ORIGINAL RESEARCH

Pre-operative testing for SARS-CoV-2 and outcomes in otolaryngology surgery during the pandemic: A multi-center experience

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Abstract

Introduction: Preoperative testing for COVID-19 has become widely established to avoid inadvertent surgery on patients with COVID-19 and prevent hospital outbreaks.

Methods: A prospective cross sectional study was carried out in two university hospitals examining the pre-operative protocols for patients undergoing otolaryngology surgery and the incidence of COVID-19 within 30 days of surgery in patients and the otolaryngologists performing surgery.

Results: One hundred and seventy-three patients were recruited. One hundred and twenty-three (71%) patients "cocooned" for 14 days prior to surgery. All completed a questionnaire prior to admission. One hundred and fifty-six patients (90%) had reverse transcriptase-polymerase chain reaction (RT-PCR) nasopharyngeal swabs, 14 patients (8%) had CT thorax. No cases of COVID-19 were detected among patients followed up at 30 days. Two surgeons developed COVID-19 early during the study period.

Conclusion: Current pre-operative testing protocols consisting primarily of questionnaires and RT-PCR resulted in zero cases of COVID in this cohort. It is possible that COVID-19 restrictions and high proportion of patients cocooning preoperatively were factors in ensuring a low rate of COVID-19 post-operatively.

KEYWORDS

COVID19, pre-operative testing, SARS-CoV-2

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1 | INTRODUCTION

Coronavirus disease 2019 (COVID-19) has had a significant impact on health care delivery globally since it was declared a pandemic.¹ During the first wave of the pandemic, reductions in surgical volume were necessary to create capacity to care for the surge of patients with COVID-19. Elective surgery was also greatly impacted by fears of disease transmission to other patients and health care workers within hospitals, and early reports of a very high case fatality rate of up to 20.5% in patients diagnosed with COVID 19 in the peri-operative period.^{2,3}

As the initial surge of the pandemic subsided and elective surgery resumed, pre-operative testing was widely adopted to test patients for COVID-19 prior to admission for elective surgery, with the aim of reducing the risks of surgery to patients with asymptomatic COVID-19, and to reduce the risk of hospital outbreaks.⁴ However, given the time sensitive nature of the situation testing protocols were developed and instituted without the normal rigorous scientific process and the evidence behind the protocols has largely been extrapolated from indirect evidence from meta-analysis on testing of symptomatic patients,⁵ and there remains little published evidence regarding the effectiveness of pre-operative testing in ruling out infection in asymptomatic patients.

The purpose of the present study was to report on the preoperative testing protocols put in place in two university hospitals in the Republic of Ireland.

2 | METHODS

Approval for the study was obtained from the Clinical Research Ethics Committee and Data Protection Offices on respective sites. The study comprised a prospective cohort study examining the preoperative testing protocols put in place for COVID-19. For most of the period of this study, standard pre-operative testing in Ireland included completion of a questionnaire prior to hospital admission, enquiring about symptoms of COVID-19, any contact with a confirmed case of COVID-19 within the preceding 14 days, or travel outside the state in the preceding 14 days (see Appendix A), and reverse transcriptase-polymerase chain reaction (RT-PCR, AllplexTM 2019 nCoV Assay, Seegene Inc.) nasopharyngeal and oropharyngeal swabs, taken within 48 hours of hospital admission. RT-PCR was not universally performed during the earliest period of the study owing to shortage of testing capacity at that time. In addition, some patients undergoing H&N resection underwent non-contrast CT chest within 24 hours of surgery to assess for COVID (separate from staging scans). This was in keeping with recommendations from professional bodies at that time.⁶

Variables collected included patient demographics, diagnosis, details of surgery performed, whether patients had "cocooned" prior to hospital admission, preoperative screening procedures (questionnaire, PCR, CT chest), PPE used in the operating room, and length of hospital stay. "Cocooning" (shielding/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" and was advised in high risk groups including people >70 and those with cancer.

The study was carried out in the South Infirmary Victoria University Hospital (SIVUH), Cork, and the Royal Victoria Eye and Ear Hospital (RVEEH), Dublin 2. Both hospitals were designated as non-COVID-19 receiving units during the pandemic.

Included patients were those undergoing otolaryngology surgeries between March 15, 2020 and June 30, 2020 in two hospitals in the Republic of Ireland and the otolaryngologists that operated on them. Informed consent was obtained from all participating patients. The study cohort included patients who were also enrolled in the multicenter CovidSurg Cancer study. In the case of SIVUH, study participants who had undergone surgery prior to the date of ethical approval (April 27) were enrolled retrospectively, and those undergoing surgery after this date enrolled prospectively. In the case of RVEEH, the study comprised a retrospective review of data that had prospectively been collected as part of the CovidSurg Cancer study.⁷

The primary outcome measure was occurrence of COVID-19 in any patients within the 30 days of surgery. Secondary outcomes measures were occurrence of symptoms of COVID-19 in patients without a positive test, and diagnosis of COVID-19 among members of the otolaryngology teams treating the patients.

Patients were followed up by telephone 30 days after the procedure to assess if they developed symptoms (survey of cardinal symptoms asked) of or were tested and diagnosed with COVID-19. Members of otolaryngology teams were surveyed at the end of the study period if they had contracted COVID-19.

2.1 | Epidemiology of COVID-19 in Ireland

Data on the 14 day cumulative incidence per 100 000 population for the duration of the study period and the total number of tests performed was obtained from daily reports from the Health Protection Surveillance Center⁸ and the European Center of Disease Control.⁹

The study was reported according to STROBE guidelines.¹⁰

3 | RESULTS

Patient demographics are presented in Table 1, and details of surgery performed and post-operative complications are shown in Table 2.

Details of preoperative testing and personal protective equipment (PPE) worn during the surgeries shown in Table 3. All patients completed a questionnaire on arrival at the hospital confirming that they had no symptoms of COVID-19, no contact with a confirmed case of COVID-19, and no foreign travel within the preceding 14 days. One hundred and twenty-three (71%) patients had "cocooned" in the 14 days prior to their procedure. All patients "cocooned" from the time their RT-PCR test was taken until the time of their surgery. One hundred and fifty-six (90.1%) patients underwent RT-PCR naso-pharyngeal and oropharyngeal swabs within 48 hours of surgery, all of which were negative for detection of SARS-CoV-2.

TABLE 1 Cohort demographics

		Number	Percentage (%)
Gender	Male	97	56
	Female	76	44
Performance status	ECOG 0	135	78
	ECOG 1	30	17
	ECOG 2	6	3
	ECOG 3	1	1
	ECOG 4	1	1
		Median	Interquartile range
Age (years)		56	41 to 69 years
Length of stay (days)		2	1 to 3 days

Fourteen (9.4%) patients had CT thorax within 24 hours of surgery. There were no positive findings on these scans suggestive of COVID-19.

3.1 | 30 day Follow up

Seventeen of patients were lost to follow up and were not contactable. Of the 156 patients who were contactable, none developed symptoms of or tested positive for COVID 19.

Nine patients were retested for COVID-19 in the postoperative period during the same in-patient stay due to postoperative pyrexia and/or respiratory symptoms. Two patients were retested twice, and three patients were retested three times, all cases were negative for detection of SARS-CoV-2. Three patients were subsequently diagnosed with aspiration pneumonia and one each with volvulus, acute kidney injury and a pharyngo-cutaneous fistulae. The average length of stay in patients who were re-swabbed was 22 days.

Two otolaryngologists tested positive for COVID-19 early during the study period. Neither of these had contact with any confirmed patients with COVID-19 and they were considered to have acquired the infection outside of the hospital. Both were self-managed at home and returned to work after resolution of symptoms. Two further surgeons were tested for COVID-19 during the study period, both tested negative and remained well.

3.2 | Epidemiology of COVID-19 in Ireland

The 14 day incidence rate of COVID-19 cases per 100 000 population in Ireland notified to public health authorities is demonstrated in Figure 1. The number of procedures included per epidemiological week is shown in Figure 2. The peak number of cases was reached in week April 20 to 27, 2020; however, it is likely that the true peak was much earlier due to the smaller number of tests carried out during the initial stages of the pandemic (Figure 3). Figures 1 and 3 reproduced from official Irish government bodies.

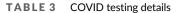
TABLE 2 Procedure details

		Number	Percentage
Type of surgery	Cancer	105	61
	Non-Cancer	68	39
Procedure type	Diagnostic	42	24
	Resection of Mucosal Cancer	18	10
	Resection of Non Mucosal Cancer	25	14
	Laser Microsurgery	21	12
	Benign	67	39
Operative site	Ear	3	2
	Hypopharynx	8	5
	Larynx	33	19
	Nasal cavity	9	5
	Neck	15	9
	Oral cavity	26	15
	Oropharynx	17	10
	Salivary	18	10
	Skin	3	2
	Thyroid	41	24
Post-operative complications	None	165	95
	Aspiration pneumonia	3	2
	Bleeding	2	1
	Volvulus	1	1
	Pharyngocutaneous Fistula	1	1
	AKI	1	1

4 | DISCUSSION

COVID-19 continues to pose a major public health problem with increasing cases, hospitalizations, and deaths globally, and has had a major impact on ability to deliver elective surgical care. The importance of pre-operative testing for COVID-19 among elective surgical patients is to reduce risks to patients, who may have a worse outcome if they become symptomatic in the perioperative period, as well as to reduce the risk of hospital outbreaks, which may lead to infection of other patients, health care workers, and need for health care workers to self-isolate, with adverse impact on the ability of the hospital to provide elective surgical services. However, testing protocols have been developed largely without evidence basis, and questions regarding the effectiveness of current strategies remain unanswered. In particular, the sensitivity of preoperative testing remains largely unknown in asymptomatic patients undergoing elective surgery and much of the available evidence has been extrapolated from a metaanalysis of symptomatic patients.⁵ With this in mind, we wished to investigate the outcomes of pre-operative testing protocols in place in two otolaryngology units in the Republic of Ireland.

		Number	Percentage
Pre-operative self-reported self-isolation	Yes	123	71
	No	50	29
Pre-operative COVID testing measures	None	17	10
	Single swab	138	80
	Single swab and CT thorax	5	3
	Two swabs	4	2
	Two swabs and CT thorax	9	5
HCW PPE intraopartively	PAPR	2	1
	FFP3 with goggles	58	34
	FFP3 without goggles	16	9
	FFP2 with googles	15	9
	FFP2 without goggles	48	28
	Standard	24	14
	Not recorded	10	6
Thirty days post-op positive for COVID-19	Patient	0	
	HCW	2	



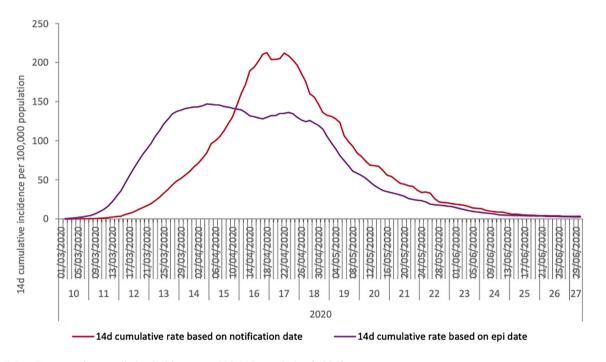
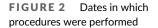


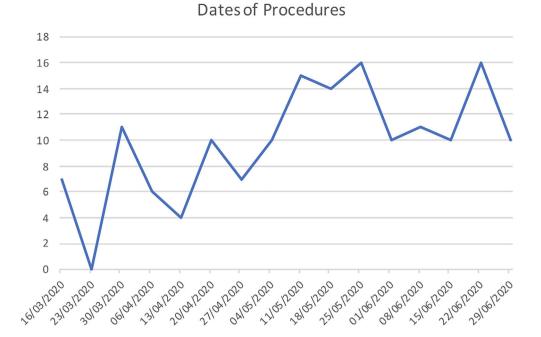
FIGURE 1 Fourteen day cumulative incidence per 100 000 population (HSPC)

Patients undergoing otolaryngology procedures were chosen as they were considered to represent a particularly high-risk group for potential disease transmission to health care staff, owing to the proximity of the surgical team to the patient's airway and pharynx during the operation, the potentially high viral loads in the pharynx in asymptomatic or pre-symptomatic patients,^{11,12} and the use of instruments which may lead to aerosolization, including electrocautery, lasers, and saws.¹³ Thus, we believe that the present cohort of patients undergoing otolaryngology surgery was a very appropriate cohort for this study. Indeed, the risk of aerosolization from surgical technique is not unique to otolaryngology.

In the present study, no diagnoses of COVID-19 were made in any of the patients during 30-day follow-up. This would appear to validate the current testing protocol. A key component of the present study was the 30-day follow-up. The incubation period for COVID-19 is generally accepted to be 2 to 14 days.¹⁴ Most protocols specify the performance of COVID-19 testing 48 to 72 hours prior to surgery. However, if testing is performed too early during the incubation



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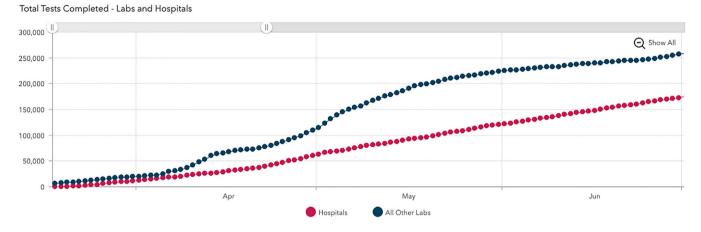


FIGURE 3 Total tests completed in Republic of Ireland for the study period (HSPC)

period, the result may be falsely negative. In addition, false negative PCR tests may arise due to insufficient collection of viral material in the specimen, laboratory errors during sampling and sample transportation.¹⁵ Therefore, there remains the risk of patients becoming symptomatic with COVID-19 during their hospital stay, despite having negative testing prior to admission, or of patients having presymptomatic or asymptomatic COVID-19 while in the hospital, with risk of disease transmission to others. Although there is increasing data on the incidence of COVID-19 positivity among patients undergoing pre-operative testing, there is a paucity of data regarding the incidence of development of COVID-19 post-operatively among patients with initial negative testing.¹⁶ In the few studies where this has been reported, this data would appear to pertain to patients who developed COVID-19 while still in-patients, or the period of follow-up is not specified.^{17,18} A major advantage of the present study was thus the systematic follow up of patients at 30 days to enquire about

diagnosis of COVID-19 or development of symptoms of COVID-19. This allowed us the opportunity to capture any patient who may have developed symptoms after hospital discharge. Of note, given the 2 to 14 day incubation period of COVID-19, a 14-day follow up would have been sufficient to capture any post-operative symptomatic case. In the present study, however, we used 30-days, to coincide with the follow-up point for patients also enrolled into the COVID-Surg Cancer study, a study whose primary endpoint is 30-day mortality.

Our results are in line with those of the largest study to date on pre-operative testing, reported by Puylaert et al, who reported no cases of symptomatic COVID-19 at 2-week follow-up among patients who tested negative by RT-PCR preoperatively, however, it is not clear in this study how symptoms or diagnosis of COVID-19 was established in patients who had been discharged from hospital.¹⁸ A large international cohort study concluded that nasopharyngeal swab testing was beneficial before major surgery in high SARS-CoV-2 risk

areas.¹⁹ Axiotakis et al also reported zero cases of COVID-19 among 170 patients undergoing preoperative RT-PCR testing preoperatively.²⁰ Specifically looking at studies including patients undergoing head and neck surgery, our results are also in line with a study of 47 head and neck patients in the United Kingdom in which there were no cases of COVID-19 diagnosed.²¹

Early in the pandemic CT thorax was suggested to have a role in pre-operative testing²² but subsequent studies failed to demonstrate its accuracy as a screening tool in the asymptomatic patients.^{23,24} Patients early in our study had this investigation carried out but as evidence, emerged protocols were changed accordingly. The evidence base has been dynamic, and guidance has changed as new evidence emerged. In general surgery, the initial advice and guidance was to advocate against the use of laparoscopy because of the aerosolization of pneumoperitoneum and through vapor formed by heat-generating cautery devices.²⁵ However, although laparoscopy has the potential to produce aerosolized blood borne viruses there was no evidence to indicate this is the effect seen in COVID-19 but there was much debate at the beginning of the pandemic about the use of minimally invasive surgical techniques²⁶ in particular around the area of appendectomy where there was a move toward non operative management and where operative management was performed there was a move toward the open appendectomy²⁷ to avoid the risks of aerosolization as described.

The pandemic has had an enormous impact on health care systems globally major changes have been required across many surgical specialties to cope with the pandemic, including changes in work practices, techniques, and prioritization of cases. Ultimately millions of operations and procedures being deferred or canceled.²⁸ Surgical strategy and work conditions for surgical teams have altered with changes in team dynamics, departmental workload and personal protective measures.²⁹ Research suggests implementation of some of these changes proposed by professional bodies has been adopted swiftly particularly in areas of organization measures but less so for PPE training and availability.³⁰ There were high levels of PPE usage in our study with no issues surrounding its provision. And although we did not investigate its impact on users interestingly, a recent survey of more than 134 surgeons from 26 countries highlighted that 54% of respondents felt their surgical performance was hampered with PPE and with most respondents felt it is an impediment for both visibility and communication and 82% reporting increased fatigue with its use.³¹

The two major limitations of this study were (a) despite being designed to maximize the capture of any case of COVID-19 postoperatively through systematic 30-day follow-up, we would not have been in a position to detect cases of COVID-19 which remained asymptomatic, unless the patient had undergone testing for other reasons; and (b) the relatively small sample size, which limits our ability to draw definitive conclusions regarding the magnitude of effectiveness of the current pre-operative testing protocol. Despite this, given the shortage of data at this time, we believe our study provides very important data that can help inform the ongoing development and validation of testing protocols. A further consideration was that during much of the period of this study, there were significant restrictions in place in Ireland, and high compliance with social distancing, and preoperative "cocooning." There was also a falling incidence of COVID-19 in Ireland during the latter part of the study, during which time a greater proportion of the procedures included in this study were carried out, although it is difficult to compare the incidence of COVID-19 during the early and later parts of the study period due to the much lower number of tests performed at the start of the pandemic. Thus, caution should be exercised in extrapolating our results to peak periods of disease surge, particularly in situations where patients who do not self-isolate pre-operatively. Finally, although pre-operative COVID-19 testing remains a cornerstone in preventing outbreaks of COVID-19 in hospitals, it does not completely supplant additional measures including optimized patient flow, social distancing within hospitals, use of masks by health care staff, hand-hygiene, and other infection control measures.

5 | CONCLUSION

In the present study, we report that a preoperative testing protocol consisting of questionnaire and RT-PCR swabs to be associated with no cases of COVID-19 infection in patients undergoing otolaryngology surgery with a 30-day follow-up. These data support use of RT-PCR swab to exclude COVID-19 prior to surgery. Further data collection in a larger cohort is required to verify these findings in the setting of further surges in open economies.

CONFLICTS OF INTEREST

None.

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SUPPORTING INFORMATION

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

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