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Quantitative Evaluation of Aerosol Generation During In-Office Flexible Laryngoscopy

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This cohort study evaluates whether flexible laryngoscopy is an aerosol-generating procedure.

Key Points

Question

Is office flexible laryngoscopy an aerosol-generating procedure?

Findings

In this cohort study of 134 patients, there were no significant changes in aerosol counts identified in patients undergoing flexible laryngoscopy, including when topical nasal spray was applied and regardless of whether the mouth was covered with a mask.

Meaning

Protocols to mitigate risk associated with aerosol-generating procedures are probably not necessary for office flexible laryngoscopy.

Abstract

Importance

Despite growing scientific knowledge and research, it is still unknown if office flexible laryngoscopy (FL) is aerosol generating and thereby potentially increases the risk of SARS-CoV-2 transmission. The limited literature that exists is conflicting, precluding formal conclusions.

Objective

To determine whether FL is aerosol generating.

Design, Setting, and Participants

This prospective cohort study included 134 patients seen in the otolaryngology clinic at a single tertiary care academic institution between February and May 2021. Two optical particle sizer instruments were used, quantifying particles ranging from 0.02 μm to 5 μm. Measurements were taken every 30 seconds, with sample periods of 15 seconds throughout the patient encounter. Instruments were located 12 inches from the patient's nares. Timing of events was recorded, including the start and end of physical examination, topical spray administration, start and end of laryngoscopy, and other potential aerosol-generating events (eg, coughing, sneezing). Data analysis was performed from February to May 2021.

Exposures

Office examination and office FL.

Main Outcomes and Measures

Bayesian online change point detection (OCPD) algorithm was used to detect significant change points (CPs) in this time-series data. The primary outcome was significant CP after FL compared with baseline physiologic variations, such as breathing and phonation.

Results

Data were collected from 134 patients between February and May 2021. Ninety-one encounters involved FL. Of this group, 51 patients (56%) wore no mask over their mouth during FL. There was no statistically significant CP in either visits involving FL or visits where FL was not performed. Use of nasal spray did not result in CP in aerosol levels. Overall, neither the number of people present in the examination room, masks over patients' mouth, the duration of the visit, nor the duration of FL were associated with mean aerosol counts, regardless of the exposure. For larger aerosol sizes (≥1 μm), however, rooms with higher air exchange rates had significantly higher reductions in mean aerosol counts for visits involving FL.

Conclusions and Relevance

The findings of this cohort study support that FL, including topical spray administration, is not a significant aerosol-generating procedure. The Bayesian OCPD model has a promising application for future aerosol studies in otolaryngology.

Introduction

The novel virus SARS-CoV-2 has engendered concern regarding periprocedural transmission. The current international COVID-19 guidelines state that SARS-CoV-2 transmission is primarily through larger respiratory fluid droplets (>5 μm diameter), while aerosols (<5 μm) are only of notable risk during aerosol-generating procedures (AGPs).[1,2] The conventional definition of AGPs is procedures that create and disperse aerosols above the baselines of coughing, talking, sneezing, or breathing.[3,4] It is essential to properly define which procedures are aerosol generating[5,6] given the high viral load in the upper airway of patients with SARS-CoV-2 infection.[7,8] Currently, the guidelines from the World Health Organization and the US Centers for Disease Control and Prevention include tracheal intubation, noninvasive ventilation, tracheostomy, cardiopulmonary resuscitation, and manual ventilation as AGPs.[4,9,10]

It has been suggested by various authors that flexible laryngoscopy (FL), a commonly performed procedure in most otolaryngology practices, is likely to be an AGP.[11,12,13] At the outset of the pandemic, many hospitals and clinics implemented new FL safety protocols that included incorporating the use of personal protective equipment, limiting the number of patients seen in clinic, restricting FL examinations to negative-pressure rooms, or enforcing room shutdowns after an examination to allow for sufficient air exchange in the room.[11,14] However, many clinical protocols for preventing transmission lack sufficient supportive evidence, and the limited empirical data that exist are conflicting.[15,16] Although there is a suggestion that more invasive head and neck procedures using powered instrumentation can be classified as AGPs, there is limited or absent evidence of viral transmission or aerosolization during FL alone.[1,14,17,18]

In this study, we test the hypothesis that FL in the clinical setting is associated with increased aerosols over baseline physiologic variations such as breathing and phonation. To test this hypothesis, we quantitatively measured aerosols during FL using optical particle sizer (OPS) instrumentation. To our knowledge, this is the first prospective trial analyzing aerosol generation during FL in the clinical setting.

Methods

Data Collection

The protocol for this study was approved by the Dartmouth-Hitchcock Medical Center Institutional Review Board (IRB Protocol No. 02001054). Patients seen at the Dartmouth-Hitchcock Medical Center Otolaryngology Clinic from February to May 2021 were selected for inclusion. Patient informed consent was waived because the study did not collect any protected health information. These patient encounters included visits involving FL as well as visits that did not. For all visits both scope and nonscope, a complete history and head and neck examination was performed, including oral cavity examination. The only difference between the scope and nonscope visits was the application of topical anesthetic spray and the laryngoscopy procedure itself during the scope visit. Other types of office visits that did not involve a complete head and neck examination, such as review of results, counseling, and other types of office procedures, were excluded.

The recording of data was performed in examination rooms with an average air change per hour (ACH) ranging from 8.2 to 13.1. Air change per hour is defined as the rate that a volume of air is added or removed from a space in 1 hour divided by the volume of that space. The higher the ACH, the more rapidly the volume of air in a particular space is replaced with a new volume of air. The rooms were grouped according to ACH into either low flow rate, which included rooms with ACH of 8.2 to 9.1 (6 rooms), or high flow rate, which included rooms with ACH of 10.2 to 13.1 (5 rooms).

During office visits, immediately following door closing, 2 OPS instruments, the AeroTrak 9306-03 (TSI) and the P-Trak 8525 (TSI), were used, in combination, providing quantification of particles ranging from 0.02 μm to 5 μm. The P-Trak reports average values of particle concentration with the size ranges of 0.02 to 1.0 μm, and the result is expressed as pts/cm^3. The AeroTrak can collect sizes ranging from 0.3 to 5.0 μm. During this study, the instrument was used in the differential Δ particle concentration setting, which counts the number of particles enabled in particular bin sizes. For example, the 0.3-μm channel measures particle concentration with sizes smaller than 0.3 μm, and the 0.5-μm channel measures the particles with size ranges from 0.3 to 0.5 μm, and so on. Results are reported as average particles/cm^3. While the P-Trak is able to detect particles within size range indiscriminately, the AeroTrak contributes an advantage of quantifying the various particle size populations. Additionally, the AeroTrak's counting efficiency for the particles is 50% at 0.3 μm and 100% at greater than 0.45 μm, so having 2 instruments overlap in their detection range provided more assurance and allowed for a wider range of particle capture that included both ultrafine and aerosol particle sizes. The instruments were located approximately 12 inches from the patient's nares with minimal instrument movement. The instruments have an internal laser system that counts the number of particles in the sampled air based on the amount of light scattered. Measurements were taken every 30 seconds, with sample periods of 15 seconds. For the AeroTrak device, air is funneled through the isokinetic inlet at a rate of 2.83 L/min, and the P-Trak has a sample flow rate of 0.1 L/min. Door opening and unnecessary movements were limited during the patient encounters. The timing of clinic events was documented and recorded, including the start and end of physical examination, topical spray

administration, start and end of laryngoscopy, and other potential aerosol-generating events (eg, coughing, sneezing). During a subset sample of visits, patients wore masks over their mouths during flexible laryngoscopy. Zero count verification was performed each morning using the high-efficiency particulate air filter provided by TSI for both instruments. Zero checks ensured that the instruments were free from leaks, residual particles, and electronic noise. Immediately prior to initiating the study, both instruments were sent to the manufacturer (TSI) for calibration using their internal controls. Further test trials were performed by the authors, which demonstrated increase in particle counts after phonation, coughing, and sneezing.

Statistical Analysis

We implemented the Bayesian online change point detection (OCPD) algorithm as described by Adams and MacKay[19] for the detection of significant change points in this multiparticle aerosol counts time-series data. Here, we define a change point as a statistically significant change in aerosol counts beyond normal physiological variations (eg, breathing, phonation). This can be due to a change in the mean, variance, or periodicity of aerosol particle counts, or a combination of the three. Briefly, Bayesian OCPD algorithm uses the Bayes framework to compute the probability of a change point in a sequence of data (ie, the prior probability). This is achieved using a combination of predictive modeling of future observations in the time series, an integer quantity, *rt*, called the run length (or the time since the last change point), and a hazard function (which computes the probability of a change point occurring with respect to the last change point). All analysis was done in R language for statistical computing version 4.1.1 (R Core Team 2013) with 2-tailed *P* values at a significance level $\alpha \leq .05$.

Change Point Detection Simulations To test how well the algorithm detects change points in a time-series data from office laryngoscopy, we simulated an office visit of 40 minutes with a known change point of a 6-minute scoping event that started at 15 minutes into the visit. Details of the simulation are documented in the Supplement (eAppendix, eFigure 1, and eFigure 2A-H).

Change Point Detection Analysis The Bayesian OCPD algorithm was then applied to the time-series multiparticle data collected during in-office laryngoscopy, modeling as a Gaussian process on the lognormal scale and allowing for parametric testing (ie, comparing trend mean to future observations in the time-series; see eAppendix in the Supplement). For a given visit, we visualized results of the change point analysis as a multiparticle series of trends, one for each sensor size. For scoped visits, we indicated the time boundaries from beginning of scoping (or time nasal spray was applied where applicable) to when scoping ended, as this is the time window of AGP for which a change point is expected.

Univariate Analysis For a given particle size, we computed the average number of aerosol particles per visit, stratified by the type of office visit (with or without scope), by the type of examination room (low or high airflow room), whether masks were covering the mouth during the scope procedure, and the

number of people present during the visit. Here, we compared the strata using either the *t* test or analysis of variance, where appropriate. Categorical data were analyzed using Pearson χ^2 test of independence.

Multivariate Analysis To determine which variables during a patient visit have a significant association with aerosol counts, we built a series of multivariate linear regression models for either the scoped or nonscoped visits. For the scoped visits, the predictors of the dependent variable (average aerosol count per visit) were the number of people in the office during the visit, whether or not a patient kept their mask on, the duration of the entire visit, the duration of the scoping event, and the type of room in which the examination occurred. Predictors in the nonscoped visit models were the number of people, duration of entire visit, and type of examination room. For each model, validity of linear regression assumptions was assessed by checking for independence, outlier observations and normality in the distribution of the outcome variable and residuals. Further, model performance was assessed using coefficient of determination (R^2), residual standard error, and the overall model's *F* statistic *P* value.

Results

Data were collected from a total of 134 patients between February and May 2021. Two-thirds of the visits (n = 91) involved FL. Table 1 summarizes study variables, stratified by examination type. While the majority of visits with scoping included use of topical anesthetic spray administered prior to laryngoscopy (86%, n = 78), none of the visits without scoping used topical spray. In total, 51 patients (56%) with a scope examination wore no mask during this portion of the patient encounter.

The Figure shows the sequence of multiparticle aerosol data for a representative scoped and nonscoped visit and their corresponding run lengths. For the entire duration of the study, we found no statistically significant change points for either type of examination. There were also no detectable change points during application of nasal spray. In the univariate analysis (Table 2), we found that for larger particle sizes (1-5 μm), particle counts were higher in the high flow rooms. Furthermore, patient's use of a mask over their mouth during FL did not result in a significant difference in aerosol counts compared with visits without patients' use of masks, except for particle size of 1 μm. With the exception of particle size of 0.7 μm, the number of people present in the examination room was not significantly associated with mean aerosol counts. However, in multivariate analysis, taking into account the number of people in the room, duration of visit, and mask usage during scoping (Table 3), we observed that rooms with high air exchange had significantly higher reductions in aerosol levels for aerosol sizes 1 μm or greater during FL. For smaller particles (<1 μm), room flow rate did not appear to be associated with particle counts. In the same analysis, mask use and number of people present were not significantly associated with mean aerosol count for any particle size (Table 4).

Discussion

The COVID-19 pandemic has required a closer examination of airway procedures and the risk they may pose to both patients and clinicians. Given the exposure of otolaryngologists to the upper respiratory tract, there is understandable concern that common procedures such as FL may be aerosol generating and as such pose a higher baseline risk of virus transmission. The goal of this study was to determine if FL generates aerosol counts greater than baseline in the clinical setting. To this end, we used 2 different OPS instruments and looked for baseline changes using Bayesian OCPD. Our study suggests that FL is likely not an AGP, which supports the preliminary observations made by earlier studies on FL by Rameau et al[20] and Boorgu et al.[21]

In comparing scoped and nonscoped patient visits, no increases in aerosols over baseline were appreciated. Rooms with higher air exchange rates were found to have significantly higher reductions in aerosol counts overall, which is in agreement with the Centers for Disease Control and Prevention recommendations for increased ACH for removal of airborne pathogens.[22] However, the differences in exchange rates were not associated with aerosol levels during FL procedures, including during the application of topical nasal spray anesthetic.

We used 2 different OPS instruments to quantify aerosol counts. The OPS instruments have been described in other aerosol studies. In a preliminary study, Rameau et al[20] used OPS measurement to examine FL in 2 healthy volunteers and revealed insignificant aerosol generation compared with breathing and phonation. Novel quantitative studies using OPS instruments have observed aerosol spikes with CO_2 laser surgery, direct laryngoscopy, endoscopic sinus surgery, and anterior skull base surgery.[18,23] Such studies have nuanced the discussion of AGPs. Brown et al,[24] using OPS, found that elective tracheal intubation, an established AGP, produced appreciable aerosol counts during extubation that were 35-fold less than that of a volitional cough. A study using OPS by O'Neil et al[25] found that bronchoscopy without nebulized medication administration and noninvasive ventilation were non–aerosol generating as well.

Limitations

We acknowledge some limitations with this study. Given limited availability of negative-pressure rooms (12 ACH), the data were split comparing low ACH rooms vs higher ACH rooms. This limited the comparison of negative-pressure rooms vs standard examination rooms. There are also limitations that exist within OPS technology. Rameau et al[11,20] highlighted that OPS instruments are typically calibrated against polystyrene latex spheres rather than aerosols or droplets, which underscores a potential yet fundamental source of error to size and count particles accurately. Despite this, portability and convenience have made OPS usage suitable for dynamic clinical research in both cadaveric and patient studies.[17,18,20,23,24] However, other sophisticated instrumentation, such as interferometric Mie imaging or laser diffractometry, has been recommended in supplementation of OPS, which should be considered in future studies.[20] Other instrumentation used in the aerosol literature include the cascade impactor. The cascade impactor is a well-published particle sizing method that describes aerosol sizes

and distribution by inertial separation of particles based on mass into a series of consecutive chambers. This method has been used, for example, in a cadaveric study by Boorgu et al[21] to describe the lack of aerosol generation in nasal endoscopy, FL, and suctioning. Given the labor-intensive process in using cascade impactor and in analyzing its results, a movement toward OPS methods has gained traction. Namely, a comparison study for detecting aerosols in metered dose inhalers between OPS and cascade impactor by Pu et al[26] concludes that OPS methods have linearly correlated detection especially in the 2- to 5-um range, although with blunted particle counts when compared with that of the CI. While OPS is limited by decreased sensitivity and poorer aerodynamic description compared with cascade impactor, the increased mobility and usability while maintaining characterization of aerosol trends are ideal for real-time patient interactions. Other limitations of this study include lack of standardization with respect to duration of patient visit, which could have influenced the average number of aerosol particles per visit. Given that this was a clinical study, standardizing the duration of sampling would be impractical because of the variable duration of clinic visits. Every attempt was made to minimize traffic into and out of the examination room once sampling was initiated. However, invariably, there were situations where aerosols counts may have been affected by this traffic, albeit a small number of cases.

To our knowledge, our study is the first application of the Bayesian OCPD on aerosol particle count time-series data collected during an FL. Time series events are commonly observed in clinical medicine. These are often physiological events with pathological perturbations. Although initially described to identify change points in time-series data in finance and engineering, the Bayesian OCPD algorithm has been used to identify change points in epilepsy,[27] preterm infant breathing and bradycardia,[28] and the dynamics of COVID-19 transmissibility.[29] The strengths of the algorithm include “online” timely detection of change points without segmentation of the time-series data and its applicability on multivariate data sets, such as these aerosol data. A major limitation of the algorithm is the need for user-defined model hyperparameters. This is, however, overcome by recent improvements in the algorithm, where it can learn model hyperparameters, such as hazard function, without the need for user input. This model has a promising application for future aerosol studies.

This study supports that office FL is not an AGP. There has been speculation throughout the COVID-19 pandemic that FL itself is aerosol generating either through instrumentation of the nasal mucosa or because of the scope examination triggering cough, gag, and sneezing. This was not observed in our study, and these findings should provide some reassurance to otolaryngologists routinely performing FL. The findings in this study do not support the need for a negative-pressure room. However, it should be noted that this study did not examine the effect of FL on droplet generation, which is defined by the World Health Organization as respiratory aerosols greater than 5 μm.[30] Therefore, we do recommend droplet precautions (use of surgical mask, eye protection, gloves, and gown) during FL. Given the important information gained from patient phonation during FL, we do not recommend eliminating this portion of the examination; however, one option would be to keep a mask over the patient’s mouth to prevent potential droplet transmission. Further study into the risk of droplet transmission during FL could potentially revise these recommendations.

Conclusions

In this cohort study, findings support that the office FL procedure, including topical spray administration, was not aerosol generating in the real-time clinical setting. The nuanced understanding of the risk of aerosol generation in common otolaryngology procedures should help inform current clinical practice to mitigate the risk of COVID-19 transmission as well as with other pathogens transmissible through aerosols.

Notes

Supplement.

eAppendix. Bayesian Online Change Point Detection (BOCPD)

eFigure 1. Overview of Bayesian online changepoint detection.

eFigure 2. Bayesian OCPD on simulated data.

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Figures and Tables

Table 1.

Baseline Characteristics

Characteristic	No. (%)		*P* value
	Scope visits	Nonscope visits	
Duration of visit, mean (SD), min	18 (9.8)	14 (10)	.01
No. of people, mean (SD)	3.5 (0.69)	3.6 (0.62)	.46
Nasal spray			
Not used	13 (14)	43 (100)	<.001
Used	78 (86)	0	
Masking over mouth during scope examination			
No	51 (56)	NA	NA
Yes	40 (44)		
Room type			
High airflow	43 (47)	13 (30)	.09
Low airflow	48 (53)	30 (70)	

Figure.

Sequence of Multiple Aerosol Data Collected During In-Office Laryngoscopy and Their Corresponding Run Lengths

A, Representative plot from a 19-minute visit (38 time points of 30-second bins) during which scoping was performed. Vertical dashed lines demarcate the time nasal spray was administered (time point 16; 8 minutes into visit) to the end of the scoping event (time point 26; 12.5 minutes into visit) and span the time window of aerosol-generating procedure, during which a significant change in aerosol particles is expected. The nonsignificant change in aerosol concentration is further confirmed by the plot (B) that shows a single run length throughout the visit. C and D, Representative plots from a nonscoped visit duration of 27.5 minutes. Nonscoped visits are without the vertical dashed lines. Max indicates maximum.

Table 2.

Univariate Analysis Examining Examination Type, Mask On or Off, Number of People in Room, and Room Type

Category	Aerosol particle count, average particles/cm^3						
	0.02-1 µm	**0.3 µm**	**0.5 µm**	**0.7 µm**	**1.0 µm**	**2.0 µm**	**5.0 µm**
Examination type							
Scoped	1.44×10^8	3.39×10^6	3.99×10^4	3.06×10^5	3.45×10^4	8.49×10^4	1.85×10^4
Nonscoped	1.21×10^8	2.98×10^6	3.39×10^4	2.79×10^5	3.92×10^4	1.02×10^5	2.43×10^4
t Statistic	1.583	1.056	1.205	0.715	−1.118	−1.239	−2.03
P value	.12	.29	.23	.48	.27	.22	.046[a]
Mask on							
Yes	1.31×10^8	3.56×10^6	4.31×10^4	3.49×10^5	4.23×10^4	1.00×10^5	2.12×10^4
No	1.54×10^8	3.27×10^6	3.74×10^4	2.72×10^5	2.84×10^4	7.28×10^4	1.63×10^4
t Statistic	−1	0.636	1.076	1.949	2.683	1.632	1.43
P value	.32	.53	.29	.06	.01[a]	.12	.16
No. (people)							
3	1.35×10^8	3.36×10^6	4.15×10^4	3.32×10^5	3.85×10^4	9.30×10^4	2.02×10^4
4	1.46×10^8	3.28×10^6	3.57×10^4	2.74×10^5	3.54×10^4	9.02×10^4	2.01×10^4
5	1.07×10^8	2.59×10^6	2.55×10^4	1.74×10^5	2.32×10^4	7.92×10^4	2.44×10^4
6	7.04×10^7	1.71×10^6	2.36×10^4	1.68×10^5	1.12×10^4	1.57×10^4	3.94×10^3
F statistic	0.658	0.535	1.509	2.675	1.704	0.428	0.592
P value	.58	.66	.22	.05[a]	.17	.73	.62
Room type							
Low flow	1.55×10^8	3.75×10^6	4.38×10^4	3.22×10^5	2.81×10^4	6.04×10^4	1.42×10^4

[a] Significant at $P \leq .05$.

Table 3.

Multivariate Analysis of Aerosol Particle Count During Visits in Which Flexible Scope Examination Was Performed

	0.02-1 µm		0.3 µm		0.5 µm		0.7 µm		1.0 µm		2.0 µm	
	β[a]	*P* value	β	*P* value	β	*P* value	β	*P* value	β	*P* value	β	*P* v
Mask on, yes	−0.026	.40	0.010	.38	0.010	.50	0.013	.23	0.015	.18	−0.001	.93
No. of people	−0.016	.45	−0.011	.18	−0.017	.11	−0.015	.05	−0.019	.02[b]	−0.015	.1(
Duration of visit	0.001	.75	0.000	.73	0.000	.74	−0.001	.31	−0.001	.05[b]	−0.001	.2(
Duration of scoping	−0.011	.43	0.002	.61	0.009	.15	0.008	.07	0.005	.24	0.002	.7(
Examination room, high flow	0.025	.45	0.010	.39	0.014	.36	0.003	.79	−0.046	<.001[b]	−0.078	<.(

[a] β: regression coefficients. Positive values mean an increase in mean aerosol count with increasing value of the corresponding predictor.

[b] Significant at $P \leq .05$.

Table 4.

Multivariate Analysis of Aerosol Particle Count During Visits in Which Flexible Scope Examination Was Not Performed

	0.02-1 µm		0.3 µm		0.5 µm		0.7 µm		1.0 µm		2.0 µm	
	β[a]	*P* value	β	*P* value	β	*P* value	β	*P* value	β	*P* value	β	*P* v
No. of people	0.035	.27	−0.017	.21	−0.028	.13	−0.021	.13	−0.006	.65	0.011	.45
Duration of visit	−0.001	.66	0.000	.84	0.000	.68	−0.001	.49	−0.002	.08	−0.002	.04
Examination room, high flow	0.058	.16	0.039	.03[b]	0.049	.04[b]	0.032	.07	0.017	.35	0.004	.85

[a] β: regression coefficients. Positive values mean an increase in mean aerosol count with increasing value of the corresponding predictor.

[b] Significant at $P \leq .05$.