the endoscopy with debridement ($p = 0.001$; 95% CI, 0.92–2.71 $\mu g/m^3$). The PM10 concentration differences for visits that included endoscopy without debridement compared to no-endoscopy visits did not meet statistical significance ($p = 0.12$; 95% CI, −0.11 to 2.14 $\mu g/m^3$). Figure 3 also shows that the PM10 concentrations were higher during endoscopy (without debridement), physical exams, and after either endoscopy or physical exam, as compared to the preprocedure times; however, these differences were not significantly different. The PM10 concentration during and after procedure for the endoscopy cohort with debridement remained lower than the other two cohorts. Particle number concentration during clinic visits was also higher than non-clinic times (Figure 2A vs. 2B and 2C).

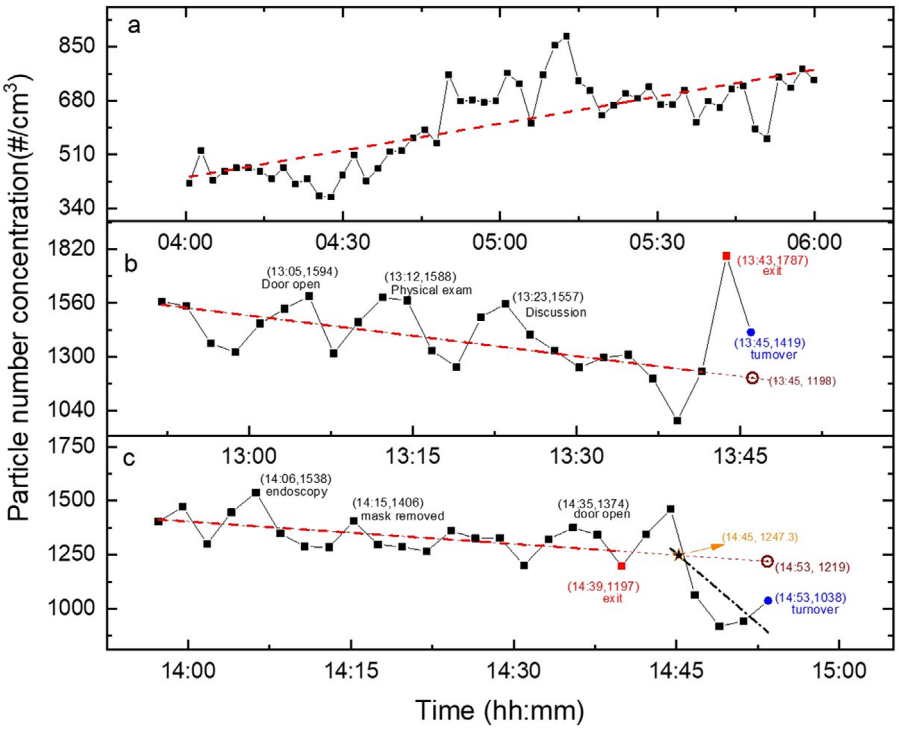

FIGURE 3 Estimated total PM10 mass concentration during preprocedure, during procedure, postprocedure, the full duration of patient visits, and during non-clinic times ($n = 15$). The cohorts included no-endoscopy clinic visits ($n = 15$), and endoscopy with ($n = 18$) and without debridement ($n = 24$). Note: the cohort size used in this analysis is less than the total study cohort size, due to loss of GRIMM measurements on March 4 ($n = 2$) and April 4 ($n = 3$). Statistically significant differences between pairs were denoted with *$p < 0.05$, and **$p < 0.01$. Abbreviations: IQR, interquartile range; PM10, particulate matter <10 μm in diameter [Correction added on 6 September 2021, after first online publication: Figure 3 has been corrected.]

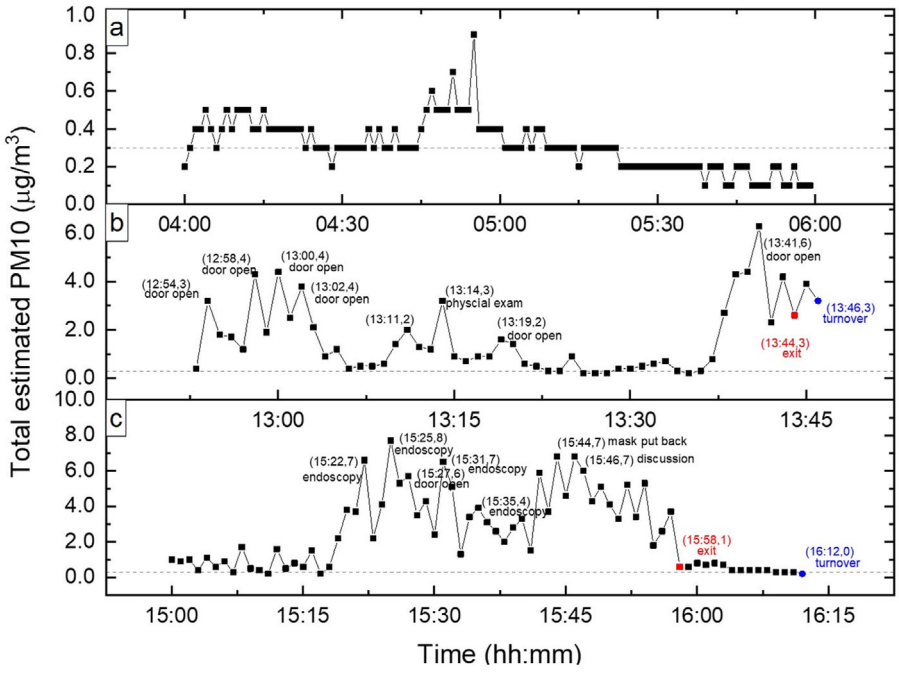

FIGURE 4 Total estimated PM10 mass concentration, as measured by GRIMM, for (A) example non-clinical times (4:00 a.m. to 6 a.m., March 22, 2021), (B) no endoscopy during the visit and no HEPA use at the end of visit, (C) endoscopy during the visit and HEPA use at the end of visit. The dotted line represents baseline fit. The red square represents exit time, and the blue circle represents turnover time. The aerosol peaks were labeled with corresponding events from the datasheet. Abbreviations: HEPA, high-efficiency particulate air; PM10, particulate matter <10 μm in diameter

TABLE 1 Demographics

	Total patients ($n = 59$)	Nasal endoscopy without debridement ($n = 25$)	Nasal endoscopy with debridement ($n = 15$)	No nasal endoscopy ($n = 19$)	p
Age (years), mean ± SD	47.9 ± 18.9	46.7 ± 19.7	44.3 ± 18.6	54.6 ± 17.4	0.26
Gender, *n*					
Male	17	8	9	9	0.20
Female	27	17	6	10	
Ethnicity, *n*					
Hispanic/Latino	1	0	0	1	0.15
Non-Hispanic/Latino	43	25	15	18	

Abbreviation: SD, standard deviation.

3.3 | Aerosol-generating events

Table 2 shows in-clinic events that tended to correspond to an increase in aerosol concentration. These events included: talking during history taking, use of nasal spray, physical exam, mask removal/mask donning, endoscopy, debridement, talking during discussion, and special events, such as coughing or sneezing. For most visits, a significant spike in particle number concentration was observed when everyone exited the room (Figure 2B,C).

Although the peaks associated with endoscopy were observed more frequently than the other events, the maximum mass concentrations were lower (compared to some of the other events, such as coughing/sneezing event, and the patient/provider discussion; Table 2). We also evaluated particle size bins associated with endoscopy procedures and identified an increase in the number concentrations for particles in the range of 80 to 300 nm (Figure S2).

3.4 | Effect of air filtration on the time needed to reach baseline aerosol levels

Table 3 compares the time to reach baseline when using a HEPA (4.75 min ± 2.97 min) filter versus no HEPA filter (8.76 min ± 2.50 min). This difference was statistically significant (two-tailed Student's t test, $p = 0.001$; CI, 1.73–6.30 min). Utilizing this information, we determined that 2.26 air changes were required to achieve baseline levels when using the HEPA filter versus 4.18 when using no HEPA filter.

The use of HEPA not only decreases the aerosol concentration to baseline more quickly, but it also reduced concentrations to below baseline. Figure 5A illustrates that with a HEPA filter, all particle concentrations at room turnover were either less than the expected baseline concentration or within the expected baseline concentration (±10%) range. Without a HEPA filter (Figure 5B), only one case had a turnover concentration less than the expected baseline concentration. For the remaining no-HEPA cases, the particle concentrations were either greater (47.3% cases) or within ±10% of the expected (47.3% cases) baseline concentration range.

4 | DISCUSSION

The COVID-19 pandemic has increased awareness about provider/patient safety during routine outpatient clinical encounters as it pertains to potential aerosol transmission of viral diseases. One critical question that remains

TABLE 2 The number and percentage of patients with classified aerosol generating events

Event	Cohort size (*n*)	Number of cases with peak observed (based on number concentration) *n* (%)	Number of cases with peak observed (based on PM10 concentration) *n* (%)	Peak PM10 concentration ($\mu g/m^3$) (mean ± SD)	*p* (with respect to endoscopy)
Endoscopy	42	17 (40.5)	37 (88.1)	5.3 ± 3.4	–
Debridement	18	1 (5.56)	8 (44.4)	4.1 ± 1.6	0.9
History/talking	29	8 (27.6)	10 (34.5)	5.1 ± 3.5	0.9
Physical exam	41	6 (14.6)	11 (26.8)	6.7 ± 5.8	0.9
Discussion	59	13 (22.0)	36 (61)	7.3 ± 5.0	0.14
Nasal spray	33	10 (30.3)	15 (45.5)	5.9 ± 2.9	0.9
Coughing/sneezing	13	4 (30.8)	5 (38.3)	9.1 ± 7.5	0.47
Mask donning/doffing	60	13 (21.7)	29 (48.3)	6.0 ± 3.5	0.9

Abbreviations: PM10, particulate matter <10 μm in diameter; SD, standard deviation.

TABLE 3 Time to reach baseline for HEPA and no-HEPA conditions

Scenario	Time to reach background (min) Mean ± SD	Maximum	Minimum	Number of air changes needed to reach background	CDC-recommended air changes
HEPA ($n = 25$)[a]	4.75 ± 2.97	10.02	0.31	2.26	6
No HEPA ($n = 7$)[a]	8.76 ± 2.50	13.48	6.06	4.18	6

Abbreviations: CDC, Centers for Disease Control and Prevention; HEPA, high-efficiency particulate air; SD, standard deviation.

[a] *n* size was determined based on the cases for which extrapolated baseline intersected the drop fit; cases where this intersection did not occur were excluded.

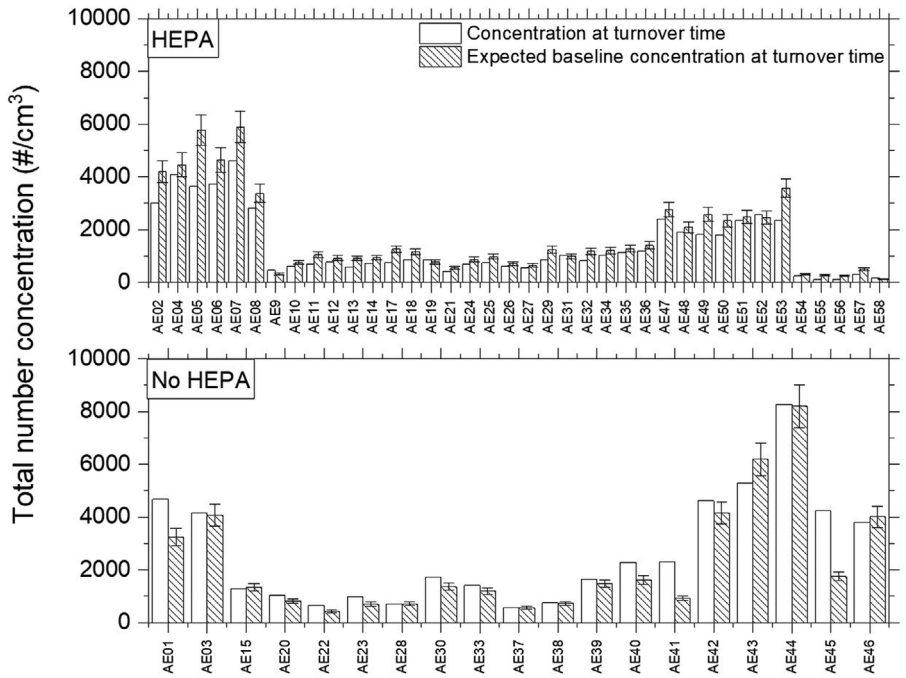

FIGURE 5 Particle concentration as measured by SMPS versus expected baseline concentration at turnover time for HEPA and no HEPA cases. The error bar represents a 10% standard error in expected aerosol baseline concentration. Abbreviations: HEPA, high-efficiency particulate air; SMPS, scanning mobility particle sizer

surrounds the amount of aerosol concentration generated with nasal endoscopy in the clinic setting, and how this compares across non-procedural aspects of a routine clinic visit, such as obtaining a clinical history, performing a physical exam, and discussion of clinical care options. To the best of our knowledge, the present investigation is the first to use both a comparative and prospective study design to demonstrate that nasal endoscopy clinic encounters generate no more aerosols than non-endoscopy patient visits independent of debridement status. Clinic encounters that included endoscopy + debridement resulted in statistically significant lower aerosol concentrations than endoscopy − debridement ($p = 0.001$; 95% CI, 0.92–2.71 $\mu g/m^3$), which the authors hypothesize to be secondary to the use of concomitant suction during debridement. Furthermore, the use of a HEPA filter at the end of clinic visits was shown to successfully decrease aerosol concentration to baseline levels significantly faster than no HEPA filter.

Despite the CDC's acknowledgement that there is very limited data to support the claim that various procedures, such as nasal endoscopy, are significantly more aerosol generating than "coughing, sneezing, talking, or breathing,"[2] these procedures continue to be considered AGPs across the literature and clinical practice.[3,12] In fact, several recent investigations of aerosol generation during bronchoscopy[13] and nasal endoscopy[11,14] in a cohort of healthy patients demonstrated no significant spike in aerosols compared to preprocedural baseline. However, the latter investigations did not use a control group, did not report baseline concentrations and room characteristics, and were limited in their ability to detect only particles between 80 and 300 nm.[11,14] These differences in study design may explain the divergence in findings compared to the present investigation. Human coronaviruses are small, with sizes generally in the range of 80 to 160 nm[11]; consequently, measuring particles smaller than 300 nm in diameter is important for understanding potential virus transmission. Indeed, the present study demonstrates increases in particle numbers during some endoscopy procedures in this 80 to 300 nm diameter range compared to baseline.

Given the lack of reporting of baseline concentration and room characteristics in prior aerosol studies of nasal endoscopy, it is not possible to compare concentration values across the studies. Thus, although Murr et al.[14] demonstrated a mean concentration of 6021 particles/ft^3 when assessing aerosols sized 0.30 to 10.0 μm, and Sharma et al.[11] demonstrated a peak concentration of 2.54 particles/cm^3 during nasal endoscopy, these absolute numbers are difficult to compare to each other or to the present study, because we do not know what the background levels were or whether they were accounted for Murr et al.[14] conducted their study with patients completely unmasked, whereas Sharma et al.[11] had patients keep the mask over their mouth only. Our data, using similar conditions as Murr et al.[14] with no masking during endoscopy, demonstrated that although nasal endoscopy did significantly increase aerosol concentration compared to baseline, similar increases were also seen in non-endoscopy visits. This observation bridges a knowledge gap that has been created during the COVID-19 pandemic surrounding the role of provider/patient masking in routine nonprocedural clinic visits as compared to nasal endoscopy encounters. Future discussions around this topic are likely inevitable as we progress through the current pandemic and the data provided herein may help better inform these considerations.

By providing measurements of aerosol concentrations during other routine clinic events, our investigation was able to provide context within which to consider endoscopy associated aerosol generation, allowing us to compare nasal endoscopy (± debridement) to other nonprocedural events. Indeed, our results suggest that the greatest aerosol concentrations occurred at the exit from clinic when the door was opened, individuals in the room stood and exited, potentially re-aerosolizing particles, and transporting them to the inlet of the aerosol measurement devices. Moreover, although the peaks associated with endoscopy were observed more frequently than the other events, the peak mass concentration observed were lower (Table 2) compared to other events. Coughing/sneezing events, followed by the patient/provider discussion events resulted in the highest estimated PM10 mass concentrations. This difference between the number of peaks and mass concentration may be because patient/provider discussion, which has slightly higher PM10 concentration, usually follows endoscopy. It is possible that the aerosols generated during endoscopy are being picked up during the discussion event, because it takes some time for the aerosols to flow to the device inlet. It is also worth noting that the discussion events tended to last longer than the endoscopy or physical exam events, which could lead to more opportunities for aerosol peaks associated with talking and/or general movement within the clinic.

In the clinic setting, the CDC has recommended a minimum of six air changes to successfully remove airborne contaminantion,[1] while acknowledging the lack of robust data on the relative aerosol generating capacity of many of these potential AGPs. To augment air exchange, many clinical practices have incorporated the use of the HEPA filter in the outpatient setting. Messina et al.[15] demonstrated improved ventilation in the operating room (OR) setting when utilizing a HEPA filter, significantly reducing concentrations of most particle sizes. However, data from within the clinic setting was lacking. Here, we demonstrated that only 2.26 air changes were required to reduce aerosols to baseline levels in the presence of a HEPA

filter utilized on high setting at the end of the clinic visit compared to 4.18 air changes needed without the use of a HEPA filter in the setting of no endoscopy. To the best of our knowledge, these findings present the first empirical evidence on the true amount of air changes required to reduce airborne contaminants to baseline concentration.

Although our study demonstrates that nasal endoscopy may not qualify as an AGP under the CDC definition, when/if AGPs are occurring in other situations, and the CDC recommendation of six air changes is to be adhered to, our data highlight the utility of the particular HEPA filter used in our study, because it was able to decrease the amount of time needed to reduce aerosols to baseline by nearly 50%. Importantly, the mean time required to reach baseline in both scenarios was less than the 12 min. Our group previously demonstrated how incorporation of the HEPA filter could theoretically drive down the time needed to achieve six air changes.[6] We now have in-clinic measurements supporting the significant difference in time needed to return aerosol concentrations to baseline in the setting of this particular HEPA filter. Although the present data highlight the minimal number of air changes required to reduce aerosol concentrations to baseline with and without nasal endoscopy, it is important to note that this reduction in time is based on the CADR rating of the particular HEPA filter used in our study (as outlined in Patients and Methods). The actual time needed to achieve six air changes will vary based on individual filters, room sizes, and room temperatures.

There are several limitations to the present study. First, although our investigation evaluated aerosol concentrations in the outpatient setting, we did not examine how this may or may not relate to infectivity of aerosol transmissible diseases. Second, the aerosol concentration entering the room from the building's air supply varies over time, and the SMPS is highly sensitive and requires >2 min to complete a scan. Consequently, the baseline measured by the SMPS was variable (Figure 2A), making it difficult to identify peaks and attribute them to a single clinical event. The variable baseline also posed difficulty in comparing average particle number concentrations during different clinical visits. Figure 5 illustrates how the expected baseline concentration varied between 300 and 8000 particles/cm^3 at room turnover time and demonstrates the challenges in comparing number concentration between different clinical visits. Third, if a clinic event occurred simultaneously with the opening of the clinic door, it was not counted as an aerosol peak because it was impossible to resolve any patient-related aerosols from those associated with door opening. Fourth, it is possible that not all aerosols measured during the clinic encounters are generated by the patient, for there are other healthcare staff and/or providers in the room at the same time. It is also possible that re-aerosolization of deposited particles is occurring, rather than generation of particles belonging to the patient. Nevertheless, providers/MA/RA were all wearing N95 respirators (N95 respirators are face masks that filter out at least 95% of 0.3-μm-sized particles) throughout the encounters and stationery/in the same position; this may minimize their potential role as major aerosol generators during the encounter. Fifth, the clinic room used for this investigation has an air return vent near the front of the door. The distance of the return vent from the sampling ports may lead to under sampling during clinic encounters and may also explain the increase in aerosol detection during entering and exiting of the room. Nevertheless, if the air return vent were a source of undersampling, presumably it would impact both endoscopy and non-endoscopy encounters equally, and thus should not affect the overall interpretation of the data.

Finally, it is important to note that a greater number of aerosol peaks corresponded to events when considering PM10 mass concentration. This could be due to the difference in the scan time of two instruments. The SMPS required 2 min 15 s per scan, while the GRIMM required only 1 min for a full scan, allowing GRIMM to capture a greater number of events than the SMPS. The aerosol peaks associated with endoscopy, discussion, and mask donning/doffing were easier to identify with PM10 mass concentration, which captures larger particles. This suggests that these events are associated with larger particles (>0.7 μm), and they were more difficult to identify when considering only particles smaller than 300 nm.

Despite these limitations, the strengths of the present investigation, including its prospective nature, comparative study design, incorporation of live patients instead of cadavers, and focus on optimizing clinic productivity, may assist healthcare providers in making evidence-based decisions regarding the need for patient/provider masking in the clinic setting, while also informing room turnover and air exchanges needed to adequately remove potential aerosol contamination.

5 | CONCLUSION

Nasal endoscopy patient encounters are no more aerosol-generating than non-endoscopy clinic visits. When aerosol peaks do occur, the use of a HEPA filter significantly reduces time to return aerosol concentrations back to baseline, driving down room turnover times.

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CONFLICT OF INTEREST

Jeremiah A. Alt: OptiNose, GlycoMira, Medtronic, and GSK. Kerry Kelly: Tetrad.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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