

Main Article

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Risk of disease transmission from flexible nasoendoscopy during the coronavirus disease 2019 pandemic

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Abstract

Background. Concerns have emerged regarding infection transmission during flexible nasoendoscopy.

Methods. Information was gathered prospectively on flexible nasoendoscopy procedures performed between March and June 2020. Patients and healthcare workers were followed up to assess for coronavirus disease 2019 development. One-sided 97.5 per cent Poisson confidence intervals were calculated for upper limits of risk where zero events were observed.

Results. A total of 286 patients were recruited. The most common indication for flexible nasoendoscopy was investigation of 'red flag' symptoms (67 per cent). Forty-seven patients (16 per cent, 95 per cent confidence interval = 13–21 per cent) had suspicious findings on flexible nasoendoscopy requiring further investigation. Twenty patients (7.1 per cent, 95 per cent confidence interval = 4.4–11 per cent) had new cancer diagnoses. Zero coronavirus disease 2019 infections were recorded in the 273 patients. No. 27 endoscopists (the doctors and nurses who carried out the procedures) were followed up. The risk of developing coronavirus disease 2019 after flexible nasoendoscopy was determined to be 0–1.3 per cent.

Conclusion. The risk of coronavirus disease 2019 transmission associated with performing flexible nasoendoscopy in asymptomatic patients, while using appropriate personal protective equipment, is very low. Additional data are required to confirm these findings in the setting of further disease surges.

Introduction

Flexible nasoendoscopy (FNE) is essential in the diagnosis and management of benign and malignant pathology in otolaryngology. It involves the insertion of a flexible scope into the nasal cavity and thence into the pharynx, and allows the direct visualisation of inflammatory, infectious and neoplastic processes in the mucosa. There is no adequate radiological substitute for the diagnosis of most laryngopharyngeal pathology, including many early cancers.

Prior to the coronavirus disease 2019 (Covid-19) pandemic, FNE was carried out in most otolaryngology units in high volumes, with minimal or no personal protective equipment (PPE). However, in the setting of the pandemic, concerns have arisen following reports of a case of 14 medical staff becoming infected after an endoscopic procedure in Wuhan (a case subsequently refuted),¹ and anecdotal reports of otolaryngologists being at particular risk from patient-to-doctor infection.²

The major risks to otolaryngologists associated with FNE are the result of high viral loads in the nasopharynx, even in asymptomatic and pre-symptomatic patients.^{3,4} Endoscopes are in close contact with the patient's airway, and can easily be contaminated with respiratory secretions by either direct contact or droplets.⁵ In addition, stimulation and irritation of the upper airway can provoke the expulsion of droplets and aerosols through sneezing, coughing and gagging, in an uncontrolled fashion. Simulated sneeze events have generated maximal aerosol distribution at 30 cm, extending up to 66 cm.⁶

In the early stages of the pandemic, concerns about the possibility of infection transmission to healthcare workers led to significant decreases in the number of FNE procedures performed. However, large reductions in FNE procedures may result in delayed diagnoses of pharyngolaryngeal cancers, and possible loss of the window wherein early cancers can be treated successfully and with minimal morbidity.

Many guidelines have been developed very expeditiously to mitigate the risk of infection, but most have not been subjected to the usual peer review processes that existed before the pandemic and there is a paucity of data on the topic. A recent systematic review found no study containing data on severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) patients undergoing FNE, and concluded that there was a substantial

lack of research, precluding any formal conclusions about the safety of FNE during the pandemic.⁷ This study aimed to evaluate the performance of FNE during the pandemic in a practical and pragmatic way, balancing the risks with the obvious benefits of the procedure.

Materials and methods

We conducted a combined retrospective and prospective observational study. Ethical approval was obtained from the Cork Clinical Research Ethics Committee, with data protection approval obtained at the respective study sites. Eligible participants were patients presenting to otolaryngology units at two participating hospitals between 15th March and 30th June, who were considered to require FNE as an essential part of their evaluation. The retrospective component of the study involved those patients included before the date of ethical approval (27th April 2020); the prospective component concerned those patients recruited after this date. Written consent for the processing of personal data was taken from the participants recruited prospectively.

The following information was gathered: patients' demographic details; the indications for FNE; whether patients self-isolated ('cocooned') prior to the appointment; whether pre-procedure Covid-19 testing was carried out and results of the same; the type of room used for PPE; the use of video stack systems; details of the PPE used; and the findings of FNE. 'Cocooning' (shielding or self-isolation) is defined by the Health Services Executive in Ireland as 'staying at home as much as possible and avoiding physical contact with other people'; it was advised in high risk groups, including people aged over 70 years and those with cancer.⁸

Patients were followed up by telephone 14 days after the procedure to assess whether they had developed symptoms of Covid-19 (via a survey of cardinal symptoms), or had been tested and diagnosed with the disease. Healthcare workers were followed up at 30-day periods during the study period to assess whether they had developed symptoms of, or had been diagnosed with, Covid-19.

Data were gathered from one hospital not receiving Covid-19 patients, the South Infirmity Victoria University Hospital in Cork (the second largest city in Ireland), and a hospital receiving Covid-19 patients, the University Hospital Waterford. The South Infirmity Victoria University Hospital is a 192-bed, mixed medical and elective surgical hospital, with a dedicated otolaryngology emergency department. The University Hospital Waterford is a 429-bed, acute medical and surgical hospital, with a dedicated emergency department.

The SARS-CoV-2 case notification rate per 100 000 population was reported in Ireland for 30th March and 30th June, along with other pertinent Covid-19 epidemiology data from reports of the Health Surveillance Protection Agency in the Republic of Ireland.^{9,10} For the study period, only cumulative incidence reports are available, with 14-day incidence reports only being published from September 2020.

Statistical analysis

Confidence intervals were calculated for binary variables using the Agresti-Coull method. One-sided 97.5 per cent Poisson confidence intervals were calculated for upper limits of risk where zero events were observed. While no sample, however large, can show that there are no risks associated with a procedure, the use of a one-sided 95 per cent confidence limit

Table 1. Demographics, indications for flexible nasoendoscopy and findings*

Parameter	Cases (%)
Gender	
– Male	51
– Female	49
Indications	
– Red flag head & neck symptoms (dysphagia, dysphonia)	67
– Symptoms in patients with HNC history	22
– Infection	4
– Other	7
Findings	
– Suspicious findings requiring investigation	16
– New cancer diagnosis	7

*Total number of patients = 286. HNC = head and neck cancer

can be used to give an estimate of the highest incidence of events that is consistent with observing no events in a sample of a given size.¹¹

Results

Patient and nasoendoscopy details

A total of 286 patients (51 per cent male) were recruited. Clinical and demographic features are given in Table 1. The most common indication for FNE was investigation of 'red flag' symptoms (67 per cent). Forty-seven patients (16 per cent, 95 per cent confidence interval (CI) = 13–21 per cent) had suspicious findings on FNE requiring further investigation. Of these, 20 patients (7.1 per cent, 95 per cent CI = 4.4–11 per cent) had new cancer diagnoses and 2 more had high-grade dysplasia diagnoses.

Patient pre-procedure status

All patients completed a questionnaire on arrival at the hospital to confirm that they had no symptoms of Covid-19, had had no contact with a confirmed case of Covid-19, and had not travelled abroad during the preceding 14 days. Sixty-five patients (24 per cent, 95 per cent CI = 20–30 per cent) were cocooned for the 14 days leading up to the FNE. Only 6 per cent ($n = 16$) of 269 patients for whom data were available had Covid-19 swabs taken prior to FNE; all of these Covid-19 swabs were negative.

Nasoendoscopy location and technique

Eighty-one per cent of the FNE procedures were performed in a hospital not receiving Covid-19 patients. All FNE procedures were performed in the same consultation room rather than a separate procedure room. Rooms did not have mechanical ventilation or negative pressure. All FNE procedures were carried out using video stack systems.

Personal protective equipment

The procedures were performed by a mix of attending surgeons, residents and advanced nurse practitioners. Gloves, and waterproof aprons or gowns were worn during all FNE

procedures. Twenty-six per cent ($n = 73$) of FNE procedures were carried out using filtering facepiece code 3 (FFP3) (equivalent to N99) masks and goggles. Fifty-nine per cent ($n = 169$) of FNE procedures were carried out using FFP code 2 (equivalent to N95) masks and goggles. Ten per cent ($n = 30$) of FNE procedures were carried out using FFP2 masks and no goggles. This information was not recorded in 5 per cent ($n = 14$) of cases.

Patient follow up

Five per cent of patients ($n = 13$) were lost to follow up and were not contactable. Of the remaining 273 patients, none developed Covid-19. Nine per cent of patients ($n = 25$) were swabbed for Covid-19 in the 14-day follow-up period. All of these swabs were negative. Of note, all of these patients were swabbed as they were booked for further procedures in the operating theatre.

Healthcare worker follow up

Twenty-seven healthcare workers were recruited to participate in the study; these comprised 10 attending surgeons, 12 residents, 2 advanced nurse practitioners and 3 nurses. Two healthcare workers developed Covid-19 symptoms and were tested. Their symptoms self-resolved and their tests were negative. No other healthcare workers had positive swabs for Covid-19 in the follow-up period.

Statistical findings

As no patients in our cohort developed Covid-19, we determine that the risk of asymptomatic patients developing Covid-19 after an FNE is 0–1.3 per cent, based on the upper 97.5 per cent Poisson confidence limit. No healthcare workers developed Covid-19, which similarly gives an upper Poisson confidence limit of 1.3 per cent per procedural exposure. However, given that healthcare workers have multiple exposures, this equates to a cumulative risk of 0–12.2 per cent over 10 exposures. At this rate (which is the upper confidence limit for risk), it requires 54 exposures before the cumulative risk reaches 50 per cent.

Epidemiology in Ireland

The total number of confirmed Covid-19 cases in Republic of Ireland during the study period was 25 474. The national cumulative incidence of confirmed cases per 100 000 population was 534.96. The total number of deaths reported was 1478, with a case fatality ratio of 5.8.

Discussion

Coronavirus disease 2019 has had a major impact on otolaryngology practice. Particular concerns have been raised regarding FNE because of: the known high viral loads in the pharynx, even in pre-symptomatic and asymptomatic patients; the close proximity of the endoscope to the patient's airway during the procedure; and the risk of disease transmission by droplets or direct contact. As a response, many professional organisations have issued guidelines that have recommended limiting FNE to cases with 'red flag' head and neck cancer symptoms, or cases where FNE results are considered likely to influence immediate management. A greater use of less invasive

diagnostic procedures where feasible has been advocated.¹² However, there remains a lack of hard data to support these guidelines.

During most of the study period, there was a national lockdown in place; a phased re-opening of the country was not completed by the time recruitment ceased. During this period, there were 25 474 cases of Covid-19 diagnosed in Ireland, with a national cumulative incidence of confirmed cases of 534.96. The number of FNE procedures included in this study ($n = 286$) represents a very small percentage (10–15 per cent) of what would normally have been performed in the participating hospitals during this time period, reflecting the significant impact on service of Covid-19.

Our results suggest that, with appropriate measures in place, the risks associated with FNE are low for both patients and healthcare workers. Twenty per cent of patients had suspicious findings on FNE and a new cancer was diagnosed in 20 patients, underlining the importance of FNE in detecting significant pathology. This is of particular relevance to pharyngolaryngeal cancers, given the improved chances of cure with early diagnosis and treatment. Moreover, our analysis would suggest that patients are at higher risk of not having cancers diagnosed (7.0 per cent) than of acquiring Covid-19 during the hospital encounter (estimated risk of less than 1.3 per cent). However, this risk analysis should be interpreted in the knowledge that FNE procedures during the study period were largely limited to patients with strong clinical indications.

We have not sought to define what the correct biosafe precautions are. Nevertheless, it is clear that there was high adherence to PPE guidance, with 85 per cent of all healthcare workers wearing FFP2 or FFP3 masks with eye protection. Previous studies have not shown FFP2 masks to be superior to surgical masks for preventing work place respiratory viral infections in healthcare workers.¹³ Work is needed to elucidate the optimal PPE required, as concerns mount regarding the availability of PPE in the coming months.¹⁴

- Advice issued at the coronavirus disease 2019 (Covid-19) outbreak suggested deferring flexible nasoendoscopy (FNE) to all but the most pressing of clinical scenarios
- This is because of the high carriage of severe acute respiratory syndrome coronavirus-2 in the nasopharynx and the close proximity of the endoscope to the airway
- With correct precautions and personal protective equipment, the risk of asymptomatic patients developing Covid-19 after FNE is 1.3 per cent
- No healthcare workers developed Covid-19, similarly giving an upper Poisson confidence limit of 1.3 per cent per procedural exposure
- Of patients, 16 per cent had clinical findings requiring further investigation and 7.1 per cent had new cancer diagnoses
- The transmission risk associated with performing FNE using filtering facepiece code 2 or 3 masks in patients screened to exclude symptomatic Covid-19 is very low

The present study has limitations that should be considered when interpreting our findings. For most of the study period, Ireland was in a state of lockdown, which may have suppressed the community transmission of the SARS-CoV-2 virus. This, combined with screening of patients to assess symptoms, contact or travel, prior to attendance, may have reduced the likelihood of patients presenting to otolaryngology departments with asymptomatic Covid-19. In addition, all procedures were performed with a high level of precaution and with PPE, and so our results may not be applicable to FNE procedures performed without video stack systems or appropriate PPE. The use of imaging modalities to detect these cancers has not been explored in this paper, and the 7 per cent risk

of missing a cancer negates the fact that many of the patients could have undergone imaging to identify these. Finally, the total number of patients included is still small, and we cannot rule out a small risk of Covid-19 infection to healthcare workers, as our statistical analysis demonstrates.

Conclusion

This study reports the experience of two institutions performing FNE during the Covid-19 pandemic and the clinical findings point to the greater risk being that of failing to scope. Low levels of infection may be reflective of national restrictions facilitating pre-procedure cocooning and the high levels of adherence with PPE amongst healthcare workers. The data support the importance and judicious use of FNE in our practice. However, additional data collection in a larger cohort is required to verify these findings in the setting of further disease surges.

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Competing interests. None declared

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