Tracheostomy and personal protective equipment (PPE) in the midst of the COVID-19 pandemic

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ABSTRACT

The primary aim was to review the guidelines published by Otolaryngology Societies for performing tracheostomies in the COVID-19 pandemic. A secondary aim was to briefly review the literature for the effectiveness of surgical masks, N-95 and FFP-3 respirators, and power air purifying respirators (PAPRs) in reducing transmission of respiratory viral infections to health care workers while performing tracheostomy. Recommendations are mainly derived from clinical case series/retrospective observational studies from the SARS 2003/2004 outbreaks or experimental evidence for effectiveness for N-95/FFP-3 respirators and PAPRs. Differences do occur due to lack of evidence for COVID-19 as to whether N-95 and FFP-3 respirators are sufficient, or PAPRs should be recommended for tracheostomy. We would recommend adopting a conservative (protective) approach for HCWs teams performing tracheostomies, by routinely utilizing additional PPE such as PAPRs. Recommendations for the timing of tracheostomy also varied, however, almost all recommend a period of delay. The optimum duration of which is still unclear.

Keywords: Coronavirus, nosocomial infection, personal proactive equipment, tracheostomy

Introduction

On December 8, 2019, the onset of symptoms in the first known case of pneumonia with unknown aetiology was observed in Wuhan City, Hubei Province, China. By December 31, 2019, China reports a cluster of 27 cases of pneumonia with unknown aetiology in Wuhan to the World Health Organization (WHO) (1). On January 7th, 2020, a new virus was identified by Chinese scientists as a novel single-strand, positive-sense RNA coronaviruses (1). By January, the 30th, 2020, WHO declared a global alert over concerns of a SARS type infection (1) and on 11th March 2020, the WHO declared a global pandemic. At the time of writing this article, we are currently in the midst of a global pandemic due to this novel coronavirus (COVID-19). It primarily affects the respiratory tree producing a SARS MERS type illness (2-4). Initial experience from China suggested a less-lethal disease (COVID-19 mortality 3.17%) (5) than the SARS (2004 - 9.6%) or MERS (2009 - 35%) outbreaks (6). The majority of patients (80.9%) with COVID-19 are considered asymptomatic or have symptoms consistent with mild pneumonia (7). Similar viral loads have been detected in both asymptomatic and mildly symptomatic patients, suggesting transmission potential for the asymptomatic patient (8). Clinical reports are now also emerging of possible transmission in asymptomatic patients (9). Due to these factors, methods of COVID-19 detection and isolation will need to be modified from those of SARS and MERS (10). In part, due to these differences in clinical progression, the COVID-19 outbreak has shown an uncontrolled exponential rise, unlike MERS or SARS, which were contained. There are currently confirmed 1.982.939 million affected and 126.761 deaths, with continued difficulties in containing the virus resulting in a global pandemic (source: John Hopkins University, Coronavirus resource centre: https://coronavirus.jhu.edu/map.html).

Nosocomial infection of health care workers (HCWs) is a serious concern with SARS types of viruses (SARS, MERS). The

Canadian SARS outbreak in 2003 resulted in 438 cases, with 51% of these being HCWs, 3 of whom died (11). In Hong Kong, over 400 out of 1755 SARS patients were HCWs (12). Unfortunately implementing infection control measures are not fail-safe with nosocomial infection of HCWs continuing, despite measures (13). The high rate of transmission to HCWs has been reproduced with the COVID-19 outbreak. Early reports make mention of 40 (29%) health care workers HCWs that were among the first 138 patients hospitalized in China (14), with 1080 HCWs in Wuhan (64% of the national total) (15). Overall HCWs represented 3.83% (n=3019) of the total number of infections in China (1).

As medical specialists such as ENT Head and Neck Surgeons/Anaesthesiologist and Pulmonologists we perform airway procedures such as tracheal intubation, non-invasive mask ventilation, bronchoscopy, tracheostomy and therefore are uniquely placed at risk of nosocomial transmission from airborne viruses (16). Assuming infection rates 1000 new cases per day, of which 5% requiring respiratory support, equates to 50 new patients per day requiring invasive ventilation. Assuming a 50% mortality of patients requiring ventilation suggests that 25 patients per day who may require longer-term ventilation and possible weaning protocols incorporating tracheostomy. At the current time (April 15, 2020), there are 1 223 COVID-19 patients in ICU in Belgium (source: Sciensano; https://epidemio.wiv-isp.be/ID/Documents/Covid19/Meest%20recente%20update.pdf). It is highly likely that ENT departments will soon be required to perform significant numbers of tracheostomies in COVID-19 positive patients.

Various ENT national societies have put forward protocols for personal protective equipment (PPE's) to managing this risk of nosocomial infection during tracheostomy, but differences do exist. This article serves to briefly review the common terminology and international standards used in managing viral infectious respiratory disease, from which the protocols are derived. Differences in standards and international protocols are highlighted. There remains the potential for shortages of PPE's in the near future, where we may be called upon to work under suboptimal conditions (crisis capacity). We hope this article will also help inform medical specialists involved in this kind of patients' care, over the possible risks of nosocomial infection they will incur, if they perform tracheostomy in the current pandemic with varying levels of personal protective equipment (PPE).

Main Points:

·   Published guidelines differ due to lack of evidence for COVID-19.
·   We recommend PAPRs for COVID-19 Positive ve tracheostomy.
·   Non-fit tested FFP-3/N95 respirators are not sufficient for COVID-19 Positive ve tracheostomies, as many individuals may have an unacceptable leak through the face seal.
·   Surgical Hoods which are not designated as PAPRs may have protection levels inferior to FFP-3 or N95 masks making their use unsuitable for protection for COVID-19.
·   Surgical tracheostomy should be delayed if possible, in COVID-19.

The basic reproduction number (R0)

The basic reproduction number is used in infectious disease epidemiology to describe how transmissible a specific infection is. The value of R is the average number of new infections attributed to a single infectious person. When R>1 the number of cases will increase, and for R<1 transmission will decrease. The R_0 of COVID-19 ranges from 2 to 3.5, which is similar to SARS (17, 18).

Transmission Modes and Precautions - CDC classification

Direct contact transmission occurs when a virus is transferred by contact from an infected person to another person, whereas indirect contact transmission involves an intermediate object (fomite). Contact precautions are used to prevent and control infection transmission via these routes. Person-to-person droplet spray transmission is through the air by droplet sprays onto exposed mucous membranes (19). Droplet precautions are used to prevent and control infection transmission over short distances (1-2 metres) via droplets (19-22). Person-to-person aerosol transmission by inspirable particles can be small enough to be inhaled into the distal lung. Airborne precautions are used to prevent transmission without necessarily close contact (19). Of interest, California became the first state in the United States in 2009 to regulate specific PPE for each level of precautions (aerosol-transmissible diseases standard-California Code of Regulations, 2010) (19) (Table 1).

At the current time, it is believed that transmission of COVID-19 requires both droplet and contact precautions. Based on historical data from SARS, it is also felt in certain circumstances such as aerosol-generating procedure (AGP) airborne precautions against aerosol are required (23, 24).

Aerosol Generating Procedure (AGP) Definition

AGPs can generate an aerosol hazard from an infection that may otherwise only be transmissible via splashes or droplets (20). Common AGPs are listed below:

·   intubation and extubation
·   non-invasive ventilation (e.g. BiPAP, CPAP), manual ventilation
·   open suctioning
·   cardiopulmonary resuscitation
·   bronchoscopy; rigid endoscopy and nasal fibre-endoscopy
·   tracheostomy and tracheostomy tube changes
·   surgery using high-speed devices (20, 25)

Table 1. Aerosol-transmissible diseases standard - California Code of Regulations

	Surgical Mask	N95 Respirator	PAPR
Droplet precautions	+	–	–
Aerosol precautions	–	+	+
Precautions against Aerosol generating procedures	–	–	+

(N95: American certified respirators with a minimum efficiency of filtration of 95% nanoparticles, PAPR: Powered air purifying respirators) (22).

Surge capacity

Refers to the capacity of a facility to manage a sudden, un-expected increase in patient volume that would otherwise severely challenge or exceed the present capacity of a facili-ty (26). Conventional capacity describes the ability to provide patient care without any change in standard daily practices (e.g. recommended PPE and general infection prevention) in healthcare settings. Contingency capacity describes a change in daily contemporary practices that may not have any signif-icant impact on the care delivered. Crisis capacity denotes a significant departure from contemporary standards of care (26).

Personal Protective Equipment (PPE)

This includes the following

· Respirator or reusable respirators (e.g., powered air-purify-ing respirators (PAPRs))
· Eye protection goggles, disposable full-face shield
· Gloves
· Gowns
· Surgical cap (27)

Gloves

Gloves act as a physical barrier between contaminated surfac-es and the skin. They also can help the individual as a reminder to avoid self-inoculation. Changing gloves between patients

Figure 1. Maximal PPE for COVID-19 positive suspect Tracheostomy: double gloves, surgical cap, goggles, disposable waterproof gown, FFP-3 fit tested and PAPR Draeger hood. Consistent with Wuhan level 3 precautions.

and adherence to hand hygiene protocols are vital to reduce contamination (19).

Eye Protection Visors and Face Shields

One study examined eye protection during orthopaedic sur-gery, making comparisons of several types of eye protection. Contamination rates showed that normal eyeglasses were no better than controls, loupes had a 50% contamination rate and surgical mask with an integrated visor had 30% contamination rate. Best protection rates were provided by wrap-round plas-tic disposable glasses, most similar to goggles (28). One study comparing full-face shield versus safety glasses in combina-tions with N95 respirators found full-face shield combinations with N95 gave the greatest protection (29).

Full-face shields should have dimensions that extend to the bottom of the chin, and a face/neck length that also covers the anterior neck area. Most visors curve around the face and the recommendations from the Center for Disease Control and Prevention (CDC) are visors should reach from ear to ear. Max-imum protection is therefore afforded by the combination of respirator + full-face shield or goggles. Safety glasses, loupes, normal glasses are not advised (30).

Surgical Masks

Surgical masks (SMs) are effective for reducing transmission for droplets, splashes and sprays that may contain viruses and bacteria. SMs do not create a tight seal against the skin leading to air influx around the SM. Thus, the filtration or fit is not ad-equate to prevent inhalation of small particles. The protection factor of face masks against particles (0.04-1.3 μm) was on average of 8 to 12 times less than N95 respirators (31). SMs are therefore used only as for protection from infectious fluids (droplets, splashes, or sprays).

Respirators (FFP2, FFP3 N95), the fit-test and its relevance

The certifications between the USA and Europe differ. The National institute for occupational safety and health (NIOSH) certified N95, N99, N100 respirators (N=not for use in an oil droplet environment) to have a minimum efficiency of filtra-tion of fine particles (NaCl approximately 300 nm) of 95%, 99% and 99.97% respectively (19, 32). Further studies have shown the efficacy of N95 to filtering aerosol particles in the 4-30 nm range (33), which is smaller than COVID-19 at 70-90 nm (34). The European Standard (EN 149:2001) classifies three classes again using NaCl particles: FFP1, FFP2, and FFP3 with a minimum efficiency of 80 and 94% and 99% respec-tively. However, a high filtration efficiency alone does not en-sure protection. The particle influx through face seal leakage of the N95 respirator far exceeds the influx through the filter. The ratio of face seal leakage to filter leakage is in the range of 7-20:1, therefore focusing on fit in disposable respirators (N95, FFP-2/3) is vitally important (35). This point is underscored by the fact that up to 25% (5-25%) of individuals do not pass a fit test with the first respirator tried (36, 37). Instructions from manufactures 3M on how to perform a fit test for an N95 mask can be found online at https://www.youtube.com/watch?v=x-l4qX6qEYXU&t=53s.

Each time a FFP3 or N95 respirator is worn, a fit-check should be performed. Whilst covering the respiratory with both hands. For a unvalved product, exhale sharply; for a valved product,

inhale sharply whilst checking for leaks around the respirator. Adjust the fit of the nosepiece or straps accordingly (20).

Powered Air Purifying Respirators

SARS transmission has occurred despite the use of N95 respirator during high-risk procedures (24, 38). An alternative PPE to disposable respirators (N95, FFP-2/3) for aerosol precautions is the Powered Air Purifying Respirator (PAPR). It is a battery-powered blower that provides positive airflow through a filter to a hood/facepiece/helmet. A common type of PAPR the medical setting is the loose fitted hood PAPR. A major benefit is that there are no requirements for a total seal around the mouth; thus, they do not require fit testing (unlike disposable respirators N95, FFP-2/3). The delivered air is under positive pressure, and the hood is not sealed. The airflow is continuous from the blower to the hood, and then the air escapes out of the hood to the surrounding. This uni-directional airflow limits entrainment of contaminated air.
The type filter can vary, for example, a high-efficiency particulate air (HEPA) filters have a similar filtration rate as a P100 (99.97% of particles 0.3 μm in diameter). Therefore, a PAPR + HEPA filter has improved respiratory protection than N95 masks. One such type is the Airmate 3M HEPA (3M, USA) (12, 38, 39). PAPR systems that are in current use during the Covid-19 pandemic include the 3M versaflo, which replaces the Airmate and the Draegar X-plore. A distinction should be made with the Stryker T4 surgical hood system (Stryker Corporation, USA) which is not certified as a PAPR. When used in isolation, it is less effective at the filtration of nanoparticles than an N95 respirator.

The assigned protection factor APF denotes the fraction of airborne contaminant present that the individual can expect to inhale (for example, APF 10=10%, APF 25=4%, APF 100=1%). It takes into account, in properly fitted and trained users, all expected sources of facepiece penetration (face seal penetration, filter penetration, and valve leakage) (40). The loose-fitting facepiece PAPR has an APF of 25, helmet PAPR has an APF of 25, and loose-fitting hood PAPR has an APF of 1000 (41, 42).

The Stryker T4 surgical hood has an suggested protection factor (APF) of 3.1, in comparison to the N95, which has an APF of greater than 10 (24, 43). However, during quantitative testing, the average ambient-to-inside device of similar sizes to the coronavirus was approximately 3.8 (the fit test factor). It performing far inferiorly to a N100 respirator and face-shield (44), and also lower than what would be expected of a minimum of 100 for a pass for an N95 respirator (ten times the APF as the Fit Factor Pass). It is recommended by the manufacturer that Stryker T4 surgical hood system (Stryker Corporation, USA) should not be used alone to protect against transmission of SARS (44), (available from: URL: http://sars.medtau.org/strykerreport.doc), and in fact it is not licensed for this purpose. It is also recommended that its helmet not be used without additional eye and respiratory protection in this setting.

The disadvantages of PAPRs are several. Donning and doffing is more complex, and a set sequence should be followed (45). There is an increase chance of contamination of the surgical site with air being blow out from under the hood by positive air pressure. The wearers unfiltered exhaled air is also included in this airflow efflux for the hood, which can, therefore, transmit the infection to other HCWs or the patient. Loose-fitting PAPRs do not totally enclose the head, so over-breathing the air blower (caused by high respiratory rates of the wearer) can occur, leading to possible contamination (43).

Combining an N95 or FFP-3 respirator with a PAPR may be one solution to the over-breathing and exhaled air issues, and it also may further increase the APF (38, 43, 45, 46). In experimental conditions, the combination of N95 respirator with a hood PAPR was shown to increase the APF from approximately 100 (N95) to 150,000 (combination N95 mask+PAPR) (41).

The combination of N95 respirator and a hood PAPRs which had been deactivated (air-purifying motor pump switched off, simulating the loss of power) has also been investigated. Deactivated hood PAPRs used in isolation (without an N95 respirator) tended to have APFs in the range 4-10, similar in range to Stryker APF of 3.1 (24), but lower than an N95 respirator (AFP usually>10) (41). Deactivated hood PAPRs+N95 respirators combinations routinely showed large increases in the APF (N95 APF approximately 100, Deactivated hood PAPRs APF approximately 4-10) to over 1000 (41). Surgical hood (Stryker T4 or other) and N95 respirator combinations were not tested (41).

Combinations of PAPRs and N95/FFP-3 respirators do have drawbacks; communication difficulties, claustrophobia and a possible higher risk of self-contamination (43). This combination is also more uncomfortable and cumbersome than using N95 or FFP-3 respirators or PAPR in isolation.

PAPRs can be re-usable, and therefore, suitable decontamination protocols must be in place if they are to be safely reused (46). Due mainly to these decontamination factors, the CDC recommends disposable filtering facepiece respirators over PAPRs (19).

PAPRs alone or a combination of respirator and PAPR can have an advantage in situations where N95 or FFP-3 respirators are used in non-ideal scenarios (facial hair or failure of a fit test) or where high-risk AGPs are performed (39, 47).

Correct donning and doffing
When donning and doffing a correct sequence should be followed to reduce the chances of self-contamination. The individual should be trained in this process and ideally be observed (buddy to checking) for adherence to the protocol. Recommendation of donning and doffing for PPE (N95/FFP-3) have been previously published and are included below.

Before leaving the relevant work area
- Gloves, gown/apron, and eye protection should be removed (in that order, where worn) and disposed of as healthcare hazard waste.
- On removal of eye protection, it should be handled by the headband or earpieces only.
- Where non-disposable eye protection has been used, appropriate measures for decontamination between uses needs to be in place.
- Hand hygiene must be performed after removal and disposal.

After leaving the area

· The respirator or surgical mask can be removed and disposed of as healthcare hazard waste.
· Untie or break the bottom ties first, followed by top ties or elastic, and remove by handling ties only.
· Hand hygiene must be performed after disposal. (20)

An example of a donning and doffing protocols for PAPRs is published for teams (45). Video demonstration of CDC compliant modules for demonstrations of PPE (PAPR and gowns combinations) donning https://www.youtube.com/watch?v=d0lLf63iyPM and also doffing https://www.youtube.com/watch?v=-X4dNMgFGyo&t=3s from Johns Hopkins Hospital for the Ebola virus outbreak are available online.

What we know from SARS

Much of the guidance for COVID-19 is based on studies of the SARS experience for the 2003-2004 outbreak. Canadian studies reported that the probability of SARS infection was 6% (8/143) per shift worked and extrapolated that if all nurses had worked eight shifts, 53% of them would become infected with SARS. Reassuringly almost an 80% reduction in risk for infection for nurses who consistently wore either surgical mask or N95 respirators was reported. out to be more protective than a surgical mask. However consistent use of an N95 respirator turned out to be more protective than a surgical mask. (48, 49). The likely modes of transmission for SARS were interpreted as either droplet or limited aerosol generation during AGPs (48-50). A systematic review looked at ten studies from the SARS 2003-2004 outbreak to analyse the risks of nosocomial infection to HCWs whilst undertaking AGPs. They found risk could be stratified according to the type of AGP. Odds ratios (ORs) for nosocomial infection were in decreasing order; tracheal intubation OR 6.6 (2.3, 18.9); non-invasive ventilation OR 6.6 (4.1, 10.6), tracheotomy OR 3.1(1.4, 6.8) and manual ventilation before intubation with an OR of 2.8 (1.3, 6.4) (16). From this, it can be concluded that tracheostomy is a high-risk procedure for nosocomial infection to HCWs in SARS. This can potentially be extrapolated to other similar respiratory infective viruses such as COVID-19. With regards to AGPs in SARS, N95 respirators may not be enough. Transmission may have occurred despite the use of appropriate respirators during a resuscitation scenario (24), and transmission occurred in 9 HCWs despite standard PPE (N95 respirators) in a difficult airway scenario (38).

Reviewing the literature on SARS tracheostomy demonstrates five reports of tracheostomy in SARS patients. They advocated standard PPE (N95 respirator, surgical cap, goggles, surgical gown) gloves and negative-pressure room in ICU or operating room. One of the main differences was whether they utilised additional PPE, such as PAPR or surgical hood in addition to N95 respirator was used. In total, 4 of 5 utilised additional PPE to N95 respirators (12, 38, 45, 51, 52).

Current ENT National Guidelines for Tracheostomy in COVID-19 crisis (46, 53-61) (Table 2)

Discussion

It is obvious we will be increasingly asked to perform tracheostomies over the coming weeks and months during the COVID-19 crisis. Many unanswered questions remain, many of which will remain definitively unanswered until after this pandemic has passed since, for example, the effectiveness of the tracheostomy in ICU for COVID 19 patients is currently unclear.

Should routine PAPR be offered as well as or instead of an N95 or FFP-3 respirator to surgeons performing tracheostomies on COVID-19 positive patients?

PAPRs are cumbersome and require specific training; however, they are highly effective in reducing aerosol transmission to the lungs and droplet transmission to the face and eyes. Hence this decision should be carefully considered.

For surgeons performing a tracheostomy which is a high-risk APG, a combination of a fit-tested respirator (FFP-3) with a suitable PAPR can improve protection levels. Alternatively, a PAPR (APF of >1000) can be used alone, instead of an FFP-3 respirator to increase the protection level. This recommendation is at the discretion of the surgeon/surgical team. Factors such as length and complexity of the surgery, viral load, surgeon tolerance for FFP-3/N95 respirators/ PAPR and the presence of any pre-existing co-morbidities in the operating team may influence this decision.

 Where a respirator (FFP-3 or N95) is worn without a PAPR, suitable eye protection is mandatory (full face shield or goggles). Importantly the use of surgical hoods systems (non-PAPRs such as the T4 Stryker system) in isolation (without an FFP-3/N95 respirator) is not recommended.

It is likely that non-fit tested respirators (FFP3 or N95) do not provide sufficient protection for a significant proportion of surgeons from COVID-19 aerosols whilst performing high-risk AGPs such as tracheostomy. It is the authors' belief that given the current evidence, when the respirator cannot be fit tested or where the surgeon is unable to pass a fit test, a PAPR or a combination of FFP-3/N95 respirator and PAPRs should be used as an alternative. This level of precautions (PAPR+FFP-3/N95) is in line with Wuhan level 3 precautions, one of the centres with the most experience in dealing with this pandemic and where it was also effectively contained (46).

COVID-19 positive PPEs

Double Gloves – aids doffing of PPE reducing the chance of self-contamination

· Surgical cap
· Disposable waterproof gown
· Goggles or a full-face shield
· FFP-3 (fit-tested) absolute minimum
· FFP-3 + hood PAPR recommended
· Hood PAPR (APF >1000) recommended

For *non-fit tested FFP-3* or for *fit test failures of FFP-3*, various options below are recommended:

· Hood PAPR
· FFP-3 non-fit tested + hood PAPR
In an emergent situation where a non-fit tested/fit test failed FFP-3 respirator is available but a PAPR is not available the tracheostomy should be delegated to a colleague with suitable PPE.

How should we proceed in the clinical setting of a request

to perform a tracheostomy in a patient for a non-COVID-19 related condition or who has tested COVID negative?

The answer relies on the accuracy of COVID-19 test. Are the PCR tests reliable enough to stratify patients into COVID-19 positive and negative patients prior to performing tracheostomy?

At the current time, it is not clearly understood what the accuracy of the PCR test for COVID-19 is. The potential for RT (Reverse Transcriptase)-PCR vulnerabilities are several; inade-

quate collection, transport and storage interfering substances, manual errors, as sample contamination, testing outside the diagnostic window, use of inadequately validated assays (62). These errors can be amplified when lab staff must adapt to work in high-throughput settings in emergencies settings (62). Some data suggests in adults sensitivity of about 60% with a false-negative rate of 30-40% (63). As an alternative, a symptom-based and PCR-test strategy is also flawed due to the fact that a significant proportion of patients are asymptomatic de-

Table 2. Tracheostomy in COVID-19 Positive Ve Patient Guidelines

	Preferred Method Open/ Percutaneous	Eye Protection	HAT/CAP	Gown	Gloves	Aerosol Protection
AMERICAN ACADEMY ORL AND HEAD NECK SURGERY AAO-HNS	No Preference	Adequate PPE	Adequate PPE	Adequate PPE	Adequate PPE	N95
ENT-UK	Local Factors, Competencies, And Experience	Surgical Mask Integrated Visor -Full Face Shield	No Comment	Fluid Resistant Disposable Gown	Yes Consider Double Gloving	FFP-3 PAPR Optional
CANADIAN SOCIETY OF OTOLARYNGOLOGY AND HEAD AND NECK SURGERY CSO-HNS	Open	Yes Full Aerosol Ppe Including Papr	Yes Full Aerosol PPE Including PAPR	Yes Full Aerosol PPE Including PAPR	Yes Full Aerosol PPE Including PAPR	N95 and/or PAPR
NETHERLANDS NERTHELANDS SOCIETY FOR ENT AND HEAD AND NECK SURGERY	No Preference	-Goggles -Full Face Shield	Full PPE Protocol According to The Hospital Guideline	Full PPE Protocol According to The Hospital Guideline	Full PPE Protocol According to The Hospital Guideline	FFP-2
FIRST AFFIATED HOSPITAL	No Preference	-Goggles -PAPR	Yes	Fluid Resistant	Yes Double Gloving	N95 and/or PAPR CHINA
ROYAL BELGIUM ORL AND CERVICOFACIAL SURGERY	Both Suitable Risk of Shedding Appears to Be Smaller In Percutaneous But Risk For The Bronchoscopic Controller	-Surgical Mask with Integrated Visor -Goggles -Full Face Shield	Yes	Fluid Resistant	FFP-2/3	FFP-2/3
FRENCH SOCIETY OF ORL/PEDATRICS SFORL PEDATRIC GUIDLINES	Not Stated	Protective Glasses	Not Stated	Not Stated	Not Stated	FFP-2 + Consider Transparent Sterile Drapes Over Operative Field
AUSTRALIA SOCIETY ORL AND HEAD NECK SURGERY ASOHS	Not Stated	Face Shield	Yes	Fluid Resistant Disposable Gown	Yes	N95
ITALIAN ORL AND HEAD NECK SURGERY	Not Stated	Face Shield	Yes	Fluid Resistant Disposable Gown	Yes	FFP-3

spite being in the infective viral shedding phase (1). There are at least two time points in the disease course where false negatives can occur due to viral loads below the analytical sensitivity of some RT-PCR assays. At the initial phase of infection of the infection, especially in asymptomatic or mildly symptomatic patients. Subsequently, a second period in the tail of the infection, where the patient is now asymptomatic, but the virus shedding may still persist (62). Incorporating chest CT scans into preoperative screening is likely to improve the accuracy of testing as it has a reported sensitivity of over 90% (64). Importantly, from two-thirds to over 90% of all patients whose RT-PCR became positive for SARS- CoV-19 after an initially negative test result had CT features suggestive of COVID-19, with a mean interval period of 5.1±1.5 days for turning positive (64).

Best Practice Tips Regarding Pre-op Screening COVID-19 Status Unknown

- Know your local unit's PCR test for COVID-19 and its false-negative rate. Are they using the CDC or WHO recommended (RT-PCR) diagnostic assay? Has it been validated?
- Provide clear instructions on how nasopharyngeal and oropharyngeal swabs should be collected and delivered to the lab – poor sampling can result in false negatives.
- Serial testing minimum of two, especially if negative RT-PCR test results and high suspicion or probability of COVID-19 infection infection, utilise CT-scan of the lung if possible (see below).
- Consider associated symptoms compatible with COVID-19. Treat as confirmed COVID-19 positive if high clinical suspicion or high chance of exposure, utilise CT-scan of the lung (see below).
- CT-scan of the lung, typical findings of infection include; ground-glass opacities, consolidation, air bronchogram signs and interlobular septal thickening. Ideally, CT chest can be combined with CT for mastoiditis, complicated sinusitis, neck abscess). If a CT scan is positive, treat as confirmed COVID-19 positive even with a negative RT-PCR test.

It is practical to consider all patients that are not confirmed as COVID-19 positive as *COVID-19 suspected* in the current crisis when performing a tracheostomy. We would recommend PPEs except for PAPR in these individuals when performing tracheostomies.

COVID-19 suspect PPEs

Double Gloves – aids doffing of PPE reducing the chance of self-contamination

- Surgical cap
- Goggles and/or Full-face shield
- Disposable waterproof gown,
- FFP-3 fit-tested – sufficient

For non-fit tested FFP-3 or for fit test failures, various options for COVID-19 suspect PPEs below are recommended:

- PAPR – Ideal compromise between surgeon comfort and high APF in fit failures
- PAPR + FFP-3 could be used to decrease the chance of

transmission from the wearer to the patient/surgical team at the expense of loss of comfort for the surgeon. However, if a significant leak is present, this advantage of the combination may be lost.

- **What is the best procedure percutaneous or open tracheostomy?**

The previous reports of tracheostomy patients in SARS all focus on open procedures (12, 38, 45, 51, 52). In general, the technique differs from a normal tracheostomy in that the patient is fully paralysed so the ventilation can be controlled. The tracheostomy then placed only during apnoea, reducing the aerosol normally produced with the standard technique. A well-designed step-by-step protocol for open tracheostomy has been devised by ENT-UK, abridged summary below (54).

1. Complete paralysis of the patient throughout the procedure to prevent coughing and to control ventilation
2. Pre-oxygenate with PEEP then stop ventilation
3. Advance cuff beyond planned tracheal window site
4. Stop ventilation and allow time for passive expiration with open APL valve
5. Create tracheal window preserving the cuff, deflate cuff then withdraw ET tube proximal to the tracheal window.
6. reducing the use of suction during the procedure, if used, this should be within a closed system with a viral filter.
7. Insert cuffed, non-fenestrated tracheal tube with non-fenestrated inner tube
8. Immediately inflate tracheostomy tube cuff and place an HME with attachment to the circuit, Resume ventilation
9. Confirm position with end-tidal CO2, and then withdraw clamped ETT carefully
10. Avoidance of monopolar diathermy which risks further aerosolization of the virus

Full guidance protocol can be found at https://www.entuk.org/sites/default/files/files/COVID%20tracheostomy%20guidance_compressed.pdf

Percutaneous tracheostomy techniques have also been adapted to be performed under full paralysis and apnoeic conditions to decrease the risk of viral aerosol. When performed by an experienced practitioner, the dilation portion of the procedure and placement of the cannula is possible under one cycle of apnoea (<30 seconds) by experienced practitioners. The tight fit of the cannula in the tract can reduce bleeding, so that cessation of anti-coagulation is not always required (65), although it is accepted that many units still routinely ask for the cessation of anticoagulation. Requirements electrocautery are almost nil, reducing concerns for smoke inhalation. Aerosol generation from around the tracheostomy tube and wound site (which if occurred would be outside the closed circuit) is reduced, lowering AGPs during routine post tracheostomy care.

Avoiding transfer of COVID positive patients for a tracheostomy to the operating room is attractive. However, bedside open tracheostomies in ICU are frequently accompanied by suboptimal lighting, surgeon positioning and patient positioning. These factors are less problematic with percutaneous tracheostomies which are routinely performed in the ICU. Whether in

the ICU or OR theatres, a negative pressure room, if available, should be the standard of care.

It should be remembered that aerosolization of saliva can occur even with minor suctioning the pharynx before intubation (16, 66) so despite these above adaptions, tracheostomy is still considered a high-risk AGP. As there is no evidence to quantify the levels produced in each adapted procedure, no specific recommendation can be made. The ability to control the level of aerosol generation in each procedure is likely correlated with the experience of the practitioner. Experienced surgeons/anaesthetists should, therefore, perform either percutaneous tracheostomy or open tracheostomy in-line with and the experience/skillset of the local unit/ICU. The concept of shared risk among experienced surgeons/anaesthetists should be adopted. Ideally, having several trained, experienced personnel performing the procedure rather than a small number of individuals repeatedly. Careful consideration should be made as to whether surgeons or anaesthetists with co-morbidities/risk factors such as hypertension, diabetes, and chronic lung disease should be allowed to perform these procedures, or rather to delegate these procedures to the next most experienced members of the medical team.

When it the best timing for COVID positive tracheostomies?

Patients with active COVID-19 have high viral titres in nasal mucosal, oral, pharyngeal, and pulmonary secretions (63) which will inevitably produce aerosols if manipulated/operated (16), placing the entire operating room personnel at risk. Smoke generated from electrocautery of infected tissue and blood is also a possible additional hazard. Infection concerns from smoke generation by electrocautery are drawn from experience from other studies where viral DNA was present in smoke fumes (67, 68). The infectivity of electrocautery smoke in COVID-19 is not clear, so at this time the use of monopolar electrocautery is advised against.

There is, therefore, a balance between the clinical urgency of tracheostomy and delaying the tracheostomy until the patient has negative PCR tests from respiratory secretions, making the patient less but not always non-infective (62). There are variabilities in recommendations. The Canadian guidelines strongly recommend against performing a tracheotomy in COVID-19 patients who are still infectious regardless of the duration of endotracheal intubation (59). American guidelines are less stringent suggesting that tracheostomy does not take place sooner than 2-3 weeks from intubation in patients with stable pulmonary status and ideally negative COVID-19 testing (58). The Dutch Society of ORL suggest no surgery within two weeks and to postpone tracheotomy until patient COVID-19 is negative if possible (57). The French Paediatric SFORL guidelines state that very few indications should be maintained and it should induce postponement of non-urgent surgeries of at least 15 days (53). The ENT-UK guidelines suggest it may be prudent to delay tracheostomy until active COVID-19 disease has passed (54, 55). The Belgium Royal Society of ORL recommends a delay if possible and to postpone the procedure until active COVID-19 has passed (61).

Unfortunately, a purely time-based system is problematic as critically ill patients may have significantly longer positive test-

ing. A mean of 31 days following onset of symptoms before the PCR in respiratory secretions is negative (69). Furthermore, despite a negative PCR of respiratory secretions and resolution of symptoms there still remains a risk that the patient may still have a sufficient viral load to be infective if a high-risk AGP (tracheostomy) is performed without suitable PPE (62). Therefore, ideally, the patient should be serially tested until COVID-negative before proceeding with a tracheostomy, to maximally reduce the viral load in the aerosol during the procedure. However, the patient must still be considered COVID positive at the time of surgery despite negative tests, and appropriate precautions should be taken by all HCWs.

Best Practice COVID positive Tracheostomies

Multidisciplinary team (MDT) decision for tracheostomy. Review indications only proceed in situations where there is a significant benefit to the patient in terms of overall mortality or morbidity.

Ideally, delay tracheostomies (unless acute airway emergencies) until COVID-negative testing in respiratory secretions.

If once COVID positive and now negative still treat as COVID positive for AGPs as low viral low can persist (62).

Ideally, delay tracheostomies until stable pulmonary status (desaturations are issues with apnoeic tracheostomies in both open and percutaneous tracheostomies).

Ideally, negative pressure room (ICU or OR Theatres), Percutaneous or Open tracheotomies, dependant on local factors and skills mix.

AGPs – standard PPE (FFP-3, fit-tested) at a minimum. Alternatively, PAPR or combinations of FFP-3 PAPR are preferred for the operating team.

Advise against performing tracheostomy in FFP-3 respirator when it is non-fit tested or where there is a fit test failure. The procedure should be delegated to colleague with appropriate PPE.

Conclusion

We have presented available evidence for several of the current guidelines used by various ENT Head and Neck Societies. Differences do occur due to lack of evidence for COVID-19. Many recommendations are based on historical data from the 2003/4 SARS outbreak. Many unanswered questions remain.

Disclaimer

The Authors have developed this information to inform its members and helpful guidance for its readership. This is based on information available at the time of writing, and the authors recognise that new information regarding COVID-19 is comes to the public domain every week. Therefore, recommendations may change over the coming months. Were lack of evidence exist, the decision has generally been to adopt the more conservative (protective) approach for HCWs teams performing tracheostomies. The guidance included in this document does not replace the application of clinical judgement to each individual presentation. The Authors are not liable for the accuracy or completeness of the information in this document.

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