Implementation of Preoperative Screening Protocols in Otolaryngology during the COVID-19 pandemic

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ABSTRACT

Objective: To highlight emerging pre-operative screening protocols and document workflow challenges and successes during the early weeks of the COVID-19 pandemic.

Methods: This study is a retrospective cohort study at a large, urban, tertiary-care medical center. 32 subjects undergoing operative procedures during the COVID-19 pandemic were placed into two different pre-operative screening protocols. Early in the pandemic a “high-risk case protocol” was utilized to maximize available resources. As information and technology evolved, a “universal point-of-care (POC) protocol” was implemented.

Results: 25 of 32 patients were screened prior to surgery. Three of these individuals (12%) tested positive for COVID-19. In all three cases the procedure was delayed, and the patient was admitted for treatment or discharged under home quarantine. 86% of operative procedures during this period were indicated for treatment of oncologic disease. There was no significant delay in arrival to the operating room for patients undergoing POC screening immediately prior to their procedure (p = 0.92).

Discussion: Currently, few studies address pre-operative screening for COVID-19. A substantial proportion of individuals in this cohort tested positive, and both protocols identified positive individuals. The major strengths of the POC protocol are ease of administration, avoiding subsequent exposures after testing, and relieving strain on “COVID clinics” or other community testing facilities.

Implications for Practice:

Pre-operative screening is a critical aspect of safe surgical practice in the midst of the widespread pandemic. Rapid implementation of universal point-of-care screening is possible without major workflow adjustments or operative delays.
Introduction

COVID-19, the disease caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), has become a worldwide pandemic and has significantly affected clinical practice in the United States. Healthcare providers have been required to alter their practices in order to conserve resources and limit contagion to healthy patients and staff. Perioperative services have been greatly affected due to recommendations from the Centers for Disease Control and Prevention (CDC) and American College of Surgeons to cancel or reschedule all surgeries considered elective or non-urgent.

Many urgent time-sensitive otolaryngology procedures require instrumentation of the airway which risks aerosolization of respiratory secretions and possible transmission of SARS-CoV-2 to all staff present in the operating room. Because of this risk, institutions around the world are quickly designing preoperative COVID-19 screening procedures. An institutional overview of the progressive burden disease is represented in Figure 1.

Here, we describe the preoperative testing protocols implemented by our department and institution. We also provide a retrospective review of otolaryngologic surgical patients from our center to analyze the testing results and the effects on surgical timing. This data and commentary may be of benefit to otolaryngology departments and/or hospitals navigating the pandemic worldwide.

Methods

Departmental High-Risk Case Testing Protocol

The otolaryngology department began preoperative COVID-19 testing of non-elective surgical procedures beginning March 23, 2020. This initial “High Risk” protocol was designed to efficiently utilize limited resources during ramp up of testing capacity (Figure 2a). Patients with symptoms of COVID-19, high risk exposures or patients whose surgery would involve instrumentation of the upper airway were required to be tested. The initial test was a nucleic acid amplification test developed by our institution’s clinical laboratory which required 1-2 days to result. Patients selected for testing were asked at least two days prior to surgery to visit an isolated “COVID Clinic” implemented by the institution for testing. Patients testing negative would proceed with their scheduled surgery. Following testing, patients
were asked to self-isolate and avoid all non-essential contact until the day of surgery to reduce the risk of exposure in the interim.

**Institutional Universal Point-of-care (POC) Testing Protocol**

The institution moved to a POC pre-operative testing workflow beginning April 10, 2020 for all patients undergoing a surgical procedure. ([Figure 2b](#)) ID NOW COVID-19, developed by Abbott Diagnostics (Scarborough, Maine) is the commercially available POC testing system that is currently utilized. This is an automated assay that uses an isothermal nucleic acid amplification reaction to identify SARS-CoV-2 genetic material in upper airway swab samples and gives the provider a qualitative result. The ID NOW system provides a result in fewer than thirteen minutes, making it amenable for use in a POC setting. The ID NOW COVID-19 system received an Emergency Use Authorization from the Food and Drug Administration (FDA). While the system has previously been fully tested approved for use by the FDA for the detection of other viruses and bacteria, only limited laboratory testing has been performed for the ID NOW COVID-19 system.

Under the new workflow, patients from the community are not required to visit a “COVID Clinic”. Upon registration at the hospital on the day of surgery, all patients are transported to a preoperative testing area (converted observation unit) in which a nasal swab for use with the ID NOW system is obtained. During the minutes required for the test system to provide a result, patients wait in a single-occupancy room. If the test result is negative, the patient proceeds to the preoperative preparation area. If the test result is positive, the hospital’s dedicated COVID-19 team comprising infectious disease specialists is consulted to evaluate the patient. Together with the surgical team, they decide whether it is clinically prudent to proceed with surgery using appropriate PPE for surgical staff, delay surgery and discharge the patient under quarantine, or admit the patient for further COVID-related treatment.

Inpatients undergoing a surgical procedure who are not admitted to a critical care unit are also transported to the POC pre-operative testing unit to obtain testing on the day of surgery. Inpatients who are admitted to critical care units undergo testing on the unit prior to surgery.

**Chart Review**
This study was approved by the Rush University Medical Center Institutional Review Board. A retrospective chart review was conducted on patients scheduled to undergo surgery with the otolaryngology department between March 23 and April 17, 2020. Data extracted from the electronic medical record included demographics, details on pre-operative COVID testing, surgical procedure, and delays in the preoperative phase. Institution-wide testing and COVID-19 disease burden data was also obtained.

Results

Operative Cases

Departmental operative volume was reduced by greater than 85% compared to baseline surgical activity prior to the pandemic due to cancellation of elective surgery. Twenty-five of the 29 cases performed were indicated for treatment of known or suspected head and neck cancer (86%). Three cases were characterized as emergent and all others were designated urgent or time-sensitive based on department guidelines.

High-Risk Testing Protocol

From March 23 to April 9 2020, during the period of the preliminary departmental preoperative testing policy, 22 cases were scheduled. One case was cancelled for non-COVID related reasons. None of the remaining 21 patients demonstrated any symptoms, but 15 of these cases qualified as high risk due to surgical airway instrumentation. These patients underwent preoperative screening on average 3 days prior to their procedure (range 1-9 days). One of the 15 patients under this protocol tested positive and had to be delayed (Table 1). The remaining 20 patients underwent their procedures without workflow alterations on the day of surgery.

POC testing protocol

Between April 10 and April 17, 2020, 11 patients scheduled for otolaryngologic procedures underwent preoperative screening according to the institution’s universal POC testing protocol. During this time, two patients screened positive on the day of surgery. The other 9 patients tested negative and underwent surgery as planned. Among the four “first-start” cases, the average delay from scheduled start
time until the patient entered the operating room was 19 minutes. The delay was not significantly different than the average delay during the previous weeks of the COVID-19 pandemic prior to implementation of same-day POC screening (20 min, p = 0.92). (Table 1)

Discussion

This study provides an initial overview of the strategic management of operative cases in a tertiary-care, otolaryngology department in the midst of the COVID-19 pandemic. We report two separate preoperative COVID-19 testing protocols implemented by the department, including a novel, POC testing protocol on the day of surgery.

Initial Testing Protocol

Time-delay in results reporting was the primary inefficiency of the initial testing protocol. Because of this, patients were required to make an additional visit to the hospital preoperatively placing them at added exposure risk. Additionally, the potential for exposure in the interval time to surgery would not be reflected in the test result. Though patients were screened for symptoms on the day of surgery, it is reported that asymptomatic carriers can transmit SARS-CoV-2.\(^\text{10}\)

POC Testing Protocol

Implementation of POC testing on the day of surgery helped to resolve the above issues, but was not without its own drawbacks. The sensitivity and negative predictive value of the POC testing system used by our institution is not published, to our knowledge. The manufacturer’s application for FDA emergency use approval presents some limited laboratory data on purified samples of SARS-CoV-2 genetic material, but no data for samples from human subjects.

Additionally, because of the time required for testing and patient transport, there is a potential for delay in operative start times. Preliminary data did not identify a significant delay, though we can only report on a limited number of cases. It is also unknown whether this workflow will remain efficient in the later days of this pandemic once elective surgeries are permitted. This would greatly increase the number
of patients requiring POC testing on a daily basis, and could result in many positive screening tests in a single day.

Managing Patients with Positive Preoperative Screening

Three patients (12%) tested positive for COVID-19 prior to their scheduled surgery, one under the initial departmental testing protocol and two under the institutional POC testing protocol. The initial case presented with a mass involving the right maxillary, ethmoid, and sphenoid sinuses with orbital extension resulting in proptosis and early loss of red color vision. Nasal endoscopy with biopsy was scheduled to guide further management. The patient denied classic symptoms of COVID-19 infection including shortness of breath, fever or cough. A COVID-19 test was obtained in accordance with the departmental testing protocol and resulted positive four days prior to the scheduled surgery. In light of this finding, surgery was postponed and rescheduled following a two-week quarantine. In the interim, the patient was treated medically for post-obstructive sinusitis, advised regarding strict self-quarantining measures, and referred to infectious disease. Two consecutive negative COVID-19 tests were subsequently obtained prior to the rescheduled surgery. The first of these was a lab test and the second was a POC test on the day of surgery. Amongst otolaryngologists, sinus surgery has been speculated to be a particularly high-risk procedure for virus transmission given the high viral loads in nasal and nasopharyngeal tissues and potential risks for aerosol generation. Thus, this case represents a critical near miss identified by the screening protocol. However, given that the accuracy of current testing is unknown, it is important to consider that a false positive result in cases such as this could unnecessarily delay oncologic treatment and result in poorer outcomes. If index of suspicion is low or the case is particularly time-sensitive a repeat test may decrease the likelihood of this event. Based on the current state of the pandemic and high local infection rate at the time of writing, our institution determined the benefit of screening to outweigh these risks. It is important to assess the local incidence when planning a screening protocol and subsequently re-evaluate protocols accordingly as the infectious process evolves over time.
The second patient who screened positive was a patient in critical condition requiring mechanical ventilation for known COVID-19 respiratory disease. As her clinical status improved and hospital disposition planning was underway, a repeat COVID test was performed 28 days after the initial positive result. This test resulted negative and the otolaryngology service was consulted to perform a tracheostomy for failure to wean mechanical ventilation. Surgery was scheduled for the operating room 2 days after the negative test, however, under the new institutional POC protocol, repeat COVID testing was required pre-procedure. As the patient remained in the ICU she underwent testing in the unit which subsequently resulted positive 2 days after the previous negative result. The scheduled surgery was canceled and tracheostomy is planned for a later date.

A few important points bear mentioning. This patient’s negative result may represent a false negative due to limitations of the test itself or error in obtaining an adequate specimen for testing. Due to the relatively rapid expansion of COVID-19 testing, the accuracy of testing is not yet fully understood and false negative results have been reported.\textsuperscript{12,13} Newly emerging data suggests the current POC test false negative rate may be as high as 15%.\textsuperscript{14} It is important to not underestimate the possibility of false negative results. One criticism of universal testing is the potential to create a false sense of security among medical personnel and result in relaxed use of proper personal protective equipment (PPE). A negative test result does not replace properly donned and doffed PPE, but allows for reconsideration for operative delay and reinforces heightened caution in cases which must proceed. However, as the availability of PPE is highly variable by medical facility and fluctuates even at the most equipped centers, knowledge of a patient’s COVID status can help stratify PPE use in situations where it is limited. This knowledge arms not only surgeons, anesthetists and nurses in the operating room, but also environmental services, ancillary operative staff, and pre/post-operative personnel. At the time of this study the local incidence of the disease was likely high. As the incidence declines, the negative predictive value of testing will increase and providers can be more confident in screening results irrespective of advancements in testing.
The final screen positive patient presented for an outpatient oncologic procedure from a local nursing facility. The patient had a history of chronic obstructive pulmonary disease, laryngeal cancer, and baseline shortness of breath. Upon testing positive, the patient disclosed a history of low-grade fever the day prior. Due to the patient’s history and symptoms at presentation, the procedure was delayed and he was admitted to the general medical unit. This process allowed the patient to receive prompt treatment while limiting exposure to hospital staff and use of emergency department services.

There is very limited literature regarding pre-operative screening during the coronavirus pandemic. Forrester et al highlighted a protocol similar to the departmental protocol above. Emergent cases proceeded with droplet precautions and N95 respirator masks, while urgent cases were stratified as low or high risk. Patients undergoing high risk procedures or demonstrating symptoms underwent testing or the case was delayed. A group from Spain briefly addressed screening perioperative patients with symptoms. However, to our knowledge no location has published a universal preoperative screening policy or documented implementation of rapid testing such as the POC system discussed above.

**Implications for Practice**

Overall, this study highlights screening protocols which were implemented rapidly and have undoubtedly protected medical personnel from potential operative and perioperative COVID-19 exposures. Pre-operative screening resulted in a change in operative planning for 12% of cases in this cohort. Based on preliminary data, the daily surgical workflow was not significantly delayed due to screening requirements. However, this study is notably limited by its sample size, particularly in evaluating the efficiency of same-day POC workflow. Nonetheless, it provides the initial proof of concept which can facilitate future large-scale investigations. The protocols at our institution are changing rapidly as more efficient technologies become available and experience is accrued. We anticipate continued adjustments as we emerge from the peak days of the pandemic and resume normal operative volume. Universal pre-operative screening is practical and should be considered for institutions during this unprecedented time and moving forward as operative services around the world slowly return to pre-pandemic norms.
Acknowledgements

We would like to acknowledge the Rush University Medical Center perioperative staff for their unwavering dedication to patient care in the midst of unprecedented circumstance.
References


Figure 1. Local institutional number of screened and positive patients.

Figure 2. Schematic for “High Risk Screening Protocol” (a) and “Universal Point of Care (POC) Screening Protocol” (b). ¹Screening to include common symptoms, exposure to COVID-19 positive or suspected, resident of long-term care facility ²Sinonasal surgery, oral surgery, oropharyngeal surgery, mastoidectomy/middle ear surgery, laryngeal or tracheal surgery ³N-95 or equivalent, face shield or goggles.
<table>
<thead>
<tr>
<th>Testing Protocol</th>
<th>Days</th>
<th>Patients screened / cases performed</th>
<th>Positive Results</th>
<th>Time from test to OR (days)</th>
<th>Delay to OR for first start cases (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk Protocol</td>
<td>14</td>
<td>15 / 21</td>
<td>1</td>
<td>3 ± 1.8</td>
<td>19.6 ± 18</td>
</tr>
<tr>
<td>Universal POC Protocol</td>
<td>7</td>
<td>11 / 11</td>
<td>2</td>
<td>0.2 ± 0.6</td>
<td>18.7 ± 10</td>
</tr>
</tbody>
</table>
Table 1. COVID-19 Pre-operative Screening Data.
This manuscript was accepted for publication in Otolaryngology-Head and Neck Surgery.
“High Risk Protocol”

Pre-operative screening phone call 3-4 days prior to surgery to assess symptoms and exposure risk¹

- Referral to COVID clinic for testing
  - Is case mucosa violating? ²
    - Proceed with case. Consider enhanced PPE³ if mucosa violating.²
    - Patient asked to isolate until surgery. Screening day of surgery.¹
      - Referral to COVID clinic for testing
        - Cancel Case. COVID Clinic Management

¹ Referral to COVID clinic for testing
² Is case mucosa violating?
³ Proceed with case. Consider enhanced PPE if mucosa violating.
"Universal Point-of-Care Protocol"

Pre-operative screening phone call
3-4 days prior to surgery to assess symptoms and exposure risk

Referral to COVID clinic for testing

Patient asked to isolate until surgery. Testing Day of Surgery (POC).

Cancel Case. COVID Clinic Management

Is case mucosa violating?

Cancel Case. COVID Clinic Management

Consider Enhanced PPE

Proceed with case
From: rush_research_portal  
Sent: Wednesday, April 15, 2020 9:45 AM  
To: Bobby Tajudeen  
Subject: RCTA: Your Exempt study has been approved

Institutional Review Board #1  
FWA #: 00000482

Notification of Exemption from IRB Review

To: Bobby Tajudeen  
ORA #: 20041307-IRB01  
Project Title: Operating room protocols during the COVID-19 pandemic: implementation of point of care preoperative screening and case restrictions  
Date Exemption Granted: April 15, 2020

Dear Bobby Tajudeen,

This exemption was granted in accordance with 45 CFR 46.104(d)(4) - Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens:

iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b).

If you change your protocol in any way, these issues must be re-reviewed.

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{The below is a representation of an electronic record that was signed electronically and is the manifestation of the electronic signature.}

John Cobb
4/15/2020 9:44 AM
Signing for Crista Brawley

Crista Brawley, PhD, CCRP
Rush University Medical Center
Assoc. VP, Research Regulatory Operations