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Audit of flexible laryngoscopy use and decontamination using a chlorine dioxide wipe system during COVID-19: Assessing the risk of disease transmission

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SUMMARY

Aim: To assess the efficiency of decontamination of flexible nasoendoscopes using a chlorine dioxide wipe system and assessing the risk of disease transmission during the COVID-19 pandemic.

Method: Prospective and retrospective review of 544 patient episodes of nasoendoscopy and a study of 41 patient procedures and 22 members of staff at an ENT Outpatient Department from September 2020 to March 2021.

Results: Among 41 randomly selected episodes of nasoendoscopy in the clinic, there was 93%—100% compliance with decontamination guidelines suggested by ENT UK. Among 544 patients who had nasoendoscopies, 20 had RT-PCR tests within two weeks and all yielded a negative result; no clusters of consecutive endoscopies were noted. None among the 22 clinic staff had symptoms of COVID-19 infection during the study period.

Conclusion: Accepting the limitations of the study design, this audit found no evidence of nosocomial transmission of SARS-CoV-2 virus related to use or reprocessing of flexible nasoendoscopes among patients and staff following good compliance to ENT UK decontamination guidelines.

Introduction

There are published reports of transmission of pathogens during colonoscopy, gastrointestinal endoscopy, and flexible bronchoscopy and transmission has been linked to shortcomings in reprocessing of the endoscope. [1—3] The incidence of nosocomial infections linked to flexible endoscopy in general is very low and is estimated at one case per 1.8 million procedures. [4]The ongoing COVID-19 pandemic has once again brought concerns about the role of flexible nasoendoscopes in disease transmission to light, as it has been established that the SAR-CoV-2 viral load is highest in the nose and throat sites among positive cases. [5] This led to new recommendations and

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guidelines released by medical associations in the initial phase of pandemic. This guidance includes recommendations of avoidance, or at least delay, of endoscopic examination of nasopharynx and larynx if it will not immediately change patient management and how to decontaminate the instrument to mitigate the risk of spread of the virus to healthcare workers. [6—8] However, flexible nasoendoscopy is one of the most common procedures in ENT clinic and is the gold standard in full examination of the head and neck region. In many cases this cannot be deferred to establish a firm diagnosis and definitive management plan. Fiber optic flexible nasoendoscopy is thus a risk for patients and an occupational hazard for ENT doctors and staff involved in instrument decontamination after use.

In the past, we routinely performed audits on decontamination procedures of flexible nasoendoscopes used in the ENT clinic and ward as part of routine infection prevention and control precautions. The standards we used were the recommendations of ENT UK, the professional body promoting Ear, Nose, and Throat Surgery in UK, published in 2017. [9] Thesewere in line with Welsh Health Technical Memorandum (WHTM 01—06) [10] on decontamination of medical devices. These guidelines highlighted the importance of tracking and traceability of individual endoscopes and their use in individual patients in the light of emergence and risks posed by transmissible spongiform encephalopathies (TSEs). This present audit is important in the light of the ongoing pandemic as new practices have been introduced in the clinic. ENT UK believes reprocessing using a chlorine dioxide wipe system (which we have been using to decontaminate flexible fiber optic nasoendoscopes for years) would suffice in avoiding nosocomial COVID-19 virus transmission. [11] Furthermore, it recommended other practices to keep not only patients safe but also the clinicians and staff during nasoendoscopy and reprocessing of the instrument that follows. Recommendations include higher thresholds in using the flexible endoscope (limiting only to urgent suspected cancer (USC) referrals and airway cases), discouraging the use of nasal spray, use of video monitor instead of looking through the eyepiece of the endoscope, use of appropriate personal protective equipment (PPE) among clinicians and clinic staff, transport of the used nasoendoscope in a covered tray, and decontamination in a room dedicated only for reprocessing of the instrument. We aimed to establish in this audit if these practices have been adhered to and more importantly if the use of flexible nasoendoscopes in ENT clinic have resulted in SARS-CoV-2 virus transmission among patients and staff.

Standards and methods

Following approval from the Audit Department of Hywel Dda University Health Board (HDdUHB), a prospective audit on adherence to infection control measures related to decontamination techniques of nasoendoscopes used in ENT clinic from September to December 2020 was performed. Data was randomly collected on the indication for use of the instrument, use of anaesthetic spray, use of video monitoring, what type of PPE was used by the doctor and the nurse or healthcare support worker (HCSW) present in the examination room, type of PPE used by the staff collecting the used instrument, whether the used nasoendoscope was transported in a covered tray, whether the decontamination was performed in a room dedicated mainly for this purpose, and the adherence on chlorine dioxide wipes manufacturer's instructions on decontamination (three consecutive wipes: clean, disinfection, and rinse). For the actual decontamination, the following data were collected: patient details, nasoendoscope number, date, time, indication for cleaning, stages of decontamination (pre-clean, sporicidal, foam activator, and rinse). A pair of traceability stickers are placed on the chlorine dioxide wipe decontamination audit book and on the patient's notes in case there would be outbreak of disease. The nasoendoscopes were cleaned immediately after use and stored in a clean tray lined with plastic sheets which also served as carrier. If the instrument had been unused and stored for more than 3 hours, it had to be decontaminated again, as per recommendation of ENT UK.

To establish potential procedure-related infection transmission, a survey among staff who performed nasoendoscopies in the clinic and those involved in the decontamination process during the study period was performed specifically inquiring if they developed COVID-19 symptoms or if they had SARS-CoV-2 RT-PCR tests. Furthermore, the digital records of all patients seen from 1 September 2020 to 30 March 2021 were retrospectively reviewed using Welsh Clinical Portal (WCP) if the patient had COVID-19 swab tests done two weeks after the date of clinic attendance where nasoendoscopy was performed. If a positive case was identified, we planned to trace back if this could be linked to the endoscope used in the clinic (i.e. if the patient whom the endoscope was used prior was also positive or clusters of consecutive positive patients reflected on chlorine dioxide wipe decontamination audit book, and/or if the staff who processed the used endoscope developed COVID-19 symptoms). WCP is a centralised database containing all results of investigations in the local health board which has a catchment population of around 387,000 people involving four district general hospitals and 48 GP surgeries. Anyone who had reverse transcription-polymerase chain reaction (RT-PCR) test for COVID-19 will be documented at WCP. Those living outside the catchment area, i.e. patients on holidays, were excluded. During the study period, ENT services were centralised at one district general hospital. There were 12 ENT doctors who performed endoscopies during the study period. They were assisted by 10 Outpatient Department (OPD) nurses and HCSWs. Three reusable flexible nasoendoscopes were used in ENT clinics.

Results

Prospective decontamination processes

Forty-one patients were selected for observation of measures on minimising risks of contamination. There was 100% compliance on the use of video monitor instead of looking at the eyepiece of the endoscope, use of level 2 (airborne) PPE [12] including use of FFP3 masks by endoscopists and the staff assisting inside the endoscopy room, removal of PPE inside the examination room, use of level 1 PPE among staff transporting and cleaning the used scope, and decontamination in a room dedicated only for this purpose. In 92.9% (n=29) of cases, the flexible nasoendoscope was used on USC referrals and airway cases only. In 2% (n=1), anaesthetic nasal spray was used. With regards to the decontamination using chlorine dioxide wipes, there was 100% compliance on pre-clean wipe, sporicidal wipe and activator foam, rinse wipe, and use of traceability stickers.

Table 1
Standards in decontamination techniques of flexible nasolaryngoscope at ENT clinic as suggested by ENT-UK. This prospective study showed high compliance at 93%—100%. (*Disposable apron (consider fluid-resistant disposable gown if apron provides inadequate cover for the procedure/task being performed), disposable gloves, and filtering face piece 3 (FFP3) respirator and eye protection or a powered hood respirator. **Disposable apron, disposable gloves, and eye & face protection (fluid-resistant Type IIR surgical face mask and goggles or full face viso). *See reference 12.*)

Intervention	Compliance (n=41)
Limit use of endoscope to USC and airways	92.9%
Discourage use of nasal decongestant/ anaesthetic spray	98%
Use of videomonitor (instead of using the endoscope eyepiece)	100%
Use of level 2 PPE* by doctor in examination room	100%
Use of level 2 PPE* by staff in examination room	100%
Removal of PPE in examination room	100%
Use of covered box to transport used endoscope	100%
Use of level 1 PPE** in transporting used endoscope	100%
Use of level 1 PPE** in cleaning/processing used endoscope	100%
Dedicated room in processing endoscope	100%
Use of Tristel wipes in processing endoscope	100%
Use of traceability stickers (Tristel Audit Book and clinic notes)	100%
Use of fresh plastic lining to store the cleaned endoscope	100%

There was also 100% compliance in using fresh plastic lining the storage box (Table 1).

Retrospective nasoendoscopy review

There were 544 patients who had nasoendoscopies in the clinic from 1 September 2020 to 30 March 2021 and 50 among them had COVID-19 RT-PCR swab tests. Among the 50, three turned positive and one resulted in death. Thirteen patients had COVID-19 swabs within a week before nasoendoscopy and had negative results; two patients were symptomatic for possible COVID-19 when they had endoscopies but had negative RT-PCR tests a day prior to clinic attendance. Twenty patients had been swabbed within two weeks after ENT clinic attendance where endoscopy was performed and all of them were negative. No clusters of consecutive endoscopies were noted among the patients who have swabbed for potential COVID-19 (run test P=0.75) (Figure 1).

Incidence of COVID-19 among staff

Among the 22 staff at ENT OPD involved in using and processing of the nasoendoscopes, 11 had COVID-19 swabs due to exposure to positive cases which all came back negative. None of the staff developed COVID-19 symptoms during the study period (Table 2).

Discussion and recommendations

Flexible nasoendoscope decontamination systems include chemical cleansing systems and endoscope washer-disinfectors (EWD), also known as automated endoscope reprocessors (AER). The gold standard in NHS Trusts is a central decontamination unit to run EWD but this is very costly and requires purchase of large number of nasoendoscopes as the process is time-consuming. This will have an impact on delivery of ENT clinic services in areas where the number of endoscopes is limited. An alternative is a wipe system (i.e. chlorine dioxide) which is quick and less expensive and may be deemed inferior to EWD but has been recommended to be fit for purpose by ENT UK. [9].

Even before the pandemic, we have heard of anecdotal complaints from a few patients having pain and nasal discharge, suggestive of infection in the sinuses and upper airways following use of flexible nasoendoscope in ENT clinics. During the start of the pandemic, at least a couple of patients politely refused the procedure for fear of disease transmission. We have not received any formal complaints of serious nasal infections nor of patients having COVID-19 infection following nasoendoscopy in our institution but we have not actively reviewed this cohort of patients for this purpose.

There were three positive COVID-19 cases among the cohort, including one death from COVID-19. However, the tests were done more than 14 days following flexible nasoendoscopy thus it was unlikely to be related to the use of the endoscope. There were 13 patients who were tested for COVID-19 before the procedure and two were symptomatic with coryzal symptoms on the day of the endoscopy but all of them had negative RT-PCR results. Considering the known RT-PCR false negative case is as high as 29% [13] and with high incidence of asymptomatic carriers, potentially there were real positive cases among the 544 patients in this cohort. We tried to establish if any among the 544 patients had turned positive following endoscopy. Fifty patients had RT-PCR tests but only 20 were done within two weeks following nasoendoscopy and were all negative. Considering the centralised testing centre in this specific catchment area, an assumption was made that the rest of the patients in the cohort were well because no COVID-19 tests were performed on them. Furthermore, assuming again that there were false negatives among these 20 cases who had COVID-19 swabs, no clustering was noted thus it is unlikely that disease transmission related to nasoendoscope use occurred.

Following review of published reports, Muscarella stated that contamination from clinical use of flexible nasoendoscopes had been documented, which could be linked from inadequate reprocessing of the instrument although the details of the reports were scant.[14]The author also highlighted that reprocessing techniques varies from centre to centre or even within same centre. A study in 2005 showed marked variations in decontamination techniques used in otolaryngology clinics in UK with 21% using disposable sheaths, 12% alcohol wipes, 12% glutaraldehyde 2% solutions, and 55% non-glutaraldehyde agents like chlorine dioxide, peracetic acid, and ortho-phthaldehyde (OPA). [15].

According to classification of medical devices proposed by American Microbiologist Earle Spalding, a flexible nasoendoscope falls under *semi-critical instrument* category similar to GI endoscopes, bronchoscopes, and cystoscopes which are

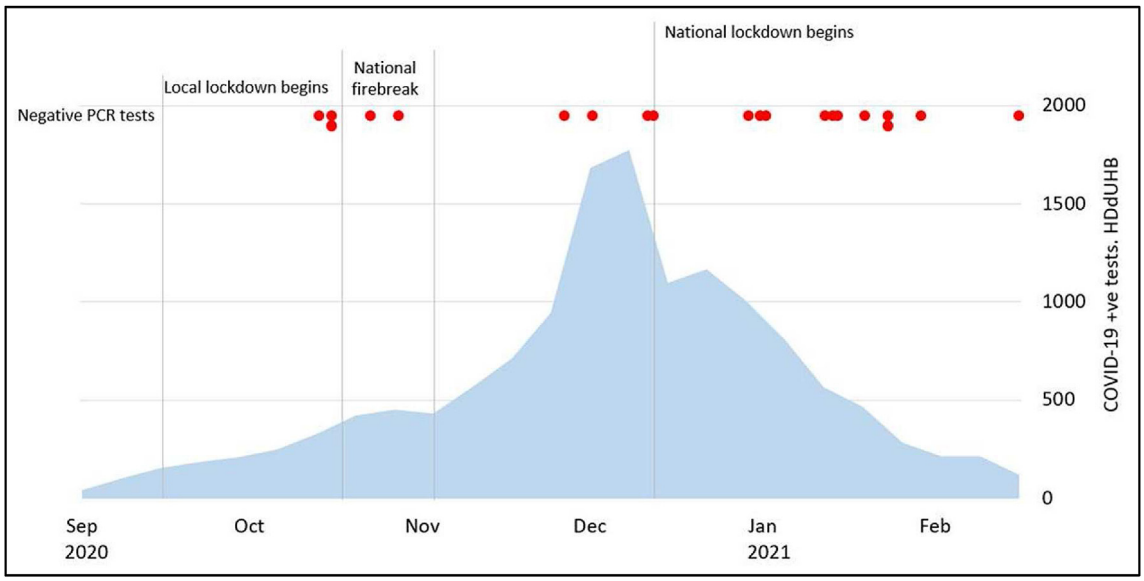

Figure 1. Occurrence of RT-PCR tests two weeks after nasoendoscopies at ENT clinics and background levels of COVID-19 in the community. No clusters of consecutive endoscopies were noted among the patients who have been swabbed for potential COVID-19 (run test P=0.75).

Table 2
Number of cases who had RT-PCR tests and COVID-19 symptoms two weeks after nasoendoscopy. No patients turned positive two weeks after nasoendoscopy. None of the staff exhibited COVID-19 symptoms during the study period

	Total	RT-PCR during study period	Positive RT-PCR during study period	RT-PCR within two weeks after endoscopy	Positive RT-PCR within two weeks after endoscopy	COVID-19 symptoms within two weeks after endoscopy
Patients	544	50	3	20	0	?
ENT doctors	12	7	0	0	0	0
OPD staff	10	4	0	0	0	0

designed to contact mucous membranes or non-intact skin. [14] In the United States, high-level disinfection (HLD) is recommended for reprocessing *semi-critical instruments* although these categorisation and terminologies are not used in UK national decontamination of medical devices guidance. The typical HLD agents or germicides include 2% glutaraldehyde, 7.5% hydrogen peroxide, or 0.2% peracetic acid which are sporicidal (limited), tuberculocidal, virucidal, fungicidal and bactericidal. In UK, glutaraldehyde is no longer used due to its toxicity and fixative properties. [10] Pre-pandemic, Ditomasso *et al*. compared the efficacy of manual cleaning using chlorine dioxide wipes and automated mechanical washing using 5% peracetic-based disinfectants and found no statistical difference between the two techniques. [16] ENT UK has recommended the use of chlorine dioxide wipes during COVID-19 pandemic without providing evidence of recent studies.

Inappropriate germicide is just one of the many steps which could lead to disease transmission. Tzanidakis *et al*. performed a prospective single blind trial on the disinfection of flexible nasoendoscopes using chlorine dioxide wipes by taking culture swab samples immediately after disinfection and before use of the instrument on patients and found its 'in use' efficacy against bacteria, fungi, and myobacteria was 100%. [17] However, the swab taken from the handle of the cleaned instrument before being used on patients grew *Staphylococcus aureus* in 9.6% (n=3; total cleaning episodes=31) and concluded that the source of contamination could be from the hands of the transporter following reprocessing or that of the user.

Our literature search yielded only one study on risk of disease transmission from flexible nasoendoscopy performed on 286 asymptomatic patients and yielded no COVID infections following a 14-day follow-up. [18] Kavanagh *et al*. concluded that the risk of patients developing COVID-19 after fibre optic nasoendoscopy is 0—1.3 per cent, based on the upper 97.5 per cent Poisson confidence limit but admitted a larger cohort is needed especially during disease surges as the low level of infections could be due to national lockdowns and patients' pre-procedure isolating. Kay *et al*. performed a systematic review on the risk of transmission of COVID-19 infection during flexible laryngoscopy and admitted a substantial gap in knowledge in this area. [19]No studies were found which precludes formal conclusions about the safety of this procedure and transmission of virus from patients to health care workers.

This audit shows very high adherence to the new decontamination protocols introduced during the COVID-19 pandemic. During the study period, we limited the use of the nasoendoscope to new USC referrals in the clinic, those with known previous history of cancer and were being reviewed for possible recurrence, and those with possible airway compromise. The rationale for the use of the endoscope brought down the number of episodes of the procedure and the reprocessing that follows thus decreasing the risk among patients and hospital staff. The use of a video system instead of looking through the eyepiece of the instrument decreased the probability of the handle touching eyelid mucosa which is a possible route of disease transmission to users. Using Optical Particle Sizer (OPS), Rameau *et al*. established that flexible nasoendoscopy is unlikely an aerosol-generating procedure (AGP). [20] However, this can potentially induce sneezing in some patients which will produce droplets. In a simulated study, Tan *et al*. established three instances of high droplet production on nasoendoscopy: sneezing, vocalisation (bilabial plosives *'per'*, lingual alveolar plosives *'tee'*, and fricatives *'fer'*), and nasal expiration following use of nasal spray decongestants. [21] One patient in this study could not tolerate the procedure and would keep on sneezing thus it was decided to use the topical decongestant with anaesthetic nasal spray. Appropriate PPEs were used by staff and removed in a designated area. A dedicated room was used for reprocessing of the soiled scopes which were transported in a sealed transporter. No change was introduced with regards to the chemical agent used for decontamination. Overall, all of these helped in minimising the risk of transmission of the disease.

There are limitations on what this study can firmly conclude. It is possible that disease transmission could have occurred but the patients were asymptomatic thus no RT-PCR tests were done. Furthermore, had there been positive cases identified within two weeks following endoscopy, it would still be difficult to pin this down to endoscope use as the patients, ENT doctors, and OPD staff were not self-isolating and could have acquired the disease elsewhere. This is a limitation of the study design and being an audit project, this was not its primary objective. An ideal design to specifically test disease transmission would be a prospective study where all participants are tested for SARS-CoV-2 virus prior to endoscopy and followed up prospectively, observing for COVID-19 symptoms and repeating RT-PCR tests at several time points of at least two weeks. A similar dataset would be collected for endoscopists and clinic staff. Furthermore, the participants would be advised to self-isolate; two weeks for patients following nasoendoscopy and for the whole duration of the study for ENT doctors and OPD staff. Another study design could be taking a swab over the tip of the nasoendoscope before use, immediately after use, and after decontamination using chlorine dioxide wipes.

Conclusion

Accepting the limitations of study design, this audit has found no evidence of nosocomial transmission of SARS-CoV-2 virus related to use and reprocessing of flexible nasoendoscopes among patients, doctors, and clinic staff when the COVID-19 decontamination guidelines are strictly adhered to.

Learning points

- Fiberoptic flexible laryngoscopy poses a risk of COVID-19 for patients and an occupational hazard for ENT doctors and staff involved in decontamination and reprocessing.
- There is a gap in knowledge on COVID-19 disease transmission during flexible nasoendoscopy in clinics.
- This audit has found no evidence of nosocomial transmission of Sars-Cov-2 virus related to use and reprocessing of flexible nasoendoscope among patients and staff following good compliance to ENT UK decontamination guidelines including use of chlorine dioxide wipes.

Ethical standards

The authors declare that this project received permission from the Audit Department of Hywel Dda University Health Board.

Conflict of interest

The authors have no competing interests to declare.

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